PCRC Proposal Cover Sheet

Title of Study or Project:	1:2:3 What Outcome have Thee? Impact of Anesthesia Staffing Ratios on Postoperative Outcomes
Primary Institution:	University of Michigan
Principal Investigator:	Leif Saager
Co-Investigators:	S. Kheterpal, J. You, A. Shanks, A. Kurz
Type of Study:	☒ Retrospective Observational ☐ Exploratory
IRB Number/Status:	Under MPOG approval
Hypothesis:	To determine the current state of anesthesia practice in regards to MD:CRNA staffing ratios and investigate if increasing staffing ratios are associated with adverse postoperative outcomes.
Number of Patients/Participants:	All adult patients who underwent non-cardiac surgery documented in the MPOG database.
Power Analysis:	We would need from 14,579 to 55,716 patients to detect an odds ratio of having in-hospital mortality or any major morbidity from 1.05 to 1.10 for a unit increase in the TWA of staffing ratio with 90% power at the significance level of 0.05, assuming an incidence rate of 10% for the collapsed composite outcome and a normal distribution with mean of 2 (SD: 1) for the TWA of staffing ratio.
Proposed statistical test/analysis:	Assess the association between TWA of staffing ratio and the collapsed composite (i.e., any versus none) of in-hospital mortality and 6 major morbidities using a multivariable logistic regression. We will assess a common effect of staffing ratio effect across the components of the collapsed composite outcome using a multivariate (i.e., multiple outcomes) generalized estimating equation (GEE) model with unstructured covariance matrix.
Resources (Brief summary of resources for data collection, personnel, financial):	Programmer to pull the data and statistical analysis

1:2:3 What Outcome Have Thee? Impact of Anesthesia Staffing Ratios on Postoperative Outcomes

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Background

The majority of anesthesia services are provided by a team. Typical teams are composed of anesthesiologists, and fellows, residents, certified registered nurse anesthetists or student nurse anesthetists. One faculty anesthesiologist can supervise / direct several anesthesia caregivers providing anesthesia in different operating rooms. For medically directed anesthesia services, an anesthesiologist is present during critical points in the procedure and is immediately available for diagnosis and treatment of emergencies. However, when a CRNA is medically supervised by the attending physician, an anesthesiologist does not have to be present during critical points in the procedure or be immediately available for diagnosis and treatment of an emergency.

Ongoing economic challenges have led hospitals to implement cost-repositioning efforts and to redesign their workflow in an attempt to increase efficiency while at the same time maintaining a high standard of care. Trends such as the American Society of Anesthesiologists' Perioperative Surgical Home or bundled payments to Accountable Care Organizations seek out the cheapest way to manage anesthetic populations. In an anesthesia team model one faculty anesthesiologist can direct up to four CRNAs parallel. Medical direction ratios of 1:2 or 1:3 are already frequently occurring, even in large academic centers.

While increasing efficiency and reducing cost are important goals to ensure financial viability of a department, quality and safety of care cannot be compromised to achieve these goals. So far, few studies investigated the effect of different staffing ratios on actual patient outcomes.

Posner and Freund measured supervisory ratios as mean monthly number of cases supervised concurrently by attending anesthesiologists and found a range of 1.6 to 2.2 cases per anesthesiologist. They conclude that most aspects of quality of anesthesia care (measured as rate of critical incidents, patient injury, escalation of care, operational insufficiencies and human errors) were not affected by increasing productivity and concurrency.[1] Silber et al. investigated more than 200,000 "directed" and "undirected" anesthesia cases from 245 hospitals using Health Care Financing Administration billing records. In this large retrospective database study both 30-day mortality and mortality after complication (failure to rescue) were lower when anesthesiologists directed anesthesia care, but unfortunately no mention of staffing concurrencies is made.[2] Dexter et al. asked CRNA's to daily evaluate the quality of medical direction by the anesthesiologist they worked with the previous day. They found essentially no influence of the MD:CRNA ratio on scores.[3]

There are not only benefits to increasing the supervising ratio. Epstein and Dexter found that at a supervision ratio of 1:2 already significant lapses on first round starts occur and these lapses would occur on 99% of the days if supervision ratio increases to 1:3.[4] Clinical outcomes where not part of the study.

Specific Aims

This project proposes to utilize the MPOG dataset to determine the current state of anesthesia practice in regards to MD: CRNA staffing ratios and investigate if increasing staffing ratios are associated with adverse postoperative outcomes.

Methods

Patient Population

The study population will consist of all adult patients who underwent non-cardiac surgery documented in the MPOG database.

