Date:	5-9-19
Title	Does procedural timing impact perioperative morbidity in elective surgery?
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IRB Review Type: ☐ **Exempt** ☒**Expedited** ☐ **Full Board**

Purpose of Study: Please describe:

To evaluate if there are differences in perioperative morbidity for elective surgery based on the time of the year surgery is performed.

Hypothesis or Research Question

We hypothesize that surgical complication rates are higher at certain times during the year than others. Specifically;
Primary hypothesis: Perioperative morbidity will be highest toward the end of the calendar year (December) corresponding with insurance deductible year-end.

Secondary hypothesis: Perioperative morbidity will be high as well with the start of academic trainees (July).

Background

Surgical complications are a significant cause of morbidity and mortality. Surgical complications account for up to 40% of hospital complications [1]. Complications and adverse events are also becoming increasingly important for measuring health care quality. Investigation into possible risk factors for complications is a popular topic for research. Studies are often designed to evaluate either patient related factors or surgeon related factors that may lead to an increase in adverse events. Common outcomes reported include surgical time, length of hospital stay, infections, injury to surrounding organs, surgeon volume, readmission, and mortality. However,

risk factors and outcome measures will vary depending on the patient population and procedures being studied.

Commonly studied patient related factors that may impact perioperative morbidity include age, body mass index (BMI), American Society of Anesthesiologists classification (ASA), and medical comorbidities such as diabetes, heart disease, and pulmonary disease. Visser and colleagues performed a systematic review that analyzed 30 articles [2]. They found 9 significant patient related factors that contribute to surgical outcomes. Age, BMI, and ASA classification were the most commonly reported and most significant factors. Increased rates of surgical site infection have been described in patients with recent hospitalization prior to surgery [3, 4]. Borenstein and colleagues found that prior admission within 30 days was associated with an increased risk of adverse outcomes such as hospital acquired infections, adverse drug reactions and length of stay [5]. However, few studies have assessed prior admissions beyond 30 days.

Patients who meet their insurance deductibles are likely more eager to proceed with an elective procedure, as they will little or no out of pocket cost. Many physician practices notice a surge of patients seeking care at the end of the year compared to other times of the year. Patients who have met their deductible likely utilize more healthcare resources because they have more health problems, or have had more procedures performed during that year. Thus there may be potential for sicker and more complicated patients to undergo surgery at the end of the year as compared to other times of the year. These patients may suffer more surgical complications that could then lead to an overall greater cost for healthcare. If so, this difference could impact future health care policy and rationing of resources.

Surgeon related factors that contribute to perioperative morbidity have also become increasingly important and some authors have evaluated these possible factors. Surgeon related factors that have been studied include surgeon volume, surgeon workload per day, procedure timing, and trainee participation. One study found that low-volume surgeons have a higher risk of complications than high-volume surgeons [6]. Hsu and colleagues found that patients receiving an implantable cardioverter-defibrillator implant in the afternoon/evening and on weekends or holidays had higher rates of adverse events [7]. The total number of hours a surgeon operates per day was found to be independently associated with an increased risk of complications when performing pulmonary lobectomies [8]. Trainee participation has been associated with major complications in vaginal hysterectomy and with minor complications in all routes of hysterectomy [9].

Prior studies have often evaluated the “July effect” which is the beginning of a new academic year at teaching hospitals. This time of the year is important, as it is when trainees are moving up in their roles involving patient care and taking on more responsibility. Not only are new interns involved in patient care but trainees at all levels are in participating in a new role. Recently graduated senior residents are now in attending surgeon positions. Findings have

been conflicting on whether there are differences in outcomes and complications at this time of the year. Englesbe and colleagues found an 18% higher postoperative morbidity rate and 41% high mortality rate in July-August compared to April-June [10]. Likewise, another study found higher morbidity and mortality in July for patients after surgery for spinal metastases [11]. However, Highstead, et al. found no difference in complications in July-August compared to April-May for over 3,000 patients admitted to a level 1 trauma service [12].

Identifying which patients are at a higher risk for perioperative morbidity is important to help prevent surgical complications and lower healthcare costs. Proper patient selection and appropriate timing for elective procedures will positively impact these adverse outcomes.

Research Plan

- **Study Design**
  - Retrospective cohort study using Electronic Privacy Identification Center (EPIC) database

- **Setting for the study**
  - Good Samaritan and Bethesda North Hospitals

- **Participants**
  - *Describe*
    - All patients 18 years and older who underwent a surgical procedure in the main operating rooms at Good Samaritan Hospital and Bethesda North Hospital between January 1, 2015 and December 31, 2016.
    - Approximately 9,000 cases are performed annually at the Good Samaritan Hospital main OR and 15,000 cases are performed annually at the Bethesda North main OR.

  - *Inclusion criteria*
    - All persons aged 18 and older undergoing surgical procedures in the main operating room during the study period

  - *Exclusion criteria*
    - Patients under the age of 18
    - Procedures done outside of the main operating suites (Endoscopy suite, Labor and Delivery)

  - *Sample Size*
    - About 48,000 chart review is expected.

- **Data Collection**
  - Basic demographics and surgical procedure data will be collected.

- Date of surgery, surgery location, and surgeon name will be collected.
- Trainee participation will be recorded – resident or fellow participation in case.
- Patient comorbidities will be collected including but not limited to obesity, tobacco use, ASA classification, DM, HTN, heart disease, pulmonary disease, chronic kidney disease, prior surgical history in past 6 months, preoperative lab data.
- Intraoperative surgical complications and hospital length of stay will be collected.
- Insurance information will be collected
- Postoperative complications including but not limited to reoperation, readmission within 90 days of surgery for any reason, death within 90 days will be collected. Complications inherent to most surgical procedures including excessive blood loss, need for blood transfusion, infection, thromboembolic events, and injury to surrounding organs will be collected.

- **Intervention or experimental aspect of the study**
  - Not applicable as it is a retrospective chart review

- **Statistical Analysis**
  - Descriptive statistics will be calculated for demographics, preoperative, and intraoperative information. Chi-squared tests will be employed for categorical variables and t test or Mann-Whitney U test for continuous variables. Mean (SD) values will be used for data meeting the assumptions for normality; median (IQR) values will be used for data not meeting the assumptions for parametric procedures. Multivariate logistic regression model will be implemented for a prediction model.

Ethical Considerations

- **Informed consent**
  - Since this is a retrospective study, waivers of Informed Consent and Authorization will be requested.
- **Privacy information**
  - Patient surgery date and procedure will be collected during this study.

Estimated Period of time to complete study:

- **When will study begin?** Following IRB approval
- **What is the estimated duration of the study?**
  - ***Pre data collection:*** July-August 2016
  - ***Data collection:*** through the end of August 2017
  - ***Data analysis:*** through December 2017
- **When and how will results be disseminated?**

- The results from this study will be presented at one of the scientific meetings for the Society of Gynecologic Surgeons or the American Urogynecology Society or another national American Medical Society.

- **References**

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