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# Hospital and Individual Variations of Surgical Errors and Complications in Caesarean Section in the United States

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### UNIVERSITY OF CALGARY

Hospital and Individual Variations of Surgical Errors and Complications in Caesarean

Section in the United States

by

Manal Salim Sheikh

# A THESIS

## SUBMITTED TO THE FACULTY OF GRADUATE STUDIES

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#### Abstract

**Background:** Caesarean Section (CS) is the most common inpatient surgery performed internationally. Although CS is typically performed to prevent adverse maternal and fetal outcomes, there is still a risk of surgical errors and complications. This study examined maternal and hospital risk factors associated with errors and complications following CS in the United States (US).

**Methods:** Data were obtained from the 2012-2014 National Inpatient Sample, a deidentified database containing a random sample of 20% of hospital discharges in the US. Surgical errors (e.g. foreign body retained during surgery) can be the result of human error, while complications (e.g. infection) can be due to external factors such as preexisting comorbidities. The overall incidence of surgical errors and complications in CS was calculated. Bivariate analysis examined the association between surgical errors and complications in CS, and potential individual and hospital level covariates. Multilevel logistic modelling examined the association between individual (e.g. race) and hospital (e.g. CS volume), and errors and complications.

**Results:** Among 648,584 CS hospitalizations, 1.98% (95%CI: 1.95%-2.01%) and 9.67% (95%CI: 9.59%-9.74%) of women had an error or complication, respectively. The odds of developing a complication were 15.90 (95%CI: 15.33-16.49) if an error also occurred. Both individual- and hospital-level factors were associated with errors and complications. Women with Medicaid had increased odds of errors (OR: 1.40 (95%CI:1.37-1.43)) but lower odds of complications (OR: 0.89 (95%CI:0.88-0.90)), compared to women with private insurance. Compared to non-Hispanic white women,

ii

all races had lower odds of error, and only non-Hispanic black women had greater odds of complications (OR: 1.14 (95%CI:1.13-1.16)). Delivering prior to 37 weeks of gestation decreased the odds of errors (OR: 0.73 (95%CI:0.71-0.76)) and maternal complications (OR: 0.73 (95%CI:0.72-0.74)). Similarly, rural hospitals had lower odds of surgical errors (OR: 0.59 (95%CI: 0.56-0.62)) and complications (OR: 0.61 (95%CI: 0.59-0.62)) while hospitals with a large bed size had greater odds of errors and complications than medium bed size hospitals, at 1.13 (95%CI:1.09-1.17), and 1.13 (95%CI:1.11-1.15), respectively.

**Conclusions:** This study identified specific risk factors for errors and complications that can be further examined through quality improvement frameworks to reduce the incidence of adverse maternal events during CS.

**Keywords:** Maternal health, surgical outcomes, caesarean section, administrative data, patient safety

Word Count: 348/350 words

# Preface

This thesis is an original, unpublished, independent work by M. Sheikh et al.. The study reported in this thesis was covered by Ethics Certificate number REB17-2453, issued by the University of Calgary Conjoint Health Ethics Board for this project on January 22, 2018.

Appendix A is modified from Kuklina et al.'s Table 1<sup>1</sup>

Appendix C is modified from Bateman et al.'s Table 3<sup>2</sup>

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# Dedication

To my parents and,

To the women whose data contributed to and enabled this study;

My endless gratitude

# **Table of Contents**

Abstractii
Prefaceiv
Acknowledgementsv
Dedicationvi
List of Tablesxii
List of Symbols, Abbreviations, & Nomenclaturexiii
CHAPTER 1: INTRODUCTION1
1.1 Aims2
1.2 Caesarean Sections2
1.2.1 Techniques and Common Practices2
1.2.2 Incidence of CS
1.2.3 Indications of CS and Maternal Outcomes4
1.2.4 Cost6
1.2.4a Healthcare System Costs6
1.3 Surgical Risks7
1.3.1 Surgical Errors7
1.3.2 Surgical Complications8
1.3.3 Scope of the Issue9
1.3.3a Surgical Errors and Complications in CS9
1.3.3b Disability-Adjusted Life Years11
1.4 Risk Factors for Surgical Errors and Complications in CS

1.4.1 Individual level factors11
1.4.2 Hospital level factors14
1.5 Gap in the Literature & Significance17
1.6 Objectives
CHAPTER 2: METHODS19
2.1 Data Source
2.2 Ethics21
2.3 Study Population21
2.4 Case definitions22
2.4.1 Obstetric Population22
2.4.2 Caesarean section22
2.4.3 Obstetric Comorbidity Index23
2.4.4 Surgical Errors and Complications ICD-9-CM Definitions23
2.4.5 Outcomes, Individual, and Hospital Factors Definitions
2.4.5a Outcomes and Individual Factors25
2.4.5b Hospital Factors27
2.6 Data Analysis28
CHAPTER 3: RESULTS
3.1 Demographics33
3.1.1 Population
Table 1: Descriptive Demographics of Hospitalizations in NIS HCUP Database
from 2012-2014 for CS Population35

3.1.2 Surgical Errors
Table 2: Surgical Errors Rate in NIS HCUP Database from 2012-2014 for CS
Population
Table 3: Number of Surgical Errors per Individual Hospitalization in NIS HCUP
Database from 2012-2014 for CS Population38
3.1.3 Surgical Complications
Table 4: Surgical Complications Rate in NIS HCUP Database from 2012-2014 for
CS Population39
Table 5: Number of Surgical Complications per Individual Hospitalization in NIS
HCUP Database from 2012-2014 for CS Population40
3.2 Bivariate Analysis40
Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical
Errors and Complications in NIS HCUP Database from 2012-2014 for CS
Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical Errors and Complications in NIS HCUP Database from 2012-2014 for CS Population
Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical         Errors and Complications in NIS HCUP Database from 2012-2014 for CS         Population         42         3.3 Multilevel Modelling
Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical         Errors and Complications in NIS HCUP Database from 2012-2014 for CS         Population
Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical         Errors and Complications in NIS HCUP Database from 2012-2014 for CS         Population         42 <b>3.3 Multilevel Modelling</b> 45         Table 7: Multilevel Model for Surgical Errors and Complications in NIS HCUP         Database from 2012-2014 for CS Population         48
Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical         Errors and Complications in NIS HCUP Database from 2012-2014 for CS         Population       42         3.3 Multilevel Modelling       45         Table 7: Multilevel Model for Surgical Errors and Complications in NIS HCUP         Database from 2012-2014 for CS Population         48         CHAPTER 4: DISCUSSION
Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical         Errors and Complications in NIS HCUP Database from 2012-2014 for CS         Population       .42         3.3 Multilevel Modelling       .45         Table 7: Multilevel Model for Surgical Errors and Complications in NIS HCUP         Database from 2012-2014 for CS Population         .48         CHAPTER 4: DISCUSSION         .50         4.1 Summary of Main Findings
Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical         Errors and Complications in NIS HCUP Database from 2012-2014 for CS         Population       .42         3.3 Multilevel Modelling       .45         Table 7: Multilevel Model for Surgical Errors and Complications in NIS HCUP         Database from 2012-2014 for CS Population         .48         CHAPTER 4: DISCUSSION         .50         4.1 Summary of Main Findings         .51         4.2 Comparison with Other Studies
Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical         Errors and Complications in NIS HCUP Database from 2012-2014 for CS         Population       .42         3.3 Multilevel Modelling       .45         Table 7: Multilevel Model for Surgical Errors and Complications in NIS HCUP         Database from 2012-2014 for CS Population         .48         CHAPTER 4: DISCUSSION         .50         4.1 Summary of Main Findings         .51         4.2 Comparison with Other Studies         .52         4.2.1 Surgical Errors and Complications

4.2.3 Median Household Income by Zip Code	54
4.2.4 Race	55
4.2.5 Timing of Admission	55
4.2.6 Preterm birth	56
4.2.7 Hospital Transfer	56
4.2.8 Hospital Model	57
4.2.9 Teaching Hospital Status	57
4.2.10 CS Volume	58
4.3 Clinical and Public Health Implications/Stakeholder Engagement	58
4.4 Strengths	61
4.5 Challenges and Limitations	62
4.6 Directions for Future Research	65
4.7 Conclusion	70
References	71
APPENDICES	
Appendix A: ICD-9-CM codes used to identify obstetric deliveries <sup>1</sup>	
Appendix B: CS procedure ICD-9-CM codes	90
Appendix C: Obstetric Comorbidity Index <sup>2</sup>	91
Appendix D: Surgical Errors ICD-9-CM codes	92
Appendix E: Surgical complications ICD-9-CM codes	95
Appendix F: Descriptive Surgical Errors after CS in NIS HCUP Database 2012	2-2014
(Stratified by Specific ICD-9-CM Codes)	

Appendix G: Descriptive Surgical Complications after CS in NIS HCUP Database 2	2012-
2014 (Stratified by Specific ICD-9-CM Codes)	105

# List of Tables

Table 1: Descriptive Demographics of Hospitalizations in NIS HCUP Database from 2012-
2014 for CS Population35
Table 2: Surgical Errors Rate in NIS HCUP Database from 2012-2014 for CS Population.37
Table 3: Number of Surgical Errors per Individual Hospitalization in NIS HCUP Database
from 2012-2014 for CS Population38
Table 4: Surgical Complications Rate in NIS HCUP Database from 2012-2014 for CS
Population
Table 5: Number of Surgical Complications per Individual Hospitalization in NIS HCUP
Database from 2012-2014 for CS Population40
Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical Errors
and Complications in NIS HCUP Database from 2012-2014 for CS Population42
Table 7: Multilevel Model for Surgical Errors and Complications in NIS HCUP Database
from 2012-2014 for CS Population48

#### List of Symbols, Abbreviations, & Nomenclature

(Listed in the order they appear in-text)

- CS Caesarean Section
- US United States
- 95%CI 95% Confidence Interval
- OR Odds Ratio
- IOM Institute of Medicine
- **GP** General Practitioner
- DALYs Disability-Adjusted Life Years
- NIS National/Nationwide Inpatient Sample
- HCUP Healthcare Cost and Utilization Project
- AHRQ Agency for Healthcare Research and Quality
- DRG Diagnosis Related Group
- ICD-9-CM International Classification of Disease Version 9 Clinical Modification
- "E" codes ICD-9-CM codes for "external cause of injury" or "misadventure codes"
- CBSA Core Based Statistical Area
- ICC Intraclass Coefficient
- NSQIP National Surgical Quality Improvement Program
- VA Veteran's Affairs
- PSIC Patient Safety Improvement Corps
- OR Operating Room

## **CHAPTER 1: INTRODUCTION**

#### 1.1 Aims

This study aimed to determine the incidence of surgical errors and maternal complications in caesarean sections in a nationally representative sample and assess individual and hospital level characteristics associated with surgical errors and complications. By reporting the incidence of surgical errors and complications in the obstetric population and factors associated with errors and complications, there may be an opportunity to use a quality improvement framework in future research to improve maternal safety during this procedure.

#### **1.2 Caesarean Sections**

#### 1.2.1 Techniques and Common Practices

Caesarean section (CS) is the surgical delivery of a neonate through the abdominal and uterine wall<sup>3</sup>. It is the most common inpatient surgery performed in the United States<sup>4</sup>, and the most common surgery performed, internationally<sup>3,5</sup>. The procedure involves making incisions to the mother's abdomen and uterus to deliver the fetus<sup>6</sup>. The most common CS procedure is known as a low cervical CS (or low segment CS), and is most commonly performed using a Pfannenstiel or horizontal incision<sup>3</sup>. Once the uterus is exposed, the lower uterine segment is then incised to deliver both the baby and the placenta<sup>6</sup>. In contrast, in a classical CS the fundal or upper segment of the uterus is incised. The horizontal incision from the lower segment has less vasculature than the fundus and there is a lower risk of rupture of the uterine scar in subsequent pregnancies<sup>6</sup>. However, a classical CS is used on occasion when the lower uterine

segment is not well developed, typically in cases of very preterm deliveries (< 26 weeks gestation).

#### 1.2.2 Incidence of CS

The rate of CS has been increasing steadily worldwide<sup>7</sup>. Every year, there are approximately 23 million CS worldwide with 1.3 million CS occurring in the United States alone<sup>4,5</sup>. In particular, the United States has a rate of 32.8% of all births occurring by CS<sup>7</sup>. There are approximately two CS started every minute in the United States<sup>8</sup>. Globally, there is wide variation in the number of births via CS, with more developed regions having 21.1% of births by CS (ranging from 6.2% to 36.0%), and least developed countries having 2.0% of births by CS (ranging from 0.4% and 6.0%) due to differences in healthcare infrastructure<sup>9</sup>. Nearly one in five women internationally, give birth by CS<sup>10</sup>. However, despite the World Health Organization's recent decision to abandon an "ideal rate" of 10-15% of CS per all live births in all geopolitical populations<sup>11</sup>, there has still been a general consensus that for developed countries, the current rate of CS is entirely too high to be justifiable by medical causes alone<sup>7</sup>. CS rates have increased in the past 20 years for women of all ages, races, gestational ages, and all states in the US<sup>12</sup>. Other factors suggested for the increasing CS rate in the United States have included increasing malpractice pressure for vaginal birth after CS<sup>13</sup>, maternal choice<sup>14</sup>, and increased clinical knowledge about risk factors for adverse events<sup>15</sup>.

Other studies examined financial incentives at the hospital level, and the effect they had on the number of CS performed, as well as the cost effectiveness of CS and the effect on parturient outcomes. Hoxha et al. recommended redesigning for-profit

hospitals' financial incentive structures to decrease the rate of CS in private hospitals<sup>16</sup>. Examples of these recommendations included: examining and identifying financial incentive structures such as those at the physician level (e.g. physician payment schemes), hospital level (e.g. whether there is institutional pressure on physicians to choose more expensive, resource-intensive procedures), as well as potentially examining non-for-profit hospitals to fully examine fee-for-service payment models<sup>16</sup>. Souza et al. and Declercq et al.'s studies reported that adverse maternal outcomes were more likely to occur when CS were performed on low-risk women<sup>17,18</sup>, lending clinical backing to Hoxha et al.'s recommendation to decrease CS rates in for-profit hospitals<sup>16</sup>. Xu et al. found that higher cost hospitals did not have better delivery outcomes than lower cost hospitals<sup>19</sup>.

Regarding the cost-effectiveness of CS, in contrast to Souza et al.'s finding that CS carried an intrinsic risk and should be only used when the benefit outweighed the cost<sup>17</sup>, Alkire et al. found that CS were still the most economically viable proposition in combating maternal mortality and morbidity by WHO standards<sup>20</sup>. Although Alkire et al. conceded that CS were not the sole measure to deal with obstetric complications such as obstructed labour, they argued that despite the potential risk for adverse maternal outcomes following CS, it was still the best cost-effective procedure to be used<sup>20</sup>.

#### 1.2.3 Indications of CS and Maternal Outcomes

CS are typically performed when there is judged to be a significant threat to either maternal or fetal health such as dystocia, obstructed labour, or fetal distress, including fetal asphyxiation<sup>20,21</sup>. As such, CS are considered life-saving procedures that

are effective at preventing maternal and fetal morbidity and mortality from obstetric complications<sup>5</sup>. For example, prolonged labour can lead to severe obstetric complications such as uterine rupture, severe postpartum hemorrhage or subsequent fistula, which can be prevented by a timely CS<sup>3</sup>. The classification of urgency for CS is (1) immediate life-threatening complications (e.g. uterine rupture, cord prolapse), (2) maternal or fetal compromise without being life-threatening (e.g. failure to progress in labour with some maternal or fetal compromise), (3) early delivery required without maternal or fetal compromise, and (4) at a time to suit both maternal and hospital services<sup>22</sup>. The classification of urgency for CS provides a more nuanced look at considerations for CS rather than a simple classification of "emergency" or "scheduled" CS<sup>6,22</sup>. Patient preference (also known as "maternal request CS") can lead to a scheduled CS without medical indications<sup>18</sup>. However, the biggest indicator of scheduled CS are prior CS also known as "elective repeat caesarean delivery"<sup>23</sup>.

Some studies have looked at the short-term adverse maternal outcomes following CS without medical indication<sup>17</sup>. Souza et al. concluded that, although CS were beneficial in some circumstances, they were still "associated with an intrinsic risk of increased severe maternal outcomes,"<sup>17</sup> and should only be performed when the benefit of the operation outweighed the risk<sup>17</sup>.

In addition, Liu et al concluded that the risks of severe maternal complications associated with elective or planned CS were higher than those associated with planned vaginal delivery<sup>24</sup>, particularly in repeat CS<sup>25</sup>. Examples of maternal complications are infection and wound complications<sup>18,25</sup>. Other studies have used randomized control

trials in multiple health centres to look at adverse fetal outcomes following scheduled CS versus unscheduled CS<sup>26</sup>. Hannah et al. conducted a randomized control trial of planned CS versus attempted vaginal delivery for breech presenting fetuses (when the baby's buttocks or feet are delivered before the head) at term <sup>26</sup>. The results from this study showed that neonatal mortality decreased significantly for a policy of scheduled CS for fetuses in breech presentation<sup>26</sup>. These studies (known at the TERM Breech follow up studies) demonstrated that planned CS was safer for a breech delivery with less rates of complications. However, the results have been subject to scrutiny, as other studies have shown lower rates of complications with planned vaginal deliveries compared to elective CS<sup>27,28</sup>. These studies demonstrate the importance of CS in preventing adverse maternal and neonatal outcomes, but also how CS can lead to complications, particularly when not medically necessary.

1.2.4 Cost

#### 1.2.4a Healthcare System Costs

In addition to the increased risk of complications in unnecessary CS, surgical delivery also increases healthcare costs. In 2003, CS cost 76% more than vaginal deliveries (\$4,372 per CS on average in 2003 US dollars), and had an additional 2.4 days longer length of hospital stay than vaginal deliveries, which amounted to 77% longer length of stay<sup>29</sup>. Multiplied by the approximately 1.3 million CS annually in the United States<sup>4,5</sup>, the total cost and burden on the healthcare system in the United States would be over \$5.68 billion US dollars (in 2003). In 1981, medical errors were estimated to cost

In 2010, the average total maternal charges of care for CS for private insurers was \$16,673 compared to \$12,520 for vaginal deliveries<sup>30</sup>. The average total maternal charges of care for CS for Medicaid-insured women was \$7,983 and \$6,117 for vaginal childbirths, about 25% lower than the cost for private insurers<sup>30</sup>. On average, the total maternal charge for CS was about 30% higher than for vaginal childbirth<sup>30</sup>. These estimates varied state to state<sup>30</sup>. Complications following CS also have considerable costs associated with them, creating a burden not only on the healthcare system, but also on public and private insurance companies, and state and federal budgets<sup>31</sup>. Nearly half of American births are financed by public insurance (e.g. Medicaid and Medicare) so there are cost implications there as well – in 2009, state Medicaid programs paid upwards of \$3 billion for CS<sup>32</sup>.

