INTRAOPERATIVE HYPOTENSION AND ACUTE KIDNEY INJURY AFTER ROBOTIC ENHANCED RECOVERY PROTOCOL SURGERY

by

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A doctoral scholarly project submitted to the faculty of
The University of North Carolina at Charlotte
in partial fulfillment of the requirements
for the degree of Doctor of Nursing Practice

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# DEDICATION

This scholarly project paper is dedicated to my parents Peter and Natalia, my siblings Katya, Alena, and Andrey, and all my peers and friends in Charlotte, NC for providing the strength and motivation to pursue my academic goals. Your love and support have made this journey possible.

# ABSTRACT

MARK FORTYGIN. Intraoperative Hypotension and Acute Kidney Injury after Robotic Enhanced Recovery Protocol Surgery.
(Under the direction of DR. DAVID LANGFORD)

Acute kidney injury (AKI) has been linked to intraoperative hypotension in previous studies. AKI may lead to prolonged recovery and hospital stays and complications such as chronic kidney disease. Factors associated with robotic surgery and enhanced recovery protocols (ERPs) may contribute to intraoperative hypotension. This quality improvement project aimed to explore the incidence of AKI in robotic cases incorporating an ERP. The project design was a retrospective review of anesthesia records of robotic surgeries performed at Atrium Health (AH) Carolinas Medical Center (CMC) over a four-month period. Records were screened for the occurrence of hypotension. The charts of patients who experienced hypotension were then screened for a pre-operative and post-operative creatinine level. AKI was defined using the Kidney Disease Improving Guidelines (KDIGO). The sample size included 34 patients who experienced hypotension. The incidence of AKI was 5.88%. AKI did not differ by age, gender, ASA score, or procedure time.

# ACKNOWLEDGEMENTS

This project was part of a larger group project and performed in collaboration with team members Lloren Hile and Ana Arias, whose work made this possible. This project was completed under the expert guidance of David Langford, PhD, and Karen Lucisano, PhD. Dr. Elena Meadows, DNP, was an important partner in developing the project topic and project plan and provided a large amount of expertise and sources for the topic of hypotension. The research problem and data pool were provided by Sherry Bernardo, DNP. The statistical analysis was completed with the invaluable assistance of Zhuo Job Chen, PhD. The research committee providing support for this project included Patricia Crane, PhD, and Jennifer Richards, DNP, and Mike Turner, PhD.

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# LIST OF ABBREVIATIONS

| | |
|---|---|
| AH | Atrium Health |
| AKI | acute kidney injury |
| ASA | American Society of Anesthesiologists |
| CMC | Carolinas Medical Center |
| EHR | electronic health record |
| ERP | enhanced recovery protocol |
| KDIGO | Kidney Disease Improving Global Outcomes |
| NSAID | non-steroidal anti-inflammatory drug |
| NIBP | non-invasive blood pressure |
| SVV | stroke volume variation |
| UOP | urine output |

# CHAPTER 1: INTRODUCTION

## Problem Statement

Two improvements in surgical techniques include using robotic surgery and reducing patients' use of opioids called Enhanced Recovery Protocol (ERP). Patients undergoing enhanced recovery after robotic surgeries may have an increased risk of developing an acute kidney injury (AKI). Robotic surgeries and enhanced recovery protocols (ERPs) each have separate attributes that, when combined, place patients at risk for developing AKI. The Kidney Disease Improving Global Outcomes (KDIGO) guidelines define AKI as an increase in serum creatinine >0.3 mg/dL in 48 hours or urine output (UOP) <0.5 ml/kg/hr for 6-12 hours (KDIGO, 2012). More concerning, AKI development can lead to increased complications and hospital costs (Joo et al., 2016; Kong et al., 2018). While studies have examined AKI development in these populations separately, the risks associated with robotic ERPs have not yet been studied.

There is an average of five robotic cases per day at Atrium Health (AH) Carolinas Medical Center (CMC), leading to approximately 25 cases per week, totaling 1,300 cases per year (Atrium Health, 2019). In addition, AKI is the number one complication in both colorectal and abdominal service lines and the fourth most common complication in the gynecologic service line at AH CMC (Centers for Medicare & Medicaid Services MedPar, 2018).

