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A Difference-in-Differences Analysis of New Persistent Opioid Use After Surgery

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Michigan Opioid Prescribing Engagement Network (OPEN)
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Michigan OPEN

The Opioid Prescribing Engagement Network (OPEN) at the University of Michigan was established in 2016 with the goal of reducing excessive opioid prescribing after surgery using evidence-based prescribing guidelines. Beginning in July 2016, OPEN began a statewide quality improvement campaign to educate providers and share prescribing best practices. In October 2017, the first prescribing guidelines were released. Although these efforts have been associated with significant decreases in postoperative opioid prescribing, it is unknown whether the incidence of new persistent opioid use after surgery has changed as well. This retrospective study examines the effect of these efforts on new persistent opioid use after surgery compared to the rest of the United States - including other states where no such program existed - using a difference-in-differences approach.

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Brief Rationale and Hypothesis

1 **Brief Summary**: The Opioid Prescribing Engagement Network (OPEN) at the University of Michigan was established in 2016 with the goal of reducing excessive opioid prescribing after surgery using evidence-based prescribing guidelines. Beginning in July 2016, OPEN began a statewide quality improvement campaign to educate providers and share prescribing best practices. In October 2017, the first prescribing guidelines were released. Although these efforts have been associated with significant decreases in postoperative opioid prescribing, it is unknown whether the incidence of new persistent opioid use after surgery has changed as well. This retrospective study examines the effect of these efforts on new persistent opioid use after surgery compared to the rest of the United States - including other states where no such program existed - using a difference-in-differences approach.

Detailed Description: It is estimated that between 5-15% of patients develop long-term opioid use after major and minor surgery. This translates to more than 2 million previously opioid-naive individuals developing chronic opioid use each year. Persistent opioid use after surgery is associated with increased readmissions, healthcare utilization, and healthcare expenditures. Moreover, long-term opioid use increases the risk of overdose and death in patients who, prior to their surgery, had no exposure to opioids.

Growing recognition of this problem has led to numerous efforts aimed at reducing opioid-associated morbidity after surgery. These include legislative limits on opioid prescribing for acute pain, procedure-specific prescribing guidelines based on patient-reported opioid use, and opioid-sparing pain management pathways. In Michigan, OPEN led a statewide quality improvement effort beginning in 2016 that focused on provider education using evidence-based opioid prescribing guidelines. Previously, these guidelines have been shown to significantly reduce excessive postoperative opioid prescribing across the state, however it is currently unknown whether these efforts have had any effect on the incidence of persistent opioid use after surgery.

Therefore, the current study will evaluate the incidence of new persistent opioid use in Michigan before and after the establishment of OPEN. In order to accomplish this goal, this study will use a difference-in-differences analysis of a nationally representative cohort of Medicare beneficiaries to compare new persistent opioid use in Michigan before and after the establishment of OPEN to other states where no such quality improvement efforts existed.

Study Design

2 Retrospective cohort study

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Data Sources

3 Medicare claims

Inclusion Criteria

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1. Adult patients (18 years and older)
2. Patients undergoing one of the following inpatient or outpatient surgical procedures: laparoscopic cholecystectomy, laparoscopic appendectomy, minor hernia repair (including laparoscopic or open inguinal, femoral, umbilical, and epigastric hernia repair), open and laparoscopic ventral/incisional hernia repair, laparoscopic colectomy, open colectomy, vaginal hysterectomy, laparoscopic hysterectomy, and open abdominal hysterectomy
3. Patients undergoing surgery between January 1, 2013 and June 30, 2019

Exclusion Crtieria

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1. Patients who are not opioid-naive at the time of surgery, defined as filling 1 or more opioid prescriptions in the 12 months to 31 days prior to surgery
2. Patients without continuous insurance enrollment for at least 12 months before and at least 6 months after the date of surgery
3. Patients still in the hospital on postoperative day 30
4. Patients not discharged home after surgery
5. Patients who underwent another surgery within 6 months of the index operation

Explanatory Variables

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1. Key exposure of interest: surgery occurring in Michigan
2. Age
3. Sex
4. Race/ethnicity
5. Year of surgery
6. Elixhauser comorbidity index
7. History of tobacco use
8. Alcohol or substance use disorders
9. Mental health disorders
10. Pain disorders
11. Opioid prescription fulfillments
12. Inpatient vs. outpatient location
13. Procedure

Primary Outcome

7 Incidence of new persistent opioid use after surgery

Definition: Among patients who undergo surgery, new persistent opioid use is defined as filling at least one opioid prescription in post-discharge days 4-90 and filling at least one opioid

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prescription in post-discharge days 91-180. Refills of opioids in postoperative days 0-3 will count toward the first epoch of time (days 4-90). This incidence will be measured before and after two intervention points: 7/1/2016 (when OPEN was established) and 10/1/2017 (when the first guidelines were published) per the analytic plan below. Outcomes will be measured at 1 year, 2 years, and 3 years post-intervention.

