

Reducing Maternal Mortality and Morbidity in Michigan:  
A Mixed Methods Analysis of the Impact of  
an Obstetric Hemorrhage Patient Safety Bundle

by

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## **DEDICATION**

This dissertation is dedicated to legacy of individuals who have died in childbirth.

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## **PREFACE**

This dissertation provides critical new knowledge and evidence on the impact of standardization of reproductive health and healthcare in Michigan hospitals.

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## **LIST OF ACRONYMS**

AIDS	Acquired Immune Deficiency Syndrome
AIM	Alliance for Innovation on Maternal Health
COVID-19	Coronavirus 2019
LHS	Learning Health System
ICC	Intra-class correlation
MHA	Michigan Health and Hospital Association
MI-AIM	Michigan Alliance for Innovation on Maternal Health
MOMMIES	Maximizing Outcomes for Moms through Medicaid Improvement and Enhancement of Services
SMM	Severe maternal morbidity
TICD	Tailored Implementation in Chronic Disease

## **ABSTRACT**

The United States has the highest rate of maternal mortality despite outspending all other resource-rich countries in per-capita reproductive health care. Contributing to this problem are a combination of factors including disparities in patient socio-economic characteristics, changing population demographics, variation in medical practice, a fragmented healthcare system, and lack of quality reproductive health data. Nationally endorsed collections of evidence-based practices called patient safety bundles were developed to address this complex issue. Bundles present a structured way of improving the processes of care and include a set of evidence-based action steps that, when performed correctly and reliably, may contribute to improved patient outcomes. However, little is known about the real-world impact of bundles, including the optimal context, resources, and processes associated with implementation performance.

Since 2016, over 80 hospitals in Michigan participated in implementation of the Alliance for Innovation on Maternal Health's obstetric hemorrhage patient safety bundle. The work presented in this dissertation assesses patient outcomes and factors that influenced the bundle implementation process across Michigan hospitals. An explanatory sequential mixed methods design informed by implementation science using the Tailored Implementation for Chronic Disease framework served as the basis for this analysis of bundle implementation in Michigan hospitals between 2012 and 2019. Variation in, and factors associated with severe maternal morbidity were quantitatively evaluated across hospitals using the Michigan Inpatient Database (Aim 1). A qualitative study using in-depth semi-structured interviews with implementation stakeholders was conducted to assess experiences and context at select sites (Aim 2). Finally, factors contributing to implementation performance across hospitals with below- and above-average severe maternal morbidity rates were examined using a mixed methods approach (Aim 3).

The results from Aim 1 show that patients with hemorrhage – specifically targeted by this intervention – showed declining rates of severe maternal morbidity in both the pre- and post-implementation periods. Variation in severe maternal morbidity across sites was observed but not attributable to hospital factors, suggesting opportunities for tailoring of initiatives for further improvement in outcomes. In Aim 2, we found that implementation stakeholders were strongly supportive of quality improvement initiatives, yet cultural and motivational barriers prevented the full integration of care practices, suggesting that strategies addressing attitudes and behaviors at the individual, team, and institutional level prior to implementation may improve effectiveness. An explanatory figure was developed to represent the relationships between themes and their influence on implementation: Altruism; Perceived impact despite limited data; Teamwork; Competing priorities; and Limited champions. In Aim 3 we found that despite variation in individual and system-level factors related to implementation, stakeholder experiences at hospitals with below- and above-average severe maternal morbidity rates were ultimately more similar than different. These findings suggest that systemic issues in medicine such as interprofessional culture or social or practice norms may be promising targets for improving performance.

Despite efforts to standardize obstetric care across Michigan hospitals with the obstetric hemorrhage bundle, variation in patient, provider, and hospital characteristics and context-specific cultural factors all influence implementation performance. Moreover, many of the factors identified as barriers to implementation are systemic to the medical field or hospital settings, presenting additional challenges. Taken together, variation in implementation performance and experiences across hospitals is related to the specific combination and respective strength of these factors. Bundle implementation is often understood as a straightforward process, but these results suggest that it may be quite the opposite.

## PROLOGUE

In a manuscript of her self-help book, Shalon Irving admitted that she was “deathly scared of heartbreak and disappointment and letting people in comes with the very real risk of both.” Although Irving jokingly reflected upon her romantic life as a “20-year debacle”, she couldn’t remember a time when she didn’t want to be a mother. A Lieutenant Commander in the United States Public Health Service Commissioned Corps and an epidemiologist at the Centers for Disease Control and Prevention, Irving earned a dual doctorate in sociology and gerontology, was an accomplished author, world traveler, and an ecstatic mother-to-be. However, in February 2017, the unthinkable had happened. Just three weeks after giving birth, Irving suffered complications from high blood pressure and died. She was just 36. Nobody could have predicted that all of Irving’s fears would be realized in the few short weeks surrounding the birth of her daughter, Soliel, nicknamed “Sunny.”

There were red flags, as noted in a news report later that year. First, a painful, tender lump formed along her Cesarean-section incision, then came alarming spikes in her blood pressure. A nurse who made visits to Irving's Atlanta home to treat her incision recorded a dangerously high blood pressure of 174 over 118. The new mother had suffered chronic pain, persistent headaches, and swelling in her legs.

She also had a complicated journey to pregnancy, with several years of fertility difficulties, a blood-clotting disorder, and surgery to treat uterine fibroids. Her health history, coupled with the known risks of postpartum hypertension and heart failure among Black mothers, suggested that Irving might require close monitoring and follow-up care after delivery. But when her January screening for postpartum pre-eclampsia came back negative, Irving's doctor sent her home without further instructions. Five days later, she visited her physician again, this time reporting feeling unwell, and significant swelling in her right leg. She had gained nine pounds in ten days. She was given a prescription to treat hypertension, and again was sent home.

That night, Irving collapsed in her home from cardiac arrest and was rushed to the hospital, where she was removed from life-support a week later. An independent autopsy her mother ordered showed that Irving had died from complications of high blood pressure. "There's no manual for overcoming the death of a child, especially when you know that her death could have been prevented if her complaints had been heard," her mother, Wanda Irving, said during a public health summit in February 2019.

The story of Shalon Irving has drawn wide attention to the hazards of maternal morbidity for Black mothers. For every story like Irving's that makes it into the headlines, there are countless others that do not. Pregnant people die because their feeling that "something is not right" goes unheeded, and their pain is not taken seriously. They die because, while medical interventions for high-risk infants have advanced, attention to reproductive health innovation has stagnated. They die because of honest oversights and egregious ones; because of racism, sexism, and lack of access to prenatal and postnatal care. They die because they happened to deliver on a weekend, when data shows that the risk of maternal mortality increases by fifty percent. They die because of complications attributed to pregnancy at advanced maternal age, because of lack of communication between healthcare providers, because of a broken medical system. They die because someone was not paying close enough attention.

## **CHAPTER ONE**

### **Literature Review**

#### **Introduction**

Childbirth is the leading reason that women are hospitalized, accounting for nearly twelve percent of all hospital stays in the United States.<sup>1</sup> However, the decision to deliver in a hospital was not always a popular one. While nearly all births occurred outside a hospital in the early 1900s, less than 2% of women delivered in their home or a birth center in 2017.<sup>2</sup>

The experience of giving birth has long-term implications for the health and well-being of the parent, child, and family.<sup>3,4</sup> Satisfaction with the childbirth experience is difficult to measure and based on a complex set of medical, technical, and social factors. In the hospital, even for what clinicians would characterize as an uncomplicated birth, labor and delivery are often managed with technology.<sup>5</sup> Most people that give birth in hospitals are connected to machines that allow continuous monitoring of the parent and fetus. Nearly half of all people delivering in the hospital receive intravenous medication to augment labor, and many receive an epidural for pain. Furthermore, nearly one in three people deliver via Cesarean section, which is associated with significant morbidity for parents and their babies.<sup>6</sup>

Decision-making surrounding childbirth is often influenced by the cultural and symbolic significance of childbirth, social discourse on an individual's knowledge about birth, and their perception of control and autonomy. Previous studies of birthplace decisions consistently show that hospital birth is associated with safety for many people.<sup>7-9</sup> Birthplace preferences are also thought to be influenced by socio-economic status,<sup>10-13</sup> access to private or publicly funded models of care,<sup>14,15</sup> moral considerations,<sup>16</sup> and cultural, religious, and ethnic influences.<sup>17</sup> The challenge of care during childbirth is to optimize parent and child health outcomes and the parent's

experience with the fewest possible interventions.<sup>18,19</sup> However, this has led to increasing debate regarding the relative risk and benefits of birth in different settings and the associated risk of medical interventions. The childbirth experience is often fraught with anxiety for expectant parents, but until recently, dying was not a primary concern.<sup>20</sup>

### *Trends in Reproductive Healthcare*

Decades of research has foreshadowed the current state of maternity care in the United States. Despite outspending all other countries in per-capita maternity care (\$60 billion annually), maternal death in the United States increased by over 25% from 18.8 in 2000 to 23.8 per 100,000 in 2014, making it one of the only developed countries where the rate is increasing, not decreasing.<sup>21,22</sup> This upward trend is also characterized by significant variation across states, with the lowest rate of 4.5 maternal deaths per 100,000 in California, and the highest in Georgia with 46.2 deaths per 100,000.<sup>23</sup> Factors such as better case ascertainment of maternal deaths at the state level, adverse changes in chronic diseases such as diabetes and pregnancy-related hypertension, insufficient healthcare access (e.g. ability to attend prenatal care visits), and social determinants of health including income, educational attainment, and insurance status have been proposed to explain the wide variation in maternal mortality across states.<sup>24–26</sup> These factors represent identifiable risks for maternal mortality that merit direct and prompt attention in public health interventions and health policies.

While awareness of the unacceptably high numbers of maternal deaths in the United States is generally limited to the medical community, increasing media coverage helped the public become more acquainted with the issue. Dozens of high-profile cases like Dr. Irving's described in the Prologue, highlight the risks faced around the world during pregnancy and labor, including complications of pregnancy, delivery, or management of the two. These cases, and a major investigation by *USA Today* made it abundantly clear that “the United States is the most dangerous place in the developed world to deliver a baby.”<sup>27</sup>



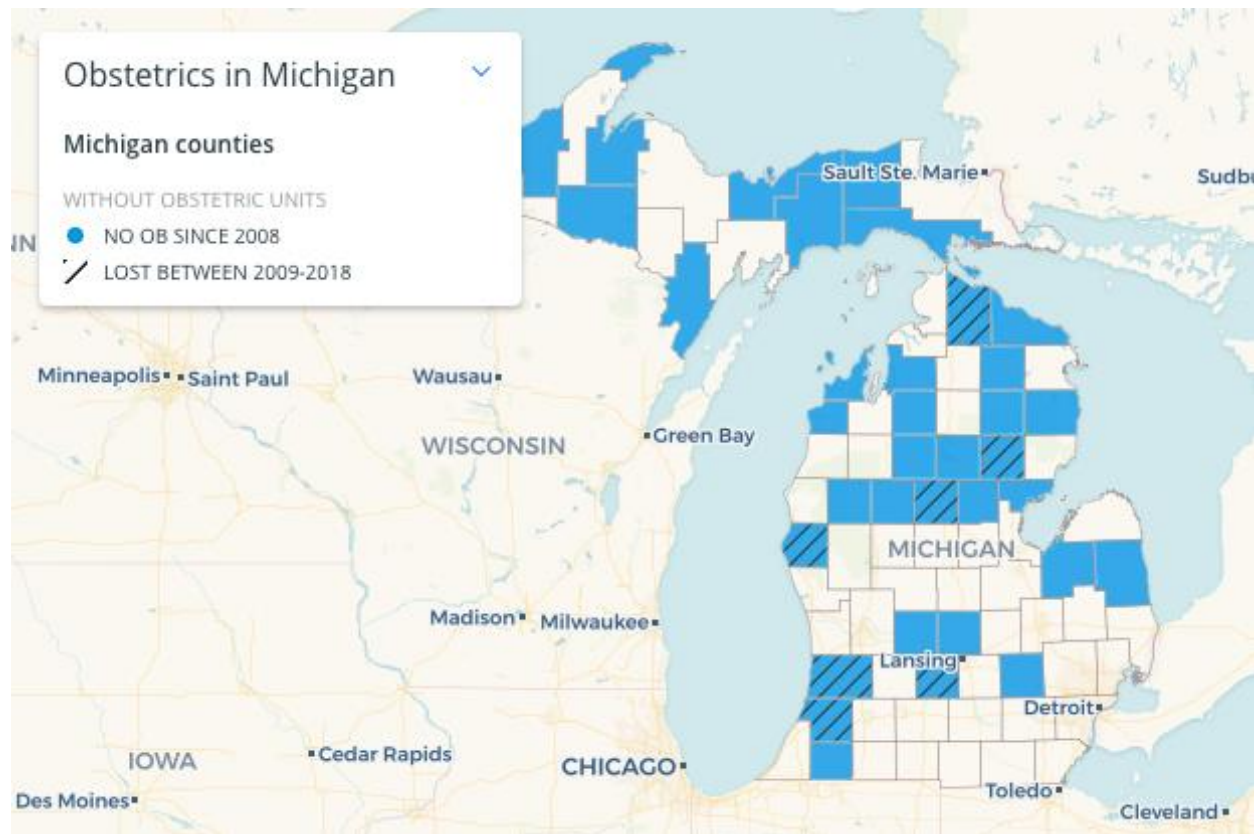
## *Maternity Care in Michigan*

Composed of 83 counties, Michigan is the 11th largest state by total square mileage and the eighth largest state by population. The state's population has grown to reach approximately 10 million people in 2019, with over 1.7 million people living in rural areas. Despite consistent population growth, birth rates in Michigan have consistently decreased since the 1950s, including a decline in teen births. Most of Michigan's population resides in the southern half of the Lower Peninsula, with approximately half of the population residing in Southeast Michigan. Michigan's population is primarily Caucasian (78.9%) and Black or African American (13.9%).<sup>28</sup> Importantly, Detroit has the highest percentage of Black or African American individuals (82.7%) in the country.<sup>29</sup>

Michigan's economy improved between 2009-2017, with the unemployment rate decreasing from 12.2% to 4.7%. However, the state still faces significant challenges that impact reproductive-age women. For instance, certain areas of the state continue to experience higher unemployment, such as Keweenaw and Alger counties, with rates of 8.4% and 7.3%, respectively.<sup>30</sup> Additionally, the majority (61%) of jobs in Michigan are low wage jobs, paying less than \$20 per hour.<sup>31</sup> Poverty also remains a significant issue, especially for Michigan's children, with approximately 23% of children living in poverty.<sup>32</sup> Of additional concern is that even in households with earnings above the federal poverty level, 40% struggle with basic necessities such as housing, child care, food, health care and transportation. In total, this equates to more than 1.54 million households struggling to meet basic needs in Michigan.<sup>31</sup> Given this environment, family support programs continue to be an important source of assistance. For example, just a third (34.1%) of pregnant persons enrolled in Michigan's Women, Infants, and Children program during their first trimester in 2015, with the vast majority of these individuals living in poverty.<sup>33</sup>

It is also getting harder to find hospitals to deliver in Michigan. The number of hospitals that offer obstetrics services has dropped significantly over the past four decades, and rural areas have been severely impacted. Since the 1980's, nearly 100 hospitals have closed in Michigan, with 11 closing since 2008. Just over half of the

remaining hospitals across a third of Michigan counties have obstetric units, leaving Michigan mothers in a difficult position. (Figure 1). The consequences of travelling farther to get obstetric care range from decreased prenatal visits, a long, hurried, or dangerous drive on delivery day, to premature births, and sometimes death.



**Figure 1.** Michigan Counties With Closed or Recently Closed Obstetric Hospitals

As of 2018, Michigan is ranked 29<sup>th</sup> in the nation for maternal deaths, with 19.4 maternal deaths per 100,000 live births. This rate – which has remained unchanged since 2016 – corresponds to approximately 25 Michiganders dying from complications related to pregnancy or childbirth.<sup>34,35</sup> In addition, for every person who dies in childbirth, 100 more suffer a severe maternal morbidity (SMM) event: a severe life threatening injury, infection or disease, such as kidney failure, shock, life-threatening blood clots, seizures, and mechanical ventilation. Conditions like these, without prevention or timely treatment, can lead to death.<sup>36</sup> Although the Michigan maternal mortality rate is not extreme compared to other states, it's unique geography, changing

demographics, and struggling economy are important indicators of the opportunity to improve their statistics.

### *Disparities in Maternal Outcomes*

Further complicating the discussion of reducing maternal mortality and morbidity is the presence of significant, well-documented racial and socioeconomic disparities. Nationally, Black non-Latina women are three times as likely to die during pregnancy or childbirth and twice as likely as White non-Latina women to experience a SMM event, regardless of underlying risk factors such as obesity and hypertension.<sup>37</sup> Specifically, Detroit has three times the nation's maternal mortality rate with African-American women having a rate three to four times that of any other racial group.<sup>34</sup> This may well be the highest disparity ratio calculated by public health officials, indicating the critical need for evidence-based interventions in Michigan in order to improve health equity.

More than 60% of pregnancy-related deaths - deaths while pregnant or within 42 days of termination of pregnancy from any cause related to or aggravated by the pregnancy or its management - in the United States are preventable, with the majority contributed by hemorrhage, cardiovascular and coronary conditions, cardiomyopathy, or infection.<sup>38</sup> However, the leading causes of death vary by race: preeclampsia and eclampsia, and embolism were the leading causes of death for non-Hispanic Black women, while mental health problems led to more deaths in non-Hispanic White women.

No group feels the negative effects of societal and healthcare disparities like Black and African American women. Race is an important component of socioeconomic status in the United States, capturing economic exploitation, political marginalization, and social stigmatization that makes consequential for virtually every aspect of life, including health. Numerous narratives exist to explain the disparities in maternal mortality and morbidity; however, they are incomplete. Contributors to these trends include the accumulation of stress among African American mothers, limited access to providers and hospitals, provider biases in culturally appropriate counseling, and failure of the health care system to listen to African American women's health concerns.

The persistence of racial inequalities in health can be partially explained by the “weathering” hypothesis, which suggests that early physiological deterioration due to the cumulative impact of multiple social disadvantages, was responsible for disparate infant mortality rates by race.<sup>39</sup> This highlights the importance of viewing race and ethnicity in terms of historic inequities in health, and not a representation of differences in individual behavior or biology.<sup>40</sup> Unfortunately, these historical injustices manifest themselves across all aspects of the pregnancy experience.

First, Black women are less likely to initiate prenatal care, with only 10% of Black mothers receiving late (third trimester) or no prenatal care, compared to 4% of White women.<sup>41</sup> Second, Black women are less likely to be able to access timely and affordable care. Only 42% of county health departments where Black mothers live provided prenatal services<sup>42</sup>, and even when these women get appointments, they face longer wait times compared to White women.<sup>43</sup> African-American women often face a “contraception desert,” wherein they live nearer to pharmacies, but those pharmacies have characteristics that may impede the purchase of contraception, such as shorter business hours, fewer female pharmacists, more difficult to access condoms, and fewer self-check-out options.<sup>44</sup> Despite an increased risk of short inter-pregnancy intervals<sup>45</sup> and poor maternal and infant health outcomes, Black low-income mothers’ are significantly less likely to attend postpartum visits and receive postpartum contraception.<sup>46</sup> Additionally, research suggests socioeconomic status is not only a confounder in the relationship between race and health, but also part of the causal pathway that links race to health.<sup>47</sup> That is, historical and contemporary racial discrimination is both created by and perpetuates racial inequities in socioeconomic status and health.

Much of biological and epidemiological research typically seeks to explain socioeconomic disparities in morbidity and mortality by evaluating downstream or proximal factors including biomedical, psychosocial, behavioral, and physiological mechanisms. However, research shows that socioeconomic inequalities in health cannot be permanently eliminated by addressing proximal risk factors of disease or death, because inequalities in knowledge, power, money, prestige, and social networks are enduring.<sup>48</sup> According to this theory, the longer-term impact of socioeconomic status

can only be eliminated by reducing inequalities in resource allocation. Despite well-documented variation in hospital size, provider expertise, and technological availability across American healthcare systems, nationally recommended strategies for implementation of evidence-based practices are rarely adjusted for resource distribution or availability. Intuitively, proper implementation of evidence-based practices would suggest equal allocation of resources to patients. However, there is not yet evidence accumulated to advise health systems on the appropriate distribution of resources to optimize patient outcomes.

