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## UCR Honors Capstones 2025-2026

### Title

EXAMINING THE RELATIONSHIP BETWEEN BIRTH DELIVERY METHODS AND OPIOID-RELATED EVENTS THROUGH NALOXONE DISPENSING IN AN MULTI-CENTER ELECTRONIC HEALTH COHORT

### Permalink

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### Publication Date

2026-06-15

EXAMINING THE RELATIONSHIP BETWEEN BIRTH DELIVERY METHODS AND  
OPIOID-RELATED EVENTS THROUGH NALOXONE DISPENSING IN AN  
MULTI-CENTER ELECTRONIC HEALTH COHORT

By

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A Capstone Project Submitted for Graduation with University Honors

May 7th, 2026

University Honors

University of California, Riverside

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## ABSTRACT

Opioid-related events are a leading and preventable contributor to maternal mortality in the United States, with the postpartum period representing a high risk yet under-studied interval. Obstetric patients frequently receive opioid prescriptions following delivery; however, the incidence and drivers of postpartum opioid-related risks remain poorly defined within the available anesthesiology literature. This study aims to quantify postpartum opioid-related risk using real-world electronic health record data to inform opioid stewardship in obstetric anesthesia.

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### **Acknowledgements**

I would like to extend my deepest gratitude to my faculty mentor, Dr. Anita Gupta, for her guidance and expertise that supported me during this process. I am sincerely appreciative of the time she invested in me and the opportunities that she has granted me while completing this research. I would also like to express my gratitude to Thanh Thanh Tran, who lent me support and helped me refine my research to allow for its success. Her input and help throughout the process were invaluable, and allowed me to grow immeasurably as a researcher. Lastly I would like to express my heartfelt appreciation to my friends and family for their constant support and encouragement throughout my project.

## INTRODUCTION AND BACKGROUND

### *Introduction*

In recent years the United States has seen a drastic upward trend of opioid-related events. While opioid-related events are increasing in frequency in the population as a whole, it is also specifically seen in the postpartum population. Opioid-related events are a leading and preventable contributor to maternal mortality rates. The incidence rates among postpartum women are often considered high risk, however, this demographic is under researched and there is a dearth of knowledge pertaining to incidence and drivers. To address the escalating issue of maternal mortality, more research regarding this topic needs to be conducted. Although there is some awareness on contributing factors, such as limited socioeconomic resources and barriers to opioid use disorder treatment, there are still many gaps in research regarding at-risk populations resulting in a deficit in knowledge (Frankenberger, 2023).

### *Opioids Defined*

Opioids are defined as both natural and synthetic compounds, and are often prescribed to patients as analgesics following medical procedures due to their ability to effectively mitigate pain. This is especially seen in the postpartum population due to the traumatic and highly painful process of giving birth, with it often being reported as a serious issue that can interfere with their daily lives (Heaman, 2008). Common forms of opioids given in medical settings include morphine, oxycodone, and buprenorphine. Opioid's mechanism works by binding to opioid G-protein coupled receptors and activating them. This has a downstream effect of closing voltage-gated calcium channels and opening potassium channels. The change in the cell charge and the concentration of calcium and potassium hyperpolarizes the cells (McDonald, 2013). The

hyperpolarization then inhibits adenylyl cyclase and cyclic adenosine monophosphate (cAMP). The decrease of adenylyl cyclase and cAMP in the cell then causes less neurotransmitters to be released from the cell, by limiting the cell signaling. This allows for opioids to inhibit nociception and decrease the signals of pain that are sent to the body (Reeves, 2022).