#### **1.3 Surgical Risks**

There are risks involved with CS, similar to any surgical procedure<sup>6</sup>. These risks can be divided into surgical errors and complications.

#### 1.3.1 Surgical Errors

In 1999, the Institute of Medicine (IOM) released their seminal work, *To Err is Human*, where they found that approximately 98,000 deaths per year resulted from medical error<sup>33</sup>. Prior studies showed that one half to two thirds of adverse events during medical care could be attributed to surgical care<sup>34,35</sup>, of which half were preventable<sup>36</sup>. In addition, the US maternal mortality rate has increased from 19 per 100,000 in 2000 to 24 per 100,000 in 2014, and 60% of maternal deaths in childbirth have been classified as being preventable<sup>37</sup>.

Surgical error can be classified into judgment errors (i.e. inadequate knowledge or failure to apply the knowledge), technical errors (i.e. generally referring to surgical errors or known as "tricks of the trade", training errors, equipment malfunctions), expectations errors (i.e. guidelines around expectations of guality of care such as a surgical checklist), systems errors (i.e. protocols in place for an operation), and mechanical errors (i.e. as related to equipment being used)<sup>38</sup>. As the most common kind of surgical error is technical error<sup>34</sup>, surgical error can be defined as a preventable mistake made during surgery<sup>36,38</sup>. It can be the result of inexperience (e.g. trainee surgeons performing the operation<sup>10</sup>), excessive workload<sup>39</sup> and fatigue<sup>40</sup>, poor communication among clinical staff<sup>36</sup>, among other factors. Examples of surgical errors during CS include surgical instruments left behind in the body cavity, accidental laceration or puncture of a blood vessel or pelvic organs, and inappropriate anaesthetic dosage or drugs provided. Surgical errors can lead to further adverse events<sup>34</sup> such as complications arising from infection, and increase the likelihood of maternal and neonatal mortality.

#### 1.3.2 Surgical Complications

Surgical complications can be defined as any undesirable or unintended result of an operation affecting the patient which should not normally occur<sup>41</sup>. Complications occur due to the presence of maternal or fetal comorbidities<sup>42</sup> (which may have influenced the decision to deliver via CS<sup>22</sup>) or surgical errors<sup>34</sup>, and may or may not be preventable. Examples of surgical complications include maternal death, infection (e.g. sepsis), cardiac complications, embolisms, wound dehiscence, and hysterectomy.

#### 1.3.3 Scope of the Issue

#### 1.3.3a Surgical Errors and Complications in CS

Since CS is the most common inpatient surgical procedure, internationally<sup>21</sup>, even a small error or complication rate can affect a considerable number of women, despite it being a relatively "safe" and low-risk surgery<sup>43,44</sup>. To put it into perspective, the burden of disease can be placed in absolute terms. As there are approximately four million births annually in the United States<sup>7</sup>, we can assume that with a CS rate of 32.8%<sup>7,11</sup>, approximately 1,312,000 of these births are via CS. Although CS are generally safe procedures<sup>43</sup>, due to the sheer volume of CS performed, the absolute number of complications and errors can add up. A 2007 Canadian study found that the error rate for specialists performing CS was  $0.7\%^{45}$ . If 0.7% of all CS have  $\geq 1$  error in the procedure<sup>45</sup>, then there is a disease burden shared by 9,184 women annually. The same study also reported that the complication rate was 2% for specialists performing the procedure<sup>45</sup>. Applying the estimate of 2% of  $\geq$ 1 complication after CS for the United States, then there is a disease burden shared by 26,240 women annually. In total, approximately 35,424 women in the United States would be affected by adverse surgical outcomes following CS each year.

An American study looking at a birth cohort from 1992 in Colorado and Utah found that the incidence of surgical adverse events was 3.1% (95%CI: 1.9-5.0) for CS<sup>35</sup>. The incidence of preventable surgical adverse events in CS was 1.7% (95%CI: 0.8-3.3)<sup>35</sup>. In absolute terms, that would mean that 40,672 women delivering via CS would have an adverse surgical event annually, out of which 22,304 would have been preventable.

The North American studies show low error and complication rates in CS. However, some international studies have found larger complication rates. A 2004 Norwegian study found that the complication rate after CS was 16% for scheduled CS and 24% for unplanned (or emergency) CS<sup>44</sup>. The researchers defined complications by variables such as blood loss (as measured in mL by the clinician), bowel/bladder lesions, and tissue damage<sup>44</sup>. Altogether, the researchers determined that 21% of women in Norway had  $\geq$ 1 complication after CS<sup>44</sup>.

However, the Norwegian study did not examine surgical errors, and the estimates may not be applicable in an American context, since the Norwegian study (and the Canadian study) was based in a universal healthcare context. In addition, while the Canadian study examined differences in surgical errors and complications between general practitioners (GPs) in rural hospitals and specialists in urban centers in Canada, there were no maternal risk factors examined<sup>45</sup>. In addition, the 10 year old study was not nationally representative of the Canadian population, and included only select errors and complications rather than a comprehensive list of all outcomes that could potentially occur in a CS<sup>45</sup>. In contrast, the American study reported estimates from over two decades ago from just Colorado and Utah<sup>35</sup>. The rate of adverse events could have changed since then due to changes in obstetric practice and guidelines and the changing maternal demographics in the US. Moreover, while the study reported surgical adverse events, and classified them into different types such as "technicalrelated complications," there was little focus on CS alone, as multiple surgeries were compared instead<sup>35</sup>.

A study looking at a nationally representative sample of CS deliveries in the US with a comprehensive list of surgical errors and complications, and their associations with maternal and hospital risk factors would provide an insight not found in previous literature.

#### 1.3.3b Disability-Adjusted Life Years

To further illustrate the seriousness of the situation, Disability-Adjusted Life Years (DALYs) can also be calculated. Since the obstetric population is younger than the general population, there may be potential for an increased number of DALYs due to the possibility of adverse maternal outcomes resulting in a disability at a younger age<sup>20</sup>. DALYs have been used, "to quantify the burden of diseases, injuries and risk factors on human populations," to better ground general healthcare delivery in strong economic and ethical principles<sup>46</sup>. This emphasis on improving healthcare delivery policies hopes to produce more equitable outcomes in healthcare<sup>46</sup>. A 2013 Iranian study found that the DALYs for CS with complications were 20.70 years per 1,000 deliveries compared to 8.89 years per 1,000 deliveries for vaginal deliveries with complications<sup>47</sup>. In private hospitals, CS with complications had DALYS of 23.40 years per 1,000 deliveries, and 15.67 years per 1,000 deliveries in governmental hospitals<sup>47</sup>. An increase in DALYs may add increased usage and economic burden on a healthcare system<sup>48</sup>.

#### 1.4 Risk Factors for Surgical Errors and Complications in CS

#### 1.4.1 Individual level factors

Individual-level factors include elements that can vary from patient to patient. Examples of individual level factors include race, payer or insurance information,

household income, gestational age at delivery, having a CS on a weekday versus the weekend (e.g. timing of admission), and medical comorbidities (pregnancy-induced or pre-existing conditions)<sup>3</sup>. Although the literature on CS outcomes by individual level factors is limited, there has been research looking at surgical outcomes by these individual factors for other procedures.

The effect of preterm delivery on CS outcomes has been examined in one study<sup>49</sup>. This study reported that as gestational age increased, the odds of having a classical CS decreased due to a difference in pregnancy characteristics<sup>49</sup>. Another finding reported that for classical CS, there was an increased risk of blood transfusion and higher maternal complication rates compared to the lower cervical transverse CS<sup>49</sup>. The rate of maternal complications was similar for lower segment CS performed in the preterm (<37 weeks of gestation) or term ( $\geq$ 37 weeks of gestation) period, suggesting that complications were associated with the type CS procedure performed, rather than the gestational age at delivery<sup>49</sup>.

Although there have been studies on the role of insurance on CS rates, where private insurance may encourage healthcare providers to provide more CS than in those using public health insurance<sup>50</sup>, there have been limited studies on surgical outcomes in CS by payer status. However, in other surgeries such as oral cancer surgery, different surgical outcomes have been observed by payer status<sup>51</sup>. Medicaid, uninsured, and Medicare recipients were more likely to develop surgical complications and have an increased length of stay following oral cancer surgery compared to individuals with private health insurance<sup>51</sup>. Similar results were found in a study on bariatric surgery,

where Medicare and Medicaid recipients had more underlying comorbidities and worse surgical outcomes compared to those with private insurance<sup>52</sup>.

Similarly, the role of neighbourhood-level median household income has not been examined in association to CS outcomes. However, it was found that patients residing in communities with lower median household income had worse outcomes for most surgical measures using a nationally representative all payer database<sup>53</sup>. While there had been improvement in income-related disparities in all surgeries examined in the study, comparing the years 2000 and 2009, households in the bottom percentile of median house income still fared worse compared to households in the top median household income percentile<sup>53</sup>.

Previous studies have shown that non-Hispanic black Americans have poorer surgical outcomes, such as higher rates of postoperative cardiac arrest and mortality, compared to non-Hispanic white Americans<sup>54</sup>. In 2005, it was estimated that if all races received equal benefit from healthcare, approximately 83,000 excess deaths per year could be avoided among non-Hispanic black Americans<sup>55</sup>, an increase from the 60,000 excess deaths reported by the 1985 Task Force<sup>56</sup>. However, other studies believe that it is a matter of comorbid conditions rather than race itself, and that to treat racial disparities, the focus should be on treating the comorbid conditions before they become surgically emergent<sup>54</sup>.

There is a limited body of literature on maternal CS outcomes and whether a woman was admitted on a weekday or weekend for her CS. However, a 2003 study looked at neonatal mortality for childbirth in hospital on a weekday compared to the

weekend in California<sup>57</sup>. This study found no significant difference in neonatal mortality between infants born on a weekday versus infants born on the weekend<sup>57</sup>. Nonetheless, in previous research, patients presenting with conditions such as "ruptured abdominal aortic aneurysm" or "pulmonary embolism," had higher odds of mortality for a weekend admission compared to a weekday admission<sup>58</sup>. The difference between the two studies could be attributed to the different conditions or procedures being examined. For example, in the case of neonatal mortality during childbirth on the weekend or weekday, childbirth can be considered more "low risk" and common<sup>43</sup> than the other conditions studied such as a pulmonary embolism<sup>58</sup>, which could have led to difference of weekend and weekday mortality have included that patients who are more ill are admitted on the weekend causing a more severe case-mix for the weekend<sup>57</sup>, since working on the weekend is unpopular and leads to uneven staffing<sup>58</sup>.

#### 1.4.2 Hospital level factors

In addition to individual level factors, it is important to consider hospital level factors when looking at surgical errors and complications following CS. Hospital level factors include hospital ownership model, teaching hospital status, hospital bed capacity and hospital volume. These factors can impact the quality of care provided.

Hospital ownership model has been shown to impact the number of CS performed<sup>16</sup>. Hoxha et al. found that CS were more likely to be performed at private for-profit hospitals compared to private non-profit hospitals, regardless of whether a

woman was low-risk<sup>16</sup>. Morris et al. also found that a parturient giving birth at for-profit hospitals had a higher odds of delivering via CS than at not-for-profit hospitals<sup>59</sup>. As discussed in previous literature, CS without medical indications increases the risk of maternal and neonatal complications<sup>17,18,26</sup>.

In addition to the hospital funding model, the impact of teaching hospitals and the location they are in can also impact maternal outcomes following CS. Aubrey-Bassler et al. examined the difference in maternal outcomes following CS between CS performed by family physicians or GPs in rural and remote communities versus specialists (i.e. obstetricians) in hospitals<sup>45</sup>. Aubrey-Bassler et al. reported that there was not a significant difference in the rate of maternal morbidity and mortality following CS in procedures performed by GPs versus specialists, once the rate of postpartum infection was removed<sup>45</sup>. Major morbidity was higher among patients operated on by GPs when the rate of postpartum infection was included, suggesting that there were some hospital factors around sterility practices between GPs and specialists that were different rather than procedural differences leading to adverse outcomes<sup>45</sup>. Another study examined the role of training in surgical trainees and the effects on CS outcomes<sup>10</sup>. Fok et al. examined surgical outcomes following ten trainees and their first fifty independent CS<sup>10</sup>. The researchers reported that it took about 10-15 CS performed independently by each of the trainees before they were proficient enough to not cause adverse surgical outcomes in the patients being operated on<sup>10</sup>. Other studies have reported that hospitals with increased teaching intensities have better surgical outcomes in general, orthopedic and vascular surgery <sup>60</sup>.

Women in rural areas generally experience poorer perinatal health outcomes overall perhaps due to limited healthcare accessibility, including obstetric healthcare, compared to their female counterparts in urban regions<sup>61</sup>. Part of this limited obstetric accessibility can be because of the greater geographic distance women in rural regions must travel to access hospitals that provide perinatal care, if not tertiary perinatal care, if required<sup>61</sup>. Kozhimannil et al. explained that this normally is not an issue as many rural women give birth safely in local hospitals, despite the distance they must travel<sup>61</sup>. The issue arises when complications from childbirth necessitates higher-acuity care (such as a consultations with maternal-fetal medicine physicians) and local hospitals are not equipped with the necessary personnel or resources to address the medical issue<sup>62</sup>. Additionally, some rural hospitals do not have full CS capabilities which may affect maternal and fetal outcomes<sup>62</sup>. These findings are not to suggest that rural hospitals do not serve a role – local obstetric care even without CS capabilities are important in delivering necessary healthcare and improve outcomes, compared to areas without intrapartum services at all<sup>16</sup>.

There was limited research on hospital bed size and CS outcomes, however, one study looking at patient safety indicators included hospital bed size as a covariate<sup>63</sup>, while another study used hospital bed size as a covariate to examine hospital volume and mortality after colorectal cancer surgery as the two hospital factors are strongly correlated with each other (i.e. larger bed size would mean that there is more capacity for increased volume of patients for that procedure)<sup>64</sup>. The results of the study found that highest volume hospitals had lower mortality than lowest volume hospitals after

adjusting for hospital bed size, especially for older patients who accounted for the majority of deaths after colorectal cancer surgery<sup>64</sup>. Dimick et al. concluded that hospital volume could be a marker of postoperative outcomes for patients in that cohort<sup>64</sup>.

Dimick et al.'s study was not alone – hospital volume has been associated with surgical outcomes in other studies. More specifically, poorer surgical outcomes at hospitals with lower hospital volumes for that specific surgery while hospitals with a higher volumes have better outcomes for that surgery<sup>65</sup>. However, a study on childbirth showed that complication rates following childbirth were not associated with hospital volume<sup>66</sup>. The authors hypothesized that this may occur since there are different protocols at different hospitals for childbirth and clinician expertise may play a bigger role than hospital volume<sup>66</sup>.

#### 1.5 Gap in the Literature & Significance

There is a marked lack of studies looking at individual factors on surgical outcomes following CS. CS is different than other surgical procedures as it is done more commonly than other inpatient surgeries<sup>4</sup>, and primarily done for fetal health considerations rather than maternal health<sup>67</sup>. Similarly, there are few studies that have looked at surgical error during CS, since most studies looked at complications after CS. Although, there have been some studies on hospital factors affecting CS outcomes<sup>45</sup>, there is still a gap in the literature to look at individual factors, hospital factors and CS outcomes – both errors and complications – that has not been done previously. By examining the association between key hospital and individual level factors and adverse

surgical outcomes following CS, we can look at the interplay between individual and hospital factors to potentially identify areas for improvement.

By examining both the incidence of surgical errors and complications following CS and risk factors for errors and complications, further research can be done to develop quality improvement frameworks to assess where exactly pre-existing guidelines should be modified or new policies should be developed. Additionally, to better understand the population that is associated with poorer outcomes in CS for anticipatory caregiver guidance, we need to first identify what individual and hospital level factors are associated with poor surgical outcomes in CS. Understanding the associations and interplay between those two kinds of factors can help us identify women who are potentially more vulnerable to poor outcomes after CS, and build on policy gaps in that area.

#### 1.6 Objectives

- To estimate the incidence of surgical errors and complications in CS in the United States from 2012-2014.
- 2. To assess the association between hospital/individual factors and surgical errors and complications in CS in the United States from 2012-2014.

# **CHAPTER 2: METHODS**

#### 2.1 Data Source

For this cross-sectional study, de-identified data were obtained from the National Inpatient Sample (previously known as the Nationwide Inpatient Sample) (NIS) database from the Healthcare Cost and Utilization Project (HCUP)<sup>68</sup>. This data is sponsored by the Agency for Healthcare Research and Quality (AHRQ) in a state-federal level partnership<sup>68,69</sup>.

This all-payer inpatient claims database contains a random sample of 20% of all patients discharged from hospitals across the United States, from hospitals participating in HCUP<sup>68</sup>. A sample of the State Inpatient Database is used to generate this database<sup>69</sup>. In 2012, the NIS HCUP database was redesigned<sup>69</sup>. Previously, it was a sample of 100% of hospitalization discharges from 20% of all hospitals participating in HCUP<sup>69</sup>. The 2012 redesign created a sample of 20% of all hospitalization discharges from all hospitals participating in HCUP<sup>70</sup>. The NIS HCUP database is the largest inpatient care database in the United States, and contains over seven million hospital stays annually, across all payer groups and comprises of 44 states and the District of Columbia<sup>69</sup>. About 94% of American hospitals participate in the HCUP, representing 96% of the US population<sup>68</sup>.

Although the NIS database contains records on hospital discharges, and does not use patients as the unit of analysis (i.e. it is not possible to determine if an individual patient is included in the database multiple times), its administrative data is one of the most comprehensive national sources of information for hospital-based care in the US and is used regularly in American health services research, including obstetric research<sup>68,69,71</sup>.

#### 2.2 Ethics

Ethics approval was obtained from the University of Calgary's Conjoint Health Research Ethics Board (REB17-2453).