What is clear however, is that Black women, in particular, have a very different birthing experience compared to White women due to a lack of trust and differential treatment within the medical system. Current and historical injustices contribute to a cycle of socioeconomic and health inequalities that severely disadvantage certain subgroups of women, a trend many researchers are working to understand, and reverse.<sup>49</sup>

### *Reproductive Health Policy*

Maternal mortality remains a pressing issue but reached the height of public discussion during the 2020 presidential election. Democratic presidential candidate Elizabeth Warren suggested hospitals that reduce deaths among African American mothers could be rewarded with bonuses, and hospitals that do not improve maternal survival rates should lose funding. Democratic presidential candidates senators (now Vice President) Kamala Harris, Kristen Gillibrand, Cory Booker, and senator Richard Blumenthal cosponsored the Maximizing Outcomes for Moms through Medicaid Improvement and Enhancement of Services (MOMMIES) Act, which extended Medicaid coverage for new mothers from 60 days after childbirth to a year, increases access to health providers, and offers services from midwives, doulas, and holistic birth workers.<sup>50</sup> Meanwhile, around the country, lawmakers introduced over 80 bills that sought to specifically address deaths among mothers of color in 2020. The MOMMIES Act – like many other bills supporting improvement in reproductive healthcare - was introduced and referred to Committee as of May 10<sup>th</sup>, 2021.

To date, federal legislation is a primary driver for state adoption of high-value maternity services, for which there has been progress in the categories of coverage and benefits, care delivery transformation, and data and oversight.<sup>51</sup> For example, federal legislation helped organize many states to build capacity for maternal mortality review committees, critical for understanding root causes of maternal mortality.<sup>52</sup> Others have adopted policies to support Medicaid coverage for the postpartum period, a critical opportunity to address maternal physical and mental health. Most recently states are also increasing flexibilities in telehealth access and coverage to meet maternity care needs following the recent national public health emergency due to the coronavirus 2019 (COVID-19) pandemic. To advance comprehensive approaches to reproductive health, stakeholders at national, state, and community levels must understand the policy landscape supporting or detracting from this work.

For the first time in history, maternal health was at the forefront of discussion in a presidential election in the United States. There was hope that this was a turning point for clinical and policy approaches to maternity care, but it's unclear whether policy has gone far enough to protect access and improve quality of reproductive healthcare. Any comprehensive approach to addressing the maternity care crisis in the United States must reshape financial and care delivery systems, ensure systematic data collection and action based on preventable risk, be anchored in the principles of racial equity and social justice, and view health holistically and across the lifespan.

### *Proposed Causes*

Three factors: the increasing prevalence of comorbidities among persons of reproductive age, lack of quality maternal mortality data, and inconsistent obstetric practice across health systems, are considered major contributors to the upward trend in maternal mortality in the United States.

First, an increasing number of women present at clinics with chronic conditions, such as hypertension, diabetes, and obesity, which contribute to pregnancy-related complications such as renal failure, shock, embolism, eclampsia, and hemorrhage. It is estimated that in 2014, almost one in ten delivery hospitalizations is complicated by a

chronic condition, an increase of over 40% since 2006. Although the frequency of these conditions increased, over time, across all socio-economic groups, the largest spikes occurred among individuals from rural and low-income communities and among patients with deliveries funded by Medicaid.<sup>53</sup> Many of these people could benefit from the closer coordination of antenatal and primary care – including case management and other community-based services that help them access care and overcome cost and other obstacles.

Second, there is a general lack of quality data and analyses on reproductive health outcomes. Prior to 2016, only half the states had maternal mortality review boards, a standard and comprehensive system to identify, review, and analyze maternal deaths, disseminate findings, and act on the results. Many received little or no funding and relied on volunteers to take on time-consuming case analyses. They published reports irregularly and, in some cases, did not address the issue of preventability at all. Even among states with a maternal mortality review, the collected data were not systematically applied to guide changes that could reduce maternal mortality and morbidity. The longstanding lack of reliable data reflects the scant importance American society places on expectant and new parents and the urgency of acting to save them.<sup>27</sup>

Only until recently was there a national forum for states to share either best practices for reviewing maternal deaths or the relevant lessons learned. Doubts about data on maternal deaths were so profound that some experts questioned whether the rise in rates over the last 25 years was a mirage, reflecting noise in the numbers rather than a real increase in deaths. Indeed, for a decade, the United States did not have an official annual count of pregnancy-related fatalities, or an official maternal mortality rate - a reflection of health officials' lack of confidence in the available data.<sup>54</sup>

Fortunately, there has been a recent resurgence of interest in maternal mortality review committees, leading many states to renew or strengthen their review of pregnancy-related deaths. Now, nearly all (42) jurisdictions have adopted a standardized review process developed by the Centers for Disease Control and Prevention, including consistent data gathering, decision-making, and development of actionable recommendations.<sup>55</sup>

The problems with maternal mortality data in the United States start at the most basic level. For more than a century, the United States largely depended on a single source of information—death certificates—to count maternal deaths and understand their causes. For everyone who dies there is a death certificate, making it the common currency of an otherwise decentralized system. Certificates are filled out with information from doctors, collected by state and local vital statistics offices, and further assessed by experts at the Centers for Disease Control and Prevention. Jurisdictions long relied on death certificates (sometimes matched with birth certificates or certificates that report deaths of fetuses too underdeveloped to survive) to identify women who died during pregnancy or within one year after giving birth. They share these records with the Centers for Disease Control and Prevention, where epidemiologists within the agency's Pregnancy Mortality Surveillance System, use standardized codes for causes of death to try to determine if a death was related to pregnancy or childbirth.

The certificate is supposed to identify the cause of death, but this may be elusive when an expectant or new parents dies. Death certificates ask for the immediate cause of death (i.e., the ailment that directly precedes it), intermediate causes (which lead to the immediate cause), and the underlying cause, which sets off the events that result in death. The Centers for Disease Control and Prevention's mortality statistics rely on the underlying cause, though this may not always demonstrate a link to pregnancy or childbirth.

Death certificates are notoriously prone to error and, often, miss critical information.<sup>56–58</sup> In the case of maternal deaths, certificates may not be filled out by an obstetrician gynecologist or anyone trained to recognize a link to pregnancy—or even anyone conscious that what they are recording has public-health implications. For decades, researchers found that many death certificates, for individuals in their reproductive years omitted they were pregnant, especially if they did not die in childbirth. Elements of how deaths are counted have also changed over time. Most significantly, since 2003, states added a checkbox to death certificates, asking if the person who died was currently pregnant, or was pregnant within the last year of their lives. The checkbox helped identify previously missed deaths, however, it may also capture cases unrelated to pregnancy.



The third, and most important contributor to increased rates of mortality for the purposes of this dissertation, is that obstetric practice is inconsistent at many levels. Hospitals across the United States lack a standard approach to managing obstetric emergencies, and the complications of pregnancy and childbirth are often identified too late due to delays in patients 1) deciding to seek care, 2) reaching an adequate facility, and 3) receiving treatment.<sup>59</sup> While many who develop complications have one or more detectable risk factors, the majority who share these risk factors do not have serious problems. Moreover, complications during pregnancy and labor may occur even in the best conditions. A large proportion of serious complications occur among women with no recognizable risk factors at all.<sup>59,60</sup>

It is long recognized that timely and adequate treatment for obstetric complications is a major factor in reducing maternal death in both high- and low-resource settings.<sup>59</sup> Interpersonal, organizational, and institutional factors such as medical errors, ineffective treatments, and lack of care coordination by clinicians and hospitals are major causes of preventable deaths across a variety of settings, and disproportionately affect marginalized populations.<sup>20</sup> Nationally endorsed plans to manage obstetric emergencies via standardization of care practices and updated training and guidance on implementing these plans is a serious and ongoing need.<sup>61</sup>

### **Patient Safety Bundles**

The bundle - a concept introduced by the Institute for Healthcare Improvement - is a structured way of improving care processes and patient outcomes.<sup>62</sup> Importantly, bundles are not intended to introduce new guidelines but are built upon established best practices. They are designed to collate a critical set of processes based on the broad universe of existing guidance, tools, and resources that were developed by trusted organizations. Bundles are intended to be universally implementable and able to be consistently used across disciplines and settings. The power of a bundle comes from the scientific evidence behind it and the consistent method of execution. A bundle ties essential practices together into a package of interventions that healthcare providers know must be followed for every patient, every single time.

Alternatively, checklists have been a leading strategy for ensuring safe and reliable care. The Agency for Healthcare Research and Quality defines a checklist as an algorithmic listing of actions to be performed in a given clinical setting, the goal being to ensure that no step will be forgotten.<sup>63</sup> Checklists have improved processes for hospital discharges<sup>64</sup> and patient transfers<sup>65</sup> as well as for patient care in intensive care<sup>66</sup> and trauma units.<sup>67</sup> Along with improving patient safety, checklists often create a greater sense of confidence that the process is completed accurately and thoroughly.

Checklists are popular because they are conceptually easy for healthcare providers to understand and carry out. Recently, however, questions have arisen about their ease of introduction into workflow patterns and their true impact on safety.<sup>68,69</sup> Thus, there are certain shortcomings of checklists worth mentioning. First, a checklist may lose its intended effect if it is poorly designed, or overly burdensome. Lengthy checklists may be difficult to answer in intense settings such as an operating room, or fatigue may encourage providers to skim questions or leave some unanswered. Furthermore, questions that are either too general, or too specific are often inadequately addressed due to differences in expertise. Second, the elements in a checklist are often a mixture of tasks or processes: some may be useful and important but with various support from the medical literature. Healthcare providers will omit or modify checklist items that do not align with their common practice, organizational culture and norms, or where the evidence-based is unclear. Third, checklists require a significant amount of interpersonal communication and coordination to complete. Poor communication between the healthcare providers, lack of leadership, inappropriate timing for checking an item, time taken up by checklist completion, and difficulty in identifying the role and responsibility of each staff member are reported barriers to checklist implementation in healthcare settings.<sup>70-72</sup>

While the goal of both checklists and bundles is to promote compliance with best practices, bundles differ and expand upon checklists in four unique ways. First, the changes recommended in bundles are considered *all necessary and all sufficient*. Modifying or removing elements from bundles will cause differing results – often meaning that the patient’s chance of getting better is decreased. Bundles should be considered a cohesive unit of steps that must *all* be completed to succeed. Second,

bundle elements are often, if not always, based on Level 1 evidence, or evidence resultant from randomized controlled trials. Given this kind of rigor, there should be little controversy surrounding the selection of bundle elements. Thus, a bundle focuses on *how* to deliver the best care, not what the care should be. This encourages providers to focus on completing the same set of steps for every patient, regardless of circumstances. Third, the changes in a bundle are considered to be straightforward - they involve *all-or-nothing measurement*. The path toward successfully implementing a bundle should be clear-cut: a provider either completes a step in a bundle, or they do not. Similarly, a provider, team, or unit, either completes the entire bundle, or they do not. There is no partial credit for doing some of the steps, some of the time. Fourth, bundle elements also *occur at a specific time and in a specific place*. A certain step might occur during morning rounds every day, or every six hours at the patient's bedside, for example.<sup>73</sup>

### *The First Bundles*

In 2001, the Idealized Design of the Intensive Care Unit initiative was created from a collaboration between the Voluntary Hospital Association and the Institute for Healthcare Improvement. This initiative was designed to re-evaluate the structure and assumptions upon which care was currently being delivered in intensive care units around the country. Teams from 13 hospital intensive care units partnered in studying clinical process that achieved improved processes and outcomes, while simultaneously introducing concepts of enhanced teamwork and communication. Teams worked toward implementing changes in many areas, including use of blood products and pain management in the intensive care unit. Although many elements related to ventilator care and central line insertions involved vigorous academic debate, certain ones had a high degree of acceptance and consensus among clinicians. From these, the faculty and teams of the Idealized Design of the Intensive Care Unit initiative selected the initial elements of the Institute for Healthcare Improvement's Ventilator Bundle and Central Line Bundle:

Ventilator Bundle: Ventilator-associated pneumonia is a serious lung infection that can happen to patients on a ventilator. The Ventilator Bundle has four care steps: raise the head of the patient bed between 30 and 40 degrees; give the patient medication to prevent stomach ulcers; prevent blood clots when patients are inactive; and see if patients can breathe on their own without a ventilator.

Central Line Bundle: This bundle is a set of five steps to help prevent catheter-related blood stream infections and deadly bacterial infections that may be introduced through an IV in a patient's vein supplying food, medications, blood, or fluid. The steps: use proper hygiene and sterile contact barriers; properly cleaning the patient's skin; find the best vein possible for the IV; check for infection every day; and remove or change the line only when needed.

In each case, a small set of previously accepted evidence-based interventions were selected as elements of care that should be delivered as usual practice. These two bundles are incredibly effective in helping hospitals reduce the incidence of common and avoidable deadly infections to nearly zero.<sup>74</sup> These interventions were a major contributor to the popularity of bundles in health systems across the United States.

Over the past two decades, health systems continued to adopt the Institute for Healthcare Improvement bundles, and newly developed bundles emerged. Recent systematic reviews suggest that care bundles may also be effective in preventing and managing a range of conditions including sepsis<sup>75</sup> and chronic obstructive pulmonary disease.<sup>76</sup> Others focused on hospital settings.<sup>77-79</sup> However, across all of the reviews, the certainty of evidence is deemed low and the risk of bias in the included studies is high, limiting the certainty of the conclusions about the overall effectiveness of care bundles.

Although it is still too early to understand the impact of bundles, they hold a great deal of promise for healthcare providers and systems focused on changing practice. Bundles are generally considered to work best for acute and chronic conditions that lend themselves to standardization (i.e., in cases when the medical community has

agreed that an optimal treatment pathway exists and can consistently deliver better results). The characteristics of childbirth – numerous interactions with a health system, healthcare providers, changing patient factors, and the risk for emergencies – make it a promising choice for standardization via bundles. Although each delivery is unique, elements addressing the readiness, recognition, response, and reporting of labor and delivery events are prime candidates for standardization.

### *Bundles in Reproductive Health*

There is a growing effort by healthcare providers, and national, state, and community organizations to address major contributors to maternal mortality. Community initiatives are coordinating care for high-risk individuals to ensure good health and management of chronic conditions during and beyond pregnancy, and more states are establishing or strengthening maternal mortality review boards. Many hospitals are beginning to implement standard approaches to managing obstetric emergencies so that, wherever a person gives birth, they receive appropriate evidence-based care. However, as of 2019, bundles created specifically for persons of reproductive age, or to address particular reproductive health concerns are limited.

Much of the initial effort to identify and evaluate the causes of maternal deaths, as well as identify preventable factors occurred in California and New York. Beginning in 2005, the California Maternal Quality Care Collaborative developed free online “toolkits” to address the leading preventable causes of maternal death in California: obstetric hemorrhage, deep vein thrombosis, and preeclampsia/eclampsia. These toolkits include a collection of articles, guidelines, implementation guides, and educational documents. Remarkable improvements were seen as hospitals across California implemented the first bundle - the obstetric hemorrhage toolkit. Over the subsequent five years, maternal mortality in California decreased by over 50% (16.9 per 100,000 in 2006 to 7.3 per 100,000 in 2013) as compared to the rising national maternal mortality rate (13.3 per 100,000 in 2008 to 22.0 per 100,000 in 2013).<sup>80</sup> These findings provide the best evidence to date that increasing education and resources and providing toolkits may have a real impact on maternal health outcomes.

Encouraged by California and other emerging national and international<sup>81</sup> toolkit implementation success stories, a group of clinicians from New York and leaders from The American Congress of Obstetricians and Gynecologists created the Safe Motherhood Initiative in 2013.<sup>82</sup> This initiative included standardized risk-assessment tables, protocols, checklists, and algorithms to minimize variability in practice. Eventually, separate hemorrhage, hypertension, and venous thromboembolism bundles were created. Like California, the Safe Motherhood Initiative also offered free, online implementation guidance and resources for interested health systems and providers.

These initiatives developed, implemented, and disseminated portfolio of resources across the country – and became the template for continued bundle creation in other disease areas. For example, in 2015 the Council on Patient Safety in Women's Health Care convened an interdisciplinary work group to develop an evidence-based patient safety bundle to address maternal mental health. The bundle provides broad direction for incorporating perinatal mood and anxiety disorder screening, intervention, referral, and follow-up into maternity care practice across health care settings.<sup>83</sup> In 2017, the same group created a safety bundle with the goal of reducing the incidence of surgical site infections among women undergoing gynecologic surgeries such as hysterectomy or Cesarean section.<sup>84</sup> And as recently as August 2019, a patient safety bundle was added to reduce adverse maternal and neonatal health outcomes associated with substance use.<sup>85</sup>

The early impact of these initiatives is mixed. Bundle implementation often results in improvements in short-term patient outcomes (e.g. increases in patients receiving timely treatment); however, large financial and human resources barriers are often cited.<sup>86,87</sup> While it is too early to fully assess the impact of implementation on long-term outcomes, such as maternal mortality, it is crucial that health systems and providers be diligent in their collection and analyses of both patient and process-related data. Moreover, the synthesis of both quantitative data and qualitative attitudes towards bundle implementation will provide crucial evidence of their impact at many levels and educate the development of future iterations of maternal health bundles.

## *Alliance for Innovation on Maternal Health Bundles*

In 2015, The Alliance for Innovation on Maternal Health (AIM) – a national data-driven maternal safety and quality improvement initiative, presented some of the most widely-implemented clinical strategies to standardize obstetric care to achieve reductions in maternal mortality and morbidity.<sup>88</sup> AIM recognizes the almost seven-fold variation in maternal mortality rates across states, and thus partnered with state teams and health systems to align national, state, and hospital level quality improvement efforts.<sup>9</sup> Any hospital in a participating AIM state or hospital system can join the growing and engaged AIM community of multidisciplinary healthcare providers, public health professionals, and cross-sector stakeholders who are committed to improving maternal outcomes in the United States

One of AIM’s major contributions is implementation and data support for AIM-supported bundles. Implementation support and data collection plans are provided in the form of patient safety bundles that focus on readiness, recognition, response, and reporting of disease processes. These bundles are a collection of 10-13 best practices for improving safety in maternity care that were scrutinized by experts in practice. The development of these bundles is ongoing, but initial releases focused on specific populations or disease processes with sufficient data and literature to support their potential impact on reducing maternal mortality and morbidity. (Table 1).

### **Table 1. Alliance for Innovation on Maternal Health Patient Safety Bundles**

#### *Core Bundles*

- Obstetric Hemorrhage
- Severe Hypertension in Pregnancy
- Safe Reduction of Primary Cesarean Birth
- Cardiac Conditions in Obstetrical Care
- Care for Pregnant and Postpartum People with Substance Use Disorder
- Postpartum Discharge Transition
- Sepsis in Obstetrical Care (in development)
- Perinatal Mental Health Conditions (in development)

### *Supporting Bundles*

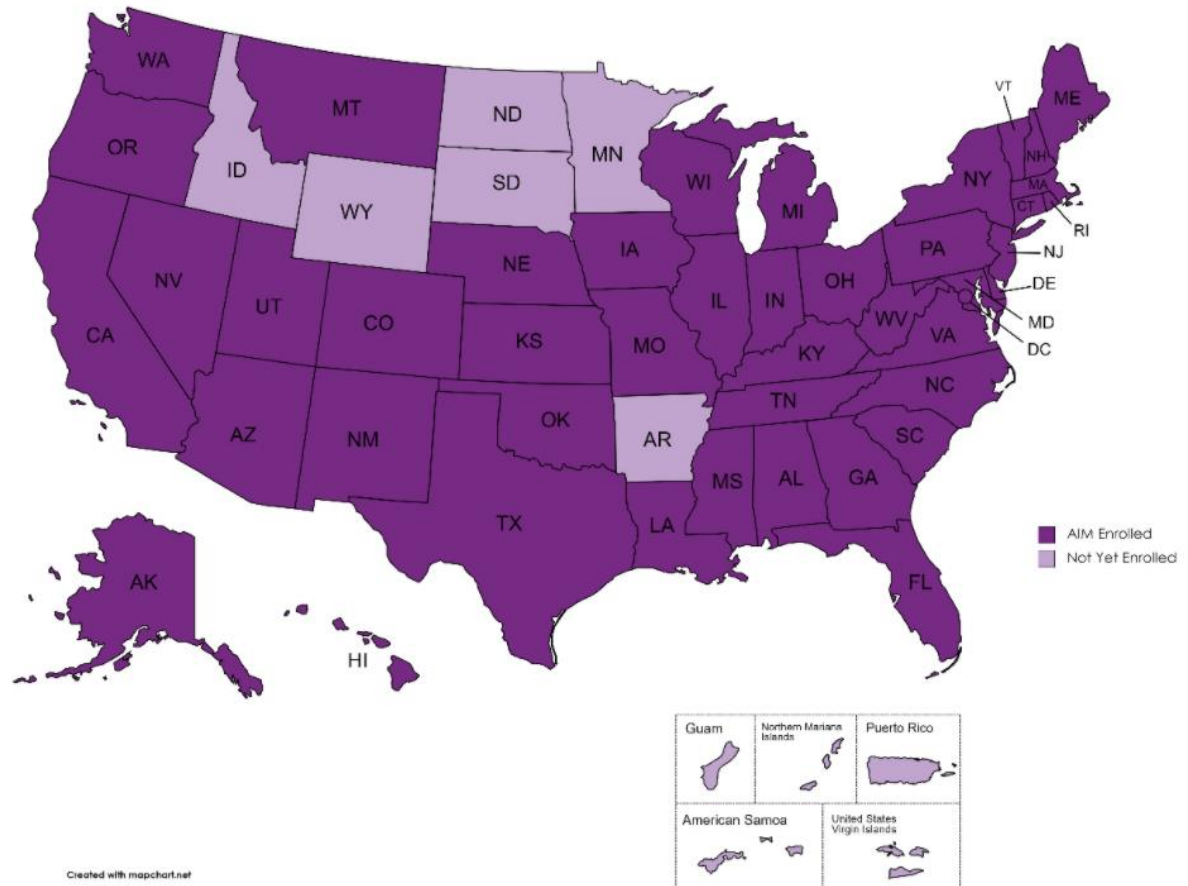
- Maternal Mental Health: Depression and Anxiety
- Reduction of Peripartum Racial/Ethnic Disparities
- Support After a Severe Maternal Event
- Obstetric Care for Women with Opioid Use Disorder
- Maternal Venous Thromboembolism
- Prevention of Retained Vaginal Sponges After Birth
- Postpartum Care Basics for Maternal Safety: Transition from Maternity to Well-Woman Care
- Postpartum Care Basics for Maternal Safety: From Birth to the Comprehensive Postpartum Visit

### *Additional (Non-Obstetric)*

- Prevention of Surgical Site Infections After Gynecologic Surgery
- Enhanced Recovery After Major Gynecologic Surgery

At the state level, the Michigan Department of Health and Human Services and Michigan Health and Hospital Association (MHA) partnered with AIM to designate Michigan an “AIM State”. Michigan is one of 44 States and territories currently implementing maternal patient safety bundles as of November 4, 2021. (Figure 2).