### *Mechanisms*

Opioids are an effective analgesic due to their ability to act directly on the central nervous system and can pass through the blood-brain barrier based on their lipophilicity (Kerrigan, 2020). The ability of opioids to pass through the blood-brain barrier is dependent on their lipophilicity which can be determined by the amount of hydroxyl functional groups (Waterhouse, 2003). The hydroxyl groups increase hydrophilicity, causing resistance when the molecule passes through the lipid bilayer membranes in the blood-brain barrier and decreases their potency. However, the increase in efficiency in opioids can also lead to an increased risk of addiction and adverse reactions from opioids. While opioids assuage pain, they also have serious risks such as central nervous system depression, bradycardia, vasomotor stimulation, and respiratory depression (Kerrigan, 2020). Effects from opioids can be life threatening and lead to mortality. Opioid-induced respiratory depression is the most common cause of opioid-related death and is defined by having less than 8 to 10 breaths per minute. Opioid-induced respiratory depression is caused by opioids depressing breathing resulting in shallower and less frequent breaths (Baldo, 2022). To prevent mortality due to opioids, medications for opioid overuse disorder can be administered to rapidly reverse an opioid overdose. Medications for opioid overuse disorders, like naloxone, have no adverse effects on the body and can prevent opioid overdoses. Naloxone works as a lipophilic competitive opioid antagonist that crosses the blood-brain barrier to bind to

the same receptors that opioids bind to, and prevents the opioid compound's cascade of reactions (Trøstheim, 2022). Naloxone is a common type of medication for opioid overuse disorder, and is often used in medical settings to counter opioid-related events. It is able to bind to these receptors due to its structural similarities to opioids, but does not activate the opioid pathways.

### *Contextualization*

Women with prior history of opioid use disorder are noted to have an increased chance of readmission and morbidity rates postpartum (Wen, 2019). Patients with a past opioid use disorder and prior overdoses were shown to be at higher risk for postpartum overdose, the increased susceptibility for overdose in these patients demonstrates the importance of understanding incidence and drivers in this population to mitigate opioid-related events (Bagley, 2018). However, it is important to note that overdoses in postpartum women are not constrained to women with a history of opioid use disorder, as in hospital settings prescriptions of opioid medications did not always account for patient reported pain levels, which could increase risk of an opioid-related event (Badreldin, 2019). Patients reported pain not being taken into account for opioid prescriptions following delivery indicates that opioid prescriptions may not always match the patient's needs, and this may increase patient's risk for an opioid-related event.

Due to the common practice of prescribing opioids following uncomplicated vaginal delivery, and that the risk of opioid use disorder increases with prescription it is apparent to address the escalating issue of maternal mortality further research regarding this topic needs to be conducted (Wiese, 2021). This study was developed to quantify if vaginal or cesarean delivery influences postpartum with the deployment of the opioid overdose reversal drug

naloxone using real-world electronic health record (EHR) data. This information can better inform opioid stewardship in obstetric anesthesia and guide targeted prevention strategies.

## METHODS

A retrospective cohort study was conducted using the database TriNetX. TriNetX is a federated multi-institutional electronic health record database that is composed of 60 healthcare organizations. This comprehensive database collects patient data from healthcare organizations and electronic medical record systems, to collect data and perform analysis tests. The platform is compliant with the Health Insurance Portability and Accountability Act and the General Data Protection Regulation standards and does not use personal or identifying patient information. For this study, the United States collaborative network was used to minimize any confounding variability in the data. Criteria for cohorts are built using international coding systems (ICD-10-CM), which standardizes the healthcare language and ensures consistency in the data.

A prescription or administration of naloxone was used as a proxy to measure opioid overdoses or opioid-related events. Naloxone was used to collect data on high risk opioid related events within a 42 day window of delivery. Data was collected from patients 18 to 55 years of age and female. Patients with neoplasms (ICD10=C00-C96) and neuroendocrine tumors (ICD10=C7A-C7B) were excluded from the study. The window of events was set to 42 days postpartum due to gaps in literature and because postpartum overdose mortality rates are the highest in the year following delivery (Goodman, 2020). The data collection's time parameters for what time frame data could be pulled from ranged from 'anytime' (all available past data on the TriNetx database) up to February 9th, 2026. The parameters matched 1,492,612 patients to the inclusion criteria. A comparative analysis between vaginal delivery and cesarean delivery

was conducted to provide information regarding the measure of association between the two cohorts. Both cohorts needed to have encounters for delivery (ICD10=O80-O82). The vaginal delivery cohort was defined by codes: vaginal delivery only (CPT=1014217); or vaginal delivery antepartum and postpartum care delivery (CPT=1008981); or routine obstetric care including antepartum care; vaginal delivery (CPT=59610). The cesarean cohort was defined by parameters: cesarean delivery only (CPT=59514); or encounter for cesarean delivery without indication (ICD10=O82); or routine obstetric care including antepartum care, cesarean delivery, and postpartum care (ICD10=59510). Each cohort excluded the criteria of the other to ensure no overlap. Boolean operator “OR” was used when making the vaginal and cesarean cohorts to ensure that patients met at least one of the criteria listed. A Kaplan-Meier survival analysis was done to determine the probability of a naloxone related event happening over the course of the 42 day postpartum period.

