©2019

Christopher M. Black

ALL RIGHTS RESERVED

RISKING LIFE TO GIVE LIFE: EPIDEMIOLOGY AND COSTS OF SEVERE MATERNAL MORBIDITY IN THE UNITED STATES

Ву

CHRISTOPHER M. BLACK

A dissertation submitted to the

School of Graduate Studies

Rutgers, The State University of New Jersey

In partial fulfillment of the requirements

For the degree of

Doctor of Philosophy

Graduate Program in Public Health

Written under the direction of

Dona Schneider, PhD MPH

And approved by

New Brunswick, New Jersey

May 2019

ABSTRACT OF THE DISSERTATION Risking Life to Give Life: Epidemiology and Costs of Severe Maternal Morbidity in the United States

By CHRISTOPHER M. BLACK

Dissertation Director:

Dona Schneider PhD, MPH

Background: Approximately four million children are born in the United States each year and childbirth are the most common reason for hospitalization. Rates of severe maternal morbidity (SMM), life threatening events occurring childbirth, have been increasing over the past 20 years in the United States. Few studies have examined the epidemiology of SMM and gaps still exist. Specific Aims: The goal of this dissertation is to understand the epidemiologic and economic burden of severe maternal morbidity (SMM) in the United States using administrative claims data. This study aims to answer three research questions: 1) What is the incidence of SMM in 2016? 2) What is the incidence rate and predictors of unplanned 30-day hospital readmissions and emergency room (ER) visits after a delivery hospitalization among women with and without SMM? and 3) What are the associated healthcare resource utilization costs associated with SMM across the prenatal, delivery, and postpartum period? Methods: This was a retrospective cohort study of women with a live inpatient delivery during 2016 in the MarketScan databases for commercially insured and Medicaid populations. The incidence of severe maternal morbidity and the frequencies of 18 individual SMM indicators, as defined by the Center for Disease Control & Prevention's algorithm of ICD-10 diagnostic and procedural codes was calculated. Incidence rates of 30-day hospital readmissions and treat-and-release ER visits were calculated and compared for women with and without SMM. Healthcare costs during the prenatal, delivery and 30-day post-

delivery period were estimated and compared by SMM status. Results: The incidence of severe maternal morbidity was 113.4 per 10,000 deliveries in the Commercial population and 109.6 per 10,000 deliveries in the Medicaid population. The most frequent severe maternal morbidity indicators were eclampsia, blood transfusion and disseminated intravascular coagulation (35.0 and 25.7 per 10,000 deliveries) in the Commercial population and eclampsia and adult respiratory distress syndrome (45.5 and 14.9 per 10,000 deliveries) in the Medicaid population. In the multivariate analysis, a cesarean delivery and multifetal gestation was associated with severe maternal morbidity in both Commercial (OR 3.37; 95% Cl 1.51, 1.84; OR: 3.37; 95% Cl 2.8, 4.10) and Medicaid populations (OR 1.99; 95%CI 1.80, 2.17; OR: 2.26; 95%CI: 1.86, 2.75). Race was also associated with an increased risk of SMM (White vs Black OR:0.78; 95%CI: 0.70, 0.87). There were 1,972 hospital readmissions and 132 ER visits in the commercially-insured population with incidence rates of 11.7 and 0.8 per 1,000 discharges. These rates were 12 and 19 times greater for women with SMM than women without SMM. In the Medicaid population there were 1,114 hospital readmissions and 119 ER visits, for incidence rates of 17.0 and 1.8 per 1,000 discharges. SMM increased these rates by 16 and 17 times for hospital readmission and ER visits, respectively. Eclampsia was the most commonly reported SMM indicator among women with a hospital readmission or ER visit in both populations. Hypertensive disorders during pregnancy and eclampsia, obstetric infections and hemorrhage were common reasons for a hospital readmission and ER visits. SMM was associated with many of the primary discharge diagnoses for hospital readmissions and ER visits. In the Commercial population, the total, per-patient mean costs of care for women without and with SMM were \$23,144 and \$47,030, respectively, with prenatal, delivery and post-delivery costs all significantly higher among women with SMM. The adjusted delivery cost for women with SMM were 20% greater than women without SMM. In the Medicaid population, the total, per-patient mean costs of care for women with and without SMM were

\$26,513 vs \$9,652, respectively. The adjusted delivery cost for women with SMM were 31% greater than women without SMM. **Conclusion**: Preventing SMM would result in significant reductions in healthcare resource utilization and associated costs and would reduce an undue burden to mothers, healthcare providers, hospital administrators, and payers.

ACKNOWLEDGEMENT

There are few moments in one's life that you point to as a moment that changed the direction of one's life. That moment for me was eleven years-ago when I met with Dr. Dona Schneider after an Introduction to Epidemiology class to enquire about career possibilities in epidemiology. It was that discussion that set me on a path to earn graduate degrees in epidemiology, employment in epidemiologic research, and to eventually teach that very class. Dr. Schneider has been my advisor and motivator for eleven years and I thank her for her tough-love and guidance.

I am lucky to have been a student of Dr. Pamela Ohman-Strickland and Dr. Kitaw Demissie, two of the smartest and kindest professors I've had the pleasure to meet. They provided insightful direction and guidance during my dissertation and I am forever grateful.

I am appreciative to have met Dr. Kimberly Vesco while working on a Merck for Mothers initiative. She has provided incredibility insightful and essential input in to my dissertation.

I would also like to thank my colleagues at Merck who have helped me during my dissertation, Drs. Felicia Allen-Ramey, Vinay Mehta, Yong Chen, and the entire Merck for Mothers organization for striving to improve maternal health worldwide.

I am utmost appreciate and grateful for my loving wife, Abby, and my entire family who have supported me during my long education journey. Without their support, no one of this would have been possible. I am forever grateful for them.

TABLE OF CONTENTS

ABSTRACT OF DISSERTATION ii
ACKNOWLEDGMENTv
TABLE OF CONTENTS vi
LIST OF TABLESvii
LIST OF FIGURESix
INTRODUCTION1
PAPER 1 – THE INCIDENCE OF SEVERE MATERNAL MORBIDITY IN THE UNITED STATES 20
PAPER 2 –RATES OF HOSPITAL READMISSIONS AND EMERGENCY ROOM VISITS IN THE 30 DAYS FOLLOWING A HOSPITALIZED DELIVERY WITH SEVERE MATERNAL MORBIDITY
PAPER 3 – THE ECONOMIC BURDEN OF SEVERE MATERNAL MORBIDITY IN THE UNITED STATES
CONCLUSION
BIBLIOGRAPHY

LIST OF TABLES

INTRODUCTION

Table 1. Preexisting Comorbidities and Obstetric Complications Identified in the Literature as Risk Factors

PAPER 1 – THE INCIDENCE OF SEVERE MATERNAL MORBIDITY IN THE UNITED STATES

Table 1. Demographics and Characteristics of All Deliveries and By Severe Maternal Mortality (SMM) Status in the Commercially Insured Population, 2016

Table 2. Demographics and Characteristics of All Deliveries and By Severe Maternal Mortality (SMM) Status in the Medicaid Population, 2015-2017

Table 1A. Severe Maternal Morbidity Indicators and Corresponding ICD-10 Codes during DeliveryHospitalization

Table 2A. Preexisting Comorbidities and Obstetric Complication Identified in the Literature as Risk Factors

Table 3A. Population Selection Process for Estimating Severe Maternal Mortality in 2016 Table 4A. Frequency, Percentage and Incidence Rates per 10,000 of Severe Maternal Mortality (SMM) and Indicators by Delivery Method in the Commercially Insured Population, 2015-2017 Table 5A. Association of Severe Maternal Mortality and Risk Factors in the Commercial Population, 2015-2017

Table 6A. Unadjusted Logistic Regression Model (Commercial)

Table 7A. Incidence of Severe Maternal Mortality and Indicators by Delivery Method in the Medicaid Population, 2015-2017

Table 8A. Association of Severe Maternal Mortality and Risk Factors in the Medicaid Population, 2015-2017

Table 9A. Unadjusted Logistic Regression Model (Medicaid)

PAPER 2 –RATES OF HOSPITAL READMISSIONS AND EMERGENCY ROOM VISITS IN THE 30 DAYS FOLLOWING A HOSPITALIZED DELIVERY WITH SEVERE MATERNAL MORBIDITY

Table 1. Demographics and Characteristics of Deliveries by 30-Day Hospital Readmission Status in the Commercially Insured Population, 2016

Table 2. Ten Most Common Primary Discharge Diagnoses for 30-day Hospital Readmissions in the Commercial Population, 2016

Table 3. Adjusted Model of Risk Factors Predictive of 30-day Hospital Readmissions following a Delivery Hospitalization Discharge in the Commercial Population, 2016

Table 4. Demographics and Characteristics of Deliveries by 30-Day Hospital Readmission Status in the Medicaid Population, 2016

Table 5. Ten Most Common Primary Discharge Diagnoses for 30-day Hospital Readmissions in the Medicaid Population, 2016

Table 6. Adjusted Model of Risk Factors Predictive of 30-day Hospital Readmissions following aDelivery Hospitalization Discharge in the Medicaid Population, 2016

Table 1A. Clinical Characteristics of Deliveries by 30-Day Hospital Readmission Status in the Commercially Insured Population, 2016

Table 2A. SMM Indicators associated with 30-day Hospital Readmission in the Commercial Population, 2016

Table 3A. Demographics and Characteristics of All Deliveries by 30-Day Emergency Room Visit in the Commercially Insured Population, 2016

Table 4A. SMM Indicators associated with 30-day Emergency Room Visits in the Commercial Population, 2016

Table 5A. Top Ten Discharge Diagnoses for 30-day Emergency Room Visit in the Commercial Population, 2016

Table 6A. Clinical Characteristics of Deliveries by 30-Day Hospital Readmission Status and SMM Status in the Medicaid Population, 2016

Table 7A. SMM Indicators associated with 30-day Hospital Readmission in the Medicaid Population, 2016

Table 8A. Demographics and Characteristics of Deliveries by 30-Day Emergency Room Visit in the Medicaid Insured Population, 2016

Table 9A. SMM Indicators associated with 30-day Emergency Room Visits in the Medicaid Population, 2016

Table 10A. Top Ten Discharge Diagnoses for 30-day Emergency Room Visit in the Medicaid Population, 2016

PAPER 3 – THE ECONOMIC BURDEN OF SEVERE MATERNAL MORBIDITY IN THE UNITED STATES

Table 1. Predictors of Adjusted Delivery Cost in the Commercial Population

Table 2. Predictors of Adjusted Delivery Cost in the Medicaid Population

Table 1A. Selected pre-existing conditions and pregnancy-related complications from the literature

Table 2A. Mean (SD) costs without and with severe maternal morbidity in the commercial population, by maternal characteristics

Table 3A. Median (IQR) costs without and with severe maternal morbidity in the commercial population, by maternal characteristics

Table 4A. Costs without and with Severe Maternal Morbidity (SMM) in the Commercial population, by payment source

Table 5A. Mean (SD) costs without and with severe maternal morbidity in the Medicaid population, by maternal characteristics

Table 6A. Median (IQR) costs without and with severe maternal morbidity in the Medicaid population, by maternal characteristics

Table 7A. Costs without and with Severe Maternal Morbidity (SMM) in the Medicaid population, by payment source

Table 8A. Demographic and Clinical Characteristics of the Primary and Sensitivity Analysis in the Medicaid Population

Table 9A. Comparison of Mean Delivery Costs between the Primary and Sensitivity Medicaid Analysis

Table 10A. Comparison of Median Delivery Costs between the Primary and Sensitivity Medicaid Analysis

LIST OF FIGURES

INTRODUCTION

Figure 1. Maternal Health Iceberg

Figure 2. Rate of Severe Maternal Morbidity per 10,000 delivery hospitalizations from 1993 to 2015

Figure 3. SMM Risk Factors Directed Acyclic Graph (DAG)

Figure 4. Percentage of first births, by age of mother: United States, 2000 – 2014

Figure 5. Rate of any severe maternal morbidity per 10,000 total delivery hospitalizations by age category in 2015

Figure 6. The distribution of age of all delivery hospitalizations, by patient race/ethnicity, and total SMM rate in 2015

PAPER 1 – THE INCIDENCE OF SEVERE MATERNAL MORBIDITY IN THE UNITED STATES

Figure 1. Distribution of Maternal Age by Delivery Method

Figure 2. Incidence of Severe Maternal Morbidity Indicators by Delivery Type

Figure 3. Distribution of Maternal Age by Delivery Method

Figure 4. Incidence of Severe Maternal Morbidity Indicators by Delivery Type

Figure 1A. Distribution of Incidence of Severe Maternal Mortality by Age in the Commercial Population

Figure 2A. Distribution of Deliveries by Severe Maternal Mortality Status in the Commercial Population

Figure 3A. Distribution of Incidence of Severe Maternal Mortality by Age in the Medicaid Population

Figure 4A. Distribution of Maternal Deliveries by Severe Maternal Mortality Status in the Medicaid Population

PAPER 2 –RATES OF HOSPITAL READMISSIONS AND EMERGENCY ROOM VISITS IN THE 30 DAYS FOLLOWING A HOSPITALIZED DELIVERY WITH SEVERE MATERNAL MORBIDITY

Figure 1A. Frequency of Days Between Delivery Discharge and Hospital Readmission in the Commercial Population, 2016

Figure 2A. Frequency of Days Between Delivery Discharge and ER Visit in the Commercial Population, 2016

Figure 3A. Frequency of Days Between Delivery Discharge and Hospital Readmission in the Medicaid Population, 2016

Figure 4A. Frequency of Days Between Delivery Discharge and ER Visit in the Medicaid Population, 2016

PAPER 3 – THE ECONOMIC BURDEN OF SEVERE MATERNAL MORBIDITY IN THE UNITED STATES

Figure 1. Total Mean Cost Across Time Periods by Severe Maternal Morbidity (SMM) Status in the Commercial Population

Figure 2. Mean Delivery Cost by SMM Indicator in the Commercial Population

Figure 3. Total Mean Cost Across Time Periods by Severe Maternal Morbidity (SMM) Status in the Medicaid Population

Figure 4. Total Mean Cost Across Race/ Ethnicity by Severe Maternal Morbidity (SMM) Status in the Medicaid Population

Figure 5. Mean Delivery Cost by Severe Maternal Morbidity (SMM) Indicator in the Medicaid Population

Figure 1A. Total Mean Cost Across Age Strata by Severe Maternal Morbidity (SMM) Status in the Commercial Population

Figure 2A. Forest Plot of Unadjusted Delivery Cost Predictors in the Commercial Population Figure 3A. Forest Plot of Unadjusted Delivery Cost Predictors in the Medicaid Population

Figure 4A. Mean Delivery Cost by Number of Severe Maternal Morbidity (SMM) Indicators in the Commercial Population

Figure 5A. Mean Delivery Cost by Number of Severe Maternal Morbidity (SMM) Indicators in the Medicaid Population

Introduction Chapter

The goal of this thesis is to understand the epidemiologic and economic burden of severe maternal morbidity (SMM) in the United States using administrative claims data. This study aims to answer three research questions: 1) "What is the incidence of SMM in 2016?" 2) "What is the incidence rate and predictors of unplanned 30-day hospital readmissions and emergency room (ER) visits after a delivery hospitalization among women with and without SMM?" and 3) "What are the associated healthcare resource utilization costs associated with SMM across the prenatal, delivery, and postpartum period?" The following section introduces SMM, including the epidemiology, risk factors, and the most recent literature on the topic. Each research question is addressed in a separate paper. Paper one addresses the epidemiology of SMM. Paper two addresses the unplanned readmission and ER visits after delivery hospitalizations. Paper three addresses the economic burden associated with SMM.

Maternal Health & Maternal Mortality

The World Health Organization (WHO) defines maternal health as the health of women during pregnancy, childbirth, and the postpartum period.¹ It encompasses the health care dimensions of family planning and preconception, prenatal, and postnatal care to ensure a positive and fulfilling experience in most cases, and to reduce maternal morbidity and mortality in others. It is estimated that every day 830 women worldwide die from preventable causes related to pregnancy and childbirth.¹ The health of mothers, infants, and children within a country predicts the future health and potential of the subsequent generations.²

High rates of maternal mortality present a serious global public health problem that has been a priority for the WHO, the United Nations (UN), and other global agencies.¹⁻³ The United Nations' Millennium Development Goals (MDGs) were eight goals that UN Member States agreed to attempt to achieve by the year 2015. These goals were set in 1990 to address poverty, hunger, disease, illiteracy, environmental degradation, and discrimination against women. Goal 5 was to improve maternal health by reducing the maternal mortality ratio (MMR) by three-quarters and achieving universal access to reproductive healthcare. Between 1990 and 2015 the number of global maternal deaths decreased from 523,000 in 1990 to 289,000 in 2015, but the MMR only decreased by half of the stated target.² Improving access to reproductive healthcare also fell short, with only 83 percent of women receiving prenatal care at least once during their pregnancies, and with only 64 percent receiving the recommended minimum of four or more visits.² While the MDGs led to a reduction in the global MMR, they also highlighted that greater work was required to address the complex issue of improving maternal health globally.

In 2016, the UN's eight MDGs were succeeded by 17 Sustained Development Goals (SDGs) with the objective of addressing social and economic development issues by 2030.⁴ The third SDG aims to ensure healthy lives and promote well-being for all persons at all ages. One of the targets of this goal is to reduce the global MMR to less than 70 deaths per 100,000 live births.⁴ The MDGs and SDGs highlight that maternal health is a global public health concern.

While the MMR in high-income countries is lower than in low-income countries, the United States ranks 46th globally behind almost every other high-income nation.⁵ The number of reported pregnancy-related deaths in the United States steadily increased from 7.2 deaths per 100,000 live births in 1987 to 14.0 deaths per 100,000 live births in 2014.⁶ With the average global MMR

decreasing over time, the fact that the MMR in the United States is increasing raises serious concerns about the quality of reproductive care in the United States.

Maternal Morbidity

The SDG and MDG establish goals to improve maternal health by reducing MMR, which is just one of the many measures of maternal health. The serious burden of maternal mortality is only a small fraction of the overall burden of maternal morbidity - health problems borne by women during pregnancy and the postpartum period.² Callaghan et al. described maternal mortality as the tip of the maternal health iceberg and maternal morbidity as the unobservable hazard lying below.⁷

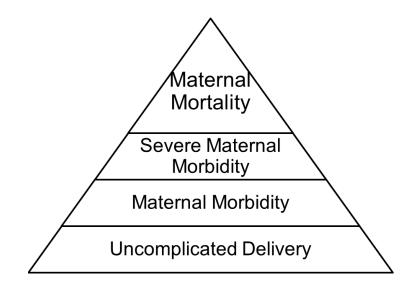


Figure 1. Maternal Health Iceberg

The WHO Maternal Morbidity Working Group defines maternal morbidity as "any health condition attributed to and/or complicating pregnancy and childbirth that has a negative impact on the woman's wellbeing and/or functioning."⁸ The adjacent unobservable but related hazard that is severe maternal morbidity (SMM) is defined by CDC as an instance in which a woman almost dies from a life-threatening complication during pregnancy or childbirth.³ Some

researchers refer to severe maternal morbidity as a "near miss."⁷⁻⁹ While maternal mortality is the more commonly measured health indicator, it is estimated that 50 to 100 women experience SMM for every maternal death in the United States. ³ SMM indicators are related to the leading causes of maternal mortality: hemorrhage, hypertension, and sepsis.¹⁰

Severe Maternal Morbidity in the United States

National rates of SMM in the United States have been reported by CDC and the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP). Both national estimates demonstrate increasing trends in SMM rates in the United States from 49.5 cases per 10,000 delivery hospitalizations in 1993¹¹ to 146.6 per 10,000 delivery hospitalizations in 2015, ⁹ increasing nearly threefold over 22 years.

CDC estimated the rate of SMM from 1993 to 2014 by analyzing data from the National Inpatient Sample (NIS), the largest all-payer hospital inpatient care database in the United States yielding national estimates of hospital inpatient stays. ^{3,7,12} NIS is sponsored by AHRQ in partnership with state-level data collection organizations to provide national estimates for inpatient care. ^{9,13} The NIS is the largest publicly available all-payer inpatient health care database in the United States, After weighting, the sample estimates more than 35 million hospitalizations nationally. HCUP data informs decision-making at the national, state, and community levels.¹² The NIS approximates a 20-percent stratified sample of discharges from U.S. community hospitals, excluding rehabilitation and long-term acute care hospitals.¹²

In September 2018, AHRQ published HCUP Statistical Brief #243 - Trends and Disparities in Delivery Hospitalizations Involving Severe Maternal Morbidity, 2006-2015. ⁹ This document presented trends and disparities in delivery hospitalizations involving SMM from 2006 through the third quarter of 2015. The fourth quarter of 2015 was excluded because of the transition of

the International Classification of Diseases (ICD) coding system from the 9th to the 10th revision. ^{9,14} The report presented analyses from the HCUP database, which brings together the data collection efforts of state, hospital, and private organizations, as well as the Federal government to create a national information resource of encounter-level health care data. HCUP includes the largest collection of longitudinal hospital care data in the United States, with all-payer, encounterlevel information beginning in 1998.

SMM Indicators and ICD transition

In October 2015, the United States transitioned to the 10th revision of the ICD, creating 19 times more procedure codes and five times more diagnostic codes. ¹⁴ CDC revised the SMM coding, updating the indicators with the new corresponding ICD-10 codes, as well as considering results from validation studies.^{3,15-17} The updated list grouped some indicators together and dropped others, reducing SMM indicators from 25 to 18. The indicators dropped were intracranial injuries, internal injuries of the thorax, abdomen, and pelvis, operations on health and pericardium, and cardio monitoring. A published ICD-9 / ICD-10 cross-reference allows researchers to identify SMM cases prior to and after the ICD-10 transition. There are no estimates of the incidence of SMM in the United States since the transition to ICD-10. The most recent CDC estimate is from 2014 and the AHRQ analysis used the ICD-9 indicator list in only the first three quarters of 2015, excluding data after the transition.^{3,9}

Among the 18 SMM indicators, the most prevalent is blood transfusion, accounting for 83 percent of cases in 2015.^{3,9} Figure 2 shows that the increasing rate of SMM in the United States since 1993 was mostly driven by the increase in blood transfusions. This is of concern since the procedure is used to address postpartum hemorrhage, the leading cause of maternal mortality.¹⁸

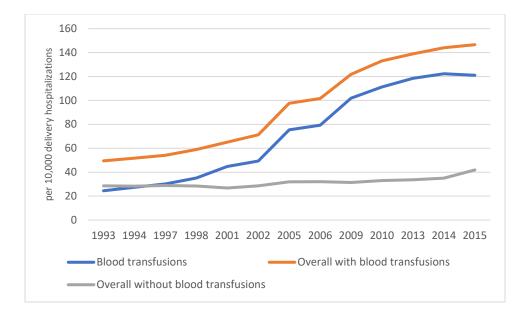


Figure 2. Rate of Severe Maternal Morbidity per 10,000 delivery hospitalizations from 1993 to 2015

Source: Adapted from Fingar KF HM, Heslin KC, Moore JE⁹

SMM Risk Factors

Several interrelated risk factors are associated with SMM. Figure 3 is a directed acyclic graph (DAG) depicting the complicated relationship between key SMM risk factors. Maternal age is important as it is directly related to many other known risk factors, specifically non-pregnancy and pregnancy-related comorbidities, multiple gestation, assisted reproductive technology (ART), parity and pregnancy history, mode of delivery, income, educational attainment, and access to prenatal care. ^{7,9,10,19-27}

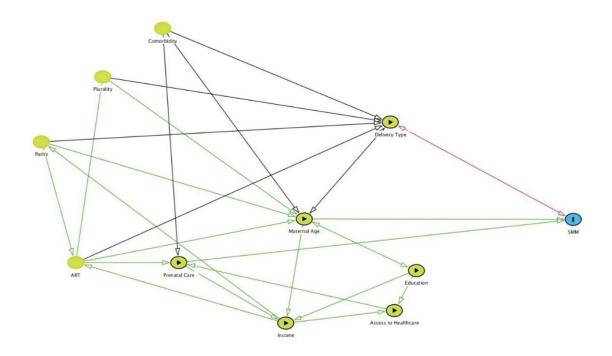


Figure 3. SMM Risk Factors Directed Acyclic Graph (DAG) Note: Figure created using Dagitty software²⁸²⁸

The average age of women at first birth has risen over the past four decades from 22.8 to 26.0 years.²⁹⁻³² This increase is in part a reflection of the shift in first births to women 35 years and older.³³ From 2000 to 2014, the proportion of first births decreased for those under 20 years, remained the same for those 20 to 24 years, and increased for those 25 years and over (Figure 4).³²

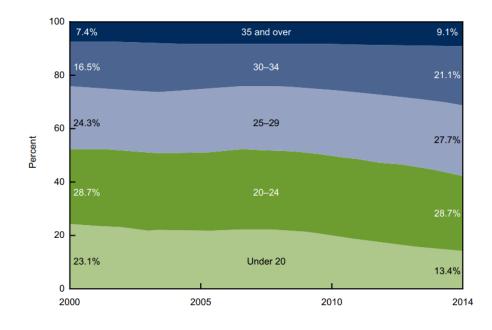


Figure 4 Percentage of first births, by age of mother: United States, 2000 - 2014Source: Adapted from Mathews TJ HB ³²

Increased health risks to older mothers, especially those 40 years and older, and their infants are well documented.^{9,30,33} First time older mothers are generally better educated and more likely to have more resources, including higher incomes, than those at the youngest reproductive ages.³⁴ With increasing maternal age comes greater risk of pregnancy-related complications and SMM. In the 2015 AHRQ analysis, the rate of SMM per 10,000 total delivery hospitalizations increased with age (from 136.3 among women aged 20 to 29 years to 248.0 among those aged 40+ years). Also, the rate of SMM was elevated among women aged less than 20 years (206.3 per 10,000 delivery hospitalizations), demonstrating a bimodal distribution of risk (Figure 5).

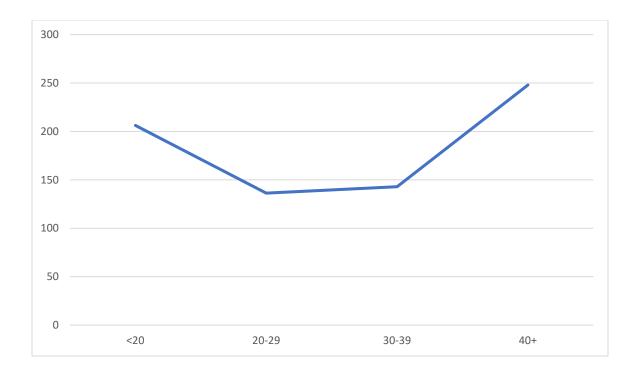


Figure 5. Rate of any severe maternal morbidity per 10,000 total delivery hospitalizations by age category in 2015 Source: Data from Fingar KF, H. M., Heslin KC, Moore JE⁹

As maternal age increases, the risk of infertility and complications also increases. Women experiencing fertility problems often use ART, a practice which has doubled over the past decade.³⁵ The Society for Assisted Reproductive Technology 2016 report states that the number of ART treatment cycles and live birth deliveries has continued to rise since 1985.³⁶ The Society estimates that about 1.5 percent of all children born in the United States are the result of ART, totaling 1.1 million children since 2006. Maternal age continues to be the strongest influence on the success of a treatment cycle.

ART has risks linked to adverse obstetric outcomes, including increased risk of gestational diabetes, hypertensive disorders of pregnancy, placenta previa, antepartum hemorrhage, placental abruption, and cesarean delivery, all of which are risk factors for SMM.³⁷⁻³⁹ An analysis by Martin et al. estimated the odds of SMM were 1.8 times higher among singleton ART

pregnancies compared to non-ART pregnancies, after controlling for several risk factors.²⁰ Retrospective analysis of administrative claims data evaluating the relationship between SMM and ART is difficult because many cases are not reimbursed by healthcare plans and will be misclassified as non-ART pregnancies.⁴⁰

Mode of Delivery

Mode of delivery is an important risk factor for SMM, other maternal morbidity, and maternal mortality. Cesarean sections are indicated for several situations: failure of labor to progress, concern for the baby, multiple gestation, placenta problems, baby size, breech presentation, maternal infections such as human immunodeficiency virus or herpes, and maternal medical conditions such as diabetes mellitus or high blood pressure.⁴¹ Ultimately, the decision about the mode of delivery is made by the mother and her physician.

Between 1970 and 2016, the cesarean delivery rate in the United States increased from 5 to 31.9 percent of all live deliveries. There are many theories proposed that attempt to explain this trend, including a decrease in vaginal births after cesarean delivery (VBAC), increased maternal requests for cesarean deliveries, increased number of expectant mothers at high risk, the obstetrical medico-legal environment, changes in provider practice patterns, and fears of malpractice litigation.⁴²⁻⁴⁵ Improvements in technology, such as high resolution ultrasounds, are suspected to be associated with the increased frequency of cesarean section as they reveal the location and position of the fetus, fetal anatomy, and detection of uterus, placenta, or cervix abnormalities.⁴⁶ This information provided during an ultrasound could influence the decision for a cesarean section.⁴¹

An examination of physician-documented indications for cesarean delivery for 32,443 live births found that half of all cesarean deliveries were to women who had a prior cesarean delivery.⁴⁵ The

increasing rate of repeat cesarean sections dates back to 1916 when Cragin coined the maxim, "Once a cesarean always a cesarean."⁴⁷ The message was a potent one, as 100 years later very low rates of vaginal births after cesarean section (VBAC) persist.⁴⁵ Publications in the 1960s reported the increased risk of uterine rupture during a trial of labor after cesarean (TOLAC).^{48,49} Investigators reevaluated the risk and recommended TOLAC for low-risk women with a previous cesarean delivery, and VBAC rates did rise from 5 percent in 1985 to 43.9 percent in 1998.⁴³ Successful attempts at TOLAC leading to VBAC resulted in lower morbidity than planned repeat procedures, however failed trials of labor resulted in increased morbidity.⁵⁰ As the number of women attempting TOLAC increased, so did the number of reports of uterine rupture and other complications related to failed TOLAC.^{51,52} Evidence about the risk of uterine rupture and elivery trends. By 2009, the VBAC rate decreased to 7.8 percent, while the total cesarean delivery rate increased to 31.9 percent in 2016.^{33,44,53} In California, some hospitals stopped offering TOLAC altogether.⁵⁴

While there is risk associated with both vaginal and cesarean section modes of delivery, cesarean section deliveries pose an increased risk of:

- maternal mortality (3.6 vs. 13.3 per 100,000 deliveries),
- amniotic fluid embolism (3.3-7.7 vs. 15.8 per 100,000 deliveries),
- blood transfusions (167.1 vs. 525.1 per 100,000 live births),
- ICU admissions (64.6 vs. 383.1 per 100,000 live births),
- unplanned hysterectomy (11.9.3 vs. 67.5 per 100,000 live births) and
- ruptured uterus (6.3 vs. 49.2 per 100,000 live births).