**Figure 2.** States Partnering With the AIM as of 2021

This partnership, called the Michigan Alliance for Innovation on Maternal Health (MI-AIM), receives tailored resources and extensive support from the national AIM program and includes over 80 hospitals in Michigan.<sup>89</sup> States elect to utilize patient safety bundles, and hospitals across Michigan are, or are in the process of implementing the “Obstetric Hemorrhage”, “Severe Hypertension and Preeclampsia”, and “Sepsis in Obstetrical Care” bundles.

Beginning in 2015, significant interest and allocation of resources dedicated to the AIM–recommended obstetric hemorrhage patient safety bundle occurred across Michigan health systems. This bundle is a collection of evidence-based practices with strong evidence that focuses on readiness, recognition, response, and reporting of obstetric hemorrhage to reduce maternal death. (Figure 3).



PATIENT SAFETY BUNDLE

Obstetric Hemorrhage

**READINESS**

Every unit

- Hemorrhage cart with supplies, checklist, and instruction cards for intrauterine balloons and compressions stitches
- Immediate access to hemorrhage medications (kit or equivalent)
- Establish a response team - who to call when help is needed (blood bank, advanced gynecologic surgery, other support and tertiary services)
- Establish massive and emergency release transfusion protocols (type-O negative/uncrossmatched)
- Unit education on protocols, unit-based drills (with post-drill debriefs)

**RECOGNITION & PREVENTION**

Every patient

- Assessment of hemorrhage risk (prenatal, on admission, and at other appropriate times)
- Measurement of cumulative blood loss (formal, as quantitative as possible)
- Active management of the 3rd stage of labor (department-wide protocol)

**RESPONSE**

Every hemorrhage

- Unit-standard, stage-based, obstetric hemorrhage emergency management plan with checklists
- Support program for patients, families, and staff for all significant hemorrhages

**REPORTING/SYSTEMS LEARNING**

Every unit

- Establish a culture of huddles for high risk patients and post-event debriefs to identify successes and opportunities
- Multidisciplinary review of serious hemorrhages for systems issues
- Monitor outcomes and process metrics in perinatal quality improvement (QI) committee

**Figure 3.** Overview of the AIM Obstetric Hemorrhage Patient Safety Bundle

Hemorrhage complicating labor, delivery, and the postpartum period continues to increase in the United States, with rates increasing by 26% between 1994 and 2006.<sup>90–94</sup> There is also evidence of increases in severe postpartum hemorrhage (hemorrhage accompanied by transfusion, hysterectomy, or surgical repair of the uterus), with rates of 1.9 per 1,000 in 1999 to 4.2 per 1,000 in 2008.<sup>90</sup>

The AIM program focuses on standardizing care specifically in the hospital obstetric care setting. This setting is an ideal place to provide standardized, evidence-based obstetric hemorrhage care. Persons receiving care in this setting have significant variation in comorbidities, medical history, and often face critical decisions regarding their delivery, and future care for themselves and their baby. Many have serious health problems that could trigger the need for emergency services during delivery or are likely to experience indications postpartum.

Although the standardization of obstetric care via bundle implementation holds significant promise, there remain many unanswered questions. While prior research shows that the implementation of AIM safety checklists and protocols for the management of certain high-risk surgical or obstetric clinical situations are effective in improving outcomes, little is known about the optimal context, resources, and processes responsible for successful implementation of an AIM bundle.<sup>95-101</sup> Additionally, although AIM collects data on patient and process outcomes, it is unclear to what extent this data will achieve the AIM's the goal of "rapid-cycle and continuous quality improvement" efforts, and what short or long-term impact the implementation of the bundles will have on health systems, physicians, and patients.<sup>102</sup>

Patient outcomes are often the primary outcomes of measuring bundle implementation success. Research is lacking regarding the comprehensive assessment of implementation problems and the use theory-informed behavior change implementation strategies. Regarding guideline implementation in obstetric care, a systematic review suggests that educational tools showed mixed effects, audit and feedback was generally effective, strategies based on opinion leaders, quality improvement tools, and academic detailing were ineffective or showed mixed effects. Reminders showed to be overall effective.<sup>103</sup> Provider-focused multi-component interventions were considered to be the most promising, yet were criticized for being methodologically lacking.

Since 2016, the implementation of obstetric hemorrhage patient safety bundle at AIM-participating health systems has been underway in Michigan. This bundle provides an evidence-based approach to standardizing obstetric care that may be more effective than prior interventions that failed to address all relevant barriers to care and treatment.

To be effective and sustained, this kind of effort requires not only significant interest, but resources and support from a variety of disciplines. However, still missing is a comprehensive understanding of the benefits and detriments of this approach, with the goal of providing scalable opportunities to increase the success of implementation at other interested institutions.

### *Implementation Challenges*

There is significant motivation and pressure for health systems across the United States to implement the AIM-recommended patient safety bundles. It is not only an advantageous marketing device to be an “AIM-State”, but the consequences of being left behind are even more noticeable. In a culture of fee-for-service care, losing patients to other high-performing systems equates to a diminished reputation, and more importantly, a loss of revenue. Combined with national recommendations and (limited) resources provided to aid in the implementation process, there is a clear incentive for health systems to standardize obstetric care. However, this urgency to implement is fraught with uncertainty.

On one hand, the standardization of obstetric care holds significant promise. Preliminary evidence from California shows significant reductions in adverse maternal events such as maternal death and severe maternal morbidity<sup>104</sup>, and initiatives such as Healthy People 2020, made improving rates of maternal and infant health national priorities.<sup>105</sup> However, these outcomes will not be achieved without careful consideration of the issues associated with standardization.

First, it is imperative that quality teams resist the impulse to label any list of good changes a bundle. The recent patient safety movement has created a tendency to want to call any checklist or toolkit involving patient care procedures a bundle. However, as previously mentioned, a bundle is not a checklist, and calling it a bundle will not necessarily improve outcomes. If the goal is to make a process more standardized and reliable, a checklist may not be sufficient; only bundles are intended to improve habits and processes.

Second, there is also temptation (and sometimes need) to modify existing, validated bundles. For example, certain health systems may not have the appropriate resources or staff to carry out an obstetric hemorrhage bundle element in the way it was intended. Changes to the massive transfusion protocol, for example, must be made in ways that do not increase the patient's likelihood of an adverse outcome. In the extreme, modifications may increase to a point where it becomes impossible for healthcare providers to implement recommended strategies, significantly reducing effectiveness. While bundles advertise consistent use across diverse disciplines and settings, there is often limited guidance for successful implementation. Moreover, when modifications are necessary, the number, and kinds of modifications acceptable to introduce into bundles remains unclear.

Third, implementation leaders cannot assume that standardization of care across diverse health systems will provide equal access, treatment, and outcomes for marginalized women. To begin to eliminate disparities in maternal and infant mortality, several steps must be taken to increase access to high-quality medical care for persons of color, particularly during pregnancy, and make sure that all care is patient-centered, culturally appropriate, and listens to patient needs. While the AIM patient safety bundles provide the basic framework, these kinds of interdisciplinary implementation protocols require careful tailoring to address the specific personal and cultural needs. Continuous efforts to combat the effects of racism and classism are key in the fight to keep all parents and babies healthy throughout pregnancy, birth, and the postpartum period.

The urgency with which bundle implementation is occurring may exacerbate these problems. Rushed decisions may direct implementation leaders to develop protocols that create (instead of breakdown) barriers to care for marginalized persons or worsen already existing disparities. Additionally, a more nuanced investigation of healthcare providers' successful adoption or adherence to protocols needs to be defined and performed. Providers perceiving their care to be standard have little reason to reflect on their own biases or those of larger society and change practice accordingly. In this scenario, initial post-implementation outcomes may be positive, but this kind of culture of complacency may eventually lead to poorer results than anticipated. The result of these often-broad recommendations is culturally-agnostic standardization – a

process that does not appropriately account for the perception, needs, and voice of marginalized persons in their healthcare decisions. This effectively denies individuals the resources they deserve. If the goal is to improve the health of *all* parents, an accounting of implicit biases and a recognition of racial and socioeconomic disparities need to be integrated into every aspect of patient safety bundles.

### **The Learning Health System**

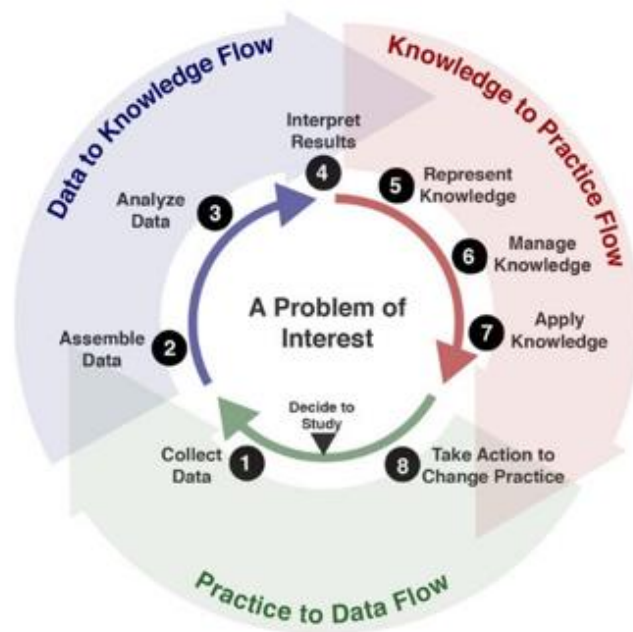
A learning health system (LHS) is a health care system focused on “the seamless and efficient delivery of best care practices and the real-time generation and application of new knowledge.” The defining feature of a LHS is its focus on building critical infrastructures and leveraging health information technologies, biomedical informatics, and implementation science to form a continuously learning environment that improves care delivery patient and outcomes.<sup>106</sup>

The LHS has the potential to bridge the gap between best practices in obstetric care and actual clinical care. The implementation of the obstetric hemorrhage patient safety bundle across Michigan hospitals presents a unique opportunity to understand the extent to which bundles bring about health system or provider behavior change to improve reproductive health outcomes. Central to the concept of LHSs is the iterative relationship between research and practice, translating population-based clinical data into actionable knowledge for improving care quality and patient outcomes. The Agency for Healthcare Research and Quality, the Patient Centered Outcomes Research Institute, and many hospital systems nationwide are supporting efforts to build consensus and infrastructure for LHSs. Adequate infrastructure should not only support the capability of large-scale rapid learning from computable knowledge, but also the implementation of practice change efforts such as the AIM obstetric hemorrhage bundle. Thus, it is critical to utilize LHS research practices and analyze the conflicts within systems that influence bundle implementation success.

## Foundations

The concept of a LHS first appeared in the National Academy of Medicine workshop summary “The Learning Healthcare System,” in 2007. Workshop attendees supported the concept of a LHS capable of generating and applying the best evidence for collaborative decision-making towards enhancing the patient-provider relationship; that improves the delivery and quality of care; that improves health; and reduces health care costs.<sup>107</sup> These objectives align with the Institute for Healthcare Improvement’s triple aims that drive quality improvement efforts nationwide: 1) improving patient care quality and satisfaction, 2) improving the health of populations, and 3) reducing per capita health care costs.<sup>108–110</sup>

Central to the concept of LHSs is the iterative relationship between research and practice, and the emphasis on improving the transformation of data to new knowledge to clinical practice.<sup>111,112</sup> Friedman et al. developed the Virtuous Cycle of Learning for LHSs, a widely accepted process model that conceptualizes the cyclical relationship, types of activities, and necessary components of a LHS: convening a learning community; a cycle of data, knowledge and practice; and supportive infrastructure composed of people, process, policy and technology (Figure 4).<sup>111</sup> Five key attributes are crucial to a fully functional LHS: 1) availability of secure, large-scale, routinely-collected patient data; 2) best-practice knowledge derived from these data capable of being computable for translating into clinical practice; 3) multiple simultaneous and continuous learning and health improvement cycles; 4) presence of infrastructures



**Figure 4.** The Learning Health Cycle

to support learning cycles; 5) identification of stakeholders and experts for establishing learning communities surrounding health-related issues.<sup>111</sup>

AIM's mission to "continually improve patient safety in women's health care through multidisciplinary collaboration that drives culture change", strongly echoes the goals of LHSs. However, many elements of a functional LHS are insufficient, or missing altogether from current initiatives. This review has discussed key elements of the LHS that need to be addressed such as the dearth of maternal health data available, and currently, limited infrastructure exists to support data collection, management, sharing, or analysis of maternal health data. In addition, best-practice knowledge is encapsulated in the bundle; however, little is known regarding concepts such as the implementation process, attitudes towards bundle elements, or perceived barriers and facilitators to implementation at the provider and system levels. Last, the resources, support structure, and individuals involved in supporting and leading the implementation of the obstetric hemorrhage bundles across health systems also remains unclear. Understanding and addressing these gaps in the LHS will be crucial to understanding factors possibly influencing variation in implementation success across systems.

### *Tools for LHS*

Many evidence-based health care interventions fail to produce successful outcomes when implemented into practice. Implementation and dissemination sciences comprise a multidisciplinary set of theories and methods to improve and expedite translating research evidence to everyday health-related practices. Both disciplines are systematic approaches to understanding how healthcare interventions can be better integrated into diverse practice settings and emphasize direct engagement with institutions and communities where health interventions take place. To optimize public health, it is essential to not only understand how to create the best interventions, but how to ensure they are effectively delivered within clinical and community practices.

Implementation science – the study of methods to promote the integration of research findings and evidence into healthcare policy and practice - is well-suited to understand and address the challenges of obstetric hemorrhage bundle implementation



in Michigan because of its emphasis on behavior change across individuals and organizations.<sup>113–116</sup> The field of Implementation Science has progressed towards increased use of theoretical approaches to provide better understanding and explanation of how and why implementation succeeds or fails. Theoretical approaches used in implementation science have three overarching aims: describing and/or guiding the process of translating research into practice (process models); understanding and/or explaining what influences implementation outcomes (determinant frameworks, classic theories, implementation theories); and evaluating implementation (evaluation frameworks).<sup>117</sup> Implementation science frameworks provide a systematic approach to identify key barriers and facilitators to changing individual and organizational behavior. In the context of this review, these frameworks can help identify how and why certain tools and strategies in the obstetric hemorrhage bundle are effective and increase the probability of improvements in obstetric practice.

Implementation guidance, often in the form of a toolkit, are a package of tools and strategies that are used to facilitate behavior change. The items in a toolkit are not prescribed – rather, the goal is for users to select and specify items from a collection of tools and strategies that are evidence-based, have proven effectiveness, and meet the user’s aims, resources, and context. Currently, there is little evidence-based guidance about which tools and strategies are effective for bundle implementation, and thus belong in an implementation toolkit. Moreover, a systematic review of toolkits called for the rigorous testing of bundles via mixed methods design, to explain factors underlying the effects and implementation of toolkit-guided practice change.<sup>118</sup> There is great need to develop robust approaches to accurately identify and monitor health systems that need, or desire bundle implementation, and to deliver adaptable and tailored support.

## **Conclusion**

This review addresses an important public health problem because obstetric hemorrhage is currently the major cause of SMM in the United States. The AIM obstetric hemorrhage patient safety bundle presents some of the most widely implemented clinical strategies to standardize obstetric care to achieve reductions in

maternal mortality and morbidity. The significant investment and momentum behind this initiative is evidenced by the over 80 Michigan health systems currently participating in implementation of this bundle. However, this kind of effort requires not only significant interest, but resources, and support from a variety of disciplines. The goal of this research is to establish a comprehensive understanding of the benefits and detriments of current approaches to bundle implementation in Michigan. The results of this research may provide scalable opportunities to increase the ease of implementation at other interested health systems.

Implementation of complex interventions such as the AIM bundle require significant and sustained behavior change on the part of clinical team members and patients. Michigan health systems partnered with national and state organizations to ensure appropriate design and delivery of implementation strategies to optimize integration of bundle elements. Successful implementation of standardized obstetric care may have a significant impact on improving maternal mortality at individual health systems, and the state level. Optimal utilization of the elements of the AIM bundle have yet to be determined.

One of the main purposes of reproductive health research is to optimize maternal health and healthcare by identifying effective healthcare interventions. Nevertheless, reproductive health research will only improve patient outcomes if the findings of research can be implemented into practice, and unfortunately, the translation of research findings into practice is often a slow process.<sup>116,119,120</sup> Thus, there is a critical need for novel approaches such as a LHS and associated implementation science theory. This approach aims to improve outcomes by identifying the most effective ways of translating research findings into practice.<sup>116</sup> Evidence-based practice requires all healthcare participants to work and think differently, because providing the evidence is necessary, but not sufficient to create change.<sup>121</sup>

## CHAPTER TWO

### Dissertation Research Proposal

#### Problem Statement

Despite outspending all other countries in per-capita maternity care (\$60 billion annually), the United States has the highest rate of maternal mortality in the developed world (26.4 v 16.9 per 100,000 births in 2015).<sup>122,123</sup> This, in addition to a complex combination of factors including disparities in patient socio-economic characteristics, changing population demographics, large variations in medical care, a fragmented health system, and lack of quality maternal health data, contribute to the problem. According to the World Health Organization, reductions in maternal death will be achieved by standardizing obstetric practice at all levels.<sup>124</sup> Hospitals across the United States lack a standard approach to managing obstetric emergencies, with adverse events linked to clinician, facility, and system factors such as inadequate training, missed or delayed diagnosis of complications, delayed or ineffective response to obstetric emergencies, or poor communication and coordination. Nationally endorsed collections of evidence-based practices, called patient safety bundles (“bundles”), have been introduced to address this complex problem. Bundles provide a structured way of improving the processes of care and include a straightforward set of evidence-based practices that, when performed correctly and reliably, may contribute to improved patient outcomes. Standardizing obstetric care with bundles represents an underutilized strategy to improve women’s health, *yet little is known about the optimal context, resources, and processes associated with successful implementation.*<sup>95–101</sup>

Since the introduction of patient safety bundles by the Institute for Healthcare Improvement in 2001, a mandate has emerged for their implementation in hospitals across the country. In Michigan, the Alliance for Innovation on Maternal Health’s obstetric hemorrhage bundles focus on the leading and most preventable causes of

maternal mortality and morbidity, and are currently being implemented at over 80 hospitals.<sup>125</sup> However, despite promising evidence, adoption of patient safety bundles within hospitals is suboptimal often due to a lack of theory-based, multi-component strategies for implementation. *Implementation science – the study of methods to promote the integration of research findings and evidence into healthcare policy and practice - is well-suited to understand and address the challenges of bundle implementation in Michigan because of its emphasis on behavior change across individuals and organizations.* Implementation science frameworks provide a systematic approach to identify key barriers and facilitators to changing individual and organizational behavior. In the context of this proposal, these frameworks can help identify how and why certain implementation tools and strategies are effective and increase the probability of improvements in obstetric practice.

Therefore, the overall research question this dissertation addresses is: *What are the outcomes and important factors that influence the bundle implementation process across Michigan hospitals?* The proposed work will collect and synthesize the best available evidence on barriers and facilitators that influence implementation at the individual and organizational level and generate recommendations to inform implementation of patient safety bundles into clinical practice, tailored to available resources, patient, provider, and hospital characteristics. The following specific aims were developed to address the overall research question:

### **Specific Aims**

**Aim 1: Quantify variation in, and factors associated with rates of SMM across Michigan maternity hospitals.** Using the Michigan Inpatient Database and linked Birth Certificate data, I will examine hospitals based on their rate of SMM in the period surrounding the implementation of the AIM's obstetric hemorrhage bundle (2012-2019), (Sub Aim 1). Next, I will evaluate how much of the variation in SMM is attributable to patient and hospital-level factors using the most recent data available (2019), (Sub Aim 2).

