Using a Standardized Pain Management Approach Through Regional Anesthesia for Major Limb Amputation Patients

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A DNP Project Manuscript
Submitted in Partial Fulfillment of the Requirements
for the Doctor of Nursing Practice Degree

School of Nursing, University of Maryland at Baltimore
May 2024

Author's note: The author has no known conflict of interest to disclose. Correspondence concerning this article should emailed to: sarah.meadowcroft@umaryland.edu

Abstract

Problem: The Vascular Surgery department at a large academic institution lacked a formalized approach to manage complex pain experienced by patients undergoing major limb amputation (MLA). Consequently, MLA patients averaged 2,352.2 total morphine milliequivalent (MME) and had prolonged hospitalizations averaging 21 days. **Purpose:** This quality improvement (QI) project is to create a formalized clinical approach for the provider to effectively manage the MLA patient's pain. This approach ensures the application of evidence-based regional anesthesia (RA) for all eligible MLA patients. **Methods**: The 22 providers managing MLA patients assessed a numeric pain score (NPS) at time of MLA consent. Patients reporting an NPS of four or higher were triaged into the RA section of this process where the provider requested RA application by the pain team. These clinicians completed an embedded MLA checklist in the daily progress note to ensure process completion. Utilizing a QR code, the providers submitted identified barriers for implementation via a survey. The lead performed chart audits assessing total MME, NPS, and length of stay (LOS). **Results**: Vascular surgeons performed 11 MLAs, with 73% completion of the provider survey and 64% compliance with the checklist. Of the MLA patients, 64% reported NPS of four or higher, 57% of which successfully received RA. The average NPS scores on post-operative day one improved from an average of 4.7 (pre-operative) to 3.2 on post-operative day one. However, the average NPS elevated to a score of five by discharge. These 11 MLA patients averaged a 28.4-day LOS and experienced a significant reduction (approximately 65%) in total MME from pre-implementation requiring an average of 842.5 MME for their hospitalization. **Conclusions**: While the new approach did not show improvement in LOS or NPS, there was a substantial reduction in total MME required by these patients. This formalized framework aids the effective management of the MLA patient's pain. For sustainability, improved education and sedation training of the advanced practice providers will allow for bedside RA application. There is a marked need to develop a formalized transition from RA to oral pain regimen prior to discharge to provide adequate coverage long-term.

Using a Standardized Pain Management Approach Through Regional Anesthesia for Major Limb Amputation Patients

Vascular surgery patients undergoing MLA (defined as proximal to the wrist/ankle) face a complex pain picture. These patients often present with chronic pain secondary to their severe peripheral artery disease (PAD), which is compounded by wound presence. MLA is associated with severe postoperative acute stump pain as well as a high prevalence of phantom/neuropathic pain impacting an estimated 80 percent of MLA patients, further complicating this pain picture (Ayling et al., 2014). Effective management initiated pre-operatively, extending through the post operative period, is imperative to prevent long-term chronic pain and its associated adverse outcomes (Bosanquet et al., 2019). Addressing this problem prevents prolonged LOS, high healthcare cost, and increased narcotic reliance frequently seen in this patient class with poorly controlled pain (Bosanquet et al., 2019; Meissner & Zaslansky, 2021).

Problem Description

The vascular surgery division of a large academic hospital in Maryland has a robust limb preservation practice aimed at preventing MLA. However, severe PAD is a progressive disease which frequently leads to MLA. This surgical group consistently saw approximately one MLA weekly. When the decision is made for an MLA, there was often no further emergent concern for preserving limbs or life, leading the team to prioritize other patients who carry a greater risk of morbidity and/or mortality. As such, the MLA patient often faced long wait times for their procedure without a standardized approach to pain management. The patients were managed at the discretion of the vascular clinicians leading to inadequate pain control (see Appendix A). Poor pain control led to reduced mobility, missed physical therapy/occupational therapy (PT/OT) sessions, adverse events, increased narcotic use, and prolonged LOS (Meissner & Zaslansky, 2021).

The average LOS among patients who underwent MLA with this vascular surgery

service between September 1, 2022, and December 15, 2022, was 21.2 days total and 17.7 days from day of surgery until discharge, twelve days more than the goal of discharge by post-operative day (POD) five. The average narcotic consumption was 2352.2 MME total with a daily average of 144.8 MME which exceeds the 100 MME daily threshold for low-dose narcotic administration (CDC, 2012). Rountree et al. (2021) found appropriately managed vascular MLA patients can maintain adequate pain control with as little as 17.6 MME daily. More than half the MLA patients declined two sessions of PT/OT due to pain which directly delayed progression towards discharge. Several patients experienced adverse events post-operatively, required readmission, and three patients died within thirty days of MLA. The purpose of this QI initiative was to standardize the approach through the application of RA which is proven to reduce LOS, total MME, NPS, and the occurrence of adverse outcomes be instituted at this site to ensure optimal outcomes for this patient population.

Aims and Available Knowledge

The aim of this project was to obtain 100 percent clinician compliance with embedding and completing the MLA Regional Anesthesia Checklist within the daily progress note for all MLA patients throughout the 15-week implementation period. The goal was to ensure RA was included in the management of the vascular MLA patients' complex pain. The use of checklists facilitated adherence and success of the standardized approach (Kelly & Baar-Daley, 2022). Checklists were proven useful tools for providing a framework to guide the clinician through each step of a new formalized patient management approach such as the application of evidence-based RA (see Appendix B).

Evidence review (see Appendices C & D) of the efficacy of RA in managing the MLA patients' pain rendered four Level I articles, one Level II article, and two Level III articles providing a strong body of evidence in support of the use of RA (see Appendices C & D). The evidence supports the use of RA including neuraxial and peripheral nerve blocks as a useful tool for the management of the MLA pain experience. RA enhances outcomes and pain control

while reducing the occurrence of adverse events. These adverse events may include cardiac complications (including exacerbation of heart failure or myocardial infarction) or respiratory distress/failure (Hall et al., 2020; Mufarrih, et al., 2023; Mufarrih et al., 2021). RA effectively reduces the experience of severe and poorly controlled postoperative pain which can impede the patient's hospital throughput (Makkar et al., 2022). The application of RA reduces the total MME required as well as the patient-reported pain level (Dumitrascu et al., 2021). Finally, RA lessens the experience of debilitating phantom limb pain (Ilfeld, et al., 2021). Utilizing a checklist within the electronic medical record (EMR) ensures completion of each formalized process step to secure the application of evidence-based RA ensuring adequate pain control, lessening the occurrence of adverse events, and reducing LOS (Kelly & Baar-Daley, 2022).

Rationale

The framework Promoting Action on Research Implementation in Health Services (PARIHS) will shape this project (see Appendix E). This framework pulls upon three components: the evidence, the context, and facilitation to help form the process and ensure success. The body of evidence strongly supports the application of RA in helping to adequately manage the MLA patient's pain. Within this setting, the vascular team and the Maryland Acute Pain and Regional Anesthesia Service (MAPRAS) work collaboratively to improve patient care. MLA patients at this institution routinely request more effective pain management and are open to alternative modalities such as RA. The facility continually advocates for QI, strives to optimize outcomes, and promotes initiatives to encourage patient progression. The facility also encourages academic endeavors and focuses on high quality, evidence-based practice (see Appendices B & C). The use of an MLA Regional Anesthesia Checklist allows the vascular clinicians to implement and adhere to the formalized approach. Weekly MLA patient chart audits as well as weekly emailed project updates and education will allow the project lead to maintain team engagement. This intervention is an evidence-based solution to the identified problem with appropriately delineated roles. The PARIHS framework supports and provides structure to this

project (see Appendix E).

Methods

Context

The site of this QI initiative was rooted in the application of evidence-based care efforts. The facility administration valued and supported QI initiatives and engaged in processes to ensure optimal outcomes. The vascular surgery team consisted of 22 clinicians focused on enhancing care, improving outcomes, preventing adverse events, and welcoming QI initiatives. The frontline caretakers of the MLA patients were the vascular surgery nursing staff. These individuals frequently communicate MLA patient requests for more effective pain management.

The site used Epic System software for an EMR. The system had the capacity to generate a “dot phrase” that allows the provider to insert the checklist into the daily progress note for guidance and documentation of this standardized approach (see Appendix F). The EMR further allowed the team lead to run weekly reports to identify all MLA patients and perform chart audit for data collection (see Appendix G). There was a secure text messaging system that allowed rapid communication with the MAPRAS team for activation of the RA protocol. MAPRAS was an established team aimed at providing RA for the treatment of pain. The medical director of MAPRAS was actively engaged in collaboration within the hospital. The MAPRAS team utilized its established processes to appropriately provide RA to all identified, eligible MLA patients. With the use of a QR Code, the vascular clinicians accessed a short provider survey that allowed them to report any identified barriers to implementation to the QI team lead (see Appendix H).

Intervention

The process for the management of vascular MLA patients was inconsistent and created a variance between each MLA patient’s regimen and inadequate pain control (see Appendix I). This project standardized the approach via an MLA Regional Anesthesia Checklist to guide collaboration among vascular and MAPRAS providers to utilize RA in the management of MLA

pain (see Appendix J). Prior to rollout, the vascular surgery provider underwent an educational session about the expectation to utilize this standardized approach. A one-page flyer was posted at the workstations as reminders of this process throughout implementation (see Appendix H). This flyer included a QR code the clinician used to complete the provider input survey.

The vascular surgery clinicians utilized this new approach throughout the implementation period which extended from September 4, 2023, through December 15, 2023. At the time of MLA consent, the vascular surgery provider assessed NPS. If the patient reported NPS less than four but received pain medication within three hours, the provider utilized the nursing NPS documentation within the EMR at time of administration. If the MLA patient reported an NPS of four or higher, the vascular provider utilized a secure text messaging system to communicate with the MAPRAS consults resident and the post-anesthesia care unit (PACU) charge nurse to request RA.

The MAPRAS team assessed the patient and coordinated with the PACU charge nurse to provide the appropriate RA in a timely manner (resource permitting). The vascular provider subsequently utilized the MLA RA Checklist in the daily progress note to ensure each step of this formalized process was complete (see Appendix F). Lastly, the vascular provider accessed the Provider Input Survey via a QR code and identified any barriers to successful implementation (see Appendix K).

The project lead performed weekly chart audits on discharged MLA patients to assess pertinent data. Utilizing the MLA Chart Audit survey, the lead monitored provider compliance, total MME, NPS findings, and application of RA (See Appendix G). Study data was collected utilizing a secure, web-based software platform called Research Electronic Data Capture, or *REDCap*, which is an electronic data capture tool hosted at the University of Maryland School of Nursing. *REDCap* is designed to support data capture for research studies with 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export

procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources (Harris et al., 2009; Harris et al., 2019; UMBC ITCR, 2023).The entirety of this project extended from January of 2023 through May of 2024 (See Appendix L). The team lead provided in-person and electronic education for the 22 vascular clinicians prior to implementation. A survey was sent to these clinicians to evaluate receipt of this education (see Appendix M).

The vascular surgery and MAPRAS teams worked collaboratively throughout the implementation process to support this process. Additionally, the team lead monitored the provider input survey responses and utilized the expertise of the clinical site representative and site sponsor to address identified issues and ensure success and sustainability. During this process, the lead updated the team on project findings, RA education, and offered ongoing encouragement for vascular clinician involvement via weekly emails.