Repeat cesarean section also has higher rates of morbidity compared to VBAC.55

Race and Ethnicity

Robust evidence exists documenting the disparate racial and ethnic risks for maternal mortality and maternal morbidity, including SMM.^{9,10,21,23,24,27,56} One factor that accounts for this risk differential is maternal age. Figure 6 depicts the differences in the distribution of maternal age and the total incidence rate of SMM by race/ethnicity group in 2015. Among delivery hospitalizations, Black and Hispanic women were younger than White and Asian/Pacific Islander women.⁹ The rate of severe maternal morbidity per 10,000 delivery hospitalizations was 240.7 for Blacks—49 percent higher than the rate among Hispanics (161.3), 74 percent higher than the rate among Asian/Pacific Islanders (138.7), and 112 percent higher than the rate among Whites (113.6).⁹ Shen et al., showed that White women have lower odds of SMM indicators and risk factors including preeclampsia, placental abruption, and diabetes compared to Black, Hispanic and Asian/Pacific Islander women.⁵⁷

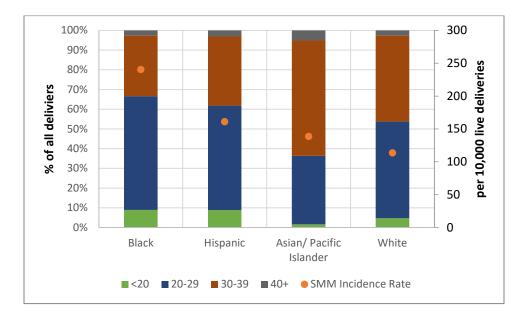


Figure 6 The distribution of age of all delivery hospitalizations, by patient race/ethnicity, and total SMM rate in 2015

Source: Fingar KF, HM, Heslin KC, Moore JE⁹

Socioeconomic Status

Education, income, and insurance coverage are risk factors for SMM.^{9,23} Women with less than a high school education are at increased risk of SMM compared to women with a high school

education.²³ Similarly, women without insurance and those who are covered by Medicaid have higher rates of SMM compared to women with private insurance (176.5 and 175.0, respectively, vs. 120.8 per 10,000 live deliveries).^{9,23} Results from the AHRQ analysis demonstrated a higher proportion of SMM deliveries occurring at hospitals that typically have a mission to serve vulnerable populations. These high risk hospitals include those considered safety-net (43.6% vs. 35.1%), minority-serving (53.4% vs. 44.3%), teaching (70.6% vs. 66.7%), and public (15.7% vs. 12.3%) hospitals, compared to other hospitals that do not fall into these categories.⁹

Clinical Risk Factors

Obesity is an established risk factor for maternal morbidity, whether it's pre-pregnancy obesity, excessive weight gain, or delivery obesity, all are related to adverse outcome.⁵⁸⁻⁶⁰ Women with obesity have higher rates of cesarean deliveries due to prolonged labor and slowed cervical dilation, reducing the opportunity for trial of labor. ⁶¹⁻⁶³ Obesity also poses a risk of anesthetic complications,⁶⁴ gestational hypertension, preeclampsia, gestational diabetes, macrosomia and wound complications. ^{64,65} Obesity is a great concern for women and their care providers in the United States since it's been estimated that more than a third of women in the United States are obese.⁶⁶

Hypertension during pregnancy has been associated with increased risk of morbidity and mortality. Chronic hypertension, which presents before a woman becomes pregnant or within the first 20 weeks, and gestational hypertension, defined as hypertension occurring after 20 weeks of gestation, are associated with increased risk of maternal morbidity and mortality.^{22,23,67,68} Hypertension places extra stress on a woman's heart and kidneys and can increase the risk for heart disease, kidney disease, and stroke.^{67,69-71} Women with hypertension are at an increased risk for obstetric complications like preeclampsia, preterm delivery, placental abruption, as well

as the increased need for a cesarean section delivery.⁷² Hypertension poses a serious risk for women during their pregnancy and is associated with an increased risk of maternal mortality.⁷³

There are many more risk pre-existing comorbidities and obstetric-related complications that increase the risk of severe maternal morbidity. This analysis included twelve obstetric complications and twenty-three preexisting comorbidities from the literature to be evaluated (Table 1).

Preexisting Comorbidities	Obstetric complications				
Nonhereditary nonhemolytic anemia	Abnormal glucose tolerance				
Hereditary hemolytic anemia	Amniotic sac				
Clotting disorders	Cervical incompetence				
Tuberculosis	Structural abnormality				
	(uterus/cervix/vagina/vulva)				
Human immunodeficiency virus	Excess vomiting				
Diabetes in pregnancy	Placenta previa without hemorrhage				
Thyroid disorders	Gestational hypertension/preeclampsia				
Gall bladder disease	Antepartum hemorrhage including placenta				
	previa with hemorrhage				
Renal disease	Postpartum hemorrhage				
Liver disorders	Pelvic and perineal trauma				
Asthma	Uterine rupture				
Neurological conditions	Obstetric infection				
Cardiovascular condition	Urinary tract infection				
Other chronic disease	Pneumonia				
Mental health conditions	Appendicitis				
Obesity	Infections not classified elsewhere				
Chronic hypertension	Breast disorders				
	Complications of anesthesia				

Table 1. Preexisting Comorbidities and Obstetric Complications Identified in the Literature as Risk Factors

The next section builds upon this material, answering the research question: What is the 2016

incidence rate and associated risk factors of SMM in a national representative sample of

commercially and Medicaid insured women?

References

- 1. Maternal Health. <u>https://www.who.int/maternal-health/en/</u>. Accessed January 27, 2019.
- 2. Beattie RM, Brown NJ, Cass H. Millennium Development Goals progress report. *Archives of Disease in Childhood*. 2015;100:S1-S1.
- Severe Maternal Morbidity. 2017; <u>http://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidit</u> <u>y.html</u>. Accessed January 13, 2017.
- 4. Lee BX, Kjaerulf F, Turner S, et al. Transforming Our World: Implementing the 2030 Agenda Through Sustainable Development Goal Indicators. *Journal of Public Health Policy*. 2016;37(1):13-31.
- 5. Trends in Maternal Mortality: 1990 to 2015. *WHO, UNICEF, UNFPA, World Bank Group, and the United Nations Population Division*. Accessed January 27, 2019.
- 6. Pregnancy Mortality Surveillance System. <u>https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-mortality-</u> <u>surveillance-system.htm</u>. Accessed January 27, 2019.
- 7. Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstet Gynecol.* 2012;120(5):1029-1036.
- 8. Vanderkruik RC, Tunçalp Ö, Chou D, Say L. Framing maternal morbidity: WHO scoping exercise. *BMC pregnancy and childbirth.* 2013;13:213-213.
- 9. Fingar KF HM, Heslin KC, Moore JE. Trends and Disparities in Delivery Hospitalizations Involving Severe Maternal Morbidity, 2006–2015. *Agency for Healthcare Research and Quality (US).* 2018.
- 10. Hirshberg A, Srinivas SK. Epidemiology of maternal morbidity and mortality. *Semin Perinatol.* 2017;41(6):332-337.
- Callaghan WM, Mackay AP, Berg CJ. Identification of severe maternal morbidity during delivery hospitalizations, United States, 1991-2003. *Am J Obstet Gynecol.* 2008;199(2):133 e131-138.
- 12. INTRODUCTION TO THE HCUP NATIONAL INPATIENT SAMPLE (NIS). 2018; <u>https://www.hcup-us.ahrq.gov/db/nation/nis/NIS_Introduction_2016.pdf</u>. Accessed 2019, January 27.
- 13. Hirshberg A, Srinivas SK. Epidemiology of maternal morbidity and mortality. (1558-075X (Electronic)).
- 14. Federal Health Information Technology Strategic Plan 2011–2015. In: Technology OotNCfHI, ed. Vol 20182011.

- 15. Creanga AA. Maternal Mortality in the United States: A Review of Contemporary Data and Their Limitations. *Clin Obstet Gynecol.* 2018;61(2):296-306.
- 16. Kuklina EV, Whiteman MK, Hillis SD, et al. An enhanced method for identifying obstetric deliveries: implications for estimating maternal morbidity. *Matern Child Health J.* 2008;12(4):469-477.
- 17. Sigakis MJ, Leffert LR, Mirzakhani H, et al. The Validity of Discharge Billing Codes Reflecting Severe Maternal Morbidity. *Anesth Analg.* 2016;123(3):731-738.
- 18. Creanga AA, Syverson C, Seed K, Callaghan WM. Pregnancy-Related Mortality in the United States, 2011-2013. *Obstet Gynecol.* 2017;130(2):366-373.
- 19. Center PR. They're Waiting Longer, but U.S. Women Today More Likely to Have Children Than a Decade Ago. 2018.
- Martin AS, Monsour M, Kissin DM, Jamieson DJ, Callaghan WM, Boulet SL. Trends in Severe Maternal Morbidity After Assisted Reproductive Technology in the United States, 2008-2012. Obstet Gynecol. 2016;127(1):59-66.
- 21. Creanga AA, Bateman BT, Kuklina EV, Callaghan WM. Racial and ethnic disparities in severe maternal morbidity: a multistate analysis, 2008-2010. *Am J Obstet Gynecol.* 2014;210(5):435 e431-438.
- 22. Kuklina EV, Ayala C, Callaghan WM. Hypertensive disorders and severe obstetric morbidity in the United States. *Obstet Gynecol.* 2009;113(6):1299-1306.
- 23. Lazariu V, Nguyen T, McNutt LA, Jeffrey J, Kacica M. Severe maternal morbidity: A population-based study of an expanded measure and associated factors. *PLoS One.* 2017;12(8):e0182343.
- 24. Metcalfe A, Wick J, Ronksley P. Racial disparities in comorbidity and severe maternal morbidity/mortality in the United States: an analysis of temporal trends. *Acta Obstet Gynecol Scand.* 2018;97(1):89-96.
- 25. New York City Department of Health and Mental Hygiene BoM, Infant, and Reproductive Health, New York City Severe Maternal Morbidity Project Team. *Pregnancy-Associated Mortality: New York City, 2006-2010.* 2015.
- 26. Grobman WA, Bailit JL, Rice MM, et al. Frequency of and factors associated with severe maternal morbidity. *Obstet Gynecol.* 2014;123(4):804-810.
- 27. Holdt Somer SJ, Sinkey RG, Bryant AS. Epidemiology of racial/ethnic disparities in severe maternal morbidity and mortality. *Semin Perinatol.* 2017;41(5):258-265.
- 28. Textor J vdZB, Gilthorpe MS, Liskiewicz M, Ellison GT. Robust causal inference using directed acyclic graphs: the R package 'dagitty'. *Int J Epidemiol.* 2016;45(6):1887-1894.
- 29. Ventura SJ. Trends and variations in first births to older women, United States, 1970-86. (0083-2030 (Print)).
- 30. Matthews TJ, MacDorman MF. Infant mortality statistics from the 2010 period linked birth/infant death data set. *Natl Vital Stat Rep.* 2013;62(8):1-26.
- 31. E. G. Ready: Why women are embracing the new later motherhood, with a new preface. Basic Books. 2012.
- 32. Mathews TJ HB. *Delayed childbearing: More women are having their first child later in life. NCHS data brief, no 21.* National Center for Health Statistics;2009.
- 33. Martin JA, Hamilton BE, Osterman MJK. Births in the United States, 2016. *NCHS Data Brief.* 2017(287):1-8.
- 34. Martinez G, Daniels K Fau Chandra A, Chandra A. Fertility of men and women aged 15-44 years in the United States: National Survey of Family Growth, 2006-2010. 2012(2164-8344 (Print)).

- 35. Farquhar C, Rishworth JR, Brown J, Nelen W, Marjoribanks J. Assisted reproductive technology: an overview of Cochrane Reviews. *Cochrane Database of Systematic Reviews*. 2015(7).
- Toner JP, Coddington CC, Doody K, et al. Society for Assisted Reproductive Technology and assisted reproductive technology in the United States: a 2016 update. *Fertil Steril.* 2016;106(3):541-546.
- Pandey S, Shetty A, Hamilton M, Bhattacharya S, Maheshwari A. Obstetric and perinatal outcomes in singleton pregnancies resulting from IVF/ICSI: a systematic review and meta-analysis. *Hum Reprod Update*. 2012;18(5):485-503.
- 38. Smithers PR, Halliday J, Hale L, Talbot JM, Breheny S, Healy D. High frequency of cesarean section, antepartum hemorrhage, placenta previa, and preterm delivery in invitro fertilization twin pregnancies. *Fertil Steril.* 2003;80(3):666-668.
- Schieve LA, Cohen B, Nannini A, et al. A population-based study of maternal and perinatal outcomes associated with assisted reproductive technology in Massachusetts. *Matern Child Health J.* 2007;11(6):517-525.
- 40. ART and Insurance. 2016; <u>https://www.cdc.gov/art/key-findings/insurance.html</u>. Accessed December 5, 2018.
- 41. Gynecologists ACoOa. Cesarean Birth. 2018; https://www.acog.org/Patients/FAQs/Cesarean-Birth. Accessed November 5, 2018.
- 42. Menacker F, Hamilton BE. Recent trends in cesarean delivery in the United States. *NCHS Data Brief.* 2010(35):1-8.
- 43. Practice Bulletin No. 184: Vaginal Birth After Cesarean Delivery. (1873-233X (Electronic)).
- 44. Menacker F, Declercq E, Macdorman MF. Cesarean delivery: background, trends, and epidemiology. *Semin Perinatol.* 2006;30(5):235-241.
- 45. Barber EL, Lundsberg LS, Belanger K, Pettker CM, Funai EF, Illuzzi JL. Indications contributing to the increasing cesarean delivery rate. *Obstet Gynecol.* 2011;118(1):29-38.
- 46. Fetal Ultrasounds. <u>https://www.mayoclinic.org/tests-procedures/fetal-ultrasound/about/pac-20394149</u>. Accessed June 27, 2019.
- 47. Cragin E. Conservatism in obstetrics. *NY Med J.* 1916(104):1-3.
- 48. Lydon-Rochelle M, Holt VI Fau Easterling TR, Easterling Tr Fau Martin DP, Martin DP.
 Risk of uterine rupture during labor among women with a prior cesarean delivery.
 2001(0028-4793 (Print)).
- 49. Greene MF. Vaginal delivery after cesarean section--is the risk acceptable? *N Engl J Med.* 2001;345(1):54-55.
- 50. Lydon-Rochelle MT, Cahill Ag Fau Spong CY, Spong CY. Birth after previous cesarean delivery: short-term maternal outcomes. 2010(1558-075X (Electronic)).
- 51. Sachs BP, Kobelin C, Castro MA, Frigoletto F. The risks of lowering the cesarean-delivery rate. *N Engl J Med.* 1999;340(1):54-57.
- 52. Flamm BL. Once a cesarean, always a controversy. 1997(0029-7844 (Print)).
- 53. Yang YT, Mello Mm Fau Subramanian SV, Subramanian Sv Fau Studdert DM, Studdert DM. Relationship between malpractice litigation pressure and rates of cesarean section and vaginal birth after cesarean section. 2009(1537-1948 (Electronic)).
- 54. Barger MK, Dunn JT, Bearman S, DeLain M, Gates E. A survey of access to trial of labor in California hospitals in 2012. *BMC Pregnancy Childbirth.* 2013;13:83.
- 55. Curtin SC, Gregory KD, Korst LM, Uddin SF. Maternal Morbidity for Vaginal and Cesarean Deliveries, According to Previous Cesarean History: New Data From the Birth Certificate,

2013. National Vital Statistics Reports: From The Centers For Disease Control And Prevention, National Center For Health Statistics, National Vital Statistics System. 2015;64(4):1.

- Anderson JG, Rogers Ee Fau Baer RJ, Baer RJ Fau Oltman SP, et al. Racial and Ethnic Disparities in Preterm Infant Mortality and Severe Morbidity: A Population-Based Study. 2017(1661-7819 (Electronic)).
- 57. Shen JJ, Tymkow C Fau MacMullen N, MacMullen N. Disparities in maternal outcomes among four ethnic populations. 2005(1049-510X (Print)).
- 58. Weiss JL, Malone Fd Fau Emig D, Emig D Fau Ball RH, et al. Obesity, obstetric complications and cesarean delivery rate--a population-based screening study. 2004(0002-9378 (Print)).
- 59. Zhang J, Troendle J Fau Reddy UM, Reddy Um Fau Laughon SK, et al. Contemporary cesarean delivery practice in the United States. 2010(1097-6868 (Electronic)).
- 60. Marshall NE, Guild C, Cheng YW, Caughey AB, Halloran DR. Maternal superobesity and perinatal outcomes. *American journal of obstetrics and gynecology*. 2012;206(5):417.e411-417.e4176.
- 61. Kawakita T, Reddy UM, Landy HJ, Iqbal SN, Huang CC, Grantz KL. Indications for primary cesarean delivery relative to body mass index. *Am J Obstet Gynecol.* 2016;215(4):515 e511-519.
- 62. Schuster M, Madueke-Laveaux OS, Mackeen AD, Feng W, Paglia MJ. The effect of the MFM obesity protocol on cesarean delivery rates. *Am J Obstet Gynecol.* 2016;215(4):492 e491-496.
- 63. Girsen AI, Osmundson SS, Naqvi M, Garabedian MJ, Lyell DJ. Body mass index and operative times at cesarean delivery. *Obstetrics and gynecology*. 2014;124(4):684-689.
- 64. Butwick A, Carvalho B Fau Danial C, Danial C Fau Riley E, Riley E. Retrospective analysis of anesthetic interventions for obese patients undergoing elective cesarean delivery. 2010(1873-4529 (Electronic)).
- 65. McLean M, Hines R Fau Polinkovsky M, Polinkovsky M Fau Stuebe A, Stuebe A Fau -Thorp J, Thorp J Fau - Strauss R, Strauss R. Type of skin incision and wound complications in the obese parturient. 2012(1098-8785 (Electronic)).
- Flegal KM, Carroll Md Fau Kit BK, Kit Bk Fau Ogden CL, Ogden CL. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010.
 2012(1538-3598 (Electronic)).
- 67. Martin JN, Jr., Thigpen Bd Fau Moore RC, Moore Rc Fau Rose CH, Rose Ch Fau Cushman J, Cushman J Fau May W, May W. Stroke and severe preeclampsia and eclampsia: a paradigm shift focusing on systolic blood pressure. 2005(0029-7844 (Print)).
- 68. Small MJ, James AH, Kershaw T, Thames B, Gunatilake R, Brown H. Near-miss maternal mortality: cardiac dysfunction as the principal cause of obstetric intensive care unit admissions. *Obstet Gynecol.* 2012;119(2):250-255.
- 69. Kuklina EV, Callaghan WM. Cardiomyopathy and other myocardial disorders among hospitalizations for pregnancy in the United States: 2004-2006. *Obstet Gynecol.* 2010;115(1):93-100.
- 70. Kuklina EV, Tong X, Bansil P, George MG, Callaghan WM. Trends in pregnancy hospitalizations that included a stroke in the United States from 1994 to 2007: reasons for concern? *Stroke*. 2011;42(9):2564-2570.

- 71. Sharshar T, Lamy C Fau Mas JL, Mas JL. Incidence and causes of strokes associated with pregnancy and puerperium. A study in public hospitals of Ile de France. Stroke in Pregnancy Study Group. 1995(0039-2499 (Print)).
- 72. Kattah AG, Garovic VD. The management of hypertension in pregnancy. *Advances in chronic kidney disease*. 2013;20(3):229-239.
- 73. Yuan S-M. Eisenmenger Syndrome in Pregnancy. *Brazilian journal of cardiovascular surgery*. 2016;31(4):325-329.

PAPER 1 – THE INCIDENCE OF SEVERE MATERNAL MORBIDITY IN THE UNITED STATES

Précis

This study helps address the question of the incidence and risk factors of severe maternal morbidity (SMM) in the commercially insured and Medicaid populations.

Abstract

Objective: To estimate the 2016 incidence rate and associated risk factors of SMM in a nationally representative sample of commercially and Medicaid-insured women

Methods: This was a retrospective cohort study of women with a live inpatient delivery during 2016 in the MarketScan databases for commercially insured and Medicaid populations. The incidence of severe maternal morbidity and the frequencies of 18 individual SMM indicators, as defined by the Center for Disease Control & Prevention's algorithm of ICD-10 diagnostic and procedural codes was calculated. Measurements also include the association in bivariate analyses with patient characteristics; association of delivery type, gestation type, and maternal age with severe maternal morbidity in multivariate logistic regression analysis, adjusted for pre-existing conditions and pregnancy-related complications.

Results: There were 170,670 live births in the commercially-insured population and 265,330 in the Medicaid population. The incidence of severe maternal morbidity was 113.4 per 10,000 deliveries in the Commercial population and 109.6 per 10,000 deliveries in the Medicaid population. The most frequent severe maternal morbidity indicators were eclampsia, blood transfusion and disseminated intravascular coagulation (35.0 and 25.7 per 10,000 deliveries) in the Commercial population and eclampsia and adult respiratory distress syndrome (45.5 and 14.9 per 10,000 deliveries) in the Medicaid population. In the multivariate analysis, a cesarean delivery and multifetal gestation was associated with severe maternal morbidity in both Commercial (OR 3.37; 95% CI 1.51, 1.84; OR: 3.37; 95%CI 2.8, 4.10) and Medicaid populations (OR 1.99; 95%CI 1.80, 2.17; OR: 2.26; 95%CI: 1.86, 2.75). Race was also associated with an increased risk of SMM (White vs Black OR:0.78; 95%CI: 0.70, 0.87)

Conclusion: The results of this analysis showed that a cesarean delivery, multifetal gestation, race, and several preexisting comorbidities and obstetric complications were associated with severe maternal morbidity in both the Commercial and Medicaid populations.

Key words: epidemiology, maternal mortality, morbidity, pregnancy complications

Introduction

The United States is one of only 17 countries where the rate of maternal death is on the rise, ¹⁻⁹ with the maternal mortality ratio more than doubling since 1990.⁹ Maternal mortality is simply the tip of the maternal health iceberg, with severe maternal morbidity (SMM) lying below the line of sight as a large and an increasing problem.¹⁰ Indeed, the incidence of SMM in the United States increased from 49.5 per 10,000 hospitalized deliveries in 1993 to 146.6 per 10,000 in 2015.^{11,12}

In October 2015, the U.S. Department of Health and Human Services (HHS) required that all health care providers, health plans, and health care clearinghouses transition to the tenth revision of the International Classification of Diseases (ICD-10).¹³ The most recent national estimate of SMM incidence was in 2014, with a 2015 estimate based off of the first three quarters of the year prior to the transition to ICD-10. ^{11,12} As the transition reduced the number of indicators from 25 to 18,¹² a new estimate of SMM incidence is sorely needed.

The National Inpatient Sample used previously to estimate the incidence of SMM^{10,12} lacked the longitudinal data necessary to assess comorbid conditions and obstetric risk factors. Longitudinal

databases, like administrative claims data, does allow for that assessment. This paper reports the results of an analysis to estimate the 2016 incidence rate and associated risk factors of SMM in a nationally representative sample of commercially and Medicaid-insured women.

Materials and Methods

Study design and data sources

This retrospective analysis utilized data from the MarketScan[®] Commercial Claims and Encounters ("Commercial") database, and the MarketScan[®] Medicaid database to create a longitudinal cohort of live births occurring in 2016. These databases include paid medical and prescription drug claims for 115 million unique patients from approximately 200 self-insured U.S. employers, 30 health plans, and 11 Medicaid agencies.¹⁴ The Commercial database contains insurance claims of employees and their dependents covered under a variety of fee-for-service and capitated health plans, including exclusive provider organizations (EPO), preferred provider organizations (PPOs), point of service (POS) plans, indemnity plans, and health maintenance organizations (HMOs). Complete payment information is captured, including both what the benefit plan and the patient paid. Furthermore, the Commercial database is geographically representative of the United States and has defined region variables, unlike the Medicaid database.¹⁴

The Medicaid database includes inpatient services and prescription drug claims, as well as information on enrollment, long-term care, and other medical care. The Medicaid database also records race as a variable, which is not available in the Commercial database. Although the patients are de-identified, long-term patient data are available longitudinally.

Study sample

The study population included all women with live births in 2016, identified by ICD-10, Current

Procedural Terminology (CPT), and Diagnosis Related Group (DRG) codes.¹ Males were excluded,

as well as deliveries with codes not indicating a live birth such as molar pregnancy or ectopic

pregnancy.²

Outcomes and Covariates

SMM was defined by the occurrence during a delivery of one or more of the 18 potentially life-

threatening maternal conditions or complications listed in ICD-10 (Appendix Table 1A):

- Acute myocardial infarction/aneurysm
- Acute renal failure
- Adult respiratory distress syndrome
- Amniotic fluid embolism
- Cardiac arrest/ventricular fibrillation/conversion of cardiac rhythm
- Disseminated intravascular coagulation
- Eclampsia
- Heart failure/arrest during surgery or procedure
- Puerperal cerebrovascular disorders
- Pulmonary edema/acute heart failure
- Severe anesthesia complications
- Sepsis
- Shock
- Sickle cell disease with crisis
- Air and thrombotic embolism
- Blood transfusion
- Hysterectomy
- Ventilation/temporary tracheostomy

¹ ICD-10 Diagnostic (Z37, O80, O300) and Procedure Codes (10D07Z3, 0W8NXZZ with: 10D07Z4, 10D07Z5,10S07ZZ, 10D07Z6, 10D07Z8, 10D07Z7, 10E0XZZ, 0UL50ZZ, 0UL53ZZ, 0UL54ZZ, 0UL60ZZ, 0UL63ZZ, 0UL64ZZ, 0UL70ZZ, 0UL73ZZ, 0UL74ZZ, 10D00Z0, 10D00Z1, 10D00Z2); CPT codes (59409, 59612, 59514, 59620); and DRG codes (767, 768, 774, 775, 765, 766).

² ICD-10-CM codes (O01, O02, O00, O03, O04, O07, O08, Z37.7); CPT codes (59840, 59841, 59850-59852, 59855-59857), and DRG codes (770, 779, 777).

Preexisting comorbidities and obstetric-related complications were identified from the literature and corresponding ICD-10 codes identified (Appendix Table 2A).¹⁵⁻¹⁷ Patient characteristics included in the study were maternal age in five-year age groups, adolescence (\leq 18 years of age), advanced maternal age (\geq 35 years of age), gestation type (singleton or multifetal), delivery type (vaginal or cesarean), geographic region (Commercial group only), and race/ethnicity (Medicaid group only). Singleton gestations were identified by ICD-10-CM codes Z37.0-Z37.1, and multifetal gestations by ICD-10-CM codes Z37.2-Z37.7. Geographic regions included the four divisions defined by the U.S. Census: Northeast, Midwest, South, and West. Race/ethnicity was categorized as White non-Hispanic, Black non-Hispanic, other non-Hispanic, or two or more races non-Hispanic.

Data analysis

The results of separate analyses of the Commercial and Medicaid populations were not pooled or compared due to different sampling methodology and coverage. The overall incidence of SMM, as well as for each SMM indicator, was calculated as a rate per 10,000 live deliveries. Chi-square tests determined the statistical significance of differences between patients with and without SMM in delivery type, gestation type, and maternal age categories, and in the frequencies of pre-existing conditions and pregnancy-related complications. Pre-existing conditions and pregnancy-related complications in frequencies for patients with and without SMM were deemed clinically meaningful and included in the model. Multivariate logistic regression modeling assessed the association of delivery type, gestation type, and maternal age with SMM, adjusted for geographical region (Commercial population only), race/ethnicity (Medicaid population only), pre-existing conditions, and pregnancy-related complications. Odds ratios and 95% confidence intervals, along with p-values <0.01 were reported. All analyses were conducted using SAS Version 9.4.31.

Results

Commercial Population

In total 271,150 deliveries were identified in the Commercial population, of which 169,787 met the study inclusion criteria (Appendix Table 3A). ICD-10 codes indicating SMM were observed in 1,902 deliveries, yielding an incidence rate of 113.4 per 10,000 live hospitalized deliveries. Table 1 shows the mean ages and the numbers and percentages of births for all women and for women with and without SMM in the Commercial population. Women with SMM were statistically significantly more likely than women without SMM to have had a cesarean delivery (P<0.01) and multifetal gestation (6.3% versus 2.2%; P<0.01). Across all deliveries, older women were more likely to have had a cesarean delivery versus a vaginal delivery (Figure 1).