There are factors related to the technique of robotic surgeries that could increase the risk of developing AKI. These factors include abdominal insufflation with carbon dioxide and extreme trendelenburg positioning in some procedures (Naito et al., 2020; Sato et al., 2020). Insufflation pressure can collapse the vasculature in the abdomen and reduce renal blood flow, while steep trendelenburg drives blood volume toward the head. In addition, robotic surgeries generally have longer surgical times than open procedures, increasing patients' exposure to anesthesia and surgical stress (Joo et al., 2016).

Enhanced Recovery Protocols are being implemented in hospital systems across the country to improve patient recovery times and reduce reliance on opioids. ERPs are a series of guidelines for surgical procedures meant to decrease recovery times after surgeries and improve patient outcomes (Zorrilla-Vaca et al., 2020). One of the complications of ERPs is that it has been found to increase AKI development (Koerner et al., 2019). A primary tenet of ERPs is restricted fluid administration during procedures, which may lead to decreased renal perfusion. Another foundation of ERPs is the decreased use of opioids and relying on more nonsteroidal anti-inflammatory drug (NSAID) use which potentially affects kidney function (Zorrilla-Vaca et al., 2020). Inhibition of the vasodilatory effects of renal prostaglandins from NSAIDs, paired with perioperative conditions such as reduced blood flow to the kidneys, place patients at increased risk for reduced kidney function (Bell et al., 2018). Many factors of ERPs could impact the risk of AKI development, but there is uncertainty about which factor has a more significant effect.

In addition to the surgical and ERP factors that may place patients at risk, individual patient risk factors can affect AKI development. For example, one study found that robotic surgery patients who were obese, had diabetes, increased baseline glomerular filtration rate (GFR), and men had a higher rate of AKI development (Martini et al., 2019). Another study examining patients participating in ERPs found that patients with hypoalbuminemia, age greater than 60 years old, male, American Society of Anesthesiologists (ASA) physical status classification III-IV, and had pre-existing chronic kidney disease were more likely to develop AKI (Zorrilla-Vaca et al., 2020).

**Purpose**

This project aims to determine the role of hypotension as a potential risk factor contributing to the development of AKI in robotic procedures at AH CMC. This is part of a larger project looking at several factors in robotic and ERP surgeries related to increased risk of AKI that was identified as an area of concern by the Anesthesia Department.

A retrospective chart review examined hypotension as a variable during robotic surgery and serum creatinine levels up to 48 hours postoperatively. Hypotension is a variable that anesthesia providers can control with fluid status management and medication administration. If the data suggest a link between hypotension and AKI development, future projects can work towards developing practice guidelines related to preventing hypotension to reduce AKI incidence at AH CMC.

**PICOT Question**

In adult patients undergoing robotic procedures utilizing an ERP, what is the incidence of AKI development related to hypotension in the 48-hour postoperative period? Acute kidney injury development will be determined by comparing preoperative serum creatinine levels to those within the 48-hour postoperative period.

# CHAPTER 2: LITERATURE REVIEW

Electronic databases were searched throughout Fall 2021 and Spring 2022 to obtain literature review data. Database access was obtained through the North Carolina Area Health Education Center (AHEC) digital library. PubMed Medline, PubMed Central, Cochrane library, and the Cumulative Index to Nursing and Allied Health Literature Complete were accessed. Boolean search operators utilized were "acute kidney injury AND Enhanced recovery protocol" and "acute kidney injury AND hypotension."

Blood pressure is composed of heart rate, stroke volume, and systemic vascular resistance and is an indicator of end-organ perfusion. It is well established that hypotension results in decreased renal perfusion and thus, increases the risk of developing AKI. Hypotension has recently received increased attention for its role in developing AKI in the perioperative period and its detrimental effect on patient outcomes. A study by Stapelfeldt et al. (2021) showed a significant association between hypotension and increased use of hospital resources in the six-month post-discharge period, which included increased emergency room visits and longer readmission length of stay. AKI was a significant factor in this study.

There is still no clear consensus on how to define hypotension. One way to measure hypotension is using the mean arterial pressure (MAP). Mean arterial pressure is an average arterial pressure throughout one cardiac cycle that includes both systole and diastole. There have been many studies done to find an optimal MAP threshold. Salmasi et al. (2017) found that pressures considered clinically acceptable, such as an absolute threshold MAP of 65 mmHg, may be associated with renal injury. Pressures lower than 65 mmHg, even in short durations, created stronger associations with organ injury. However, they state that "… a strategy aimed at maintaining MAP above 65 mmHg appears to be as good as one based on the percentage reduction from baseline" (p. 60). A MAP of 65 mmHg is a widely used threshold used by providers for preventing or promptly treating lower pressures and is likely effective in preventing organ hypoperfusion.