Measurement

The primary goal of this project was to maintain 100 percent provider compliance with the MLA Checklist within the daily progress note on date of consent for MLA. The team lead performed chart audits every Friday to evaluate provider compliance with the MLA Checklist (see Appendix G). The project lead sent weekly emails to the vascular providers with updated data findings as well as ongoing RA education to maintain compliance with this formalized approach. The team lead compared the number of MLA patients with the MLA Checklist included in their daily progress note to the total amount of MLA patients throughout the implementation period.

The secondary goals included 100 percent completion of the Provider Input Survey by the clinician on the day of MLA consent to identify barriers. Of eligible MLA patients, 100 percent would receive RA from the MAPRAS team, and there would be a reduction in LOS and NPS. The team lead monitored the completion of this communication process as well as the successful application of RA to all eligible MLA patients through chart audit following discharge.

The number of eligible patients with documented communication and the total who successfully received RA were compared to the total number of eligible MLA patients.

Lastly, the project lead calculated total MME for each MLA patient, documented NPS scores (pre-operatively, on POD1, and at discharge), and LOS. The project lead assessed the total LOS. The project lead calculated total MME and compared these to the pre-implementation MME findings to garner further provider buy-in for this process. Based upon the thorough literature review, it was anticipated that these elements would improve with the application of RA in the MLA patient. All vascular providers were expected to complete a two-question survey pertaining to the receipt of education, and responses were compared to the total number of vascular providers. All data was stored in the secure *REDCap* system for data protection and analysis.

Ethical Considerations

The project lead was responsible for upholding the ethical standard for this QI project designed to apply evidence-based RA to the management of MLA patients. The data was kept in a secure system for data analysis for Health Insurance Portability and Accountability Act compliance. The selection of appropriate RA application was at the discretion of the MAPRAS team using its currently utilized standard of care to prevent psychological/physiological harm to the patients. All data was maintained confidentially. Prior to implementation, the team lead ensured Institutional Review Board approval for implementation and ongoing data collection. The team lead disclosed that the site of implementation is their place of employment. Lastly, the team lead maintained Collaborative Institutional Training Initiative education throughout the duration of this project through May 15, 2024.

Results

Analytics

The vascular surgery team managed the pain for 11 MLA procedures; seven of which were eligible to receive the new formalized approach. The team lead provided in-person

education as well as electronic education via *PowerPoint* for ongoing reference to the 22 providers responsible for these patients. Of the eight respondents to the MLA Education Survey, 100% reported undergoing the in-person education, and 50% endorsed receipt of the electronic education *PowerPoint* (see Appendix N). This new approach added four new tasks to the process of consenting and managing the MLA patient: NPS assessment, communicating the need for RA, completion of the MLA Checklist, and utilizing the QR code to complete the Provider Input Survey.

Using a secure text messaging system, the vascular surgery provider notified the MAPRAS team and PACU charge RN of all seven eligible patients and requested application of RA on the day of consent. As a result of this proactive communication, MAPRAS provided RA to 57% of eligible MLA patients with 36.4% percent of all MLA patients receiving RA prior to the procedure to ensure adequate control (see Appendix O).

The vascular provider then embedded the MLA Checklist into the daily progress note to ensure completion of each step. Chart audits reflected that of the 11 MLA patients, 64% of the patients had the MLA Checklist included in the daily progress note on the day of consent (see Appendix P). As such, 36% of providers managing MLA patients on the day of consent did not complete this important element to guide the new process and ensure completion of each step. Lastly, the vascular provider completed the Provider Input Survey to identify barriers requiring response by the QI team to ensure the effectiveness of this process. Of the 11 MLA cases, 73% of the clinicians maintained compliance with this step (see Appendix Q). Of these responses, no provider identified any significant barriers impeding the use of RA in eligible patients.

Among the 11 MLA patients audited, the average NPS preoperatively was 4.73. For these patients, their average NPS improved to 3.46 on POD one. However, at discharge their mean NPS elevated to 5 after transition from RA to oral pain medications (see Appendix R). While RA was proven an effective modality and the expectation was that this modality would improve pain experience, the patients did require adjunctive options in a multimodal approach.

These medications include options such as Tylenol, topical lidocaine patches, and narcotics (see Appendix S). Of the 11 MLA patients, the average LOS is 28.4 days during the implementation period. One patient required urgent readmission and return to the operating room for MLA revision. No further adverse events were found.

Discussion

The vascular providers did not meet the primary goal of 100% compliance with both the MLA Checklist to guide practice and the Provider Input Survey as originally planned. Despite this adherence issue, these clinicians became acutely aware of the benefit of and necessity for the providing of evidence-based RA to the MLA pain management approach, and they successfully ensured the use of RA in 57% of eligible MLA patients. The 11 MLA patients during implementation required 842.5 total MME for their hospitalization. This is a substantial improvement from the pre-implementation data findings where MLA patients averaged a 2,352.2 MME demand for hospitalization. All the MLA patients, regardless of RA application, received multimodal pain approaches similar to pre-implementation. The team expected a reduction in LOS, however, the MLA patients' average LOS increased from 21 days pre-implementation to 28.4 during this project. There was a reduction of NPS reflecting adequate pain control during the initial postoperative period while RA was applied to the patients (pre-operative mean=4.73, postoperative day one mean=3.46). Unfortunately, the MLA patients experienced a subsequent increase of NPS by time of discharge with the removal of RA and transition to oral regimen (mean=5) (see Figure 6).

The evidence supported the use of checklists to guide a standardized practice approach, however, 71% of eligible patients where the clinician utilized the checklist successfully received RA. One eligible patient successfully received RA without the use of the checklist (Kelly & Baar-Daley, 2022). The literature showed that the use of RA significantly reduced the MME requirements for adequate pain control. This was reflected in this QI initiative where pre-implementation average total requirement was 2352.2 MME total with a daily average of 144.8

MME. During the implementation, the vascular surgery team saw an improvement to 842.5 MME total with a daily average of 37.9 MME. Evidence supported the use of RA in MLA pain management for reduction of adverse respiratory and cardiac events (Hall et al., 2020; Mufarrih, et al., 2023; Mufarrih et al., 2021). The team saw no adverse events of this nature during this implementation period, which was in accordance with the literature. Kelly & Baar-Daley (2022) found that through the application of RA, LOS was reduced in MLA patients. However, the vascular surgery team found that LOS increased during the implementation period to 28.4 from 21.2 days on average prior to implementation. Lastly, Dumitrascu et al. (2021) note that the use of RA in the MLA patient results in reduced NPS reports. The team saw NPS reports reduce from 4.73 pre-operatively to 3.45 following their procedure which was expected.

Limitations

While no barriers are identified through the provider input checklist, there are limitations in this process. The design of this QI project did not consider the management of patients undergoing multiple MLA procedures within one hospitalization. As a result, confusion arose surrounding the procedure for adhering to this new process under this circumstance and two patients did not receive this QI approach when undergoing a second MLA on a contralateral extremity while receiving RA on the original MLA limb. Furthermore, the management of the MLA patient arriving for elective amputation from home placed undue burden on the provider responsible for consenting patients during the busy early morning timeframe. As such, the providers were not able to adhere to this process as expected. In grounding this project in the PARIHS framework, further insight into both the context and facilitation elements in this setting might help guide this process to success. When the decision for amputation is arrived upon in the outpatient setting, the advanced practice provider for the specific surgeon must request MAPRAS RA application when posting the case to ensure application preoperatively while awaiting amputation. The team found that MLA patients' pain was inadequately controlled at time of discharge compared to during their hospitalization. The team must work collaboratively

with the MAPRAS team to devise a systematic approach to transitioning these patients to an effective oral regimen.

The MAPRAS team utilizes the PACU to provide RA due to the necessity for moderate sedation. While the vascular unit has telemetry monitoring and can accommodate this process, they do not have the nurse-to-patient ratio to sustain its application within this setting. As such, the patients' receipt of RA is dependent upon PACU space availability which can be a complex process. To further root this quality improvement initiative in the PARIHS framework, further insight into the context element might help the team successfully resolve this issue. For sustainability, training the vascular advance practice provider team to manage moderate sedation would allow the vascular providers and MAPRAS team optimal opportunity to ensure RA early and successfully. Given the improved pain control with this QI initiative, the application of RA to MLA patients organization-wide must be the next step to continue to further this valuable project.

Conclusion

This standardized approach is designed to provide a framework for optimal pain management in the setting of complex pain experienced by MLA patients. The project entails the use of the MLA Checklist within the daily progress note to guide the steps of ensuring the application of evidence-based RA to the multimodal pain management regimen. This approach helps to reduce the total MME required to control pain adequately and reduce NPS, providing the patient a more comfortable experience and enabling them to participate in care activities such as PT/OT. This is likely to help ultimately reduce the total LOS required for these patients to be ready for successful and safe discharge. Furthermore, it will help enhance their progression to prosthesis and return to functional life. The approach helps prevent adverse cardiac and/or respiratory events further enhancing their progression and providing a framework to progress them safely through their hospitalization. The quality of the care the MLA patient will receive because of this new approach is profoundly improved and likely to enhance outcomes

and improve patient satisfaction. The successful application of a nurse practitioner-led evidence-based QI project enhances the perception of the nurse practitioner within the hospital and practice alike. It instills further emphasis on the knowledge, skills, critical thinking, and high-quality care the nurse practitioner provides within this practice setting.

Given the known benefits of RA, the team and patients alike will see a significant reduction in healthcare costs associated with their hospitalization. This standardized approach has shown an effective process to manage complex acute on chronic pain. The team continues to utilize the approach in the MLA patient with plans to expand this to a new QI project entailing standardizing the pain management approach for all critical limb ischemia patients. It would be appropriate to expand this approach to other surgical services' management of MLA patients within the facility. Furthermore, for ease of RA application given the PACU space limitations and vascular RN demands, it is essential that the vascular surgery advanced practice provider team undergo moderate sedation training. This new standardized approach reduces narcotic requirements, adverse events, and is anticipated to reduce total LOS. It is essential that the team continues to use this approach and expand it into successful application of standardized pain control through RA in other clinical pictures and to other surgical services.