**Aim 2: Qualitatively characterize healthcare provider bundle implementation experiences.** To explore the spectrum of implementation experiences in Michigan maternity hospitals, we will identify a small cohort of healthcare providers and staff with direct implementation experience at their site(s) to conduct key informant and semi-structured interviews.

**Aim 3: Identify implementation challenges and potential solutions, informed by findings in Aims 1 and 2 using a mixed methods approach.** Using data acquired in Aims 1 and 2, comparisons across sites and an explanatory, sequential mixed method approach will be used to identify individual and organizational-level barriers and describe strategies and best practices associated with implementation performance.

Guided by a theory-based determinants implementation framework - the Tailored Implementation in Chronic Disease (TICD)<sup>126</sup> - our hypothesis is that the bundle implementation process in Michigan hospitals is influenced by key individual and organizational factors. It is the specific combination and respective strength of these factors that may be related to variation in implementation performance and experiences across hospitals. For example, successful implementation at one site may be driven by strong stakeholder leadership, and at another, limited leadership, but significant resources and patient interest. The ultimate goals of the proposed research are to 1) provide critical new knowledge and recommendations to improve the implementation experience for healthcare professionals and hospitals in Michigan, and 2) provide insights and recommendations for future bundle evaluation initiatives in other implementing states.

### **Theoretical Framework**

To develop tools and resources that are contextualized for use in real-world clinical settings, our study design is informed by implementation science, an emerging field of methods and approaches that address the challenges of implementing health interventions in usual practice settings.<sup>127</sup> This study will employ the use of TICD

conceptual framework to guide both quantitative and qualitative data collection and analysis.<sup>113</sup> The TICD was developed as a comprehensive, integrated checklist of determinants of implementation success, reconsolidating across 12 different reviews of implementation determinants.<sup>126</sup> By integrating elements from other commonly used frameworks, e.g., the Consolidated Framework for Implementation Science and the Theoretical Domains Framework, it aims to be an easily used checklist to identify determinants of practice for implementation strategy development and program evaluation.<sup>113,128</sup> The TICD developers intended it to be used as a screening tool that can help identify implementation determinants that warrant further investigation and to facilitate tailoring of more effective change interventions and evaluation. Importantly, in this study constructs in the TICD that are associated with bundle implementation but are currently unmeasured by the quantitative data will be directly explored in the qualitative data analysis. Specific barriers and facilitators to bundle implementation by healthcare professionals have not been thoroughly examined, and the use of implementation frameworks, such as the TICD, to evaluate implementation efforts remains inadequately studied. The proposed dissertation study design presents a novel application of the TICD in this context.

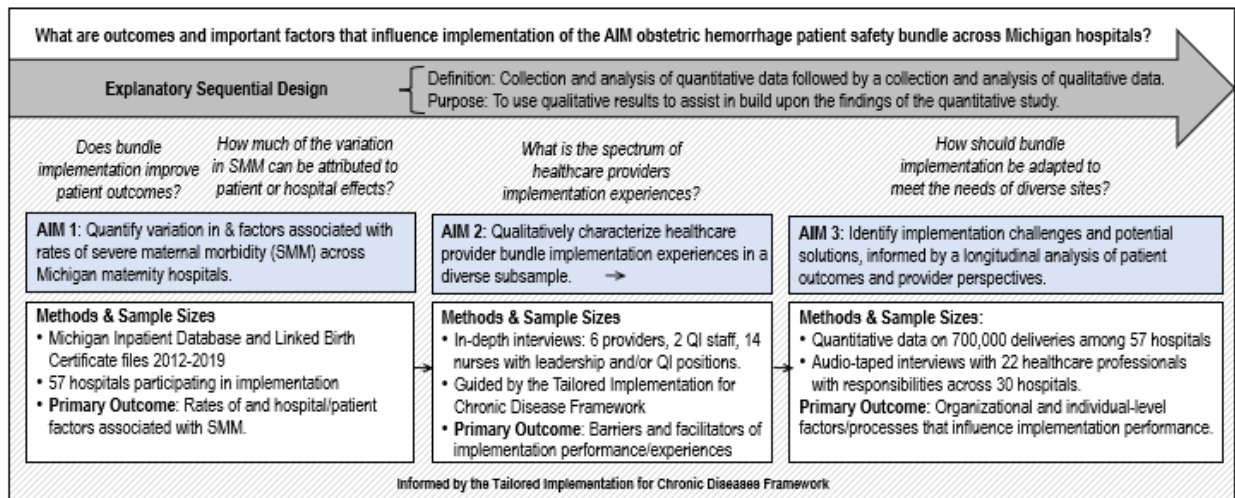
### **Rationale for Mixed Methods Study Design**

This mixed methods study uses an explanatory sequential design that consists of two distinct and consecutive phases: collection and analysis of quantitative data, then collection and analysis of qualitative data. The underlying rationale for collecting, integrating, and analyzing both qualitative and quantitative data are multifold: (1) quantitative data collected from Michigan hospital claims data will provide descriptive statistics to allow for comparison with other practice settings and populations, (2) qualitative interview data will provide a deeper understanding of the lived experiences of healthcare professionals with respect to their role in bundle implementation at their respective site(s), (3) leveraging the complementary nature of quantitative data and qualitative data maximizes our capacity to assess a broader range of theoretical constructs and contextual factors than if quantitative or quantitative methods were used

alone<sup>129</sup>, and (4) collecting data via multiple methods improves the robustness and credibility of our findings.<sup>130</sup>

## Methods

The proposed dissertation research is a retrospective analysis of the implementation of AIM obstetric hemorrhage bundle by healthcare providers within Michigan hospitals between 2012 and 2019. To understand the important factors that influence bundle implementation, I will quantitatively evaluate variation in, and factors associated with SMM across Michigan hospitals using the Michigan Inpatient Database and linked Birth Certificate files (Aim 1), conduct an in-depth qualitative study of the implementation context at select sites (Aim 2), and generate tools that describe best practices and strategies for implementation by merging the quantitative and qualitative data (Aim 3). A schematic of these research questions and associated aims is presented in Figure 5 below.



**Figure 5.** Schematic of Study Design

### Specific Aim 1

*To quantify variation in, and factors associated with rates of SMM across Michigan maternity hospitals.*

As Michigan hospitals begin, continue, and complete implementation of the AIM patient safety bundle, it is crucial to understand the influence of bundle implementation on health outcomes. To achieve this, the analysis will be split into two sub aims which allows us to answer two questions with the same data: 1) *Does bundle implementation improve patient outcomes?* and 2) *how much of the variation in SMM can be attributed to patient or hospital effects?* I will first assess the impact of bundle implementation on rates of SMM during the period surrounding implementation (2012-2019), (Sub Aim 1). Next, I will evaluate how much of the variation in SMM is attributable to patient and hospital-level factors using the most recent data available (2019). In effect, this will indicate the primary drivers of implementation success and point to potential gaps in care. (Sub Aim 2)

### **Sub Aim 1**

*Describe trends in SMM before, during, and after bundle implementation.*

Using the Michigan Inpatient Database and linked Birth Certificate files, an interrupted time series analytic approach will be used to examine the SMM rate over time. This aim will evaluate SMM as it relates to these time indicators, while also controlling for patient and hospital specific variation.

#### *Database Description*

The Michigan Department of Health and Human Services serves as the primary state data manager for Michigan, responsible for collecting both inpatient and outpatient data from Michigan hospitals and compiling databases which are used by researchers, policy analysts, members, and clients. Their focus on stewardship dictates a commitment to protecting the privacy and security of the data. Access to data is governed by strict Access and Use Procedures and Agreements.



Data on patient outcomes are stored as administrative claims data at the inpatient and outpatient levels, known as the Michigan Inpatient Database and Michigan Outpatient Database. Michigan hospitals voluntarily submit demographic, diagnostic, and procedure data on all patients admitted to Michigan hospitals to these databases. The Michigan inpatient and outpatient data is a comprehensive source of all-payer, administrative data that includes virtually all inpatient and outpatient activity at Michigan hospitals. The Michigan inpatient and outpatient data is used in various patient safety and quality initiatives including the MHA Service Corporation Keystone Center's safety and quality initiatives as well as specific focus areas such as readmissions. In addition, the MHA utilizes the inpatient and/or outpatient data to augment its efforts around transparency, provide analytics to better understand the impact of healthcare regulatory and legislative policies on hospital utilization.

Since 2011, the MHA has also maintained a private, voluntary hospital database that collects two types of information: process and structure data. First, implementation process data is manually entered by hospitals as a way for the MI-AIM program to track compliance with the obstetric hemorrhage bundle. Many of the metrics collected reflect educational milestones with healthcare providers on the patient safety bundles and clinical domains. Compliance data for certain bundle components (e.g., obstetric hemorrhage risk assessment completion, quantitative blood loss utilization, and timely treatment for severe hypertension) are also collected in the MHA. Next, data from a "structure" survey is manually entered by hospitals on an annual basis. The purpose of the structure survey is to identify implementation progress of the obstetric hemorrhage bundle. Three of the implementation questions are general (patient, family, and staff support, multidisciplinary teams, and case reviews), and the remainder of the questions are specific to each bundle. (Figure 6)

## MI AIM QUESTIONS

### Obstetric Hemorrhage and Severe Hypertension – HEM/HTN - Patient, Family, and Support Staff

- Has your hospital developed OB specific resources and protocols to support patients, family and staff through major OB complications?
  - Yes
  - No

If yes, when was this implemented? (mm/dd/yyyy)

### HEM/HTN - Debriefs

- Has your hospital established a system in your hospital to perform regular formal debriefs after cases with major complications?
  - Yes
  - No

If yes, when was this implemented? (mm/dd/yyyy)

### HEM/HTN - Multidisciplinary Case Reviews

- Has your hospital established a process to perform multidisciplinary systems-level reviews on all cases of severe maternal morbidity (including women admitted to the ICU, receiving ≥4 units RBC transfusions, or diagnosed with a VTE)?
  - Yes
  - No

If yes, when was this implemented? (mm/dd/yyyy)

### Obstetric Hemorrhage – HEM - Hemorrhage Cart

- Does your hospital have OB hemorrhage supplies readily available, typically in a cart or mobile box?
  - Yes
  - No

If yes, when was this implemented? (mm/dd/yyyy)

### HEM - Unit Policy and Procedure

- Does your hospital have an OB hemorrhage policy and procedure (reviewed and updated in the last 2-3 years) that provides a unit-standard approach using a stage-based management plan with checklists?
  - Yes
  - No

### HEM - EHR Integration

- Were some of the recommended OB Hemorrhage bundle processes (i.e. order sets, tracking tools) integrated into your hospital's Electronic Health Record system?
  - Yes
  - No

If yes, when was this implemented? (mm/dd/yyyy)

**Figure 6.** Excerpt From the 2020 MI-AIM Structure Survey

### *Inclusion/Exclusion Criteria*

To evaluate trends in SMM over time, the analysis for Sub Aim 1 will include all reproductive age persons (15-45) who delivered at a Michigan hospital between January 1, 2012, and December 31, 2019. Patients with singleton and multiple gestations (twins, triplets, etc.) will be included, identified by ICD-9 codes and ICD-10 codes. Repeat pregnancies, (e.g., women with more than one pregnancy in the study period) will be identified and included as separate episodes of care. The subset of hospitals having implemented, or currently implementing the AIM obstetric hemorrhage bundle will be identified in the dataset using hospital identifiers. Births that occur outside of a birthing hospital (home births, freestanding clinics, etc.), and sites that have opened or closed during the study period will be excluded from the analysis. Sites that report fewer than 20 SMM events over the study period that satisfy our criteria will be excluded because the very low hospital-specific case volume may compromise hospital anonymity.

### *Outcomes and Key Independent Variables*

The primary outcome of interest for Sub Aim 1 is whether a patient had an indication of SMM during delivery or postpartum hospitalization. To identify delivery hospitalizations with SMM, the Centers for Disease Control and Prevention's list of 21 indicators and corresponding ICD-9 and ICD-10 codes will be used.<sup>31</sup> Separate SMM definitions specific to obstetric hemorrhage, including outcomes with or without transfusion will be explored. To assess trends over time, two approaches for identifying pre- and post-implementation periods will be evaluated and compared: 1) reported dates for implementation start and end, where applicable, from the MHA database, and 2) known dissemination of bundle recommendations in 2016 will be evaluated for each of the hospitals contained in the database.

## Data Analysis

The number of SMM events per year at each hospital will be identified, and descriptive statistics such as patient demographic and clinical characteristics and medical comorbidities will be assessed yearly from 2012 to 2019. Differences in demographic characteristics in the pre-implementation and post-implementation periods will also be described. Missing data can present major problems for time series analyses, and thus the degree and patterns of missing data will also be assessed. If data are missing, multiple imputation – a process that predicts missing data with plausible values to create multiple completed data sets – will be considered.<sup>131</sup>

The interrupted time series (ITS) framework will be used to estimate the effect of bundle implementation on SMM. ITS is a quasi-experimental design used to examine the effectiveness and longitudinal effects of an intervention. The main advantage of this approach over alternative approaches is that it can make full use of the longitudinal nature of the data and account for pre-intervention trends. Another strength is that ITS analyses are generally unaffected by confounding variables and allow for stratified analyses of subpopulations to derive different causal effects. We can specify the following regression model to estimate the level and trend in SMM before bundle implementation and the changes in level and trend following implementation:

$$Y_t = \beta_0 + \beta_1 * \text{time}_t + \beta_2 * \text{intervention}_t + \beta_3 * \text{time after intervention}_t + \alpha_t + \gamma_t + \epsilon_t$$

Here,  $Y_t$  is whether a patient had SMM in year  $t$ ;  $\text{time}_t$  is a continuous variable indicating time in years at time  $t$  from the start of the observation period;  $\text{intervention}_t$  is an indicator for time  $t$  occurring before ( $\text{intervention} = 0$ ) or after ( $\text{intervention} = 1$ ) bundle implementation, and  $\text{time after intervention}_t$  is a continuous variable counting the number of years after the intervention at time  $t$ , coded 0 before implementation. In this model,  $\beta_0$  estimates the baseline level of the outcome, SMM at time zero;  $\beta_1$  estimates the change in the rate of SMM per site that occurs with each year before the intervention (i.e., the baseline trend);  $\beta_2$  estimates the level change in SMM per site immediately after the intervention; and  $\beta_3$  estimates the change in the trend in SMM

after implementation, compared with the annual trend before implementation. The sum of  $\beta_1$  and  $\beta_3$  is the post-intervention slope. The term  $\alpha_t$  represents the patient fixed effects, and  $\gamma_t$  represents the hospital fixed effects. The error term  $\epsilon_t$  at time  $t$  represents the random variability not explained by the model.

Statistical dependence arises in the Michigan Inpatient Database due to multiple deliveries per patient and patients clustering in hospitals. Hospital ( $\gamma_t$ ) and patient ( $\alpha_t$ ) specific fixed effects will be added to the model to appropriately account for this dependence when assessing trends in SMM over time. Regression models with associated postestimation commands will be used to obtain the estimated trends over time (slope) in SMM both before and after the bundle implementation. Data management will be conducted with SAS version 9.4 (SAS Institute Inc. Cary, NC), and analyses performed using Stata version 14 (StataCorp LLC, College Station, TX). Statistical significance will be assessed utilizing a 95% confidence interval but note that this should be interpreted with caution due to the very large sample size.

## **Sub Aim 2**

*Evaluate the influence of patient and hospital-level factors on variation in SMM post bundle implementation.*

Sub Aim 1 described the relationship between bundle implementation and SMM over time in Michigan hospitals. However, regardless of the direction and strength of this relationship, the subsequent question is, why? Sub Aim 2 seeks to answer the question: *how much of the variation in SMM can be attributed to patient or hospital effects?* This analysis will use the most recent data contained in the Michigan Inpatient Database (2019) and multilevel analysis to evaluate the separate and combined contribution of patient and hospital factors on SMM across Michigan hospitals participating in implementation.

### *Inclusion/Exclusion Criteria*

This analysis will include all persons who delivered at a Michigan hospital between January 1, 2019, and December 31, 2019, contained in the Michigan Inpatient Database (described previously). Patients with singleton and multiple gestations will be included and identified by ICD-9 and ICD-10 codes. Patients with repeat pregnancies, (e.g., persons with more than one pregnancy during the study period), will be identified and included as separate episodes of care. The subset of hospitals having implemented, or currently implementing the AIM obstetric hemorrhage bundle will be identified in the dataset using hospital identifiers. Births that occur outside of a birthing hospital (home births, freestanding clinics, etc.), and sites that have opened or closed during the study period will be excluded from the analysis. Sites that report fewer than 20 SMM events that satisfy our criteria during the study period will be excluded because the very low hospital-specific case volume may compromise hospital anonymity.

### *Outcomes and Key Independent Variables*

The primary outcome of interest for Sub Aim 2 is whether a patient had an indication of SMM during delivery in 2019. To identify delivery hospitalizations with SMM, the Centers for Disease Control and Prevention's list of 21 indicators and corresponding ICD-9 and ICD-10 codes will be used.<sup>31</sup> Separate SMM definitions specific to obstetric hemorrhage, including outcomes with or without transfusion will be explored.

Patient demographic and clinical characteristics, medical comorbidities, and antenatal care information including variables such as age, race/ethnicity, body mass index calculated as weight (kg)/height (m<sup>2</sup>), insurance status, tobacco use during pregnancy, alcohol use during pregnancy, number of prenatal visits, prenatal visit in the first trimester, diabetes, hypertension, and gestational age at delivery will be included in the analysis. Additionally, the MI-AIM has developed a hospital performance index (range 0-100) to indicate individual hospital performance across a variety of domains (e.g., MI-AIM commitment, data reporting, bundle implementation progress). This

variable, or specific subcomponents of this variable may be included as an important predictor of hospital implementation progress and may be explored. (Figure 7).

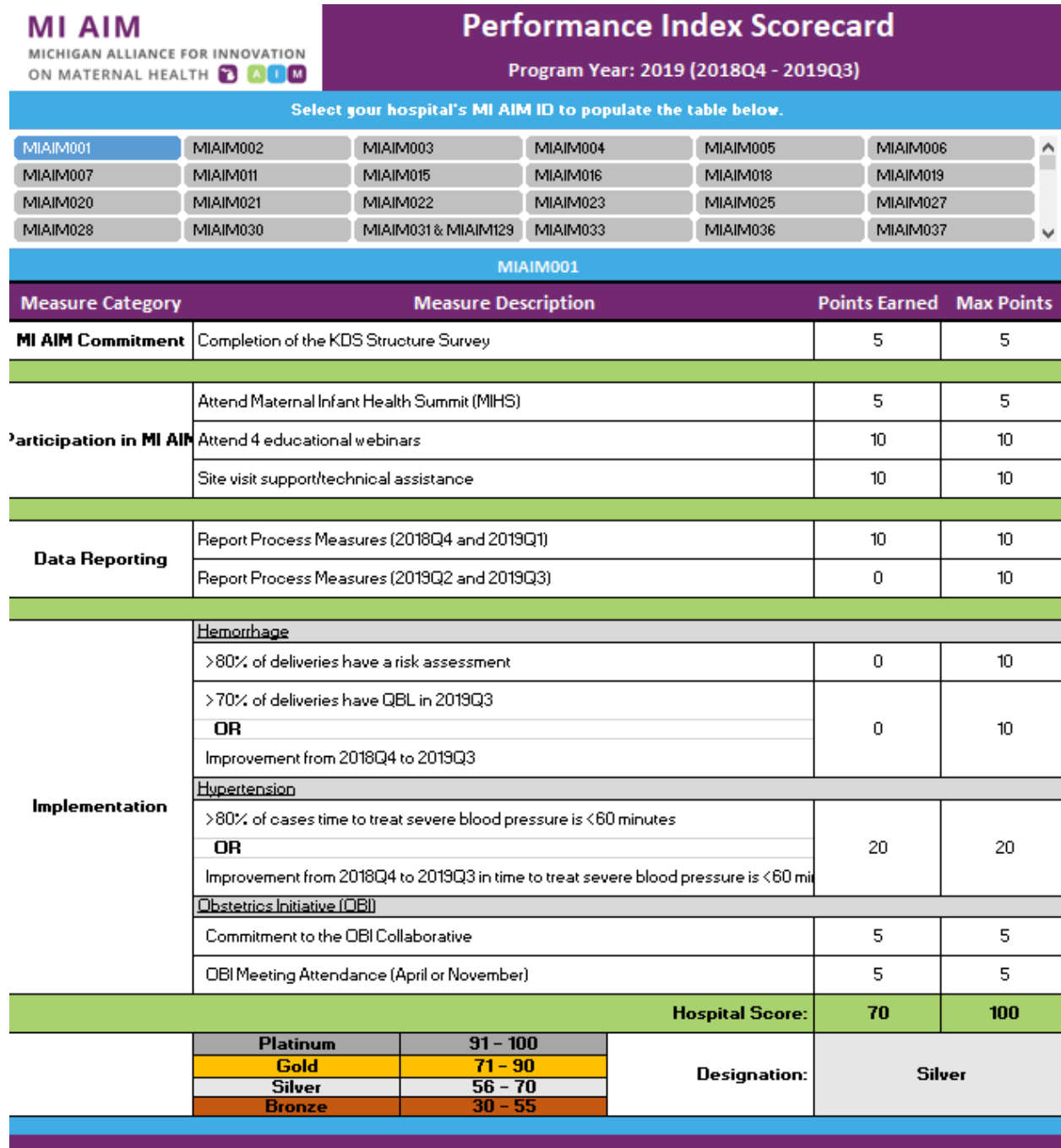


Figure 7. MI-AIM Performance Index Scorecard (Program Year 2019)

## *Data Analysis*

Patient SMM will be modeled with multilevel logistic regressions (also known as generalized linear mixed models).<sup>132</sup> This modeling framework allows for the examination of patient- and hospital-specific variables while accounting for statistical dependence due to patients clustering within hospitals. An unconditional model with only a random intercept for hospital will first be assessed. We will calculate the Intraclass Correlation Coefficient (ICC), which quantifies the extent of systematic variations between elements at a higher level.<sup>133–135</sup> In this study, an ICC is defined as the variance in SMM (at the patient level) between hospitals divided between the total variance (the sum of the “between” and the “within” variance). The greater the “between” variance is, the smaller the “within”, and the greater the ICC. An ICC that approaches one indicates that SMM is determined at the hospital level, and conversely, and ICC approaching zero indicates very little hospital-specific variation.