Blood pressure is influenced by fluid status and hypovolemia will often lead to hypotension. Characteristics of ERPs such as limited fluid administration may contribute to an already hypovolemic state and result in exaggerated hypotension intraoperatively. Hypovolemia combined with insufflation and steep Trendelenburg positioning performed with robotic surgeries may cause further hypotension and low organ perfusion states.

In addition to preoperative hypovolemia, chronic hypertension is another risk factor for intraoperative hypotension. Factors such as impaired blood pressure autoregulation and blood pressure agents such as beta-blockers and ACE-inhibitors predispose patients to large swings in blood pressure in the operative setting. A study by Levy et al. (2008) found that in addition to being at higher risk for intraoperative hypotension, tissues may be more vulnerable to ischemia in chronically hypertensive patients.

Advanced age is another risk factor for developing intraoperative hypotension. Both intraoperative hypotension and an age ≥ 65 years were risk factors for AKI. Blood loss is a significant complication in some surgeries, such as liver resections, and can also result in significant hypotension (Liao et al., 2020).

Hypotension is a risk throughout the intraoperative phase due to anesthetic agents and resulting changes in blood pressure autoregulation. However, the post-induction, pre-incision period is when most cases of hypotension occur. Hypotension occurred in one-third of elective non-cardiac surgeries before incision (Maheshwari et al., 2018). Thus, it is recommended to frequently measure blood pressure during induction and prior to incision and promptly manage a

MAP less than 65 mmHg so that any period of hypotension is limited to less than four minutes (El-Ghazali and Pandit, 2019).

# CHAPTER 3: METHODOLOGY

## Conceptual Framework

The conceptual framework for the project is the Plan-Do-Study-Act (PDSA) model (Plan-Do-Study-Act, 202). The "Plan" is to identify the relationship between hypotension and AKI development in the 48-hour postoperative period. The occurrence of hypotension for 30 patients undergoing robotic procedures with ERPs will be recorded, as well as the preoperative and postoperative creatinine for the "Do" step. These data will be analyzed to determine how hypotension affected the incidence of AKI in this population. In the final step of the model, if the findings show that hypotension does affect AKI incidence, the "Act" phase will result in recommendations for future scholarly projects to develop and implement protocols that can be quickly assessed to address hypotension in robotic ERP surgical patients to reduce the risk of AKI development.

## Methodology and Project Design

This project is a quality improvement project which aims to improve patient outcomes after robotic surgery using a retrospective, correlational design. Curtis et al. (2016) state that a correlational study is used to determine the prevalence and relationship between variables. The variables in question will be hypotension and incidence of AKI (measured by pre and post operative creatinine levels). Data will be retrieved from patient medical records over a 4-month period from May 2022 to August 2022.

## Setting

The patients included in the project were adults undergoing robotic procedures incorporating ERPs at AH CMC. AH CMC is a Level 1 Trauma center serving the large urban city of Charlotte, North Carolina. In 2018, 43% of AH CMC Main patients came from

Mecklenburg County, and 57% came from surrounding counties (Atrium Health, 2019). The medical center has 38 operating rooms, including four dedicated C-section rooms and one trauma room.

There were 43,331 surgeries performed at AH CMC Main and AH Mercy in 2018, averaging 833 operations per week (Atrium Health, 2019). In the AH CMC operating rooms, 41.8% of the patients were racial and ethnic minorities, and 26.7% were elderly (Atrium Health, 2019). Those having surgery included 7% that were self-pay, 28.2% that paid with Medicare, 18.9% that paid with Medicaid, and 42.8% that paid using private insurance (Atrium Health, 2019). Statistics prior to the Covid-19 pandemic were used, as they most accurately reflect the current trends at this institution.

**Sample**

The sample was extracted from the medical record. Eligible records were adult patients (18 years and older) undergoing robotic procedures incorporating ERPs at AH CMC and those with pre and post operative creatinine measures. The sample was obtained from electronic health records from May 2022 through August 2022. Thirty-four patients met the sampling criteria. The types of surgeries included were general and thoracic services. Patients in the sample needed to be admitted for at least one night to obtain a postoperative creatinine level. Patients having pre-existing kidney disease, urologic procedures, surgeries converting to non-robotic surgery, outpatient procedures, and emergency procedures were excluded from the project.