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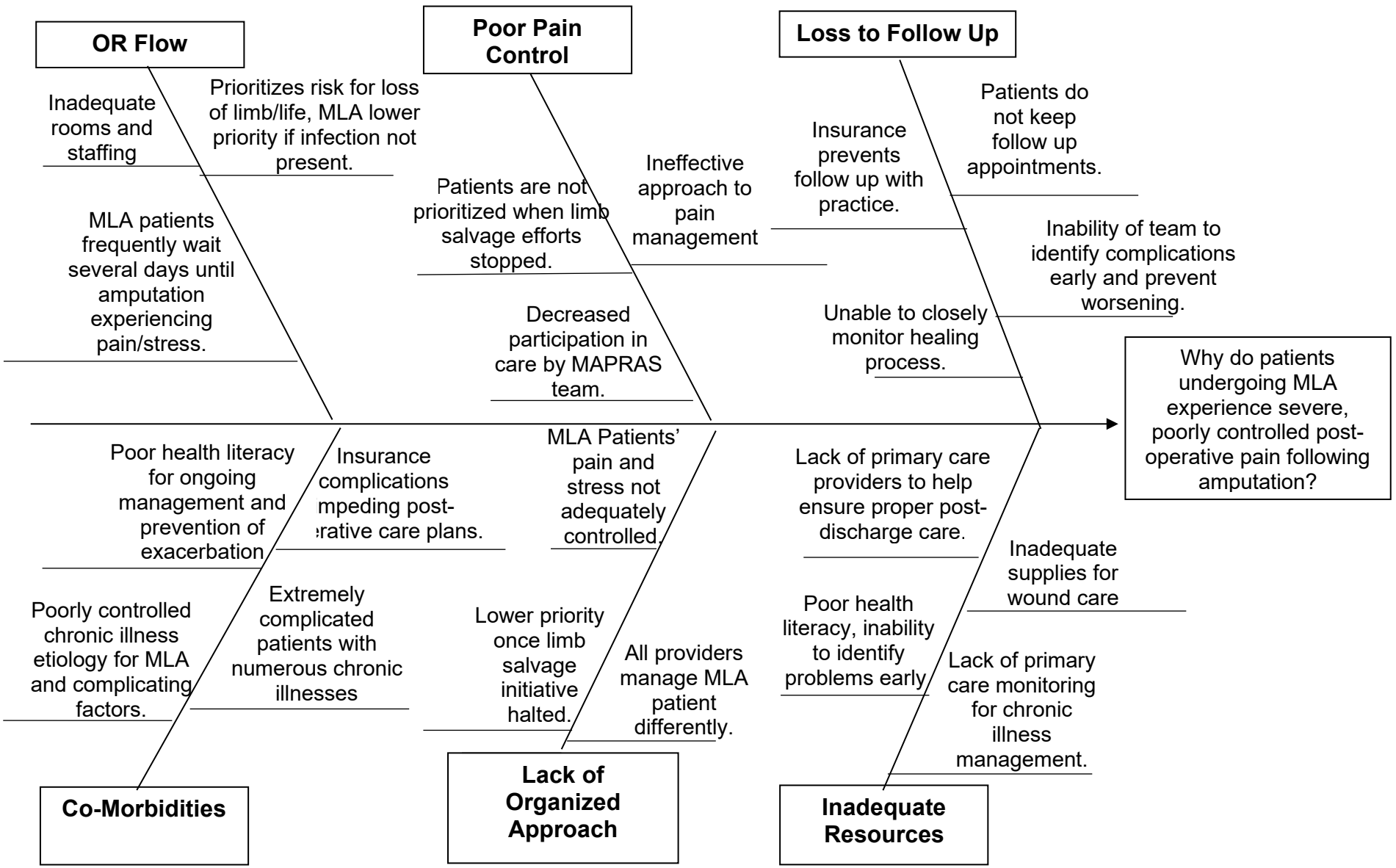
Appendix A

Fishbone Analysis of MLA Post-Operative Pain



Appendix B

Project Charter

PROJECT OVERVIEW – Section 1	
Project Title	Using a Standardized Pain Management Approach Through Regional Anesthesia for Major Limb Amputation Patients
Student Name, Program	Sarah J. Meadowcroft Post-Master's Doctor of Nursing Practice
Faculty Advisor, CSR, Sponsor:	Student working under the direction of the assigned Faculty Advisor in conjunction with a clinical site representative and site sponsor to guide this scholarly work and address the identified practice need.
Problem/issue statement w/background (include population and site/setting)	Vascular patients at a tertiary hospital in Baltimore, Maryland, planned for Major Limb Amputation (MLA) receive suboptimal pain management leading to increased occurrence of adverse outcomes including poorly controlled pain, Narcan requirement, wound dehiscence/infection, increased length of stay, and increased readmission rate.
Project Purpose Statement:	The purpose of this quality improvement project is to create a standardized approach to managing the pain of MLA patients with the goal of reducing the occurrence of adverse outcomes.

ASSESS – Section 1		
Root Cause Analysis Summary (See Appendix A): Over the past year, MLA patients under the vascular surgery service at a tertiary facility in Baltimore, Maryland, has experienced a significant increase in post-operative complications secondary to poor pain management from the point in time when decision for MLA is made (between the team and patient) onward throughout hospitalization. Upon identification of amputation as definitive treatment in these complex patients, management varies drastically in the realm of pain control without a coordinated and comprehensive approach available. Furthermore, these patients often have complex pain presentations secondary to the presence of co-morbidities complicating the process further. Lastly, there is a distinct lack of available operating room resources for prompt surgical intervention leading to delays and prolonged pre-operative pain experience complicating the post-operative hospital stay.		
Site Structures Assessed	Site Processes Assessed (current/desired maps – Appendix B, C)	Site Outcome(s) Assessed (Pre-project)
1. The medical system is proactively engaged in creating coordinated approaches embedded into EMR for surgical patients. 2. Pain team (MAPRAS) actively placing regional blocks and performing	1. Patient identified for MLA. 2. Vascular Surgery provider creates pain management regimen. 3. Nurses initiate plans and perform frequent reassessments of pain.	1. Total morphine milliequivalents (MME) required on MLA patients during hospitalization. 2. Total length of stay as well as number of days from operative date to discharge. 3. NPS score pre-operatively, post-operative day 1, and at discharge.

procedures under regional anesthesia where appropriate for patient safety. 3. P0CA and other pain control mechanisms are available.	4. Pain regimen altered daily (or more frequently) to get better control. 5. Patient taken to OR for MLA. 6. Pain process starts over with new regimen given the post operative pain is frequently different from the pre-operative experience.	4. Application of RA in the MLA patient.
Project Structure Goal(s)	Project Process Goal(s)	Outcome Goal(s)
1. With 100% of vascular MLA patients, the vascular team will work congruently with the patient to decide upon appropriateness of MLA and obtain signed consent at time of decision for prevention of care delays. 2. Vascular surgery provider who performs consent on the MLA patient will notify MAPRAS and PACU charge RN of need for RA administration in 100% of MLA patients during 15-week implementation period. 3. 100% of eligible MLA patients receive RA by the MAPRAS team throughout the 15-week implementation period. 4. The vascular provider consenting for MLA inputs the provider checklist into the daily progress notes for 100% of MLA patients regardless of eligibility. 5. The vascular provider completes the provider input survey for 100% of MLA patients during the 15-week implementation period. 6. 100% of vascular providers will report	1. The Vascular Surgery team will collaborate with MAPRAS in the care of vascular MLA patients with an NPS > 4, 100% during 15-week implementation period. 2. MAPRAS will administer RA to 100% of eligible MLA patients during 15-week implementation period. 3. The vascular provider will input the vascular checklist to guide the standardized process in 100% of MLA patients regardless of eligibility for RA. 4. The vascular provider completes the provider input survey in 100% of MLA patients regardless of eligibility status for RA.	1. 100% Compliance with MLA RA Checklist among vascular providers managing MLA patients at time consent for MLA throughout the 15-week implementation period. 2. The vascular provider performing consent on the eligible MLA patient will communicate request for RA to MAPRAS and PACU Charge RN for 100% of procedures. 3. 100% of eligible MLA patients will receive RA from MAPRAS. 4. The vascular provider will complete the provider input survey for 100% of MLA patients regardless of RA eligibility.

receipt of in-person and electronic Power Point education.		

PLAN – Section 2	
Implementation	
This quality improvement project is designed to engage the Vascular Surgery and MAPRAS teams to work collaboratively in their management of the vascular MLA patients at a tertiary medical center in Baltimore, Maryland through application of RA. Upon obtaining consent for MLA, the teams will identify those appropriate for RA which will be initiated within 12 hours of that signature. RA helps to provide consistent and effective pain control to help reduce post-operative complications including the occurrence of uncontrolled post-operative pain, the experience of phantom pain, adverse respiratory or cardiac events, and reduce length of stay (Mufarrih et al., 2021; Dumitrascu et al., 2021).	
Action to Achieve Goals (Bingham ABCDE strategies and tactics)	Goal the Action will Achieve
Accountability 1. Obtain verbal commitment from each vascular provider prior to roll-out of this intervention. 2. Revise professional roles of the vascular provider team and provide education prior to implementation. 3. Provide clinical supervision to the vascular and MAPRAS teams prior to and throughout implementation. 4. Perform tests of change every week throughout implementation.	1. Structure Goal 1-2. 2. Outcome Goal 1 & 4. Structure Goal 3-6. 3. Process Goal 1. Project Goal 4. Structure Goals 1-4. 4. Outcome Goal 1-4. Process Goal 2.
Buy-In 1. Provide education pertaining to the benefits of RA in the management of the MLA patient to engage participation.	1. Project Goals 1-4. Outcome Goals 1-2. Structure Goals 1-6.
Collaboration/Communication 1. Identify champions including a vascular attending, a MAPRAS attending, a vascular APP, and a vascular RN. 2. Conduct open discussion pertaining to the problem and intervention with both the Vascular and the MAPRAS teams. 3. Engage patients in this process. 4. Provide formal blueprint with visual one-pager to help guide providers from implementation onward. 5. Provide feedback email with updates on implementation and data findings every other week throughout implementation. 6. Work with informaticist to develop a BKA report to obtain vital data weekly pertaining to these patients.	1. Outcome Goal 1. Structure Goals 1-4. 2. Outcome Goal 1. 3. Outcome Goals 1-3. Structure Goals 1-2. 4. Outcome Goals 1-3. 5. Outcome Goal 1. 6. Outcome Goal 1.

Data 1. Complete audits of all BKA patients every other Friday (Weeks 1, 3, 5, 7, 9, 11, 13, 15), provide feedback on the following Monday to the vascular and MAPRAS teams. 2. Critically analyze the data at the above intervals.	1. Outcome Goal 1. 2. Outcome Goal 1.
Education 1. Provide pre-implementation (as well as as-needed) training to all members of the Vascular and MAPRAS teams. 2. Develop a one-page summarization of the current literature supporting this intervention.	1. Outcome Goals 1-3. Structure Goals 1-6. 2. Outcome Goals 1-3.

The Implementation of this project will commence April 1, 2023, with thorough and formal introduction to the project to team members. This will be supplemented by a literature review handout allowing the team to substantiate the validity of this intervention for the treatment of the MLA patient. Signed role agreements will be obtained prior to further efforts to ensure member engagement. Prior to rollout, the teams will receive education specific to their role in the intervention process. Also prior to the implementation, the team lead and informaticist will work collaboratively to develop a report sheet in Epic to provide vital data collection. Visual guides of each team's role will be placed in their respective workspaces to help act as reminders and assistance for the process. Upon roll out of this intervention, the team lead will run bi-weekly reports, analyze data, and provide communication to the team with valuable updates to promote engagement. The team lead will also analyze individual roles in fulfilling the intervention process and identify those who complied offering a $5 Starbucks coffee reward (See Appendix D).