After we understand how much variation in patient SMM is due to patient- and hospital-level factors, we will add patient and hospital variables to the model to explain SMM variation. Interaction terms will be assessed and included in the model where appropriate. To gain an indication of the contribution of both patient- and hospital-level characteristics on the variation in SMM, total explained variances ( $R^2$ ) will also be calculated at the patient and hospital levels. Data management will be performed using SAS version 9.4 (SAS Institute Inc. Cary, NC), and all analyses using Stata version 14 (StataCorp LLC, College Station, TX), and will utilize a 95% confidence level.

### *Summary for Specific Aim 1*

This quantitative analysis of inpatient claims data will 1) identify the trends in SMM rates over time across Michigan hospitals implementing the AIM obstetric hemorrhage bundle and 2) identify the relative contribution of patient and hospital-level factors associated with variation in SMM. I hypothesize that although measurable patient and hospital factors will explain some variation in SMM across Michigan hospitals, the portion of variation unexplained by quantitative data alone will be critical



to understand. I further hypothesize that this unexplained variation is driven by concepts such as stakeholder involvement, the presence of implementation champions, and interprofessional dynamics. The identification of these factors will be best captured with qualitative data collection and analysis as described subsequently in Specific Aim 2.

## **Specific Aim 2**

*To qualitatively characterize healthcare provider bundle implementation experiences in a diverse subsample of Michigan hospitals.*

Although patient and hospital-level factors may explain some of the variation in implementation success across hospitals (as measured by the SMM rate), there are particularly salient concepts such as previous experience with quality improvement efforts, or an organizational commitment to implementation approaches that may be best captured using qualitative methods. To explore the spectrum of bundle implementation experiences in Michigan hospitals, we will conduct key informant and semi-structured interviews with healthcare providers and staff with direct implementation experience at their site(s). Key informant interviews will aid in the development of a theory-informed interview guide, and semi-structured interviews will provide robust information on factors associated with implementation that stakeholders have or are currently experiencing. Observation and collection of implementation artifacts will be considered. Consistent with core principles of qualitative research, Aim 2 is not hypothesis driven but rather exploratory and inductive in nature.

### *Site and Subject Recruitment*

Interviews will be conducted with healthcare providers or staff with direct implementation experience at their site(s). Participants will be recruited from the MI-AIM operations committee meetings, which occur monthly on Monday afternoons. One or two opportunities to introduce the research and elicit interest from meeting attendees will be requested of the organizer. Meeting attendees include physicians and nurses

with extensive experience in quality improvement or implementation activities: some with appointments at the national or state level, and all with detailed knowledge, experience, and oversight for implementation processes at their site(s). Interview respondents will be selected to ensure a variety of perspectives on bundle implementation, including but not limited to: attendings, residents, medical students, nursing representatives (head nurse, night charge nurse, staff nurse), nursing and/or quality improvement administration staff, and senior administrative staff, and medical support staff involved in bundle implementation processes and practices. Consistent with the goals of qualitative purposeful sampling, these providers may not be representative of experiences at all Michigan hospitals but rather reflect characteristics that may underlie variations in implementation.<sup>136</sup> Most importantly, consideration of provider and hospital access and feasibility of gaining meaningful information will be crucial for eligibility.

Due to COVID-19 pandemic protocols beginning in March 2020, we will not be visiting sites for observation. Alternatively, during video visits, we will use semi-structured interview guides to conduct in-depth interviews with implementation stakeholders. Interviews will last approximately 30 to 60 minutes, audio-recorded, and transcribed verbatim. Details of this process are further described in the “Data Analysis” section.

### *Data Collection and Management*

We will use the TICD to guide qualitative data collection and analysis. The TICD was developed as a comprehensive, integrated checklist of determinants of implementation success, reconsolidating across 12 different reviews of implementation determinants.<sup>126</sup> By integrating elements from other commonly used frameworks, e.g., the Consolidated Framework for Implementation Science and the Theoretical Domains Framework, it aims to be an easily used checklist to identify determinants of practice for implementation strategy development and program evaluation.<sup>113,128</sup> Importantly, in this study constructs in the TICD that are associated with bundle implementation but are currently unmeasured by the quantitative data (Aim 1) will be directly explored in the

qualitative data analysis. As is recommended by the TICD authors, the framework's exhaustive checklist of twelve domains and 57 associated determinants of practice will be reviewed. Domains and determinants of practice that are most relevant to the bundle implementation process among Michigan hospitals will be selected.

In Aim 2 we will collect transcribed, audio-recorded semi-structured interviews with implementation stakeholders. The semi-structured interview guide will prompt respondents to discuss their practice context as it relates to their experiences with implementing the obstetric hemorrhage bundle, and we will probe respondents regarding the barriers and facilitators they experienced when implementing the entire bundle, or its components. We will ask questions about specific TICD constructs, including but not limited to (1) how the bundle (or bundle components) are being operationalized in their unit (or at their site); (2) how practices and workflows supported (or did not support) bundle implementation; (3) what has been challenging (the most challenging) with operationalizing bundle implementation; (4) what people, tools, resources, collaborations, etc. have been helpful with operationalizing bundle implementation; and (5) how coworkers or other clinical groups were reacting to the bundle implementation process. To further develop the interview guide, key-informant interviews (n = 2) will be conducted with implementation stakeholders at the University of Michigan. These interviews will serve to pilot-test the guide, and refinements will be made based on respondent feedback and research team members' perceptions of the usefulness of the data collection instruments for eliciting salient information. The final, refined data collection instruments will be used for the proposed in-depth interviews (Table 2).

Concept/Construct <sup>1</sup>	Questions	Probes
<i>Warmup/Rapport building</i>	1. What is your role in the MI-AIM patient safety bundle implementation process at [SITE]?	<ul style="list-style-type: none"> <li>• How long have you been involved?</li> <li>• Has your role changed over time? In what ways?</li> </ul>
<i>Guideline factors</i>	2. How were the bundle/bundle implementation tools introduced in your area? 3. Are your colleagues aware of and familiar with bundle implementation? 4. Who else is involved with bundle implementation at your site? 5. How feasible is it/has it been to implement the bundle elements? 6. How much effort is required to implement the bundle elements? What factors make them easier or more difficult?	<ul style="list-style-type: none"> <li>• Are the bundle elements consistent with other guidelines or recommendations you work with routinely? Are they compatible with the way you currently practice?</li> <li>• What could be done to improve knowledge or awareness of this topic?</li> <li>• Have you noticed any specific improvements after bundle implementation?</li> <li>• In your opinion, what knowledge or expertise do [ROLE] need to implement the bundle?</li> <li>• What skills are needed to implement appropriately, and do [ROLE] here have those skills?</li> </ul>
<i>Individual health professional factors</i>	7. What has been your general view of the bundle implementation process so far? 8. Why do people at your organization/in your unit think bundle implementation is important? 9. Do you or your colleagues believe that implementing the bundles will lead to better outcomes (for patients, providers, the health system)?	<ul style="list-style-type: none"> <li>• What concerns do you or your colleagues have about bundle implementation?</li> <li>• Are there other personal or professional factors that impact your or your colleagues ability to participate in bundle implementation?</li> </ul>
<i>Patient factors</i>	10. How much of a problem do you feel that obstetric hemorrhage is at [SITE]? In your community? 11. Can you describe how bundle implementation has influenced the patient experience?	<ul style="list-style-type: none"> <li>• What can be done to improve knowledge on this topic?</li> <li>• Are there any particular examples of how the bundles have affected patient care you that stick out to you?</li> </ul>
<i>Professional interactions</i>	12. Are there specific individuals, organizations, or norms/values that you are aware of that affect how you perceive the bundles or implementation process? 13. Are there team or workflow issues that affect bundle implementation? 14. Do you think feedback on your success with these bundles would be beneficial? 15. Can you describe how has the COVID-19 pandemic impacted the implementation process?	<ul style="list-style-type: none"> <li>• Are changes needed in referral processes, or interactions with other systems or groups, to be able to improve implementation?</li> <li>• What specific feedback would be most helpful?</li> </ul>
<i>Incentives and resources</i>	16. What resources would be helpful in getting you or your colleagues to participate in bundle implementation more fully or consistently? 17. What could be done to make it easier to follow implementation guidelines? 18. How much extra effort is required for bundle implementation? What/who contributes to the extra effort? 19. What could be done to reduce that extra effort?	<ul style="list-style-type: none"> <li>• Are the necessary resources available?</li> <li>• What financial incentives do: you or your colleagues, system administrators, patients, and others have in conducting Goals of care conversations? What about non-financial incentives?</li> <li>• How does the information system/EHR (Epic) help or hinder the implementation process?</li> </ul>
<i>Capacity for organizational change</i>	20. What kind of oversight is there for this program? 21. What leadership or management support is needed to assist you or your colleagues in implementation? In your opinion, is this available, and do clinicians know how to access it? 22. How much of a priority is bundle implementation compared with other initiatives and activities going on in your setting? 23. How useful is monitoring and feedback? Is it available? 24. What aspects of bundle implementation have gone really successfully? 25. What are challenges to bundle implementation that you are facing currently, or still facing? 26. If you compare [SITE] with other places, are there any significant differences or similarities that you notice in the implementation process? 27. If you could change anything about the implementation process, what would you like to be different?	<ul style="list-style-type: none"> <li>• Is the style of leadership being used helpful?</li> <li>• Who supports bundle implementation and who doesn't (or supports it less)?</li> <li>• What kind of follow-up or tracking is being done?</li> <li>• Are there specific aspects of [SITE] that drive this success?</li> <li>• Are there specific aspects of [SITE] make this process challenging?</li> <li>• What do you think it would take to make that (change) happen?</li> </ul>
<i>Social, political, and legal factors</i>	28. What is your understanding of why bundles are being encouraged? 29. Are there any payer or funder policies or issues that you're aware of that impact bundle implementation?	<ul style="list-style-type: none"> <li>• Do real or perceived risks of malpractice complaints impact implementation?</li> <li>• Do influential people or groups outside [SITE] impact implementation?</li> </ul>
<i>Conclusion</i>	30. Is there anything else I didn't ask you about, that you think I should know? 31. Do you have any questions for me?	

<sup>1</sup> Constructs and concepts come from the Tailored Implementation in Chronic Disease project: <http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-8-35>

**Table 2.** Semi-Structured Interview Guide Using the TICD Domains and Determinants

The data acquired from the semi-structured interviews will provide perspectives on the extent to which bundle implementation and the resultant process changes were understood and supported by staff throughout the hospital. We will obtain as complete of a picture as possible of the bundle implementation experience in clinical setting.

### *Data Analysis*

All interview recordings will be transcribed verbatim. The transcripts will be uploaded and organized using MaxQDA (2020 version, VERBI Software, 2020).<sup>137</sup> Qualitative analysis is an iterative process during which investigators go through cycles of reading, summarizing, and re-reading data. A qualitative team (EKK, LMM) will be composed to review transcripts independently and code the content of each transcript. Because our research design is driven by predetermined theoretical constructs, the initial coding will be done with a theory-generated template. We will generate code reports from for each hospital that included all the data segments coded for each TICD domain or determinant. Within each report, data will be organized by TICD domain and determinant. For example, the code report for “care coordination” will include all codes on how the hospital made changes to implement care coordination and what barriers and facilitators that the hospital experienced in making those changes, grouped by each of the TICD domains. Summaries will be developed for each of the five hospitals. In vivo coding will also occur as new themes emerge from the data. The team will discuss, compare, and reconcile differences in coding and create a consensus code template, which will then be used to code the remainder of the transcripts. Themes and patterns will be identified and synthesized, using a pre-identified theoretical constructs as a guide, as well as new themes as they emerge.<sup>138</sup> Data collection continues until saturation is reached, or until we no longer identify new or disconfirming or confirming data with respect to the original research aim. Analysis of patterns of barriers and facilitators across sites will be performed to identify similarities, differences, and trends in how providers or hospitals experienced implementation.

## *Summary for Specific Aim 2*

Drawing on the TICD domains and determinants, the results from Aim 2 will describe factors associated with bundle implementation as they emerge across the sampled providers and associated hospitals. Qualitative reporting of these findings will convey the richness of this information and preserve the complexity of these patterns while maximizing learning across hospitals. A narrative report of these findings will include a summary of factors associated with bundle implementation organized by TICD domain. These results will identify barriers or facilitators that were common across the hospitals, as well as those that were unique to each hospital - identifying key areas where additional support could be important for implementation performance.

## **Specific Aim 3**

*To identify implementation challenges and potential solutions, informed by findings in Aims 1 and 2 using a mixed methods approach.*

To better understand mechanisms by which effective interventions achieve their results and which populations benefit most from specific interventions, a sequential, explanatory mixed methods approach will be used to analyze and integrate the quantitative and qualitative results from Aims 1 and 2, respectively.<sup>139</sup> Strands of data will be merged by identifying content from both datasets to compare, contrast, and synthesize. A final interpretation will summarize how, and to what extent the results from the qualitative and quantitative data contribute to the identification of patient-, provider-, and hospital-level factors that drive the implementation of the AIM bundles. Specifically, Aim 3 seeks to answer the question: *How should AIM bundle implementation be adapted to meet the needs of diverse sites?* The results of these analyses will highlight specific elements of the implementation process that affect sites' ability to be successful.

## *Methods*

This sequential explanatory mixed methods investigation consisted of (1) quantitative evaluation of variation in, and factors associated with SMM across Michigan hospitals using the Michigan Inpatient Database, and (2) an in-depth qualitative study of the implementation context and experiences at select sites. The results from Aims 1 and 2 will be integrated and presented alongside each other using a matrix.<sup>140</sup>

Integration is a process in mixed methods research in which the qualitative and quantitative strands of a study “come into conversation with each other.”<sup>141</sup> The integration of quantitative and qualitative data in this study will occur at three points of interface. First, using a connecting approach<sup>142</sup>, the results from quantitative analysis will be used to identify diverse sites in order to selectively sample participants for the qualitative interviews. Second, using a building approach<sup>142</sup>, qualitative interview data will be used to tailor the interview guides to specific subgroups of interest. Third, using a merging approach<sup>142</sup>, a data display will be created to link major quantitative and qualitative findings to identify points of convergence and divergence. (Table 2).

## *Outcomes*

The goals for the qualitative aim of the study are to obtain robust descriptions of variables associated bundle implementation and describe experiences and relationships potentially influencing implementation performance. Because the number of participants able to be interviewed is limited by available resources, the relevance of information obtained during each interview will be prioritized. Therefore, we used the SMM rates and site characteristics to develop profiles that guide selection of the interview sample. This strategy will ensure that we obtain narratives from a diverse set of participants with varied characteristics that may influence implementation.

The connecting strategies that resulted in the site profiles to sample participant interviews, may facilitate subsequent integration procedures that enable the development of analytic products needed to expand or explain quantitative findings. These may include of the development of: (a) a graphical user interface for hospital

needs assessment, (b) tailored interview guides, (c) in-depth narrative descriptions to explain unexpected quantitative findings, and (d) outlier case studies to extend expected quantitative findings.<sup>143,144</sup> Any final products will be determined based on findings from this analysis and current needs of implementation stakeholders, ultimately refined to provide the most useful tools to improve the implementation process and/or experience.

For example, using a building approach, a graphical user interface may be created for currently implementing hospitals, and future interested sites. A graphic nomogram will be generated to represent the final logistic regression model from Aim 1. Using this nomogram, the predicted chance of SMM for women who are laboring and delivering can be calculated for different hospitals. This approach acknowledges the differences between sites on many factors associated with SMM, including patient demographics, comorbidities, and hospital characteristics, to individualize prediction of risk. Users of this interface would be provided with individualized tools and strategies tailored to their input criteria and final predicted risk (or “score”). This type of tailoring accounts for the scenario where hospitals with similar risks may require very different strategies of care depending on the available resources.

Using a building integration approach, tailored interview guides may be created for healthcare participant groups (e.g., staff, residents, nurses, providers). The questions on the guide will correspond to data collected through interviews, and map to TICD domains, to obtain targeted information about the specific implementation experiences. The items will invite participants to elaborate on their thoughts about the bundle implementation process or components, describe their day-to-day experiences related to implementation, and consider how these experiences influenced their clinical decision-making. The creation of tailored interview guides specific to the patient experience may also be of interest for future work. Understanding patient knowledge, needs, and perceptions of the implementation experience may be novel and critical information for optimizing outcomes.

Using a merging integration approach, narrative summaries will be created. This analysis allows for the identification of both outliers and groups with commonalities of experience, attitudes, or characteristics across stakeholders, and sites, thus providing



the opportunity to offer a more thorough understanding of the findings. Data from both quantitative and qualitative aims will be used to construct a narrative summary.

The integration strategies outlined here provide a transparent description of practical processes that will be used for achieving optimal integration in mixed methods analyses. Maximizing and optimizing the integration of data in this way will provide the most relevant, robust, and targeted information required to address the study aims.

### *Summary*

Research findings have already begun to influence the bundle implementation process in Michigan. Implementation champions have been identified, and committees and teams have been organized to lead and organize implementation efforts at the unit, hospital, and state levels. Numerous meetings, educational sessions, and conferences have helped facilitate knowledge sharing across sites as well. This research seeks to consolidate and synthesize the abundant conversations, actions, and data surrounding these efforts, and identify practical solutions to improve and sustain bundle implementation activities at all levels. This highlights the power of mixed methods in this context: our qualitative findings give us narrative stories and on-the-ground experiences, while our quantitative findings give us data that illuminate the relationship between patients, hospitals, and implementation outcomes. Together this information provides insights that will help shape the future planning and strategies for AIM bundle implementation.

### **Limitations**

There are several limitations to the proposed research aims. First, this protocol describes a pragmatic study design which is necessarily limited by the availability of data and limitations on timescales and funding. In particular, the evaluation of this complex intervention is further complicated by the historically slow speed of implementation initiatives at this scale. We are unable to quantitatively account for fluctuations in implementation due to external factors such as policy or environmental

changes. Second, there were no specific identifiers for “implementation start”, thus, a proxy will be used to artificially set a baseline for hospitals. Third, this study will include qualitative data from providers with roles and responsibilities across many hospitals, therefore, findings presented here may not be representative of other institutions, provider experiences, or patient populations. Fourth, due to time constraints and delays due to the COVID-19 pandemic, qualitative data analysis did not include in-person observation or artifact collection.

### **Summary**

The results of this work will inform our understanding of the AIM bundle implementation process across diverse sites and provide Michigan hospitals with tailored recommendations and inform best practices for bundle implementation. The proposed work is innovative because it 1) will quantitatively evaluate claims-based measures of SMM across a large sample of Michigan hospitals; 2) will collect and summarize novel, qualitative narratives from a diverse group of implementation stakeholders across multiple sites; 3) uses a mixed methods approach to merge and synthesize implementation process data, which will increase the validity and explanatory power of our findings; 4) uses an established implementation framework to organize promising strategies and tools for dissemination; and 5) incorporates principles of implementation science, with a goal of accelerating adoption of evidence-based care into standard clinical practice.