#### 2.3 Study Population

Childbirth is the most common reason for hospitalization in the United States<sup>72</sup>. Almost all births occur in-hospital in the United States, with only 1.18% of births occurring out of hospital<sup>73</sup>. Out of hospital births generally refer to births at home or in a birthing center, which are not covered by the NIS HCUP database. For this study, we looked at the years 2012-2014 captured in the NIS HCUP database, and included only discharge records that were coded as female. Using a predefined algorithm for identifying the obstetric population using clinical diagnosis codes found on discharge records<sup>1</sup> (see section 2.4.1 and Appendix A), we identified all deliveries captured between the years 2012-2014. To examine the CS population alone, we then isolated all CS cases from the larger obstetric deliveries to create our study sample. The CS cases included procedures such as: classical CS, low cervical CS (or low segment CS), extraperitoneal CS, and other specified and unspecified CS types. From there, we included only discharge records that listed maternal age before the natural age of menopause (e.g. 15-50 years old).

#### 2.4 Case definitions

#### 2.4.1 Obstetric Population

The algorithm developed and validated by Kuklina et al was used to define the obstetric population<sup>1</sup>. This algorithm includes Diagnosis Related Group (DRG) and International Classification of Disease Version 9 Clinical Modification (ICD-9-CM) diagnostic and procedural codes related to the outcome of delivery and procedures used to facilitate obstetric delivery (Appendix A). This validated algorithm has been found to identify more obstetric deliveries than use of outcome of delivery codes (i.e. ICD-9-CM: V27) alone; particularly deliveries involving complications<sup>1</sup>.

#### 2.4.2 Caesarean section

To define the sub-population of women that had delivered via CS from the total obstetric population derived from Kukalina et al.'s algorithm, we used ICD-9-CM procedure codes for CS (Appendix B). We did not use indicators for CS as a proxy (as has been done in previous studies<sup>74–76</sup>) to avoid potential overestimation of CS incidence in the sample, as indicators for CS have been shown to have only 60% sensitivity in accurately diagnosing a CS, according to study that validated those codes<sup>77</sup>. These codes for CS were validated by Yasmeen et al. by comparing California discharge data with a chart review to examine accuracy of coding<sup>77</sup>. CS coded with these ICD-9-CM codes were accurately reported with sensitivities and positive predictive values greater than 90%<sup>77</sup>.
#### 2.4.3 Obstetric Comorbidity Index

The algorithm developed and validated by Bateman et al. in 2013 was used to create a maternal comorbidity index to predict severe maternal morbidity (defined as acute maternal end-organ injury or mortality)<sup>2</sup>. The obstetric comorbidity index includes ICD-9-CM diagnostic and procedural codes to provide a single numerical score that incorporates multiple maternal comorbidities<sup>77–79</sup> (Appendix C). This score can help control for confounding in epidemiological studies by accounting for maternal-specific comorbidities<sup>2</sup> that could influence surgical prognosis after CS. Metcalfe et al. validated the obstetric comorbidity index in an external population to show that it could be used with hospitalization discharge data for obstetric deliveries (as is the case with NIS HCUP data)<sup>80</sup>.

## 2.4.4 Surgical Errors and Complications ICD-9-CM Definitions

Surgical errors and complications were defined *a priori* in this study, and developed in conjunction with clinical experts in the field. Specific conditions were then organized into clinically meaningful categories. For example, errors were organized by body systems or specific types of errors (Appendix D) while complications were organized into similar clinical categories such as embolisms, and anaesthetic complications (Appendix E). Using ICD-9-CM codes, composite scores for both surgical errors and surgical complications were created to serve as two outcomes. Whenever possible, ICD-9-CM codes that had been validated in previous studies were used to identify errors and complications; however, validated case definitions did not exist for all conditions examined in the present study. "E" codes refer to ICD-9-CM codes that stand for "external cause of injury" or "misadventure codes"<sup>68</sup>. In the past decade, reporting of "E" codes have become mandatory in some states such as California<sup>68</sup>. Due to the staggered release and inconsistent reporting standards state-to-state regarding "E" codes, they are incompletely reported in the NIS HCUP data<sup>68</sup> but still included in our definitions since they provide an insight into potential error reporting.

As some procedures that would typically be used to address a surgical error or complication in CS may be planned if a CS was done in a women with a gynecological cancer<sup>81,82</sup>, hysterectomies, myomectomies, oophorectomies, and ovarian cystectomies were not considered a surgical complication in women that had a comorbid diagnosis of gynecological cancer (e.g. cervical cancer (ICD 9-CM code: 180), ovarian cancer (ICD 9-CM code: 183), vaginal cancer (ICD 9-CM code: 184.0), vulvar cancer (ICD 9-CM code: 184.4), and uterine cancer (ICD 9-CM code: 182)).

# 2.4.5 Outcomes, Individual, and Hospital Factors Definitions

Individual risk factors (or hospitalization level risk factors) and hospital risk factors as explained in sections 1.4.1 and 1.4.2 included variables from the NIS HCUP database. Bed size differed by location and teaching hospital status – for example, a small bed size in an urban teaching hospital in the Northeast region is defined as 1-249 beds, while in the Western region, it is defined as 1-199 beds<sup>68</sup>. Similarly, CS volume was calculated by creating a CS rate variable, as there is no hospital volume indicator in the NIS HCUP database after the 2012 redesign<sup>69</sup>. The total number of CS per hospital was divided by the total number of deliveries per hospital. That CS rate was then grouped by deciles – from hospitals that had the highest proportion of CS

deliveries/total deliveries to the bottom decile that had the lowest proportion of CS delivers/total deliveries (<10%). This final ranked CS rate by deciles is our CS volume covariate.

2.4.5a Outcomes and Individual Factors

Outcomes and individual level risk variables included:

- Maternal age in years at admission
  - $\circ$   $\;$  Not included in bivariate and multilevel modelling as it was included in

the obstetric comorbidity index<sup>2</sup>

- Expected primary payer
  - o Medicare
  - $\circ$  Medicaid
  - Private insurance
  - Self-pay
  - o No charge
  - o Other
- Median household income by ZIP code (derived from income level of the

community<sup>53</sup>)

- \$1-\$39,999 (0-25th percentile)
- \$40,000-\$50,999 (26th-50th percentile)
- \$51,000-\$65,999 (51th-75th percentile)
- \$66,000+ (76th-100th percentile)
- Race

- o Non-Hispanic White
- Non-Hispanic Black
- o Hispanic
- Asian or Pacific Islander
- o Native American
- o Other
- Diagnosis
  - Primary and secondary diagnoses Primary or otherwise up to 25 (2012 and 2013) or 30 (2014) additional diagnoses listed); ICD-9-CM codes used to classify term birth<sup>77</sup>, obstetric population<sup>1</sup>, surgical errors,

complications, comorbidities<sup>2</sup> and gynaecological cancers

ECODE diagnosis – Up to 4 codes; misadventure or external cause of

injury<sup>68</sup> to classify surgical errors

- o DRG groups used to classify obstetric population<sup>1</sup>
- Timing of admission
  - o Admitted Monday-Friday
  - Admitted Saturday-Sunday
- Transfer in indicator
  - o Not transferred in
  - o Transferred in from a different acute care hospital

- Transferred in from another type of health facility (e.g. other healthcare facility such as long term care, birthing center, intermediate care facility or otherwise<sup>68</sup>)
- Preterm Birth Onset (spontaneous) of delivery, before 37 completed weeks of gestation (Created using ICD-9-CM Disease and Injuries code: 644.2<sup>77</sup>)
  - Delivery before 37 completed weeks of gestation
  - Delivery after 37 completed weeks of gestation

# 2.4.5b Hospital Factors

Hospital level variables included:

- Hospital Ownership
  - o Public
  - o Private non-profit
  - Private for profit
- Hospital location and teaching status (Location designation in the following categories is determined by Core Based Statistical Area (CBSA)<sup>68</sup>. Counties with a CBSA designation of metropolitan are "urban" (urban core population of at least 50,000) while micropolitan (urban core population of at least 10,000 to under 50,000) or non-core are "rural"<sup>68</sup>. Teaching hospitals needed an American Medical Association approved residency program, to be part of the Council of Teaching Hospitals, or the ratio of interns/residents to beds is 0.25 or higher, in order to be classified as such<sup>68</sup>. Rural teaching hospitals were not classified as they are rare<sup>68</sup>.)

- o Rural
- Urban non-teaching
- o Urban teaching
- Bed size of hospital (Absolute numbers differed by geographic region and hospital teaching status<sup>68</sup>)
  - Small (ranges from 1-249, depending on geographic region and hospital teaching status)
  - Medium (ranges from 24-449, depending on geographic region and hospital teaching status)
  - Large (ranges from 50+ to 450+, depending on geographic region and hospital teaching status)
- CS Volume: (calculated by CS rate = Proportion of total CS per

hospital/proportion of total deliveries per hospital) - ranked by deciles of CS rate

- o ≤20th percentile
- o 21st 79th percentile
- ≥80th percentile

# 2.6 Data Analysis

In this study, the incidence of surgical errors and complications following CS in the United States from 2012-2014 was estimated dividing all CS hospitalizations with at least one surgical error or complication by all CS hospitalizations. Further stratification by individual and hospital risk factors, as well as by CS type and the proportion of hospitalizations with multiple surgical errors or complications were created. The odds of a complication following an error during CS were calculated.

We then conducted bivariate analyses using chi-square tests to examine the associations between the risk factors and surgical errors and complications in CS. Since this study looked at 10 hospital and individual level factors in total, the Bonferroni method was used to account for multiple hypothesis testing<sup>83</sup>. The Bonferroni method divides the original alpha value (0.05) by the number of variables being compared (number of variables = 10) to give a new alpha value of significance (0.005) that each p-value must surpass to be considered statistically significant.

Two-level multilevel logistic (generalized linear mixed model) regression models were created to examine risk associations between risk factors and surgical errors and complication. Multilevel modelling is the preferred method for dealing with clustered data<sup>84</sup>. Clustered data violates the independence between the different patient measurements we would otherwise expect from statistical modelling, making the outcomes more similar than otherwise (e.g., two women at the same hospital may have more similar outcomes than two women at two different hospitals)<sup>84</sup>. Moreover, observations are nested in groups, and within group observations are more similar to each other than between group observations (i.e. they are not independent of each other)<sup>85</sup>. This commonality affects the outcome being examined<sup>85</sup>. However, cluster analysis is not enough to assess two different levels of covariates and their associations with surgical errors and complications.

The variance at one level (for example individual-level) may be underestimated, while the variance for the other level (in this example, hospital-level) may similarly be far from the "true value," further biasing the results<sup>86</sup>. A multilevel model accounts for multiple analyses of variances such as fixed effects and random effects<sup>86</sup>. Fixed effects are constant across individuals and random effects vary<sup>87</sup>. Random effects can also be conceptualized as random intercepts for individual clusters, not known parameters<sup>88</sup>. Least squares or maximum likelihood are used to estimate fixed effects, while random effects are estimated with linear unbiased prediction<sup>87</sup>. In this study, we were not using a prediction model; however, our second objective required assessed two separate levels of covariates in clustered data, necessitating the use of a multilevel model. We controlled for the effect on the outcome by assuming that the effect of clustering was the same among all hospitalizations in a hospital, but across hospitals, it was selected from a random draw that was based on a statistical distribution, with the overall residual of the model being uncorrelated<sup>85</sup>.

Following bivariate analyses, we ran two single level logistic regression models for surgical errors and surgical complications separately using all 10 individual and hospital factors. Following logistic modelling, we ran an empty two two-level multilevel logistic models<sup>89</sup> with just surgical errors and complications (separately) grouped by hospital ID. These models would show us if multilevel modelling was necessary for this dataset based on the intraclass coefficient (ICC).

Following the empty models, we then ran two two-level multi-level logistic models with surgical errors and complications as separate outcomes. Initially, we

incorporated all 10 variables under consideration, as well as the obstetric comorbidity index to help control for confounding. However, as NIS HCUP data requires weighting, we then reran the model using the discharge-level weight in the dataset. No hospital level weighting was required in NIS HCUP data after 2012<sup>69</sup>. The self-weighting nature of the data ensures that the margins of errors are kept small and more stable estimates are calculated <sup>69</sup>. All data analysis were conducted using STATA version 15<sup>90</sup>.

# **CHAPTER 3: RESULTS**

#### 3.1 Demographics

#### 3.1.1 Population

Using Kukalina et al.'s algorithm for identifying obstetric deliveries<sup>1</sup>, 2,174,530 deliveries were identified in the NIS from 2012-2014. Approximately, 32.8% (n=712,198) were CS deliveries, of which, 648,584 fit our age criteria. Amongst women who had a CS, age was normally distributed in the sample, with an average maternal age of 29.71 (SD: 6.48) years (Table 1). Our study found that approximately 77.44% of the population had 2 or less comorbidities identified by the obstetric comorbidity index. The majority of hospitalizations in this study occurred Monday-Friday. The majority of patients were non-Hispanic White (52.31% (95%CI: 52.18%-52.43%)), had either private health insurance (51.85% (95%CI: 51.73%-51.97%) or were insured by Medicaid (41.52% (95% CI: 41.40%-51.64%), and delivered at term (92.16% (95%CI: 92.09%-92.22%)) (Table 1). Approximately, 24.73% (95%CI: 26.23%-24.84%) of the population had no comorbidities (Table 1).

In addition, median household incomes by ZIP code were roughly evenly split, with more hospitalizations reporting the 0-25<sup>th</sup> quartile (28.39% (95%CI: 28.27%-28.50%)), and the least reported quartile being those with an income of \$66,000 or higher, (22.10% (95%CI: 22.00%-22.21%)). Almost all women (98.68% (95%CI: 98.65%-98.71%)) delivered at the hospital they initially went to (i.e. they were not transferred) (Table 1). Most hospitalizations were in private non-profit hospitals (71.71% (95%CI: 71.60%-71.82%)), in an urban teaching hospital (55.81% (95%CI: 55.69%-55.94%)) with a large bed size (57.52% (95%CI: 57.40%-57.64%)) and medium CS volume (63.54%

(95%CI: 63.42%-63.65%)). About 95.62% (95% CI: 95.57%-95.67%) of all CS performed were low cervical CS (or low segment CS). (Table 1).

Demographics	N <sup>a</sup>	N <sup>b</sup>	% (95% CI) <sup>c</sup>
Sample size of hospitalizations	648,584	3,241,690	100
Individual Level Factors			
Mean Maternal Age (Standard Deviation) - years	648,338	3,241,690	29.71 (6.48)
Obstetric Comorbidity Index			
Score 0	160,356	801,780	24.73 (24.63-24.84)
Score 1-2	341,724	1,708,620	52.69 (52.57-52.81)
Score 3+	146,504	731,290	22.59 (22.49-22.69)
Payer Information			
Medicare	7,639	38,195	1.18 (1.15-1.21)
Medicaid	268,650	1,343,250	41.52 (41.40-41.64)
Private insurance	335,512	1,677,560	51.85 (51.73-51.97)
Self-pay	16,438	82,190	2.54 (2.50-2.58)
No charge	631	3,155	0.10 (0.09-0.11)
Other	18,229	91,145	2.82 (2.78-2.86)
Median House Income			
\$1-\$39,999 (0-25 <sup>th</sup> percentile)	180,900	904,500	28.39 (28.27-28.50)
\$40,000-\$50,999 (26 <sup>th</sup> -50 <sup>th</sup> percentile)	159,996	799,980	25.11 (25.00-25.21)
\$51,000-\$65,999 (51 <sup>th</sup> -75 <sup>th</sup> percentile)	155,533	777,665	24.41 (24.30-24.51)
\$66,000+ (76 <sup>th</sup> -100 <sup>th</sup> percentile)	140,868	704,340	22.10 (22.00-22.21)
Race			
Non-Hispanic White	320,368	1,601,840	52.31 (52.18-52.43)
Non-Hispanic Black	97,906	489,530	15.99 (15.89-16.08)
Hispanic	127,223	636,115	20.77 (20.67-20.87)
Asian or Pacific Islander	32,591	162,955	5.32 (5.27-5.38)
Native American	4,545	22,725	0.74 (0.72-0.76)
Other	29,840	149,200	4.87 (4.82-4.93)
Day of Admission			
Weekday Admission	558,516	2,792,580	86.15 (86.07-86.23)
Weekend Admission	89,822	449,110	13.85 (13.77-13.94)
Preterm Birth			
Gestational age <37 weeks	50,842	254,210	7.84 (7.78-7.91)
Gestational age ≥37 weeks	597,496	2,987,480	92.16 (92.09-92.22)
Transfer Status			
Not transferred in	635,948	3,179,740	98.68 (98.65-98.71)
Transferred in from a different acute care hospital	5,052	25,260	0.78 (0.76-0.81)

Table 1: Descriptive Demographics of Hospitalizations in NIS HCUP Database from 2012-2014 for CS Population

Demographics	N <sup>a</sup>	N <sup>b</sup>	% (95% CI) <sup>c</sup>
Transferred in from another type of health facility	3,448	17,240	0.54 (0.52-0.55)
Type of CS			
Classical CS	6,595	32,975	1.02 (0.99-1.04)
Low cervical CS (or low segment CS)	619,934	3,099,670	95.62 (95.57-95.67)
Other CS	21,809	109,045	3.36 (3.32-3.41)
Sample size of hospitals	4,764	-	-
Hospital Level Factors			
Hospital Ownership Model			
Public	80,161	400,805	12.36 (12.28-12.44)
Private non- profit	464,918	2,324,590	71.71 (71.60-71.82)
Private for profit	103,259	516,295	15.93 (15.84-16.02)
Hospital Teaching Status			
Rural	63,545	317,725	9.80 (9.73-9.87)
Urban non-teaching	222,927	1,114,635	34.38 (34.27-34.50)
Urban teaching	361,866	1,809,330	55.81 (55.69-55.94)
Hospital Bed size			
Small	83,073	415,365	12.81 (12.73-12.89)
Medium	192,357	961,785	29.67 (29.56-29.78)
Large	372,908	1,864,540	57.52 (57.40-57.64)
CS Volume (CS/Delivery Rate)			
≤20 <sup>th</sup> percentile	54,721	273,605	8.44 (8.37-8.51)
21 <sup>st</sup> – 79 <sup>th</sup> percentile	411,932	2,059,659	63.54 (63.42-63.65)
≥80 <sup>th</sup> percentile	181,685	908,425	28.02 (27.91-28.13)

a Unweighted sample size (from 2012-2014 NIS data)

b Weighted sample size (representative of national population)

c Weighted proportion

# 3.1.2 Surgical Errors

Overall, 1.98% (95%CI: 1.95%-2.01%) of women hospitalized for CS experienced at least one surgical error (Table 2 and Appendix F). The largest proportion of surgical errors were related to anaesthesia (0.93% (95%CI: 0.91%-0.96%), more specifically in the category of the wrong substance was administered or the patient was overdosed (Table 2 and Appendix D). Following that, the second largest proportion of surgical errors involved blood vessel error at 0.45% (95%CI: 0.44%-0.45%). There were no errors involving bowels reported, and very few "E" codes were reported (e.g. failure to introduce or to remove other tube or instrument, mismatched blood in transfusion, et cetera) (Table 2 and Appendix D). The least common error appeared to be any error involving foreign bodies or substances at 0.01% (95% CI: 8.13 x 10<sup>-5</sup>% –0.01%) (Table 2 and Appendix D).