**Measurement Tools**

The measures used in the project were physiologic measures captured from electronic health records that include creatinine and blood pressure monitoring. Preoperative creatinine level and the highest postoperative creatinine within 48 hours after surgery was recorded.

Postoperative creatinine levels ≥0.3 mg/dL served as the measure of AKI. Measurement of AKI will use the KDIGO guidelines, which state AKI as an increasing serum creatinine (SCr) ≥0.3 mg/dL in 48 hours or urine output <0.5 mL/kg/hr 6-12 hrs. Because urine output may not always be accurately tracked postoperatively, creatinine levels will be used as the primary measure of AKI. Hypotension will be treated as nominal data and will be recorded as a "yes or no" category.

Mean arterial pressure (MAP) is a blood pressure metric that measures average arterial pressure throughout one cardiac cycle, which includes both systole and diastole. The formula to calculate MAP can be found in Appendix A. MAP can be obtained from arterial line monitoring or from a non-invasive blood pressure (NIBP). Periods of intraoperative hypotension will be defined as a MAP less than 65 for a period longer than three minutes. Arterial line monitoring provides a continuous MAP with each heartbeat, while NIBP monitoring is typically programmed to automatically measure MAP at an interval of three minutes. However, one single hypotensive measurement makes it challenging to determine an exact measurement of time spent hypotensive, and the time until a repeat blood pressure measurement may vary across providers. Intraoperative hypotension with NIBP monitoring will thus be identified as two consecutive measurements of a MAP less than 65 within six minutes.

**Data Collection**

Data collection involved retrospectively extracting patient records from the electronic health record at Atrium Health. Atrium Health converted to a new EHR in April of 2022, so access to patient data was limited to the start of the new EHR system in May of 2022. The data champion created a database that was de-identified and made available to the project coordinator to include the records meeting the sampling criteria. Surgeries from May 1st, 2022 to August

30th, 2022 were included. The data collection form can be found in Appendix A. The criteria below were used to identify the sample.

- All the surgeries from May 1st to August 30th, 2022
- Filtered to the operating rooms with robotic capabilities
- Anesthesia type was filtered to general anesthesia with an endotracheal tube
- Age was filtered to only include patients over 18 years old
- A filter was applied to assess for multimodal pain management which was used to determine an enhanced recovery protocol was used
- The records were examined for the presence of preoperative and postoperative creatinine levels

All patients who fit the inclusion criteria and experienced hypotension were included. The timeline is presented in Appendix B.

**Data Management and Confidentiality**

The resulting patient data were de-identified and transferred to a password-protected Microsoft Excel sheet for data analysis. The data were only available to project directors and authorized team members. The project was reviewed by the hospital Institutional Review Board (IRB) and university IRB and determined to be a quality improvement project that required no further approval. The IRB letters can be found in Appendix C and D.

**Data Analysis**

Data analysis was based on a sample size of 34 patients. The descriptive demographic analysis evaluated the statistical significance of hypotension, age, gender, ASA score, and anesthesia time. Logistic regression was used to predict the relationship between these variables and the incidence of AKI.

# CHAPTER 4: RESULTS

A retrospective analysis was performed of anesthesia case records of procedures taking place at Atrium Health CMC Main from May 1st 2022 through August 31st 2022. The filters used to generate a sample from the electronic health record included general anesthesia with an endotracheal tube, age greater than or equal to 18, operating rooms in which robotic surgeries are performed, and multimodal anesthesia use. The anesthesia records were then manually screened for a robotic approach, documented preoperative and postoperative creatinine lab values, and the occurrence of perioperative hypotension defined as a MAP <65 in two consecutive measurements.

A total of N = 34 patients were included in this project. The majority ($n$ = 20, 58.88%) underwent thoracic surgery, and 41.18% ($n$ = 14) underwent general surgery. The majority (61.94%) of the sample was male ($n$ = 19). The mean age was 61.94 years old ($SD$ = 14.76). The average procedure time was 297.71 minutes ($SD$ = 128.31). Two (5.88%) individuals developed AKI.