## CHAPTER THREE

### Trends in Severe Maternal Morbidity Across Michigan Hospitals Implementing a National Patient Safety Bundle Targeting Obstetric Hemorrhage: 2012-2019

#### Abstract

**Objective:** To describe the relationship between the implementation of a national obstetric hemorrhage patient safety bundle and rates of SMM across Michigan hospitals between 2012 and 2019.

**Methods:** We conducted a serial cross-sectional study of persons of reproductive-age delivering at bundle-participating Michigan hospitals from 2012 to 2019 using the Michigan Department of Health and Human Service's Inpatient Database and Birth Certificate files. The primary outcome was SMM without transfusion during delivery hospitalization, identified using the Centers for Disease Control and Prevention's list of indicators. Descriptive statistics were used to summarize SMM events, patient demographic and clinical characteristics, and comorbidities yearly. We used an interrupted time series framework to compare quarterly SMM incidence pre-implementation (Q1 2012-Q2 2016) to post-implementation of the bundle (Q3 2016-Q4 2019). Multivariable multilevel logistic regression models assessed patient- and hospital-level predictors of SMM in 2019

**Results:** Among 731,710 deliveries among 658,630 patients at 57 implementing hospitals, the rate of SMM was 65 (95% CI: 60-71) per 10,000 deliveries in 2012 and 72 (95% CI: 67-78) per 10,000 in 2019 ( $p=0.07$ ). During the same period however, SMM among patients with hemorrhage decreased significantly from 708 (95% CI: 627-796) to 482 (95% CI: 449-565) per 10,000, ( $p<0.001$ ) In 2019, parent age, race/ethnicity,

payment source, gestational age at delivery, delivery method, chronic hypertension, and hospital size were associated with SMM.

**Conclusion:** After standardizing obstetric care across Michigan hospitals, patients with hemorrhage – specifically targeted by this intervention – showed declining rates of SMM in both the pre- and post-implementation periods. Failure to detect substantial deviations among all deliveries suggests that bundles are one of many tools necessary to address complexities in maternity care. Further investigation into the barriers and facilitators of implementation will optimize health outcomes.

## Introduction

The pregnancy-related mortality rate in the United States has risen steadily over the past 30 years, disproportionately affecting communities of color, and straining the country's health care system.<sup>145,146</sup> A major contributor to this growing problem is inconsistent obstetric practice.<sup>124</sup> Previously, hospitals lacked standard approaches to managing obstetric care, with adverse events linked to factors such as inadequate training, missed or delayed diagnosis, or poor communication and coordination.<sup>57,82,147,148</sup> Nationally-endorsed collections of evidence-based practices, called patient safety bundles, were introduced to address this complex issue. Bundles provide a structured way of improving care processes and include a set of action steps that, when performed correctly and reliably, may contribute to improved patient outcomes.<sup>74</sup> Standardizing obstetric care with bundles represents an underutilized strategy to improve health, yet little is known about the impact of these initiatives on health outcomes.<sup>95–101,149</sup> In Michigan, the Alliance for Innovation on Maternal Health's obstetric hemorrhage bundle focuses on the leading and most preventable cause of maternal mortality and morbidity, and since 2016, over 80 hospitals have started implementation.<sup>125</sup> This tool contains 13 strategies that standardizes practice under four domains: readiness, recognition and prevention, response, and reporting and systems learning (Figure 8).



PATIENT SAFETY BUNDLE

Obstetric Hemorrhage

**READINESS**

*Every unit*

- Hemorrhage cart with supplies, checklist, and instruction cards for intrauterine balloons and compressions stitches
- Immediate access to hemorrhage medications (kit or equivalent)
- Establish a response team - who to call when help is needed (blood bank, advanced gynecologic surgery, other support and tertiary services)
- Establish massive and emergency release transfusion protocols (type-O negative/uncrossmatched)
- Unit education on protocols, unit-based drills (with post-drill debriefs)

**RECOGNITION & PREVENTION**

*Every patient*

- Assessment of hemorrhage risk (prenatal, on admission, and at other appropriate times)
- Measurement of cumulative blood loss (formal, as quantitative as possible)
- Active management of the 3rd stage of labor (department-wide protocol)

**RESPONSE**

*Every hemorrhage*

- Unit-standard, stage-based, obstetric hemorrhage emergency management plan with checklists
- Support program for patients, families, and staff for all significant hemorrhages

**REPORTING/SYSTEMS LEARNING**

*Every unit*

- Establish a culture of huddles for high risk patients and post-event debriefs to identify successes and opportunities
- Multidisciplinary review of serious hemorrhages for systems issues
- Monitor outcomes and process metrics in perinatal quality improvement (QI) committee

**Figure 8.** The AIM Obstetric Hemorrhage Patient Safety Bundle

As hospitals begin, continue, and complete bundle implementation, it is crucial to understand the early impact of this initiative on health outcomes. The objective of this analysis was to describe the relationship between the Alliance for Innovation on Maternal Health’s obstetric hemorrhage bundle implementation and the SMM rate

across Michigan hospitals between 2012 and 2019, and describe patient and hospital factors that explain SMM rates

## Methods

We conducted a serial cross-sectional study of individuals delivering at Michigan hospitals from 2012 to 2019 using the Michigan Department of Health and Human Service's resident Inpatient Database and linked Birth Certificate files. This large state database includes demographic characteristics such as age, race, and insurance status, along with patient comorbid conditions, International Classification of Diseases, 9th and 10<sup>th</sup> Revision, Clinical Modification (ICD-9-CM, ICD-10-CM) diagnosis, and procedure codes. Information on hospital Alliance for Innovation on Maternal Health initiative participation, characteristics (size: <500 births, 500-999 births, 1000-1999 births, ≥2000 births, and urban/rural classification: based on the Federal Office of Rural Health Policy criteria<sup>150</sup>), implementation dates, and progress was collected from the MHA Keystone Center Collaborative database.

Our analytic sample was drawn from a population of 928,410 delivery hospitalizations among 834,027 individuals at 80 Michigan birthing hospitals between January 1, 2012, and December 31, 2019. We restricted our sample to hospitals participating in the MI-AIM program as of December 2019, reporting implementation progress measures to the MHA, and with at least 20 SMM events during the study period to be able to reliably compare hospital sites and identify outliers. We further restricted our sample to persons of reproductive age (age 15-45), and included repeat pregnancies (e.g., persons with more than one pregnancy during the study period) were considered separate episodes of care. Births that occurred outside of a birthing hospital (home births, freestanding clinics, etc.) were excluded from the analysis. After applying these criteria there were 731,710 deliveries among 658,630 individuals at 57 hospitals eligible for analysis.

The primary outcome of SMM without transfusion during delivery or postpartum hospitalization was identified using the Centers for Disease Control and Prevention's list of indicators.<sup>91,151</sup> This measure was chosen to align with the most recent

recommendations by the Maternal and Child Health Bureau, which continues to exclude blood transfusion alone due to significant decreases because of the transition to ICD-10-CM in the last quarter of 2015.<sup>152,153</sup> In addition, data for 2015 represents only three quarters of the year (January through September); thus the rate should be interpreted with caution as it does not represent a full year of change relative to 2014.<sup>154,155</sup>

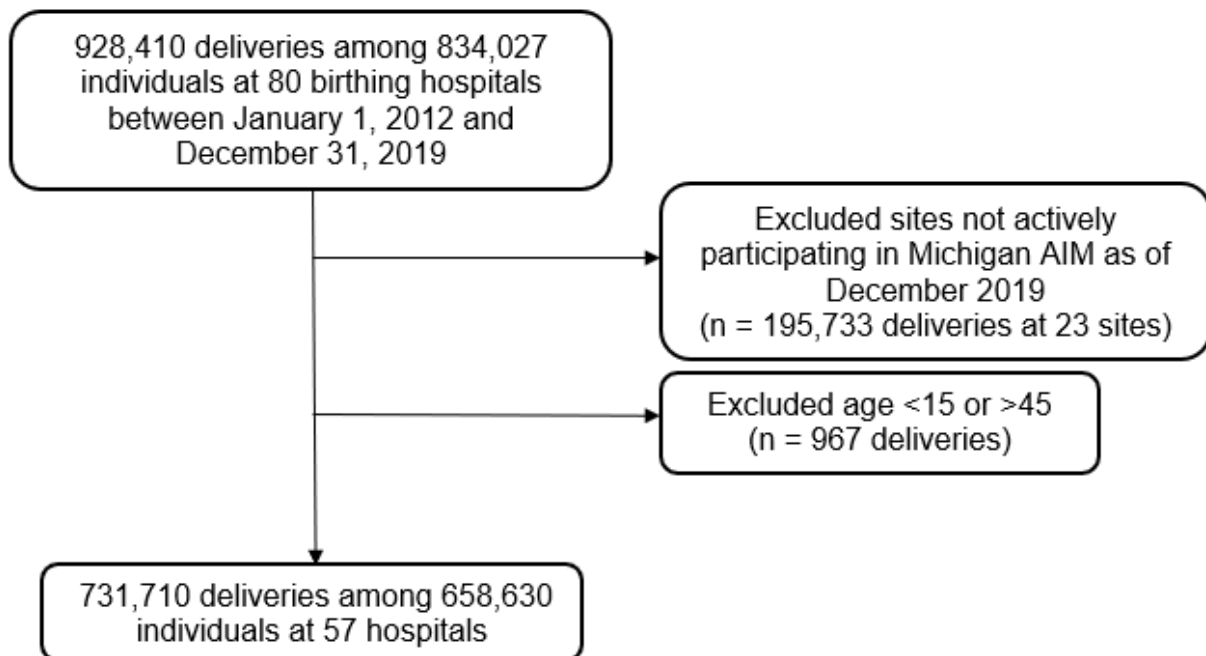
Delivery hospitalizations were identified by diagnosis codes for an outcome of delivery, diagnosis-related group delivery codes, and procedure codes for selected delivery-related procedures.<sup>156</sup> The MI-AIM initiative began in January 2016, collecting hospital participation and implementation progress with a quarterly survey. To account for variation in implementation start dates, we chose July 2016 as our intervention date, creating a pre-implementation period (January 2012 to June 2016), and post-implementation period (July 2016 to December 2019) for analysis.

Descriptive statistics summarized patient demographic and clinical characteristics and medical comorbidities. We used an interrupted time series framework to compare quarterly SMM incidence pre-implementation to post-implementation. The interrupted time series model was implemented using a multilevel model to account for the clustering of patients within each hospital. Predicted SMM levels and trends over time (slopes) were obtained for pre- and post-implementation time periods. A subgroup analysis was performed among patients with hemorrhage, as this group represents a more specific group targeted by this patient safety bundle. Next, we modeled 2019 SMM incidence with a multivariable multilevel model to better understand patient and hospital specific variation in SMM incidence and its predictors. This multilevel model accounted for patient clustering within each hospital with the inclusion of hospital specific random effects. Predictors included patient age, race (non-Hispanic white, non-Hispanic black, Hispanic, Other non-Hispanic), insurance status (Private, Medicaid, Self-Pay/Other), gestational age at delivery, delivery method (spontaneous vaginal, assisted vaginal, or Cesarean), and hospital size (<500, 500-999, 1000-1999, ≥2000 births). This model was then used to rank hospitals based on adjusted SMM incidence. The Intraclass Correlation Coefficient (ICC) was used to estimate the homogeneity of SMM at the hospital level, defined as the variance in SMM (at the patient level) between hospitals divided between the total variance (the sum of

the “between” and the “within” variance). A 95% confidence level was used for all analyses. All data management was performed using SAS version 9.4 (SAS Institute Inc., Cary, N.C.), and analyses performed with Stata (2015, Stata Statistical Software, release 14.1; Stata Corp LP, College Station, TX). This study was approved by the University of Michigan Institutional Review Board (HUM00191708).

## Results

Our final analytic sample consisted of 731,710 deliveries among 658,630 individuals at 57 hospitals. See Figure 9 for construction of the analytic sample.



**Figure 9.** Construction of Analytic Sample

Table 3 describes the demographic and clinical characteristics of this sample over time. The number of births in our sample increased annually from 88,469 to 89,486 between 2012 and 2019. Patients had a median age of 28.0 years (23.0, 32.0), were predominantly non-Hispanic White (70.9%, 95% CI: 70.8-71.0), had completed high school or General Educational Development test (24.8%, 95% CI: 24.7-24.9), and had



private insurance (55.9%, 95% CI: 55.8-56.0). Trends in demographic characteristics (age, body mass index) and risk factors for SMM (history of gestational diabetes, chronic hypertension, prior preterm birth, prior Cesarean delivery, and prolonged labor) increased during the study period. Hospitals were predominantly urban (34/57, 59.7%, 95% CI: 46.9-72.4) and had less than 1000 births (36/57, 63.2%, 95% CI: 50.6-75.7) (Hospital data not shown).

Characteristic <sup>a</sup>	2012 (n=88,469)	2013 (n=88,521)	2014 (n=90,072)	2015 (n=88,834)	2016 (n=96,736)	2017 (n=95,851)	2018 (n=93,741)	2019 (n=89,486)
<b>Demographic</b>								
Age, years <sup>a</sup>	28.0 (23.0, 32.0)	28.0 (23.0, 32.0)	28.0 (24.0, 32.0)	28.0 (24.0, 32.0)	28.0 (24.0, 32.0)	28.0 (24.0, 32.0)	29.0 (25.0, 32.0)	29.0 (25.0, 33.0)
Race/ethnicity								
Non-Hispanic White	59,495 (71.9)	58,253 (71.3)	59,417 (71.8)	58,522 (71.5)	62,770 (71.1)	62,196 (70.3)	59,396 (69.7)	56,571 (69.8)
Non-Hispanic Black	12,274 (14.8)	12,500 (15.3)	12,286 (14.8)	12,178 (14.9)	13,131 (14.9)	13,705 (15.5)	13,772 (16.2)	12,752 (15.7)
Hispanic	6,026 (7.3)	5,765 (7.1)	5,914 (7.1)	5,930 (7.3)	6,511 (7.4)	6,608 (7.5)	6,275 (7.4)	6,138 (7.6)
Other Non-Hispanic	5,008 (6.1)	5,170 (6.3)	5,190 (6.3)	5,193 (6.4)	5,901 (6.7)	5,956 (6.7)	5,821 (6.8)	5,554 (6.9)
Body mass index, kg/m <sup>2</sup>	25.2 (22.0, 30.3)	25.4 (22.1, 30.4)	25.6 (22.1, 30.8)	25.7 (22.3, 31.0)	25.8 (22.3, 31.1)	25.9 (22.4, 31.3)	26.3 (22.5, 31.6)	26.4 (22.7, 31.8)
Education								
Less than high school	11,312 (12.8)	11,182 (12.7)	10,438 (11.6)	10,063 (11.4)	10,743 (11.2)	10,654 (11.2)	9,860 (10.6)	8,950 (10.1)
High school graduate or GED	22,323 (25.3)	21,425 (24.3)	22,189 (24.7)	21,363 (24.2)	23,691 (24.7)	23,706 (25.0)	22,993 (24.8)	22,504 (25.4)
Some college, no degree	22,786 (25.9)	23,035 (26.1)	22,078 (24.6)	21,826 (24.7)	22,775 (23.8)	22,076 (23.2)	21,391 (23.0)	19,499 (22.0)
Associate degree	6,942 (7.9)	7,306 (8.3)	7,755 (8.7)	7,747 (8.8)	8,656 (9.0)	8,232 (8.7)	8,023 (8.6)	7,618 (8.6)
Bachelors degree	15,768 (17.9)	16,136 (18.3)	17,348 (19.3)	17,540 (19.9)	19,223 (20.0)	19,547 (20.6)	19,740 (21.2)	19,126 (21.6)
Masters degree or higher	9,008 (10.2)	9,084 (10.3)	9,870 (11.0)	9,684 (11.0)	10,819 (11.3)	10,785 (11.4)	10,909 (11.7)	10,922 (12.3)
Source of payment								
Private Insurance	47,151 (53.4)	47,340 (53.6)	48,825 (54.3)	49,920 (56.3)	54,352 (56.3)	54,382 (56.9)	54,963 (58.4)	51,717 (57.9)
Medicaid	40,030 (45.4)	40,016 (45.3)	39,900 (44.4)	37,703 (42.5)	40,910 (42.4)	40,259 (42.1)	37,933 (40.5)	36,414 (40.8)
Self Pay/Other	1,097 (1.2)	988 (1.1)	1,157 (1.3)	1,057 (1.2)	1,267 (1.3)	999 (1.0)	986 (1.1)	1,166 (1.3)
<b>Pregnancy</b>								
Any prenatal care	85,333 (98.9)	85,310 (98.6)	87,222 (98.9)	85,718 (98.8)	93,569 (98.6)	92,104 (98.3)	90,845 (98.7)	86,820 (98.5)
Prenatal visit in the first trimester	67,077 (77.8)	66,094 (76.4)	66,876 (75.8)	66,179 (76.3)	72,596 (76.5)	72,599 (77.5)	70,171 (76.2)	67,603 (76.7)
Prenatal visits, number <sup>b</sup>	12.0 (10.0, 14.0)	12.0 (10.0, 14.0)	12.0 (10.0, 14.0)	12.0 (10.0, 15.0)	12.0 (10.0, 15.0)	12.0 (10.0, 15.0)	12.0 (10.0, 15.0)	13.0 (10.0, 15.0)
Number of gestations								
Single	85,080 (96.2)	85,078 (96.1)	86,629 (96.2)	85,313 (96.0)	92,648 (95.8)	91,700 (95.7)	90,006 (96.0)	85,839 (95.9)
Twin	3,235 (3.7)	3,282 (3.7)	3,328 (3.7)	3,380 (3.8)	3,938 (4.1)	3,995 (4.2)	3,630 (3.9)	3,559 (4.0)
Triplets or more	154 (0.2)	161 (0.2)	115 (0.1)	141 (0.2)	149 (0.2)	156 (0.2)	105 (0.1)	87 (0.1)
Gestational age at delivery, weeks <sup>c</sup>	39.0 (38.0, 40.0)	39.0 (38.0, 40.0)	39.0 (38.0, 40.0)	39.0 (38.0, 40.0)	39.0 (38.0, 40.0)	39.0 (38.0, 40.0)	39.0 (38.0, 40.0)	39.0 (38.0, 40.0)
Delivery method								
Spontaneous vaginal	55,335 (62.6)	55,644 (62.9)	56,770 (63.0)	56,999 (64.2)	62,451 (64.6)	62,117 (64.8)	60,296 (64.3)	57,224 (64.0)
Assisted vaginal	2,773 (3.1)	2,567 (2.9)	2,662 (3.0)	2,458 (2.8)	2,643 (2.7)	2,643 (2.8)	2,650 (2.8)	2,576 (2.9)
Cesarean	30,349 (34.3)	30,296 (34.0)	30,625 (34.0)	29,361 (33.1)	31,631 (32.7)	31,066 (32.4)	30,781 (32.8)	29,679 (33.2)
Obstetric hemorrhage	4,958 (5.6)	4,808 (5.4)	5,093 (5.7)	3,737 (5.6)	5,869 (6.1)	6,341 (6.6)	6,395 (6.8)	6,996 (7.8)
<b>Risk Factors</b>								
Tobacco use during pregnancy	20,067 (22.8)	20,380 (23.1)	18,904 (21.0)	17,829 (20.2)	18,624 (19.4)	17,906 (18.7)	16,778 (18.0)	14,933 (16.8)
Alcohol use during pregnancy	495 (0.6)	883 (1.0)	696 (0.8)	623 (0.7)	911 (1.1)	1,085 (1.1)	1,691 (1.8)	1,676 (1.9)
Gestational diabetes	5,690 (6.5)	5,083 (5.8)	5,086 (5.7)	5,160 (5.8)	5,648 (5.9)	6,056 (6.3)	6,247 (6.7)	6,004 (6.7)
Chronic hypertension	4,865 (5.5)	5,001 (5.7)	5,235 (5.8)	5,944 (7.3)	7,049 (7.3)	7,706 (8.1)	8,420 (9.0)	8,975 (10.1)
Prior preterm birth	2,824 (3.2)	3,136 (3.6)	3,496 (3.9)	3,534 (4.0)	3,697 (3.8)	3,827 (4.0)	4,132 (4.4)	3,964 (4.4)
Prior Cesarean delivery	12,362 (14.0)	12,800 (14.5)	13,409 (14.9)	13,633 (15.4)	14,576 (15.1)	14,412 (15.1)	14,403 (15.4)	13,929 (15.6)
Prolonged labor (≥ 20 hours)	1,590 (1.8)	1,451 (1.6)	1,397 (1.6)	1,524 (1.7)	1,527 (1.6)	1,938 (2.0)	2,301 (2.5)	2,153 (2.4)
Length of stay, days <sup>b</sup>	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)

<sup>a</sup> Data are presented as n (percentage) unless otherwise specified.