Exclusion Criteria

Specific case types may be associated with a fixed staffing ratio. For example, patients undergoing Liver transplantation will have a caregiver team with a fixed ratio of 1:1 assigned at most centers. Similar, cataract surgeries might frequently be associated with a 1:4 staffing ratio. We will therefore assess variation of staffing ratio per CPT code and exclude cases with insufficient variability in staffing ratios. Since this is reflective of intentional staffing decisions we will report descriptive statistics on these excluded surgical categories.

Furthermore, we will exclude:

- Cases with staff supervision of residents only
- Cases with resident involvement for >25% of case duration
- Cases with medically directed SRNA's
- Cases with documented ASA 5 or 6 status
- Cases performed on weekends or holidays

Medical Direction Ratio

For each individual case we will calculate the time-weighted average (TWA) of staffing ratio for the whole case. For example, staffing ratios are 1:2, 1:3, and 1:4 for 10%, 50%, and 40% of the case time (not necessary to be contiguous), respectively. Then the TWA of staffing ratio is 1:3.3 (i.e., $2 \times 0.1 + 3 \times 0.5 + 4 \times 0.4 = 3.3$).

Primary Outcome

We will assess the association between TWA of staffing ratio a composite of in-hospital mortality and 6 major morbidities including serious cardiac, respiratory, gastrointestinal, urinary, bleeding, and infection, based on the U.S. Agency for Healthcare Research and Quality's single-level Clinical Classifications Software categories for International Classification of Diseases, 9th Revision, Clinical Modification diagnosis codes.

Major Morbidity	AHRQ CCS category*	ICD-9 code	ICD-9 code description
Cardiac	16.10.2.1	429.4	Functional disturbances following cardiac surgery
		458.21	Hypotension of hemodialysis
		458.29	Other iatrogenic hypotension
		997.1	Cardiac: arrest during or resulting from a procedure insufficiency during or resulting from a procedure
Respiratory	16.10.2.2	518.7	Transfusion related acute lung injury (TRALI)
		997.3	Respiratory complications
		997.31	Ventilator associated pneumonia

		997.32	Postprocedural aspiration pneumonia
		997.39	Other respiratory complications
Gastrointestinal	16.10.2.3	539.01	Infection due to gastric band procedure
		539.09	Other complications of gastric band procedure
		539.81	Infection due to other bariatric procedure
		539.89	Other complications of other bariatric procedure
		564.2	Postgastric surgery syndromes
		564.3	Vomiting following gastrointestinal surgery
		564.4	Other postoperative functional disorders
		569.6	Colostomy and enterostomy complications
		569.71	Pouchitis
		569.79	Other complications of intestinal pouch
		579.3	Other and unspecified postsurgical nonabsorption
		997.4	Digestive system complications
		997.41	Retained cholelithiasis following cholecystectomy
		997.49	Other digestive system complications
Urinary	16.10.2.4	596.81	Infection of cystostomy
		997.5	Urinary complications
Bleeding	16.10.2.5	998.1	Hemorrhage or hematoma or seroma complicating a procedure
		998.11	Hemorrhage complicating a procedure
		998.12	Hematoma complicating a procedure
		998.13	Seroma complicating a procedure
Infection	16.10.2.6	519.01	Infection of tracheostomy
		536.41	Infection of gastrostomy
		530.86	Infection of esophagostomy
		997.62	Infection (chronic)
		998.5	Postoperative infection
		998.51	Infected postoperative seroma
		998.59	Other postoperative infection
		999.3	Other infection

AHRQ = U.S. Agency for Healthcare Research and Quality
ICD = International Classification of Diseases
* Multi-level Clinical Classifications Software for International Classification of Diseases, 9th Revision, Clinical Modification diagnosis codes.

Secondary Outcomes

For our secondary outcomes we intend to calculate:

- Return to operating room within 7 days
- Length of PACU stay (for centers contributing PACU LOS data)
- Length of hospital stay
- A composite of 9 ASPIRE Performance Measures including Neuromuscular Blocking, Glucose, Ventilator, Blood Pressure and Transfusion Management.