Surgical Errors <sup>*</sup>	N <sup>a</sup>	N <sup>b</sup>	% (95%)°	Error rate <sup>d</sup>
Error Involving the Uterus	1,425	7,125	0.22 (0.21-0.22)	219.71
Error Involving the Ureter	743	3,715	0.11 (0.11-0.12)	114.56
Error Involving Blood Vessels	2,894	14,470	0.45 (0.44-0.45)	446.2
Error Involving the Bladder	2,210	11,050	0.34 (0.33-0.35)	340.74
Error Involving Bowel	0	-	-	-
Error Involving Foreign Bodies or Substances	67	335	0.01 (8.13 x 10 <sup>-5</sup> –0.01)	10.33
Anaesthetic Error	6,045	30,225	0.93 (0.91-0.96)	932.03
Procedural Error	11	55	0.17 x 10 <sup>-4</sup> (9.40 x 10 <sup>-6</sup> - 3.06 x 10 <sup>-5</sup> )	1.70
At least one surgical error	12,838	64,190	1.98 (1.95-2.01)	1,979.39

Table 2: Surgical Errors Rate in NIS HCUP Database from 2012-2014 for CS Population

\* Each composite score looks at least one error reported

a Unweighted sample size (from 2012-2014 NIS data)

*b* Weighted sample size (representative of national population)

c Weighted proportion

d Errors rate per 100,000 CS hospitalizations

Most CS hospitalizations had no surgical errors in CS (Table 3). Out of the CS

hospitalizations that did have a surgical error, most had only 1 error (1.76% (95%CI:

1.73%%-1.80%); however, less than 1% of the overall sample, and approximately 1% of

women who experienced any surgical errors had multiple surgical errors during CS

(Table 3). Low cervical CS (or low segment CS) had the lowest surgical errors at 1.73%

(95%CI: 1.70%-1.76%) (p-value < 0.0001).

*Table 3: Number of Surgical Errors per Individual Hospitalization in NIS HCUP Database from 2012-2014 for CS Population* 

Surgical Errors (N=648,584 <sup>a</sup> /3,241,690 <sup>b</sup> )							
Number	N <sup>a</sup>	N <sup>b</sup>	% (95%) <sup>c</sup>				
0	635,746	3,177,500	98.02 (97.99-98.05)				
1	11,438	57,190	1.76 (1.73-1.80)				
2	1,276	6,380	0.20 (0.19-0.21)				
3	110	550	0.02 (0.01-0.02)				
4	14	70	2.16 x 10 <sup>-5</sup> (1.28 x 10 <sup>-5</sup> – 3.64 x 10 <sup>-5</sup> )				

a Unweighted sample size (from 2012-2014 NIS data)

*b* Weighted sample size (representative of national population) *c* Weighted proportion

# 3.1.3 Surgical Complications

Overall, 9.67% (95%CI: 9.59%-9.74%) of women hospitalized for CS experienced at least one complication (Table 4 and Appendix G). Hysterectomies contributed the largest proportion of surgical complications (2.19% (95%CI: 2.17%-2.20%), particularly, "total abdominal hysterectomy," (1.42% (95%CI: 1.41%-1.43%)) (Table 4 and Appendix E). The second largest proportion of surgical complications was due to postpartum hemorrhage at 2.05% (95%CI: 2.04%-2.07%), followed by infectious complications at 1.59% (95%CI: 1.58%-1.60%). The least common complication was maternal mortality at 0.04% (95%CI: 0.03%-0.04%) (Table 4).

Surgical Complications*	N <sup>a</sup>	N <sup>b</sup>	% (95%) <sup>c</sup>	Complications rate <sup>d</sup>
Maternal Mortality	229	1,145	0.04 (0.03-0.04)	35.31
Infectious Complications	10,338	51,690	1.59 (1.58-1.60)	1,593.93
Cardiac Complications	4,162	20,810	0.64 (0.63-0.65)	641.71
Complications of the Bowel	3,864	19,320	0.6 (0.59-0.60)	595.76
Fistulas	481	2,405	0.07 (0.07-0.08)	74.16
Shock-Related Complications	1,589	7,945	0.25 (0.24-0.25)	90.81
Respiratory Complications	6,348	31,740	0.98 (0.97-0.99)	978.75
Dehiscence Complications	961	4,805	0.15 (0.14-0.15)	148.17
Postpartum Hemorrhage	13,321	66,604	2.05 (2.04-2.07)	2,053.86
Embolisms	390	1,950	0.06 (0.06-0.06)	60.13
Miscellaneous Complications	4,760	23,530	0.73 (0.72-0.74)	733.91
Hysterectomy	14,170	70,850	2.19 (2.17-2.20)	2,184.76
Anaesthetic Complications	3,610	18,050	0.56 (0.54-0.58)	556.60
Myomectomy	2,585	12,925	0.40 (0.39-0.40)	398.56
Oophorectomy	4,411	22,055	0.68 (0.67-0.69)	680.10
Ovarian Cystectomy	14	70	2.16 x 10 <sup>-5</sup> (1.71 x 10 <sup>-5</sup> – 2.73 x 10 <sup>-5</sup> )	2.16
ALL SURGICAL COMPLICATIONS	62,698	313,490	9.67 (9.59-9.74)	9,666.91

Table 4: Surgical Complications Rate in NIS HCUP Database from 2012-2014 for CS Population

\* Each composite score looks at least one complication reported

a Unweighted sample size (from 2012-2014 NIS data)

*b* Weighted sample size (representative of national population)

c Weighted proportion

d Complications rate per 100,000 CS hospitalizations

The majority of women with a complication experienced a single isolated

complication, approximately 7.21% (95%CI: 7.14%-7.21%), of the overall sample;

however, approximately 2% of the overall sample, and approximately 22% of women

who experienced any complications had multiple complications (Table 5). In addition,

low cervical CS (or low segment CS) had the lowest complications at 7.62% (7.56%-

7.69%) (p-value <0.0001).

Table 5: Number of Surgical Complications per Individual Hospitalization in NIS HCUP Database from 2012-2014 for CS Population

Surgical Complications (N=648,584 <sup>a</sup> /3,241,690 <sup>b</sup> )								
Number	N <sup>a</sup>	N <sup>b</sup>	% (95%) <sup>c</sup>					
0	590,109	2,949,314	90.98 (90.91-91.05)					
1	46,763	233,815	7.21 (7.14-7.27)					
2	9,428	47,140	1.45 (1.42-1.48)					
3	1,515	7,575	0.23 (0.22-0.25)					
4	443	2,215	0.07 (0.06-0.07)					
5	218	1,090	0.03 (0.03-0.04)					
6	69	345	0.01 (0.84 x 10 <sup>-4</sup> -0.01)					
7	27	135	4.47 x 10 <sup>-5</sup> (3.11 x 10 <sup>-5</sup> – 6.44 x 10 <sup>-5</sup> )					
≥8	12	60	1.85 x 10 <sup>-5</sup> (1.05 x 10 <sup>-5</sup> – 3.26 x 10 <sup>-5</sup> )					

a Unweighted sample size (from 2012-2014 NIS data)

*b* Weighted sample size (representative of national population) *c* Weighted proportion

The odds of developing a surgical complication in CS if there was a surgical error

as well was 15.90 (95%CI: 15.33-16.49) times the odds of developing a surgical

complication in CS without a surgical error during the procedure.

#### 3.2 Bivariate Analysis

Payer information, race, inter-hospital transfer, hospital ownership model,

hospital teaching status, hospital bed size, and CS volume were significantly associated

with both surgical errors and complications, while median household income was only

significantly associated with surgical errors, and timing of admission (delivering on the weekday versus delivering on the weekend) and preterm birth were only significantly associated with complications (Table 6). All significant associations had p-values of <0.0001. Timing of admission (p=0.60) and preterm birth (p=0.27) were not significantly associated with surgical errors in CS, but were associated with complications, both with p-values < 0.0001. More women on Medicare as their primary insurance had a surgical error or developed a complication 11.31% (95%CI: 10.62%-12.04%), and 29.95% (95%CI: 28.93%-30.99%), respectively. Median household income was a significant factor for surgical errors (p-value < 0.0001) and complications (p-value = 0.003). For both surgical errors and complications, non-Hispanic black women had the highest proportions, 2.25% (95%CI:2.16%-2.35%), and 11.97% (95%CI: 11.77%-12.17%), respectively, compared to other races. For CS hospitalizations that were transferred in from a different acute care hospital, the proportion of surgical errors in CS was 4.35% (95%CI: 3.83%-4.95%), and the complications proportion was 19.83% (95%CI: 18.76%-20.96%), compared to CS hospitalizations that were not transferred or transferred from other health facilities. Public hospitals had the highest proportion of surgical errors and complications at 2.33% (95%CI:2.23%-2.44%) and 10.99% (95%CI: 10.77%-11.21%), respectively (Table 6), compared to private for-profit and private non-profit hospitals. For both surgical errors and complications, urban teaching hospitals had the highest proportions at 2.29% (95%CI: 2.24%-2.34%), and 11.20% (95%CI: 11.10%-11.30%), respectively, compared to urban non-teaching hospitals and rural hospitals.

Table 6: Bivariate Analysis of Individual o Population	and Hospito	al Level Fac	tors and Surgical Erro	ors and Comp	lications in	NIS HCUP Do	atabase from 2012-20	014 for CS
Surgical Errors (N=12,357 <sup>a</sup> /61,785 <sup>b</sup> )					Surg	ical Complica	tions (N=60,619ª/303,0	95 <sup>b</sup> )
	N <sup>a</sup>	N <sup>b</sup>	% (95% CI) <sup>c</sup>	p <sup>d</sup>	N <sup>a</sup>	N <sup>b</sup>	% (95% CI) <sup>c</sup>	pď
Individual Level Factors								
Payer Information	12,810	64,050		<0.0001	62,608	313,040		<0.0001
Medicare	864	4,320	11.31 (10.62-12.04)		2,288	11,440	29.95 (28.93-30.99)	
Medicaid	5,795	28,975	2.16 (2.10-2.21)		24,025	120,125	8.94 (8.84-9.05)	
Private insurance	5,485	27,425	1.63 (1.59-1.68)		32,822	164,110	9.78 (9.68-9.88)	
Self-pay	324	1,620	1.97 (1.77-2.20)		1,686	8,430	10.26 (9.80-10.73)	
No charge	24	115	3.65 (2.43-5.43)		129	645	20.44 (17.47-23.77)	
Other	319	1,595	1.75 (1.57-1.95)		1,658	8,290	9.10 (8.69-9.52)	
Median Household Income	12,608	63,040		<0.0001	61,430	307,150		0.003
\$1-\$39,999 (0-25 <sup>th</sup> percentile)	3,830	19,150	2.12 (2.05-2.18)		17,551	87,755	9.70 (9.57-9.84)	
\$40,000-\$50,999 (26 <sup>th</sup> -50 <sup>th</sup> percentile)	3,350	16,750	2.09 (2.02-2.17)		15,052	75,260	9.41 (9.27-9.55)	
\$51,000-\$65,999 (51 <sup>th</sup> -75 <sup>th</sup> percentile)	2,937	14,685	1.89 (1.82-1.96)		15,046	75,230	9.67 (9.53-9.82)	
\$66,000+ (76 <sup>th</sup> -100 <sup>th</sup> percentile)	2,491	12,455	1.77 (1.70-1.84)		13,781	68,905	9.78 (9.63-9.94)	
Race	12,026	60,130		<0.0001	58,952	294,760		<0.0001
Non-Hispanic White	6,981	34,905	2.18 (2.13-2.23)		31,052	155,255	9.69 (9.59-9.80)	
Non-Hispanic Black	2,205	11,025	2.25 (2.16-2.35)		11,718	58,590	11.97 (11.77-12.17)	
Hispanic	1,803	9,015	1.42 (1.35-1.48)		10,074	50,370	7.92 (7.77-8.07)	
Asian or Pacific Islander	453	2,265	1.39 (1.27-1.52)		2,877	14,385	8.83 (8.52-9.14)	
Native American	75	375	1.65 (1.32-2.06)		413	2,065	9.09 (8.29-9.96)	
Other	509	2,545	1.71 (1.56-1.86)		2,819	14,095	9.45 (9.12-9.78)	
Timing of Admission	12,838	64,190		0.599	62,698	313,490		<0.0001

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Population	ια ποsριτα	ii Levei Fuci	ors and surgical Erro	rs una comp		NIS HEOF DE		114 JUI CS
Surgical Errors (N=12,357 <sup>a</sup> /61,785 <sup>b</sup> )				Surg	Surgical Complications (N=60,619 <sup>a</sup> /303,095 <sup>b</sup> )			
	N <sup>a</sup>	N <sup>b</sup>	% (95% CI) <sup>c</sup>	p <sup>d</sup>	N <sup>a</sup>	N <sup>b</sup>	% (95% CI) <sup>c</sup>	$p^d$
Mon-Fri Admission	11,039	55,195	1.98 (1.94-2.01)		54,461	272,305	9.75 (9.67-9.83)	
Sat-Sun Admission	1,799	8,995	2.00 (1.91-2.10)		8,237	41,185	9.17 (8.98-9.36)	
Preterm Birth	12,838	64,190		0.270	62,698	313,490		<0.0001
Birth before 37 weeks	1,040	58,990	2.05 (1.93-2.17)		5,375	26,875	10.57 (10.31-10.84)	
Birth after 37 weeks	11,798	5,200	1.97 (1.94-2.01)		57,323	286,615	9.59 (9.52-9.67)	
Inter-Hospital Transfer	12,778	63,890		<0.0001	62,388	311,940		<0.0001
Not transferred in	12,476	62,380	1.96 (1.93-2.00)		60,992	304,960	9.59 (9.52-9.66)	
Transferred in from a different acute care hospital	220	1,100	4.35 (3.83-4.95)		1,002	5,010	19.83 (18.76-20.96)	
Transferred in from another type of health facility	82	410	2.38 (1.92-2.94)		394	1,970	11.43 (10.41-12.53)	
Hospital Level Factors								
Hospital Ownership Model	12,838	64,190		<0.0001	62,698	313,490		<0.0001
Public	1,870	9,350	2.33 (2.23-2.44)		8,807	44,035	10.99 (10.77-11.21)	
Private non- profit	9,476	47,380	2.04 (2.00-2.08)		46,209	231,045	9.94 (9.85-10.03)	
Private for profit	1,492	7,460	1.44 (1.37-1.52)		7,682	38,410	7.44 (7.28-7.60)	
Hospital Teaching Status	12,838	64,190		<0.0001	62,698	313,490		<0.0001
Rural	1,073	5,365	1.69 (1.59-1.79)		4,538	22,690	7.14 (6.94-7.34)	
Urban non-teaching	3,484	17,420	1.56 (1.51-1.62)		17,638	88,190	7.91 (7.80-8.02)	
Urban teaching	8,281	41,405	2.29 (2.24-2.34)		40,522	202,610	11.20 (11.10-11.30)	
Hospital Bed size	12,838	64,190		<0.0001	62,698	313,490		<0.0001
Small	1,442	7,210	1.74 (1.65-1.83)		7,211	36,055	8.68 (8.49-8.87)	
Medium	3,558	17,790	1.85 (1.79-1.91)		17,337	86,685	9.01 (8.89-9.14)	

Table 6: Bivariate Analysis of Individual and Hospital Level Factors and Surgical Errors and Complications in NIS HCUP Database from 2012-2014 for CS Population

Surgical Errors (N=12,357 <sup>a</sup> /61,785 <sup>b</sup> )						Surgical Complications (N=60,619 <sup>a</sup> /303,095 <sup>b</sup> )		
	N <sup>a</sup>	N <sup>b</sup>	% (95% CI) <sup>c</sup>	p <sup>d</sup>	N <sup>a</sup>	N <sup>b</sup>	% (95% CI) <sup>c</sup>	pď
Large	7,838	39,190	2.10 (2.06-2.15)		38,150	190,750	10.23 (10.13-10.33)	
CS Volume (CS/Delivery)	12,838	64,190		<0.0001	62,698	313,490		<0.0001
≤20 <sup>th</sup> percentile	1,205	6,025	2.20 (2.08-2.33)		5,520	27,600	10.09 (9.84-10.34)	
21 <sup>st</sup> – 79 <sup>th</sup> percentile	8,407	42,035	2.04 (2.00-2.08)		40,685	203,425	9.88 (9.79-9.97)	
≥80 <sup>th</sup> percentile	3,226	16,130	1.78 (1.72-1.84)		16,493	82,465	9.08 (8.95-9.21)	

a Unweighted sample size (from 2012-2014 NIS data)

b Weighted sample size (representative of national population)

c Weighted proportion

d Bonferroni adjusted level of significance is 0.005

## 3.3 Multilevel Modelling

For surgical errors in CS, nearly all individual and hospital level factors were statistically significant with p-values of <0.0001, with the exception of "Other" in payer information, weekend admission, transfer from another type of health facility, and CS volume (Table 7). Nearly all individual and hospital level risk factors for surgical complications were statistically significant with p-values ranging from 0.004 to <0.0001 (Table 7).

All insurance compared to private insurance was associated with increased odds of surgical errors and complications, with the exception of Medicaid and Other for complications. Compared to hospitalizations reporting private insurance, those on Medicare had 5.85 (95%: 5.62-6.08) times the odds of having a surgical error in CS. Those that reported Medicare for payer information had 2.86 (95%CI: 2.78-2.94) times the odds of developing a surgical complication in CS compared to those with private insurance (Table 7). Similarly, those who reported no charge for payer information were 2.22 (95%CI: 2.01-2.43) times the odds at risk of surgical complication than those with private insurance (Table 7).