Table 1. Demographics and Characteristics of All Deliveries and By Severe Maternal Mortality (SMM) Status in the Commercially Insured Population, 2016*

Variable	All Births N=170,670		No SMM N=168,858		SMM N=1,902	
Demographics	Mean <u>+</u> SD		Mean <u>+</u> SD		Mean <u>+</u> SD	
Age	31.95 <u>+</u> 5.35 years		31.94 <u>+</u> 5.34 years		32.38 <u>+</u> 5.90 years	
	N	%	N	%	N	%
Age Categories ⁺						
14-18	484	0.3	479	0.3	5	0.3
19-24	15,381	9.0	15,207	9.0	174	9.1
25-30	48,767	28.6	48,287	28.6	480	25.2
31-35	62,033	36.3	61,399	36.4	634	33.3
36-40	35,570	20.8	35,112	20.8	458	24.1
41-45	7,726	4.5	7,599	4.5	127	6.7
45+	799	0.5	775	0.5	24	1.3
Delivery Type†						
Vaginal	114,72 8	67.2	113,78 4	67.4	944	49.6
Cesarean	56,032	32.8	55,074	32.6	958	50.4
Gestation Type ⁺						
Singleton	148,51 5	97.4	147,14 0	97.5	1,375	92.0
Multifetal	3,894	2.6	3,775	2.5	119	8.0
Region†						
Midwest	35,757	35406	35,406	21.5	351	18.9

Northeast	28,687	28377	28,377	17.3	310	16.7
South	71,832	71090	71,090	43.3	742	40.0
West	29,929	18.0	29,477	17.9	452	24.4
Obstetric Complications						
Abnormal glucose tolerance	15,459	9.1	15,285	9.1	174	9.1
Amniotic sac complications ⁺	20,767	12.2	20,402	12.1	365	19.2
Cervical incompetence ⁺	3,295	1.9	3,235	1.9	60	3.2
Structure abnormality ⁺	14,331	8.4	14,095	8.3	236	12.4
Excess vomiting ⁺	12,409	7.3	12,214	7.2	195	10.3
Gestational	4,179	2.4	4,102	2.4	77	4.0
hypertension/preeclampsia ⁺	.,		.,			
Unspecified hypertension complicating	23,359	13.7	22,414	13.3	945	49.7
pregnancy childbirth or the						
puerperium [†] Antepartum hemorrhage including	9,585	5.6	9,414	5.6	171	9.0
placenta previa with hemorrhage	5,505	5.0	5,414	5.0	1/1	5.0
Postpartum hemorrhage ⁺	4,151	2.4	3,950	2.3	201	10.6
Pelvic and perineal trauma ⁺	14,980	8.8	14,654	8.7	326	17.1
Uterine rupture†	145	0.1	134	0.1	11	0.6
Obstetric infection ⁺	10,055	5.9	9,777	5.8	278	14.6
Preexisting Comorbidities						
Urinary tract infection ⁺	23,935	14.0	23,588	14.0	347	18.2
Pneumonia†	593	0.3	517	0.3	76	4.0
Appendicitis	139	0.1	137	0.1	2	0.1
Infections not classified elsewhere	1,607	0.9	1,588	0.9	19	1.0
Breast disorders ⁺	239	0.1	226	0.1	13	0.7
Complications of anesthesia ⁺	473	0.3	448	0.3	25	1.3
Preexisting anemias ⁺	21,887	12.8	21,469	12.7	418	22.0
Hereditary hemolytic anemia ⁺	472	0.3	455	0.3	17	0.9
Clotting disorders ⁺	3,106	1.8	2,933	1.7	173	9.1
Tuberculosis	96	0.1	96	0.1	0	0.0
HIV	124	0.1	123	0.1	1	0.1
Diabetes in pregnancy ⁺	18,755	11.0	18,465	10.9	290	15.2
Thyroid disorders ⁺	28,452	16.7	28,006	16.6	446	23.4
Gall bladder disease ⁺	1,011	0.6	985	0.6	26	1.4
Renal disease ⁺	2,054	1.2	1,983	1.2	71	3.7
Liver disease ⁺	1,752	1.0	1,712	1.0	40	2.1
Asthma†	8,487	5.0	8,354	4.9	133	7.0
Neurologic conditions	195	0.1	191	0.1	4	0.2
Cardiovascular conditions [†]	2,888	1.7	2,684	1.6	204	10.7
Other Chronic Diseases, including auto- immune ⁺	1,942	1.1	1,898	1.1	44	2.3

Mental health conditions ⁺	14,553	8.5	14,320	8.5	233	12.3
Obesity†	16,604	9.7	16,319	9.7	285	15.0
Chronic hypertension ⁺	9,174	5.4	8,700	5.2	474	24.9

*Data from MarketScan[®] Commercial Claims and Encounters database

[†]Chi-square between SMM and No SMM = P<0.01 ^Gestation type data was not available for 18,198 women. [!] Region data was not available for 4,555 women

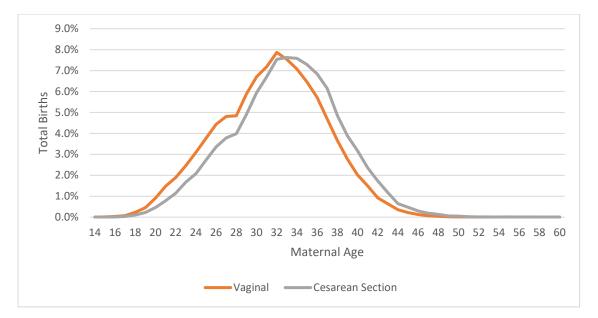


Figure 1. Distribution of Maternal Age by Delivery Method* *MarketScan[®] Commercial Claims and Encounters, 2016

The average maternal age in the Commercial population was 32.0 ± 5.35 years, where women with SMM were older (32.3 ± 5.61 years) compared to women without SMM (32.0 ± 5.30 years; P<0.01). The risk of SMM was approximately 100 cases per 10,000 live deliveries until the age of 35, where the risk increased until the highest risk of 300.38 per 10,000 live deliveries for those over the age of 45 (Appendix Figure 1A and 2A).

All but one obstetric complication listed in Table 1 was significantly more frequent in patients with SMM than in patients without SMM in the Commercial population (P<0.01). Unspecified hypertension complicating pregnancy, childbirth or the puerperium, obstetric infection, postpartum hemorrhage, pelvic and perineal trauma, and amniotic sac complications differed by more than five percentage points between women with SMM and those without SMM.

Figure 1 shows that among women with SMM, the most commonly observed indicators were eclampsia, blood transfusions, and disseminated intravascular coagulation. The total number of SMM indicators observed among the 1,902 women was 2,288, or 1.20 per woman with SMM. The majority of SMM cases experienced only one SMM indicator (86.3%), whereas 11.7% and 5.2% of women experienced two and three or more indicators, respectively. Among women with SMM, cesarean sections were more common than vaginal deliveries (P<0.01). Except for blood transfusions, there were significant differences in the indicators for women with SMM who delivered via cesarean section compared to those who delivered vaginally. These include eclampsia, disseminated intravascular coagulation, pulmonary edema/acute heart failure, adult respiratory distress syndrome, and acute renal failure (Appendix Table 4A).

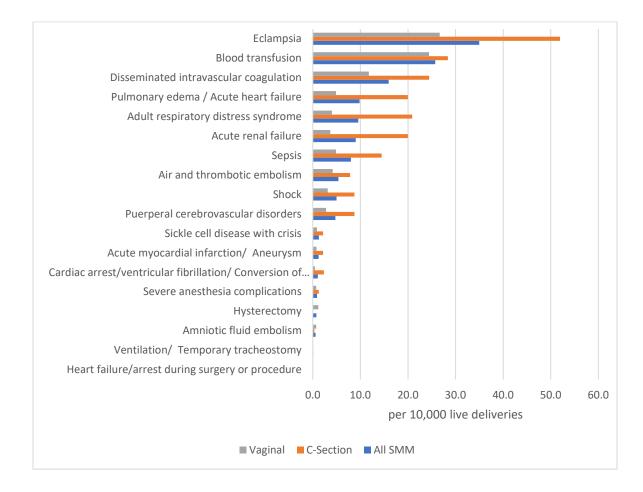


Figure 2. Incidence of Severe Maternal Morbidity Indicators by Delivery Type* *MarketScan[®] Commercial Claims and Encounters, 2016

**All comparisons were statistically significant except amniotic fluid embolism, severe anesthesia complications, blood transfusion, and ventilation/temporary tracheostomy. The results of the adjusted multivariate logistic regression analysis in Appendix Table 5A reveal that most pre-existing comorbidities were significantly more frequent (P<0.01) in patients with SMM than in patients without SMM in the Commercial population. As in Table 1, the greatest differences between the groups was in the prevalence of chronic hypertension, clotting disorders, cardiovascular conditions, and pre-existing anemias.

After adjusting for demographics, preexisting comorbidities, and obstetric complications in the multivariate model, SMM was more likely to occur with cesarean deliveries than with vaginal deliveries, in multifetal gestations than in singleton gestations, and in the West region than in the Northeast, South, and Midwest regions (Table 3). Advanced maternal age (Appendix Table 5A) was not independently predictive of SMM.

Several pre-existing comorbidities and obstetric complications were independently predictive of SMM: pneumonia, cardiovascular conditions, complications of anesthesia, unspecified hypertension complicating pregnancy, childbirth or the puerperium, clotting disorders, postpartum hemorrhage, breast disorders, pelvic and perineal trauma, obstetric infection, liver disease, renal disease, chronic hypertension, preexisting anemias, and gestational hypertension/preeclampsia (Appendix Table 5A).

Medicaid Population

The Medicaid population included 265,330 deliveries, of which 219,495 met the study inclusion criteria (Appendix Table 3A). ICD-10 codes indicating SMM were observed in 2,408 deliveries, yielding an incidence rate 109.6 per 10,000 live hospitalized deliveries. Table 2 reveals that SMM is significantly more prevalent among Black women, women who delivered via cesarean section,

and women with multifetal gestation (P<0.01). The risk of SMM among Blacks (150.7 per 10,000 live deliveries) was disproportionately higher compared to Hispanics, Whites, and Other non-Hispanic races (P<0.01).

Variable	All B	irths	No S	MM	SMM		
Variable	N=219,670		N=217,262		N=2,408		
Demographics	Mea	n <u>+</u> SD	Mea	n <u>+</u> SD	Mea	n <u>+</u> SD	
Age	27.49 <u>+</u> 5.	.56 years	27.47 <u>+</u> 5.	55 years	28.32+6.	02_years	
Age Categories ⁺	n	%	n	%	n	%	
14-18	3,738	1.7	3,697	1.7	41	1.7	
19-24	71,539	32.6	70,849	32.6	690	28.7	
25-30	84,065	38.3	83,216	38.3	849	35.3	
31-35	38,881	17.7	38,383	17.7	498	20.7	
36-40	17,226	7.8	16,972	7.8	254	10.5	
41-45	3,987	1.8	3,917	1.8	70	2.9	
45+	234	0.1	228	0.1	6	0.2	
Delivery Type†							
Vaginal	154,410	70.3	153,299	70.6	1,111	46.1	
Cesarean	65,260	29.7	63,963	29.4	1,297	53.9	
Gestation Type ^{+^}							
Singleton	186,390	97.9	184,683	97.9	1,707	92.6	
Multifetal	4,003	2.1	3,867	2.1	136	7.4	
Race/Ethnicity ^{†!}							
Black	72,856	34.1	71,758	34.0	1,098	47.2	
Hispanic	13,615	6.4	13,526	6.2	89	3.8	
Other	20,448	96	20,247	9.6	201	8.6	
White	106,541	49.9	105,601	50.0	940	40.4	
Obstetric Complications							
Abnormal glucose tolerance	14,193	6.5	14,034	6.5	159	6.6	
Amniotic sac complications ⁺	26,499	12.1	25,998	12.0	501	20.8	
Cervical incompetence ⁺	3,392	1.5	3,338	1.5	54	2.2	
Structure abnormality ⁺	12,663	5.8	12,480	5.7	183	7.6	
Excess vomiting ⁺	34,990	15.9	34,517	15.9	473	19.6	
Gestational hypertension/ preeclampsia ⁺	3,910	1.8	3,821	1.8	89	3.7	
Unspecified hypertension complicating pregnancy childbirth or the puerperium [†]	32,147	14.6	30,635	14.1	1,512	62.8	

Table 2. Demographics and Characteristics of All Deliveries and By Severe Maternal Mortality (SMM) Status in the Medicaid Population, 2015-2017*

Antepartum hemorrhage including placenta previa with hemorrhage ⁺	15,832	7.2	15,503	7.1	329	13.7
Postpartum hemorrhage [†]	5,622	2.6	5,382	2.5	240	10.0
Pelvic and perineal trauma ⁺	20,790	9.5	20,366	9.4	424	17.6
Uterine rupture†	185	0.1	176	0.1	9	0.4
Obstetric infection ⁺	16,920	7.7	16,450	7.6	470	19.5
Preexisting Comorbidities						
Urinary tract infection ⁺	47,205	21.5	46,505	21.4	700	29.1
Pneumonia†	848	0.4	709	0.3	139	5.8
Appendicitis ⁺	154	0.1	142	0.1	12	0.5
Infections not classified elsewhere ⁺	3,888	1.8	3,825	1.8	63	2.6
Breast disorders ⁺	480	0.2	462	0.2	18	0.7
Complications of anesthesia ⁺	434	0.2	405	0.2	29	1.2
Preexisting anemias ⁺	47,649	21.7	46,853	21.6	796	33.1
Hereditary hemolytic anemia ⁺	1,734	0.8	1,691	0.8	43	1.8
Clotting disorders ⁺	3,497	1.6	3,305	1.5	192	8.0
Tuberculosis†	134	0.1	129	0.1	5	0.2
HIV†	327	0.1	318	0.1	9	0.4
Diabetes in pregnancy ⁺	20,900	9.5	20,567	9.5	333	13.8
Thyroid disorders ⁺	37,752	17.2	37,071	17.1	681	28.3
Gall bladder disease ⁺	1,929	0.9	1,886	0.9	43	1.8
Renal disease ⁺	2,576	1.2	2,449	1.1	127	5.3
Liver disease	1,975	0.9	1,942	0.9	33	1.4
Asthma†	17,023	7.7	16,766	7.7	257	10.7
Neurologic conditions	271	0.1	264	0.1	7	0.3
Cardiovascular conditions ⁺	3,493	1.6	3,181	1.5	312	13.0
Other chronic diseases - including auto-immune ⁺	1,136	0.5	1,092	0.5	44	1.8
Mental health conditions ⁺	27,691	12.6	27,261	12.5	430	17.9
Obesity†	32,504	14.8	31,891	14.7	613	25.5
Chronic hypertension ⁺	13,205	6.0	12,436	5.7	769	31.9

*Data from MarketScan[®] Medicaid database

[†]Chi-square between SMM and No SMM = P<0.01 ^Gestation type data was not available for 29,277 women. ¹Race data was not available for 6,210 women

The average maternal age in the Medicaid population was 31.9±5.35 years, and older women were more likely to have a cesarean section (Figure 3). Women with SMM were slightly older compared to women without SMM (P<0.01). The risk of SMM by age followed a U-shaped curve with rates decreasing from 109.7 per 10,000 live deliveries among women 18 years or younger to

96.5 per 10,000 live deliveries among women 19-24, and consistently increasing to the peak of 256.4 per 10,000 live deliveries for women over the age of 45 (Appendix Figure 3A).

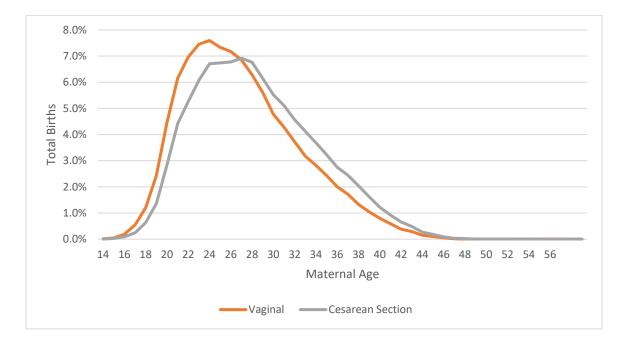


Figure 3. Distribution of Maternal Age by Delivery Method* *MarketScan[®] Medicaid database, 2016

All but two pre-existing comorbidities were significantly more frequent at P<0.01 in patients with SMM than in patients without SMM in the Medicaid population. The greatest numerical difference between the groups was in the prevalence of chronic hypertension, cardiovascular conditions, preexisting anemia, diabetes, and obesity.

Twelve obstetric complications were significantly more frequent in patients with SMM than in patients without SMM in the Medicaid population (P<0.01). Unspecified hypertension complicating pregnancy, childbirth or the puerperium, obstetric infection, amniotic sac complications, postpartum hemorrhage, and pelvic and perineal trauma differed by more than five percentage points between women with SMM and those without SMM.

The total number of SMM indicators among the 2,408 women was 3,111, or 1.29 per woman with SMM. The most commonly observed SMM indicators were eclampsia, adult respiratory distress

syndrome, pulmonary edema/acute heart failure, disseminated intravascular coagulation, and acute renal failure (Figure 4). Blood transfusions were observed in only 163 deliveries, accounting for 7.4% of SMM cases. For women with SMM who delivered via cesarean section compared to vaginal delivery, there were significant differences observed for eclampsia, adult respiratory distress syndrome, pulmonary edema/acute heart failure, disseminated intravascular coagulation, sepsis, and acute renal failure (Appendix Table 7A).

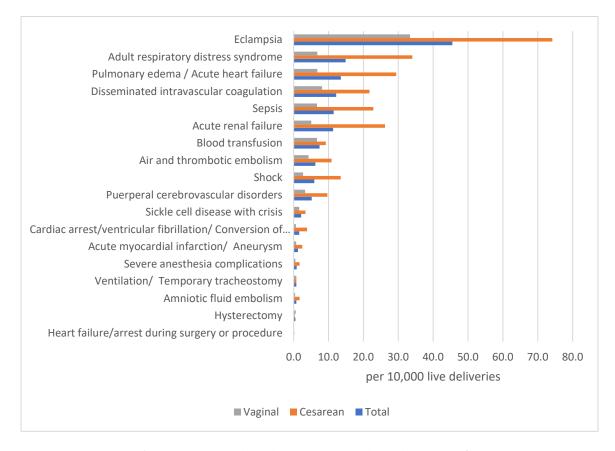


Figure 4. Incidence of Severe Maternal Morbidity Indicators by Delivery Type*

*MarketScan[®] Medicaid database, 2016 ** All comparisons were statistically significant except heart failure/arrest during surgery or procedure, hysterectomy, ventilation/temporary tracheostomy

In the multivariate analysis, SMM was more likely to occur with cesarean deliveries than with vaginal deliveries, in multifetal gestations than in singleton gestations, and among Blacks compared to non-Hispanic Whites and Hispanics (Appendix Table 8A). Adolescent age was not

independently predictive of SMM; however, the following obstetric complications were predictive of SMM: gestational hypertension/preeclampsia, unspecified hypertension complicating pregnancy, childbirth or the puerperium, antepartum hemorrhage including placenta previa with hemorrhage, postpartum hemorrhage, pelvic and perineal trauma, obstetric infection, pneumonia, preexisting anemias, clotting disorders, renal disease, cardiovascular conditions, and chronic hypertension.

After adjusting for other risk demographic and pregnancy-related characteristics, the following obstetric complications were predictive of SMM: gestational hypertension/preeclampsia, unspecified hypertension complicating pregnancy, childbirth or the puerperium, antepartum hemorrhage including placenta previa with hemorrhage, postpartum hemorrhage, pelvic and perineal trauma, obstetric infection, pneumonia, preexisting anemias, clotting disorders, renal disease, cardiovascular conditions, and chronic hypertension (Appendix Table 8A).

Discussion

This retrospective analysis estimated the incidence and associated risk factors of SMM in a nationally representative sample of commercially and Medicaid-insured women in 2016. To our knowledge, this is the most recent estimate of the incidence of SMM and the first estimate attempted after the transition to ICD-10 and revision of SMM algorithm. These results highlight the current risk of SMM in the United States in both privately and publicly insured populations. The analysis also identifies associated SMM risk factors, such as cesarean delivery, gestation type, race, region, and several obstetric complications and pre-existing comorbidities.

The proportion of births delivered by cesarean section in the Commercial population (32.8%) are similar to national averages (31.9%).¹⁸ The lower occurrence of cesarean sections in the Medicaid population (29.7%) is consistent with a recent meta-analysis that reported the odds of delivery by

caesarean section as 1.13 times higher among privately insured women compared to women with public insurance coverage. Consistent with the literature, this analysis identified a twofold increased risk of SMM among women having delivered via cesarean section vs. vaginal delivery. Caution is necessary when interpreting these results as the clinical rationale for why a cesarean section was used is not available in claims data, specifically if a prior cesarean section had occurred, and other delivery-related factors.

The estimated incidence rates of 113.4 per 10,000 live deliveries in the Commercial population and 109.6 per 10,000 live deliveries in the Medicaid population are lower than the 2015 AHRQ national estimate of 146.6 cases per 10,000 live deliveries. The different data sources and methods applied may account for the divergent rates. This paper presents results from separate longitudinal analyses of administrative claims data from a geographically representative employer-sponsored insurance database and from 11 Medicaid state agencies, whereas prior analyses utilized the NIS nationally representative sample of individuals with and without insurance coverage discharged from community hospitals. These key differences in populations, especially insurance status (a proxy for SES), could account for the different risk estimates.^{11,12}

Another unique feature of this analysis was the SMM indicator list using ICD-10 to identify SMM cases, which had 5 less SMM indicators compared to the ICD-9 version. While this analysis used the ICD code crosswalk published by CDC, differences in incidence of SMM and the prevalence of specific SMM indicators may be also be attributed to the transition from ICD-9 to ICD-10 where 19 times more procedure codes and five times more diagnosis codes were created. For example, the prevalence of blood transfusions in both populations in this analysis was surprisingly lower than the prior estimate of 82.6% of all SMM cases using ICD-9 codes. We suspect the difference in the prevalence of blood transfusions is attributable to the differing data sources and the new

ICD-10 indicator list. Additional studies of SMM using the new ICD-10 list are needed to further investigate this difference.

This longitudinal analysis evaluated the association between literature-defined obstetric complications and preexisting comorbidities and SMM. It is not surprising that many of the preexisting comorbidities and pregnancy-related complications were independently predictive of SMM as they are clinically related to SMM indicators. These results raise the need to monitor pregnant women with these comorbidities as they have an increased risk of SMM.

To develop the most comprehensive cohort this analysis only required enrollment in the MarketScan databases during the delivery hospitalization. This was particularly important in the Medicaid population where it is common to have fragmented enrollment patterns due to the recurrent nature of Medicaid enrollment. Due to loosen enrollment criteria, preexisting comorbidities and obstetric complications measured during the prenatal period may be underestimated.

Limitations

This retrospective analysis explored administrative claims data, which is subject to several limitations. Claims data track health care services rendered by providers for administrative purposes and are subject to miscoding and under-coding errors. These errors could introduce misclassification bias.

Commercial claims databases are based on a large convenience sample, mostly from large employers; medium and small firms are not well represented. Because the sample is not random, it may contain biases or fail to generalize well to other populations. However, these data can complement other datasets or be used as benchmarks. Like all claims data, only billed and coded services are recorded and analyzed. This may cause an underestimation of the number of births and incidence of SMM. Additionally, other unmeasured services or patient characteristics could affect the outcomes being evaluated.

The CDC algorithm for defining SMM, though amenable for use with administrative data, has low sensitivity and positive predictive value,¹⁹ thus prompting investigators to apply additional criteria (e.g. length of stay or transfer to another facility). This analysis only analyzed the CDC algorithm, but other amended version may produce different results. Confirmation of SMM cases identified by ICD codes via medical chart review increases the accuracy of SMM incidence estimates. However, it is not possible in this dataset to apply criteria beyond ICD-10 codes to identify SMM, including length of hospitalization and measures of comorbidity severity, as these variables were not available in the data source.

The Medicaid database represented only births from 11 states in 2016 and it is not possible to generalize the Medicaid results to a national population due to the small number of states and the variability in Medicaid benefits by those states. Due to privacy agreements between the Medicaid state agencies and the agency that manages the coordination of benefits, Truven, the states included are not publicly identifiable.

Claims data lack the ability to infer the rationale for procedures, especially cesarean section. Cesarean section has been associated with increased risk of SMM, however it is unclear whether a cesarean section was elective or an emergency decision, a complication for determining temporality.

Conclusion

This study provides the most recent estimate of SMM in the United States after the transition from ICD-9 to ICD-10. The results highlight the serious issue of SMM and its associated risk factors.

Clinical management of these identified risk factors among pregnant women could reduce the risk of SMM if addressed early. Additional research using electronic medical records from a nationally representative database is needed to fully understand the occurrence of events experienced during high-risk delivery hospitalizations.

References

- 1. Hirshberg A, Srinivas SK. Epidemiology of maternal morbidity and mortality. *Semin Perinatol.* 2017;41(6):332-337.
- 2. Ronsmans C, Graham WJ. Maternal mortality: who, when, where, and why. *The Lancet*. 2006;368(9542):1189-1200.
- 3. Hedgecock S. Why Maternal Mortality Is Rising In The U.S. 2015; <u>https://www.forbes.com/sites/sarahhedgecock/2015/04/24/why-maternal-mortality-is-</u> rising-in-the-u-s/#5a750a474243. Accessed February 21, 2018.
- 4. Creanga AA, Syverson C, Seed K, Callaghan WM. Pregnancy-Related Mortality in the United States, 2011-2013. *Obstet Gynecol.* 2017;130(2):366-373.
- 5. Creanga AA, Berg CJ, Syverson C, Seed K, Bruce FC, Callaghan WM. Pregnancy-related mortality in the United States, 2006-2010. *Obstet Gynecol.* 2015;125(1):5-12.
- 6. Creanga AA, Berg CJ, Ko JY, et al. Maternal mortality and morbidity in the United States: where are we now? *J Womens Health (Larchmt).* 2014;23(1):3-9.
- 7. Beattie RM, Brown NJ, Cass H. Millennium Development Goals progress report. *Archives* of Disease in Childhood. 2015;100:S1-S1.
- Pregnancy Mortality Surveillance System. <u>https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-mortality-surveillance-system.htm</u>. Accessed January 27, 2019.
- 9. Trends in Maternal Mortality: 1990 to 2015. *WHO, UNICEF, UNFPA, World Bank Group, and the United Nations Population Division*. Accessed January 27, 2019.
- 10. Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstet Gynecol.* 2012;120(5):1029-1036.
- 11. Fingar KF HM, Heslin KC, Moore JE. Trends and Disparities in Delivery Hospitalizations Involving Severe Maternal Morbidity, 2006–2015. *Agency for Healthcare Research and Quality (US).* 2018.
- 12. Severe Maternal Morbidity. 2017; <u>http://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidit</u> <u>y.html</u>. Accessed January 13, 2017.
- 13. Federal Health Information Technology Strategic Plan 2011–2015. In: Technology OotNCfHI, ed. Vol 20182011.
- 14. *Commercial Claims and Encounters. Data Year 2016 Edition.* IBD Watson Health;2016.
- 15. Bruce FC, Berg CJ, Joski PJ, et al. Extent of maternal morbidity in a managed care population in georgia. 2012(1365-3016 (Electronic)).
- 16. Bruce FC, Berg CJ, Hornbrook MC, et al. Maternal morbidity rates in a managed care population. 2008(0029-7844 (Print)).
- 17. Small MJ, James AH, Kershaw T, Thames B, Gunatilake R, Brown H. Near-miss maternal mortality: cardiac dysfunction as the principal cause of obstetric intensive care unit admissions. *Obstet Gynecol.* 2012;119(2):250-255.
- 18. Martin JA, Hamilton BE, Osterman MJK. Births in the United States, 2016. *NCHS Data Brief.* 2017(287):1-8.
- 19. Main EK, Abrero A, McNulty J. Measuring severe maternal morbidity: valdiation of potential measures. *Am J Obstet Gynecol.* 2016;214(5):643.e641-643.e610.

Appendix Tables and Figures

Table 1A. Severe Maternal Morbidity Indicators and Corresponding ICD-10 Codes during Delivery Hospitalization*

SMM Indicator	Diagnosis (DX) or Procedure (PR)	ICD-10 Codes
Acute myocardial	DX	I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3, I21.4, I22.0, I22.1, I22.2, I22.8, I22.9
infarction/ Aneurysm	DX	171.00 – 171.03, 171.1, 171.2, 171.3, 171.4, 171.5, 171.6, 171.8, 171.9, 179.0
Acute renal failure	DX	N17.0, N17.1, N17.2, N17.8, N17.9, O90.4
Adult respiratory distress syndrome	DX	J80, J95.1, J95.2, J95.3, J95.821, J95.822, J96.00, J96.01, J96.02, J96.20, J96.21, J96.22, R09.2
Amniotic fluid embolism	DX	O88.11x*, O88.12 (childbirth), O88.13 (puerperium) * x=1st, 2nd and 3rd trimester
Cardiac	DX	146.2, 146.8, 146.9, 149.01, 149.02*, * Ventricular flutter
arrest/ventricular fibrillation/ Conversion of cardiac rhythm	PR	5A2204Z, 5A12012
Disseminated intravascular coagulation	DX	D65, D68.8, D68.9, O72.3*
Eclampsia	DX	O15.02, O15.03, O15.1, O15.2, O15.9, O14.22 – HELLP syndrome (HELLP), second trimester, O14.23 – HELLP syndrome (HELLP), third trimester, HELLP syndrome is not included currently (ranges in severity, more research is needed)
Heart failure/arrest during surgery or procedure	DX	197.120, 197.121, 197.130, 197.131
Puerperal cerebrovascular disorders	DX	I60.0x-160.9, I61.0x-161.9, I62.0x, 162.1,162.9, I63.0x-163.9, I65.0x, 165.1, I65.2x, 165.8,165.9, I66.0x, 166.1x, I66.2x, 166.3, 166.8,166.9, 167.1, 167.2, 167.3, 167.4, 167.5, 167.6, 167.7, 167.8x, 167.9, 168.0, 160.8, 168.9, O22.50, O22.51, O22.52, O22.53, I97.810, I97.811, I97.820, I97.821, O873
Pulmonary edema / Acute heart failure	DX	J81.0, I50.1, I50.20, I50.21, I50.23, I50.30, I50.31, I50.33, I50.40, I50.41, I50.43, I50.9,
Severe anesthesia complications	DX	74.0, 074.1, 074.2, 074.3, 089.01*, 089.09 089.1, 089.2, 089.01
Sepsis	DX	O85 or T80.211A or T81.4XXA plus A40.0, A40.1 , A40.3 , A40.8, A40.9, A41.0, A41.0Z1, A41.1, A41.2, A41.3, A41.4, A41.50, A41.51, A41.52, A41.53, A41.59, A41.81, A41.89, A41.9, A32.7 plus severity: R65.20
Shock	DX	O75.1, R57.0, R57.1, R57.8, R57.9, R65.21, T78.2XXA, T88.2XXA, T88.6XXA, T81.10XA, T81.11XA, T81.19XA
Sickle cell disease with crisis	DX	D57.00, D57.01, D57.02, D57.211, D57.212, D57.219, D57.411, D57.412, D57.419, D57.811, D57.812, D57.819 (5th digit: unspecified, acute chest syndrome or splenic sequestration)

Air and thrombotic embolism	DX	I26.01, I26.02, I26.09, I26.90, I26.92, I26.99, O88.011-O88.019, 088.02, O88.03, O88.211-O88.219, O88.22, O88.23, O88.311- O88.319, O88.32, O88.33, O88.81, O88.82, O88.83, * I26.0 – Pulmonary embolism with acute corpulmonale (acute right ventricle heart failure)
Blood transfusion	PR	30233H1, 30233K1, 30233L1, 30233M1, 30233N1, 30233P1, 30233R1, 30233T1, 30240H1, 30240K1, 30240L1, 30240M1, 30240N1, 30240P1, 30240R1, 30240T1, 30243H1, 30243K1, 30243L1, 30243M1, 30243N1, 30243P1, 30243R1, 30243T1, 30233N0, 30233P0, 30240N0, 30240P0, 30243N0, 30243P0
Hysterectomy	PR	0UT90ZZ, 0UT94ZZ, 0UT97ZZ, 0UT98ZZ, 0UT9FZZ
Ventilation/	PR	5A1935Z, 5A1945Z, 5A1955Z
Temporary tracheostomy	PR	0B110Z4, 0B110F4, 0B113Z4, 0B113F4, 0B114Z4, 0B114F4

Table 2A. Preexisting Comorbidities and Obstetric Complication Identified in the Literature as Risk Factors

Preexisting Comorbidities	Obstetric complications
Urinary tract infection	Abnormal glucose tolerance
Pneumonia	Amniotic sac
Appendicitis	Cervical incompetence
Infections not classified elsewhere	Structural abnormality
	(uterus/cervix/vagina/vulva)
Breast disorders	Excess vomiting
Complications of anesthesia	Placenta previa without hemorrhage
Nonhereditary nonhemolytic anemia	Gestational hypertension/preeclampsia
Hereditary hemolytic anemia	Antepartum hemorrhage including placenta
	previa with hemorrhage
Clotting disorders	Postpartum hemorrhage
Tuberculosis	Pelvic and perineal trauma
Human immunodeficiency virus	Uterine rupture
Diabetes in pregnancy	Obstetric infection
Thyroid disorders	
Gall bladder disease	
Renal disease	
Liver disorders	