ASPIRE Performance Measures

Abbrev	Measure Title	Measure Description
NMB 01	Train of Four Monitor Documented After Last Dose of Non-depolarizing Neuromuscular Blocker	The Train of Four Documented measure states the percentage of the EP's cases with documentation of a Train of Four count or acceleromyography result after the last dose of a non-depolarizing muscle relaxant
NMB 02	Administration of Neostigmine before Extubation for Cases with Nondepolarizing Neuromuscular Blockade	The Administration of Neostigmine measure states the percentage of your patients that receive neostigmine after you have given a non-depolarizing neuromuscular blocker.
GLU 01	Administration of insulin or glucose recheck for patients with hyperglycemia	The Treatment of Perioperative Hyperglycemia measure states the percentage of occurrences that the EP administered insulin or checked a glucose level within 90 minutes of when the documented glucose level was greater than 200 mg/dL.
GLU 02	Administration of dextrose containing solution or glucose recheck for patients with perioperative hypoglycemia	The Treatment of Intraoperative Hypoglycemia measure states the percentage of cases that the EP administered a dextrose containing solution or checked a glucose level within 90 minutes of when the documented glucose level was less than 60 mg/dL.
PUL 01	Avoiding excessively high tidal volumes during positive pressure ventilation	The lung protective ventilation measure states the percentage of cases that the provider administered a lung protective (less than 10 ml/kg ideal body weight) ventilation technique
BP 01	Avoiding intraoperative hypotension	This measure evaluates the percentage of cases with mean arterial pressure less than 55 mmHg for 20 minutes or longer (cumulative)
BP 02	Avoiding monitoring gaps	This measure evaluates the percentage of cases without intraoperative gaps in mean arterial pressure of 10 minutes or more (continuous)
TRAN 01	Transfusion administration vigilance	Discretionary, unnecessary packed red blood cell administration is associated with poor outcomes and increased costs. A mainstay of ensuring necessary transfusions is to measure the patient's hemoglobin or hematocrit prior to RBC transfusion. This measure evaluates the proportion of patients with documented pre-transfusion hemoglobin or hematocrit within 60 minutes of intraoperative transfusion.
TRAN 02	Avoidance of over transfusion	The use of homologous red blood cell transfusion is rarely indicated to achieve a hemoglobin > 10 mg/dl. In patients without massive transfusion or bleeding, the measurement of a hemoglobin after transfusion should demonstrate a hemoglobin <= 10 mg/dl or hematocrit of 30%.

Statistical Analysis

Primary analysis

We will assess the association between TWA of staffing ratio and the collapsed composite (i.e., any versus none) of in-hospital mortality and 6 major morbidities using a multivariable logistic regression. We will adjust for age, gender, race, body mass index, comorbidities, preoperative tests, ASA status, emergent procedure, type of anesthesia, start time of procedure, number of anesthesia handovers, type, duration, and year of procedure, and institution. In addition, we will assess the heterogeneity of the association across the institutions by testing the team-by-institution interaction in a separate logistic regression.

Type of procedure will be characterized into one of 244 mutually-exclusive clinically-appropriate categories using the Agency for Healthcare Research and Quality's Clinical Classifications categories. Number of anesthesia handovers includes handovers among attending anesthesiologists and handovers among medical directed anesthesia providers including residents and fellows, certified registered nurse anesthetists, and student nurse anesthetists. For medical directed anesthesia providers, breaks of less than 40 minutes will not be counted as a handovers; that is, a provider relieves someone, say for lunch, and then returns within 40 minutes.

Furthermore, we will assess a common effect of staffing ratio effect across the components of the collapsed composite outcome using a multivariate (i.e., multiple outcomes) generalized estimating equation (GEE) model with unstructured covariance matrix. We will evaluate the heterogeneity of staffing ratio effect across the components of the outcome by testing the treatment–by-outcome interaction in a "distinct-effect" GEE model. The association between TWA of staffing ratio and each individual component will be reported regardless of the existence of the interaction. The significance criterion will be 0.007 for each of the 7 components of the composite (i.e., 0.05/7).

Secondary analysis

We will assess the association between the collapsed composite in-hospital mortality / morbidity and TWA of staffing ratio during pre- and post- incision periods simultaneously (i.e., from start of case to time of incision and from incision to end of surgery), using a single multivariable logistic regression.

We will assess the association between the TWA of staffing ratio during the whole case and the following 3 secondary outcomes, including re-operation, length of PACU stay, and length of hospital stay. We will use a logistic regression model for re-operation, and Kaplan Meier analysis and Cox hazard regression for length of PACU stay and length of hospital stay, respectively. In the Cox hazard regression model, patients who died before PACU (hospital) discharge will be considered as never having the event and will be assigned a censoring time using the observed longest duration among those discharged alive.

All the above analyses will adjust for the same set of potential confounding variables. The significance criterion will be 0.01 for each of the 5 secondary analyses (i.e., 0.05/5).

In addition, we will descriptively summarize all the individuals ASPIRE performance measures using standard summary statistics. Since the ASPIRE performance measures are institution level data, we will assess the association between the institution average staffing ratio and each ASPIRE measure using linear regression.

