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Study Protocol: Assessment of Racial/Ethnic Disparities in the Timeliness and Comprehensiveness of Surgery for Colorectal Cancer

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1

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This retrospective cohort study will investigate the timeliness of surgery based on the racial/ethnic group of patients who under colorectal surgery for cancer. Patients are included if they underwent surgical procedures for colon cancer between January 1, 2015 and April 30, 2020. The primary exposure of interest is the racial/ethnic group of the patient. The primary outcome is the the timeliness of surgery, defined as having urgent/emergent surgery (less timely) vs. elective surgery (more timely). Secondary outcomes relate to comprehensiveness of surgery, and include performance of preoperative staging tests, preoperative lab testing, and preoperative teaching of patients, as well as length of stay and additional clinical outcomes. Multivariable logistic regression models will be used to adjust for other demographic and clinical differences between study groups.

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Brief Rationale and Hypothesis

- 1 Although disparities in access to healthcare are widely recognized as a critical issue in the United States, it is often difficult to identify these disparities and their subsequent impact due to their multifactorial nature. One manifestation of imbalances in access to care for surgical patients is delays in the receipt of elective surgery. For example, identifying populations that undergo a higher proportion of emergent operations for a condition that is typically treated in the elective setting may serve as a way to identify groups with limited access to care. Colectomy and other colorectal surgeries for malignancy provides an example of a surgical procedure where almost all patients are anticipated to undergo elective surgery - given its ubiquitous screening and slow natural progression - and late presentation of disease may therefore stem from limited access or delays in seeking care. The key research question for this study is whether race/ethnicity is associated with timeliness of surgical treatment for colorectal cancer.

Study Design

- 2 Retrospective cohort study using a statewide clinical registry.

Data Sources

- 3 **Michigan Surgical Quality Collaborative (MSQC) Clinical Registry:** The MSQC maintains a clinical registry that collects patient demographics, perioperative processes, and 30-day outcomes for patients undergoing surgery in Michigan. Participating hospitals receive funding from Blue Cross Blue Shield of Michigan to fund trained data abstractors that use standardized methods to obtain data for patients. Cases are audited annually for accuracy and reviewed using a sampling algorithm designed to minimize selection bias.

Inclusion Criteria

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 1. Adult patients (18 years of age and older) undergoing colorectal surgery for colon or rectal cancer
 2. Valid demographic data
 3. Date range: patients undergoing surgery between January 1, 2015 to April 30, 2020

Exclusion Criteria

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 1. Non-cancer indication for colorectal surgery
 2. Missing race/ethnicity data
 3. Missing zip code
 4. Missing clinical data (comorbidities, surgical status, etc)

Explanatory Variables

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 1. **Key explanatory variable (i.e., study groups):** race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, and other)
 2. Demographics: age, sex, Social Deprivation Index, insurance group (private, Medicare, Medicaid, dual Medicare/Medicaid, other, and unknown)
 3. Patient characteristics: American Society of Anesthesiologists (ASA) classification, obesity, cancer diagnosis, tobacco use in the year prior to surgery, diabetes, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), hypertension (HTN), chronic steroid use, dialysis, functional status (independent vs. non-independent)
 4. Clinical characteristics: surgical approach (open vs. minimally invasive), length of stay

Primary Outcome

- 7 Timeliness of care, defined as a dichotomous outcome of urgent/emergent surgical priority for colorectal surgery vs. elective surgical priority for colorectal surgery.

Secondary Outcomes

- 8 Measures of comprehensiveness of preoperative evaluations, based on the following preoperative services:
 1. Performance of a preoperative staging test
 2. Documentation of a preoperative carcinoembryonic antigen (CEA) level
 3. Documentation of wound ostomy teaching
 4. Length of time in days between documentation of CEA value and date of surgery

Postoperative outcomes: 30-days complications, emergency department visits, hospital readmission, reoperation, non-home discharge

Statistical Analysis

- 9
 1. Descriptive characteristics of patients who undergo colorectal surgery for colon or rectal cancer by race/ethnicity
 2. Multivariable logistic regression of timeliness of surgery, with race/ethnicity being the key covariate of interest
 3. Multivariable regressions for receipt of preoperative services, with race/ethnicity being the key covariate of interest
 4. Sensitivity analysis including interactions between race/ethnicity * gender, race/ethnicity * age, and race/ethnicity * Social Deprivation Index