Asthma	
Neurological conditions	
Cardiovascular condition	
Other chronic disease	
Mental health conditions	
Obesity	
Chronic hypertension	

Table 3A. Population Selection Process for Estimating Severe Maternal Mortality in 2016

Variable	Commercial Database*					
Variable	# Included	# Excluded	% of Original Sample			
With Birth DRG codes of live birth in 2016	261,407					
No more than 2 births in one year	261,374	33	100%			
Exclude Males	260,561	813	100%			
Continuous enrollment for 30 days	187,850	72,711	72%			
Aged between 14 and 60 years	170,760	170,760 17,090				
	Medicaid Database ⁺					
With Birth DRG codes of live birth in 2016	265,330					
No more than 2 births in one year	265,298	32	100%			
Exclude Males	265,114	184	100%			
Continuous enrollment for 30 days	235,622	29,492	89%			
Aged between 14 and 60 years	219,495	16,127	83%			

*MarketScan® Commercial Claims and Encounters, 2015-2017

⁺MarketScan[®] Medicaid, 2015-2017

Table 4A. Frequency, Percentage and Incidence Rates per 10,000 of Severe Maternal Mortality
(SMM) and Indicators by Delivery Method in the Commercially Insured Population, 2015-2017*

	All SMM			Cesarean Section			Vaginal		
Variables	N	%	Incidence Rate per 10,000	N	%	Incidence Rate per 10,000	N	%	Incidence Rate per 10 000
Total SMM deliveries	1,90 2		111.38	958		170.97	944		82.28

SMM Indicator									
Eclampsia†	597	31.4	35.0	291	30.4	51.9	306	32.4	26.7
Blood transfusion	439	23.1	25.7	159	16.6	28.4	280	29.7	24.4
Disseminated intravascular coagulation†	272	14.3	15.9	137	14.3	24.5	135	14.3	11.8
Pulmonary edema / Acute heart failure†	168	8.8	9.8	112	11.7	20.0	56	5.9	4.9
Adult respiratory distress syndrome†	163	8.6	9.5	117	12.2	20.9	46	4.9	4.0
Acute renal failure†	154	8.1	9.0	112	11.7	20.0	42	4.4	3.7
Sepsis†	137	7.2	8.0	81	8.5	14.5	56	5.9	4.9
Air and thrombotic embolism†	92	4.8	5.4	44	4.6	7.9	48	5.1	4.2
Shock†	85	4.5	5.0	49	5.1	8.7	36	3.8	3.1
Puerperal cerebrovascular disorders†	81	4.3	4.7	49	5.1	8.7	32	3.4	2.8
Sickle cell disease with crisis†	22	1.2	1.3	12	1.3	2.1	10	1.1	0.9
Acute myocardial infarction/ Aneurysm†	21	1.1	1.2	12	1.3	2.1	9	1.0	0.8
Cardiac arrest/ventricular fibrillation/ Conversion of cardiac rhythm†	18	0.9	1.1	13	1.4	2.3	5	0.5	0.4
Severe anesthesia complications	15	0.8	0.9	7	0.7	1.2	8	0.8	0.7
Hysterectomy†	13	0.7	0.8	0	0.0	0.0	13	1.4	1.1
Amniotic fluid embolism	10	0.5	0.6	2	0.2	0.4	8	0.8	0.7
Ventilation/ Temporary tracheostomy	1	0.1	0.1	0	0.0	0.0	1	0.1	0.1
Heart failure/arrest during surgery or procedure†	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0

*Data from MarketScan[®] Commercial Claims and Encounters database [†]Chi-square between cesarean section and vaginal deliveries were statistically significant = P<0.01

Table 5A. Association of Severe Maternal Mortality and Risk Factors in the Commercial Population,
2015-2017*

Variable	Odds Ratio	95% Confidence Interval	
Delivery Type			
Cesarean vs Vaginal	1.67	1.51	1.84
Gestation Type			
Multifetal vs Singleton	3.37	2.8	4.10
Region			
Midwest vs West	0.65	0.56	0.74
Northeast vs West	0.71	0.62	0.82
South vs West	0.68	0.61	0.77
Obstetric Complications			
Gestational hypertension/preeclampsia	1.49	1.17	1.90
Unspecified hypertension complicating pregnancy childbirth or			
the puerperium	4.53	4.05	5.05

			1
Postpartum hemorrhage	3.95	3.36	4.65
Pelvic and perineal trauma	2.48	2.18	2.82
Obstetric infection	2.19	1.91	2.51
Pneumonia	9.25	6.98	12.2
Breast disorders	2.66	1.42	4.98
Complications of anesthesia	4.56	2.92	7.12
Preexisting Comorbidities			
Preexisting Anemias	1.59	1.41	1.78
Clotting disorders	4.47	3.75	5.32
Renal Disease	1.69	1.30	2.21
Liver Disease	1.77	1.27	2.46
Cardiovascular Conditions	4.82	4.09	5.68
Chronic Hypertension	1.66	1.46	1.89

*Data from MarketScan® Commercial Claims and Encounters database

[†]OR=Odds Ratio; LCL=Lower 95% Confidence Level; UCL=Upper 95% Confidence Level [‡]Multivariate logistic regression analysis statistically significant at P<0.01

Table 6A. Unadjusted Logistic Regression Model (Commercial)*

Demographics	Odds Ratio	95% Confidence Interva	
Age Categories (n, %)			
14-18 vs 45+	0.337	0.128	0.889
19-24 vs 45+	0.369	0.240	0.570
25-30 vs 45+	0.321	0.212	0.487
31-35 vs 45+	0.333	0.220	0.504
36-40 vs 45+	0.421	0.278	0.639
41-45 vs 45+	0.540	0.347	0.840
Advanced Maternal Age	1.25	1.14	1.37
Delivery Type			
Cesarean vs Vaginal	2.097	1.915	2.295
Gestation Type			
Multifetal vs Singleton	3.374	2.790	4.080
Region			
Midwest vs West	0.647	0.562	0.744
Northeast vs West	0.712	0.616	0.824
South vs West	0.681	0.605	0.766
Obstetric Complications			
Abnormal glucose tolerance	1.01	0.86	1.18
amniotic sac complications	1.72	1.54	1.93
Cervical incompetence	1.66	1.28	2.15
Structure abnormality	1.55	1.35	1.78
Excess vomiting	1.46	1.26	1.70
Gestational hypertension/ preeclampsia	1.69	1.34	2.13
Unspecified hypertension complicating pregnancy childbirth	6.45	5.88	7.04
or the puerperium			
Antepartum hemorrhage including placenta previa with	1.67	1.42	1.96
hemorrhage			
Postpartum hemorrhage	4.92	4.25	5.71
Pelvic and perineal trauma	2.17	1.93	2.45
Uterine rupture	7.35	3.95	13.5

2.78	2.45	2.10
	2.45	3.16
1.37	1.22	1.54
13.5	10.6	17.2
1.29	0.32	5.23
1.06	0.67	1.67
5.12	2.93	9.00
5	3.33	7.51
1.93	1.73	2.15
3.33	2.05	5.43
5.64	4.83	6.66
0.72	0.10	5.15
1.46	1.29	1.66
1.54	1.38	1.71
2.36	1.59	3.49
3.26	2.56	4.14
2.10	1.52	2.88
1.44	1.20	1.72
1.86	0.69	5.02
7.46	6.41	8.62
2.08	1.54	2.82
1.50	1.31	1.73
1.64	1.45	1.86
6.09	5.49	6.80
	13.5 1.29 1.06 5.12 5 1.93 3.33 5.64 0.72 1.46 1.54 2.36 3.26 2.10 1.44 1.86 7.46 2.08 1.50 1.64	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

*Data from MarketScan[®] Commercial Claims and Encounters database ‡Multivariate logistic regression analysis statistically significant at P<0.01

Table 7A. Incidence of Severe Maternal Mortality and Indicators by Delivery Method in the
Medicaid Population, 2015-2017*

	All SMM		Cesarean Section		rean Section Vaginal				
Variable	n	%	Incidence Rate per 10,000	n	%	Incidence Rate per 10,000	n	%	Incidence Rate per 10,000
Total SMM deliveries	2408		109.6 2	1297		198.7 4	1111		71.95
Deliveries with:									
Eclampsia†	1000	729.9	45.5	484	681.7	74.2	516	781.8	33.4
Adult respiratory distress syndrome†	327	238.7	14.9	222	312.7	34.0	105	159.1	6.8
Pulmonary edema / Acute heart failure†	297	216.8	13.5	192	270.4	29.4	105	159.1	6.8

Disseminated intravascular coagulation†	268	195.6	12.2	142	200.0	21.8	126	190.9	8.2
Sepsis†	252	183.9	11.5	149	209.9	22.8	103	156.1	6.7
Acute renal failure†	249	181.8	11.3	171	240.8	26.2	78	118.2	5.1
Blood transfusion [†]	163	119.0	7.4	60	84.5	9.2	103	156.1	6.7
Air and thrombotic embolism†	137	100.0	6.2	71	100.0	10.9	66	100.0	4.3
Shock†	130	94.9	5.9	88	123.9	13.5	42	63.6	2.7
Puerperal cerebrovascular disorders†	114	83.2	5.2	63	88.7	9.7	51	77.3	3.3
Sickle cell disease with crisis†	47	34.3	2.1	22	31.0	3.4	25	37.9	1.6
Cardiac arrest/ventricular fibrillation/ Conversion of cardiac rhythm	35	25.5	1.6	25	35.2	3.8	10	15.2	0.6
Acute myocardial infarction/ Aneurysm†	27	19.7	1.2	16	22.5	2.5	11	16.7	0.7
Severe anesthesia complications†	19	13.9	0.9	11	15.5	1.7	8	12.1	0.5
Amniotic fluid embolism†	17	12.4	0.8	11	15.5	1.7	6	9.1	0.4
Ventilation/ Temporary tracheostomy	17	12.4	0.8	5	7.0	0.8	12	18.2	0.8
Hysterectomy	11	8.0	0.5	2	2.8	0.3	9	13.6	0.6
Heart failure/arrest during surgery or procedure	1	0.7	0.0	1	1.4	0.2	0	0.0	0.0

*Data from MarketScan[®] Commercial Claims and Encounters database †Chi-square between Cesarean and Vaginal = P<0.01

Table 8A. Association of Severe Maternal Mortality and Risk Factors in the Medicaid Population, 2015-2017*

Variable	Odds	95% Confidence Interval	
Delivery Type			
Cesarean vs Vaginal	1.99	1.80	2.17
Race/ Ethnicity			
Hispanic vs Black	0.68	0.51	0.89
Other vs Black	0.89	0.74	1.10
White vs Black	0.78	0.70	0.87
Gestation Type			
Multifetal vs Singleton	2.26	1.86	2.75
Obstetric Complications			
Gestational hypertension/preeclampsia	1.61	1.20	2.03
Unspecified hypertension complicating pregnancy childbirth or the puerperium	6.88	6.20	7.59

Antepartum hemorrhage including placenta previa with	1.47	1.20	1.67
hemorrhage			
Postpartum hemorrhage	3.90	3.30	4.53
Pelvic and perineal trauma	2.56	2.20	2.87
Obstetric infection	2.35	2.10	2.62
Pre-existing Comorbidities			
Pneumonia	13.45	10.70	16.85
Preexisting medical conditions - Anemias	1.38	1.20	1.51
Clotting disorders	4.00	3.30	4.73
Renal Disease	2.51	2.00	3.09
Cardiovascular Conditions	5.53	4.80	6.38
Chronic Hypertension	1.48	1.30	1.65

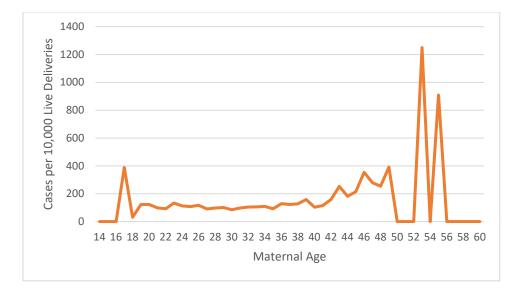
*Data from MarketScan[®] Commercial Claims and Encounters database \$Multivariate logistic regression analysis statistically significant at P<0.01

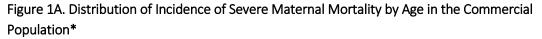
Table 9A. Unadjusted Logistic Regression Model (Medicaid)*	
Demographics	(

Demographics	Odds	95% Co	nfidence
	Ratio	Inte	erval
Age Categories (n, %)			
19-24 vs 14-18	1.13	0.83	1.56
25-30 vs 14-18	1.08	0.79	1.49
31-35 vs 14-18	0.85	0.62	1.17
36-40 vs 14-18	0.74	0.53	1.03
41-45 vs 14-18	0.62	0.42	0.91
45+ vs 14-18	0.42	0.17	0.99
Adolescent Age	1.00	0.73	1.36
Delivery Type			
Cesarean vs Vaginal	2.79	2.58	3.03
Gestation Type			
Multifetal vs Singleton	3.80	3.18	4.54
Race/ Ethnicity			
Hispanic vs Black	2.33	1.87	2.89
Other vs Black	1.54	1.33	1.79
White vs Black	1.71	1.58	1.88
Obstetric Complications			
Abnormal glucose tolerance	1.02	0.87	1.20
amniotic sac complications	1.93	1.75	2.13
Cervical incompetence	1.47	1.11	1.93
Structure abnormality	1.35	1.16	1.57
Excess vomiting	1.29	1.16	1.43
Gestational hypertension/ preeclampsia	2.14	1.73	2.65
Unspecified hypertension complicating pregnancy childbirth or the	10.3	9.43	11.2
puerperium			
Antepartum hemorrhage including placenta previa with hemorrhage	2.06	1.83	2.31

Postpartum hemorrhage	4.36	3.80	5.00
Pelvic and perineal trauma	2.06	1.85	2.29
Uterine rupture	4.62	2.36	9.09
Obstetric infection	2.95	2.67	3.27
Pre-existing Comorbidities			
Urinary tract infection	1.50	1.37	1.64
Pneumonia	18.8	15.6	22.7
Appendicitis	7.63	4.23	13.8
Infections not classified elsewhere	1.49	1.16	1.93
Breast disorders	3.53	2.20	5.68
Complications of anesthesia	6.53	4.46	9.52
Preexisting Anemias	1.79	1.64	1.95
Hereditary hemolytic anemia	2.32	1.70	3.14
Clotting disorders	5.61	4.83	6.53
Tuberculosis	3.49	1.43	8.54
HIV	2.55	1.31	4.97
Diabetes in pregnancy	1.53	1.36	1.72
Thyroid disorders	1.91	1.75	2.09
Gall bladder disease	2.07	1.53	2.81
Renal Disease	4.87	4.06	5.88
Liver Disease	1.54	1.08	2.17
Asthma	1.42	1.25	1.62
Neurologic Conditions	2.39	1.12	5.07
Cardiovascular Conditions	10.00	8.84	11.3
Other Chronic Diseases - including auto-immune	3.69	2.71	5.00
Mental Health Conditions	1.51	1.36	1.68
Obesity	1.98	1.80	2.17
Chronic Hypertension	7.75	7.09	8.40

*Data from MarketScan[®] Commercial Claims and Encounters database ‡Multivariate logistic regression analysis statistically significant at P<0.01





*MarketScan® Commercial Claims and Encounters, 2015-2017

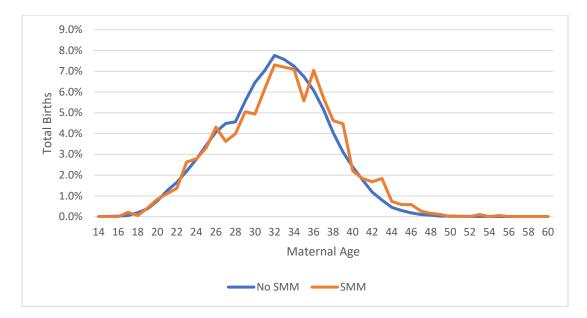
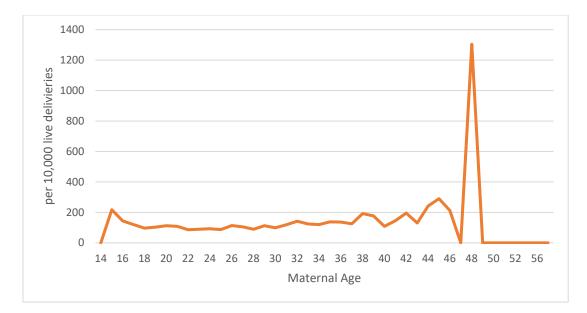
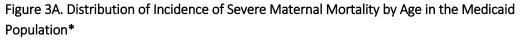


Figure 2A. Distribution of Deliveries by Severe Maternal Mortality Status in the Commercial Population*

*MarketScan® Commercial Claims and Encounters, 2015-2017





*MarketScan® Medicaid database, 2015-2017

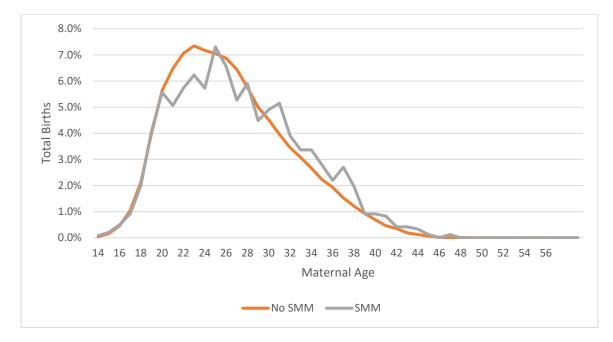


Figure 4A. Distribution of Maternal Deliveries by Severe Maternal Mortality Status in the Medicaid Population*

*MarketScan[®] Medicaid database, 2015-2017

PAPER 2 –RATES OF HOSPITAL READMISSIONS AND EMERGENCY ROOM VISITS IN THE 30 DAYS FOLLOWING A HOSPITALIZED DELIVERY WITH SEVERE MATERNAL MORBIDITY

Précis

This study helps address the question of the incidence and reasons for 30-day hospital readmissions and treat-and-release ER visits after a delivery discharge among women with and without severe maternal morbidity (SMM).

Abstract

Objective: To estimate incidence rates and predictors of unplanned 30-day hospital readmissions and treat-and-release ER visits after delivery hospitalization among women with and without SMM.

Methods: This was a retrospective cohort study of women with a live inpatient delivery during 2016 in the MarketScan databases for commercially insured and Medicaid populations. The incidence of hospital readmissions and treat-and-release ER visits within 30-days following a delivery discharge were calculated. Primary discharge diagnoses for hospital readmission and ER visits were recorded and ranked. Rates were compared by SMM status. Measurements also include the association in bivariate analyses with patient characteristics; association of delivery type, gestation type, and maternal age with hospital readmissions and ER visits in multivariate logistic regression analysis, adjusted for pre-existing conditions and pregnancy-related complications.

Results: There were 1,972 hospital readmissions and 132 ER visits in the commercially-insured population with incidence rates of 11.7 and 0.8 per 1,000 discharges. These rates were 12 and 19 times greater for women with SMM than women without SMM. In the Medicaid population there

were 1,114 hospital readmissions and 119 ER visits, for incidence rates of 17.0 and 1.8 per 1,000 discharges. SMM increased these rates by 16 and 17 times for hospital readmission and ER visits, respectively. Eclampsia was the most commonly reported SMM indicator among women with a hospital readmission or ER visit in both populations. Hypertensive disorders during pregnancy and eclampsia, obstetric infections and hemorrhage were common reasons for a hospital readmission and ER visits. SMM was associated with many of the primary discharge diagnoses for hospital readmissions and ER visits. Seventy-one and fifty-three new cases of SMM were observed in the postpartum period in the Commercial and Medicaid populations. In the multivariate analysis of hospital readmissions, SMM, a cesarean delivery, multifetal gestation, delivery stay longer than 3 days, and race was associated with an increased risk

Conclusion: The results of this analysis showed that a SMM increases the risk and many of the times is the reason for hospital readmission and ER visits. Cesarean delivery, multifetal gestation, race, and several preexisting comorbidities and obstetric complications were associated with severe maternal morbidity in both the Commercial and Medicaid populations.

Key words: epidemiology, severe maternal mortality, hospital readmission, ER visit

Introduction

Severe maternal morbidity (SMM) includes unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health.¹ These traumatic episodes require precise and careful medical care during and after the delivery in order to reach a full recovery. . Length of delivery stay for uncomplicated births range from 2 to 3 days for vaginal and cesarean deliveries, respectively.^{2,3}. Blumenfeld et al. demonstrated that among cesarean section deliveries, perioperative complications increased the risk of prolonged lengths of stays, which resulted in increased delivery-related costs.²

An analysis of discharge records from acute care hospitals in California, Florida, and Nebraska in 2008 and 2009 revealed high rates of hospital readmissions and treat-and-release emergency room (ER) visits 30 days after delivery hospitalization.⁴ These rates emphasize the seriousness of childbirth and the importance of proper discharge decisions. Vaginal births accounted for 12.4% of all medical-related hospital discharges and had a 30-day ER visit rate and a hospital readmission rate of 34.4 per 1,000 discharges and 7.6 per 1,000 discharges, respectively. Uncomplicated and complicated cesarean sections accounted for 11.4% and 3.3% of all surgical-related hospital discharges respectively. Complicated cesarean sections had a higher ER visit rate (84.6 vs. 55.4 per 1,000 discharges) and a hospital readmission rate (71.6 vs. 15.0 per 1,000 discharges) compared to uncomplicated cesarean sections. These rates emphasize the seriousness of childbirth and the importance of proper discharge decisions.

Childbirth accounts for most hospitalizations in the United States with varying risks of readmissions and ER visits.⁴ Understanding and addressing predictors and risk factors of unplanned hospital readmissions and ER visits could help healthcare providers prevent future episodes, while improving outcomes for their patients. To date there is no literature estimating the readmission rates of women experiencing SMM events during delivery. The objective of this

analysis is to estimate incidence rates and predictors of unplanned 30-day hospital readmissions and ER visits after delivery hospitalization among women with and without SMM.

Materials and Methods

Study design and data sources

This retrospective cohort study used a primary base of beneficiaries enrolled in the *MarketScan* Commercial Claims and Encounters ("Commercial") database and Medicaid database to identify cases of SMM. The Commercial database is a demonstrative claims database including paid medical and prescription drug claims from approximately 200 self-insured U.S. employers and 30 health plans.⁵ The Medicaid database contains the pooled healthcare experience of approximately seven million Medicaid enrollees in 11 states.

Study sample

The study population included all women with inpatient live births in 2016, identified by ICD-10 diagnostic and procedure codes, CPT, and DRG codes. Continuous coverage for 30 days after discharge was required to capture readmissions and ER visits. Pre-delivery data were analyzed to identify risk factors and patient characteristics available in-patient records. Males were excluded, as were deliveries with codes not indicating a live birth, such as molar pregnancy or ectopic pregnancy, based on ICD-10-CM codes, CPT codes, and DRG codes.

Outcome definitions

Hospital readmissions were defined as any inpatient stay within 30 days of the index discharge date. A treat-and-release ER visit was defined as an ER visit within 30 days of the delivery discharge date, where the patient was discharged to home or self-care, and the length of stay was less than two days long. Any ER visit that resulted in an admission was defined as a hospital readmission. SMM was defined by the occurrence during a delivery of one or more of the 18 potentially life-threatening maternal conditions or complications identified by the diagnostic and procedural ICD-

10 codes identified by CDC. ¹ Total cost of care during the delivery stay and 30-day period were recorded.

Outcomes and Covariates

Pre-existing conditions and pregnancy-related complications were identified from the literature.⁶⁻ ¹⁰ Patient characteristics included in the study were maternal age in five-year age groups, adolescence (≤18 years of age), advanced maternal age (≥35 years of age), gestation type (singleton or multifetal), delivery type (vaginal or cesarean), geographic region (Commercial population only), and race/ethnicity (Medicaid population only). Race/ethnicity was categorized as White non-Hispanic, Black non-Hispanic, Hispanic, other non-Hispanic, or two or more races non-Hispanic.

Statistical Analysis

The results of separate analyses for the Commercial and Medicaid populations were not pooled or compared due to different sampling methodology and coverage. The overall incidence of hospital readmissions and ER visits by SMM status was calculated as a rate per 1,000 discharges. Chi-square tests determined the statistical significance of differences between patients with and without hospital readmissions and ER visits in the categories of delivery type, gestation type, and maternal age, and in the frequencies of pre-existing conditions and pregnancy-related complications. Risk ratios were calculated to compare the risk of hospital readmissions and ER visits by SMM status and delivery type. Multivariate logistic regression modeling assessed the association of delivery type, gestation type, and maternal age with SMM, adjusted for geographical region (Commercial population only), race/ethnicity (Medicaid population only), pre-existing conditions, and pregnancy-related complications. Odds ratios and 95% confidence intervals, along with p-values were calculated. All analyses were conducted using SAS Version 9.4.31.

Results

Commercial Population

Hospital Readmissions

This analysis identified 165,444 live deliveries in 2016 that had continuous enrollment during the delivery hospitalization and the 30 days following the delivery discharge. From this population, 1.2% of discharges had a hospital readmission within 30 days, yielding an incidence rate of 11.7 per 1,000 discharges. Table 1 describes the demographics and pregnancy characteristics by hospital readmission status. Women with hospital readmissions were older, more likely to have had a cesarean section delivery, multifetal gestation, or pre-existing comorbidities, and more likely to have experienced obstetric complications during pregnancy and/or delivery (Table 1 and Appendix Table 1A).

	No Readmission Rea		dmission		
	163,5	517	1	,927	p-value
Demographics					
Age (mean, SD)	31.98	5.98	32.45	5.8	<.0001
Age Categories	Ν	%	N	%	<.0001
14-18	458	0.3	7	0.4	
19-24	14,609	8.9	193	10.0	
25-30	46,356	28.3	508	26.4	
31-35	59,740	36.5	588	30.5	
36-40	34,183	20.9	475	24.6	
41-45	7,410	4.5	137	7.1	
45+	761	0.5	19	1.0	
Delivery Type					<.0001
Vaginal	53,400	32.7	870	45.1	
Cesarean	110,117	67.3	1,057	54.9	
Gestation Type [^]					<.0001
Singleton	142,453	87.1	1,529	79.3	
Multifetal	3,650	2.2	97	5.0	
Severe Maternal Morbidity Status					<.0001
SMM	1,474	0.9	252	13.1	
No SMM	162,043	99.1	1,675	86.9	

Table 1. Demographics and Characteristics of Deliveries by 30-Day Hospital ReadmissionStatus in the Commercially Insured Population, 2016*

*Data from MarketScan® Commercial Claims and Encounters database

⁺Chi-square between SMM and No SMM [^]Gestation type data was not available for 17,715 women.

Hospital readmissions were more common in the 1,999 women with SMM compared to women without SMM (RR: 12.24, 130.8 per 1,000 discharges vs. 10.7 per 1,000 discharges, P<0.001; Appendix Table 2A). Concurrence of SMM indicators was associated with increased risk of hospital readmission, and eclampsia was the most common of the 18 SMM indicators among women with hospital readmissions (Appendix Table 2A). Type of delivery was associated with hospital readmissions, with readmission rates 70% higher among cesarean section deliveries (16.3 per 1,000 discharges) compared to vaginal deliveries (9.6 per 1,000 discharges, RR:1.70, P<0.001). Rates of hospital readmissions when complicated by SMM increased to 148.4 per 1,000 discharges and 143.4 per 1,000 discharges for cesarean section deliveries and vaginal deliveries, respectively.

The ten most common discharge diagnoses from hospital readmissions are presented by SMM status in Table 2. Groups of related diagnoses were observed where most of the diagnoses were related to hypertensive disorders of pregnancy and eclampsia, obstetric infections, and hemorrhage. Most of the top ten hospital readmission discharge diagnoses were related to SMM indicators, such as eclampsia or pre-eclampsia, sepsis and obstetric infection, hemorrhage, and cardiovascular emergencies (Table 2). Some of these diagnosis codes are codes used to indicate SMM, e.g. Eclampsia complicating the puerperium (O15.2) and Sepsis (O85). The discharge diagnoses did not differ greatly by delivery type except for infection of an obstetric surgical wound, which was more prevalent among cesarean deliveries.

Rank	No SMM (N=1,675)	SMM (N=252)
1	Other complications of the puerperium, not elsewhere classified (O90.89) N=203	Eclampsia complicating the puerperium (O15.2) N=98
2	Endometritis following delivery (O86.12) N=127	Other complications of the puerperium, not elsewhere classified (O90.89) N=40
3	Infection of obstetric surgical wound (O86.0) N=119	Unspecified pre-eclampsia, unspecified trimester (O14.90) N=10

Table 2. Ten Most Common Primary Discharge Diagnoses for 30-day Hospital Readmissions in the Commercial Population, 2016*

4	Unspecified pre-existing hypertension complicating the puerperium (O10.93) N=81	Unspecified pre-existing hypertension complicating the puerperium (O10.93) N=6
5	Diseases of the digestive system complicating the puerperium (O99.63) N=76	Severe pre-eclampsia, unspecified trimester (O14.10) N=6
6	Puerperal sepsis (O85) N=71	Puerperal sepsis (O85) N=6
7	Delayed and secondary postpartum hemorrhage (O72.2) N=52	Diseases of the circulatory system complicating the puerperium (O99.43) N=6
8	Unspecified pre-eclampsia, unspecified trimester (O14.90) N=49	Delayed and secondary postpartum hemorrhage (O72.2) N=5
9	Severe pre-eclampsia, unspecified trimester (O14.10) N=32	Peripartum cardiomyopathy (O90.3) N=5
10	Nonpurulent mastitis associated with the puerperium (O91.22) N=31	Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium (O99.89) N=5

*Data from MarketScan® Commercial Claims and Encounters database

One half of hospital readmissions occurred within the first week following the delivery discharge, and the average time between discharge and hospital readmission was 9.4 days (SD:7.6) (see Appendix: Figure 1A). This time was shorter among women with SMM at 7.2 days compared to women without SMM 9.7 days (P<0.001). Women with readmissions had longer mean delivery stays (2.9 days vs. 2.6 days, P<0.001) with a greater proportion staying three days or longer (22.4% vs. 13.6%, P<0.001) compared to women without readmissions. Overall, women with SMM also had significantly longer delivery stays compared to women without SMM (3.0 days vs. 2.6 days; P<0.001).

Healthcare costs incurred during the delivery stay did not differ (\$13,3344 vs. \$13,679, P=0.244) between women with and without subsequent hospital readmissions, but costs incurred during the 30 days post-delivery were twice as high for women with hospital readmissions compared to women without hospital readmissions (\$6,777 vs. \$3,095, P<0.001). Healthcare costs were even

greater for women with SMM, who incurred \$14,245 (SD: \$23,028) in delivery costs and \$8,051 (SD: \$17,715) in post-delivery costs.