Median household income by ZIP code was associated with increased odds of surgical errors and complications relative to the top quartile, with the exception of the third quartile for complications (Table 7). Those from a neighbourhood with a median household income between \$40,000 and \$50,999 reported 1.18 (95%CI: 1.14-1.21) times the odds of a surgical error in CS compared to those from the lowest quartile of median neighbourhood household income of <\$24,999(Table 7). For complications, the

odds ratios were roughly equal to one another, with the top quartile as the baseline (Table 7). Those from a neighbourhood with a median household income \$39,999 or below had 1.04 (95%CI:1.03-1.06) times the odds of developing a surgical complication compared to the top quartile (those with a median household income of \$66,000 or higher).

Compared to non-Hispanic white women, all races had lower odds of surgical errors and complications, with the exception of non-Hispanic black women for complications, who had 1.14 (95%CI: 1.13-1.16) times the odds at risk of developing a surgical complication post-CS (Table 7). In particular, Hispanic women had 0.60 (95%CI: 0.58-0.62) times the odds of surgical error during CS compared to non-Hispanic white women (Table 7).

Timing of admission was not significant for surgical errors but showed lower odds of complications in CS (OR:0.93 (95%CI: 0.92-0.94)). For both surgical errors and complications, preterm birth showed lower odds of surgical errors (OR: 0.73 (95%CI: 0.71-0.76)) and maternal complications (OR: 0.73 (95%CI: 0.72-0.74)) compared to those that delivered at term.

Being transferred in from a different acute care hospital had higher odds of surgical errors (OR:1.17 (95%CI: 1.09-1.26)) and complications (OR:1.25 (95%CI: 1.21-1.30)), compared to not being transferred in. However, being transferred in from another type of health facility was not significant for surgical errors (p-value = 0.012) and showed higher odds of complications (OR: 1.07 (95%CI: 1.01-1.13)).

Compared to private non-profit hospitals, delivering in public hospitals had higher odds of surgical errors (OR: 1.13 (95%CI:1.08-1.18)) and complications (OR:1.15 (95%CI: 1.13-1.18)). Delivering in private for-profit hospitals had lower odds of surgical errors (OR: 0.82 (95%CI:0.78-0.86)) and complications (OR: 0.96 (95%CI: 0.94-0.98)). Compared to urban teaching hospitals, both rural and non-teaching urban hospitals had lower rates of surgical errors (OR: 0.59 (95%CI: 0.56-0.62), and OR: 0.73 (95%CI: 0.71-0.76), respectively) and complications (OR: 0.61 (95%CI: 0.59-0.62), and OR: 0.76 (95%CI: 0.75-0.77), respectively).

Hospitals with large bed capacities had higher odds of surgical errors (OR: 1.13 (95%CI: 1.09-1.17)) and complications (OR: 1.13 (95%CI: 1.11-1.15)) compared to hospitals with medium bed capacities. CS volume was not significant for either surgical errors or complications.

The random intercept variance (i.e. the level 2 residual) for Model 2 (full model with all covariates with surgical errors as the outcome) is 1.1804 (Table 7). The ICC is 0.2641, meaning that approximately 27% of the chance of surgical error during CS is explained by between hospital differences (Table 7). The random intercept variance for Model 4 (full model with all covariates with complications as the outcome) is 0.5335 (Table 7). The ICC is 0.1395, meaning that approximately 14% of the chance of developing a complication in CS is explained by between hospital differences (Table 7) between hospital differences (Table 7). Between hospital differences accounted for nearly double the chance of surgical errors compared to complications.

		Surgical Errors Complications			;		
Demographics	Description	Adjusted OR	95% CI	P-Value <sup>b</sup>	Adjusted OR	95% CI	P-Value <sup>b</sup>
Individual Level Fact	ors	•					
Payer Information	Private Insurance	1	1	Reference	1	1	Reference
	Medicare	5.85	5.62-6.08	< 0.0001	2.86	2.78-2.94	<0.0001
	Medicaid	1.40	1.37-1.43	<0.0001	0.89	0.88-0.90	<0.0001
	Self-pay	1.39	1.32-1.47	<0.0001	1.09	1.07-1.12	<0.0001
	No charge	2.05	1.68-2.50	<0.0001	2.21	2.01-2.43	<0.0001
	Other	1.07	1.01-1.13	0.022	0.95	0.93-0.98	<0.0001
Median Household	\$66,000+ (76 <sup>th</sup> -100 <sup>th</sup> percentile)	1	1	Reference	1	1	Reference
Income based on	\$1-\$39,999 (0-25 <sup>th</sup> percentile)	1.15	1.12-1.19	< 0.0001	1.04	1.03-1.06	<0.0001
	\$40,000-\$50,999 (26 <sup>th</sup> -50 <sup>th</sup> percentile)	1.18	1.14-1.21	<0.0001	1.02	1.01-1.03	0.003
	\$51,000-\$65,999 (51 <sup>th</sup> -75 <sup>th</sup> percentile)	1.06	1.03-1.09	<0.0001	1.01	1.00-1.02	0.060
Race	Non-Hispanic White	1	1	Reference	1	1	Reference
	Non-Hispanic Black	0.75	0.73-0.77	< 0.0001	1.14	1.13-1.16	<0.0001
	Hispanic	0.60	0.58-0.62	<0.0001	0.85	0.84-0.86	<0.0001
	Asian or Pacific Islander	0.66	0.63-0.69	<0.0001	0.88	0.86-0.90	<0.0001
	Native American	0.68	0.61-0.76	<0.0001	0.90	0.86-0.95	<0.0001
	Other	0.71	0.68-0.74	< 0.0001	0.93	0.91-0.94	<0.0001
Timing of Admission	Weekend Admit (Referent group – Weekday admit)	1.02	1.00-1.05	0.068	0.93	0.92-0.94	<0.0001
Preterm birth	Before 37 weeks' gestation (Referent group – term birth)	0.73	0.71-0.76	<0.0001	0.73	0.72-0.74	<0.0001
Transfer In	Not transferred in	1	1	Reference	1	1	Reference

Table 7: Multilevel Model for Surgical Errors and Complications in NIS HCUP Database from 2012-2014 for CS Population

		Surgical Errors	rgical Errors Complications			Complications		
Demographics	Description	Adjusted OR	95% CI	P-Value <sup>b</sup>	Adjusted OR	95% CI	P-Value <sup>b</sup>	
	Transferred in from a different acute care hospital	1.17	1.09-1.26	<0.0001	1.25	1.21-1.30	<0.0001	
	Transferred in from another type of health facility	0.86	0.76-0.97	0.012	1.07	1.01-1.13	0.016	
Hospital Level Facto	rs							
Hospital Model	Private non- profit	1	1	Reference	1	1	Reference	
	Public	1.13	1.08-1.18	< 0.0001	1.15	1.13-1.18	<0.0001	
	Private for profit	0.82	0.78-0.86	< 0.0001	0.96	0.94-0.98	<0.0001	
Teaching Hospital	Urban teaching	1	1	Reference	1	1	Reference	
Status	Rural	0.59	0.56-0.62	<0.0001	0.61	0.59-0.62	<0.0001	
	Urban non-teaching	0.73	0.71-0.76	< 0.0001	0.76	0.75-0.77	< 0.0001	
Hospital Bed size	Medium	1	1	Reference	1	1	Reference	
	Small	0.90	0.86-0.94	< 0.0001	0.98	0.96-1.00	0.042	
	Large	1.13	1.09-1.17	< 0.0001	1.13	1.11-1.15	<0.0001	
CS Volume (by	≤20 <sup>th</sup> percentile	1	1	Reference	1	1	Reference	
CS/delivery rate)	21 <sup>st</sup> – 79 <sup>th</sup> percentile	0.96	0.87-1.07	0.461	0.92	0.87-0.98	0.013	
	≥80 <sup>th</sup> percentile	0.91	0.81-1.03	0.127	0.91	0.84-0.98	0.025	
Variance Component	Model 1ª	Model 2	-	-	Model 3ª	Model 4	-	
Intercept Variance	0.2960	1.1804	-	-	0.3136	0.5335	-	
Intraclass correlation coefficient (%)	0.0825	0.2641	-	-	0.0870	0.1395	-	

a Empty model with no covariate (xtmelogit) b Bonferroni adjusted level of significance is 0.005

# **CHAPTER 4: DISCUSSION**

#### 4.1 Summary of Main Findings

Among 648,584 CS hospitalizations included in the NIS HCUP database from 2012-2014, 1.98% (95%CI: 1.95%-2.01%) and 9.67% (95%CI: 9.59%-9.74%) of women experienced at least one surgical error or one complication respectively. The odds of developing a complication was 15.90 (95%CI: 15.33-16.49) if an error also occurred although this interpretation is limited as the temporality between the incidence of complication and error could not be determined. All other insurance increased the odds of surgical errors during CS compared to private insurance. Similarly, all other insurance with the exception of Medicaid increased the odds of complications after CS compared to private insurance. Median household income by ZIP code increased the odds of an error during CS, compared to the top quartile of median household income, indicating a community level association with errors in CS. Compared to non-Hispanic white women, all races had lower odds of surgical errors during CS, while only non-Hispanic black women had higher odds of developing a surgical complication post-CS compared to non-Hispanic white women. Timing of hospital admission and preterm birth was not significantly associated with surgical errors, but was statistically associated with complications. Weekend admission for a CS hospitalization had higher odds of surgical errors but lower odds of surgical complication post CS. Delivering before 37 weeks of gestation also showed lower odds of both surgical errors and complications. Delivering at public hospitals increased the odds of surgical errors and surgical complications, while delivering at private for profit hospitals decreased the odds of both. Compared to urban

teaching hospitals, all other hospitals showed lower odds of surgical error and complications.

The population was young and relatively healthy. There were far more complications than surgical errors reported, and multiple errors were less frequent than multiple complications. The variation and differences in maternal and hospital risk factors for surgical errors and complications has not been examined previously. This study fills a gap in the literature to establish a nationally representative baseline of the incidence of surgical errors and complications in CS hospitalizations, and further examines the incidences by both maternal and hospital risk factors. By assessing the variation and differences between different risk factors on two levels, there is an opportunity to develop quality improvement frameworks to establish new guidelines or modify existing ones to improve patient safety in an obstetric population.

## 4.2 Comparison with Other Studies

#### 4.2.1 Surgical Errors and Complications

The overall error score for CS found in this study from 2012-2014 was 1.98% (95%CI: 1.95%-2.01%). This estimate is comparable to a previous American study that found that the proportion of preventable adverse events in CS in 1992 was 1.7% (95%CI: 0.8-3.3)<sup>35</sup>. In the present study, the highest composite score for surgical errors belonged to anaesthetic errors; this result was unexpected as anaesthesia has long been thought of as a leader in patient safety<sup>91,92</sup>. However, this result may be due to the history of non-punitive investigation that has had anaesthesia as a specialty target efforts to remove barriers to reporting adverse events<sup>93</sup> compared to other specialties

like obstetrics that report confusion around adverse event reporting procedures and do not provide a reliable index of the rate of adverse incidents<sup>94</sup>. These results may also underestimate the errors rate as many "E" codes may have been underutilized due to inconsistent reporting and standards across the United States<sup>68</sup>.

The overall proportion of surgical complications was 9.67% (95%CI: 9.59%-9.74%). Aubrey-Bassler et al. reported a complication rate of CS of 2% by Canadian specialists<sup>45</sup>. This discrepancy could again be because of the different contexts, and also because our definition for surgical complications was more comprehensive. The highest composite score for surgical complications was for any kind of hysterectomy at 2.19% (95%CI: 2.17-2.20). This result has been shown in past literature to have higher levels of adverse surgical outcomes as a procedure on its own with an incidence of adverse events of 4.4% (95%CI: 2.9-6.8) and an incidence of preventable adverse events of 2.8% (95%CI: 1.6-4.7)<sup>35</sup>. Although the incidence of overall adverse events is higher than our estimate, it may also be because hysterectomies are often performed for other comorbid conditions such as gynecological cancer<sup>81</sup> which was excluded in our estimate of hysterectomy complications.

# 4.2.2 Payer information

All payer groups had higher odds of surgical error during CS than those with private insurance, particularly women on Medicare. There were similar results for complications, with Medicare having the highest odds of developing a surgical complication compared to private insurance, although Medicaid and "Other" had lower odds. Although, Medicare is often associated with those past natural childbearing years (>65 years of age), about 13% of the beneficiaries of Medicare are <65 years, and are covered due to disabilities such as end-stage renal disease, severe mental illness, back and joint problems, and cardiovascular problems<sup>95</sup>. In previous literature, being a Medicare recipient under the age of 65 years was associated with higher adverse events and mortality in bariatric surgery<sup>96</sup>. This finding is not unanticipated as the underlying comorbidities that made the person under the age of 65 eligible for Medicare may in themselves increase their risk of complications<sup>96</sup>. Interestingly, Medicaid had lower odds of surgical complications compared to private insurance despite the indication that those with low income, eligible for Medicare, may have poorer health outcomes. A previous study showed that women on Medicaid with low risk births had lower odds of CS compared to women with private insurance with low risk births had lower with private insurance<sup>97</sup>, despite Medicaid recipients having lower odds of delivering via CS in the first place compared to women with private insurance<sup>71</sup>.

# 4.2.3 Median Household Income by Zip Code

Although the bivariate analysis showed a non-significant p-value for median household income by ZIP code and complications, the multilevel logistic models for both surgical errors and complications both showed significant p-values for those with median household incomes by ZIP code below the 50<sup>th</sup> percentile or below \$50,999, compared to those in the top quartile. These results match what has been found in previous literature in that pregnancy outcomes such as preterm birth are more common

in women from neighbourhoods with lower incomes (such as preterm birth)<sup>98</sup> as well as other adverse maternal mental and physical outcomes<sup>99</sup>.

## 4.2.4 Race

All races compared to non-Hispanic white women had lower odds of surgical errors in CS, and only non-Hispanic black women had increased odds of surgical complications compared to non-Hispanic white women. The literature is mixed when it comes to examining differences between non-Hispanic black women and non-Hispanic white women and their risk of CS delivery. Non-Hispanic black women with low risk births have higher odds of CS delivery, compared to non-Hispanic white women<sup>97</sup>. However, non-Hispanic black women with high risk births have lower odds for CS delivery, compared to non-Hispanic white women<sup>97</sup>. Previous research has looked at other surgeries and outcomes by race. Non-Hispanic black patients had worse outcomes in colorectal cancer resection<sup>100</sup>, and increased mortality at teaching hospitals compared to non-Hispanic black patients<sup>60</sup>. There is limited research on surgical errors and race.

#### 4.2.5 Timing of Admission

Interestingly, getting admitted on a weekend increased the odds of surgical errors compared to getting admitted for a CS on a weekday, but decreased the odds of surgical complications. This result could be because of potential uneven staffing numbers on weekends, leading to most emergency procedures are performed by trainees, and possibly a decrease in the quality of care on the weekend<sup>57</sup>. Most emergency CS (second stage of labour CS) are performed by obstetric trainees<sup>101</sup>, and in

general, second stage of labour CS have been shown to have increased intraoperative maternal complications and neonatal comorbidity<sup>102</sup>. Trainees performing a CS, especially an emergency CS can lead to surgical errors, particularly when they have performed the procedure less than 15 times<sup>6,10</sup>. This finding is also in line with previous research on the higher rates of neonatal mortality for infants born during the weekend<sup>103</sup>. Recent research shows that there is no difference in mortality between neonates born on the weekend versus the weekday in California<sup>57</sup>, while another study showed no significant differences in mortality between weekend and weekday admissions for a nationwide, registry-based study of acute stroke patients<sup>104</sup>.

# 4.2.6 Preterm birth

Women who delivered before 37 weeks of gestation had lower odds of surgical error and surgical complication than women who delivered at term. This result could be because these were most likely scheduled CS that were planned ahead of time which could reduce error<sup>49</sup>. As previous literature has shown, most preterm neonates were delivered by low cervical CS (or low segment CS) rather than classical CS which could also have led to there could have been less maternal complications<sup>49</sup>. These CS could also have been managed more carefully by staff due to the fragility of the neonate, thus lowering the risk of complications as well.

## 4.2.7 Hospital Transfer

Women who were not transferred to another facility for CS had lower odds of surgical error and complications in CS. In other words, women who had a CS at the same hospital they were admitted to had lower odds of surgical errors and

complications in CS. The reason behind this might be that women who had to be transferred were high risk cases that reflected a case-mix of women more likely to develop a complication or with a unique set of clinical circumstances that caused a CS to not go as planned. Moreover, women who were not transferred may have been low risk cases as they remained in the hospital they arrived at to delivery via CS. The impact of delay in CS due to being transferred could also play a role in explaining this finding. *4.2.8 Hospital Model* 

Most CS were performed in private non-profit hospitals. Multilevel modelling shows that CS at public hospitals had higher odds of surgical errors and complications, compared to private non-profit hospitals, while the private for-profit hospitals had lower odds of surgical error and complications. A previous study from 1989 showed lower mortality rates for private non-profit hospitals, even lower than private for-profit hospitals<sup>105</sup>. Our results contradict this finding, perhaps due to the time elapsed since the previous study took place, or perhaps because the study looked at mortality and severity of illness, both of which are not similar or relevant to an obstetric population in quite the same way.

#### 4.2.9 Teaching Hospital Status

Both rural and urban non-teaching hospitals had lower odds of surgical errors and complications compared to urban teaching hospitals. This result may be due to the presence of trainees assisting with CS, and the more complex hierarchical structure of urban teaching hospitals <sup>36</sup>. In a previous study, errors by trainees accounted for 55% of all errors<sup>36</sup>, providing a potential explanation for why urban teaching hospitals have

higher odds of surgical errors and complications compared to non-teaching hospitals. Another explanation for this difference could be because urban teaching hospitals see different patient populations than other hospitals which could then influence their surgical errors and complications in CS.