To minimize any potential selection bias in the dataset, propensity score matching was conducted for characteristics such as age, race, ethnicity, and comorbidities. Comorbidities up until the 42 day index included: nicotine dependence (ICD10=F17), tobacco use (ICD10=Z72.0), personal history of nicotine dependence (ICD10=Z87.3891), (alcohol related disorders (ICD10=F10), depressive episode (ICD10=F32), major depressive disorder recurrent (ICD10=F33), generalized anxiety disorder (ICD10=F41.9), anxiety disorder unspecified (ICD10=F41.9), chronic pain not elsewhere classified (ICD10=G89.2), low back pain (ICD10=M54.5), pelvic and perineal pain (ICD10=R10.2), gestational diabetes mellitus (ICD10=O24.4), gestational [pregnancy-induced] hypertension without significant proteinuria (ICD10=O13), pre-eclampsia (ICD10=O14), oxycodone (RxNorm=7804), hydrocodone

(RxNorm=5489), morphine (RxNorm=7052), tramadol (RxNorm=10689), fentanyl (RxNorm=4337), type 2 diabetes mellitus (ICD10=E11), and hypertensive disease (ICD10=I10-I1A). Cohorts were then propensity matched based on these characteristics. TriNetX uses propensity scores to demonstrate the likelihood of exposure based on the defined criteria. Propensity score matching allows for the covariates in the cohort to be balanced as if it was a randomized control study.

## RESULTS

From the data collected up to February 9th on TriNetX, the general postpartum opioid overdose frequency showed a 23.014% risk and a Kaplan-Meier analysis of a 76.876% survival probability by the end of the 42 day period.

In the comparative analysis test vaginal delivery, when looked at next to cesarean delivery, had a statistically significant 16.86% point decrease in risk of overdose ([95% CI] = (-17.03-16.69)  $P < 0.0001$ ). In Kaplan-Meier analysis, cesarean delivery was associated with a higher likelihood of naloxone-related events compared to vaginal delivery. The survival probabilities of cesarean were 81.62%, and vaginal were 98.71% by the end of the 42 day time frame. Vaginal delivery was associated with a significantly lower hazard of opioid-related events compared to cesarean delivery (Hazard Ratio (HR)=0.065, 95% CI: 0.062–0.067,  $p < 0.0001$ ).

## DISCUSSION

### *Data Analysis*

Data analysis illustrated that 23.014% of women in this population experience an opioid-related event within 42 days following birth. For this study opioid-related events were defined by naloxone capture. Naloxone capture is the binding of naloxone to opioid receptors to

rapidly reverse an opioid overdose. Naloxone was used as the proxy for this study to indicate high risk opioid-related events. A 42 day period was set postpartum to collect data from, this time frame was set because of gaps in the research in this period. Due to the risk for opioid-related events being higher when in the time frame closer to the delivery date, this short period following birth was selected to further analyze demographics at risk. Further examination of the data shows that there is a 16.86% decrease in vaginal delivery. This statistic indicates that there is a higher frequency of opioid-related events in the cesarean delivery population compared to the vaginal delivery. This can be seen in Figure 1 which shows the graphical analysis of cohort 1, vaginal delivery, and cohort 2, cesarean delivery, in a comparative analysis. The comparative analysis of the two subgroups demonstrate how there is higher risk of opioid-related events in the cesarean delivery cohort. This high incidence demonstrates the importance of implementing and refining standardized strategies, including prescribing practices, to better serve postpartum women who are more vulnerable to opioid-related risks. It also indicated how there is a need for improvements on medication safety.