<sup>b</sup> Data are presented as median (interquartile range)

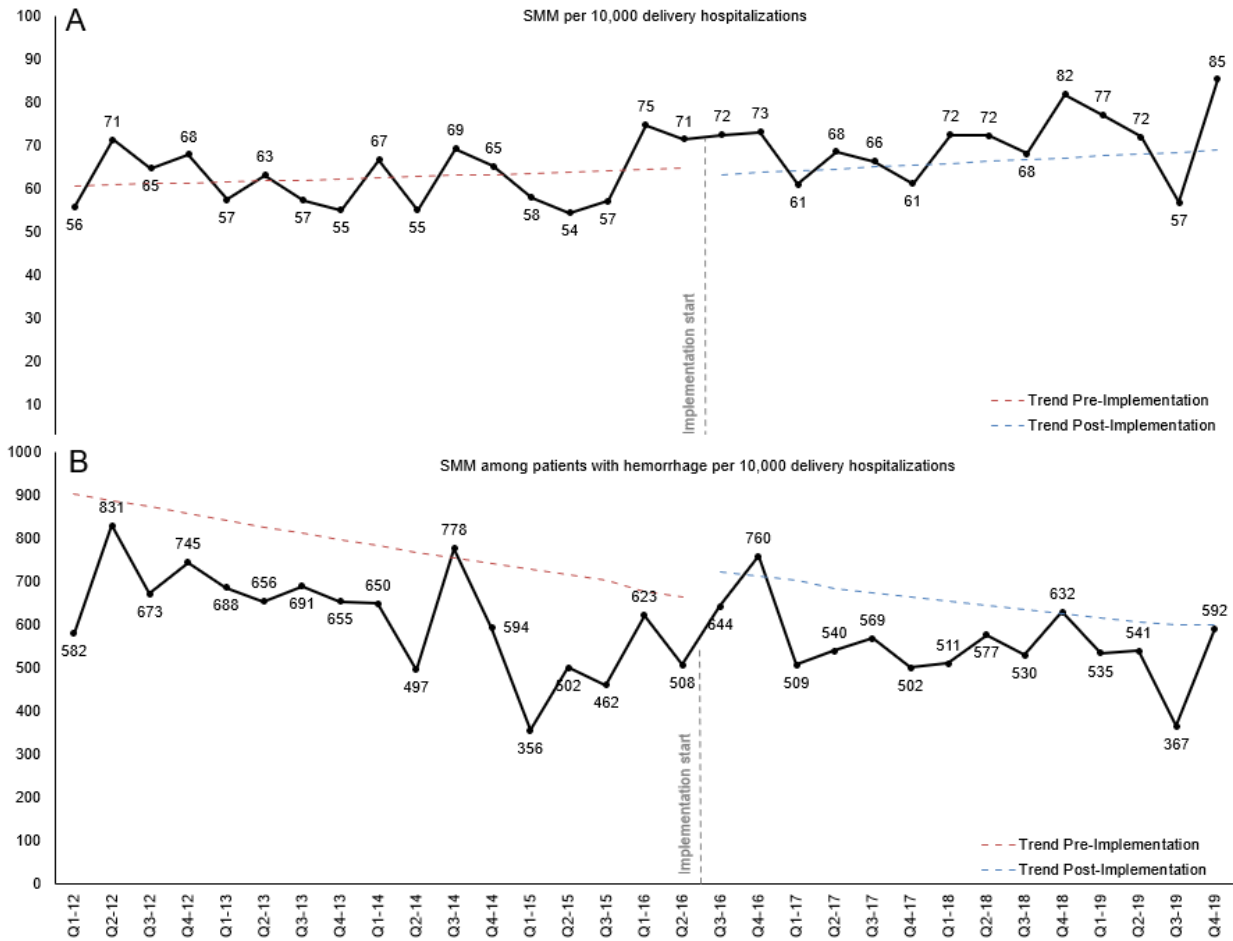
GED: General Educational Development

**Table 3.** Demographic, Obstetric, and Hospital Characteristics for 57 Hospitals by Year

Overall, the rate of SMM was 65 (95% CI: 60-71) per 10,000 deliveries in 2012 and 72 (95% CI: 67-78) per 10,000 in 2019 (p=0.07). We failed to detect meaningful deviations in overall SMM before and after the implementation of the obstetric

hemorrhage patient safety bundles. Incidence of SMM was statistically flat in both the pre-implementation period (estimated slope = 0.0000205,  $p=0.39$ ) and the post-implementation period (estimated slope = 0.0000362,  $p=0.22$ ) and these trends did not differ between periods ( $p=0.68$ ). (Figure 10A)

Subgroup analysis was performed among 36,588 patients with obstetric hemorrhage at 25 hospitals during the study period. This analysis demonstrated a decrease in SMM incidence from 2012 to 2019 from 708 (95% CI: 627-796) to 505 (95% CI: 449-565) per 10,000,  $p<0.001$ ). The SMM incidence trend among patients with hemorrhage was decreasing in the pre-implementation period (slope = -0.0012059,  $p=0.001$ ) and statistically flat in the post-implementation period (slope = -0.001052,  $p=0.11$ ). Despite declining rates of SMM among patients specifically targeted by implementation of this bundle, we failed to find statistical differences in rates before and after implementation ( $p=0.83$ ). (Figure 10B).



**Figure 10.** Rates of SMM by Quarter and Estimated Slopes, 2012-2019

Results from a multivariable multilevel model for SMM in 2019 are shown in Table 4. Parent age, race/ethnicity, source of payment, gestational age at delivery, delivery method, chronic hypertension, and hospital size were all associated with SMM. Non-Hispanic Black and Hispanic patients had significantly higher odds of a SMM event compared to Non-Hispanic White patients (OR, 1.30; CI, 1.03, 1.64, and OR, 1.37; CI, 1.01, 1.86), respectively. Patients using Medicaid (OR, 1.46; CI, 1.20, 1.77), delivering via assisted vaginal or Cesarean (OR, 2.31; CI, 1.33, 4.01, and OR, 3.96; CI, 3.26, 4.79, respectively), or diagnosed with chronic hypertension (OR, 2.26; CI, 1.84, 2.78) also had higher odds of a SMM. Decreased odds of a SMM event was associated with increasing gestational age (OR, 0.86; CI, 0.84, 0.87) and hospital size: mid-size hospitals (1000-1999 births) had a significantly lower SMM relative to large ( $\geq 2000$

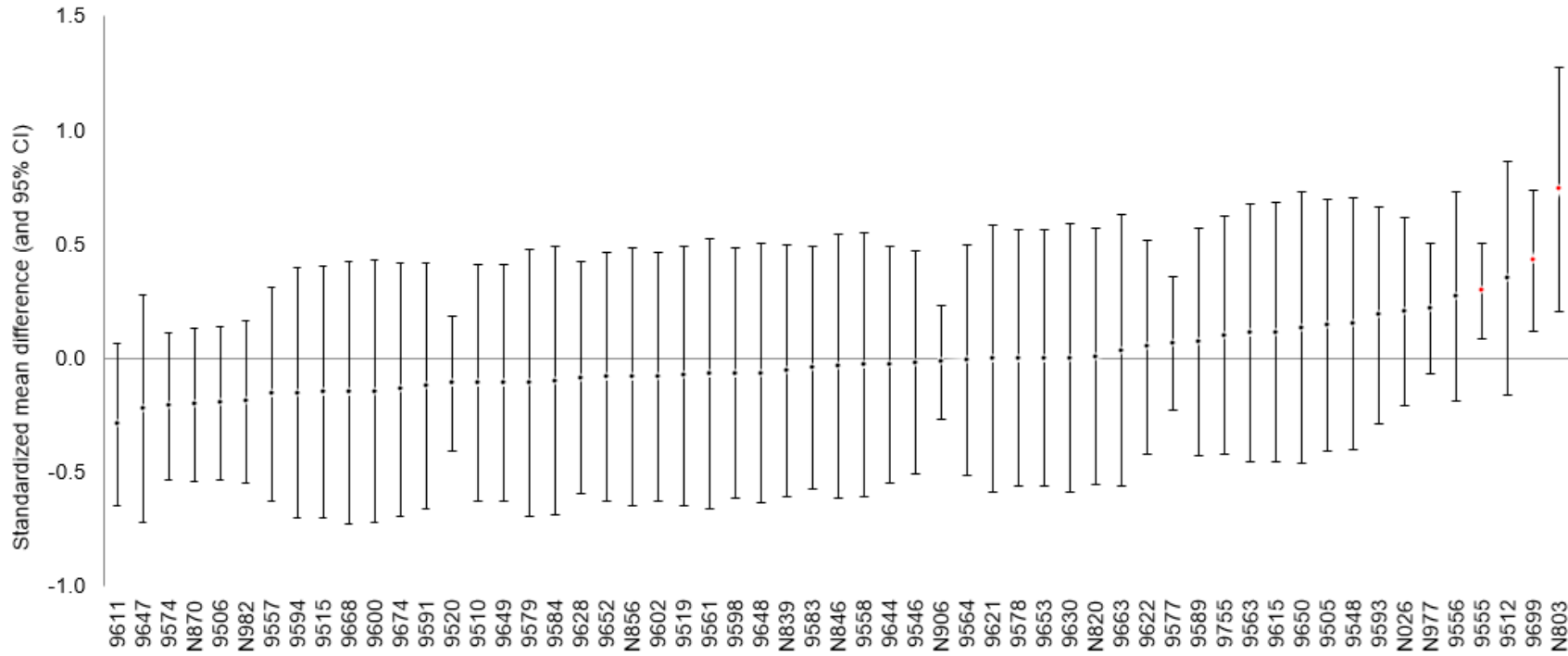
births) hospitals (OR, 0.58; CI, 0.38, 0.89). For the null model, only 6.2% (CI: 3.2-11.6) of the variation in SMM was due to hospital (ICC=0.062).

**Table 4.** Multivariable Multilevel Model for the Probability of SMM, 2019

Variable	Odds Ratio	95% Confidence Interval	p-value
Time, quarter	1.02	(0.94, 1.10)	0.69
Age, years	1.03	(1.02, 1.05)	<.0001
Race/ethnicity			
Non-Hispanic White	Reference	Reference	
Non-Hispanic Black	1.30	(1.03, 1.64)	0.03
Hispanic	1.37	(1.01, 1.86)	0.05
Other Non-Hispanic	0.99	(0.69, 1.42)	0.97
Source of payment			
Private Insurance	Reference	Reference	
Medicaid	1.46	(1.20, 1.77)	<.0001
Self Pay/Other	1.60	(0.78, 3.27)	0.20
Gestational age at delivery, weeks	0.86	(0.84, 0.87)	<.0001
Delivery method			
Spontaneous vaginal	Reference	Reference	
Assisted vaginal	2.31	(1.33, 4.01)	0.003
Cesarean	3.96	(3.26, 4.80)	<.0001
Chronic hypertension	2.26	(1.84, 2.78)	<.0001
Hospital bedsize			
<500	0.69	(0.44, 1.10)	0.12
500-999	0.94	(0.65, 1.35)	0.73
1000-1999	0.58	(0.38, 0.89)	0.01
≥2000	Reference	Reference	

After adjusting for patient- and hospital-level factors, the adjusted mean rate of SMM was 73 (95% CI: 62-85) per 10,000 delivery hospitalizations. Adjusted hospital-specific random effects are displayed in Figure 11.

**Figure 11.** Caterpillar Plot of Hospital Effects on SMM, 2019



NOTE: The 57 hospitals implementing the AIM obstetric hemorrhage patient safety bundles are ranked from left (lowest) to right (highest) deviation from the overall mean SMM rate. The error bars demonstrate the 95% confidence interval. Red color indicates significant deviation from the mean rate of SMM.

Hospitals were ranked according to their adjusted SMM incidence which allowed for the identification of outlier hospitals. Overall, few hospitals were substantively better or worse than the average hospital, shown by hospitals at each end of the figure whose outcomes were consistently and reliably better (left) or worse (right) than average. There were three hospitals with adjusted SMM incidence substantively higher than the mean, but no hospitals with meaningfully lower than average adjusted incidence.

## Discussion

In this retrospective study of births occurring at Michigan hospitals participating in the implementation of the Alliance for Innovation on Maternal Health's obstetric hemorrhage bundle, patients with hemorrhage – specifically targeted by this intervention – showed declining rates of SMM in both the pre- and post-implementation periods. Parent age, race/ethnicity, source of payment, gestational age at delivery, delivery method, chronic hypertension, and hospital size demonstrated an association with SMM. Variation in SMM across sites was observed, but not attributable to hospital factors, suggesting opportunities for tailoring of initiatives for further improvement in health outcomes. These findings reflect evidence of the impact of bundle implementation at the state level.

This study aligns with the findings of the California Maternal Quality Care Collaborative implementation of their obstetric hemorrhage bundle. Bundle implementation was initiated within 29 different delivery units varying in size from <200 to >6,000 births annually, accounting for more than 60,000 births. Main outcomes were total number of units of blood transfused and number of peripartum hysterectomies. From baseline to 10-month post implementation, use of blood products was reduced from 35.9 to 26.6 units per 1,000 deliveries.<sup>157</sup> The present study extends this work by presenting results stratified by hospital characteristics to determine differences attributable to practices at individual sites. More recently, Srinivas et al presented analysis after six months of implementation of a hemorrhage bundle at a single, large academic institution, demonstrating nonsignificant trends toward increased rates of postpartum hemorrhage and blood transfusion.<sup>158</sup> Our analysis provides both pre- and

post-implementation data over an eight-year period, and suggests that significant changes in a rare outcome such as SMM may require a significantly longer investment of time and resources.

Effective July 1, 2020, the Joint Commission will require hospitals to have evidence-based practice elements like the Alliance for Innovation on Maternal Health's obstetric hemorrhage bundle, aimed at improving hemorrhage-related maternal morbidity and mortality.<sup>159</sup> However, despite significant hemorrhage prevention awareness and resources, this analysis failed to find statistical differences in SMM trends before and after bundle implementation. While there may be a positive effect in quality of care, these findings suggest that implementation may be happening too slowly, or non-uniformly across hospitals to account for increasing risk factors among persons of reproductive age leading to SMM. Increases in SMM are driven by a combination of factors, including increases in parent age<sup>160</sup>, pre-pregnancy obesity<sup>161,162</sup>, and preexisting chronic medical conditions<sup>163,164</sup> – trends we also observed in this analysis. However, we observed that changes in the underlying health of the obstetrical population did not explain the sudden change in SMM among patients with hemorrhage, which suggests that targeting some of the most preventable risk factors of SMM with bundles may be an effective strategy.

Moving forward, it remains unclear what “successful” implementation means in this context. Bundles provide a structured way of improving care processes and include a set of evidence-based practices that, when performed together, consistently, correctly, and reliably, contribute to improved patient outcomes. However, it is common practice for hospitals to tailor implementation of bundle elements to meet personnel, logistical, and financial needs at their site. The extent to which tailoring is performed, under what circumstances, and the impact that it may have on the effectiveness of the bundle or corresponding elements has not been assessed or measured.

There were several strengths to this analysis. We followed rigorous procedures per the Centers for Disease Control and Prevention and Health Resources and Services Administration and used a robust set of diagnosis and procedure codes to ascertain delivery hospitalizations, SMM, and obstetric hemorrhage subgroups. The Michigan Department of Health and Human Service's resident Inpatient Database and linked Birth

Certificate files are a high-quality and comprehensive database that includes all-payer, administrative data that is used in patient safety and quality initiatives and informs legislative policies on utilization.<sup>165–167</sup> As of 2019, Michigan was ranked 30<sup>th</sup> in the nation, with 27.6 maternal deaths per 10,000 live births.<sup>168</sup> Although this rate is not extreme compared to other states, Michigan’s unique geography, changing patient demographics, and struggling economy make it a unique reference point to compare with other states, and reflect the opportunity to significantly improve its statistics. Finally, our use of an interrupted time series framework using a multilevel model allows for comparison of quarterly SMM incidence pre-implementation to post-implementation while accounting for the clustering of patients within each hospital. To date, this is the first attempt at evaluating outcomes surrounding the Alliance for Innovation on Maternal Health’s obstetric hemorrhage bundle at the state level, based on our literature search on PubMed and Cochrane Library.

There are a few limitations to note. First, elements of the obstetric hemorrhage bundle such as establishing a hemorrhage cart, unit education and drills, quantitative blood loss initiatives, and hemorrhage risk assessments were sometimes implemented simultaneously, or in various order depending on the hospital. These aspects of implementation were not measured precisely, and thus we were not able to assess the impact of any particular element or to assume consistency in implementation across hospitals. Second, although the obstetric hemorrhage bundle was the first to be implemented at many hospitals, there may be overlap in implementation of the severe hypertension bundle, for example, that we were unable to account for in statistical analyses. Third, we expressed rates of SMM without transfusion, rather than SMM with transfusion as has been reported in many previous studies. This outcome was selected based on the latest recommendations from the Health Resources and Services Administration, which provide detailed notes and code to enable states to make comparisons to national and other state data.<sup>169</sup> Fourth, while using state-level inpatient data offers the opportunity to examine changes in large populations, it has inherent weaknesses. Variation in coding and documentation may play a role in the variation in SMM we observed. Further, the interrupted time series models that were used for



significance testing did control for dependence due to patients receiving care within the same site, but we did not control for patients seeking care across multiple hospitals.

## **Conclusion**

Quality improvement efforts to reduce maternal morbidity and mortality are essential and patient safety bundles are viewed as reasonable actions to implement. However, hospitals still struggle to operationalize these elements making the long-term impact of these initiatives on patients less clear. After participating in bundle implementation across 57 Michigan hospitals, patients with hemorrhage – specifically targeted by this intervention – showed declining rates of SMM in both the pre- and post-implementation periods. Limited variation in SMM attributable to hospital suggests that patient safety bundles are only one tool to address a complex issue. Future studies will need to assess the aspects of implementation that are more difficult to measure, such as personal or professional barriers and facilitators to bundle implementation efforts.

## CHAPTER FOUR

### **Factors Influencing Implementation of an Obstetric Hemorrhage Patient Safety Bundle: A Qualitative Analysis of Healthcare Providers' Experiences in Michigan**

#### **Abstract**

**Objective:** To characterize stakeholder experiences implementing a nationally endorsed obstetric hemorrhage patient safety bundle in Michigan hospitals.

**Methods:** Using key informant interviews, we developed an interview guide informed by the TICD. We conducted in-depth semi-structured interviews with data collected through audio transcripts. Two independent coders performed a content analysis using a priori codes from the theoretical framework but open to inductive codes that arose from the data. Thematic analysis was then completed and synthesized into an explanatory model.

**Results:** We conducted a total of 19 interviews with 22 implementation stakeholders including nurses, physicians, and quality improvement staff that represent responsibilities across 30 hospitals. Key themes included: 1) Altruism: participants are motivated to implement safety bundles to improve their patients' health and save lives; 2) Perceived impact despite limited data: participants cited strong evidence-base for implementation work despite limited information on improvement at their own institutions; 3) Teamwork: team trust, respect, and psychological safety are critical factors that impact success of bundle implementation; 4) Competing priorities: competing priorities at the individual and institutional level are significant barriers to change; and 5) Limited champions: bundle implementation work falls on the shoulders of a few, limiting sustainability. An explanatory figure was developed to represent the relationships between themes and their influence on implementation.

**Conclusion:** This explanatory model synthesizes factors that influence implementation of a nationally endorsed obstetric hemorrhage bundle. Participants were strongly supportive of quality improvement initiatives. However, cultural and motivational barriers prevented the full integration of all care practices, suggesting that strategies addressing attitudes and behaviors at the individual, team, and institutional level prior to implementation may improve effectiveness.

## Introduction

Collections of evidence-based practices, called patient safety bundles, are now critical tools in the prevention of maternal mortality and morbidity in the United States. A 'bundle' is a structured way of improving the processes of care and includes a set of evidence-based strategies or practices that, when performed correctly and reliably, contribute to improved patient outcomes.<sup>170</sup> Importantly, the bundle creation process does not develop new guidelines, but rather packages existing guidelines and tools in ways for them to be consistently and universally implemented. In 2015, the Alliance for Innovation on Maternal Health – a national data-driven maternal safety and quality improvement initiative, presented some of the most widely-implemented set of clinical strategies in the form of bundles to standardize obstetric care to achieve reductions in maternal mortality and morbidity.<sup>88</sup>

Beginning in 2016, 80 hospitals in Michigan were encouraged to initiate the Alliance for Innovation on Maternal Health's obstetric hemorrhage bundle ("the bundle"), which focuses on the leading and most preventable cause of maternal mortality and morbidity. However, despite promising evidence, adoption of the bundles within health systems remains challenging. While prior research demonstrates that the implementation of safety checklists and protocols for the management of certain high-risk surgical or obstetric clinical situations is effective in improving outcomes, little is known about the optimal context, resources, and processes responsible for reliable and successful implementation of a bundle.<sup>95–101</sup> To understand the challenges of implementation, we conducted a qualitative study using a theory-informed framework to

explore healthcare provider experiences implementing a nationally-endorsed obstetric hemorrhage patient safety bundle in Michigan hospitals.