# 4.2.10 CS Volume

In previous literature, higher volume hospitals have had lower operative mortality for different surgical procedures such as cardiovascular procedures and cancer resections in the Medicare population<sup>65</sup>. However, the results from that study were limited to the cardiovascular and oncological surgical procedures tested<sup>65</sup>. A recent study, however, found that despite advances in surgical patient safety, higher volume hospitals are still associated with lower rates of operative mortality than lower volume hospitals<sup>106</sup>. In our sample, higher CS volume hospitals (greater than the 80<sup>th</sup> percentile) had lower rates of both surgical errors and complications in CS with a p-value <0.001 using a bivariate analysis. CS volume was non-significant in the multilevel models. These mixed findings suggest that a different definition of CS volume needs to be considered when conducting future research. As the NIS HCUP database no longer uses hospital volume<sup>69</sup> after the 2012 redesign, using a hospital volume variable in a different database that better approximates this characteristic could provide a more consistent findings, in a similar vein to previous studies.

# 4.3 Clinical and Public Health Implications/Stakeholder Engagement

This study provides a nationally representative picture of maternal and hospital demographics in the US, and the associations with surgical errors during and
complications after CS. As a cross-sectional study, it provides a useful snapshot of three years' worth of data on what individual and hospital level factors are associated with surgical errors and complications after CS. It provides important information for four types of stakeholders – quality improvement specialists, policy-makers, clinicians, and public health researchers.

Quality improvement specialists can build on the results of this research as now a baseline has been established for further inquiry into specific factors. For example, quality improvement specialists now have a foundation to create specific quality improvement cycles or metrics to assess obstetric complications and errors, similar to National Surgical Quality Improvement Program's (NSQIP) work in the Veteran's Affairs (VA) Healthcare system<sup>107</sup>. NSQIP provides hospitals with risk-adjusted outcomes that can then be compared to external benchmarks<sup>107</sup>. By working with clinicians and healthcare providers involved in CS (particularly having surgeon champions and surgeon buy-in<sup>107</sup>), these strategies and efforts may improve both patient care and reduce cost, providing far-reaching public health and clinical implications.

Policy-makers may also find this research interesting as it shows the landscape of obstetric surgical care across the United States. By being able to see what individual and hospital risk factors are associated with poorer surgical outcomes in CS, policymakers can then have evidence-based results to make adjustments to existing guidelines or policies or promote further research to develop alternate interventions in the interest of public health and patient safety. For example, since urban teaching hospitals have higher odds of both surgical errors and complications, compared to urban

non-teaching hospitals and rural hospitals, these hospitals may find working with clinician-educators to develop common error-specific and complication-specific curriculum modules to be useful, much like what was done for trainees through the Patient Safety Improvement Corps (PSIC), a nationwide training program being carried out as part of AHRQ<sup>108</sup>. PSIC provided trainees across the United States to investigate medical errors (including close calls and near misses) by looking at system factors, and develop sustainable interventions on those findings<sup>108</sup>. A similar project dedicated to obstetric trainees and CS-specific errors and complications could potentially reduce the incidence of both and improve patient safety from both a clinical and public health standpoint.

Another stakeholder group that may find these results interesting is obviously clinicians. A British study from 2012 found a large discrepancy between staff surgeon and trainee perceptions of a patient safety culture<sup>109</sup>. To help improve that understanding in an obstetric context, a nationally representative baseline rate of surgical errors and complications across individual and hospital factors would increase awareness, and potentially lead to further research focused on quality improvement metrics. As patient safety is paramount and quality improvement is constantly developing in healthcare, this research will also be very useful to clinicians, specifically because it shows both individual and hospital level risk factors that can be a basis for improvements. For example, since there are higher odds for surgical errors on weekends, compared to weekday admissions, there may be certain policies that could be changed or certain procedures identified for specific errors. Additional research and

inquiry could illuminate the precise cause, and develop a solution that is clinician-led and clinician-implemented, which can have positive ramifications in clinical practice in regards to improving patient safety and public health.

Finally, the results of this project may be of interest to public health researchers who can use this descriptive study as a reference to look at patient safety in other contexts using the NIS database or other publicly available administrative data, and contribute to the body of public health and patient safety literature. It has been nearly 20 years since the IOM released their seminal work, *To Err is Human*<sup>33</sup>, and the changes in healthcare delivery and outcomes since then have opportunities for research that have large implications on public health and developing new metrics and benchmarks for patient safety in different patient populations.

### 4.4 Strengths

This study had several strengths. There were over half a million hospitalization records used for analysis. This large sample size gave more precise estimates, and smaller confidence intervals, which gives more confidence in null findings<sup>110</sup>, and avoiding Type II error. The increased power from such a large sample size was ideal to examine rare outcomes like surgical errors that may not be observed in a smaller sample. It also provides the ability to examine clinical subgroups (such as types of CS, and the associated errors and complications) without compromising power associated with the large sample size<sup>110</sup>.

Since 94% of American hospitals participate in the HCUP by providing data to the NIS, this study has a representative sample of hospitals across the United States, while

also representing 96% of the US population<sup>68</sup>. As this is a random sample of 20% allpayer hospital discharges<sup>68</sup>, it adds a level of protection against residual confounding variables that could otherwise influence the results. It also provides new information on surgical outcomes in CS in a nationally representative discharge database. This database has been identified as having the best childbirth-related healthcare services detail in among administrative US datasets<sup>97</sup>.

#### 4.5 Challenges and Limitations

As with all studies, there are also some limitations. As a cross-sectional study, causality and temporality cannot be determined between CS and a surgical error and/or complication in CS. For example, for a woman who had both a hysterectomy and a CS, a surgical error could have occurred during a hysterectomy rather than the CS, but would still be classified in our study as an error during CS. We are also unable to determine if the complication was the reason for the CS or if it occurred as a result of the CS.

As the unit of analysis is not patient level, there is limited data on hospital readmissions which can also lead an underestimation of complications of CS after the initial discharge and chronic conditions. The hospitalization format of the NIS database, also prevents maternal and infant linkages which would provide a more nuanced look at surgical errors and complications, and whether there were differences in mothers and babies, and who in particular was affected by a specific risk factor. For example, preterm birth was associated with lower odds for both surgical errors and complications, with a p-value <0.0001, which would not be the same for an infant population<sup>111</sup>.

Another limitation of this study is that after the 2012 NIS redesign no longer looks as hospital or state specific discharge records<sup>69</sup>. Due to this, the use of state specific or hospital estimates is discouraged<sup>68,112</sup> which could inhibits the use of specific state level estimates and allows us to only provide federal level patterns, limiting generalizability (or external validity) to federal generalizability or by pre-specified NIS stratums and regions. Similarly, we also could not look at clinician-level (specialty training or discipline of the person who performed the CS) within the hospital, which would have provided a new factor to consider in this study.

Additionally, we were limited by what was included in the NIS database – for example, information on parity, return to operating room (OR), and gestational age were not included in the database, both of which are important maternal risk factors to include. We also are unable to tell if a CS was due to an underlying maternal or fetal comorbidity as there are no specific ICD-9-CM codes indicating the reason for the CS, but rather would be clinical detail gained through a chart review. Moreover, we could not characterize spontaneous versus indicated preterm birth which could affect the outcome as indicated birthday are more likely to have significant individual factors that could lead to complications. In addition, this database has no details on the reason for CS or information on obstetric care and guidelines or policies from hospital to hospital to further assess the care that was provided. Additionally, some ICD-9-CM codes used to define surgical errors and complications were not validated in external databases, which is another limitation of this study. However, the CS codes used had sensitivities and positive predictive values of 100%<sup>77</sup>.

There is also potential for limited reporting of "E" codes in this database. Since these "E" codes are inconsistently reported or mandatory across states <sup>68</sup>, there is potential for underestimation of both surgical errors and complications in CS in this study, as they were may have been underutilized for many surgical error and complication categories. Surgical errors may be underreported as well, since many are not reported at morbidity and mortality meetings<sup>36</sup>, for fear of blame or other consequences, leading to a potential underestimation of error in our study. However, there were laparoscopic and vaginal hysterectomies reported in postpartum women, which are uncommon, suggesting that there may have been data entry limitations in this database. In addition, there could be some other reporting or data entry errors in this collection of hospital discharge abstracts, which could lead to non-differential misclassification bias as it is not directional. Similarly, other studies have reported that their hospital discharge records have some issues with underreporting care processes such as the use of oxytocin or the length of labour, and also inaccurately reporting unexpected complications that occur during some obstetric procedures<sup>113</sup>. This potential error could lead to misclassification bias as the wrong ICD-9-CM codes would be reported in the analysis. In addition, it is possible maternal mortality has been underestimated since this database only shows in-hospital deaths. A previous study found that only 16.6% of pregnant women died on the day of delivery or pregnancy termination in the United States<sup>114,115</sup>.

Finally, since median household income was calculated based on ZIP codes, the information is not reflective of individual socioeconomic status variables but rather

community level of socioeconomic status<sup>53</sup>, leaving it vulnerable to the ecological fallacy. The interpretation of this variable is then limited to comparing women from low income communities versus women from high income communities<sup>53</sup>. However, community level proxies for patient income have been used in previous studies looking at socioeconomic status and surgery<sup>116,117</sup>.

## 4.6 Directions for Future Research

Further research involving longitudinal analysis to examine surgical errors and complications in CS could provide a temporal assessment of the effect of adverse surgical outcomes on both maternal and infant health. Data linkage could help create comprehensive databases that allowed for assessment of both mothers and babies post-CS, and include variables such as gestational age, parity, potential psychiatric factors in addition to physical conditions, and return to OR.

Another direct follow up to this study could be to validate the surgical errors and complications included in this study by conducting a full chart review. The clinical detail gained from chart review would add a more nuanced description of women that were affected by a surgical error or complication by assessing indicators for comorbidities or unexpected circumstances, clinician's notes, and other related documentation.

Incident reports such as confidential interviews of clinicians performing CS could provide valuable insight into the why and how of surgical error and complications, in a non-punitive setting. A previous study examined surgical error through this lens for general surgery, and found this method to show detailed clinical and systems level explanations not found in administrative data such as "communication breakdown," or

"lack of clear clinician in charge cited as contributing to error,"<sup>36</sup>. This level of detail can provide better understanding of how human, social, organizational and systems factors contribute to surgical errors and complications in an obstetric population.

The United Kingdom's Confidential Enquiry into Maternal Mortality is an example of such a clinical audit held every three years in England, Scotland, and Wales<sup>118</sup>. Beginning in the mid-19<sup>th</sup> century, it monitors the causes of maternal death to an effort to improve maternal safety by using anonymized case records<sup>118</sup>. The number of maternal deaths are split into the causes – whether pregnancy related or not – and then are followed by recommendations for specialists such as midwives, general practitioners, and emergency medicine practioners<sup>119</sup>. Some recommendations from the 2005-2008 Confidential Enquiry into Maternal Mortality included, pre-pregnancy counselling, professional interpretation services, and an emphasis on clinical skills and training<sup>119</sup>. The end results, after a comprehensive review by regional and national assessors, have led to standardization of care and recommendations, and has been emulated internationally<sup>118</sup>.

Although one study found that surgical errors and complications were due to human factors rather than system level factors<sup>120</sup>, there is still effort being made to look at system level factors by using the "critical incident" technique adapted by Cooper et al. from aviation in the late 1970's for anaesthesiology<sup>91</sup>. Although the "critical incident" technique looks at human factors, Cooper et al. found that a majority of the adverse outcomes in anesthesiology were occurring due to poor systems processes in place<sup>91</sup>. Since then, anaesthesia has become known as a leader in patient safety, based

on changing system level factors such as making medical equipment "engineered safety devices" or failsafe against errors, and by measures such as implementing staffing requirements like the requirement of an anesthesiologist for the entirety of a procedure<sup>121</sup>. To that end, further research could be performed using "incident reports," to identify "critical incidents," which can then create guidelines to improve obstetric patient safety and reduce the incident of surgical errors and complications in CS. Data in 1992 showed that the incidence of surgical adverse events was 3.1% (95%CI: 1.9-5.0) for CS, while the incidence of preventable surgical adverse events in CS was 1.7% (95%CI: 0.8-3.3), and that further systems level analysis was required to reduce preventable adverse events<sup>35</sup>. Although there may be both organizational and individual factors, identifying systems strategies to most effectively reduce surgical adverse events remains a priority<sup>35</sup>.

This study also has the potential to have quality improvement research stem from its findings, as the results have established a baseline for incidence of surgical errors and complications in CS, and the associated maternal and hospital characteristics. Once the baseline has been established, as was the case with NSQIP identifying major causes of morbidity and mortality in the VA Health System by collecting data on major operations at 44 of the largest hospitals for two years<sup>107</sup>, there can be further research done to continue the process of the quality improvement cycle. For example, further research can be done to capture quality specific metrics like the Donabedian model consisting of structure (e.g. resources offered by a hospital for patient care), process (e.g. treatments provided in light of compliance with recommended clinical guidelines),

and outcome (e.g. measures such as length of stay, costs of care, and so on)<sup>107,122,123</sup>. These quality metrics can then be potentially translated into elements of a modified obstetric surgical safety checklist through additional research.

A surgical checklist was created by the World Health Organization (WHO) in 2008 identifying recommended surgical practices that provided a standardized guideline for surgical patient safety<sup>124</sup>. Elements of the 19-item Safety Checklist range from, "Confirms that all team members have been introduced by name and role," to "Confirms that prophylactic antibiotics have been administered ≤60 minutes before incision is made or that antibiotics are not indicated,"<sup>124</sup>. The introduction of this general surgical checklist showed significant improvements in surgical outcomes and a reduction in both complication rates and mortality across diverse hospitals<sup>124</sup>. A modified obstetric surgical checklist was created in 2013, and included specific instructions for patient positioning and warning, anticipated blood loss protocols, and medications<sup>125</sup>. The results from our study could include specific and simple modifications based on the results of this study – for example, there could be an element for the anesthetist to confirm the correct dosage and drug is being administered as that was the largest composite error category, which could easily be added to the category on "anesthesia equipment safety check" or "anesthesiologist(s) review(s)"<sup>125</sup>. In addition, a surgical checklist could also be treated as a decision tree – for example, if the indication for CS is obstructed labour, it may be an indication for postpartum hemorrhage and additional care may be required to mitigate that risk<sup>126</sup>.

An example of this decision tree approach is found in California. California has seen the statewide maternal mortality trend decrease compared to the nationwide average which has been increasing<sup>37</sup>. Part of this trend has been attributed to obstetric bundle of guidelines for postpartum hemorrhage through Stanford University's California Maternal Quality Care Collaborative<sup>127</sup>. This collaborative created the foundations for the National Partnership for Maternal Safety Consensus Bundle for Obstetric Hemorrhage<sup>127</sup>. A study looking at the effectiveness of this obstetric care bundle for postpartum hemorrhage, in particular, showed that implementation of these guidelines can be used in a very large number of hospitals that cover a range of sizes, ownership models and neonatal intensive care units<sup>127</sup>. The study also found that the obstetric bundles reduced severe maternal morbidity by 20.8% for hemorrhage patients and by 11.7% for the parturient population in general<sup>127</sup>.

Adding specific elements to a modified obstetric surgical checklist from systems aspects such as, "check correct dosage or drug is being administered" to clinical detail such as "review postpartum hemorrhage procedures if indication is for obstructed labour," could be an outcome of future research based on this study. Another example could be to specify "patient positioning" in the checklist by including, "confirm parturient is positioned supine with 15 degree lateral tilt," as that improves venous blood in a heavily pregnant woman<sup>128</sup>. This modification to the checklist could help delineate the differences between negligence and potential sources of surgical error more closely<sup>34</sup> and potentially improve patient safety.

# 4.7 Conclusion

Surgical errors during and complications following CS vary greatly by individual and hospital risk factors. The most common surgical error was anaesthetic error while the most common surgical complication was hysterectomy. Although multiple surgical errors and complications per CS are uncommon, there is still room for improvement. As maternal mortality continues to increase in the US<sup>37</sup>, along with CS rates<sup>129</sup>, and their increased risk of maternal complications<sup>25</sup>, there needs to be an increased emphasis on maternal safety in CS, particularly with changing maternal demographics and indicators at the hospital level. This study serves as an important baseline for incidence of surgical errors and complications to further develop quality improvement frameworks and modify existing obstetric policies and guidelines to potentially reverse this trend.