Measures

Project Goals	Measure Pre-Implementation	Measure During Implementation
1. With 100% of vascular MLA patients, the vascular team will work with the patient to decide upon appropriateness of MLA and obtain signed consent at time of decision for prevention of care delays	Chart audit of the provider documentation.	Chart audit of provider documentation.
2. The vascular surgery provider will assess NPS to evaluate appropriateness of RA at time of consent in 100% of vascular MLA patients and document in the MLA checklist during 15-week implementation period	Checklist for documentation will not be available until September 4, 2023.	Chart audit performed every other Friday by team lead.
3. Vascular surgery provider who consents the patient for MLA procedure	Checklist for documentation will not be available until September 4, 2023.	Chart audit performed every other Friday by team lead.

will notify MAPRAS and PACU charge RN of need for RA administration in 100% of eligible MLA patients during 15-week implementation period and document in the MLA provider checklist.		
4. 100% of eligible MLA patients receive RA within 12 hours of consent signature by MAPRAS team throughout the 15-week implementation period.	Checklist for documentation will not be available until September 4, 2023.	100% of eligible MLA patients receive RA within 12 hours of consent signature by MAPRAS team throughout the 15-week implementation period
Process		
1. The Vascular Surgery team will collaborate with MAPRAS in the care of eligible vascular MLA patients 100% during 15-week implementation period.	**Numerator:** # of documented collaborative efforts to manage MLA patients **Denominator**: Total # of vascular MLA Patients.	**Numerator:** # of documented collaborative efforts to manage MLA patients **Denominator**: Total # of vascular MLA Patients
2. MAPRAS will administer RA to 100% of eligible MLA patients.	**Numerator:** Number of patients who received RA within 12 hours of consent. **Denominator:** Total # of vascular MLA Patients	**Numerator:** Number of patients who received RA within 12 hours of consent. **Denominator:** Total # of vascular MLA Patients
Outcome		
1. 100% of vascular providers managing MLA patients will comply with the MLA RA Provider Checklist.	No measurement as tool will not be available until September 4, 2023.	**Numerator:** # of MLA patients with checklist in progress note with time documentation appropriate for consent. **Denominator:** Total # of MLA patients.
2. 100% of vascular providers managing MLA patients will complete the provider input survey on day of consent.	No measurement as tool will not be available until September 4, 2023.	**Numerator:** # of completed provider surveys **Denominator**: Total # of MLA procedures performed.

Measurement Plan

Project Goals	Data Collection Procedures (who, how, when)	Name of Data Collection Tool
100% Compliance with MLA RA Checklist among vascular providers managing MLA patients at time consent for MLA throughout	Chart audit for presence of checklist on date of consent by vascular provider. This audit will be	MLA Chart Audit

the 15-week implementation period.	performed by the team lead on the Friday following discharge.	
The vascular provider performing consent on the eligible MLA patient will communicate request for RA to MAPRAS and PACU Charge RN for 100% of procedures.	Chart audit performed on Friday following discharge by team lead to assess for documentation of this communication within the MLA RA checklist.	MLA Chart Audit
100% of eligible MLA patients will receive RA from MAPRAS.	The chart audit was performed on Friday following discharge by team lead. Assess confirmation of RA application in checklist. If checklist not present, assess MAPRAS progress notes documenting RA application.	MLA Chart Audit
The vascular provider will complete the provider input survey for 100% of MLA patients regardless of RA eligibility.	The team lead will evaluate data input into the *REDCap* secure system every Friday. The provider will input MRN and date of surgery to allow the lead to ensure each procedure for the specific patient is input into this system and the survey completed.	MLA Provider Input Survey

Appendix C

Evidence Review Tables

Citation #1 (hyperlink): Mufarrih, S. H., Qureshi, N. Q., Yunus, R. A., Katsiampoura, A., Quraishi, I., Sharkey, A., Mahmood, F., & Matyal, R. (2022). A systematic review and meta-analysis of general versus regional anesthesia for lower extremity amputation. *Journal of Vascular Surgery, 77*(5). https://doi-org.proxy-hs.researchport.umd.edu/10.1016/j.jvs.2022.10.005

Level: I

Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
The researchers sought to produce a body of evidence evaluating the efficacy of regional anesthetic versus general anesthetic in the management of the lower extremity amputation patient.	The researchers performed a Level I systematic review of randomized controlled trials providing evidence with a quality rating of A.	The researchers utilized the databases PubMed, Embase, MEDLINE, Web of Science and Google Scholar. They narrowed the search to studies of anesthesia approaches to managing lower extremity amputation patients which were performed since 2010. They included prospective and retrospective studies in their final list. They did not narrow the location of these studies. The included studies required full text availability. This process was completed independently by three of the	The interventions of each study allowed in this review included regional anesthesia including neuraxial anesthesia and peripheral nerve blockade. General anesthesia included use of all medications typically used for surgery under general anesthesia. The intervention was identified by the primary author, and if the intervention was not in accordance with this, the research was excluded.	The primary outcome evaluated was the 30-day mortality rate reported by the authors of each study where it was included in measurement. Other outcomes also evaluated through data provided by the primary researchers included surgical site infections (SSI), sepsis, respiratory events, cardiac events, urinary tract infection (UTI), renal failure (RF), venous thromboembolism (VTE), and pneumonia.	The primary outcome was included in only one study where there was no significant difference in mortality rates between general and regional anesthesia in this patient class. Four studies showed significant prevalence of respiratory failure in amputation patients. Only one article found a higher incidence of cardiac complications in patients receiving general anesthesia. One found a statistically significantly higher risk of pneumonia and two studies found higher risk of sepsis among general anesthesia patients.

		researchers and approved by two professors of anesthesia. In total, 10 studies were included in the analysis.			Three studies found a significantly longer length of stay for patients receiving general anesthesia than regional. There was no significant difference between the groups in the occurrence of UTI, SSI, RF, VTE, or myocardial infarction. The use of regional anesthesia reduces the risk of adverse events during the hospitalization for lower extremity amputation.

Citation #2: Mufarrih, S. H., Qureshi, N. Q., Schaefer, M. S., Sharkey, A., Fatima, H., Chaudhary, O., Krumm, S., Baribeau, V., Mahmood, F., Schermerhorn, M., & Matyal, R. (2021). Regional anaesthesia for lower extremity amputation is associated with reduced post-operative complications compared with general anaesthesia. *European Journal of Vascular and Endovascular Surgery, 62*(3), 476–484. https://doi-org.proxy-hs.researchport.umd.edu/10.1016/j.ejvs.2021.05.040

Level: III

Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**
The purpose of this research was to evaluate how regional anesthesia may reduce the incidence of respiratory complications as well as other post-operative complications compared to general anesthesia.	The authors utilized a level III retrospective quasi-experiment with a quality rating of B.	The researchers selected participants aged >18 who underwent lower extremity amputation between the years of 2005 and 2018 utilizing the American College of Surgeons National Safety Quality Improvement Program database utilizing CPT Codes. Exclusion criteria included patients without regional anesthesia, those undergoing minor amputation, those with an ASA score of six, and trauma patients, those with known pneumonia pre-operatively, and finally those who were ventilator dependent prior to	The patients were identified through chart evaluation of anesthesiology documentation as either having received regional anesthesia including neuraxial or peripheral nerve blocks (n=5,466) or general anesthesia (n=40,026).	The primary outcome explored in this study was the experience of respiratory events (pneumonia, unplanned intubation, or difficulty with ventilator weaning post-operatively after 48 hours). Other outcome evaluated included pulmonary emboli, renal failure, urinary tract infection, surgical incision site infections, myocardial infarction, cerebrovascular events, septic shock, need for further surgical intervention, and unplanned readmissions. All of these were measured through careful chart	Regional anesthesia was used in older patients with more comorbidities than general anesthesia. Of the 908 total patients experiencing respiratory complications post-operatively within 48 hours, significantly more received general anesthesia (n=518) versus regional (n=321; p=.047). Furthermore, only 797 regional patients required blood transfusion, significantly less than the 7,190 patients in the general anesthesia group who did (p=<.001). There was also an increased prevalence of return to OR for patients receiving general

		their procedure. 48,548 patients were initially identified, of which 3,056 were excluded. This included 29,279 males (64.4%) and 16,182 females (35.6%).		audits of the documentation by the primary surgical teams.	anesthesia (p=.023). Patients receiving general also carried a higher experience of septic shock post-operatively (p=.025). However, the length of stay average was 14.3 days for regional patients versus 12. 2 days for general (p=.001). Regional anesthesia helps reduce the risk of adverse events as compared to the use of general anesthesia in the surgical management of the lower extremity amputation.

Citation #3: Hall, M. R., Kalbaugh, C. A., Tsujimoto, T. H. M., & McGinigle, K. L. (2020). Regional anaesthesia alone is reasonable for major lower extremity amputation in high-risk Patients and may initiate a more efficacious enhanced recovery programme. *European Journal of Vascular and Endovascular Surgery, 60*(5), 747–751. https://doi-org.proxy-hs.researchport.umd.edu/10.1016/j.ejvs.2020.06.034

Level: III

Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
The use of regional anesthesia for patients undergoing lower extremity amputation reduces the prevalence of adverse events in the post operative setting.	The researchers designed a Level III retrospective quasi-experiment to analyze how regional anesthesia improves patient outcomes compared to the use of general anesthesia in patients requiring major lower extremity amputation. The quality rating for this body of evidence is B.	Patients were selected utilizing the U.S. Vascular Quality Initiative where patients aged >18 who underwent elective lower extremity amputations in the United States between the years 2013 and 2018. 5,567 patients were included in the study. Of those, 65% were male and 35% female. The average age was 64.9 years. 43.4% of the patients underwent BKA, 31.2 underwent AKA, and 25.4% underwent foot/ankle amputation.	The patients were categorized as having received regional anesthesia including spinal, epidural, and peripheral block (n=719) versus general anesthesia (n=4,848)	The primary outcomes measured by the authors were the occurrence of major adverse cardiac events and death. Outcomes were measured through careful chart review of the primary surgical team's documentation of experienced events.	328 patients died within 30 days of their amputation, 1,391 died within one year of their procedure, and 1,734 died through the entire period studied, however there was no difference between the two groups. Of the two groups, those receiving regional anesthesia were found to have higher prevalence of diabetes (p=<.001), end-stage renal disease (p=<.001) more likely to have comorbidity of heart failure (p=<.01), and higher prevalence of coronary artery disease (p=>.01). The patients who received regional anesthesia were at a

					higher risk with more co-morbidities present than those who were selected by their anesthesiology team for general anesthesia. However, after receiving regional anesthesia, their mortality and cardiac event incidence remained insignificantly different from those with lesser risk selected for general anesthesia.