Logistic regressions tested the degree to which AKI was influenced by age, gender, ASA score, and anesthesia time. AKI did not differ by age ($b$ = -.02, $p$ = .732), gender ($b$ = -.25, $p$ = .863), ASA score ($b$ = .44, $p$ = .836), or procedure time ($b$ = -.01, $p$ = .369). Table 1 displays all patients that experienced hypotension, and how these variables differed in the non-AKI and AKI groups.

Table 1.
*Descriptive analysis and comparison between non-AKI and AKI groups (n = 34)*

| | non-AKI ($n$ = 32) | AKI ($n$ = 2) | $p$-value |
|---|---:|---:|---:|
| Average Age | 62.18 ± 15.22 | 58.5 ± .71 | p = .732 |
| Gender (% of female) | 43.75 | 50 | p = .863 |
| ASA | 2.94 ± .44 | 3 | p = .836 |
| Anesthesia time (minutes) | 302.69 ± 130.73 | 218 ± 2.83 | p = .369 |

This project did not find any statistically significant ($p = \leq 0.05$) difference in AKI by age, gender, ASA score, or procedure time in patients who experienced hypotension.

# CHAPTER 5: DISCUSSION

## Implications for Practice

This project found a low incidence of AKI in patients who experienced hypotension during robotic surgery incorporating an ERP at AH CMC. This finding does not reflect what is suggested in previous literature and may not be reliable due to a limited sample size or periods of hypotension that were addressed quickly enough that AKI did not occur. Considering the supporting literature that has suggested the correlation between intraoperative hypotension and AKI, anesthesia providers should still exercise extreme vigilance in managing intraoperative blood pressure variations to maintain adequate perfusion to the kidneys.

An alternative method of monitoring blood pressure and fluid volume is the use of invasive intra-arterial monitors. These produce continuous measures that the anesthesia provider can quickly respond to changes. However, there are risks to this kind of monitoring such as temporary vascular occlusion, ischemia, hematoma, nerve damage, infection, and sepsis (Nuttall et al., 2016). In addition, this kind of monitoring is more costly than NIBP and therefore may need to only be recommended for high-risk patients.

Although recommendations vary for blood pressure goals under anesthesia, it is widely recommended to maintain blood pressure within 20 percent of the patient's baseline and MAPs of at least 65 mmHg and systolic pressures greater than 100 mmHg (London, 2022). Patients with chronic hypertension or other comorbidities may require higher goals for adequate organ perfusion.

Furthermore, the frequency in which the readings are taken and recorded are often left to the discretion of the anesthesia provider. Reviewing institution guidelines and chart audits on how often intraoperative blood pressures are measured may be one way to address increased awareness of changes.

**Limitations**

There were several limitations to this project. The available data pool was limited in size due to a recent switch in EHR at Atrium Health CMC Main. Only the case records that were on the new EHR system, starting May 2022, were accessible limiting the sample size. The EHR was limited in identifying the utilization of ERPs. The "multimodal" filter thus may have not provided a sufficient stratification of patients undergoing an ERP. The sample size was further limited by inconsistency in available measured preoperative and postoperative creatinine levels. Additionally, some of the common robotic procedures performed could not be included in the project. Many of the gynecological procedures were not included because the patients were not admitted long enough to get a post-operative creatinine value. Urology and prostate surgery are common robotic procedures, but these patients were not included due to the surgery's direct interference with the renal system anatomy.

**Recommendations**

Evidence surrounding the dangers of intraoperative hypotension continues to grow and the occurrence of hypotension during surgery is a potential risk factor for patients experiencing AKI. A larger study and sample size would provide more data points and potentially more conclusive and statistically significant results. The inclusion of a control group that did not experience hypotension would provide a baseline to better analyze the relationships.

This subproject in combination with the other parts of a larger project begin the process of exploring the variables at AH CMC to affect the incidence of AKI. Because the robotic ERP population has been identified as a practice problem, it is recommended that institution guidelines be created that identifies patients undergoing these procedures that could be at higher risk for hypotension or AKI. The development of an assessment risk tool could also indicate the need for closer monitoring, such as with invasive intraarterial blood pressure measurement.

**Conclusion**

AKI is an adverse event that has been associated with intraoperative hypotension. Factors surrounding robotic surgeries and enhanced recovery protocols may contribute to intraoperative hypotension. This project found a low incidence of AKI in patients undergoing robotic surgery with an enhanced recovery protocol and who experienced an episode of hypotension. There was no statistical significance between AKI and age, gender, ASA class, or anesthesia time. However, AKI in this patient population requires continued investigation.