**Figure 1**

Risk of Outcome

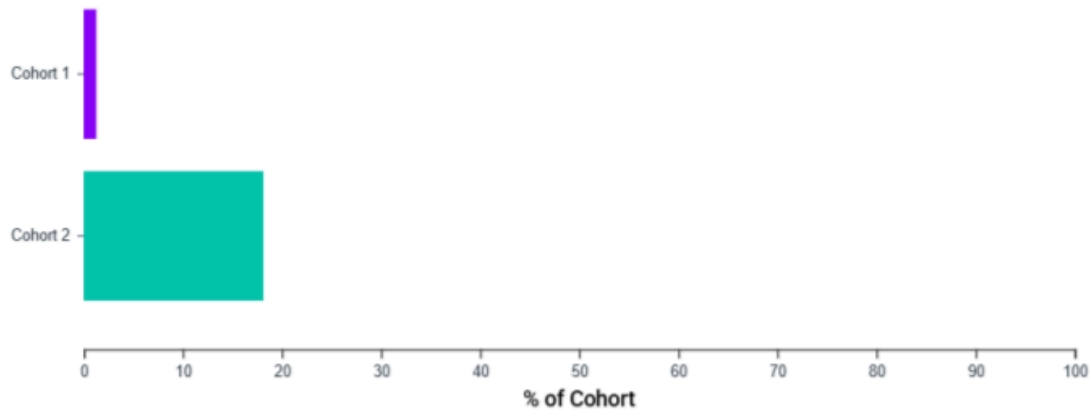


**Figure 1. Comparative analysis between vaginal and cesarean delivery.** Vaginal delivery, cohort 1, has a 16.86% decrease in event risk compared to cesarean delivery, cohort 2, (95% CI: -17.03 to -16.69;  $p < 0.0001$ ). Data was collected up 42 days following delivery.

Furthermore, the research demonstrates that cesarean delivery was at higher risk for opioid-related events compared to vaginal delivery within the population. Women who underwent cesarean delivery had a higher frequency of naloxone capture compared to women who had a vaginal delivery (18.126% to 1.264%).

The Kaplan-Meier survival showed that in the data subset about 98.71% of the vaginal delivery cohort did not experience an opioid-related event over the 42 day period, whereas in patients who underwent cesarean delivery about 81.62% of the population did not experience an opioid-related event. The survival graph seen in Figure 2 demonstrates how about 18.3% of the

cesarean population experienced this event, which is markedly higher compared to the vaginal delivery cohort.

The data showed accurate propensity score matching, which ensured that the cohorts were able to be randomized and produce accurate data analysis. The improvement of propensity scores can be seen in Figure 3. The two graphs show how after conducting the propensity score matching, the densities of the two cohorts were able to align better, indicating the elimination of confounding factors in the dataset.

Additionally, the hazard ratio denotes that patients who delivered vaginally had a 93.5% lower risk of overdosing compared to a patient who delivered vaginally ( $HR=0.065$ ). Hazard ratios indicate the likelihood of a cohort's survival, or as defined in this research, the chance of an opioid-related event occurring. Because the hazard ratio was less than one, the vaginal delivery cohort is shown to have a higher survival rate and being less prone to opioid related events when compared to the cesarean delivery cohort. The strong significance ( $P < 0.0001$ ) and narrow confidence intervals found in the data collection support the data's reliability. The low P-values showed that there was a relationship between the variables, and rejects the null hypothesis. The confidence interval was 95% which demonstrates how if the experiment were to be run again the the results of the experiment would likely fall in the expected interval ranges and provide similar results to this experiment. The confidence interval for vaginal deliveries compared to cesarean was between -17.03 and -16.69, the narrow range in the results indicates high accuracy and certainty in the data outcomes. Moreover, the hazards ratio depicting vaginal delivery with a lower chance of an opioid-related event occurring also had a 95% confidence interval, with intervals between 0.062 and 0.067. The hazard ratio's intervals also depict a very

narrow difference between the values. This once again demonstrates that the analysis in the study was highly accurate. This accuracy can be accounted for partly because of the large population size that was able to be collected for this study. Pulling data from multiple health care organizations in the United States collaborative network allowed for a substantial amount of patients matching the study's criteria to be collected. And the propensity score matching is another factor which allowed for high accuracy, as it reduced a significant amount of variability and bias in the population sample. These data factors show the accuracy and validity of this experiment, and help substantiate the research results.