Several independent predictors of hospital readmissions were identified in the adjusted logistic regression model, where SMM was the strongest predictor. Other significant predictors were advanced maternal age, method of delivery, gestation type and delivery stay longer than three days (Table 3). Several of the predictive obstetric complications occurring during the pregnancy or delivery period were related to reasons for readmission, such as obstetric infection, postpartum hemorrhage, and hypertension complicating childbirth (Table 2 and Table 3). Multiple pre-existing conditions were identified as risk factors for readmission, with the strongest associations being complications of anesthesia, breast disorders and gall bladder disease (Table 3).

 Table 3. Adjusted Model of Risk Factors Predictive of 30-day Hospital Readmissions following

 a Delivery Hospitalization Discharge in the Commercial Population, 2016*

Variable	Odds Ratio (95%CI)
Severe Maternal Morbidity	9.43 (7.87 - 11.24)
Advanced Maternal Age	1.19 (1.07 - 1.32)
Delivery Type	
Cesarean Section vs. Vaginal Delivery	1.28 (1.15 - 1.44)
Gestation Type	
Multifetal Gestation vs. Singleton	1.55 (1.24 - 1.94)
Length of Delivery Stay Longer than 3 days	1.17 (1.02 - 1.35)
Obstetric Complications	
Cervical incompetence	1.53 (1.13 - 2.07)
Structure abnormality	1.22 (1.02 - 1.46)
Excess vomiting	1.38 (1.17 - 1.62)
Unspecified hypertension complicating pregnancy childbirth or the puerperium	2.4 (2.10 - 2.74)
Antepartum hemorrhage including placenta previa with hemorrhage	1.4 (1.18 - 1.68)
Postpartum hemorrhage	1.74 (1.37 - 2.21)
Pelvic and perineal trauma	1.50 (1.28 - 1.75)
Obstetric infection	1.51 (1.27 - 1.8)
Pre-existing Comorbidities	
Urinary tract infection	1.36 (1.19 - 1.54)

Breast disorders	2.26 (1.04 - 4.93)
Complications of anesthesia	2.59 (1.48 - 4.55)
Pre-existing anemias	1.32 (1.16 - 1.51)
Thyroid disorders	1.31 (1.14 - 1.5)
Gall bladder disease	2.18 (1.46 - 3.25)
Renal disease	1.55 (1.13 - 2.11)
Liver disease	1.51 (1.02 - 2.22)
Asthma	1.39 (1.16 - 1.68)
Mental health conditions	1.23 (1.06 - 1.44)
Obesity	1.24 (1.05 - 1.45)
Chronic hypertension	1.60 (1.36 - 1.88)

*Data from MarketScan® Commercial Claims and Encounters database. CI: Confidence Interval

Emergency Room Visits

In the 30 days following delivery discharge, a total of 132 women visited the ER without being admitted, resulting in a rate of 0.8 ER visits per 1,000 discharges. These women were more likely to have had a cesarean delivery or multifetal gestation (Appendix Table 3A). Rates of ER visits among women who had cesarean sections were 81% greater than women who had vaginal deliveries (1.1 per 1,000 vs. 0.6 per 1,000 discharges).

The rate of ER visits among women with SMM was 12.8 per 1,000 discharges, compared to 0.7 per 1,000 discharges for women without SMM (RR:18.96, P<0.001). Rates of ER visits increased substantially when complicated by SMM; rates for cesarean deliveries and vaginal deliveries increased to 14.3 per 1,000 discharges and 11.0 per 1,000 discharges, respectively. Eclampsia was the most common SMM indicator observed (Appendix Table 4A) and the most common reason for ER visits (Appendix Table 5A).

The mean length of delivery stays was shorter for women with subsequent ER visits compared to women without ER visits (1.5 vs. 2.6 days, P<0.001) and less than 7.0% of women with ER visits had delivery stays longer than three days, compared to 13.7% of women without ER visits. Women with SMM had a mean delivery length of stay of 1.5 days compared to women without SMM with

2.6 days (P<0.001). The average length of time between the delivery discharge and the ER visit was 9.3 days (SD:6.9) and half of ER visits occurred within six days (Figure Appendix 2A). Women with SMM had a significantly shorter period between delivery discharge and ER visit of 8.8 days compared 9.8 day of women without SMM (P<0.001). Appendix Table 2A describes the obstetric complication history and pre-existing comorbid profile of women with and without ER visits.

Medicaid Population

Hospital Readmissions

In the Medicaid population 219,670 live deliveries were identified and 66,492 satisfied the continuous enrollment criteria. The rate of hospital readmission was 16.8 per 1,000 discharges. Hospital readmissions were most common among older women, Black women, women who had cesarean section deliveries, and women with multifetal gestations (Table 4. all P<0.001). Among the obstetric complications and pre-existing comorbidities recorded, all but two complications and four comorbidities were significantly more prevalent among women with hospital readmissions compared to women without (Table 4 and Appendix Table 6A).

	No Read	mission	Read	Readmission		
	65,378 1,114		,114	p-value		
Demographics						
Age (mean, SD)	27.23	5.53	27.57	5.6	<.0001	
Age Categories	N	%	N	%	0.006	
14-18	1,423	2.2	23	2.1		
19-24	21,799	33.3	330	29.6		
25-30	24,926	38.1	415	37.3		
31-35	11,253	17.2	213	19.1		
36-40	4,794	7.3	103	9.2		
41-45	1,106	1.7	29	2.6		
45+	77	0.1	1	0.1		
Delivery Type					<.0001	
Vaginal	47,451	72.6	651	58.4		
Cesarean	17,927	27.4	463	41.6		
Gestation Type					<.0001	

Table 4. Demographics and Characteristics of Deliveries by 30-Day Hospital Readmission
Status in the Medicaid Population, 2016*

Singleton	56,449	86.3	901	80.9	
Multifetal	1,069	1.6	37	3.3	
Race/Ethnicity					<.0001
Black	19,824	30.3	460	41.3	
Hispanic	5,782	8.8	64	5.7	
Other	4,436	6.8	51	4.6	
White	33,409	51.1	520	46.7	
Severe Maternal Morbidity Status					<.0001
SMM	467	0.7	145	13.0	
No SMM	64,911	99.3	969	87.0	

*Data from MarketScan® Medicaid database

[†]Chi-square between Readmission and No Readmission ^Gestation type data was not available for 8,036 women. ¹Race data was not available for 1,946 women

The incidence of readmissions among women with SMM was 16 times greater than women without SMM (RR: 16.10, 236.9 per 1,000 discharges vs. 14.7 per 1,000 discharges, P<0.001; Appendix Table 7A). An increasing number of concurrent SMM indicators was associated with an increasing risk of hospital readmission. Women who had cesarean section deliveries (25.2 per 1,000 discharges) were at 86% greater risk of hospital readmission compared to women who had vaginal deliveries (13.5 per 1,000 discharges, RR: 1.86, P<0.001). Rates of readmission for both delivery methods complicated by SMM during the delivery were substantially higher, with rates 8.2 and 25.4 times that of cesarean section deliveries and vaginal deliveries without SMM, respectively.

Among the 18 SMM indicators, eclampsia was the most common indicator observed and was significantly more prevalent among women with readmissions (Appendix Table 7A). *Other complications of the puerperium, not elsewhere classified* was the most common discharge diagnosis recorded for hospital readmissions (Table 5). Along with eclampsia and pre-eclampsia, obstetric infections, endometritis, and sepsis were among the top ten discharge diagnoses.

Among women experiencing SMM, many of the ten most common hospital readmission discharge diagnoses were related to SMM indicators, such as hypertensive disorders of pregnancy and

eclampsia, sepsis and obstetric infection, and hemorrhage. Except for infection or disruption of cesarean section incisions, discharge diagnoses did not differ greatly between the different methods of delivery.

Half of the hospital readmission occurred within eight days of the delivery discharge, with an average of 10.4 days (SD:7.7) (Appendix Figure 3A). Women with SMM had a shorter period between delivery discharge and hospital readmission compared to women without SMM, 8.2 vs 10.7 days, respectively (P<0.001). Delivery stays longer than three days were associated with readmissions (27.4% vs. 11.2%, P<0.001) and women with readmissions had longer average delivery stays of 3.4 days (SD:4.6) compared to 2.5 days (SD:2.2) for women without readmissions (P<0.001). Women with SMM had longer delivery stays of 3.5 days compared to women without SMM of 2.5 days (P<0.001).

Delivery costs were not significantly different between women with and without readmissions (\$4,188, vs. \$3,882, P=0.244), however costs during the post-delivery period were significantly higher among women with readmissions (\$1,401 vs. \$3,361, P<0.001). Women with SMM and hospital readmissions had similar healthcare costs as the entire group of women with readmissions.

Table 5. Ten Most Common Primary Discharge Diagnoses for 30-day Hospital Readmissions inthe Medicaid Population, 2016*

Rank	No SMM (N=969)	SMM (N=145)
1	Other complications of the puerperium, not elsewhere classified (O90.89) N=116	Eclampsia complicating the puerperium (O15.2) N=58
2	Infection of obstetric surgical wound (O86.0) N=100	Other complications of the puerperium, not elsewhere classified (O90.89) N=17
3	Endometritis following delivery (O86.12) N=90	Endometritis following delivery (O86.12) N=7
4	Puerperal sepsis (O85) N=53	Diseases of the circulatory system complicating the puerperium (O99.43) N=5

5	Diseases of the digestive system complicating the puerperium (O99.63) N=42	Puerperal sepsis (O85) N=4
6	Unspecified pre-eclampsia, unspecified trimester (O14.90) N=28	Unspecified pre-existing hypertension complicating the puerperium (O10.93) N=3
7	Unspecified pre-existing hypertension complicating the puerperium (O10.93) N=26	Severe pre-eclampsia, unspecified trimester (O14.10) N=3
8	Delayed and secondary postpartum hemorrhage (O72.2) N=22	Diseases of the respiratory system complicating the puerperium (O99.53) N=3
9	Peripartum cardiomyopathy (O90.3) N=22	Pre-existing hypertension with pre-eclampsia, third trimester (O11.3) N=2
10	Severe pre-eclampsia, unspecified trimester (O14.10) N=20	Unspecified pre-eclampsia, unspecified trimester (O14.90) N=2

*Data from MarketScan® Medicaid database

The strongest predictor in the adjusted multivariate model was SMM status, even after adjusting for all other risk factors (Table 6). Other significant risk factors in the model were type of delivery, delivery stay longer than three days, and race/ethnicity, specifically Black women compared to White women. Among the obstetric complications measured, five complications were predictive of hospital readmissions. These complications are also related to many of the discharge diagnoses in Table 5, specifically obstetric infection, hypertension complicating pregnancy, and pelvic and perineal trauma. Several pre-existing comorbidities and obstetric complications were identified as risk factors for hospital readmissions.

Table 6. Adjusted Model of Risk Factors Predictive of 30-day Hospital Readmissions following
a Delivery Hospitalization Discharge in the Medicaid Population, 2016*

Variable	Odds Ratio (95%Cl)
Severe Maternal Morbidity	10.87 (8.47 - 13.89)
Delivery Type	
Cesarean Section vs. Vaginal Delivery	1.31 (1.13 - 1.52)
Length of Delivery Stay Longer than 3 days	1.57 (1.33 - 1.87)
Race/Ethnicity	
Black vs. White	1.22 (1.06 - 1.42)

Hispanic vs. White	0.80 (0.59 - 1.07)
Other vs. White	0.84 (0.61 - 1.16)
Obstetric Complications	
Amniotic sac complications	1.25 (1.02 - 1.55)
Excess vomiting	1.28 (1.08 - 1.51)
Unspecified hypertension complicating pregnancy childbirth or the puerperium	1.73 (1.45 - 2.06)
Pelvic and perineal trauma	1.56 (1.27 - 1.92)
Obstetric infection	1.30 (1.03 - 1.65)
Pre-existing Comorbidities	
Urinary tract infection	1.19 (1.02 - 1.39)
Diabetes in pregnancy	1.35 (1.11 - 1.63)
Gall bladder disease	2.66 (1.71 - 4.12)
Other Chronic Diseases - including auto-immune	2.23 (1.25 - 3.98)
Mental health conditions	1.85 (1.58 - 2.17)
Obesity	1.38 (1.17 - 1.62)
Chronic hypertension	1.59 (1.28 - 1.98)

*Data from MarketScan[®] Medicaid database CI: Confidence Interval

Emergency Room Visits

In the Medicaid population 119 women were treated and released from the ER, resulting in a rate of 1.8 per 1,000 discharges. These women tended to be older, more likely to have had a cesarean section delivery, and more likely to have had a shorter length of delivery stay (1.4 vs. 2.6 days, P<0.001) compared to women without ER visits (Appendix Table 8A).

The rate of ER visits was 16 times greater among women with SMM compared to women without SMM (RR:16.72, 26.1 vs. 1.6 per 1,000 discharges, P<0.001). Deliveries complicated by SMM increased the rates of ER visits for cesarean deliveries and vaginal deliveries to 18.0 per 1,000 discharges and 35.8 per 1,000 discharges, respectively. Like the hospital readmission results, eclampsia was the most common SMM indicator observed (Appendix Table 9A) and was one of the most common reasons for ER visits among women with SMM (Appendix Table 10A).

Following the delivery discharge, one half of the women who visited the ER did so within eight days, and the average time between the delivery discharge and ER visit was 10.3 days (SD:7.4)(Appendix Figure 4A). Women with SMM had a shorter length of time between delivery discharge and ER visit (9.9 vs 10.4, P<0.01) compared to women without SMM. Women without ER visits were more likely to have had a delivery stay longer than three days, compared to women with ER visits (11.5% vs. 5.9%; P<0.001, respectively). Women with SMM had shorter delivery stays compared to women without SMM, 1.1 vs 2.6 days respectively (P<0.001).

Discussion

This is the first study to analyze 30-day hospital readmissions and ER treat-and-release visits among women with deliveries complicated by SMM. The rates of 30-day hospital readmission following a hospitalized delivery were 11.7 per 1,000 discharges and 16.8 per 1,000 discharges in the Commercial and Medicaid populations, respectively. Most of the hospital readmissions occurred shortly after the delivery discharge, within a week. Women with SMM during their deliveries were at a significantly higher risk of readmissions, between 12 and 16 times that of women without SMM. Race, length of delivery stay, and delivery type were predictive of hospital readmissions, where Black women, women with cesarean section deliveries and women with delivery stays longer than three days were at an increased risk.

Rates of treat-and-release ER visits were lower than hospital readmission rates in both the Commercial and Medicaid populations, 0.8 per 1,000 discharges and 1.8 per 1,000 discharges, respectively. These low rates could indicate that the more severe cases present at the ER and are subsequently admitted to the hospital. Like hospital readmissions, the occurrence of SMM substantially increased the risk of ER visits.

Vashi et al., estimated the rates of 30-day hospital readmissions and treat-and-release ER encounters for all reasons using the Healthcare Cost and Utilization Project State Inpatient and Emergency Department Databases for California, Florida and Nebraska. The incidence of hospital readmission following vaginal deliveries (9.6 vs. 7.6 per 1,000 discharges) and cesarean deliveries (16.3 vs. 15.0 per 1,000 discharges) were very similar to the results from this analysis. Rates of ER visits were very different between the two analyses, which may be a result of differing selection criteria and ER treat-and-release encounter definitions. This analysis defined treat-and-release ER visits as those in which the discharge status was labeled as discharged to home or self-care, and only included ER visits with length of stay less than two days. The primary discharge diagnoses associated with hospital readmissions and ER visits provided rationale for why women were seeking additional medical care following delivery discharge. Among women without SMM during the delivery stay with a hospital readmission, 71 in the Commercial and 53 in the Medicaid population had primary discharge diagnoses of sepsis using the same ICD-10 diagnosis code as the SMM indicator (O85). These new cases of SMM identified during the hospital readmission demonstrate that even if a woman does not experience SMM during her delivery she can still be at risk of SMM in the postpartum.

The most common diagnosis observed in both populations was ICD-10 diagnosis code O90.89 other complications of the puerperium, not elsewhere classified.¹¹ In addition to this diagnosis code, other diagnosis groups were observed in the most common diagnoses: hypertensive disorders of pregnancy and eclampsia, obstetric infection, and hemorrhage. These diagnoses each have associated risk factors, treatment strategies, and follow-up protocols suggested by the American College of Obstetricians and Gynecologists (ACOG).¹²⁻¹⁶ The frequency of these diagnoses highlight that certain conditions require greater attention during the delivery stay and immediate postpartum period to prevent additional hospitalizations.

The results of this study support the postpartum care paradigm shift proposed by ACOG, which has advocated to move from a single six-week postpartum visit to a more comprehensive care plan, which includes coordinated care with a primary maternal care provider and other care providers to manage other chronic conditions.¹² The postpartum care process recommends early contact with the maternal care provider within the first three weeks, which includes a blood pressure check within the first three days postpartum and additional follow-up visits for high-risk patients. ¹² Changes in reimbursement policies to support postpartum care as an ongoing process

could allow women to seek additional care and reduce preventable hospital readmissions and ER visits.¹²

Limitations

MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. However, these data can complement other datasets or be used as benchmarks against them.

The continuous enrollment period might reduce the ability to infer towards the larger base population who may not have the same length of continuous enrollment for different reasons such as loss of employment or changing employment status. However, this is a commonly accepted and applied principle in health services research and is fundamental to the assessment of the objectives.

CDC algorithm for defining SMM, though amenable to use with administrative data, has low sensitivity and positive predictive value,¹⁷ thus prompting investigators to apply additional criteria, e.g., length of stay or transfer to another facility. Confirmation of SMM cases identified by ICD codes via medical chart review would increase the accuracy of SMM incidence estimates. However, it is not possible to apply criteria beyond ICD-10 codes to identify SMM, including length of hospitalization and measures of comorbidity severity, as these variables were not available in the data source.

The Medicaid database represented only 11 states for the 2015-2017 period. Because of the small number of states and the variability in Medicaid benefits by state, it is not possible to generalize the Medicaid results to a national population.

Like all claims data, only billed and coded services are recorded and analyzed. This may cause an underestimation of the number of births and incidence of SMM. Additionally, there may be other services or patient characteristics that are unmeasured and affect the outcomes evaluated.

Conclusions

With childbirth accounting for the most hospitalizations in the United States, preventing costly and resource-intensive postpartum hospital readmissions would benefit not only patients, but payers and hospital administrators. This analysis highlighted the importance of and the need to address SMM, which increased the risk and cost of hospital readmissions and ER visits. Postpartum care and treatment protocols for hypertensive disorders of pregnancy and eclampsia, obstetric infection, and hemorrhage complications should be emphasized as these conditions were the most common reasons for hospital readmission and ER visits.

References

- 1. Severe Maternal Morbidity. 2017; <u>http://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidit</u> <u>y.html</u>. Accessed January 13, 2017.
- 2. Blumenfeld YJ, El-Sayed YY, Lyell DJ, Nelson LM, Butwick AJ. Risk Factors for Prolonged Postpartum Length of Stay Following Cesarean Delivery. *Am J Perinatol.* 2015;32(9):825-832.
- 3. Campbell OMR, Cegolon L, Macleod D, Benova L. Length of Stay After Childbirth in 92 Countries and Associated Factors in 30 Low- and Middle-Income Countries: Compilation of Reported Data and a Cross-sectional Analysis from Nationally Representative Surveys. *PLoS medicine.* 2016;13(3):e1001972-e1001972.
- 4. Vashi AA, Fox JP, Carr BG, et al. Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA*. 2013;309(4):364-371.
- 5. *Commercial Claims and Encounters. Data Year 2016 Edition.* IBD Watson Health;2016.
- 6. Small MJ, James AH, Kershaw T, Thames B, Gunatilake R, Brown H. Near-miss maternal mortality: cardiac dysfunction as the principal cause of obstetric intensive care unit admissions. *Obstet Gynecol.* 2012;119(2):250-255.
- 7. Bateman BT, Mhyre JM, Hernandez-Diaz S, et al. Development of a comorbidity index for use in obstetric patients. *Obstet Gynecol.* 2013;122(5):957-965.
- 8. Bruce FC, Berg CJ, Joski PJ, et al. Extent of maternal morbidity in a managed care population in Georgia. *Paediatr Perinat Epidemiol.* 2012;26(6):497-505.
- 9. Creanga AA, Bateman BT, Butwick AJ, et al. Morbidity associated with cesarean delivery in the United States: is placenta accreta an increasingly important contributor? *Am J Obstet Gynecol.* 2015;213(3):384 e381-311.
- Kuklina EV, Callaghan WM. Cardiomyopathy and other myocardial disorders among hospitalizations for pregnancy in the United States: 2004-2006. *Obstet Gynecol.* 2010;115(1):93-100.
- 11. International statistical classification of diseases and related health problems 10th Version. World Health Organization; 2016.
- 12. ACOG Committee Opinion No. 736: Optimizing Postpartum Care. *Obstetrics & Gynecology.* 2018;131(5).
- 13. ACOG Practice Bulletin No. 203 Summary: Chronic Hypertension in Pregnancy. *Obstetrics & Gynecology.* 2019;133(1873-233X (Electronic)).
- 14. ACOG Committee Opinion No. 767: Emergent Therapy for Acute-Onset, Severe Hypertension During Pregnancy and the Postpartum Period. *Obstetrics & Gynecology*. 2019;133(1873-233X (Electronic)).
- 15. Waldman R. ACOG Practice Bulletin No. 198: Prevention and Management of Obstetric Lacerations at Vaginal Delivery. *Obstetrics & Gynecology*. 2018;133(1873-233X (Electronic)).
- 16. Practice Bulletin No. 183: Postpartum Hemorrhage. *Obstetrics & Gynecology*. 2018;130(1873-233X (Electronic)).
- 17. Main EK, Abrero A, McNulty J. Measuring severe maternal morbidity: valdiation of potential measures. *Am J Obstet Gynecol.* 2016;214(5):643.e641-643.e610.

Appendix Tables and Figures

	No Rea	dmission	Readr	nission	
	163	,517	1,	927	p-value
	Ν	%	N	%	
Obstetric Complications					
Abnormal glucose tolerance	14,753	9.0	210	10.9	<.0001
Amniotic sac complications	19,771	12.1	344	17.9	<.0001
Cervical incompetence	3,085	1.9	74	3.8	<.0001
Structure abnormality	13,583	8.3	250	13.0	0.7314
Excess vomiting	11,736	7.2	220	11.4	<.0001
Gestational hypertension/preeclampsia	3,972	2.4	64	3.3	<.0001
Unspecified hypertension complicating pregnancy childbirth or the puerperium	21,775	13.3	745	38.7	<.0001
Antepartum hemorrhage including placenta previa with hemorrhage	9,053	5.5	179	9.3	<.0001
Postpartum hemorrhage	3,924	2.4	99	5.1	<.0001
Pelvic and perineal trauma	14,231	8.7	241	12.5	0.6846
Uterine rupture	139	0.1	3	0.2	<.0001
Obstetric infection	9,508	5.8	204	10.6	<.0001
Pre-existing Comorbidities					
Urinary tract infection	22,731	13.9	402	20.9	<.0001
Pneumonia	530	0.3	26	1.3	<.0001
Appendicitis	127	0.1	5	0.3	<.0001
Infections not classified elsewhere	1,528	0.9	25	1.3	0.0206
Breast disorders	214	0.1	10	0.5	<.0001
Complications of anesthesia	442	0.3	17	0.9	0.0043
Pre-existing anemias	20,778	12.7	367	19.0	<.0001
Hereditary hemolytic anemia	449	0.3	10	0.5	<.0001
Clotting disorders	2,930	1.8	56	2.9	<.0001
Tuberculosis	90	0.1	-	0.0	<.0001

Table 1A. Clinical Characteristics of Deliveries by 30-Day Hospital Readmission Status in the Commercially Insured Population, 2016*

HIV	105	0.1	3	0.2	0.0116
Diabetes in pregnancy	17,773	10.9	345	17.9	<.0001
Thyroid disorders	26,925	16.5	538	27.9	<.0001
Gall bladder disease	935	0.6	40	2.1	<.0001
Renal disease	1,916	1.2	57	3.0	<.0001
Liver disease	1,655	1.0	40	2.1	0.2922
Asthma	8,070	4.9	158	8.2	<.0001
Neurologic conditions	174	0.1	7	0.4	<.0001
Cardiovascular conditions	2,682	1.6	91	4.7	<.0001
Other chronic diseases - including auto-immune	1,844	1.1	35	1.8	0.0050
Mental health conditions	13,804	8.4	252	13.1	0.1005
Obesity	15,631	9.6	379	19.7	<.0001
Chronic hypertension	8,410	5.1	395	20.5	<.0001

*Data from MarketScan® Commercial Claims and Encounters database †Chi-square between Readmission and No Readmission

	No Readmission		Readmission		
	(N=163,517)		(N=1,927)		p-value†
	Ν	%	N	%	
SMM	1747	1.1	252	13.1	<.0001
Concurrent SMM Indicators					<.0001
1	1316	0.8	189	9.8	
2	106	0.1	43	2.2	
3+	52	0.0	20	1.0	
SMM Indicators [^]					
Eclampsia	316	0.2	178	9.2	<.0001
Pulmonary edema / Acute heart failure	122	0.1	29	1.5	<.0001
Acute renal failure	112	0.1	24	1.2	<.0001
Blood transfusion	395	0.2	23	1.2	<.0001
Adult respiratory distress syndrome	131	0.1	20	1.0	<.0001

Table 2A. SMM Indicators associated with 30-day Hospital Readmission in the Commercial Population, 2016*

*Data from MarketScan[®] Commercial Claims and Encounters database [†]Chi-square between Readmission and No Readmission ^ 5 most prevalent SMM Indicators

	No ER visit		ER Visit		
	165,31	13	13	32	p- value
Demographics					
Age (mean, SD)	31.98	5.34	31.5 3	5.9	0.3785
Age Categories (n, %)	Ν	%	Ν	%	0.0018
14-18	464	0.3	1	0.8	
19-24	14,778	8.9	24	18.2	
25-30	46,834	28.3	31	23.5	
31-35	60,294	36.5	34	25.8	
36-40	34,623	20.9	35	26.5	
41-45	7,541	4.6	6	4.5	
45+	779	0.5	1	0.8	
Delivery Type					0.0005
Vaginal	54,209	32.8	62	47	
Cesarean	111,104	67.2	70	53	
Gestation Type					<.0001
Singleton	143,878	87	105	79.5	
Multifetal	3,738	2.3	9	6.8	
Region					0.6826
Midwest	34,690	21	25	18.9	
Northeast	27,835	16.8	21	15.9	
South	69,478	42	63	47.7	
West	28,887	17.5	21	15.9	
Obstetric Complications					
Abnormal glucose tolerance	14,951	9	12	9.1	0.985
Amniotic sac complications	20,098	12.2	17	12.9	0.7999
Cervical incompetence	3,156	1.9	3	2.3	0.7603
Structure abnormality	13,813	8.4	20	15.2	0.0048
Excess vomiting	11,933	7.2	23	17.4	<.0001
Gestational hypertension/ preeclampsia	4,034	2.4	2	1.5	0.491
Unspecified hypertension complicating pregnancy childbirth or the puerperium	22,469	13.6	52	39.4	<.0001
Antepartum hemorrhage including placenta previa with hemorrhage	9,222	5.6	10	7.6	0.3177
Postpartum hemorrhage	4,013	2.4	10	7.6	0.0001
Pelvic and perineal trauma	14,457	8.7	15	11.4	0.2872
Uterine rupture	142	0.1	-	0	0.7362

Table 3A. Demographics and Characteristics of All Deliveries by 30-Day Emergency Room Visitin the Commercially Insured Population, 2016*

Obstetric infection	9,703	5.9	9	6.8	0.643
Pre-existing Comorbidities					
Urinary tract infection	23,107	14	26	19.7	0.0582
Pneumonia	555	0.3	1	0.8	0.4025
Appendicitis	132	0.1	-	0	0.7453
Infections not classified elsewhere	1,551	0.9	2	1.5	0.492
Breast disorders	224	0.1	-	0	0.6721
Complications of anesthesia	457	0.3	2	1.5	0.0068
Pre-existing Anemias	21,113	12.8	32	24.2	<.0001
Hereditary hemolytic anemia	458	0.3	1	0.8	0.2941
Clotting disorders	2,980	1.8	6	4.5	0.018
Tuberculosis	90	0.1	-	0	0.7886
HIV	108	0.1	-	0	0.7689
Diabetes in pregnancy	18,098	10.9	20	15.2	0.1221
Thyroid disorders	27,424	16.6	39	29.5	<.0001
Gall bladder disease	972	0.6	3	2.3	0.0115
Renal Disease	1,968	1.2	5	3.8	0.006
Liver Disease	1,692	1	3	2.3	0.1542
Asthma	8,216	5	12	9.1	0.0295
Neurologic Conditions	181	0.1	-	0	0.7037
Cardiovascular Conditions	2,767	1.7	6	4.5	0.0102
Other Chronic Diseases - including auto-immune	1,875	1.1	4	3	0.0399
Mental Health Conditions	14,039	8.5	17	12.9	0.0708
Obesity	15,982	9.7	28	21.2	<.0001
Chronic Hypertension	8,774	5.3	32	24.2	<.0001

*Data from MarketScan® Commercial Claims and Encounters database

⁺Chi-square between Readmission and No Readmission ^Gestation type data was not available for 17,715 women.