# REFERENCES

Atrium Health. (2019, October 15). Carolinas medical center operating rooms certificate of need. Charlotte, NC.

Centers for Medicare & Medicaid Services Medpar 2019. (n.d.). Room for Improvement: Complications in the Abdominal, Colorectal, Gyn Service Line.

Joseph, R. (2021, August 9). *Correlation and P value*. The Data School. Retrieved May 17, 2022, from https://dataschool.com/fundamentals-of-analysis/correlation-and-p-value/

Curtis, E. A., Comiskey, C., & Dempsey, O. (2016). Importance and use of Correlational Research. *Nurse Researcher*, *23*(6), 20–25. https://doi.org/10.7748/nr.2016.e1382

El-Ghazali, S. K., & Pandit, J. J. (2019). Pre-incision hypotension and the association with postoperative acute kidney injury – an opportunity to improve peri-operative outcomes? *Anaesthesia*, *74*(12), 1611–1614. https://doi.org/10.1111/anae.14822

Joo, E. Y., Moon, Y. J., Yoon, S. H., Chin, J. H., Hwang, J. H., & Kim, Y. K. (2016). Comparison of acute kidney injury after robot-assisted laparoscopic radical prostatectomy versus retropubic radical prostatectomy. *Medicine*, *95*(5). https://doi.org/10.1097/md.0000000000002650

*KDIGO – kidney disease | improving global outcomes*. KDIGO. (n.d.). Retrieved April 12, 2022, from https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-AKI-Guideline-English.pdf

Koerner, C. P., Lopez-Aguiar, A. G., Zaidi, M., Speegle, S., Balch, G., Shaffer, V. O., Staley, C. A., Srinivasan, J., Maithel, S. K., & Sullivan, P. S. (2019). Caution: Increased acute kidney injury in enhanced recovery after surgery (ERAS) protocols. *The American Surgeon*, *85*(2), 156–161. https://doi.org/10.1177/000313481908500221

Levy, B. I., Schiffrin, E. L., Mourad, J. J., Agostini, D., Vicaut, E., Safar, M. E., & Struijker-Boudier, H. A. J. (2008). Impaired tissue perfusion. *Circulation*, *118*(9), 968–976. https://doi.org/10.1161/circulationaha.107.763730

Liao, P., Zhao, S., Lyu, L., Yi, X., Ji, X., Sun, J., Jia, Y., & Zhou, Z. (2020). Association of intraoperative hypotension with acute kidney injury after liver resection surgery: An observational cohort study. *BMC Nephrology*, *21*(1). https://doi.org/10.1186/s12882-020-02109-9

London, M. J. (2022, May 5). *Hemodynamic management during anesthesia in adults*. UpToDate. Retrieved June 2, 2022, from https://www.uptodate.com/contents/hemodynamic-management-during-anesthesia-in-adults#H1743600392

Maheshwari, K., Turan, A., Mao, G., Yang, D., Niazi, A. K., Agarwal, D., Sessler, D. I., & Kurz, A. (2018). The association of hypotension during non-cardiac surgery, before and after skin incision, with postoperative acute kidney injury: A retrospective cohort analysis. *Anaesthesia*, *73*(10), 1223–1228. https://doi.org/10.1111/anae.14416

Naito, A., Taguchi, S., Suzuki, M., Kawai, T., Uchida, K., Fujimura, T., Fukuhara, H., & Kume, H. (2020). Transient acute kidney injury observed immediately after robot-assisted radical prostatectomy but not after open radical prostatectomy. *Molecular and Clinical Oncology*, *13*(3). https://doi.org/10.3892/mco.2020.2087

Nuttall, G., Burckhardt, J., Hadley, A., Kane, S., Kor, D., Marienau, M. S., Schroeder, D. R., Handlogten, K., Wilson, G., & Oliver, W. C. (2016). Surgical and patient risk factors for severe arterial line complications in adults. *Anesthesiology*, *124*(3), 590–597. https://doi.org/10.1097/aln.0000000000000967

*Plan-do-study-act (PDSA) directions and examples*. AHRQ. (2020, September). Retrieved March 25, 2022, from https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.html