Mediation analysis

We will perform a mediation analysis to explore the mechanism in which the staffing ratio affects the primary composite outcome by estimating the amount of the staffing ratio effect goes through a pre-specified mediator. We proposed that blood pressure management during surgery is a mediator in the relationship between staffing ratio and the outcome. Specifically, we will explore the following measurements for the blood pressure management performance, including time-weighted average mean arterial blood pressure (MAP), minimum MAP, epoch units of minimum MAP, duration of hypotension, and duration of hypertension.

First, we will assess whether there is any evidence for mediation for each mediator mentioned above as follows: (1) we will assess whether each mediator is associated with the primary composite outcome (collapsed composite of in-hospital mortality and 6 major morbidities) using a logistic regression; (2) we will assess whether staffing ratio is associated with each mediator using a multivariable linear regression model. All these analyses will adjust for the same potentially confounding variables included in the primary analysis. If there is no association in neither of models, we can conclude that there is no evidence of mediation without further analysis.

If there is evidence there are significant associations in both models (1) and (2), we will estimate the mediation "effect" using the standardized product method. First, we will standardize coefficients of models (1) and (2) in order to ensure they are on the same scale by dividing by the variance of the outcome in their respective equations. Next, we will estimate the mediation "effect" by multiplying the coefficients from models (1) and (2). The proportion mediated will be estimated by dividing the mediation "effect" by the total effect, defined as the "effect" of staffing ratio on the primary composite ignoring (i.e., not adjusting for) the mediator. Confidence intervals of these approaches will be obtained from bootstrap resampling.

We will also estimate the total "effect" (defined as the "effect" of staffing ratio on the primary composite ignoring possible mediation from blood pressure management) and the direct "effect" (defined as the "effect" of staffing ratio on the primary composite after accounting for potential mediation from blood pressure management).

Missing Data

We will use multiple imputation or excluding, as appropriate.

Sample size consideration

The sample size consideration is based on our primary outcome of the collapsed composite of in-hospital mortality and 6 major morbidities. In a retrospective analysis previously performed at our institution based on 25,546 adults who had non-cardiac surgery at our institute main campus between 2005 and 2012, we observed an incidence rate of 10.65% for the collapsed composite of in-hospital mortality and major morbidities.[5]

We would need from 14,579 to 55,716 patients to detect an odds ratio of having in-hospital mortality or any major morbidity from 1.05 to 1.10 for a unit increase in the TWA of staffing ratio with 90% power at the significance level of 0.05, assuming an incidence rate of 10% for the collapsed composite outcome and a normal distribution with mean of 2 (SD: 1) for the TWA of staffing ratio. We will utilize all available patients accrued in the MPOG database, approximately 4.5 million records, thus we would have adequate power. It is known that 900,000 of these records currently include discharge ICD9 amenable to outcome ascertainment. SAS software version 9.3 (SAS Institute, Cary, NC, USA) will be used for all statistical analysis.

Human Subjects' Risks and Data Protection

Data analysis will be restricted to aggregated group data. Data will be de-identified regarding individual hospitals. While hospital and hospital characteristics might be part of the analysis to account for practice variation, no individual hospitals will be identifiable in the results or publication. Each group will contain a sufficient number of hospitals and cases to ensure de-identification or no group analysis will be performed. Again, data analysis and results will not allow identification of individual contributing sites.

Data will also be de-identified regarding individual providers and no analysis of individual providers (*faculty* or *CRNA*) will be performed. Each group will contain a sufficient number of providers to ensure de-identification or no analysis will be performed.

Data will be maintained on a password protected secure MPOG server hosted. The study data will be accessible only to the statistical team directly involved with analyzing the data. The system fully meets all applicable HIPAA privacy and security rules. Access to the database and backups are strictly monitored according to need.

The final dataset will contain no patient or caregiver identifier. No protected health information or identifying information about individual patients, caregivers or hospitals will be part of a publication.

Impact

The majority of anesthesia services are provided by a team. Ongoing economic challenges have led hospitals to implement cost-repositioning efforts and to redesign their workflow in an attempt to increase efficiency while at the same time maintaining a high standard of care. Increasing efficiency and reducing cost are important goals to ensure financial viability of a department, but quality and safety of care cannot be compromised to achieve these goals. The proposed large and well-powered study will be the first to determine the extent to which various MD:CRNA staffing ratios actually occur. Determining the actual incidence and the possibly associated adverse consequences will presumably lead a better decision making process, balancing cost effectiveness and quality of care.

References

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