Citation #4: Dumitrascu, C. I., Warner, N. S., Stewart, T. M., Amundson, A. W., Bruns, D. L., Hanson, A. C., Schulte, P. J., Smith, M. M., Brown, M. J., Niesen, A. D., Mantilla, C. B., & Warner, M. A. (2021). Peripheral nerve blockade with combined standard and liposomal bupivacaine in major lower-extremity amputation. *Journal of World Institute of Pain, 21*(3), 299–307. https://doi.org/10.1111/papr.12959

Level: II

Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**
The authors' hypothesis was that regional anesthesia via peripheral nerve block (PNB) would enhance pain management compared to traditional analgesic efforts.	This article describes a Level II Quasi-Experiment with a quality rating of B. This study was a retrospective observational study analyzing how different approaches to pain management in patients undergoing lower extremity amputation reduced the requirement for post operative opioids. The authors selected patients within their parameters and performed chart reviews to obtain objective data by which to compare the groups (no PNB versus PNB Bupivacaine versus PNB with liposomal bupivacaine).	The researchers selected 578 patients aged >18 years who underwent lower extremity amputation. The researchers selected to exclude patients who did not give authorization for inclusion, patients who underwent disarticulation, those who received neuraxial anesthesia, patients who received PNB following their procedures, and those who received more than one limb amputation during the hospitalization.	Three interventions were compared. The first is receipt of PNB utilizing 0.5% Bupivacaine only (n=84). The second is receipt of PNB utilizing 0.25% Bupivacaine and Liposomal Bupivacaine in equal parts (n=131). The third grouping received general anesthesia only without use of PNB (n=416). The PNB injected 20ml into the site via ultrasound guidance during the perioperative setting.	The primary outcome the researchers evaluated was reduction of post operative pain experienced in patients who underwent lower extremity amputation utilizing a 10-point pain scale. The primary measurement was a reduction of morphine milliequivalents (MME) required post-amputation in patients receiving PNB versus the non-PNB patient group through chart review and calculation. The secondary measurement researchers utilized documented pain scores on a 10-point	Patients who received combination PNB saw the greatest reduction of MMEs compared to non-PNB patients (p=.007). Bupivacaine only PNB also saw a reduced MME requirement post operatively from non-PNB (p=.085). However, they saw no difference in MME utilization among the Bupivacaine only versus the combination PNB groups The researchers further saw improved pain scores at 24-hours post-operative but there was no significant difference at the 72-hour post-operative mark.

				scale. Lastly, the researchers evaluated the occurrence of respiratory events post-operatively through chart review of documented occurrences.	There was no significant difference in the occurrence of respiratory events between PNB Bupivacaine only (n=0), PNB combination (n=4), and non-PNB (n=16). The use of PNB helps improve the experience of pain and reduce the total MME used during the post operative period showing it to be a more efficacious management modality in amputation patients.

Citation #5: Ilfeld, B. M., Khatibi, B., Maheshwari, K., Madison, S. J., Esa, W. A. S., Mariano, E. R., Kent, M. L., Hanling, S., Sessler, D. I., Eisenach, J. C., Cohen, S. P., Mascha, E. J., Ma, C., Padwal, J. A., Turan, A., & PAINfRE Investigators (2021). Ambulatory continuous peripheral nerve blocks to treat postamputation phantom limb pain: A multicenter, randomized, quadruple-masked, placebo-controlled clinical trial. *Pain*, *162*(3), 938–955. https://doi.org/10.1097/j.pain.0000000000002087

Level: I

Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**
The researchers sought to evaluate whether continuous PNB would provide a long-lasting analgesic effect in amputation patients who frequently suffer from long-lasting chronic pain secondary to their amputation. They hypothesized that use of a 6-day PNB would reduce pain experience continuously through the four-week post-operative mark.	This research is a level I randomized controlled trial with a quality rating of A. The design selected by the researchers was a "quadruple-masked, placebo-controlled, parallel-arm clinical trial." The participants were randomly assigned to one of two groups, active group participants received PNB versus the placebo group participants who did not receive PNB. They were subsequently compared for reduction of pain experience at four weeks from catheter removal.	The researchers selected 144 patients from four medical centers in San Diego, California, who were aged >18 who recently underwent traumatic or surgical limb amputation distal to the hip or mid-humerus of at least one metatarsal or metacarpal bone greater than 12 weeks prior to enrollment. The patients reported pain rating two or higher three times weekly for eight weeks' duration prior to enrollment. There were 51 females and 93 males with an average age of 49 in the PNB group versus 50 for the placebo group. The participants were	PNB was performed on participants in the active group for either upper or lower extremity pain symptoms. For upper extremity patients, one catheter was inserted into the brachial plexus whereas two catheters were inserted into the femoral and sciatic nerve region for lower extremity amputation. The active group received ropivacaine 0.5% (n=71) while the placebo group received saline infusion (n=73) into their catheters. The femoral catheter infused at 2.5ml/hour, the sciatic catheter at	The outcomes focused on by the researchers were pain score localized to the stump site, pain score localized to the lost body part, and non-painful sensations of the lost body part anticipated to be reduced over the duration of the study for participants of the active group. Outcomes were measured at time of insertion through in-person report, and through a pain inventory questionnaire on day 1 (while infusing), 7, 14, 21, and 28 for short-term effect, as well as at 6 months and 12 months for long-term outcome.	At time of insertion, there was no difference in pain score between the active and placebo participants. However, there was a significant difference in average phantom pain intensity between active participants of 3 and placebo participants of 4.5 at 28 days post insertion (p=.003). The researchers also saw a significant reduction of pain severity among the active participants reduction of 2.4 points compared to a reduction of 0.9 points at the same point in the study (p=.002). Due to various factors, the authors were unable

		primarily lower extremity amputation patients with 58 in the PNB group and 50 in the placebo group.	5ml/hour, and the infraclavicular at 7.5ml/hour. All other pain management previously utilized by the patients remained unchanged throughout the duration of this study. Any accidental removal of the catheter would be replaced at the request of the participant.		to statistically assess the 6- and 12-month impact of PNB on pain experience. The use of PNB helped better control the experience of pain in the amputation patient showing it to be an efficacious and effective management tool.

Citation #6: Makkar, J. K., Bandyopadhay, A., Jain, K., Jafra, A., Gopinathan, N. R., & Singh, P. (2022). Effect of perioperative sciatic nerve block on chronic pain in patients undergoing below-knee amputation: A randomised controlled trial. *Indian Journal of Anaesthesia, 66*(Suppl 6), S300–S306. https://doi.org/10.4103/ija.ija_796_21

Level: I

Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
The use of an ultrasound guided nerve block in patients with traumatic below knee amputation would experience reduced frequency and severity of pain long-term, reduced MME requirements, reduced pain reports during the post-operative period, and reduction of nausea and vomiting.	The authors selected a double-blinded, randomized controlled trial design rendering their work a level I body of evidence with a quality rating of A.	The research was performed at a tertiary medical center in India where 106 patients aged 18-60 who require traumatic lower extremity amputation were selected for participation. Exclusion criteria included bilateral amputation, ischemic limb, malignancy, diabetic ulcers, pregnancy, coagulopathy, or head injury excluding 56 participants rendering a study of 50 total participants. The average age of participants in the control group is 36.87 and the blockade group is 31.87.	The participants were randomly enrolled into either the blockade group (n=24) or the control group (n=26). The blockade group where 0.75% ropivacaine was utilized and 20 milliliters were injected via ultrasound guidance to create a sciatic nerve block. The control group received a sciatic injection of 20 milliliters of saline solution. The injection solution was drawn up by an anesthesiologist not involved in the injection process to create blinding of the injecting anesthesiologist. The investigator performing data	The primary outcome was reduction of total MME requirements in patients receiving blockade compared to the control group. This is measured by the amt of MME utilized via their PCA. The secondary outcomes included presence of nausea and vomiting measured on a four-point scale, reduced pain report and long-term pain experienced measured via the McGill Pain Questionnaire.	The authors saw a significant reduction in frequency of activating their PCA with an average of three times for the blockade group versus 14 for the control group (p=.000). The control group had a total MME of 13.4milligrams versus an average of five milligrams for the blockade group (p=.000). There was a 13% improvement in the experience of phantom limb pain in the blockade group (95% CI). There was also a significant difference in the experience of post-operative nausea/vomiting with the blockade group reporting no and two

			recording was also blinded to the solution injected into each participant. All patients received patient-controlled analgesia (PCA) infusing morphine during the first 48 hours post-operative. Patients were instructed to push their PCA button with each experience of pain. Patients also received gabapentin as it is standard of care for the research facility.		participants in the control group experiencing it. The use of PNB decreased the experience of pain and total MME as well as reduced prevalence of phantom limb pain making it an effective tool in managing the MLA patient's pain.

Citation #7: Weinstein, E. J., Levene, J. L., Cohen, M. S., Andreae, D. A., Chao, J. Y., Johnson, M., Hall, C. B., & Andreae, M. H. (2018). Local anaesthetics and regional anaesthesia versus conventional analgesia for preventing persistent postoperative pain in adults and children. *The Cochrane database of systematic reviews*, *6*(6), CD007105 https://doi.org/10.1002/14651858.CD007105.pub4

Level: Level I

Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
To identify whether local pain blocks reduce the experience of post operative pain (the authors extended their consideration to three months post op)	This is a level I Systematic Review with a quality rating of A. The authors accessed various databases as well as references listed in articles to find 63 RCTs. They evaluated each independently by at least two authors and the original authors were contacted directly for additional insights. The articles were considered in grouping by surgical procedure explored, however for the final analysis 39 RCTs they were pooled,	The study included 39 RCTs exploring the use of continuous regional anesthesia for the reduction of post-operative pain. This included 3027 individuals undergoing a variety of procedures including limb amputation. All studies were performed primarily in North America and Europe (some from China, Egypt, and Brazil). One study included adolescents >10 years of age. However, all others included adults >18 years of age.	The RCTs explored the application of local anesthetics at the site of the surgery and regional anesthesia including epidural and nerve root anesthetic administration compared to traditional pain management approaches including systemic algesia administration.	The primary outcome was the presence/absence of "persistent postoperative pain" (PPP) at >3 months after surgery". However, a precise definition was not offered. The primary author's definition for evaluation was utilized (opioid use or pain presence for example) for identifying PPP. Secondary outcomes assessed included adverse outcomes from the intervention, required pain medications, and/or hyperalgesia.	The studies showed moderate-quality evidence supporting the use of regional anesthesia for the prevention of post operative pain extending beyond three months. The authors further found that more studies are warranted to explore the use of regional pain blockade in the management of pre-operative as well as post-operative amputation pain experienced by patients (including vascular patients with CLI requiring amputation for definitive treatment).