Salmasi, V., Maheshwari, K., Yang, D., Mascha, E. J., Singh, A., Sessler, D. I., & Kurz, A. (2017). Relationship between intraoperative hypotension, defined by either reduction from baseline or absolute thresholds, and acute kidney and myocardial injury after noncardiac surgery. *Anesthesiology*, *126*(1), 47–65. https://doi.org/10.1097/aln.0000000000001432

Sato, H., Narita, S., Saito, M., Yamamoto, R., Koizumi, A., Nara, T., Kanda, S., Numakura, K., Inoue, T., Satoh, S., Abe, K., & Habuchi, T. (2020). Acute kidney injury and its impact on renal prognosis after robot-assisted laparoscopic radical prostatectomy. *The International Journal of Medical Robotics and Computer Assisted Surgery*, *16*(5), 1–7. https://doi.org/10.1002/rcs.2117

Stapelfeldt, W. H., Khanna, A. K., Shaw, A. D., Shenoy, A. V., Hwang, S., Stevens, M., & Smischney, N. J. (2021). Association of perioperative hypotension with subsequent greater healthcare resource utilization. *Journal of Clinical Anesthesia*, *75*. https://doi.org/10.1016/j.jclinane.2021.110516

Zorrilla-Vaca, A., Mena, G. E., Ripolles-Melchor, J., Lorente, J. V., Ramirez-Rodriguez, J. J., & Grant, M. C. (2020). Risk factors for acute kidney injury in an enhanced recovery pathway for colorectal surgery. *Surgery Today*, *51*(4), 537–544. https://doi.org/10.1007/s00595-020-02107-2

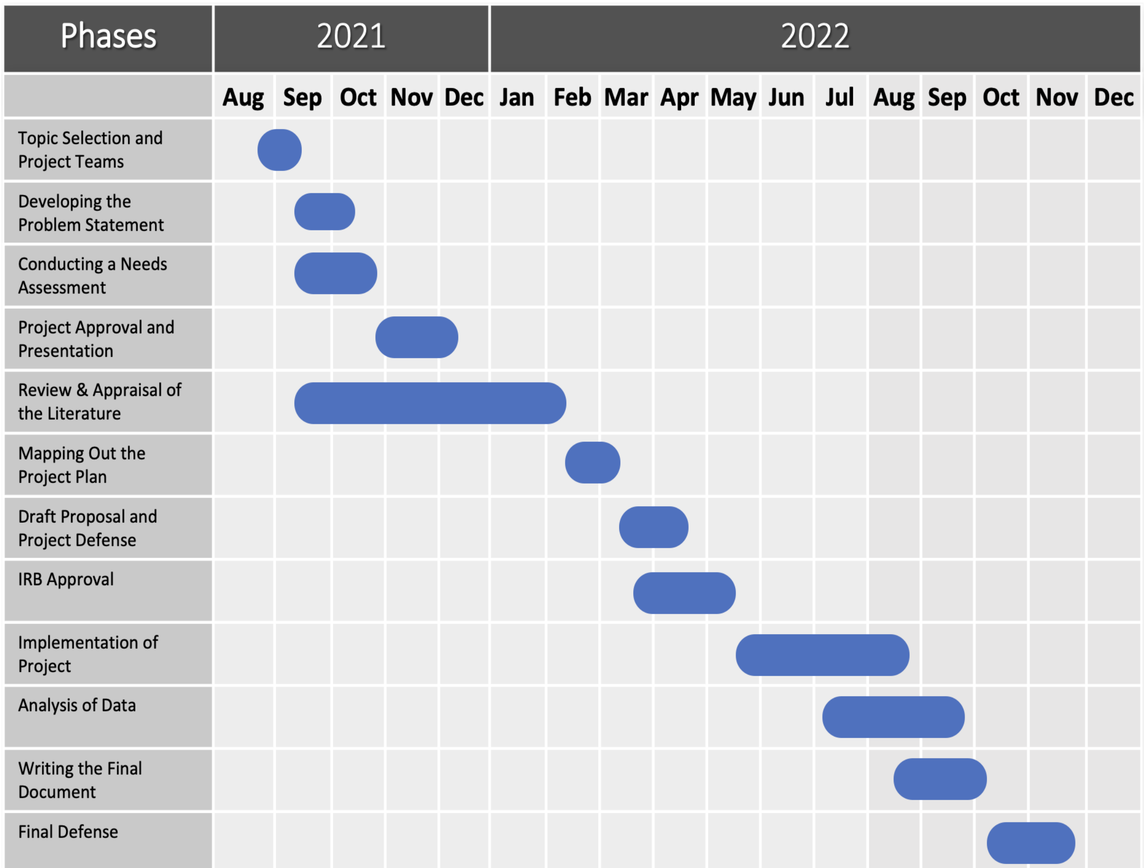
# APPENDIX A: FORMULA TO CALCULATE MEAN ARTERIAL PRESSURE (MAP)

$$\text{MAP} = \frac{(\text{systolic blood pressure} + (2 \times \text{diastolic blood pressure}))}{3}$$