Rationale: Beginning in July 2016, OPEN began working with the Michigan Surgical Quality Collaborative to implement quality improvement measures around opioid prescribing. These included presentations regarding safe prescribing, dissemination of evidence-based prescribing guidelines, raising awareness of the risks of opioids after surgery, and instructions for safe disposal. The first OPEN presentation was given in July 2016. In October 2017, the first prescribing guidelines for the included procedures were presented to the statewide quality collaborative.

Secondary Outcome

8 Total quantity of opioids filled after surgery

Definition: Among patients who undergo surgery, the quantity of opioids filled after surgery is defined as the total milligrams of oral morphine equivalents (mg OME) filled at any time between post-discharge day 0 and post-discharge day 180. This will be measured before and after two intervention points: 7/1/2016 (when OPEN was established) and 10/1/2017 (when the first guidelines were published) per the analytic plan below. Outcomes will be measured at 1 year, 2 years, and 3 years post-intervention.

Rationale: Beginning in July 2016, OPEN began working with the Michigan Surgical Quality Collaborative to implement quality improvement measures around opioid prescribing. These included presentations regarding safe prescribing, dissemination of evidence-based prescribing guidelines, raising awareness of the risks of opioids after surgery, and instructions for safe disposal. The first OPEN presentation was given in July 2016. In October 2017, the first prescribing guidelines for the included procedures were presented to the statewide quality collaborative.

Statistical Analysis

9 The main statistical analysis will be a difference-in-differences analysis of the two main outcomes (new persistent opioid use and total quantity of opioids filled) as follows:

For patient *i*, receiving surgery *j*, in hospital *k*, in state *l*, calendar month *m*, in period *t*, our main estimating equation will be:

$$Y_{ijlmt} = b_0 + b_1 X_{ijlmt} + b_2 Surgery_j + b_4\, calendar\ month_m + b_5 Michigan_l + b_6\, Post\ July\ 2016_t + b_7 Post\ October\ 2017_t + \alpha_1 (Michigan_l * Post\ July\ 2016_t) + \alpha_2 (Michigan_l * Post\ October\ 2017_t) + e_{ijlmt}$$

Where *X* is a vector of patient covariates, *Surgery* is a vector of dummy variables for each included surgery, calendar month is a vector of dummy variables to account for seasonality,

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Michigan is a dummy variable indicating the surgery occurred in Michigan, *Post July 2016* and *Post October 2017* are dummy variables indicating that the surgery occurred after the start of two key interventions, and e is an idiosyncratic error term. The coefficients α_1 and α_2 will test the effects of the two OPEN interventions. Standard errors will be clustered at the state level.

Before estimating Equation 1, we will evaluate the parallel trends assumption. If the assumption is violated, we will pursue various remediation strategies. Otherwise, the comparison group will consist of all surgeries outside of Michigan that meet our inclusion and exclusion criteria.

We will also re-estimate Equation 1 separately for each surgery in the main analysis but not for sensitivity analyses.

Sensitivity analysis will re-estimate equation among the following different comparison groups:

1. Indiana and Wisconsin. **Rationale**: Indiana and Wisconsin were chosen as they are neighboring Midwestern states which also implemented 7-day legislative prescribing limits similar to those in Michigan, however they *did not have a collaborative quality improvement initiative related to postoperative opioid prescribing*. Given that the goal of this study is to attempt to assess the effect of OPEN efforts, inclusion of these two states allows for comparison to states that are similar in most ways except for the presence of an effort like OPEN. This sensitivity analysis will be performed for both primary and secondary outcomes.
2. 11 other Midwest states (Illinois, Indiana, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin). **Rationale**: Given that postoperative opioid prescribing has been shown to vary geographically, geographically similar states from the same region were also included for secondary analysis. This sensitivity analysis will be performed for both primary and secondary outcomes.
3. Repeat primary analysis excluding patients with a diagnostic code for cancer at the time of surgery. Although other analyses of new persistent opioid use have included patients with cancer, there is strong evidence that these patients may receive long-term prescriptions for opioids following surgery that are unrelated to their surgical episode (e.g., for cancer-related pain, end-of-life care). Therefore we will repeat the primary difference-in-differences analysis excluding patients with a cancer diagnosis.

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