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Description	Code
Outcome of delivery	ICD-9-CM = V27
Normal delivery	ICD-9-CM = 650
DRG delivery codes	370 (complicated CS), 371 (uncomplicated CS), 372 (complicated vaginal delivery), 373 (uncomplicated vaginal delivery), 374 (uncomplicated vaginal delivery with sterilization and/or dilatation & curettage), 375 (vaginal delivery with operation room procedure except sterilization and/or dilatation & curettage)
Selected delivery related procedures	ICD-9-CM = 720, 721, 7221, 7229, 7231, 7239, 724, 726 (forceps), 7251, 7252, 7253, 7254 (breech extraction) 7271, 7279 (vacuum extraction), 728, 729 (other specified and unspecified delivery), 7322 (internal and combined version and extraction), 7359 (other manually assisted deliveries), 736 (episiotomy), 740, 741, 742, 744, 7499 (CS)
Exclusions	ICD-9-CM 630 (hydatidiform mole), 631 (other abnormal product of conception), 633 (ectopic pregnancy), 632, 634, 635, 636, 637, 638, 639, 69.01, 69.51,74.91, 75.0 (abortion)

Appendix A: ICD-9-CM codes used to identify obstetric deliveries<sup>1</sup>

All ICD-9-CM codes have been validated<sup>1</sup>

# Appendix B: CS procedure ICD-9-CM codes

Caesarean Section	ICD-9-CM Codes
Caesarean section and removal of fetus	<b>7</b> 4 <sup>*77</sup>
Classical caesarean section	74.0 <sup>*77</sup>
Low cervical caesarean section	<b>74.1</b> * <sup>77</sup>
Extraperitoneal caesarean section	<b>74.2</b> * <sup>77</sup>
Caesarean section of other specified type	<b>74.4</b> * <sup>77</sup>
Caesarean section of unspecified type	74.99 <sup>*77</sup>

Asterisk indicates ICD-9-CM code has been validated

Appendix	C:	Obstetric	Comorbidity	Index <sup>2</sup>
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Comorbidity	ICD-9-CM Codes
Pulmonary hypertension	416.0x, 416.8x, 416.9x
Placenta previa	641.0x, 641.1x
Sickle cell disease	282.4x, 282.6x
Gestational hypertension	642.3x (without preeclampsia/eclampsia or pre-existing hypertension)
Mild preeclampsia or unspecified preeclampsia	642.4x, 642.7x (without severe preeclampsia/eclampsia)
Severe preeclampsia/eclampsia	642.5x, 642.6x
Chronic renal disease	581.x–583.x, 585.x, 587.x, 588.x, 646.2x
Pre-existing hypertension	401.x-405.x, 642.0x-642.2x, 642.7x
Chronic ischemic heart disease	412.x-414.x
Congenital heart disease	745.0x–747.4x, 648.5x
Systemic lupus erythematosus	710.0x
Human immunodeficiency virus	042.x, V08.x
Multiple gestation	V27.2–V27.8, 651.x
Drug abuse	304.x, 305.2x-305.9x, 648.3x
Alcohol abuse	291.xx, 303.xx, 305.0x
Tobacco use	305.1x, 649.0x
Cardiac valvular disease	394.x–397.x, 424.x
Chronic congestive heart failure	428.22, 428.23, 428.32, 428.33, 428.42, 428.43
Asthma	493.x
Pre-existing diabetes mellitus	250.x, 648.0x
Gestational diabetes mellitus	648.8x (without pre-existing diabetes)
Obesity	278.0x, 649.1x , V85.3, V85.4
Cystic fibrosis	277.0x
Previous CS	654.2x

All ICD-9-CM codes have been validated<sup>2</sup>

Surgical	Specific ICD Description	ICD-9-CM	ICD-9-CM
Error		Procedure	Diseases and
Category		Code	Injuries Code
Error Involvi	ng the Uterus		-
	Repair of uterine supporting structures	69.2	
	Repair of current obstetric laceration of	75.5x	
	uterus	• 75.51	
	Repair of current obstetric	• 75.52	
	laceration of cervix		
	Repair of current obstetric		
	laceration of corpus uteri	CCF 2	
		665.3	
	Any surgical error affecting the uterus		
Error Involvi	ng the Ureter		C. C
	Ureteric injury (without mention of open	867.2, 867.3	
	wound into cavity and with mention of		
	Stricture or kinking of urotor		E02 2
	Angulation of ureter (nostonerative)		333.3
	Constriction of ureter (postoperative)		
	Other ureteric obstruction		593.4
	Any surgical error affecting the ureter		
Error Involvi	ng Blood Vessels		
	Injury to blood vessels of abdomen and		902.x
	pelvis		• 902.8
	Other specified blood vessels of		• 902.81
	abdomen and pelvis		• 902.82
	Ovarian artery		• 902.87
	Ovarian vein		• 902.89
	<ul> <li>Multiple blood vessels of</li> </ul>		
	abdomen and pelvis		
	Other		
	Suture of vessel	39.3x	
	<ul> <li>Suture of unspecified blood</li> </ul>	• 39.30	
	vessel	• 39.31	
	Suture of artery	• 39.32	
	Suture of versal with tissue patch	39 56	
	graft	39.30	
	Repair of blood vessel with synthetic	39.57	
	patch graft		
	Repair of blood vessel with unspecified	39.58	
	type of patch graft	20.50	
	other repair of vessel	22.22	

# Appendix D: Surgical Errors ICD-9-CM codes

Surgical	Specific ICD Description	ICD-9-CM	ICD-9-CM	
Error		Procedure	Diseases and	
Category		Code	Injuries Code	
	Any surgical error affecting blood vessels			
Error Involvi	Error Involving the Bladder			
	Repair of current obstetric laceration of	75.61		
	bladder or urethra			
	Other injury to pelvic organs – injury to		665.5* <sup>78</sup>	
	bladder, urethra			
	Any surgical error affecting the bladder			
Error Involvi	ing Bowels			
	Suture of fallopian tube	66.71		
	Suture of laceration of duodenum	46.71		
	Suture of laceration of small intestine,	46.73		
	except duodenum			
	Suture of laceration of large intestine	46.75		
	Other repair of intestine	46.79		
	Perforation of intestine (Rudd et al 2017		569.83	
	say that this is most common cause of			
	developing sepsis <sup>130</sup> )			
	Any surgical error affecting the bowel			
Error Involvi	ng Foreign Body or Substance			
	Foreign body accidentally left during a		998.4 <sup>*131</sup>	
	procedure not elsewhere classified		E871.0	
			E871.1	
	Acute reaction to foreign substance		998.7*	
	accidentally left during a procedure not			
	Any surgical error due to foreign body or			
	substance			
Apposthatic	Fror			
Andesthetic	Mismatched blood in transfusion		E876.0	
	Wrong fluid in infusion		E876.1	
			E070.1	
			E075	
	during anesthetic procedure		E8/0.3	
	Accidental cut nuncture perforation or		F870.0	
	hemorrhage during medical care.		E870.5	
	surgical operation or, Aspiration of fluid			
	or tissue, puncture, and catheterization			
	Abdominal paracentesis			
	Aspirating needle biopsy			
	Blood sampling			
	Lumbar puncture			
	Thoracentesis			

Surgical	Specific ICD Description	ICD-9-CM	ICD-9-CM
Error		Procedure	Diseases and
Category		Code	Injuries Code
	Contaminated or infected blood, other		E875
	fluid, drug, or biological substance		
	Poisoning by other central nervous		968
	system depressants and anesthetics		
	(overdose or wrong substance given)		
	Any surgical error during anaesthesia		
Procedural Error			
	Failure in suture and ligature during		876.2
	surgical operation		
	Failure to introduce or to remove other		E876.4
	tube or instrument		
	Performance of inappropriate operation		E876.5
	Failure of sterile precautions during		E872
	procedure		
	Mechanical failure of instrument or		E874.0
	apparatus during procedure		
	Any surgical error during procedure		

Asterisks indicate ICD-9-CM codes have been in previous studies "E" codes refer to ICD-9-CM codes that stand for "external cause of injury" or "misadventure codes"<sup>68</sup>
Surgical	Specific ICD Description	ICD-9-CM	ICD-9-CM
		Code	Diseases and Injuries Code
Maternal Mortal	lity	couc	injunes coue
	Maternal death in hospital <ul> <li>Maternal death</li> <li>Maternal death</li> <li>Instantaneous death</li> </ul>	Coded as "DIED" in NIS HCUP database • 761.6 • 798.1	
Infectious Comp	lications		
	Systemic inflammatory response syndrome (SIRS) • Sepsis • Severe Sepsis		995.9x <sup>*132</sup> <ul> <li>995.91</li> <li>995.92</li> </ul>
	Septicemia		038
	Septic shock		785.52 <sup>*132</sup>
	Major puerperal infection (includes endometritis)		670* <sup>77</sup>
	Acute and subacute bacterial endocarditis		421.0
	Acute endocarditis, unspecified		421.9
	Any infectious surgical complication		
Cardiac Complica	ations		
	Cardiac complications (Cardiac arrest or failure following anesthesia or other sedation in labor and delivery		668.1
	Cardiac complications		997.1
	Sudden cardiac arrest		V12.53
	Myocardial infarction		410 <sup>*133</sup>
	Acute coronary syndrome		411.1 <sup>*79</sup>
	Cardiac arrest		427.5
	Heart failure		428* <sup>78</sup>
	Subarachnoid hemorrhage		430*134
	Intracerebral hemorrhage		<b>431</b> * <sup>134</sup>
	Occlusion and stenosis of precerebral arteries		433
	Occlusion of cerebral arteries		<b>434</b> * <sup>134</sup>
	Transient cerebral ischemia		435x* <sup>78</sup>
	<ul> <li>Unspecified transient cerebral ischemia</li> </ul>		• 435.9

## Appendix E: Surgical complications ICD-9-CM codes

Surgical	Specific ICD Description	ICD-9-CM	ICD-9-CM
Complications		Procedure	Diseases and
Category		Code	Injuries Code
	Acute, but ill-defined,		436 <sup>*134</sup>
	cerebrovascular disease (Apoplexy,		
	apoplectic:		
	NOS		
	attack		
	cerebral		
	seizure		
	Cerebral seizure)		
	Ischemic stroke		437 <sup>*134</sup>
	latrogenic cerebrovascular		997.02
	infarction or hemorrhage		
	Any cardiac surgical complication		
Bowel Complicat	tions		
	Intestinal obstruction without		560x
	mention of hernia		• 560 1
	Paralytic ileus or bowel		• 560.9
	obstruction		• 500.9
	• Small howel obstruction		
	Small bower obstruction		
Fistulas			_
	Closure of fistula of small intestine,	46.74	
	except duodenum		
	Closure of fistula of large intestine	46.76	
	Closure of other fistula of urethra	58.43	
	Fistula of stomach or duodenum		537.4
	Fistula of intestine, excluding		569.81
	rectum and anus		
	Ureteral fistula - intestinoureteral		593.82
	fistula		
	Urethral fistula - urethroperineal,		599.1
	urethrorectal, Urinary fistula NOS		
	Fistula involving female genital tract		619.0
	Fistula of bile duct		576.4
	Choledochoduodenal fistula		
	Vesical fistula, not elsewhere		596.2
	classified		
	bladder NOS		
	urethrovesical		
	vesicocutaneous		
	vesicoperineal		
	Persistent postoperative fistula		998.6

Surgical	Specific ICD Description	ICD-9-CM	ICD-9-CM
Complications		Procedure	Diseases and
Category	Any fistula-related surgical	Code	injuries code
	complication		
Shock-Related C	omplications		
	Shock during or following labor and		669.1
	delivery		
	Maternal hypotension syndrome		669.2
	Postoperative hypotension		458.29
	(latrogenic)		
	Any shock-related surgical		
Respiratory Com	Directions		
Respiratory con	Pneumothoray		512v
	rieumotiorax		
	latrogenic pneumothorax		• 512.1*133
	Other spontaneous		• 512.8
	pneumothorax		
	Pulmonary edema, postoperative		518.4
	Respiratory arrest following trauma		518.5 <sup>*135</sup>
	or surgery		
	Acute respiratory failure		518.81
	Cardiopulmonary resuscitation, not		99.60**
	Influenza with pneumonia		487.0
	Pneumonitis due to solids and		487.0
	liquids		507
	• Due to inholation of food or		• 507.0
	Due to initialition of food of vomitus (aspiration		• 507.1
			• 507.8
	<ul> <li>Due to inhalation of oils and</li> </ul>		
	essences		
	Due to other solids and		
	liquids		
	Respiratory complications		997.3x
	Other respiratory		• 997.39
	complications		• 997.31
	Ventilator associated		
	pneumonia		
	Any respiratory surgical		
	complication		
Dehiscence Com	plications		

Surgical	Specific ICD Description	ICD-9-CM	ICD-9-CM
Complications		Procedure	Diseases and
Category		Code	Injuries Code
	Disruption of internal operation		998.31 <sup>*135</sup>
	(surgical) wound		
	Disruption of external operation		<b>998.32</b> * <sup>135</sup>
	(surgical) wound (Dehiscence)		
	Disruption of caesarean wound		674.1
	(dehiscence or disruption of uterine		
	wound)		
	Any surgical complication due to		
Postnartum Hem	orrhage		
rostpartummen			666y
	Postpartum nemormage		000X
	<ul> <li>Third-stage postpartum</li> </ul>		<ul> <li>666.0*<sup>77</sup></li> </ul>
	hemorrhage		• 666.1* <sup>77</sup>
	Other immediate		• 666.2* <sup>77</sup>
	postpartum hemorrhage		• 666.3
	<ul> <li>Delayed and secondary</li> </ul>		
	postpartum hemorrhage		
	<ul> <li>Postpartum coagulation</li> </ul>		
	defects		
Embolisms			
LIIDOIISIIIS	Contio nulmonory ombolism		415 10
	Septic pullionary embolism		415.12
	Obstetrical pulmonary embolism		673X
	Amniotic fluid embolism		• 673.1
	Obstetrical blood-clot		• 673.2
	embolism		• 673.8
	Fat embolism		
	Any embolism surgical complication		
Nincelleneeue	Any embolism surgicul complication		
wiscellaneous			660.2
	Acute renal failure following labor		669.3
	Doon philopothromhosis		C71 1*78
	nostnartum		071.4
	Other complications of obstetrical		674 3* <sup>78</sup>
	surgical wounds (includes:		074.5
	hematoma of caesarean section or		
	perineal wound, hemorrhage of		
	caesarean section or perineal		
	wound, infection of caesarean		
	section or perineal wound)		
	Rectus sheath hematoma		729.92

Surgical	Specific ICD Description	ICD-9-CM	ICD-9-CM
Complications		Procedure	Diseases and
Category	Nonhealing surgical wound	Code	age 83
			338.83
	complication		
Hysterectomies	(not including any hospitalizations with	n gynaecological c	ancers)
	Subtotal abdominal hysterectomy	68.3x	
	Laparoscopic supracervical	• 68.31	
	hysterectomy [LSH]	• 68.39	
	Other and unspecified		
	subtotal abdominal		
	hysterectomy		
	Total abdominal hysterectomy	68.4x	
	Laparoscopic total	• 68.41	
	abdominal hysterectomy	• 68.49	
	Total laparoscopic		
	hysterectomy [TLH]		
	Other and unspecified total		
	abdominal hysterectomy		
	Hysterectomy: extended		
	Laparoscopically assisted vaginal	68.51	
	Other and unspecified vaginal	68.59	
	hysterectomy	00.00	
	Radical abdominal hysterectomy	68.6x	
	Laparoscopic radical	• 68.61	
	abdominal hysterectomy	• 68.69	
	Other and unspecified		
	radical abdominal		
	hysterectomy		
	Radical vaginal hysterectomy	68.7x	
	Laparoscopic radical vaginal	• 68.71	
	hysterectomy [LRVH]	• 68.79	
	Other and unspecified		
	radical vaginal hysterectomy		
	Other and unspecified hysterectomy	68.9	
	Any hysterectomy		
Anaesthetic Com	nplications		

Surgical	Specific ICD Description	ICD-9-CM	ICD-9-CM
Complications		Procedure	Diseases and
Category		Code	Injuries Code
	Other complications of anesthesia		668.8
	or other sedation in labor and		
	delivery		
	Other continuous invasive		96.7x
	mechanical ventilation		• 96.70
	Continuous invasive		
	mechanical ventilation of		
	unspecified duration		
	Shock due to apposition (when		005 /
	correct substance and dose		555.4
	administered)		
	Halothane causing adverse effects in		F938.1
	therapeutic use		
	Other gaseous anesthetics causing		E938.2
	adverse effects in therapeutic use		
	Ether		
	Halogenated hydrocarbon		
	derivatives, except halothane		
	Nitrous oxide		
	Intravenous anesthetics causing		E938.3
	adverse effects in therapeutic use		
	Ketamine		
	Methonexital [methonexitone]		
	sodium		
	Other and unspecified general		F938.4
	anesthetics causing adverse effects		2550.4
	in therapeutic use		
	Surface and infiltration anesthetics		E938.5
	causing adverse effects in		
	therapeutic use		
	Cocaine		
	Lidocaine [lignocaine]		
	Procaine		
	letracaine Deviational a serie de la deviation		5020.0
	Peripheral nerve- and plexus-		E938.6
	offects in the rapeutic use		
	Spinal aposthetics causing adverse		F938 7
	effects in therapeutic use		LJJ0./
	Other and unspecified local		E938.9
	anesthetics causing adverse effects		
	in therapeutic use		

Surgical Complications	Specific ICD Description	ICD-9-CM Procedure	ICD-9-CM Diseases and
Category		Code	Injuries Code
	Any anesthesia-related surgical		
	complication		
Myomectomies	excluding those hospitalizations with a	gynecological can	cers)
	Other excision or destruction of	68.29	
	lesion of uterus		
	Uterine myomectomy		
Oophorectomies	e (excluding those hospitalizations with	gynecological car	ncers)
	Unilateral oophorectomy	65.3x	
	Laparoscopic unilateral	• 65.31	
	oophorectomy	• 65.39	
	Other unilatoral conherectory		
		CF 44	
	Unhateral salpingo-oophorectomy	05.4X	
	<ul> <li>Laparoscopic unilateral</li> </ul>	• 64.41	
	salpingo-oophorectomy	• 65.49	
	Other unilateral salpingo-		
	oophorectomy		
	Bilateral oophorectomy	65.5	
	Bilateral salpingo-oophorectomy	65.6	
	Total bilateral salpingectomy	66.5	
	Total oophorectomy group		
Ovarian cystecto	mies (excluding those hospitalizations	with gynecologica	al cancers)
	Total cystectomy	57.7x	
	Includes: total cystectomy with	• 57.79	
	urethrectomy		
	Other total cystectomy		

Asterisks indicate ICD-9-CM codes have been in previous studies

"E" codes refer to ICD-9-CM codes that stand for "external cause of injury" or "misadventure codes"68

## Appendix F: Descriptive Surgical Errors after CS in NIS HCUP Database 2012-2014 (Stratified by Specific ICD-9-CM Codes)

Surgical Errors Category/Specific ICD Description	N <sup>a</sup> (N=648,584)	N <sup>b</sup> (N=3,241,690 <sup>b</sup> )	% (95%) <sup>c</sup>
Error Involving the Uterus			
Repair of uterine supporting structures	1,425	7,125	0.22 (0.21-0.22)
Repair of current obstetric laceration of uterus:			
<ul> <li>Repair of current obstetric laceration of cervix</li> <li>Repair of current obstetric</li> </ul>			
laceration of corpus uteri	0	-	-
Laceration of cervix	0	-	-
Any surgical error affecting the uterus	1,425	7,125	0.22 (0.21-0.22
Error Involving the Ureter			
Ureteric injury (without mention of open wound into cavity and with mention of open wound into cavity)	≤10	-	<0.001
Stricture or kinking of ureter:			
<ul> <li>Angulation of ureter (postoperative)</li> <li>Constriction of ureter (nostoperative)</li> </ul>	183	915	0 03 (0 03-0 03)
Other ursteric obstruction	575	2 875	0.09 (0.09-0.09)
Any suraical error affecting the ureter	743	3 715	0.11 (0.11-0.12)
Error Involving Blood Vessels	743	5,715	0.11 (0.11 0.12)
Injury to blood vessels of abdomen and			
<ul> <li>Pelvis:</li> <li>Other specified blood vessels of abdomen and pelvis</li> <li>Ovarian artery vein</li> <li>Multiple blood vessels of abdomen and pelvis</li> <li>Other</li> </ul>	2 264	11 320	0 35 (0 34-0 36)
Suture of vessel:	2,204	11,520	0.55 (0.54 0.50)
Suture of unspecified blood vessel     Suture of artery     Suture of voin	606	2 490	0 11 (0 10 0 11)
Renair of blood vessel with tissue natch graft	<10	5,400	0.001
Repair of blood vessel with synthetic patch graft	≤10	-	<0.001
Repair of blood vessel with unspecified type of patch graft	≤10	-	<0.001