# APPENDIX B: SAMPLE DATA FORM

| Patient # | Surgery Date | Anesthesia time | Surgical service | Age | Gender | ASA score | Preop Cr | Postop Cr | Difference in Cr |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | |
| 2 | | | | | | | | | |
| 3 | | | | | | | | | |
| Etc. | | | | | | | | | |

# APPENDIX C: TIMELINE



APPENDIX D: WAKE FOREST/ATRIUM HEALTH IRB APPROVAL

# MEMORANDUM

To: Elena Meadows
Clinical and Translational Science Institute {CTSI}

From: Jeannie Sekits, Senior Protocol Analyst
Institutional Review Board

Date: 7/12/2022

Subject: Not Human Subjects Research: IRB00086555
Enhanced Recovery after Robotic Surgery & Acute Kidney Injury

The Wake Forest University School of Medicine Institutional Review Board has reviewed your protocol and determined that it does not meet the federal definition of research involving human subject research as outlined in the federal regulations 45 CFR 46. 45 CFR 46.102(f) defines human subjects as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

The information you are receiving is not individually identifiable. In recent guidance published by the Office of Human Research Protections (OHRP) on the Guidance on Research Involving Coded Private Information or Biological Specimens, OHRP emphasizes the importance on what is being obtained by the investigator and states "if investigators are not obtaining either data through intervention or interaction with living individuals, or identifiable private information, then the research activity does not involve human subjects."

Note that only the Wake Forest University School of Medicine IRB can make the determination for its investigators that a research study does not meet the federal definition of human subject research. Investigators do not have the authority to make an independent determination that a study does not meet the federal requirements for human subject research. Each project requires a separate review and determination by the Board. The Board must be informed of any changes to this project, so that the Board can determine whether it continues to not meet the federal requirements for human subject research. If you have any questions or concerns about this information, please feel free to contact our office at 716-4542.

# APPENDIX E: UNCC APPROVAL

| | |
|---|---|
| **To:** | Ana Arias<br>University of North Carolina at Charlotte |
| **From:** | Office of Research Protections and Integrity |
| **Date:** | 27-Jul-2022 |
| **RE:** | Determination that Research is not Human Subjects and does not require IRB Approval |
| **Study #:** | IRB-23-0030 |
| **Study Title:** | Enhanced Recovery After Robotic Surgery & Acute Kidney Injury |

This submission was reviewed by the Office of Research Protections and Integrity, which has determined that this submission does not constitute human subjects as defined under federal regulations 45 CFR 46.102(e) and 21 CFR 56.102(e) and does not require IRB approval.

**Study Description:**
This quality improvement (QI) project was chosen by the Safety and Quality Coordinator for the Anesthesia Department at Atrium Health (AH) Main facility. This project will look specifically at factors leading to acute kidney injury (AKI) in robotic surgeries with early recovery after surgery (ERAS) protocols at AH Main. In 2018, AKI was the most common complication in colorectal and abdominal surgeries at AH Main, and the fourth most common complication in gynecologic surgeries. The three team members will each be looking at a specific variable that could be affecting AKI development. The variables being examined are stroke volume variation (SVV), hypotension, and non-steroidal anti-inflammatory (NSAID) administration. These variables were chosen because they are all within the control of the anesthesia provider during the perioperative period. This QI project uses a retrospective, correlational design. Data will be collected via electronic health record (EHR) review and stored in the RedCap secure database. Patients will be deidentified in RedCap- medical record number (MRN), name, and any other identifying information will not be stored. The data that will be recorded is patient age, patient gender, surgical procedure, preoperative creatinine value, postoperative creatinine value, average SVV, minutes with MAP <65, and NSAID dose administered. The comparison of preoperative creatinine and postoperative creatinine will be used to determine if an AKI occurred within the 48-hour postoperative period.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records), even though IRB approval is not required.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.