**Figure 2**

Kaplan-Meier Survival Curve

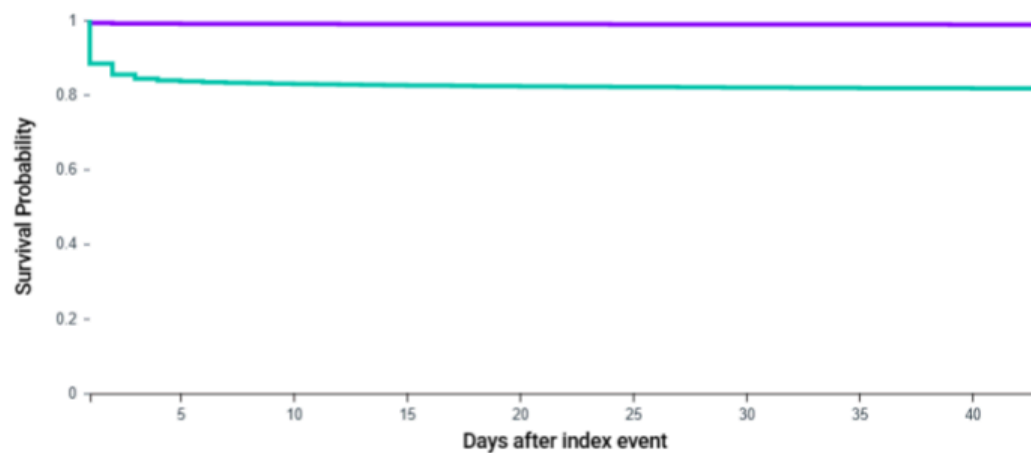


**Figure 2. Kaplan-Meier graph for vaginal and cesarean delivery.** Measured the probability of a opioid-related event happening in the 42 day period postpartum defined as survival probability on the Y-axis. Vaginal delivery, cohort 1, had a higher survival probability at end of time window of compared to cesarean delivery, cohort 2.

**Figure 3**

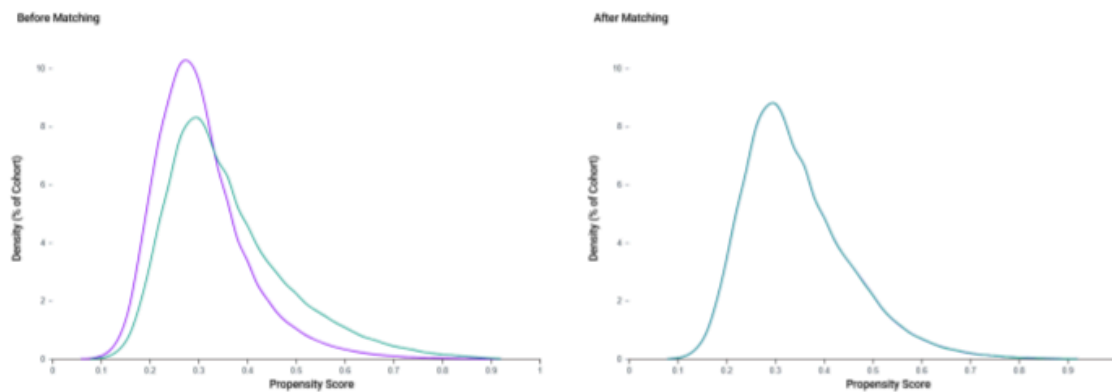


**Figure 3. Propensity score matching of cohorts.** Before the vaginal and cesarean delivery cohorts were propensity matched (graph on the left) there is significant variation in cohort density. After propensity score matching the density of the cohorts better aligned and bias was reduced (graph on the right)

### *Understanding The Results*

These findings could be influenced by a myriad of factors like opioid prescribing practices and differences in expected postoperative pain across delivery methods. Existing studies have indicated that in general there is lack of standardization in opioid prescribing practices following delivery. Previous studies have shown that there is a trend of women being prescribed more opioids than needed (Osmundson, 2017). It has been seen that in some hospital settings patients are prescribed opioids without sufficient and thorough consideration of the patient's reported pain levels, and similar morphine equivalent doses given to all patients without discerning factors such as pain level or type (Badreldin, 2019). The lack of individualized prescribing practices may contribute to increased opioid exposure overall and higher event risk.