Surgical Errors Category/Specific ICD Description	N <sup>a</sup> (N=648,584)	N <sup>b</sup> (N=3,241,690 <sup>b</sup> )	% (95%) <sup>c</sup>
Other repair of vessel	14	70	2.16 x 10 <sup>-5</sup> (1.17 x 10 <sup>-5</sup> – 2.73 x 10 <sup>-5</sup> )
Any surgical error affecting blood vessels	2,894	14,470	0.45 (0.44-0.45)
Error Involving the Bladder			
Repair of current obstetric laceration of bladder or urethra	916	4,580	0.14 (0.14-0.15)
Other injury to pelvic organs – injury to bladder, urethra	2,137	10,685	0.33 (0.32-0.34)
Any surgical error affecting the bladder	2,210	11,050	0.34 (0.33-0.35)
Error Involving Bowels			
Suture of fallopian tube	0	-	-
Suture of laceration of duodenum	0	-	-
Suture of laceration of small intestine, except duodenum	0	-	-
Suture of laceration of large intestine	0	-	-
Other repair of intestine	0	-	-
Perforation of intestine (Rudd et al 2017 says that this is most common cause of developing sepsis) <sup>130</sup>	0	_	_
Any surgical error affecting the bowel	0	-	_
Error Involving Foreign Bodies or Substances			
Foreign body accidentally left during a procedure not elsewhere classified	67	335	0.01 (8.13 x 10 <sup>-5</sup> –0.01)
Acute reaction to foreign substance accidentally left during a procedure not elsewhere classified	0	-	_
Any surgical error due to foreign body or substance	67	335	0.01 (8.13 x 10 <sup>-5</sup> –0.01)
Anaesthetic Error			
Mismatched blood in transfusion	≤10	-	<0.001
Wrong fluid in infusion	0	-	-
Failure in dosage	≤10	-	<0.001
Endotracheal tube wrongly placed during anesthetic procedure	0	-	-

Surgical Errors Category/Specific ICD Description	N <sup>a</sup> (N=648,584)	N <sup>b</sup> (N=3,241,690 <sup>b</sup> )	% (95%) <sup>c</sup>
Accidental cut, puncture, perforation, or hemorrhage during medical care, surgical operation or,			
Aspiration of fluid or tissue, puncture, and catheterization Abdominal paracentesis			
<ul> <li>Aspirating needle biopsy</li> <li>Blood sampling</li> <li>Lumbar puncture</li> <li>Thoracentesis</li> </ul>	694	3.470	0.11 (0.10-0.11)
Contaminated or infected blood, other fluid, drug, or biological substance	0	-	-
Poisoning by other central nervous system depressants and anaesthetics (overdose or wrong substance given)	5,376	26,880	0.83 (0.82-0.84)
Any surgical error during anaesthesia	6,045	30,225	0.93 (0.91-0.96)
Procedural Error			
Failure in suture and ligature during surgical operation	≤10	30	9.25 x 10 <sup>-6</sup> (4.16 x 10 <sup>-6</sup> – 2.06 x 10 <sup>-5</sup> )
Failure to introduce or to remove other tube or instrument	0	-	-
Performance of inappropriate operation	0	-	-
Failure of sterile precautions during procedure	≤10	-	<0.001
Mechanical failure of instrument or apparatus during procedure	≤10	20	6.17 x 10 <sup>-6</sup> (2.31 x 10 <sup>-7</sup> – 1.64x 10 <sup>-5</sup> )
Any surgical error during procedure	11	55	0.17 x 10 <sup>-4</sup> (9.40 x 10 <sup>-6</sup> – 3.06 x 10 <sup>-5</sup> )
ALL SURGICAL ERRORS	12,838	64,190	1.98 (1.95-2.01)

a Unweighted sample size (from 2012-2014 NIS data) b Weighted sample size (representative of national population) c Weighted proportion

## Appendix G: Descriptive Surgical Complications after CS in NIS HCUP Database 2012-2014 (Stratified by Specific ICD-9-CM Codes)

Surgical Complications Category/Specific	N <sup>a</sup>	N <sup>b</sup>	% (95%) <sup>c</sup>
ICD Description	(N=648,584)	(N=3,241,690 <sup>b</sup> )	
Maternal Mortality			
Maternal death in hospital:	229	1,145	0.04 (0.03-0.04)
Maternal death			
Instantaneous death			
Infectious Complications			
Systemic inflammatory response syndrome	1,436	7,180	0.22 (0.22-0.23)
(SIRS): Sepsis, severe sepsis	1.050	24.245	0.77 (0.76.0.70)
Septicemia	4,969	24,845	0.77 (0.76-0.78)
Septic shock	240	1,200	0.04 (0.03-0.04)
Major puerperal infection (including	5,182	25,910	0.80 (0.70-0.81)
A sute and subsoute besterial and condition	74	270	0.01 (0.01.0.01)
Acute and subacute bacterial endocarditis	74	370	0.01 (0.01-0.01)
Acute endocarditis, unspecified	≤10	-	<0.001
Any infectious surgical complication	10,338	51,690	1.59 (1.58-1.60)
Cardiac Complications			
Cardiac complications (Cardiac arrest or	60	300	9.25 x 10 <sup>-5</sup> (8.26 x 10 <sup>-5</sup> − 0.01)
sedation in labor and delivery			
Cardiac complications	522	2 660	0.08 (0.08 0.09)
	532	2,000	0.08 (0.08-0.09)
Sudden cardiac arrest	0	-	-
	0	-	-
Acute coronary syndrome	0	-	-
Cardiac arrest	194	970	0.03 (0.03-0.03)
Heart failure	1,507	7,535	0.23 (0.23-0.24)
Subarachnoid hemorrhage	795	3,975	0.12 (0.12-0.13)
Intracerebral hemorrhage	411	2,055	0.06 (0.06-0.07)
Occlusion and stenosis of precerebral	216	1,080	0.03 (0.03-0.04)
Occlucion of corobral artorios	151	755	0.02 (0.02.0.02)
	151	/55	0.02 (0.02-0.03)
transient cerebral ischemia; Unspecified	48	240	7.40 X 10° (6.52 X 10° – 8.40 X 10°)
Acute, but ill-defined, cerebrovascular	355	1,775	0.05 (0.05-0.06)
disease (Apoplexy, apoplectic: NOS. attack			
	4.07		
Ischemic stroke	167	835	0.03 (0.02-0.03)

Surgical Complications Category/Specific	$N^a$	N <sup>b</sup>	% (95%) <sup>c</sup>
	(N=648,584)	(N=3,241,690°)	
latrogenic cerebrovascular infarction or	<10		
hemorrhage	210	-	<0.001
Any cardiac surgical complication	4,162	20,810	0.64 (0.63-0.65)
Complications of the Bowel			
Intestinal obstruction without mention of hernia	3,864	19,320	0.6 (0.59-0.60)
<ul><li>Paralytic ileus or bowel obstruction</li><li>Small bowel obstruction</li></ul>			
Fistulas			
Closure of fistula of small intestine, except duodenum	≤10	-	<0.001
Closure of fistula of large intestine	0	-	-
Closure of other fistula of urethra	0	-	-
Fistula of stomach or duodenum	21	105	3.24 x 10 <sup>-5</sup> (2.68 x 10 <sup>-5</sup> – 3.92 x 10 <sup>-5</sup> )
Fistula of intestine, excluding rectum and anus	22	110	3.39 x 10 <sup>-5</sup> (2.81 x 10 <sup>-5</sup> – 4.09 x 10 <sup>-5</sup> )
Ureteral fistula - intestinoureteral fistula	0	-	-
Urethral fistula - urethroperineal, urethrorectal, Urinary fistula NOS	343	1,715	0.05 (0.05-0.06)
Fistula involving female genital tract	74	370	0.01 (0.01-0.01)
Fistula of bile duct, Choledochoduodenal fistula	0	-	-
Vesical fistula, not elsewhere classified: bladder NOS, urethrovesical, vesicocutaneous, vesicoperineal	≤10	-	<0.001
Persistent postoperative fistula	32	160	4.94 x 10 <sup>-5</sup> (4.23 x 10 <sup>-5</sup> – 5.76 x 10 <sup>-5</sup> )
Any fistula-related surgical complication	481	2,405	0.07 (0.07-0.08)
Shock-Related Complications			
Shock during or following labor and delivery	210	1,050	0.03 (0.03-0.03)
Maternal hypotension syndrome	864	4,320	0.13 (0.13-0.14)
Postoperative hypotension (latrogenic)	547	2,734	0.08 (0.08-0.09)
Any shock-related surgical complication	1,589	7,945	0.25 (0.24-0.25)
Respiratory Complications			
<ul> <li>Pneumothorax:</li> <li>latrogenic pneumothorax</li> <li>Other spontaneous pneumothorax</li> </ul>	713	3,565	0.11 (0.11-0.11)
Pulmonary edema, postoperative	265	1,325	0.04 (0.04-0.04)

Surgical Complications Category/Specific	N <sup>a</sup>	N <sup>b</sup>	% (95%) <sup>c</sup>
ICD Description	(N=648,584)	(N=3,241,690 <sup>b</sup> )	
Respiratory arrest following trauma or surgery	520	2,600	0.08 (0.08-0.08)
Acute respiratory failure	1,428	7,140	0.22 (0.22-0.23)
Cardiopulmonary resuscitation, not	45	225	6.94 x 10 <sup>-5</sup> (6.09 x 10 <sup>-5</sup> – 7.91 x 10 <sup>-5</sup> )
otherwise specified			
Influenza with pneumonia	49	245	7.56 x 10 <sup>-5</sup> (6.67x 10 <sup>-5</sup> – 8.57 x 10 <sup>-5</sup> )
Pneumonitis due to solids and liquids:	3,467	17,335	0.53 (0.53-0.54)
<ul> <li>Due to inhalation of food or vomitus (aspiration pneumonia),</li> <li>Due to inhalation of oils and essences,</li> <li>Due to other solids and liquids</li> </ul>			
Respiratory complications:	286	1,430	0.04 (0.04-0.05)
<ul><li>Other respiratory complications</li><li>Ventilator associated pneumonia</li></ul>			
Any respiratory surgical complication	6,348	31,740	0.98 (0.97-0.99)
Dehiscence Complications			
Disruption of internal operation (surgical) wound	39	195	6.02 x 10 <sup>-5</sup> (5.23 x 10 <sup>-5</sup> – 6.92 x 10 <sup>-5</sup> )
Disruption of external operation (surgical) wound (Dehiscence)	42	210	6.48 x 10 <sup>-5</sup> (5.66 x 10 <sup>-5</sup> – 7.42 x 10 <sup>-5</sup> )
Disruption of caesarean wound (dehiscence or disruption of uterine wound)	880	4,400	0.14 (0.13-0.14)
Any surgical complication due to dehiscence	961	4,805	0.15 (0.14-0.15)
Postpartum Hemorrhage			
Postpartum hemorrhage:	13,321	66,604	2.05 (2.04-2.07)
<ul> <li>Third-stage postpartum hemorrhage</li> <li>Other immediate postpartum hemorrhage</li> <li>Delayed and secondary postpartum hemorrhage</li> <li>Postpartum coagulation defects</li> </ul>			
Embolisms			
Septic pulmonary embolism	44	220	6.79 x 10 <sup>-5</sup> (5.95x 10 <sup>-5</sup> – 7.75 x 10 <sup>-5</sup> )
Obstetrical pulmonary embolism:	347	1,735	0.05 (0.05-0.06)
<ul> <li>Amniotic fluid embolism</li> <li>Obstetrical blood-clot embolism</li> <li>Fat embolism</li> </ul>			
Any embolism surgical complication	390	1,950	0.06 (0.06-0.06)

Surgical Complications Category/Specific	N <sup>a</sup>	N <sup>b</sup>	% (95%) <sup>c</sup>
ICD Description	(N=648,584)	(N=3,241,690 <sup>b</sup> )	
Miscellaneous Complications			
Acute renal failure following labor and	498	2,490	0.08 (0.07-0.08)
delivery			
Deep phlebothrombosis, postpartum 49	92	460	0.01 (0.01-0.02)
Other complications of obstetrical surgical	4,116	20,580	0.63 (0.63-0.64)
section or perineal wound hemorrhage of			
caesarean section or perineal wound,			
infection of caesarean section or perineal			
wound)	20	1.10	
Rectus sheath hematoma	28	140	$4.32 \times 10^{-3} (3.66 \times 10^{-3} - 5.10 \times 10^{-3})$
Nonhealing surgical wound	18	90	$2.78 \times 10^{-6} (2.26 \times 10^{-7} - 3.41 \times 10^{-5})$
Any miscellaneous surgical complication	4,760	23,530	0.73 (0.72-0.74)
Hysterectomy (excluding those with gynecological cancer)			
Subtotal abdominal hysterectomy:	1,693	8,465	0.26 (0.26-0.27)
Laparoscopic supracervical			
hysterectomy [LSH]			
abdominal hysterectomy			
Total abdominal hysterectomy:	9,210	46,050	1.42 (1.41-1.43)
Laparoscopic total abdominal			
hysterectomy			
<ul> <li>Total laparoscopic hysterectomy</li> </ul>			
<ul> <li>Other and unspecified total</li> </ul>			
abdominal hysterectomy			
Hysterectomy: extended			
Laparoscopically assisted vaginal hysterectomy (LAVH)	2,323	11,615	0.36 (0.35-0.36)
Other and unspecified vaginal hysterectomy	104	520	0.02 (0.01-0.02)
Radical abdominal hysterectomy:	660	3,300	0.10 (0.01-0.01)
Laparoscopic radical abdominal			
hysterectomy			
<ul> <li>Other and unspecified radical abdominal hysterectomy</li> </ul>			
Radical vaginal hysterectomy:	109	545	0.02 (0.02-0.02)
Laparoscopic radical vaginal			
hysterectomy [LRVH]			
Other and unspecified radical			
vaginal hysterectomy			

Surgical Complications Category/Specific	N <sup>a</sup> (N=648.584)	N <sup>b</sup> (N=3.241.690 <sup>b</sup> )	% (95%) <sup>c</sup>
		(	
Other and unspecified hysterectomy	96	480	0.01 (0.01-0.02)
Any hysterectomy	14,170	70,850	2.19 (2.17-2.20)
Anaesthetic Complications			
Other complications of anesthesia or other sedation in labor and delivery	2,587	12,935	0.40 (0.39-0.41)
Other continuous invasive mechanical ventilation: Continuous invasive mechanical ventilation of unspecified duration	490	2,450	0.08 (0.07-0.08)
Shock due to anaesthesia (when correct substance and dose administered)	183	915	0.03 (0.03-0.03)
Halothane causing adverse effects in therapeutic use	0	-	-
Other gaseous anesthetics causing adverse effects in therapeutic use:	≤10	-	<0.001
<ul> <li>Ether Halogenated hydrocarbon derivatives, except         <ul> <li>Halothane</li> <li>Nitrous oxide</li> </ul> </li> </ul>			
Intravenous anesthetics causing adverse effects in therapeutic use:	16	80	2.47 x 10 <sup>-5</sup> (1.51 x 10 <sup>-5</sup> – 4.03 x 10 <sup>-5</sup> )
<ul> <li>Ketamine</li> <li>Methohexital [methohexitone]</li> <li>Thiobarbiturates, such as thiopental sodium</li> </ul>			
Other and unspecified general anesthetics causing adverse effects in therapeutic use	48	240	0.74 x 10 <sup>-4</sup> (5.58 x 10 <sup>-5</sup> – 9.82 x 10 <sup>-5</sup> )
Surface and infiltration anesthetics causing adverse effects in therapeutic use:	13	65	0.20 x 10 <sup>-4</sup> (1.16 x 10 <sup>-5</sup> – 3.45 x 10 <sup>-5</sup> )
<ul> <li>Cocaine</li> <li>Lidocaine [lignocaine]</li> <li>Procaine</li> <li>Tetracaine</li> </ul>			
Peripheral nerve- and plexus-blocking anesthetics causing adverse effects in therapeutic use	33	165	5.09 x 10 <sup>-5</sup> (3.62 x 10 <sup>-5</sup> – 7.16 x 10 <sup>-5</sup> )
Spinal anesthetics causing adverse effects in therapeutic use	324	1,620	0.05 (0.04-0.06)
Other and unspecified local anesthetics causing adverse effects in therapeutic use	≤10	-	<0.001
Any anesthesia-related surgical complication	3,610	18,050	0.56 (0.54-0.58)

Surgical Complications Category/Specific ICD Description	N <sup>a</sup> (N=648,584)	N <sup>b</sup> (N=3,241,690 <sup>b</sup> )	% (95%) <sup>c</sup>
Myomectomy (excluding those with gynecological cancer)			
Other excision or destruction of lesion of uterus: Uterine myomectomy	2,585	12,925	0.40 (0.39-0.40)
Oophorectomy (excluding those with gynecological cancer)			
Unilateral oophorectomy: • Laparoscopic unilateral oophorectomy • Other unilateral conhorectomy	3,670	18,350	0.56 (0.56-0.57)
<ul> <li>Unilateral salpingo-oophorectomy:</li> <li>Laparoscopic unilateral salpingo- oophorectomy</li> <li>Other unilateral salpingo- oophorectomy</li> </ul>	185	925	0.03 (0.03-0.03)
Bilateral oophorectomy	576	2,880	0.09 (0.09-0.09)
Bilateral salpingo-oophorectomy	≤10	-	<0.001
Total bilateral salpingectomy	≤10	-	<0.001
Total oophorectomy group	4,411	22,055	0.68 (0.67-0.69)
Ovarian Cystectomy (excluding those with gynecological cancer)			
<ul> <li>Total cystectomy:</li> <li>Includes: total cystectomy with urethrectomy</li> <li>Other total cystectomy</li> </ul>	60 619	303 095	2.16 x 10 <sup>-5</sup> (1.71 x 10 <sup>-5</sup> – 2.73 x 10 <sup>-5</sup> )
	00,019	505,095	3.35 (3.32-3.38)

a Unweighted sample size (from 2012-2014 NIS data) b Weighted sample size (representative of national population) c Weighted proportion