	No ER Visit		E	R Visit	
	163,	517		1,627	p-value†
	Ν	%	N	%	
SMM	1704	1.0	22	1.4	<.0001
Concurrent SMM Indicators					<.0001
1	1486	0.9	19	1.2	
2	148	0.1	1	0.1	
3+	70	0.0	2	0.1	
SMM Indicators					
Eclampsia	480	0.3	14	0.9	<.0001
Blood transfusion	412	0.2	6	0.4	<.0001
Disseminated intravascular coagulation	260	0.2	2	0.1	<.0001
Puerperal cerebrovascular disorders	69	0.0	2	0.1	<.0001
Pulmonary edema / Acute heart failure	149	0.1	2	0.1	<.0001

Table 4A. SMM Indicators associated with 30-day Emergency Room Visits in the CommercialPopulation, 2016*

*Data from MarketScan[®] Commercial Claims and Encounters database [†]Chi-square between Readmission and No Readmission

^ 5 most prevalent SMM Indicators

Table 5A. Top Ten Discharge Diagnoses for 30-day Emergency Room Visit in the CommercialPopulation, 2016*

Rank	No SMM	SMM
	(N=110)	(N=222)
	Diseases of the digestive system complicating	Other complications of the puerperium, not
1	the puerperium	elsewhere classified (O90.89)
	(O99.63) N=40	N=34
	Other complications of the puerperium, not	Eclampsia complicating the puerperium
2	elsewhere classified (O90.89)	(O15.2)
_	N=36	N=16
	Endometritis following delivery (O86.12)	Unspecified pre-existing hypertension
3	N=24	complicating the puerperium
5		(010.93)
		N=9
	Unspecified pre-existing hypertension	Spinal and epidural anesthesia-induced
4	complicating the puerperium (O10.93)	headache during the puerperium (O89.4)
	N=19 Delayed and secondary postpartum	N=8 Diseases of the circulatory system complicating
	hemorrhage (072.2)	the puerperium
5	N=16	(099.43)
		N=6
	Bacteremia (R78.81)	Delayed and secondary postpartum
6	N=15	hemorrhage (072.2)
		N=5
	Pre-existing essential hypertension	Severe pre-eclampsia, unspecified trimester
7	complicating the puerperium	(O14.10) N=4
	(O10.03) N=13	
	Pre-existing hypertensive heart disease	Diseases of the nervous system complicating
8	complicating the puerperium (010.13)	the puerperium (O99.355)
_	N=13	N=3
	Pyrexia of unknown origin following delivery	Other pulmonary embolism without acute cor
9	(O86.4)	pulmonale (I26.99)
	N=13	N=2
	Diseases of the circulatory system	Other immediate postpartum hemorrhage
10	complicating the puerperium	(07.21)
	(O99.43) N=13	N=2
L	CT-N	

*Data from MarketScan[®] Commercial Claims and Encounters database

Table 6A. Clinical Characteristics of Deliveries by 30-Day Hospital Readmission Status and SMM Status in the Medicaid Population,2016*

	No Readmission		Read	dmission	
	65,378		1	1,114	p-value†
Obstetric Complications	Ν	%	N	%	
Abnormal glucose tolerance	4,161	6.4	79	7.1	0.3247
Amniotic sac complications	7,134	10.9	201	18.0	<.0001
Cervical incompetence	668	1.0	21	1.9	0.0048
Structure abnormality	2,944	4.5	74	6.6	0.0007
Excess vomiting	9,194	14.1	242	21.7	<.0001
Gestational hypertension/preeclampsia	1,093	1.7	20	1.8	0.75
Unspecified hypertension complicating pregnancy childbirth or the puerperium	9,189	14.1	403	36.2	<.0001
Antepartum hemorrhage including placenta previa with hemorrhage	4,059	6.2	113	10.1	<.0001
Postpartum hemorrhage	1,598	2.4	43	3.9	0.0025
Pelvic and perineal trauma	6,004	9.2	141	12.7	<.0001
Uterine rupture	54	0.1	3	0.3	0.0347
Obstetric infection	4,963	7.6	163	14.6	<.0001
Pre-existing Comorbidities					
Urinary tract infection	12,563	19.2	305	27.4	<.0001
Pneumonia	203	0.3	23	2.1	<.0001
Appendicitis	40	0.1	1	0.1	0.7031
Infections not classified elsewhere	1,162	1.8	33	3.0	0.0032
Breast disorders	113	0.2	8	0.7	<.0001
Complications of anesthesia	126	0.2	4	0.4	0.2127
Pre-existing anemias	14,414	22.0	321	28.8	<.0001
Hereditary hemolytic anemia	329	0.5	12	1.1	0.0078
Clotting disorders	1,054	1.6	35	3.1	<.0001

Tuberculosis	30	0.0	1	0.1	0.5011
HIV	60	0.1	4	0.4	0.0043
Diabetes in pregnancy	6,008	9.2	174	15.6	<.0001
Thyroid disorders	10,480	16.0	307	27.6	<.0001
Gall bladder disease	489	0.7	34	3.1	<.0001
Renal disease	624	1.0	27	2.4	<.0001
Liver disease	519	0.8	20	1.8	0.0002
Asthma	5,415	8.3	152	13.6	<.0001
Neurologic conditions	79	0.1	2	0.2	0.5776
Cardiovascular conditions	820	1.3	42	3.8	<.0001
Other chronic diseases - including auto- immune	308	0.5	18	1.6	<.0001
Mental health conditions	8,986	13.7	304	27.3	<.0001
Obesity	9,784	15.0	314	28.2	<.0001
Chronic hypertension	3,360	5.1	205	18.4	<.0001

*Data from MarketScan® Medicaid database †Chi-square between Readmission and No Readmission

	No Readmission		Readr	Readmission		
	(N=65	(N=65,378)		(N=1,114)		
	Ν	%	N	%		
SMM	467	0.7	145	13.0	<.0001	
Concurrent SMM Indicators					<.0001	
1	394	0.6	113	10.1		
2	48	0.1	24	2.2		
3+	24	0.0	8	0.7		
SMM Indicators [^]						
Eclampsia	156	0.2	94	8.4	<.0001	
Pulmonary edema /		0.1	14	1.3		
Acute heart failure	56				<.0001	
Acute renal failure	43	0.1	11	1.0	<.0001	
Blood transfusion	31	0.0	11	1.0	<.0001	
Adult respiratory		0.1	10	0.9		
distress syndrome	79				<.0001	

Table 7A. SMM Indicators associated with 30-day Hospital Readmission in the Medicaid Population, 2016*

*Data from MarketScan[®] Medicaid database [†]Chi-square between Readmission and No Readmission ^ 5 most prevalent SMM Indicators

	No ER	Visit	El	R Visit	
	165,3	1		132	p-value†
Demographics	N	%	N	%	
Age (mean, SD)	27.28	5.56	29.01	5.9	<.0001
Age Categories (n, %)					0.0362
14-18	1,445	2.2	1	0.8	
19-24	22,104	33.3	26	21.8	
25-30	25,292	38.1	49	41.2	
31-35	11,441	17.2	25	21.0	
36-40	4,884	7.4	13	10.9	
41-45	1,130	1.7	5	4.2	
45+	78	0.1	-	0.0	
Delivery Type					<.0001
Vaginal	48,033	72.4	70	58.8	
Cesarean	18,341	27.6	49	41.2	
Gestation Type	· · ·				0.3494
Singleton	57,250	86.3	101	84.9	
Multifetal	1,102	1.7	4	3.4	
Race/Ethnicity					0.2443
Black	20,240	30.5	44	37.0	
Hispanic	5,840	8.8	6	5.0	
Other	4,480	6.7	7	5.9	
White	33,869	51.0	61	51.3	
Obstetric Complications	,				
Abnormal glucose tolerance	4,231	6.4	10	8.4	0.3655
amniotic sac complications	7,319	11.0	16	13.4	0.4001
Cervical incompetence	687	1.0	2	1.7	0.4871
Structure abnormality	3,010	4.5	8	6.7	0.252
Excess vomiting	9,408	14.2	29	24.4	0.0015
Gestational hypertension/ preeclampsia	1,111	1.7	2	1.7	0.9954
Unspecified hypertension complicating pregnancy childbirth or the puerperium	9,557	14.4	35	29.4	<.0001

Table 8A. Demographics and Characteristics of Deliveries by 30-Day Emergency Room Visit in the Medicaid Insured Population, 2016*

Antepartum hemorrhage including placenta previa with hemorrhage	4,161	6.3	11	9.2	0.1812
Postpartum hemorrhage	1,630	2.5	11	9.2	<.0001
Pelvic and perineal trauma	6,130	9.2	15	12.6	0.2048
Uterine rupture	57	0.1	-	0.0	0.7491
Obstetric infection	5,105	7.7	21	17.6	<.0001
Pre-existing Comorbidities					
Urinary tract infection	12,830	19.3	38	31.9	0.0005
Pneumonia	225	0.3	1	0.8	0.3478
Appendicitis	41	0.1	-	0.0	0.7862
Infections not classified elsewhere	1,191	1.8	4	3.4	0.1986
Breast disorders	120	0.2	1	0.8	0.0917
Complications of anesthesia	130	0.2	-	0.0	0.6289
Pre-existing Anemias	14,706	22.2	29	24.4	0.5613
Hereditary hemolytic anemia	340	0.5	1	0.8	0.6166
Clotting disorders	1,084	1.6	5	4.2	0.0274
Tuberculosis	31	0.0	-	0.0	0.8136
HIV	63	0.1	1	0.8	0.0088
Diabetes in pregnancy	6,161	9.3	21	17.6	0.0017
Thyroid disorders	10,752	16.2	36	30.3	<.0001
Gall bladder disease	516	0.8	7	5.9	<.0001
Renal Disease	647	1.0	4	3.4	0.0082
Liver Disease	537	0.8	2	1.7	0.2894
Asthma	5,557	8.4	10	8.4	0.9902
Neurologic Conditions	81	0.1	-	0.0	0.703
Cardiovascular Conditions	859	1.3	3	2.5	0.2372
Other Chronic Diseases - including auto- immune	324	0.5	2	1.7	0.0628
Mental Health Conditions	9,262	14.0	28	23.5	0.0026
Obesity	10,067	15.2	31	26.1	0.0009
Chronic Hypertension	3,548	5.3	17	14.3	<.0001

*Data from MarketScan® Medicaid database +Chi-square between Readmission and No Readmission

	No ER Visit		ER	Visit	
	N=66,374		N=	N=119	
	Ν	%	N	%	
SMM	596	0.9	16	13.4	<.0001
Concurrent SMM Indicators					<.0001
1	493	0.7	14	11.8	
2	71	0.1	1	0.8	
3+	32	0.0	1	0.8	
SMM Indicators [^]					
Eclampsia	239	0.4	11	9.2	<.0001
Sepsis	56	0.1	2	1.7	<.0001
Acute renal failure	53	0.1	1	0.8	0.0036
Adult respiratory distress	88	0.1	1	0.8	
syndrome					0.0349
Disseminated intravascular	58	0.1	1	0.8	
coagulation					0.0058

Table 9A. SMM Indicators associated with 30-day Emergency Room Visits in the Medicaid Population, 2016*

*Data from MarketScan[®] Medicaid database [†]Chi-square between Readmission and No Readmission ^ 5 most prevalent SMM Indicators

Rank	No SMM (N=103)	SMM (N=16)
1	Other complications of the puerperium, not elsewhere classified (O90.89) N=48	Eclampsia complicating the puerperium (O15.2) N=32
2	Type 1 diabetes mellitus with ketoacidosis without coma (E10.10) N=41	Severe pre-eclampsia, unspecified trimester (O14.10) N=5
3	Endometritis following delivery (O86.12) N=22	Other complications of the puerperium, not elsewhere classified (O90.89) N=4
4	Delayed and secondary postpartum hemorrhage (O7.22) N=19	lleus, unspecified (K56.7) N=3
5	Infection of obstetric surgical wound (O86.0) N=11	Endometritis following delivery (O86.12) N=2
6	Unspecified pre-existing hypertension complicating the puerperium (O10.93) N=10	Delayed and secondary postpartum hemorrhage (O72.2) N=1
7	Third-stage hemorrhage (O72.0) N=10	
8	Peripartum cardiomyopathy (O90.3) N=9	
9	Acute systolic (congestive) heart failure (I50.21) N=7	
10	Diseases of the nervous system complicating the puerperium (O99.355) N=7	

Table 10A. Top Ten Discharge Diagnoses for 30-day Emergency Room Visit in the MedicaidPopulation, 2016*

*Data from MarketScan[®] Medicaid database

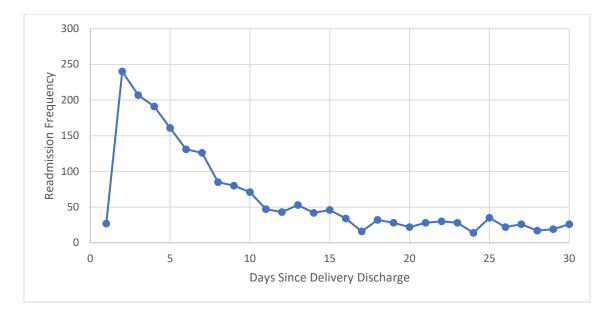


Figure 1A. Frequency of Days Between Delivery Discharge and Hospital Readmission in the Commercial Population, 2016*

*Data from MarketScan[®] Commercial Claims and Encounters database

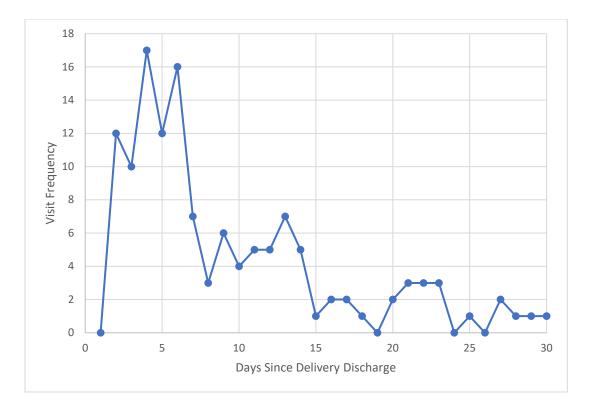


Figure 2A. Frequency of Days Between Delivery Discharge and ER Visit in the Commercial Population, 2016*

*Data from MarketScan[®] Commercial Claims and Encounters database

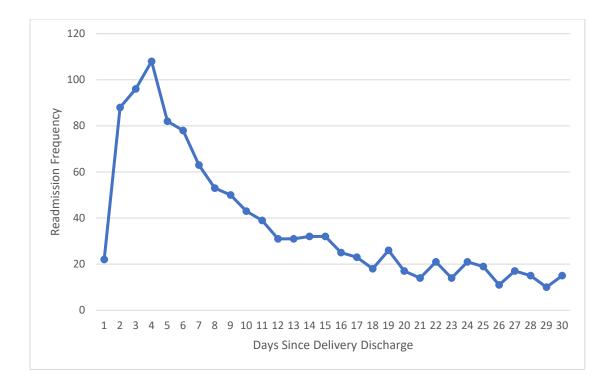


Figure 3A. Frequency of Days Between Delivery Discharge and Hospital Readmission in the Medicaid Population, 2016*

*Data from MarketScan® Medicaid database

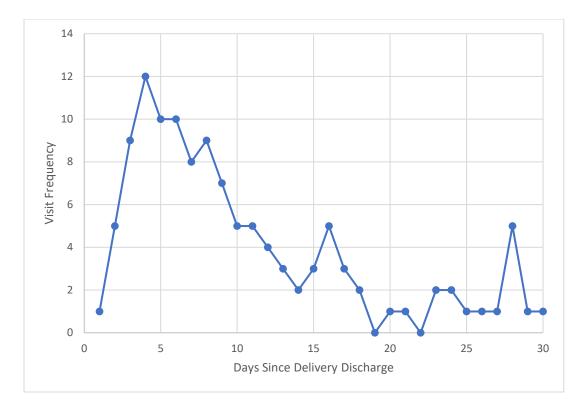


Figure 4A. Frequency of Days Between Delivery Discharge and ER Visit in the Medicaid Population, 2016*

*Data from MarketScan® Medicaid database

PAPER 3 – THE ECONOMIC BURDEN OF SEVERE MATERNAL MORBIDITY IN THE UNITED STATES Précis

This study helps address the question of the direct costs associated with severe maternal morbidity in commercially insured and Medicaid populations.

Abstract

Objective: To estimate the economic burden of SMM by deriving estimates of prenatal, delivery, and post-delivery costs from a nationwide sample of commercially and Medicaid-insured women.

Methods: A retrospective cohort study of women identified in the MarketScan Commercial and Medicaid health insurance claims databases with live inpatient birth in the calendar year 2016, with continuous enrollment 9 months before and 30 days after delivery. Costs were defined as the amounts paid by insurers plus out-of-pocket and third-party payments. Severe maternal morbidity as identified using Centers for Disease Control & Prevention algorithm of 18 ICD-10 diagnostic and procedural codes. Generalized linear models were used to analyze demographic and clinical variables influencing delivery costs. Mean costs were estimated and cost ratios were reported. Sensitivity analyses were conducted to assess the impact of continuous enrollment.

Results. We identified 1,486 women in the Commercial population who had a live birth in 2016 and met the criteria for severe maternal morbidity. The total, per-patient mean costs of care for women without and with SMM were \$23,144 and \$47,030, respectively, with prenatal, delivery and post-delivery costs all significantly higher among women with SMM. The differences in costs for women with and without SMM during the prenatal, delivery and post-delivery period were \$10,279, \$7,824, and \$5,783, respectively. The adjusted delivery cost for women with SMM were 20% greater than women without SMM. 342 live births in the Medicaid population met the criteria for severe maternal morbidity. The total, per-patient mean costs of care for women with SMM were 177% higher than women with SMM. Differences in the prenatal, delivery, and post-delivery costs for women with and without SMM were \$7,034, \$3,755, and \$6,162, respectively. The adjusted delivery cost for women with SMM were 31% greater than women without SMM. Variables independently predictive of increased delivery costs in both Commercial and Medicaid populations were delivery by cesarean section, and multifetal gestation. Sensitivity analysis loosening the continuous enrollment criteria revealed higher costs healthcare costs in both the non and SMM groups, but the cost-ratios were similar to the primary analysis.

Conclusions. The occurrence of severe maternal morbidity was associated with an increase in maternity-related costs of 20% in the commercial and 31% in the Medicaid population. Some of the factors associated with increased delivery hospitalization costs may be treated or prevented.

Key words. Comorbidity, health care costs; hospitalization, insurance claim review, pregnancy complications, United States

Introduction

The most common reason for hospitalization in the United States is childbirth, with almost 4 million deliveries occurring every year.¹ National estimates of the cost of hospital deliveries in the United States vary, but the Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project estimates the average at \$4,500 per stay.² The mode of delivery influences the cost of care (from \$1,900 to \$2,600 for vaginal and cesarean section deliveries, respectively²) and complications increase the number of resources required. Additionally, the cost of pregnancy increased substantially over the past several decades, primarily due to increases in the frequency of cesarean deliveries^{2,3} and multifetal pregnancies⁴. As women with pre-existing medical

conditions^{5,6} and complications² incur greater pregnancy costs, the total cost for each of their pregnancies, including prenatal and post-partum healthcare, can be more than \$30,000.³

Severe maternal morbidity (SMM) refers to scenarios in which women almost die from one or more life-threatening complications during pregnancy or childbirth.⁷ Women experiencing SMM require specific care and attention, which can result in substantial healthcare resources use and associated costs.^{8,9} Mean delivery costs associated with SMM have been estimated to be 1.7 to 2.2 times those of deliveries without SMM.^{8,9} The existing literature focuses on hospital delivery costs from discharge data but there is a dearth of literature describing the prenatal and post-delivery costs associated with SMM The objective of this analysis was to estimate the economic burden of SMM by deriving estimates of prenatal, delivery, and post-delivery costs from a nationwide sample of commercially and Medicaid-insured women.

Materials and Methods

Study design and data sources

This retrospective analysis utilized data from the MarketScan® Commercial Claims and Encounters ("Commercial") database and the MarketScan® Medicaid database to create a longitudinal cohort of live births occurring in 2016. These databases include paid medical and prescription drug claims for 115 million unique patients from approximately 200 self-insured U.S. employers, 30 health plans, and 11 Medicaid agencies.¹⁰ The Commercial database contains insurance claims of employees and their dependents covered under a variety of fee-for-service and capitated health plans, including exclusive provider organizations (EPO), preferred provider organizations (PPOs), point of service (POS) plans, indemnity plans, and health maintenance organizations (HMOs). Complete payment information is captured, including costs paid by both the benefit plan and the patient. The geographic composition of the Commercial database is representative of the US population and includes defined region variables, unlike the Medicaid database.

The Medicaid database contains the pooled healthcare experience of approximately seven million Medicaid enrollees from 11 state contributors and Medicaid-managed care plans. It includes inpatient services and prescription drug claims, as well as information on enrollment, long-term care, and other medical care. Complete payment information is captured, including costs paid by both the benefit plan and the patient. The Medicaid database also records race as a variable, which is not available in the Commercial database.

Study sample

The study population included all women with live births in 2016, identified by ICD-10 diagnostic and procedure codes, Current Procedural Terminology (CPT), and Diagnosis Related Group (DRG) codes.^{11,12} Males were excluded, as well as deliveries with codes not indicating a live birth such as molar pregnancy, or ectopic pregnancy.¹ Continuous enrollment was required during the nine months prior to the delivery and 30 days following the delivery. This analysis is referred to later as the primary analysis. A sensitivity analysis was conducted removing the continuous enrollment criterion to account for potential selection bias, specifically in the Medicaid population which was observed to have a fragmented enrollment history.

SMM was defined by the occurrence during a delivery of one or more of the 18 potentially lifethreatening maternal conditions or complications listed in ICD-10.¹¹ Preexisting comorbidities and obstetric-related complications were identified from the literature and corresponding ICD-10 codes identified (Appendix Table 1A).¹³⁻¹⁵ Patient characteristics included in the study were maternal age in 5-year age groups, adolescence (\leq 18 years of age), advanced maternal age (\geq 35 years of age), gestation type (singleton or multifetal), delivery type (vaginal or cesarean), geographic region (Commercial population only), and race/ethnicity (Medicaid population only).

¹ ICD-10-CM codes (O01, O02, O00, O03, O04, O07, O08, Z37.7); CPT codes (59840, 59841, 59850-59852, 59855-59857), and DRG codes (770, 779, 777).

Geographic regions included the four divisions defined by the US Census: Northeast, Midwest, South, and West. Race/ethnicity was categorized as White non-Hispanic, Black non-Hispanic, other non-Hispanic, or two or more races non-Hispanic.

Cost calculations

All-cause costs incurred during the observation period were classified based on the prenatal period (nine months prior to delivery hospitalization admission), delivery period (costs during hospitalization), and post-delivery period (30 days following delivery hospitalization discharge). Total costs were estimated for all services using the amounts paid by insurers plus out-of-pocket and third-party payments.

Statistical Analysis

Cost data are calculated as mean, standard deviations (SD), median and interquartile ranges (IQRs). Costs were also calculated by SMM status, delivery type, gestation type, maternal age categories, region in the Commercial population, and race in the Medicaid population. Comparison of mean and median costs between women with and without SMM were tested using T-tests and nonparametric Kruskal-Wallis tests, respectively.

Generalized linear models were used to analyze demographic and clinical variables influencing delivery costs. The models used a log link and gamma error distribution functions that conform to the non-normal cost distributions that are typical of healthcare costs. Results are presented as cost ratios with 95% confidence intervals and estimated mean costs with 95% confidence intervals. All analyses were conducted using SAS Version 9.4.31.

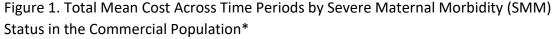
Results

Commercial Population

A total of 130,297 live deliveries in 2016 met the study inclusion criteria, of which 1,486 (1.1%) deliveries were classified as SMM based on ICD-10 diagnostic and procedure codes.¹¹ The total,

per-patient mean costs of care for women with and without SMM were \$23,144 and \$47,030, respectively, with prenatal, delivery and post-delivery costs all significantly higher among women with SMM (P<0.001 for all comparisons; (Figure 1 & Appendix Table 2A) . The differences in costs for women with and without SMM during the prenatal, delivery and post-delivery period were \$10,279, \$7,824, and \$5,783, respectively (P<0.001 for all comparisons). Delivery costs constituted a smaller proportion of the total cost for women with SMM (45.5% vs 58.7%). For women with SMM, prenatal costs (34.7% vs 26.0%) and post-delivery costs (19.8% vs 15.2%) accounted for a greater proportion of the total cost compared to women without SMM.





*Data from MarketScan[®] Commercial Claims and Encounters database

The concurrence of more than one SMM indicator was associated with increased delivery costs (Table 1). Among the SMM indicators, the greatest delivery costs were observed in women experiencing cardiac arrest/ ventricular fibrillation/ conversion of cardiac rhythm, followed by adult respiratory distress syndrome, shock, and amniotic fluid embolism (Figure 2).

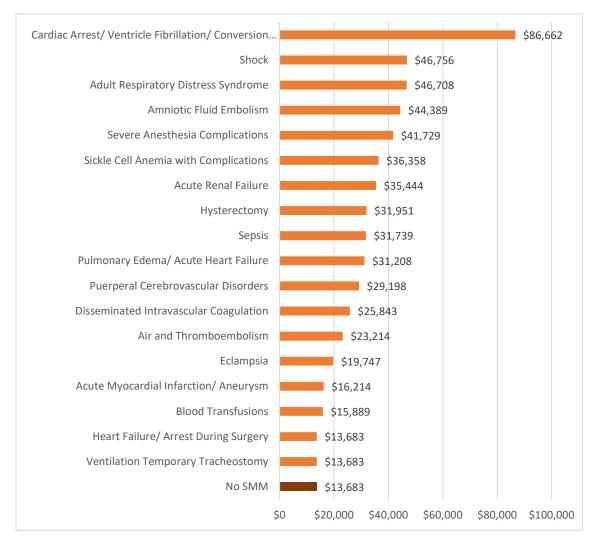


Figure 2. Mean Delivery Cost by SMM Indicator in the Commercial Population* *Data from MarketScan® Commercial Claims and Encounters database

Among demographic and clinical characteristics, the total costs of care for women without and with SMM were greater for delivery by cesarean section and for multifetal gestations (P<0.001;

Table 1). Increasing age was associated with increased healthcare costs with the greatest costs incurred among the older age stratum (Appendix Figure 1A).

After adjusting for demographic and delivery characteristics, such as method and gestation type, deliveries with SMM were still significantly costlier compared to deliveries without SMM (P<0.001, Table 1). The adjusted delivery cost for women with SMM was 20% greater than women without SMM. Overall, adjusted mean delivery costs remained high for all demographic and delivery characteristics, although those 14-18 were no longer statistically different compared to referent of women 31-35 years of age. In addition to SMM status, delivery method, gestation type, region and presence of any obstetric complications or preexisting comorbidities were independently predictive of increased delivery costs (Table 1). In an unadjusted analysis, maternal age and concurrence of SMM indicators was predictive of increased delivery costs (Appendix Figure 2A).

	Adjusted Cost Ratio	Adjusted Mean Cost
	(95% CI)	(95% CI)
Intercept	-	\$15,607#
SMM (referent: No SMM)	1.2 (1.17 - 1.24) †	\$22,672 (\$21,277 - \$24,154)
Delivery (referent: Vaginal)		
Cesarean	1.17 (1.17 - 1.18) †	\$22,103 (\$21,220 - \$23,024)
Maternal Age (referent: 31-35)		
14-18	0.94 (0.85 - 1.05)	\$17,781 (\$15,430 - \$20,490)
19-24	0.94 (0.92 - 0.96) †	\$17,692 (\$16,726 - \$18,715)
25-30	0.96 (0.94 - 0.97) +	\$18,041 (\$17,177 - \$18,949)
36-40	1.02 (1.01 - 1.04) +	\$19,287 (\$18,339 - \$20,282)
41-45	1.08 (1.04 - 1.11) †	\$20,243 (\$18,993 - \$21,575)
45+	1.09 (1 - 1.2) †	\$20,590 (\$18,151 - \$23,356)
Gestation Status (referent:		
Singleton)		
Multifetal	1.09 (1.07 - 1.11) †	\$20,422 (\$19,372 - \$21,528)
Region (referent: West)		
Midwest	0.86 (0.85 - 0.87) †	\$16,242 (\$15,522 - \$16,995)
Northeast	1.22 (1.2 - 1.23) †	\$22,929 (\$21,890 - \$24,017)
South	0.85 (0.85 - 0.86) †	\$16,045 (\$15,366 - \$16,756)

Table 1. Predictors of Adjusted Delivery Cost in the Commercial Population*

Pregnancy-related	1.04 (1.04 - 1.05) †	\$19,633 (\$18,843 - \$20,457)
complication (referent: no		
presence of complications)		

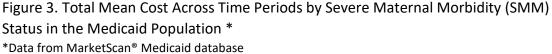
*Data from MarketScan[®] Commercial Claims and Encounters database. [#]Estimated cost for a woman with no SMM, vaginal delivery, age 31-35, singleton, West, and no presence of complications. CI: 95% confidence interval. [†] Multivariate regression analysis statistically significant at P<0.05

After adjusting for demographic and pregnancy characteristics, several pre-existing and obstetric complications were independently predictive of increased delivery costs with greatest cost ratios among pregnancies affected by obstetric infection (1.17, 95%Cl 1.14 - 1.2), pneumonia (CR:1.17, 95%Cl 1.06 - 1.29), and postpartum hemorrhage (CR:1.16, 95%Cl 1.12 - 1.21). Other statistically significant comorbidities and complications were gestation hypertension/ preeclampsia, unspecified hypertension complication pregnancy, childbirth, or puerperium, pelvic and perineal trauma, pre-existing anemia, clotting disorders, liver disease, cardiovascular disease, and chronic hypertension.

Medicaid Population

A total of 29,763 live deliveries in 2016 met the study inclusion criteria, of which 342 (1.2%) deliveries were classified as SMM based on ICD-10 diagnostic and procedure codes.¹¹ The total, per-patient mean costs of care for women with SMM were 177% higher than women without SMM (\$26,513 vs \$9,652; Figure 3 & Appendix Table 4). Differences in the prenatal, delivery, and post-delivery costs between women with and without SMM were \$7,034, \$3,755, and \$6,162, respectively (P<0.001 for all comparisons, Appendix Table 4). Costs were distributed relatively equal across the three-time periods for women with and without SMM





Among demographic and clinical characteristics, the total costs of care for women without and with SMM were greater for delivery by cesarean section and for multifetal gestations (P<0.001; Appendix Table 5A). Black women incurred the greatest total healthcare cost during the observation window, compared to Hispanic, non-Hispanic White, and other races. Within each race and ethnicity category except "Other", women with SMM incurred significantly greater healthcare costs compared to women without SMM across the observation periods (p<0.001 for Black, Hispanic and White, Figure 4 & Appendix Table 5A).

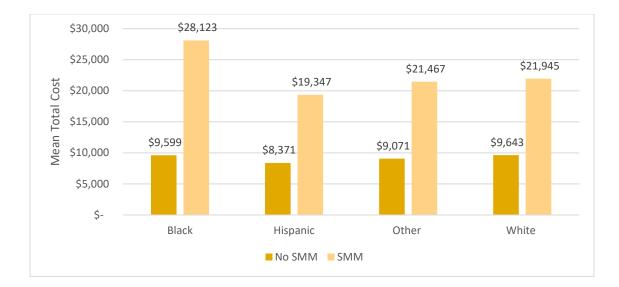


Figure 4. Total Mean Cost Across Race/ Ethnicity by Severe Maternal Morbidity (SMM) Status in the Medicaid Population*

*Data from MarketScan[®] Medicaid database.

Most of the costs were paid by the insurer—83.4% and 88.2% for women without and with SMM, respectively—while 15.5% and 10.7% were paid out-of-pocket by women without and with SMM (Appendix Table 7A).

The presence of concurrent SMM indicators was associated with increased delivery costs (Appendix Table 2A). Among the SMM indicators, the greatest delivery costs were observed in women experiencing shock, sepsis, disseminated intravascular coagulation, amniotic fluid embolism, and acute renal failure (Figure 3A).