This is particularly true among patients undergoing cesarean delivery, as it is an invasive surgical procedure that may require more intensive pain management, thus often inherently increasing opioid exposure. Compared to vaginal delivery, it often is reported with higher levels of pain, and while the pain levels generally decrease over time cesarean patient's reported pain remains higher throughout time compared to vaginal delivery patients (Hardy-Fairbanks, 2013). Women who undergo cesarean delivery instead of vaginal have reported levels of more lateral pain and are often prescribed narcotics to help lessen their pain. To reduce patient's pain, women who undergo cesarean deliveries may receive different dosages of opioids compared to patients who gave birth vaginally. Additionally, existing literature suggests that there is a higher chance for chronic pain following cesarean delivery (Nikolajsen, 2004). Long-term pain may cause more reliance on opioids, this may be another influence on the risk of opioid-related events within the cesarean delivery population. Even at low doses, prescription opioid use has been associated with increased risk of opioid-related events, including persistent opioid use, opioid use disorder, overdose, and opioid-related death (Wiese, 2021). Existing research shows a trend of postpartum patients who underwent cesarean delivery being more likely to be prescribed opioids compared to those who underwent vaginal (Badreldin, 2019). This could be a reason why those who underwent cesarean delivery had a higher risk of opioid-related events. However, it is important to acknowledge that overprescribing also affects the vaginal delivery population (Osmundson, 2017). Both subgroups do face notable risk of opioid-related events, but the cesarean population may have higher risk due to the extent of the overprescription of opioids. The wide range of dosages prescribed to patients highlights a systemic inconsistency underlining the need for evidence-based standardization (MacKeen, 2022).

Filling prescription opioids of any dosage following delivery is shown to increase risk of opioid-related events (Wiese 2021). Previous research also demonstrates that there is a lack of standardization in prescribing practices following delivery. The wide range of dosages prescribed to patients demonstrates the consistency in the inconsistent prescribing patterns in postpartum patients, underscoring the importance of standardized practices (Makeen, 2022).

Moreover, physicians were noted to be more prone to placing greater emphasis on delivery methods rather than the patients reported pain and pain types when prescribing opioids (Badreldin, 2019). Incorporating more detailed pain assessments may allow for better targeted and tailored individualized pain management and switching opioid prescriptions for other analgesics to help efficiently treat pain. Detailed pain assessments include asking patients about their pain levels and using more descriptive language when asking patients to characterize the type of pain they are feeling. This could allow physicians to prescribe different analgesics better suited for targeting the patient's specific pain complaints, instead of a general prescription of opioids. For instance, vaginal delivery is often associated with cramping pain, whereas patients who underwent a cesarean reported more complex, acute surgical postoperative pain (Lim, 2022). Tailoring treatment plans to pain type (affective, nociceptive, and neuropathic) may help mitigate unnecessary exposure to opioids while maintaining adequate pain control. Nonsteroidal anti-inflammatory drugs can be prescribed to treat specific types of pain, like the cramping commonly seen in postpartum patients, and effectively curtail the pain. By reducing exposure to opioids the postpartum population's risk for an opioid-related event may decrease, and contribute to a decrease in maternal mortality.

These differences may account for and contribute to the higher risk for postpartum women who underwent cesarean delivery compared to vaginal delivery. Not taking into consideration the patient's conditions and prescribing an extensive range of morphine equivalence can prove to be more harmful to patients and increase their risk of opioid-related events and mortality. These findings emphasize the need for more judicious and individualized prescribing practices.