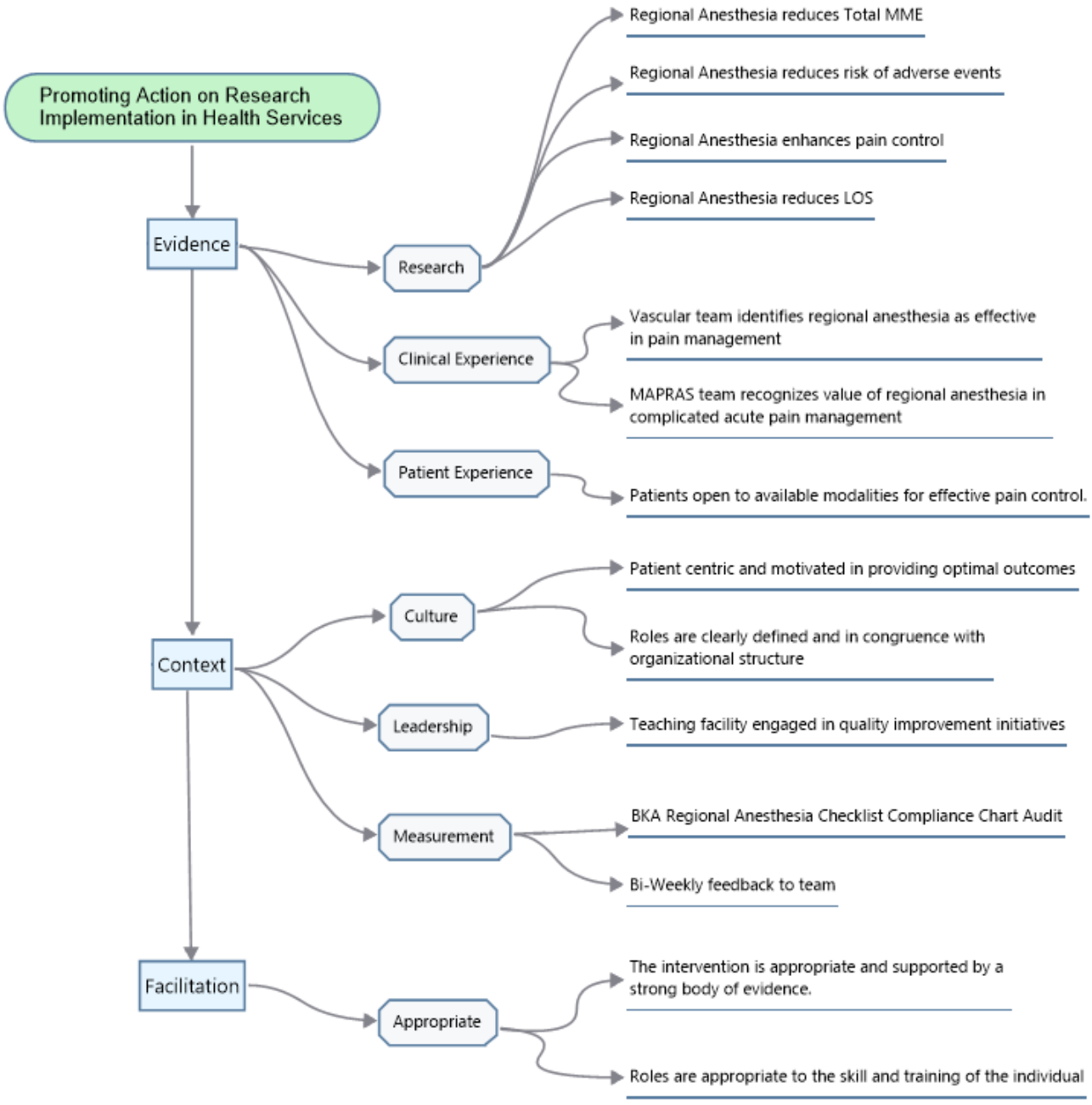
Appendix D
Evidence Synthesis Template

Project Title: Using a Standardized Pain Management Approach Through Regional Anesthesia for Major Limb Amputation Patients			
JHNEBP Model Level	**Total Number of Sources**	**Author and Quality Rating of each study**	**Synthesis of Findings**
Level 1 Experimental study · Randomized Controlled Trial (RCT) · Systematic review of RCTs with or without meta-analysis	4	(Mufarrih et al., 2022) – A (Ilfeld et al., 2021) – A (Makkar et al., 2022) – A (Weinstein et al., 2019) - A	Of the four articles selected, three pertained specifically to the use of regional anesthesia in the management of lower extremity amputation patients. The fourth explored its use in pain control of a variety of post-operative patients. One study focused on the use of regional anesthesia for the procedure of amputation and its reduction of adverse events. However, all studies found enhanced control of the pain experience during the post-operative period. It can reduce the incidence of adverse events among BKA patients as well as poor outcomes. Patients receiving regional anesthesia and PNB reported less occurrence of phantom limb pain and had a significant reduction of total MME utilization during their post-operative setting. The Level I body of evidence provide strong support for the use of regional blockade in the management of BKA patients.
Level II Quasi-experimental studies · Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis.	1	(Dumitrascu et al., 2022) - B	The authors provided strong support for the use of regional blockade in managing BKA patients in the reduction of pain experience post-operatively.
Level III Non-experimental study · Systematic review of a combination of RCTs, quasi-experimental, and non-experimental studies, or non-experimental studies only, with or without meta-analysis ·	2	(Hall et al., 2020) – B (Mufarrih et al., 2021) - B	The authors of one article found that regional anesthesia used intraoperatively may have equalized the occurrence of adverse post-operative events among the high-risk regional patients and lower risk general anesthesia patients. The second article supports the use of

Qualitative study or systematic review of qualitative studies with or without meta-synthesis			regional anesthesia in reducing post-operative pain in the BKA patients.
Level IV Opinion of respected authorities and/or reports of nationally recognized expert committees/consensus panels based on scientific evidence			
Level V Evidence obtained from literature reviews, quality improvement, program evaluation, financial evaluation, or case reports · Opinion of nationally recognized expert(s) based on experiential evidence			
Overall Quality Rating w/rational and Recommendation: B -The evidence provides consistent evidence in support of this practice change implementing the use of regional block for the management of the below knee amputation for the reduction of post-operative pain and adverse events.			

Appendix E

Promoting Action on Research Implementation in Health Services



Appendix F

MLA RA Checklist

MLA Documentation	
Image of Consent in Epic?	Yes
Date of Consent?	
Date of Surgical Procedure?	
Numeric Pain Score at Time of Consent?	7
If 4 or Higher, MAPRAS/PACU Charge RN Notified?	Yes
Was message sent to PACU Charge RN and MAPRAS Consults Resident on TigerConnect requesting Regional Anesthesia?	Yes
Patient Posted for OR?	Yes
Was Regional Anesthesia Request Placed into Special Needs Section of Order?	Yes
Has Patient Received Regional Anesthesia?	Yes
If Patient Did Not Receive Regional Anesthesia, Why Not?	Not Applicable, Patient Received RA.
Patient Pain Score Today?	3

Note. Sample of the Vascular Surgery MLA checklist utilized by the provider to guide adherence to all necessary steps to ensure application of RA.

Appendix G

MLA Chart Audit

MLA Chart Audit

Please complete the survey below.

Thank you!

1) Did vascular provider include MLA Documentation dot phrase into the daily progress note on day of consent?
- ○ Yes
- ○ No

2) Which extremity was amputated?

_____

3) Data and Time of Consent for MLA?

_____

4) MLA Patient's pain score at time of consent?

_____

5) Did the MLA patient receive Regional Anesthesia?
- ○ Yes
- ○ No

6) Total Morphine Milliequivalents administered during hospitalization?

_____

7) Which pain medications were administered using multimodal approach with RA?
- ☐ IV Morphine
- ☐ IV Dilaudid
- ☐ PO Dilaudid
- ☐ Oxycodone
- ☐ MS Contin
- ☐ Methadone
- ☐ IV Fentanyl
- ☐ Tramadol
- ☐ Percocet
- ☐ PO Tylenol
- ☐ IV Tylenol
- ☐ Gabapentin
- ☐ Lyrica
- ☐ Lidocaine Patch
- ☐ Ibuprofen
- ☐ IV Toradol
- ☐ PO Buprenorphine

8) Numeric Pain Score POD1

_____

9) Final documented Numeric Pain Score prior to discharge?

_____

Appendix H
MLA Provider Input Survey

MLA Provider Input

Please complete this survey pertaining to the standardized approach of the MLA patient you recently cared for.

1) Patient MRN _____

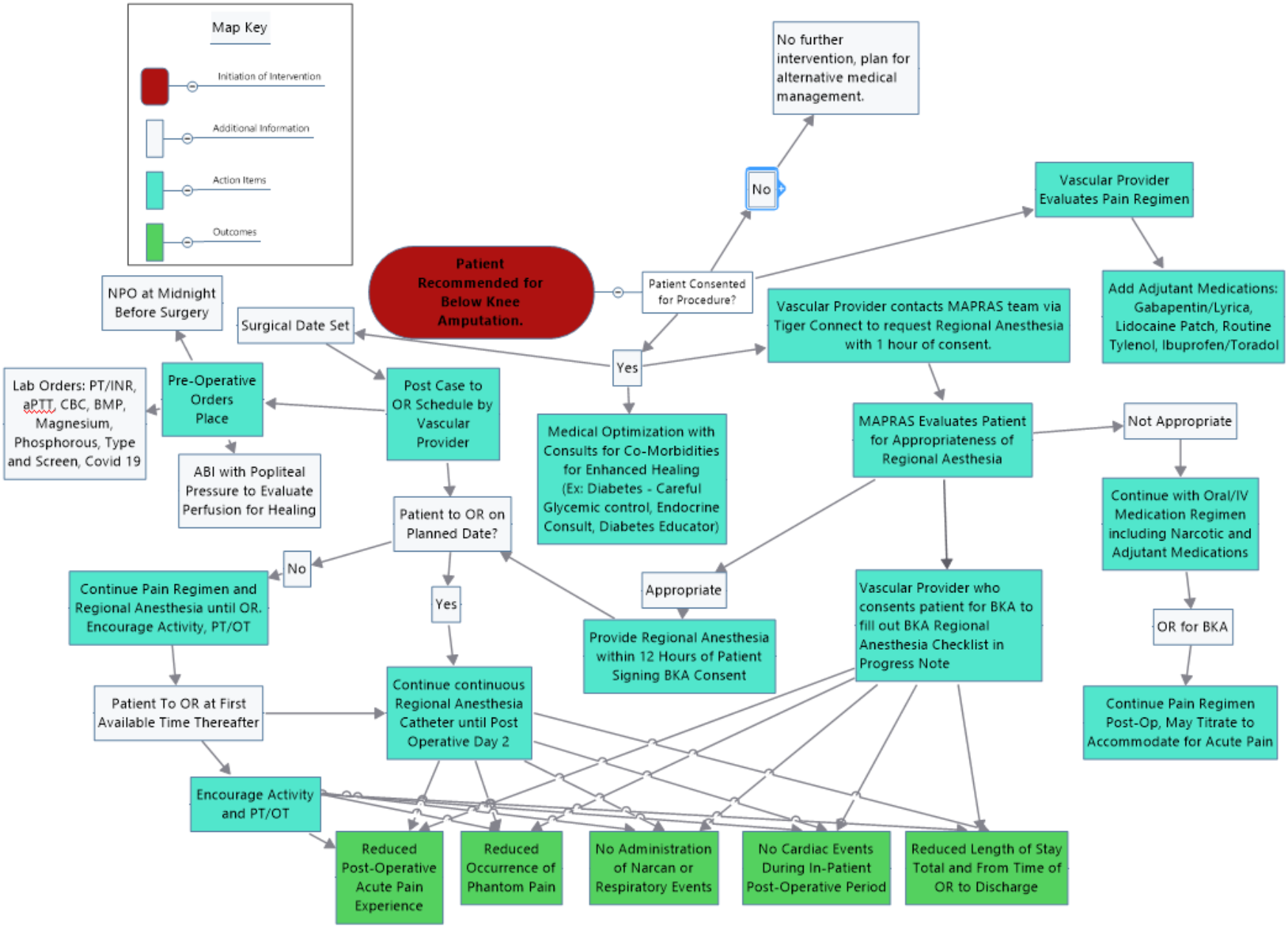
2) If Pain Score 4 or higher, was MAPRAS contacted via Tiger Connect secure texting service?
- ○ Yes
- ○ No

3) If MLA patient had NPR of 4 or higher but not a primary patient of Vascular Surgery (or housed on a closed unit), was the primary provider for the patient notified with request for regional anesthesia?
- ○ Yes
- ○ No

4) If MAPRAS not contacted for MLA Patient with NPS 4 or higher, why not? _____

Appendix I

Current Practice in Managing the MLA Patient



Appendix J

Proposed Practice in Managing the MLA Patient

Appendix K

MLA Education Flyer and Flow Chart

Using a Standardized Pain Management Approach Through Regional Anesthesia for Major Limb Amputation Patients

What is it?

This is a quality improvement (QI) process designed to standardize the pain management approach to inpatient Vascular Surgery amputee patients using regional anesthesia (RA). The aim of this project is to effectively manage perioperative acute pain to optimize outcomes.