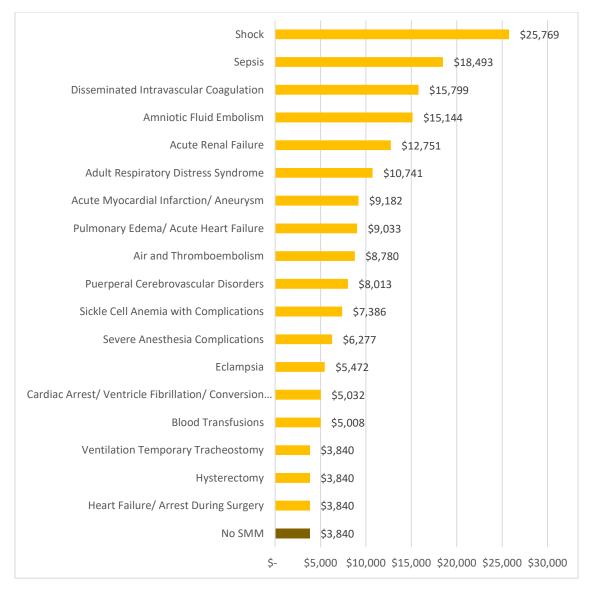


Figure 5. Mean Delivery Cost by Severe Maternal Morbidity (SMM) Indicator in the Medicaid Population*

*Data from MarketScan® Medicaid database

Figure 3A shows the shows the unadjusted demographic and clinical characteristics predictive of delivery costs. Delivery costs among women with SMM were 99% greater than women without SMM (P<0.001). In addition to SMM status, concurrence of SMM indicators, delivery method, gestation type, adolescent maternal age, and race/ethnicity were predictive of delivery costs (P<0.001; Table 2 & Appendix Figure 3A).

Results from the generalized linear regression model adjusting for demographic and pregnancy characteristics demonstrated that delivery costs of women with SMM were significantly higher than women without SMM (P<0.001, Table 2). The adjusted delivery cost for women with SMM were 31% greater than women without SMM. Adjusted mean delivery costs remained high for all demographic and pregnancy characteristics except for women younger than 30 years of age and Other race/ethnicity. The delivery method, gestation type, region and presence of any obstetric complications or preexisting comorbidities remained independently predictive of increased delivery costs (Table 2). Also, adolescent age and concurrence of SMM indicators was predictive of increased delivery costs (Appendix Figure 4). After adjusting for demographic and pregnancy characteristics, postpartum hemorrhage (1.13, 95%CI: 1.04 - 1.23), obstetric infection (CR:1.08, 95%CI: 1.03 - 1.13), and pneumonia (CR:1.3, 95%CI: 1.1 - 1.54) were independently predictive of increased delivery costs.

	Delive	ery Costs†
	Adjusted Cost Ratio (95% CI)	Adjusted Mean Cost (95% Cl)
Intercept	-	\$5,932#
SMM (referent: no SMM)	1.31 (1.23 - 1.40) †	\$7,796 (\$6,772 - \$8,974)
Delivery (referent: Vaginal)		
Cesarean	1.16 (1.15 - 1.18) †	\$6,908 (\$6,300 - \$7,575)
Maternal Age (referent: 31- 35)		
14-18	0.96 (0.89 - 1.03)	\$5,674 (\$4,886 - \$6,589)
19-24	0.96 (0.92 - 0.99) †	\$5,667 (\$5,051 - \$6,359)
25-30	0.96 (0.93 – 0.99) †	\$5,706 (\$5,085 - \$6,402)
36-40	1.03 (0.97 - 1.09)	\$6,122 (\$5,337 - \$7,022)
41-45	1.08 (0.96 - 1.21)	\$6,395 (\$5,262 - \$7,773)
45+	1.03 (0.7 - 1.53)	\$6,138 (\$3,831 - \$9,835)
Gestation Status (referent: Singleton)		
Multifetal	1.1 (1.06 - 1.15) †	\$6,530 (\$5,791 - \$7,363)
Race/ Ethnicity (referent: Black)		
Hispanic	1 (0.95 - 1.05)	\$5,943 (\$5,224 - \$6,761)
Other	1.03 (0.97 - 1.09)	\$6,105 (\$5,323 - \$7,000)

Table 2. Predictors of Adjusted Delivery Cost in the Medicaid Population*

White	0.97 (0.94 - 0.99) †	\$5,742 (\$5,172 - \$6,373)
Pregnancy-related	1.03 (1.01 - 1.05) †	\$6,101 (\$5,551 - \$6,706)
complication (referent:		
presence of complication)		

*Data from MarketScan[®] Medicaid database. CI: 95% confidence interval. [#]Estimated cost for a woman with no SMM, vaginal delivery, age 31-35, singleton, Black, and no presence of complications. [†]Multivariate regression analysis statistically significant at P<0.05

Sensitivity Analysis

A sensitivity analysis was conducted without the continuous enrollment criterion. There were 170,060 live deliveries identified in the Commercial dataset. The risk of SMM was similar between the primary analysis and the sensitivity analysis (1.1% each). While mean costs were slightly higher during the prenatal, delivery, and post-delivery periods, these differences were not statistically significant. Results of the multivariate analysis were also similar in both enrollment cohorts. There was no significant difference in the pre-existing comorbidities and obstetric complications profiles between the primary and sensitivity analysis in the commercial dataset.

After removal of the continuous enrollment criterion, there were 219,670 live deliveries identified with similar risk of SMM (1.1% vs to 1.2%) in the primary analysis in the Medicaid population. Appendix Table 8A describes the demographic and clinical characteristics of women in the primary and sensitivity analysis. Descriptively, women in the sensitivity analysis were older, had more cesarean section deliveries, and were classified as other race/ethnicity. Prevalence of obstetric complication were similar between the two analysis populations, except for excess vomiting, which was more prevalent in the primary analysis. With regards to preexisting comorbidities, women in the primary analysis had greater prevalence of urinary tract infections, pre-existing anemias, asthma, and mental health conditions.

Overall, delivery costs in the sensitivity analysis were 101% greater than in the primary analysis, but the cost ratios between women with SMM and no SMM were similar between the two analyses (Appendix Table 9A). These total cost differences are less severe when evaluating the median costs, where the sensitivity analysis costs are around 40% greater than the primary analysis (Appendix Table 10A). Delivery costs were greater in the sensitivity analysis across all demographic and delivery characteristics, with the greatest increase observed in Black women. The greatest differences in mean cost ratios was observed in the other race/ethnicity and singleton group in the primary analysis compared to the sensitivity analysis.

Discussion

This is the first analysis of healthcare costs associated with SMM after the 2015 conversion to ICD-10 and the first to include the prenatal and post-delivery costs.¹⁶ This analysis estimated the economic burden of SMM using 2016 MarketScan data sets of employer-sponsored insurance and Medicaid beneficiaries. The occurrence of SMM during delivery hospitalization was associated with an increase in total mean healthcare costs of 58-99% in the Commercial and Medicaid populations. SMM was an independent predictor of increased delivery hospitalization costs in the multivariate analysis. The presence of concurrent SMM indicators was associated with increased delivery costs. The mean delivery costs increased from \$13,594 to \$65,176 in the Commercial Population, and from \$3,797 to \$33,012 in the Medicaid population as the number of indicators increased from 0 to 3 or more.

Other factors predictive of increased delivery costs in both populations were delivery by cesarean section and multifetal gestation. In addition, geographic location, maternal age, gestational hypertension/ preeclampsia, postpartum hemorrhage, obstetric infection was independently associated with increased delivery costs in both the Commercial population, and the Medicaid population. Racial and ethnic disparities were observed with elevated costs among Black women compared to White and Hispanic women, which is consistent with the literature.⁸

Two previous studies have reported delivery hospitalization costs associated with SMM using discharge data from the 2011 National Inpatient Sample (NIS) and a dataset of all live deliveries in New York City (NYC) from 2008 to 2012.^{8,9} Both analyses applied the list of 25 ICD-9 SMM

indicators, as the observation window predated the 2015 transition to the ICD-10. These analyses estimated the costs expended by the hospital excluding physician expenses. These studies found that the incremental cost associated with SMM ranged from \$6,126 to \$6,800, which was similar to the \$7,824 incremental cost found in the Commercial population, but greater than the \$3,755 incremental cost found in the Medicaid population.^{8,9} Additionally, the NIS analysis estimated an adjusted delivery cost ratio comparing delivery costs among women with SMM to women without SMM of 2.1, which was close to the Medicaid cost ratio of 1.99 and greater than the Commercial cost ratio of 1.58.⁸

Direct comparison of the delivery cost estimates is difficult given the homogenous nature of the Commercial and Medicaid populations in this analysis, and the very heterogenous populations in the literature. This analysis separately analyzed populations of employer-sponsored insurance beneficiaries and Medicaid beneficiaries from 11 states, which vary in demographics and reimbursement structures. Commercial insurance is known to reimburse for services at higher payment rates compared to government sponsored insurance, as much as 75% higher than Medicare and Medicaid.¹⁷ In contrast, the NIS and NYC studies analyzed more heterogeneous populations; the former 50% commercial and 44% Medicaid patients, and the latter 38% commercial and 58% Medicaid patients.^{8,9} These different population structures and sources of payment may explain the differences in cost estimates and may not reflect the true cost to the institution, provider or patient.

Black and Hispanic race/ethnicity was associated with increased delivery costs in the Medicaid population in the present study. (Race/ethnicity data was not available for the Commercial population.) A relationship between race/ethnicity and the frequencies of SMM has been reported in several studies.¹⁸⁻²¹ Fingar et al., found that SMM disproportionately affects minority

and low-income pregnant women, especially non-Hispanic Black women and those with Medicaid coverage.²¹ The analysis also found that a large percentage of Black and Hispanic women with a delivery hospitalization were in the youngest age groups, which are known risk factors for SMM. Maternal age varies greatly across different race and ethnic groups and therefore can affect the risk of SMM and associated costs. ^{21,22}

The continuous enrollment criteria did not influence the results in the Commercial population but did reduce the number of live deliveries included in the primary analysis of the Medicaid population. This requirement differentially impacts the Medicaid population due to the recurrent nature of Medicaid coverage resulting in fragmented enrollment. Delivery costs in the sensitivity analysis were greater overall and across all demographic and delivery characteristics, yet the SMM cost ratios were not different. Noted differences in the demographic and clinical profile of the women in the sensitivity analysis could explain the increased costs but further research would be necessary to understand the specific cost drivers.

Lastly, women with SMM had a greater prevalence of preexisting comorbidities and obstetric complications, which could explain the additional costs during the prenatal and post-delivery periods as compared to women without SMM. These preexisting comorbidities and obstetric complications have been shown to increase the risk of SMM, therefore managing these risk factors in the prenatal period could potentially reduce the risk of SMM and associated costs.^{15,23-28}

Limitations

This retrospective analysis of cost data has several limitations. Analyzing cost data is known to be difficult because the data tends to be non-negative, positively skewed, and with heavy tails. This analysis is no exception, with median costs values lower than means (median costs are shown in

Appendix Tables 2 and 5 for the Commercial and Medicaid populations, respectively).²⁹ Still, the differences in median costs for women with and without SMM mirror those for mean costs, and the generalized linear model methodology applied has been recommended as a modelling technique for skewed cost data.²⁹

The continuous enrollment criterion significantly reduced the analytic sample for the primary analysis of the Medicaid patient population where it is common to have fragmented enrollment patterns due to the recurrent nature of enrollment. The risk of SMM and delivery cost ratio in the sensitivity analysis was not different, however the differences in absolute costs within demographics could indicate potential selection bias. However, continuous enrollment is a best practice in healthcare services research and allows for a more complete measurement of healthcare utilization during the observation period.

The Medicaid database represented only births from 11 states in 2016 and it is not possible to generalize the Medicaid results to a national population due to the small number of states and the variability in Medicaid benefits offered by those states. Due to privacy agreements between the Medicaid state agencies and Truven, the states included are not publicly available.

The continuous enrollment period criterion may reduce the ability to infer towards the larger base population, who may not have continuous enrollment for different reasons such as job loss or changing employment status. However, this is a commonly accepted and applied principle in health services research and is fundamental to the assessment of the objectives.

Conclusion

Women experiencing SMM incur significantly greater healthcare costs during the prenatal, delivery hospitalization, and 30-day post-delivery period compared to women without SMM.

Several demographics, pre-existing comorbidities and obstetric complications are associated with increased delivery hospitalization costs. Many of the studied preexisting comorbidities and obstetric complications are preventable, therefore proper care and attention to women at high risk of SMM could potentially reduce the risk of SMM and decrease the overall economic burden.

References

- 1. Martin JA, Hamilton BE, Osterman MJK. Births in the United States, 2016. *NCHS Data Brief.* 2017(287):1-8.
- 2. Podulka J, Stranges E, Steiner C. *Hospitalizations Related to Childbirth, 2008: HCUP Statistical Brief #110.* Agency for Healthcare Research and Quality, Rockville, MD. <u>http://www.hcup-us.ahrq.gov/reports/statbriefs/sb110.pdf</u>. 2011.
- 3. *The Cost of Having a Baby in the United States: Executive Summary.* Truven Health Analytics;2013.
- 4. Lemos EV, Zhang D, Van Voorhis BJ, Hu XH. Healthcare expenses associated with multiple vs singleton pregnancies in the United States. *Am J Obstet Gynecol.* 2013;209(6):586 e581-586 e511.
- 5. James AH, Patel ST, Watson W, Zaidi QR, Mangione A, Goss TF. An assessment of medical resource utilization and hospitalization cost associated with a diagnosis of anemia in women with obstetrical bleeding in the United States. *J Womens Health* (*Larchmt*). 2008;17(8):1279-1284.
- Law A, McCoy M, Lynen R, et al. The Additional Cost Burden of Preexisting Medical Conditions During Pregnancy and Childbirth. *J Womens Health (Larchmt).* 2015;24(11):924-932.
- 7. Maternal Health. <u>https://www.who.int/maternal-health/en/</u>. Accessed January 27, 2019.
- 8. Chen HY, Chauhan SP, Blackwell SC. Severe Maternal Morbidity and Hospital Cost among Hospitalized Deliveries in the United States. 2018(1098-8785 (Electronic)).
- 9. Howland RE, Angley M, Won SH, Wilcox W, Searing H, Tsao TY. Estimating the Hospital Delivery Costs Associated With Severe Maternal Morbidity in New York City, 2008-2012. *Obstet Gynecol.* 2018;131(2):242-252.
- 10. *Commercial Claims and Encounters. Data Year 2016 Edition.* IBD Watson Health;2016.
- 11. Severe Maternal Morbidity. 2017; <u>http://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidit</u> <u>y.html</u>. Accessed January 13, 2017.
- 12. Kuklina EV, Whiteman MK, Hillis SD, et al. An enhanced method for identifying obstetric deliveries: implications for estimating maternal morbidity. *Matern Child Health J*. 2008;12(4):469-477.
- 13. Bruce FC, Berg CJ, Joski PJ, et al. Extent of maternal morbidity in a managed care population in georgia. 2012(1365-3016 (Electronic)).
- 14. Bruce FC, Berg CJ, Hornbrook MC, et al. Maternal morbidity rates in a managed care population. 2008(0029-7844 (Print)).
- 15. Small MJ, James AH, Kershaw T, Thames B, Gunatilake R, Brown H. Near-miss maternal mortality: cardiac dysfunction as the principal cause of obstetric intensive care unit admissions. *Obstet Gynecol.* 2012;119(2):250-255.
- 16. Federal Health Information Technology Strategic Plan 2011–2015. In: Technology OotNCfHI, ed. Vol 20182011.
- Selden TM, Karaca Z, Keenan P, White C, Kronick R. The Growing Difference Between Public And Private Payment Rates For Inpatient Hospital Care. *Health Affairs*. 2015;34(12):2147-2150.
- 18. Howell EA, Egorova N, Balbierz A, Zeitlin J, Hebert PL. Black-white differences in severe maternal morbidity and site of care. *Am J Obstet Gynecol.* 2016;214(1):122 e121-127.

- 19. Creanga AA, Bateman BT, Kuklina EV, Callaghan WM. Racial and ethnic disparities in severe maternal morbidity: a multistate analysis, 2008-2010. *Am J Obstet Gynecol.* 2014;210(5):435 e431-438.
- 20. Geller SE, Koch AR, Martin NJ, Rosenberg D, Bigger HR. Assessing preventability of maternal mortality in Illinois: 2002-2012. 2014(1097-6868 (Electronic)).
- 21. Fingar KF HM, Heslin KC, Moore JE. Trends and Disparities in Delivery Hospitalizations Involving Severe Maternal Morbidity, 2006–2015. *Agency for Healthcare Research and Quality (US).* 2018.
- 22. Creanga AA, Bateman BT, Kuklina EV, Callaghan WM. Racial and ethnic disparities in severe maternal morbidity: a multistate analysis, 2008-2010. *Am J Obstet Gynecol*. 2013;210(5):435 e431-438.
- 23. Bateman BT, Mhyre JM, Hernandez-Diaz S, et al. Development of a comorbidity index for use in obstetric patients. *Obstet Gynecol.* 2013;122(5):957-965.
- 24. Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstet Gynecol.* 2012;120(5):1029-1036.
- 25. Callaghan WM, Kuklina EV, Berg CJ. Trends in postpartum hemorrhage: United States, 1994-2006. *Am J Obstet Gynecol.* 2010;202(4):353 e351-356.
- 26. Kuklina EV, Ayala C, Callaghan WM. Hypertensive disorders and severe obstetric morbidity in the United States. *Obstet Gynecol.* 2009;113(6):1299-1306.
- 27. Kuklina EV, Tong X, Bansil P, George MG, Callaghan WM. Trends in pregnancy hospitalizations that included a stroke in the United States from 1994 to 2007: reasons for concern? *Stroke*. 2011;42(9):2564-2570.
- 28. Mhyre JM, Shilkrut A, Kuklina EV, et al. Massive blood transfusion during hospitalization for delivery in New York State, 1998-2007. *Obstet Gynecol.* 2013;122(6):1288-1294.
- 29. Mihaylova B, Briggs A, O'Hagan A, Thompson SG. Review of statistical methods for analysing healthcare resources and costs. *Health Econ.* 2011;20(8):897-916.

Appendix Tables and Figures

Table 1A. Selected pre-existing conditions and pregnancy-related complications from the literature

Pre-existing condition	Pregnancy-related complications
Nonhereditary nonhemolytic	Abnormal glucose tolerance
anemia	
Hereditary hemolytic anemia	Amniotic sac
Clotting disorders	Cervical incompetence
Tuberculosis	Structural abnormality (uterus/cervix/vagina/vulva)
Human immunodeficiency virus	Excess vomiting
Diabetes in pregnancy	Placenta previa without hemorrhage
Thyroid disorders	Gestational hypertension/preeclampsia
Gall bladder disease	Antepartum hemorrhage including placenta previa with
	hemorrhage
Renal disease	Postpartum hemorrhage
Liver disorders	Pelvic and perineal trauma
Asthma	Uterine rupture
Neurological conditions	Obstetric infection
Cardiovascular condition	Urinary tract infection
Other chronic disease	Pneumonia
Mental health conditions	Appendicitis
Obesity	Infections not classified elsewhere
Chronic hypertension	Breast disorders
	Complications of anesthesia

		Total			Prenatal			Delivery			Post-delivery	
	No SMM	SMM	Differen ce	No SMM	SMM	Differen ce	No SMM	SMM	Differen ce	No SMM	SMM	Differen ce
All patients	23,144±18, 747	47,030±61, 870	23,886†	6,021±9,86 8	16,300±36, 127	1,0279†	13,594±8,0 43	21,418±23, 191	7,824†	3,529±10,3 20	9,312±22,7 43	5,783†
Age Categories												
14-18	21,923±15, 798	38,207±28, 932	1,6284	6,203±6,66 9	955±1,197	-5,248†	11,452±4,9 95	31,126±22, 612	1,9674	4,269±10,4 22	6,126±6,78 9	1,857
19-24	22,446±18, 006	47,503±96, 169	25,057†	6,348±9,90 3	16,670±42, 167	10,322†	11,977±6,7 47	17,852±16, 551	5,875†	4,121±9,22 1	12,981±53, 756	8,860†
25-30	20,705±15, 937	40,023±55, 088	19,318†	5,180±8,67 8	15,575±38, 383	10,395†	12,596±6,9 41	17,181±12, 258	4,585†	2,929±7,83 9	7,267±15,7 06	4,338
31-35	22,611±19, 051	49,118±69, 662	26,507†	5,513±10,6 40	16,841±44, 776	11,328†	13,733±7,5 49	23,678±29, 902	9,945†	3,365±11,2 64	8,599±15,6 04	5,234†
36-40	25,765±19, 878	47,864±41, 652	22,099	7,047±9,20 0	15,599±17, 223	8,552†	14,724±9,3 18	21,856±21, 309	7,132	3,994±11,2 35	10,409±18, 737	6,415†
41-45	29,831±22, 796	54,368±41, 626	24,537†	9,131±11,5 96	17,521±18, 234	8,390†	16,003±11, 081	26,973±26, 397	10,970†	4,697±11,9 96	9,874±13,4 12	5,177†
45+	33,494±27, 322	61,811±52, 630	28,317	10,227±11, 741	22,239±31, 570	12,012	16,909±13, 550	23,753±11, 723	6,844†	6,358±13,5 89	15,819±23, 182	9,461
Delivery Method												
Cesarean	27,694±22, 309	49,299±64, 728	21,605†	7,098±12,7 55	15,357±34, 881	8,259†	16,771±10, 607	25,333±28, 695	8,562†	3,825±11,1 63	8,609±22,4 38	4,784†
Vaginal	20,929±16, 288	44,797±58, 881	23,868†	5,497±8,04 7	17,228±37, 312	11,731†	12,048±5,8 40	17,566±15, 086	5,518†	3,385±9,88 1	10,003±23, 033	6,618†
Gestation Type												
Singleton	22,380±17, 021	45,687±61, 103	23,307†	5,634±9,27 0	15,654±38, 182	10,020†	13,342±7,0 85	21,318±24, 786	7,976†	3,404±9,11 0	8,715±16,9 91	5,311†
Multi-fetal	36,634±31, 177	59,772±35, 081	23,138†	13,922±19, 615	25,472±20, 596	11,550†	17,835±14, 921	24,810±23, 563	6,975	4,877±10,7 19	9,489±10,1 96	4,612†
Region												
Midwest	21,033±16, 915	49,188±66, 849	28,155†	5,374±7,02 7	18,713±43, 305	13,339†	12,052±5,7 83	19,941±24, 575	7,889†	3,608±12,5 55	10,534±21, 248	6,926†
North East	28,772±21, 128	56,453±44, 766	27,681†	7,945±13,7 00	19,639±24, 676	11,694†	16,946±8,5 89	25,797±19, 899	8,851†	3,881±9,33 8	11,017±16, 599	7,136†
South East	20,855±16, 184	44,019±39, 437	23,164†	5,335±8,14 7	15,200±20, 165	9,865†	12,142±6,3 20	20,353±24, 065	8,211†	3,378±9,61 3	8,466±13,7 09	5,088†
West	25,855±22, 683	45,261±90, 836	19,406†	6,598±11,9 33	14,667±53, 036	8,069†	15,837±11, 558	21,513±22, 808	5,676	3,419±10,0 45	9,080±35,6 51	5,661

Table 2A. Mean (SD) costs without and with severe maternal morbidity in the commercial population, by maternal characteristics*

*Data from MarketScan[®] Commercial Claims and Encounters database. †Difference of means tested using the T-test using Satterthwaite assumption of unequal variance = P<0.001

		Total			Prenatal			Delivery			Post-delivery	
	No SMM	SMM	Differen ce	No SMM	SMM	Differen ce	No SMM	SMM	Differen ce	No SMM	SMM	Differen ce
All patients	19,078±12,5 18	32,120±31,9 10	13,042†	3,746±4,92 3	7,252±14,69 9	3,506†	12,071±6,4 29	15,880±11,9 02	3,809†	1,150±2,9 42	2,915±9,85 0	1,765†
Age Categories												
14-18	18,155±12,0 93	24,050±29,6 81	5,895	4,048±5,85 9	594±1,711	-3,454†	10,723±5,1 40	21,627±25,9 28	10,904†	1,750±3,9 98	4,337±8,22 4	2,587
19-24	18,230±12,6 50	26,360±26,4 66	8,130†	3,836±5,31 9	5,331±14,85 8	1,495†	10,840±5,6 28	14,246±10,5 90	3,406†	1,354±3,8 48	2,351±8,35 9	997†
25-30	17,298±10,6 15	28,016±28,7 08	10,718†	3,151±4,18 3	5,783±13,36 0	2,632†	11,333±5,7 57	14,350±10,2 38	3,017†	967±2,422	1,931±8,06 8	964†
31-35	18,746±11,7 46	30,987±32,0 61	12,241†	3,379±4,30 2	6,491±13,22 8	3,112†	12,232±6,4 20	15,505±12,2 32	3,273†	1,128±2,7 40	2,457±9,34 4	1,329†
36-40	21,432±13,7 66	37,196±32,2 50	15,764†	4,693±5,64 6	9,672±16,15 1	4,979†	13,040±7,0 25	17,039±14,3 30	3,999†	1,297±3,3 43	4,797±11,2 71	3,500†
41-45	24,562±16,9 75	41,661±43,7 71	17,099†	6,349±7,25 1	11,728±15,7 32	5,379†	13,935±7,7 69	19,770±19,4 16	5,835†	1,543±4,1 96	5,298±10,3 47	3,755†
45+	27,519±21,3 46	50,941±31,6 07	23,422†	7,788±9,00 8	11,646±19,7 21	3,858	14,446±9,8 89	19,952±14,2 21	5,506†	2,287±5,5 40	7,342±20,2 55	5,055†
Delivery Method												
Cesarean	22,757±14,0 29	34,008±31,7 42	11,251†	4,377±5,85 3	7,262±13,74 0	2,885†	14,888±6,9 65	18,008±11,8 79	3,120†	1,164±3,1 45	2,590±8,44 7	1,426†
Vaginal	17,352±11,0 28	29,045±32,2 62	11,693†	3,482±4,47 5	6,995±15,32 0	3,513†	10,932±5,3 12	13,088±10,6 80	2,156†	1,145±2,8 59	3,394±10,6 76	2,249†
Gestation Type												
Singleton	18,678±11,8 54	30,583±29,5 18	11,905†	3,570±4,57 9	6,464±13,52 8	2,894†	11,942±6,2 32	15,469±11,4 89	3,527†	1,132±2,8 58	2,701±9,31 6	1,569†
Multi-fetal	29,296±22,2 64	54,360±48,6 38	25,064†	9,266±12,1 90	19,475±32,4 58	10,209†	14,771±8,8 52	17,773±11,9 84	3,002†	1,433±4,3 15	5,607±16,2 78	4,174†
Region												
Midwest	17,596±10,0 21	30,189±31,8 02	12,593†	3,471±4,25 4	7,887±15,77 0	4,416†	1,1171±4,8 57	14,464±9,72 0	3,293†	1,177±3,0 52	3,552±10,7 77	2,375†

Table 3A. Median (IQR) costs without and with severe maternal morbidity in the commercial population, by maternal characteristics*

North East	24,619±14,8	43,436±41,0	18,817†	5,208±6,10	10,437±17,4	5,229†	15,605±8,3	22,080±15,8	6,475†	1,412±3,3	4,415±12,8	3,003†
	11	76		9	32		10	22		89	18	
South East	17,460±10,4	32,971±32,3	15,511†	3,283±4,39	7,715±15,54	4,432†	11,164±5,4	14,893±10,5	3,729†	1,071±2,7	3,702±10,6	2,631†
	92	75		9	5		16	01		61	54	
West	21,083±14,7	26,479±24,9	5,396†	3,940±5,48	5,216±7,999	1,276†	13,638±8,1	15,647±12,2	2,009	1,082±2,7	1,651±6,51	569
	44	98		2			48	07		33	0	

^{*}Data from MarketScan® Commercial Claims and Encounters database. Difference of medians tested using Wilcoxon-Rank Sum Test (2 level) or Kruskal-Wallis Test (3 or more levels) of median costs. †P<0.001

Table 4A. Costs without and with Severe Maternal Morbidity (SMM) in the Commercial population, by payment source*

		Total	Pre	natal	De	livery	Post-deliv	very
	No SMM	SMM	No SMM	SMM	No SMM	SMM	No SMM	SMM
Mean costs ^a								
Total	23,795±20,897	50,212±71,974†	5,821±10,179	16,755±41,700+	1,4348±9,726	22,951±27,103†	3,626±11,337	10,506±27,517+
Direct	12,203±20,897	20,935±71,974†	4,378±10,179	14,277±41,700+	12,203±9,726	20,935±27,103†	3,022±11,337	9,413±27,517†
Out-of- pocket	1,907±9,498	1,800±26,827	1,390±9,568	2,379±41,004†	1,907±9,498	1,800±26,827	576±10,819	10,41±26,672†
Third party	238±1,601	216±2,855	53±1,514	98±2,828	238±1,601	216±2,855	27±1,123	52±1,907
Median costs ^b								
Total	19,102±13,289	32,418±34,023†	3,452±4,929	6,706±14,970†	12,343±6,998	16,448±13,138†	1,123±3,000	2,704±10,018†
Direct	10,339±7,073	14,413±12,837†	2,204±4,041	5,020±12,743†	10,339±7,073	14,413±12,837†	796±2,276	2,147±8,820†
Out-of- pocket	1,667±1,926	1,406±2,291†	937±1,532	1,491±2,517†	1,667±1,926	1,406±2,291†	147±630	303±1,240†
Third party	0±0	0±0	0±0	0±0	0±0	0±0	0±0	0±0

*Data from MarketScan[®] Commercial Claims and Encounters database. ^a Difference of means tested using the T-test using Satterthwaite assumption of unequal variance. ^b Difference of medians tested using Wilcoxon-Rank Sum Test (2 level) or Kruskal-Wallis Test (3 or more levels) of median costs. †P<0.001

Table 5A. Mean (SD) costs without and with severe maternal morbidity in the Medicaid population, by maternal characteristics*

		Total		Prenatal				Delivery		Post-delivery		
	No SMM	SMM	Differen	No SMM	SMM	Differen	No SMM	SMM	Differen	No SMM	SMM	Differen
			ce			ce			ce			ce
All patients	9,562±8,043	26,513±34,2	1,6951†	3,175±3,9	10,209±17,8	7,034†	3,797±1,7	7,552±12,19	3,755†	2,591±4,9	8,753±15,65	6,162
		21		06	10		42	7		81	9	
Age												
Categories												