Existing research has shown that medications for opioid overuse disorders like methadone, naloxone, and buprenorphine are effective at reducing overdose risk in highly susceptible patient populations, including postpartum mothers (Frankenberger, 2023). However, various social factors such as fear of legal consequences of loss of child custody often prevent patients from seeking help or treatment (Han, 2024). Potential issues regarding custody and child welfare involvement are often cited as a reason for not seeking treatment, and is particularly pertinent to this population due to the recent experience of giving birth. These barriers to patient care are especially relevant to our study population, as they may contribute to delayed initiation or underutilization of medications for opioid overuse disorder and thereby increase vulnerability to opioid-related adverse outcomes. Existing studies showed that increasing insurance eligibility and coverage up to 60 days following delivery and providing continuing care to patients may help reduce barriers to treatment (Ellick, 2024). Additionally, expansion of insurance coverage, improved care delivery systems, and long-term interaction of patients with support facilities have been associated with improved outcomes in postpartum populations (Patton, 2019). Postpartum women have reported stigma regarding substance use as another barrier to accessing help, increasing aid and interventions for women pregnant and postpartum could help reduce stigmas

associated with opioid use (Martin, 2022). Improving access to medications for opioid overuse disorders, ensuring continuity of care, and reducing stigma surrounding this topic may help reduce postpartum overdose risk overall. Through policy change and allowing more access to resources women could be less inhibited to gain access to treatments and medications for opioid use disorder. Increasing patient safety and access to support has the ability of improving patient outcomes and decreasing maternal mortality. Advocacy for policies and laws to be put in place that allows for postpartum patients to seek help without fear of legal repercussions or loss of child custody is also important and plays a role in decreasing the stigma surrounding the topic. Furthermore, refining opioid prescribing guidelines after delivery is another factor that may also help reduce variability and improve patient safety.

### LIMITATIONS

Several limitations in this research should be considered. The TriNetX database collects information from healthcare systems and may overrepresentation of insured populations, and therefore limits generalizability. Additionally, the database is only able to capture documented clinical encounters and is not able to capture unreported overdose events or events that happen outside a medical setting. Since naloxone is available over the counter and does not require a prescription, it can be administered outside of medical settings and incidences would not be captured in these datasets. Another limitation to be considered is the use of naloxone administration as a proxy for opioid-related events has a high likelihood of capturing prophylactic co-prescribing as well, instead of isolated acute overdose events. This can potentially overestimate actual overdose incidence, although high risk opioid exposure is still accurately reflected. Factors such as mental disorders and access to resources were not able to be

fully taken into account, as well as any societal and interpersonal factors that could have influenced overdose event risk.

Further research should be done to investigate if any comorbidities affect postpartum patients' risk for an opioid-related event. More knowledge is required to draw accurate conclusions regarding social influences on opioid-related events. Additionally, it would be beneficial to conduct studies on the efficiency and effectiveness of policy and guideline changes on the postpartum population. This research could help give a better understanding on what is occurring and how best to navigate the issue to reduce opioid-related events and mortality.

## CONCLUSION

With rising frequencies of opioid-related events, postpartum women face an increased risk of opioid-related events in part because of the commonality of prescribing opioids following delivery to help mitigate patient's pain. The research's data findings suggest that cesarean delivery is associated with an increased risk of opioid-related events. In the postpartum cohort those who underwent cesarean delivery faced higher risk of an opioid-related event, defined by naloxone capture, compared to those who underwent vaginal delivery. Further examination on demographics that face higher risks allows healthcare providers to make better informed choices regarding prescribing opioids and focus on providing personalized support where it is most needed. Because cesarean delivery is among the most common medical events and make up about one third of all births, recognizing that this demographic is more vulnerable and at higher risk of opioid-related events can allow for more conscientious practices to be put in place to reduce maternal mortality (Bateman, 2016).

These results can help physicians and care teams make better informed decisions and implement more effective support plans for women recovering from childbirth to improve patient outcomes. Focusing on preventative measures, particularly for more vulnerable demographics such as individuals who underwent cesarean delivery, and ensuring that patients have access to ongoing care and follow-ups could have a positive impact in reducing maternal mortality and reducing risk of an opioid-related event.

While opioids remain a necessary and significant tool for post-surgical recovery, these results underscore the imperative need for more standardized and individualized prescribing practices postpartum. It is incumbent to treat women's pain without increasing their risk of an opioid-related event and mortality. By recognizing the influence of opioid prescribing practices on various factors in the delivery and postpartum period, physicians and other healthcare professionals may actively work to enact preventative protocols to better protect postpartum patients and improve their outcomes.

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