When will implementation occur?

The implementation period will extend from September 4, 2023, through December 15, 2023.

Who will this quality improvement process impact?

All patients undergoing Major Limb Amputation (MLA) proximal to the wrist/ankle performed by the University of Maryland Vascular Surgery team.

Where will this QI take place?

This QI project will occur at the University of Maryland Medical Center Downtown Campus.

Why Regional Anesthesia for the amputation patient?

- Numeric Pain Score – Use of RA significantly reduces the patient-reported Numeric Pain Score post-operatively (Dumitrascu et al., 2021).
- Morphine Milliequivalents (MME) – RA can lower daily MME usage to less than 20 MME. (Rountree et al., 2021).
- Vasodilation - RA helps increase perfusion and healing capacity (Jorgensen, et al., 2020).
- Phantom Pain – RA decreases phantom pain experience post-operatively (Ilfeld et al., 2021).
- Adverse Outcomes – RA reduces the occurrence of major adverse respiratory or cardiac events, and reduce length of stay (Mufarrih et al., 2021; Dumitrascu et al., 2021).

How will this QI project work?

Please see Page 2 for the new workflow for managing pain in the Vascular Surgery MLA patient.

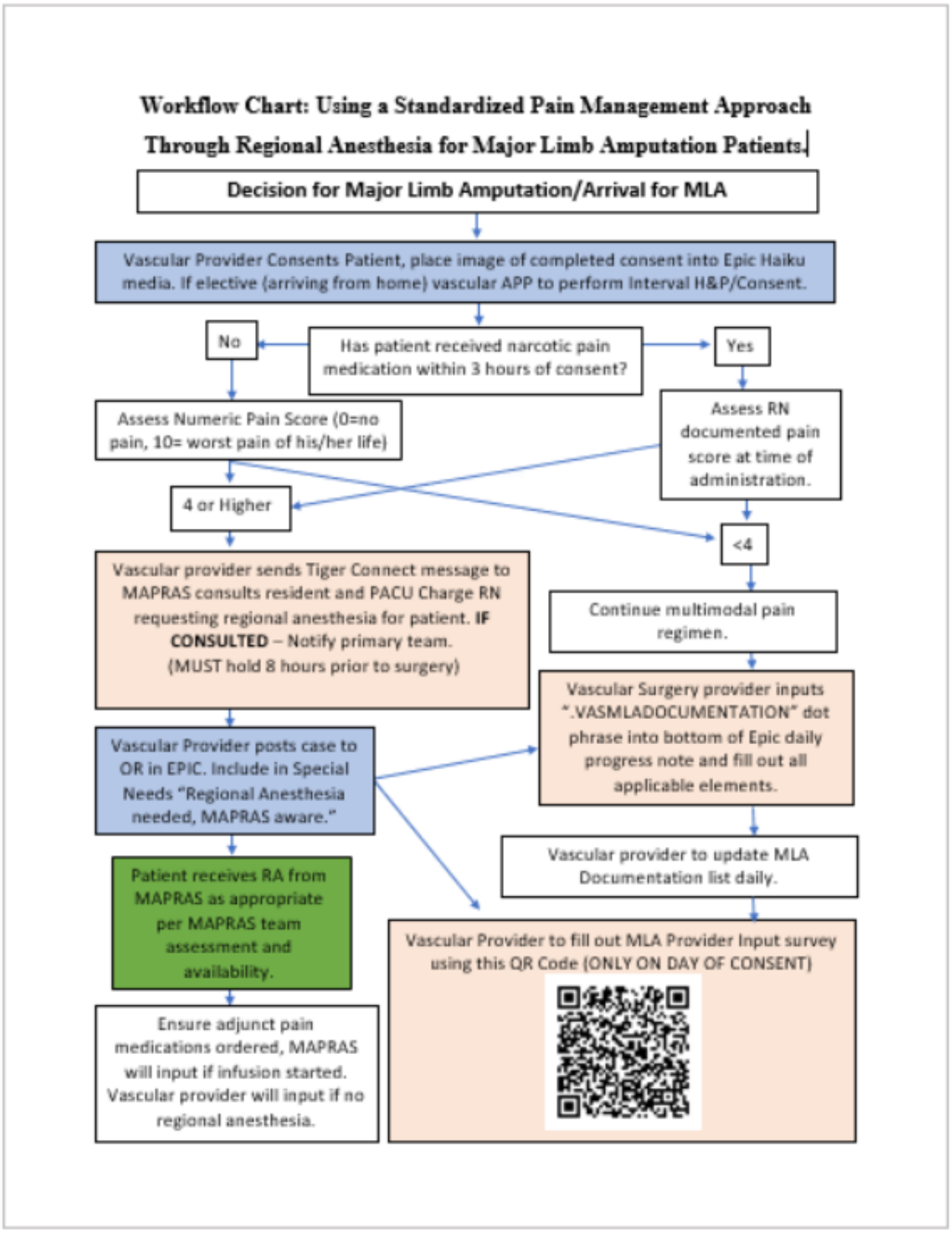
Dumitrascu, C. I., Warner, N. S., Stewart, T. M., Amundson, A. W., Bruns, D. L., Hanson, A. C., Schultz, P. J., Smith, M. M., Brown, M. J., Nissen, A. D., Mantilla, C. B., & Warner, M. A. (2021). Peripheral Nerve Blockade with Combined Standard and Liposomal Bupivacaine in Major Lower-Extremity Amputation. *Journal of World Institute of Pain, 21*(3), 299–307. https://doi.org/10.1111/papr.12959

Ilfeld, B. M., Khatibi, B., Mahadwari, K., Madison, S. J., Esa, W. A. S., Mariano, E. R., Kent, M. L., Hanling, S., Sessler, D. I., Eisenach, J. C., Cohen, S. P., Mascha, E. J., Ma, C., Pabon, J. A., Turan, A., & PAINFREE Investigators (2021). Ambulatory continuous peripheral nerve blocks to treat postamputation phantom limb pain: a multicenter, randomized, quadruple-masked, placebo-controlled clinical trial. *Pain, 162*(3), 938–955. https://doi.org/10.1097/j.pain.0000000000002087

Jorgensen, M. S., Farrus, H., Juman, B. L. W., Li, Z., Alrawey, T., Sheikh-Ali, R., Clendaniel, S., Rohanda, C., Erben, Y., Oldenburg, W. A., & Halkos, A. G. (2020). The Role of Regional versus General Anesthesia on Arteriovenous Fistula and Graft Outcomes: A Single-Institution Experience and Literature Review. *Annals of vascular surgery*, 62, 287–294. https://doi.org/10.1016/j.avsg.2019.05.016

Mufarrih, S. H., Qureshi, N. Q., Schaefer, M. S., Sharkey, A., Fatima, H., Chaudhary, O., Krumm, S., Baribeau, V., Mahmood, F., Schermerhorn, M., & Matyal, R. (2021). Regional anaesthesia for lower extremity amputation is associated with reduced post-operative complications compared with general anaesthesia. *European Journal of Vascular and Endovascular Surgery, 62*(3), 478–484. https://doi-org.proxy-hs.researchport.umd.edu/10.1016/j.ejvs.2021.05.040

Rountree, K., Smith, J. B., Balasundaram, N., Bath, J., & Vogel, T.R. (2021). Opioid usage after lower extremity amputation and discharge prescribing recommendations. *Journal of Vascular Surgery, 17085381221097163*. https://doi.org/10.1177/17085381221097163


Workflow Chart: Using a Standardized Pain Management Approach Through Regional Anesthesia for Major Limb Amputation Patients.
Decision for Major Limb Amputation/Arrival for MLA
Vascular Provider Consents Patient, place image of completed consent into Epic Haiku media. If elective (arriving from home) vascular APP to perform Interval H&P/Consent.
Has patient received narcotic pain medication within 3 hours of consent?
No
Yes
Assess Numeric Pain Score (0=no pain, 10= worst pain of his/her life)
Assess RN documented pain score at time of administration.
4 or Higher
<4
Vascular provider sends Tiger Connect message to MAPRAS consults resident and PACU Charge RN requesting regional anesthesia for patient. IF CONSULTED – Notify primary team. (MUST hold 8 hours prior to surgery)
Continue multimodal pain regimen.
Vascular Surgery provider inputs ".VASMLADOCUMENTATION" dot phrase into bottom of Epic daily progress note and fill out all applicable elements.
Vascular Provider posts case to OR in EPIC. Include in Special Needs "Regional Anesthesia needed, MAPRAS aware."
Vascular provider to update MLA Documentation list daily.
Patient receives RA from MAPRAS as appropriate per MAPRAS team assessment and availability.
Vascular Provider to fill out MLA Provider Input survey using this QR Code (ONLY ON DAY OF CONSENT)
Ensure adjunct pain medications ordered, MAPRAS will input if infusion started. Vascular provider will input if no regional anesthesia.

Appendix L

Gantt Chart: Timeline for Implementation

			2023																							2024									
Task	Team Member	Due Date	Jan 15-31	Feb 1-15	Feb 16-28	Mar 1-15	Mar 16-31	Apr 1-15	Apr 16-30	May 1-15	May 16-31	Jun 1-15	Jun 16-30	July 1-15	July 16-31	Aug 1-15	Aug 16-31	Sept 1-15	Sept 16-30	Oct 1-15	Oct 16-31	Nov 1-15	Nov 16-30	Dec 1-15	Dec 16-31	Jan 1-15	Jan 16-31	Feb 1-15	Feb 16-29	Mar 1-15	Mar 16-31	Apr 1-15	Apr 16-30	May 1-15	May 16-31
CITI/Red Cap/ HIPAA	Sarah M	23-Jan																																	
Overview/ Mobilize	Sarah M	30-Jan																																	
Root Cause	Sarah M	13-Feb																																	
Project Charter	Sarah M	13-Mar																																	
Project Proposal	Sarah M	4-Apr																																	
Final Proposal	Sarah M	24-Apr																																	
IRB Eval	Sarah M	24-Apr																																	
Literature Handout	Sarah M	1-May																																	
Introduce Project	Sarah M	1-Jun																																	
Role Contracts	Sarah M	1-Jun																																	
EPIC Report	Tiffany Kuebler	1-Aug																																	
Team Education	Sarah M	1-Aug																																	
Develop Flyer	Sarah M	1-Sep																																	
Implement	Team	15-Dec																																	
Email 1	Sarah M	8-Sep																																	
Report 1	Sarah M	8-Sep																																	
Email 2	Sarah M	15-Sep																																	
Report 2	Sarah M	15-Sep																																	
Email 3	Sarah M	22-Sep																																	
Report 3	Sarah M	29-Sep																																	