14-18	9,552±6,451	14,850±6,87	5,298	3,090±2,8	4,364±4,576	1,274	3,681±2,4	6,319±2,384	2,638	2,781±4,6	4,166±4,145	1,385
		7		10			46			93		
19-24	9,406±6,847	29,346±47,6	19,940†	3,190±3,4	12,028±23,8	8,838†	3,677±1,3	7,791±17,72	4,114††	2,540±4,2	9,527±20,75	6,987†
		87		66	60		98	7		71	5	
25-30	9,484±8,591	25,215±26,9	15,731†	3,151±4,1	9,736±17,12	6,585†	3,774±1,5	6,742±6,012	2,968†	2,558±5,3	8,737±12,61	6,179†
		37		13	6		17			96	4	
31-35	9,806±9,199	23,969±19,1	14,163†	3,204±4,6	8,794±9,126	5,590†	3,971±2,2	7,626±7,395	3,655†	2,631±5,1	7,549±12,25	4,918†
		83		27			77			19	7	
36-40	10,152±8,58	27,253±27,6	17,101	3,153±3,6	8,627±8,028	5,474†	4,167±2,1	8,907±12,93	4,740++	2,831±5,7	9,719±13,87	6,888†
	6	85		98			28	8		26	4	
41-45	10,489±9,89	28,709±24,6	18,220†	3,371±4,0	1,1313±8,93	7,942†	4,314±3,5	9,981±13,53	5,667†	2,804±6,7	7,416±7,386	4,612†
	3	65		18	1		24	2		00		
45+	10,928±6,86	0±0	-10,928†	3,260±2,8	0±0	-3,260	4,303±1,0	0±0	-4,303++	3,365±4,9	0±0	-3,365
	7			16			97			76		
Delivery												
Method												
Cesarean	11,127±8,38	24,091±21,9	12,964†	3,601±4,5	7,733±8,730	4,132†	4,787±2,4	8,592±8,676	3,805†	2,739±4,5	7,766±14,03	5,027†
	9	59		02			68			87	2	
Vaginal	8,983±7,833	28,908±42,9	19,925†	3,017±3,6	12,656±23,3	9,639†	3,430±1,1	6,524±14,83	3,094†	2,536±5,1	9,728±17,10	7,192†
		78		49	48		86	7		18	1	
Gestation												
Туре												
Singleton	9,436±7,977	25,222±29,3	15,786†	3,101±3,8	10,670±18,3	7,569†	3,770±1,4	6,649±6,950	2,879†	2,565±5,0	7,903±11,68	5,338†
		49		74	81		63			34	0	
Multi-fetal	12,336±10,9	35,861±58,1	23,525†	4,673±5,4	8,836±9,153	4,163†	4,911±5,3	13,648±35,6	8,737	2,753±3,7	13,377±27,9	10,624
	01	74		65			61	99		56	02	
Race/												
Ethnicity												
Black	9,599±7,198	28,123±39,2	18,524†	3,246±3,9	11,364±19,5	8,118†	3,878±1,6	7,676±15,20	3,798†	2,474±4,1	9,083±17,07	6,609†
		31		62	29		53	2		76	0	
Hispanic	8,371±12,25	19,347±15,1	10,976†	2,525±4,5	7,169±5,595	4,644†	3,791±2,0	5,422±3,048	1,631†	2,055±7,8	6,756±10,19	4,701++
	2	61		70			71			84	2	
Other	9,071±9,152	21,467±14,9	12,396	2,664±3,2	5,155±3,740	2,491	3,973±2,6	11,548±13,9	7,575	2,435±6,4	4,765±6,604	2,330
		24		68			07	37		60		
White	12,354±10,8	57,354±60,5	45,000+	4,037±6,4	29,864±44,3	25,827†	4,986±2,4	8,692±4,791	3,706†	3,332±5,5	18,798±17,0	15,466
	53	63		52	72		59			88	68	

*Data from MarketScan[®] Medicaid database. [†]Difference of means tested using the T-test using Satterthwaite assumption of unequal variance = P<0.001

Table 6A. Median (IQR) costs without and with severe maternal morbidity in the Medicaid population, by maternal characteristics*

		Total			Prenatal			Delivery			Post-delivery	
	No SMM	SMM	Differen ce	No SMM	SMM	Differen ce	No SMM	SMM	Differen ce	No SMM	SMM	Differen ce
All patients	7,786±4,90 0	16,163±19,6 55	8,377†	2,332±2,4 31	5,527±8,398	3,195†	3,606±1,4 23	5,260±3,2 39	1,654†	1,271±2,8 13	3,279±7,672	2,008†
Age Categories												
14-18	8,162±4,48 9	15,820±11,9 44	7,658†	2,369±2,1 91	3,325±2,688	956	3,512±1,1 08	5,523±3,2 80	2,011†	1,741±2,5 52	2,231±6,411	490
19-24	7,818±4,71 3	14,756±17,7 26	6,938†	2,388±2,3 56	4,602±8,837	2,214†	3,551±1,3 20	5,087±2,5 28	1,536†	1,403±2,6 81	3,837±6,857	2,434†
25-30	7,703±4,85 5	17,363±20,0 12	9,660†	2,296±2,4 64	5,818±8,167	3,522†	3,606±1,4 35	5,304±3,2 93	1,698†	1,187±2,8 51	3,838±10,44 5	2,651†
31-35	7,749±5,24 8	15,830±20,1 05	8,081†	2,275±2,5 58	6,263±7,419	3,988†	3,677±1,4 27	5,532±3,7 32	1,855†	1,095±2,9 36	2,469±7,505	1,374†
36-40	8,009±5,40 6	15,676±25,6 79	7,667†	2,291±2,6 00	5,325±10,34 9	3,034†	3,839±1,6 25	5,632±3,2 08	1,793†	1,079±2,9 39	3,569±12,57 8	2,490†
41-45	7,591±5,81 1	18,587±17,9 48	10,996†	2,343±2,5 45	8,510±7,220	6,167†	3,826±1,5 10	5,505±4,2 53	1,679†	821±2,846	6,204±10,28 9	5,383†
45+	9,282±6,35 3	0±0	-9,282	2,186±3,6 68	0±0	-2,186	4,208±1,6 14	0±0	-4,208	1,233±3,9 01	0±0	-1,233
Delivery Method												
Cesarean	9,037±5,54 9	15,874±20,3 92	6,837†	2,607±2,7 64	4,496±6,327	1,889†	4,455±1,1 93	5,854±4,0 66	1,399†	1,280±3,0 28	2,297±7,147	1,017†
Vaginal	7,343±4,52 1	16,888±18,9 70	9,545†	2,240±2,3 28	6,793±9,837	4,553†	3,396±968	4,701±2,8 12	1,305†	1,267±2,7 43	4,075±7,741	2,808†
Gestation Type												
Singleton	7,702±4,72 9	16,163±18,2 53	8,461†	2,290±2,3 56	6,241±8,934	3,951†	3,606±1,3 89	5,107±2,6 22	1,501†	1,256±2,7 72	3,940±7,271	2,684†
Multi-fetal	10,290±6,1 96	13,379±28,0 74	3,089†	3,500±3,6 90	4,351±14,59 4	851	4,415±1,9 34	6,353±3,7 38	1,938†	1,478±3,0 95	2,131±3,678	653
Race/ Ethnicity												
Black	7,975±4,58 7	15,955±1,94 37	7,980†	2,392±2,3 88	5,818±8,812	3,426†	3,656±1,3 82	5,214±2,3 92	1,558†	1,353±2,6 19	3,279±7,095	1,926†
Hispanic	7,020±3,64 5	16,008±1,51 89	8,988†	1,938±1,8 26	4,312±8,698	2,374†	3,579±1,3 59	5,023±2,2 08	1,444†	1,004±2,0 53	4,623±8,098	3,619†
Other	7,052±4,53 7	18,350±1,00 78	11,298†	1,867±2,1 81	3,831±6,614	1,964†	3,606±1,4 87	7,255±4,3 15	3,649†	1,008±2,2 52	3,300±5,007	2,292
White	9,423±8,18 6	34,138±3,41 63	24,715†	2,412±3,7 41	13,081±18,3 68	10,669†	4,963±1,9 32	7,784±4,0 64	2,821†	1,289±4,0 59	15,484±20,7 19	14,195†

*Data from MarketScan[®] Medicaid database. Difference of medians tested using Wilcoxon-Rank Sum Test (2 level) or Kruskal-Wallis Test (3 or more levels) of median costs. †P<0.001

	-	Total	Pre	natal	De	livery	Post-deli	very
	No SMM	SMM	No SMM	SMM	No SMM	SMM	No SMM	SMM
Mean costs ^a								
Total	9,562±8,043	26,513±34,221†	430±1,802	1,453±7,594†	3,797±1,742	7,552±12,197†	351±2,036	1,243±6,639†
Direct	3,589±8,043	7,329±34,221†	418±1,802	1,425±7,594†	3,589±1,742	7,329±12,197†	338±2,036	1,204±6,639†
Out-of- pocket	40±1,835	13±12,140†	5±1,784	7±7,545	40±1,835	13±12,140†	5±1980	7±6,526†
Third party	167±360	210±91	7±74	21±91	167±360	210±91	9±56	32±58
Median costs ^b								
Total	7,786±4,900	16,163±19,655†	0±0	0±0	3,606±1,423	5,260±3,239†	0±0	0±0
Direct	3,561±1,442	5,148±3,174†	0±0	0±0	3,561±1,442	5,148±3,174†	0±0	0±0
Out-of- pocket	0±0	0±0	0±0	0±0	0±0	0±0	0±0	0±0
Third party	0±0	0±0	0±0	0±0	0±0	0±0	0±0	0±0

Table 7A. Costs without and with Severe Maternal Morbidity (SMM) in the Medicaid population, by payment source*

Data from MarketScan[®] Medicaid database. ^a Difference of means tested using the T-test using Satterthwaite assumption of unequal variance. ^b Difference of medians tested using Wilcoxon-Rank Sum Test (2 level) or Kruskal-Wallis Test (3 or more levels) of median costs. [†]P<0.001 Table 8A. Demographic and Clinical Characteristics of the Primary and Sensitivity Analysis in the Medicaid Population

		Primary A	nalysis (Ei	nrollment	Criterion)		Ser	Sensitivity Analysis (No Enrollment Criterion)				
Variable	All B	irths	No S	MM	SN	1M	All B	irths	No S	MM	SN	1M
	29,	29,763		29,421		342		219,670		217,262		108
Incidence of SMM (cases per 10,000 live deliveries)		114.9				109.6						
Demographics	Mear	1 <u>+</u> SD	Mea	Mean <u>+</u> SD		Mean <u>+</u> SD		n <u>+</u> SD	Mean <u>+</u> SD		Mean <u>+</u> SD	
Age (mean, SD)	26.6	5.5	26.5	5.3	27.6	6.2	27.5	5.6	27.5	5.6	28.3	6
Age Categories (n, %)	n	n % n %		n	%	n	%	n	%	n	%	
14-18	1,056	3.5	1,050	3.6	6	1.8	3,738	1.7	3,697	1.7	41	1.7
19-24	10,991	36.9	10,875	37.0	116	33.9	71,539	32.6	70,849	32.6	690	28.7

		-			-			-				
25-30	10,862	36.5	10,745	36.5	117	34.2	84,065	38.3	83,216	38.3	849	35.3
31-35	4,612	15.5	4,551	15.5	61	17.8	38,881	17.7	38,383	17.7	498	20.7
36-40	1,837	6.2	1,807	6.1	30	8.8	17,226	7.8	16,972	7.8	254	10.5
41-45	379	1.3	367	1.2	12	3.5	3,987	1.8	3,917	1.8	70	2.9
45+	26	0.1	26	0.1	-	0.0	234	0.1	228	0.1	6	0.2
Delivery Type												
Vaginal	21,646	72.7	21,474	73.0	172	50.3	154,41 0	70.3	15,329 9	70.6	1,111	46.1
Cesarean	8,117	27.3	7,947	27.0	170	49.7	65,260	29.7	63,963	29.4	1,297	53.9
Gestation Type												
Singleton	25,957	97.8	25,719	97.9	238	89.8	186,39 0	97.9	18,468 3	97.9	1,707	92.6
Multifetal	583	2.2	556	2.1	27	10.2	4,003	2.1	3867	2.1	136	7.4
Race/ Ethnicity												
Black	11,147	38.1	10,973	38.0	174	53.2	72,856	34.1	71,758	34.0	1,098	47.2
Hispanic	1,982	6.8	1,967	6.8	15	4.6	13,615	6.4	13,526	6.4	89	3.8
Other	1,434	4.9	1,424	4.9	10	3.1	20,448	9.6	20,247	9.6	201	8.6
White	14,660	50.2	14,532	50.3	128	39.1	106,54 1	49.9	105,60 1	50.0	940	40.4
Obstetric Complications												
Abnormal glucose tolerance	2,102	7.1	2,086	7.1	16	4.7	14,193	6.5	14,034	6.5	159	6.6
amniotic sac complications	3,483	11.7	3,412	11.6	71	20.8	26,499	12.1	25,998	12.0	501	20.8
Cervical incompetence	406	1.4	397	1.3	9	2.6	3,392	1.5	3,338	1.5	54	2.2
Structure abnormality	1,654	5.6	1,624	5.5	30	8.8	12,663	5.8	12,480	5.7	183	7.6
Excess vomiting	6,114	20.5	6,013	20.4	101	29.5	34,990	15.9	34,517	15.9	473	19.6
Gestational hypertension/ preeclampsia	607	2.0	593	2.0	14	4.1	3,910	1.8	3,821	1.8	89	3.7
Unspecified hypertension complicating pregnancy childbirth or the puerperium	4,608	15.5	4,401	15.0	207	60.5	32,147	14.6	30,635	14.1	1,512	62.8

Antepartum hemorrhage including placenta previa with hemorrhage	2,477	8.3	2,424	8.2	53	15.5	15,832	7.2	15,503	7.1	329	13.7
Postpartum hemorrhage	673	2.3	643	2.2	30	8.8	5,622	2.6	5,382	2.5	240	10.0
Pelvic and perineal trauma	2,649	8.9	2,590	8.8	59	17.3	20,790	9.5	20,366	9.4	424	17.6
Uterine rupture	29	0.1	29	0.1	-	0.0	185	0.1	176	0.1	9	0.4
Obstetric infection	2,591	8.7	2,516	8.6	75	21.9	16,920	7.7	16,450	7.6	470	19.5
Pre-existing Comorbidities												
Urinary tract infection	8,166	27.4	8,035	27.3	131	38.3	47,205	21.5	46,505	21.4	700	29.1
Pneumonia	171	0.6	146	0.5	25	7.3	848	0.4	709	0.3	139	5.8
Appendicitis	31	0.1	28	0.1	3	0.9	154	0.1	142	0.1	12	0.5
Infections not classified elsewhere	599	2.0	588	2.0	11	3.2	3,888	1.8	3,825	1.8	63	2.6
Breast disorders	86	0.3	81	0.3	5	1.5	480	0.2	462	0.2	18	0.7
Complications of anesthesia	53	0.2	47	0.2	6	1.8	434	0.2	405	0.2	29	1.2
Preexisting Anemias	7,790	26.2	7,639	26.0	151	44.2	47,649	21.7	46,853	21.6	796	33.1
Hereditary hemolytic anemia	216	0.7	205	0.7	11	3.2	1,734	0.8	1,691	0.8	43	1.8
Clotting disorders	522	1.8	503	1.7	19	5.6	3,497	1.6	3,305	1.5	192	8.0
Tuberculosis	16	0.1	14	0.0	2	0.6	134	0.1	129	0.1	5	0.2
HIV	48	0.2	48	0.2	-	0.0	327	0.1	318	0.1	9	0.4
Diabetes in pregnancy	2,855	9.6	2,808	9.5	47	13.7	20,900	9.5	20,567	9.5	333	13.8
Thyroid disorders	5,736	19.3	5,636	19.2	100	29.2	37,752	17.2	37,071	17.1	681	28.3
Gall bladder disease	345	1.2	337	1.1	8	2.3	1,929	0.9	1,886	0.9	43	1.8
Renal Disease	462	1.6	443	1.5	19	5.6	2,576	1.2	2,449	1.1	127	5.3
Liver Disease	261	0.9	258	0.9	3	0.9	1,975	0.9	1,942	0.9	33	1.4
Asthma	3,463	11.6	3,407	11.6	56	16.4	17,023	7.7	16,766	7.7	257	10.7
Neurologic Conditions	34	0.1	31	0.1	3	0.9	271	0.1	264	0.1	7	0.3
Cardiovascular Conditions	512	1.7	472	1.6	40	11.7	3,493	1.6	3,181	1.5	312	13.0
Other Chronic Diseases - including auto-immune	211	0.7	202	0.7	9	2.6	1,136	0.5	1,092	0.5	44	1.8
Mental Health Conditions	5,923	19.9	5,829	19.8	94	27.5	27,691	12.6	27,261	12.5	430	17.9

Obesity	5,353	18.0	5,251	17.8	102	29.8	32,504	14.8	31,891	14.7	613	25.5
Chronic Hypertension	2,108	7.1	1,999	6.8	109	31.9	13,205	6.0	12,436	5.7	769	31.9

*Data from MarketScan® Medicaid database

Table 9A. Comparison of Mean Delivery Costs between the Primary and Sensitivity Medicaid Analysis*

	Pri	mary Analysis		Sensi	tivity Analysis		
	Mean ± SD	Mean ± SD	Cost Ratio †	Mean ± SD	Mean ± SD	Cost Rati o†	Cost Ratio Difference [±]
Total	3797 ± 1,742	7,552 ± 12,197	1.99	7,677 ± 8,849	15,210 ± 30,229	1.98	-0.01
Age							0
14-18	3,681 ± 2,446	6,319 ± 2,384	1.72	6,597 ± 6,215	9,455 ± 8,818	1.43	-0.29
19-24	3,677 ± 1,398	7,791 ± 17,727	2.12	7,850 ± 9,068	14,216 ± 26,424	1.81	-0.31
25-30	3,774 ± 1,517	6,742 ± 6,012	1.79	7,746 ± 8,967	15,035 ± 27,729	1.94	0.15
31-35	3,971 ± 2,277	7,626 ± 7,395	1.92	7,421 ± 8,497	16,757 ± 35,297	2.26	0.34
36-40	4,167 ± 2,128	8,907 ± 12,938	2.14	7,455 ± 8,546	16,879 ± 40,777	2.26	0.12
41-45	4,314 ± 3,524	9,981 ± 13,532	2.31	7,562 ± 8,958	13,723 ± 16,636	1.81	-0.5
45±	4,303 ± 1,097	6,597 ± 6,215	1.53	7,413 ± 9,180	11,656 ± 5,096	1.57	0.04
Delivery Method							0
Cesarean	4,787 ± 2,468	8,592 ± 8,676	1.79	10,013 ± 11,467	16,844 ± 28,782	1.68	-0.11
Vaginal	3,430 ± 1,186	6,524 ± 14,837	1.9	6,702 ± 7,273	13,302 ± 31,743	1.98	0.08
Gestation Type							0

Singleton	4,911 ±	13,648 ±	2.78	10,658 ±	14,259 ±	1.34	-1.44
	5,361	35,699		13,341	23,045		
Multifetal	3,770 ±	6,649 ± 6,950	1.76	7,676 ± 8,721	14,974 ±	1.95	0.19
	1,463				30,659		
Race/							0
Ethnicity							
Black	3,878 ±	7,676 ± 15,202	1.98	15,762 ±	41,600 ±	2.64	0.66
	1,653			14,467	60,365		
Hispanic	3,791 ±	5,422 ± 3,048	1.43	8,616 ± 9,565	14,636 ±	1.7	0.27
	2,071				28,981		
Other	3,973 ±	11,548 ±	2.91	5,674 ± 6,003	9,929 ± 12,761	1.75	-1.16
	2,607	13,937					
White	3,676 ±	7,186 ± 8,073	1.96	7,887 ± 9,601	16,742 ±	2.12	0.16
	1,594				24,568		

*Data from MarketScan[®] Medicaid database. [†]Unadjusted Cost Ratio, SD: Standard Deviation, + Difference between Sensitivity – Primary Analysis Cost Ratios

Table 10A. Comparison of Median Deliver	v Costs botwoon the Briman	and Soncitivity	Modicaid Analy	vcic*
Table TUA. Comparison of Median Deliver	y costs between the Primary	y and Sensitivity	/ ivieuicalu Analy	/515 '

	Pri	imary Analysis		Ser	sitivity Analysis		
	Median ± IQR	Median ± IQR	Cost Ratio†	Median ± IQR	Median ± IQR	Cost Ratio†	Cost Ratio Difference [±]
Total	3,606 ± 1,423	5,260 ± 3,239	1.46	5,055 ± 5089	7,537 ± 9,182	1.49	0.03
Age							
14-18	3,512 ± 1,108	5,523 ± 3,280	1.57	4,778 ± 4734	6,396 ± 5,939	1.34	-0.23
19-24	3,551 ± 1,320	5,087 ± 2,528	1.43	5,069 ± 5679	7,358 ± 8,126	1.45	0.02
25-30	3,606 ± 1,435	5,304 ± 3,293	1.47	5,061 ± 5152	7,543 ± 9,570	1.49	0.02
31-35	3,677 ± 1,427	5,532 ± 3,732	1.5	5,002 ± 4470	7,828 ± 9,751	1.57	0.07
36-40	3,839 ± 1,625	5,632 ± 3,208	1.47	5,067 ± 4343	7,462 ± 9,537	1.47	0
41-45	3,826 ± 1,510	5,505 ± 4,253	1.44	5,102 ± 4266	7,830 ± 9,393	1.53	0.09
45±	4,208 ± 1,614	4,778 ± 4,734	1.14	5,039 ± 4029	10,729 ± 9,510	2.13	0.99
Delivery M	ethod						
Cesarean	4,455 ± 1,193	5,854 ± 4,066	1.31	6,266 ± 6895	4,415 ± 1,934	0.7	-0.61
Vaginal	3,396 ± 968	4,701 ± 2,812	1.38	4,561 ± 4386	3,606 ± 1,389	0.79	-0.59
Gestation 1	Гуре						

Singleton	4,415 ± 1,934	6,353 ± 3,738	1.44	6,300 ± 7532	8,269 ± 10,176	1.31	-0.13
Multifetal	3,606 ± 1,389	5,107 ± 2,622	1.42	5,055 ± 5071	7,370 ± 8,776	1.46	0.04
Race/ Ethn	icity						
Black	3,656 ± 1,382	5,214 ± 2,392	1.43	10,924 ± 17610	16,757 ± 40,228	1.53	0.1
Hispanic	3,579 ± 1,359	5,023 ± 2,208	1.4	5,582 ± 6385	7,615 ± 9,134	1.36	-0.04
Other	3,606 ± 1,487	7,255 ± 4,315	2.01	4,047 ± 3377	6,028 ± 7,467	1.49	-0.52
White	3,566 ± 1,393	5,062 ± 3,471	1.42	4,875 ± 4890	9,035 ± 11,533	1.85	0.43

*Data from MarketScan[®] Medicaid database. [†]Unadjusted Cost Ratio, IQR: Interquartile Range, + Difference between Sensitivity – Primary Analysis Cost Ratios



Figure 1A. Total Mean Cost Across Age Strata by Severe Maternal Morbidity (SMM) Status in the Commercial Population* *Data from MarketScan® Commercial Claims and Encounters database

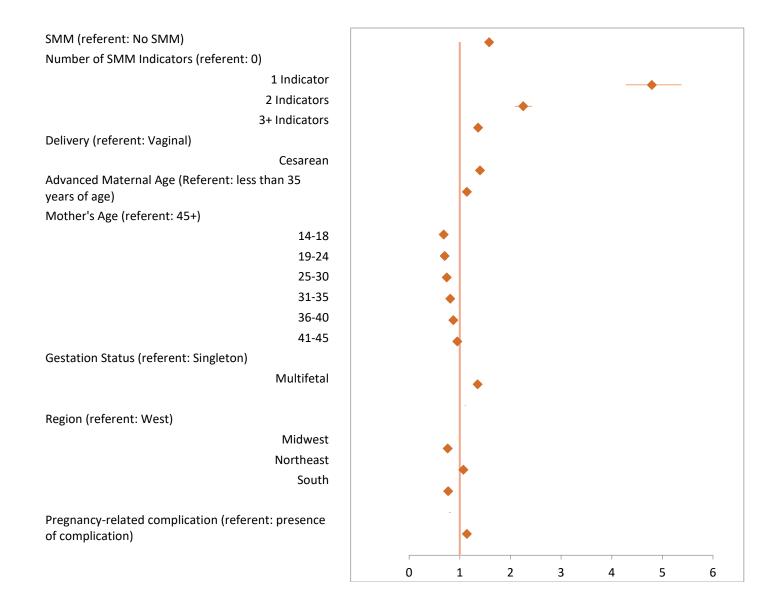


Figure 2A. Forest Plot of Unadjusted Delivery Cost Predictors in the Commercial Population* *Data from MarketScan® Commercial Claims and Encounters database. CR: Cost Ratio; CI: 95% confidence interval

Cost Ratio (95% CI)

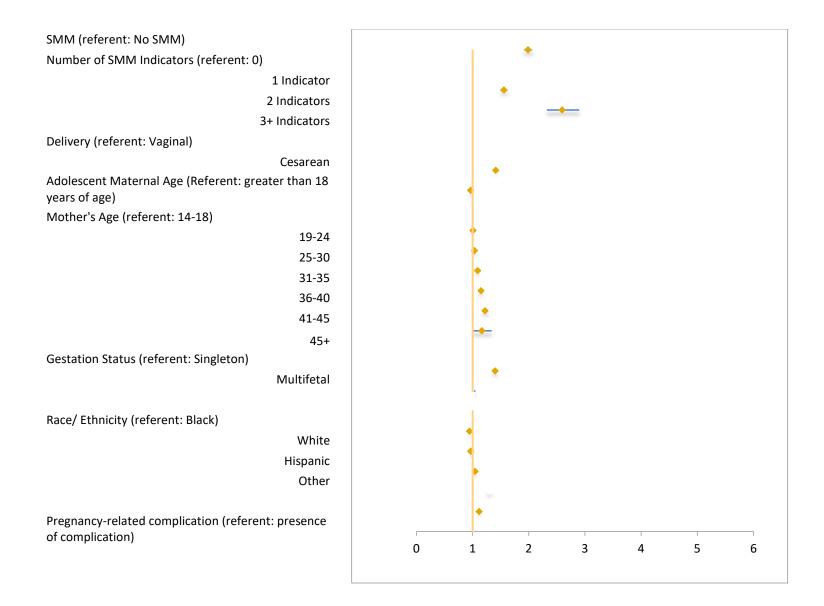


Figure 3A. Forest Plot of Unadjusted Delivery Cost Predictors in the Medicaid Population* *Data from MarketScan® Medicaid database. CR: Cost Ratio; CI: 95% confidence interval

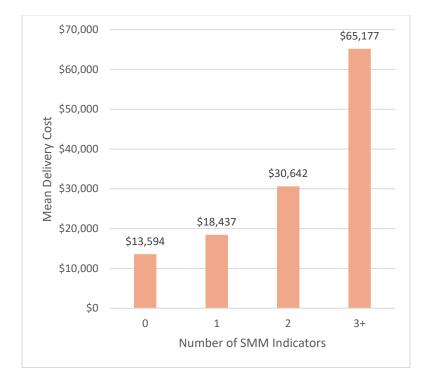


Figure 4A. Mean Delivery Cost by Number of Severe Maternal Morbidity (SMM) Indicators in the Commercial Population* *Data from MarketScan® Commercial Claims and Encounters database

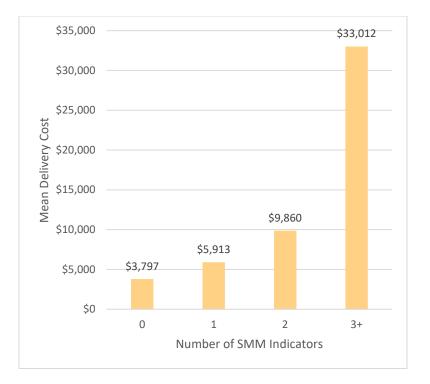


Figure 5A. Mean Delivery Cost by Number of Severe Maternal Morbidity (SMM) Indicators in the Medicaid Population* *Data from MarketScan® Medicaid database

CONCLUSION

The health of mothers, infants, and children within a country predicts the future health and potential of the subsequent generations.¹ With approximately four million children born ever year in the United States², it is concerning that the rate of SMM has been steadily increased nearly three-fold since 1993³ to 146.6 per 10,000 delivery hospitalizations in 2015.⁴ The confluence of demographics, pre-existing comorbidities, pregnancy characteristics, and obstetric complications contribute to the increased risk of SMM.

The incidence of SMM is on the rise in the United States. This analysis confirms the increased risk to women in the United States, specifically to those enrolled in employer-sponsored health insurance and Medicaid. Demographic and pregnancy-related risk factors were identified in this analysis, which require additional care and supervision during the prenatal period. SMM poses a risk to the overall health of mothers and their newborns.

SMM not only increased the risk of 30-day hospital readmissions and ER visits, in many cases SMM indicators were the primary reasons for the unplanned visits. Appropriate care protocols should be followed for women who experience pre/eclampsia, obstetric-related infection, hemorrhage, or hypertension during their delivery as they are likely to return to the hospital. The postpartum care process can be optimized by early and often contact with a primary maternal care provider starting shortly after the delivery discharge through the transition to well-women care.⁵ Reimbursement for this paradigm would enable follow-up visits to measure blood pressure and screen women with high-risk deliveries in order to address residual delivery complications. Addressing complications like eclampsia, hypertension, obstetric infections, and hemorrhage in the outpatient setting would avoid costly hospital readmissions and ER visits.

Additional screening and monitoring of high-risk women with pre-existing comorbidities and obstetric complications could reduce the risk of SMM. Women with SMM incurred greater healthcare costs during their prenatal, delivery and post-delivery periods. Preventing SMM would result in significant reductions in healthcare resource utilization and associated costs and would reduce an undue burden to mothers, healthcare providers, hospital administrators, and payers. No woman should risk her life to give life.

- 1. Beattie RM, Brown NJ, Cass H. Millennium Development Goals progress report. *Archives* of Disease in Childhood. 2015;100:S1-S1.
- 2. Martin JA, Hamilton BE, Osterman MJK. Births in the United States, 2016. *NCHS Data Brief.* 2017(287):1-8.
- Callaghan WM, Mackay AP, Berg CJ. Identification of severe maternal morbidity during delivery hospitalizations, United States, 1991-2003. *Am J Obstet Gynecol.* 2008;199(2):133 e131-138.
- 4. Fingar KF HM, Heslin KC, Moore JE. Trends and Disparities in Delivery Hospitalizations Involving Severe Maternal Morbidity, 2006–2015. *Agency for Healthcare Research and Quality (US).* 2018.
- 5. ACOG Committee Opinion No. 736: Optimizing Postpartum Care. *Obstetrics & Gynecology.* 2018;131(5).

BIBLIOGRAPHY

INTRODUCTION	
REFERENCES	15
PAPER 1 – THE INCIDENCE OF SEVERE MATERNAL MORBIDITY IN THE UNI	TED STATES
REFERENCES	
PAPER 2 –RATES OF HOSPITAL READMISSIONS AND EMERGENCY ROOM V FOLLOWING A HOSPITALIZED DELIVERY WITH SEVERE MATERNAL MORB	
REFERENCES	71
PAPER 3 – THE ECONOMIC BURDEN OF SEVERE MATERNAL MORBIDITY I	N THE UNITED STATES
REFERENCES	
CONCLUSION	
REFERENCES	