			2023																						2024									
Task	Team Member	Due Date	Jan 15-31	Feb 1-15	Feb 16-28	Mar 1-15	Mar 16-31	Apr 1-15	Apr 16-30	May 1-15	May 16-31	Jun 1-15	Jun 16-30	July 1-15	July 16-31	Aug 1-15	Aug 16-31	Sept 1-15	Sept 16-30	Oct 1-15	Oct 16-31	Nov 1-15	Nov 16-30	Dec 1-15	Dec 16-31	Jan 1-15	Jan 16-31	Feb 1-15	Feb 16-29	Mar 1-15	Mar 16-31	Apr 1-15	Apr 16-30	May 1-15	May 16-31
Staff Eval 1	Sarah M	29-Sep																																
Email 4	Sarah M	6-Oct																																
Report 4	Sarah M	6-Oct																																
Email 5	Sarah M	13-Oct																																
Report 5	Sarah M	13-Oct																																
Email 6	Sarah M	20-Oct																																
Report 6	Sarah M	20-Oct																																
Staff Eval 2	Sarah M	20-Oct																																
Email 7	Sarah M	27-Oct																																
Report 7	Sarah M	27-Oct																																
Email 8	Sarah M	3-Nov																																
Report 8	Sarah M	3-Nov																																
Email 9	Sarah M	10-Nov																																
Report 9	Sarah M	10-Nov																																
Staff Eval 3	Sarah M	10-Nov																																
Email 10	Sarah M	17-Nov																																
Report 10	Sarah M	17-Nov																																
Email 11	Sarah M	24-Nov																																
Report 11	Sarah M	24-Nov																																
Email 12	Sarah M	24-Nov																																
Report 12	Sarah M	1-Dec																																
Staff Eval 4	Sarah M	1-Dec																																
Email 13	Sarah M	8-Dec																																
Report 13	Sarah M	8-Dec																																
Written Report	Sarah M	15-Dec																																

			2023																						2024									
Task	Team Member	Due Date	Jan 15-31	Feb 1-15	Feb 16-28	Mar 1-15	Mar 16-31	Apr 1-15	Apr 16-30	May 1-15	May 16-31	Jun 1-15	Jun 16-30	July 1-15	July 16-31	Aug 1-15	Aug 16-31	Sept 1-15	Sept 16-30	Oct 1-15	Oct 16-31	Nov 1-15	Nov 16-30	Dec 1-15	Dec 16-31	Jan 1-15	Jan 16-31	Feb 1-15	Feb 16-29	Mar 1-15	Mar 16-31	Apr 1-15	Apr 16-30	May 1-15	May 16-31
Identify Poster Present	Sarah M, Sarah R, Patti M.	31-Dec																																
Gift Card Delivery	Sarah M	31-Dec																																
Data Analysis	Sarah M	15-Mar																																
Ongoing Plan	Team	31-Mar																																
Develop Poster	Sarah M	1-Apr																																
Present	Sarah M	15-Apr																																
Final Written Project	Sarah M	1-May																																
Complete Program	Sarah M	15-May																																

Appendix M

Provider Education Survey

MLA Education

Please complete the survey below.

Thank you!

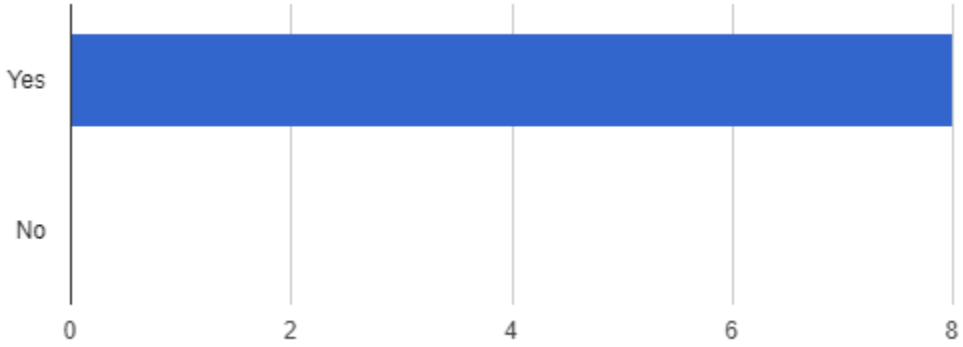
1) Did you receive in-person education of the standardized MLA management process?
- ○ Yes
- ○ No

2) Did you receive an electronic recording of the education regarding the new standardized MLA management process?
- ○ Yes
- ○ No

Appendix N

Figure 1

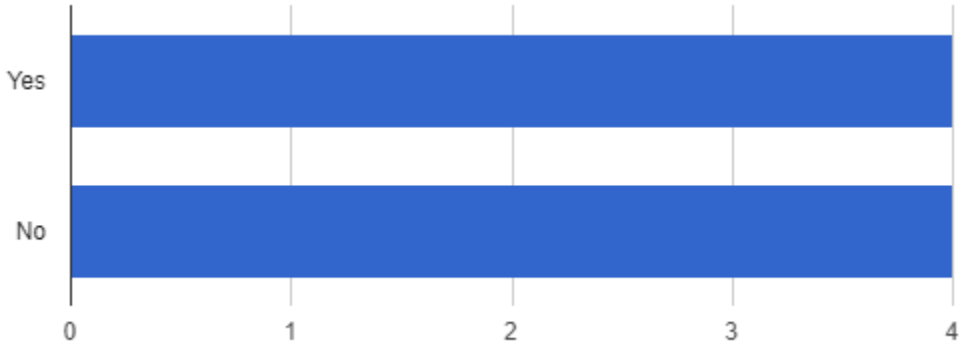
Vascular Provider In-Person Education Receipt



Note. Of the providers who responded, 100% endorsed receipt of in-person education pertaining to this QI project.

Figure 2

Vascular Provider Electronic Education Receipt



Note. Of the providers who responded, 50% report receiving the electronic PowerPoint education for ongoing referral throughout the implementation period.

Appendix O

Figure 3

Rate of Regional Anesthesia Application to MLA patients

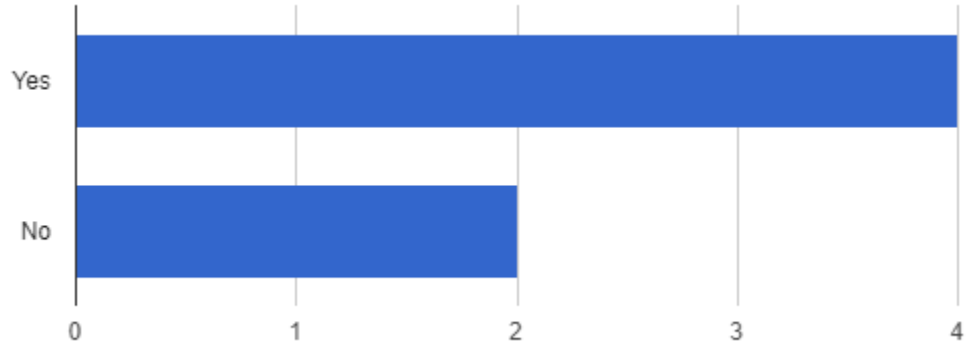
Application of Regional Anesthesia Among Eligible MLA Patients		
Timing of RA Receipt	**Number of Patients**	**Percentage of Patients**
Preoperative Application	1	9.1%
Intraoperative Application	3	27.3%
Post-Operative Application	0	0%
Eligible but didn't Receive RA	3	27.3%
Not Eligible to Receive RA	4	36.3%
TOTAL	**n = 11**	**100%**

Note. The vascular team ensures RA application in 80% of eligible patients, 83.3% of total patients. Of these, 16.67% of total MLA patients received RA prior to the procedure optimizing pain control while awaiting *or* through their operative and post-operative acute pain phase.

Appendix P

Figure 4

MLA Checklist Completion in Daily Progress Note by Vascular Providers

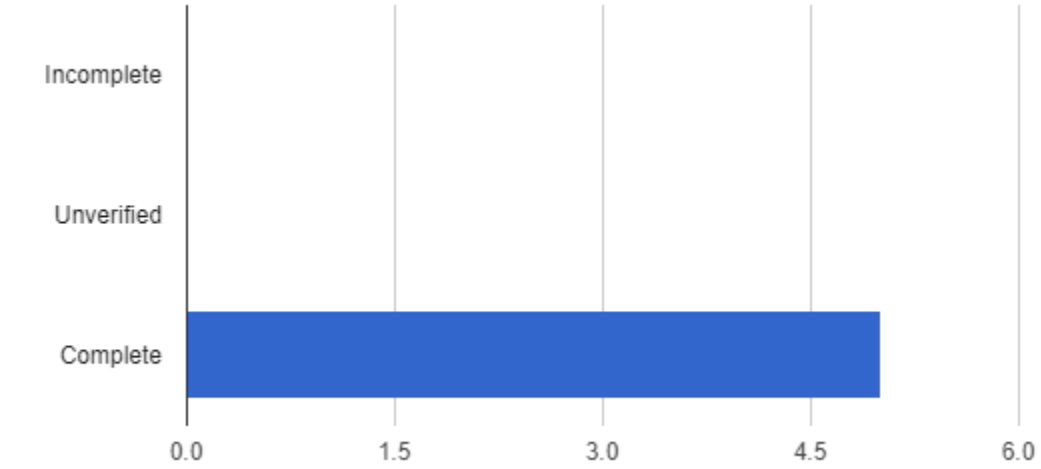


Note. Through chart audit, it is found that four of the six providers caring for the MLA patient on date of consent input the MLA checklist into the daily progress note. This checklist is designed to provide a framework to guide adherence to this process and ensure RA application. Two providers did not complete this component.

Appendix Q

Figure 5

Vascular Provider Completion of the Provider Input Survey

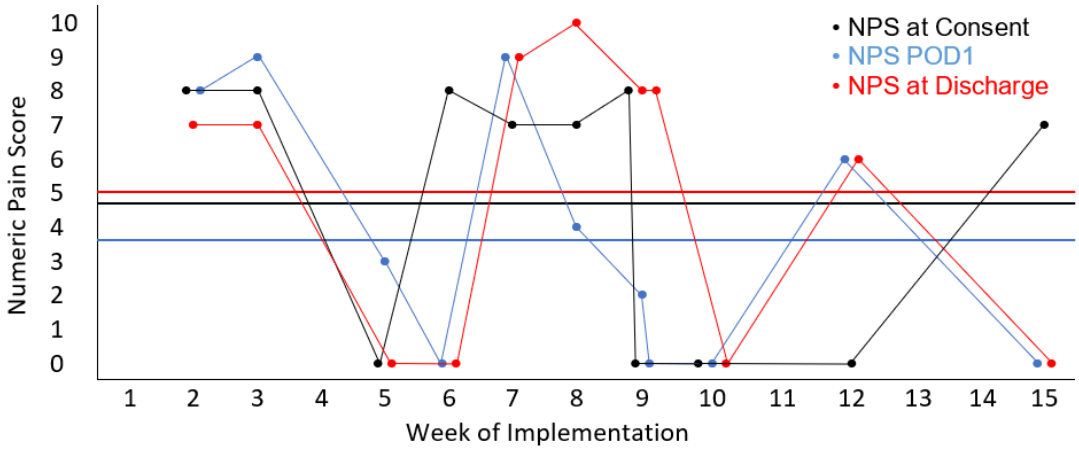


Note. There are eight MLA procedures completed. However, only five providers have completed the MLA Provider Input Survey. This survey is designed to help identify each MLA patient, their eligibility, and any barriers identified which may impair the capacity of the vascular provider to ensure application of RA.

Appendix R

Figure 6

Average Numeric Pain Score Documentation Throughout Implementation



Note. MLA patients' NPS improved from the pre-operative period (mean = 4.73) to post-operative day one (mean = 3.46) before increasing on discharge day (mean = 5.0) with the removal of RA and transition to an oral pain regimen.

Appendix S

Table 1

Selection of Adjunct Pain Medications Utilized