## **Methods**

We performed a qualitative study using semi-structured interviews, to identify factors that function as barriers and/or facilitators to the implementation of the obstetric hemorrhage bundle in Michigan. Interviews were conducted with healthcare providers and staff with direct implementation experience at their site(s), including nurses, physicians, and quality improvement staff. Participants were recruited from the MI-AIM operations committee meetings. This study was determined exempt by the University of Michigan Institutional Review Board (HUM00202266). All participants were provided a written informed consent document, and all interviewees provided verbal consent to participate.

The TICD was used to guide qualitative data collection and analysis. This framework was developed as a comprehensive, integrated checklist of determinants of implementation success, consolidating across 12 different reviews of implementation determinants.<sup>126</sup> By integrating elements from other commonly used frameworks, the TICD aims to be an easily used checklist to identify determinants of practice for implementation strategy development and program evaluation.<sup>113,128</sup> As is recommended, the framework's exhaustive checklist of seven domains and 57 associated determinants of practice were reviewed.

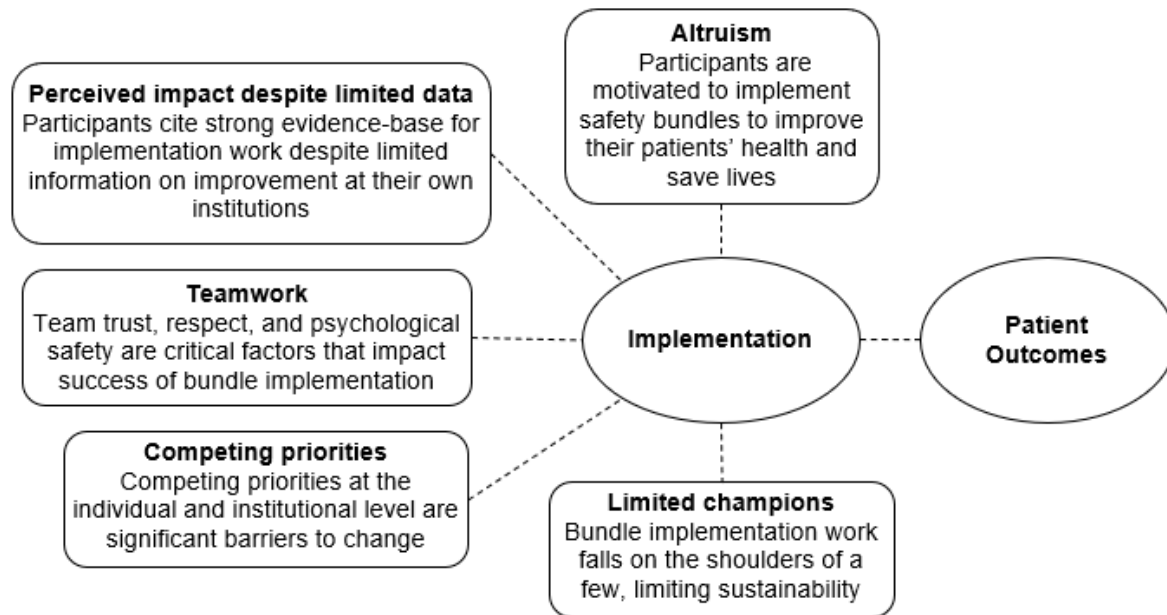
The lead author conducted semi-structured interviews with participants from November 2021 – March 2022. An interview guide with open-ended questions was used to elicit participants' experiences, attitudes, and perceptions of bundle implementation in their role(s) or hospital(s). Interviews began with an introduction and rapport building question and then proceeded into the TICD domains, with additional probes regarding barriers and facilitators of implementation. (File 13 at end of Chapter). Interviews were audio recorded via Zoom, and professionally transcribed. We used MAXQDA (version 20.4.1)<sup>137</sup> to analyze interview data using content analysis approach.<sup>171</sup> A qualitative team (EKK, LAM) reviewed transcripts independently and coded the content of each

transcript using the previously developed theory-generated template. An inductive approach using open, in vivo coding was also used to identify factors outside of this framework. After independently coding the initial transcripts, coding differences were resolved through discussion. This process was repeated until we developed a consensus coding strategy.<sup>138</sup> Themes and patterns were identified and synthesized as well as new themes as they emerged. Higher order analyses of codes and themes were performed via review and discussion with three qualitative experts (JPW, LKL, CAM).<sup>172</sup> Patterns of barriers and facilitators by role and across sites were analyzed to identify similarities, differences, and trends in how stakeholders described their implementation experiences. We continued sampling and analysis until we reached theoretical saturation of implementation experiences.<sup>138</sup>

## **Results**

The mean interview duration was 55 minutes (SD 10) and ranged between 43-82 minutes. Thematic saturation was reached after 19 interviews with 22 participant stakeholders (nursing leadership, which includes quality improvement leadership [14], Obstetrician-Gynecologist physicians [6] and quality improvement staff [2]) with responsibilities across 30 hospitals.

Data were organized into five interrelated themes: 1) Altruism: participants are altruistically motivated to implement safety bundles to improve their patients' health and save lives; 2) Perceived impact despite limited data: participants cited strong evidence-base for implementation work despite limited information on improvement at their own institutions; 3) Teamwork: team trust, respect, and psychological safety are critical factors that impact success of bundle implementation; 4) Competing priorities: competing priorities at the individual and institutional level are significant barriers to change; and 5) Limited champions: bundle implementation work falls on the shoulders of a few, limiting sustainability. These themes informed the development of an explanatory figure representing the relationships of factors influencing implementation success (Figure 12).



**Figure 12.** Explanatory Figure of Factors Influencing Bundle Implementation Among Healthcare Providers

This model demonstrates how aspects of the bundle itself, individual healthcare provider, healthcare team, and institutional-level factors function as barriers and facilitators of bundle implementation affect patient and process outcomes. In this model, factors can both support or detract from implementation efforts to varying degrees, but ultimately must align to improve outcomes and foster sustainability of these initiatives. Each theme is described below, supported by participant-generated quotations.

## Key Themes

**Theme 1: Altruism.** Participants are motivated to implement safety bundles to improve their patients' health and save lives, reporting strong ethical reasons for engaging in implementation work. Emergency situations resulting in maternal or neonatal death, occasionally motivated participants' engagement, and desire to see improvement in patient outcomes.

General impressions of bundle implementation were positive, with participants indicating strong support for the implementation work happening at hospitals across the state. When asked to reflect on first learning of the bundle, stories of sentinel events were often described as motivators for adopting the initiative more seriously. A participant reflected on the impact that adverse clinical events can have on staff:

*We did not want patients to suffer, or staff to have to go through that experience again. To lose an OB patient is phenomenally difficult on your staff... Even once in a career, it's hard to maintain staff. So the motivation was there in the beginning, to save lives...*

[NURSE]

Given these difficult experiences, participants voiced hope and anticipation that bundle implementation would have a large impact on patient outcomes. A participant summarized this theme, saying:

*We're doing this because we're saving lives by doing this. This is shown that we're saving lives and the nation in all hospitals are taking this into perspective, because we want to do better for our patients.*

[NURSE]

**Theme 2: Perceived impact despite limited data.** Participants reported early adoption of implementation work, however information on improvement at their own institutions remains limited. The high degree of effort to acquire “real-time” or recent institutional data from the electronic health record was a major barrier to understanding the impact of implementation on patient outcomes.

Many participants expressed long-standing engagement and participation with bundle implementation activities in their role or at their site(s), enabling broad retrospection of these activities. Participants reflected that most bundle elements were feasible to implement after addressing certain barriers – but often underestimated the significant

challenges these barriers can present. One participant characterized this feeling, saying:

*Yeah, I think it was very feasible. Again, once the buy-in was there and once allocation of resources and education was given, then it became feasible.*

[CLINICIAN]

Participants were unsure or unable to provide evidence that implementation has improved outcomes at their institutions - often unaware of how or where information regarding patient or process outcomes related to implementation could be determined. Others cited high amount of effort to acquire “real-time” or recent institutional data from the electronic health record as a major barrier to understanding the impact of implementation. Most participants reported regularly auditing charts by hand, which requires extra time and effort, and slows the speed of critical information dissemination. Said one participant,

*I think we collectively all share the same concerns and the same roadblocks and difficulties, but I will say that the biggest difference that varies from organization to organization is your use of EMR and your ability to run reports without being specific to any program.*

[NURSE]

**Theme 3: Teamwork.** Participants felt that a culture of mutual trust, respect, and the ability to ask questions without fear of repercussions was both critical for, and a byproduct of implementation success.

There were many examples of negative interactions between healthcare providers reported by participants, reflecting poor unit culture and often characterized as a significant barrier to implementation. One participant reflecting on their hospital culture said,



*So we have a really significant culture problem on the unit. It's between providers and nurses. We've tried to define a lot of the reasons for it, and certainly they are many, but what's going on is that we work totally in silos. And it has an effect on implementing, on getting across the here's why we want to do this. And we spend a lot of time trying to overcome those barriers when it comes to the implementation. But just the convincing someone of the reason for needing change is just more challenging than I've seen it anywhere.*

[CLINICIAN]

Cultural issues were often manifested as a lack of psychological safety - participants believed they would be punished or humiliated for speaking up with thoughts, concerns, or feedback on implementation procedures. Breakdowns in culture and communication also had consequences for patients. One participant reflected,

*Unfortunately, there were a lot of examples where physicians couldn't agree on transfusion and treatment and morbidity. Some morbidity occurred that didn't need to. Some ICU admissions occurred that didn't need to. Women's lives were impacted when they maybe didn't need to.*

[CLINICIAN]

Several observed that structural racism and sexism in hospitals continues to perpetuate maternal health inequities. A clinician suggested implementation of another Alliance for Innovation on Maternal Health bundle – the diversity, equity, and inclusion bundle, as a strategy:

*And I think the DEI bundle, that bundle, it just has branches that would cross all of the bundles because there's so much structural like, misogyny, racism in everything that we do in every initiative... I'm in the hospital almost every day, just when people talk, it's just everywhere.*

[CLINICIAN]

Bundle implementation both brought to light existing cultural issues and was an opportunity to improve culture – sometimes at the same hospitals. Participants noticed that implementation may have a positive impact on more than just patients

*So, I think all of these things, although they're time consuming in their additional work per se, they do have nonclinical benefits of changing a unit culture and making nurses and people, staff to empowered to speak up, in fostering those nurse-physician relationships.*

[NURSE]

**Theme 4: Competing priorities.** Implementation champions reported volunteering their time to build the program for years, however, reliance on volunteers may not be effective long term. Changes in priorities of bundle implementation were reported often due to limited capacity, time, and COVID-19 pressures.

Lack of funding and the reliance on volunteer effort was frequently mentioned as a barrier and limitation to sustainability. Most participants either carved out time in their role or volunteer in addition to their regular work responsibilities. Many felt this approach was forcing a difficult choice between “doing the right thing” and demonstrating value through financial incentives. Others felt that lack of funding would significantly affect continued recruitment of hospitals to participate in bundle implementation, and the sustainability of existing initiatives. Said one,

*One of the issues with AIM is that as a collaborative, it's purely voluntary. There's no funding for it, and there's no actual reward for participation beyond kudos and doing the right thing. And that's been one of the challenges, for sure. Just getting administration to have any interest in it has been challenging.*

[CLINICIAN]

Reasoning for the AIM obstetric hemorrhage bundles receiving less attention and effort was often made in comparison to competing quality improvement initiatives, which were

pay-for-performance based. One participant characterized the link between incentives and participation saying,

*[OTHER QI INITIATIVE] has an incentive. It's a pay for performance, definitely. When there's pay for performance and there's a paycheck that's involved, everybody really listens.*

[NURSE]

Additionally, the COVID-19 pandemic put significant strain on the healthcare system, causing continued turnover and staff shortages. Participants had many examples of how staffing shortages affected engagement with implementation. Said one,

*They're [STAFF/CLINICIANS] going to the ER, they're all over. So it's really hard to keep them engaged in our department and in our initiatives when they're not here a lot. So that's a really big challenge right now.*

[NURSE]

Unfortunately, many participants were also not optimistic about how or when these staffing issues would be addressed moving forward. Competing priorities such as lack of funding and the strain due to COVID-19 were also linked to the bundles “falling off the radar” by many participants. The implementation portion of the bundle has been demonstrated to be a long-term project, and continued sustainability of these initiatives are a concern for many participants. Noted one,

*It's going to fall off radars. They're going to say, look, we had that baby down pat. We had that thing hardwired. We went onto this next initiative. We lost sight of our previous initiative. It's hard to keep all the balls juggling in the air at the same time... It's not going to go away... So it's got to stay on our radar.*

[NURSE]

**Theme 5: Limited champions.** Most of the work and leadership rests on a few champions, and to complicate matters more, staff shortages and turnover related to the COVID-19 pandemic threaten implementation success and sustainability. The transition from individual champions to team ownership of the initiative is a key factor to integration of the bundle in care practices.

Many participants indicated they were one of few individuals responsible for conducting and leading implementation work at their hospital or system. However, the presence of both a physician and nurse champion and their impact on the speed of implementation was affirmed by many. As one put it,

*So, some sites that don't have... that don't have people that are really interested and don't have those champions in both arenas, provider level and nursing level. It just goes slower."*

[NURSE]

Participants noted experience and institutional knowledge are held primarily within a small group of implementation champions. The reliance on a few individuals in addition to COVID-19 staff shortages points to a significant workforce capacity issue and an organizational approach that may threaten the sustainability of these initiatives.

However, participants were aware of these issues and had similar strategies for the future. Overall, there was a desire to transition to a stage where the bundle was more integrated into care: implementation champions introduced the bundles, cultivated engagement, and initiated processes, but some felt their teams had reached a critical point where implementation would be more successful when it was more fully "owned" by the team. Reflected one participant,

*I feel like we're continuing to transition. ...there's more ownership. There's more accountability on the providers. There's more accountability on the nurses and they want to be accountable. They don't complain about it... Because they want to*

*because they know it's important. It's like that importance piece finally triggered for them.*

[NURSE]

## Discussion

In this qualitative study of implementation stakeholders across bundle-implementing hospitals in Michigan, we developed an explanatory figure to represent the relationships of factors that influence participation and motivation in obstetric hemorrhage bundle implementation. This work advances implementation science research in several ways. First, we used the TICD to identify factors influencing bundle implementation experiences. This is one the first analyses to use the TICD for guiding data collection, analysis, and interpretation of bundle implementation experiences in the setting of labor and delivery. Second, we expanded upon the framework's domains and constructs to identify novel codes and themes important to understanding bundle implementation.

Much of the work in optimizing bundle implementation focuses on clinical processes and pathways, without taking into consideration the providers and systems within which they operate. Similar to findings from the literature, participants in this study described challenges to bundle implementation at the individual, team, and organizational levels, including time and resource constraints<sup>173–175</sup>, interprofessional team dynamics<sup>176,177</sup>, burden of workload<sup>178</sup>, limited personal motivation and incentives to encourage engagement and adherence<sup>175,176</sup>, and complexity of observing and measuring outcomes.<sup>178</sup> Many participants seemed proud when recounting their experiences addressing or overcoming these challenges as an individual and as a team. However, feelings of frustration and uncertainty regarding future implementation efforts were fueled by the pandemic, adding stress to an already complicated process, and undermining the sustainability of implementation. This study describes the primary factors influencing implementation processes and our explanatory figure specifically highlights both the independent effects and the intersectionality of these themes on implementation success. These findings suggest that when planning complex changes

in practice, implementation strategies that address both the individual and compound effect of potential barriers at the individual, organizational, and social levels will optimize implementation.

There were few study weaknesses. First, the findings should be understood within the context of the timing of the interviews (November 2021 to March 2022) given the continued pressure on healthcare providers due to the COVID-19 pandemic. It is possible that individuals who would otherwise participate in this type of study were not available. Second, consistent with the goals of qualitative purposeful sampling, participants and their affiliated hospitals may not be representative of all Michigan participants or hospitals, but rather reflect characteristics that may underlie variations in implementation.<sup>136</sup> Finally, we aimed to understand implementation experiences across a range of roles and hospitals, which limited our ability to probe differences between these factors. This study also had several strengths. We used rigorous qualitative methods in sampling, and data collection and analysis. The theoretical basis for this study increases the likelihood its findings can be clinically translated to effective strategies and interventions.

Overall, participants were strongly supportive of quality improvement initiatives; however, cultural, and motivational barriers prevented the full integration of these practices into care. Future research should seek to measure the relative importance of the factors influencing implementation across diverse sites, and better describe relationships between these factors. Better understanding of the individual and combined impact of these themes in predicting implementation success will be crucial to providing tailored implementation strategies to improve health outcomes.

**Figure 13.** Interview Guide for Healthcare Providers Participating in Implementation

**INTRODUCTION**

Thank you very much for agreeing to speak to me today. The purpose of this interview is gain insight into your experience as a [ROLE] participating in the implementation of the Alliance for Innovation on Maternal Health’s obstetric hemorrhage patient safety bundles at your organization. More specifically, I’d like to understand your responsibilities, impressions, and the context in which this work happens.

With your permission, I’d like to record this interview. The recording would be for learning purposes only and would be destroyed at the end of my dissertation research. Do you have any questions for me before we begin?

Date:

Time:

Role/Position(s):

Site(s):

<b>Concept/Construct<sup>1</sup>: Warmup/Rapport building</b>	
Questions	Probes
1. What is your role in the MI-AIM patient safety bundle implementation process at [SITE]?	<ul style="list-style-type: none"> <li>• Do you have previous experience with implementing bundles?</li> <li>• How long have you been involved?</li> <li>• Has your role changed over time? In what ways?</li> <li>• What kind of training do you have?</li> </ul>
<b>Concept/Construct<sup>1</sup>: Guideline factors</b>	
Questions	Probes
2. How were the bundle/bundle implementation tools introduced in your area? 3. Can you describe how this initiative is organized at your site? How do you feel the organization at [SITE] compares to other sites? 4. Are your colleagues aware of and familiar with bundle implementation? 5. Who else is involved with bundle implementation at your site? 6. How feasible is it/has it been to implement the bundle elements? 7. How much effort is required to implement the bundle elements? What factors make them easier or more difficult?	<ul style="list-style-type: none"> <li>• Are the bundle elements consistent with other guidelines or recommendations you work with routinely? Are they compatible with the way you currently practice?</li> <li>• What could be done to improve knowledge or awareness of this topic?</li> <li>• Have you noticed any specific improvements after bundle implementation?</li> <li>• In your opinion, what knowledge or expertise do [ROLE] need to implement the bundle?</li> <li>• What skills are needed to implement appropriately, and do [ROLE] here have those skills?</li> </ul>

<b>Concept/Construct<sup>1</sup>: Individual health professional factors</b>	
<b>Questions</b>	<b>Probes</b>
<p>8. What has been your general view of the bundle implementation process so far?</p> <p>9. Why do people at your organization/in your unit think bundle implementation is important?</p> <p>10. Do you or your colleagues believe that implementing the bundles will lead to better outcomes (for patients, providers, the health system)?</p>	<ul style="list-style-type: none"> <li>• What concerns do you or your colleagues have about bundle implementation?</li> <li>• Are there other personal or professional factors that impact your or your colleagues' ability to participate in bundle implementation?</li> </ul>
<b>Concept/Construct<sup>1</sup>: Patient factors</b>	
<b>Questions</b>	<b>Probes</b>
<p>11. How much of a problem do you feel that obstetric hemorrhage is at [SITE]? In your community?</p> <p>12. Can you describe how bundle implementation has influenced the patient experience?</p>	<ul style="list-style-type: none"> <li>• What can be done to improve knowledge on this topic?</li> <li>• Are there any examples of how the bundles have affected patient care you that stick out to you?</li> </ul>
<b>Concept/Construct<sup>1</sup>: Professional interactions</b>	
<b>Questions</b>	<b>Probes</b>
<p>13. Are there specific individuals, organizations, or norms/values that you are aware of that affect how you perceive the bundles or implementation process?</p> <p>14. Do you think feedback on your success with these bundles would be beneficial?</p> <p>15. Can you describe how has the COVID-19 pandemic impacted the implementation process?</p>	<ul style="list-style-type: none"> <li>• Are there team or workflow issues that affect bundle implementation?</li> <li>• Are changes needed in referral processes, or interactions with other systems or groups, to be able to improve implementation?</li> <li>• What specific feedback would be most helpful?</li> </ul>
<b>Concept/Construct<sup>1</sup>: Incentives and resources</b>	
<b>Questions</b>	<b>Probes</b>
<p>16. What resources would be helpful in getting you or your colleagues to participate in bundle implementation more fully or consistently?</p> <p>17. What could be done to make it easier to follow implementation guidelines?</p> <p>18. How much extra effort is required for bundle implementation? What/who contributes to the extra effort?</p> <p>19. What could be done to reduce that extra effort?</p>	<ul style="list-style-type: none"> <li>• Are the necessary resources available?</li> <li>• What financial incentives do: you or your colleagues, system administrators, patients, and others have in conducting Goals of care conversations? What about non-financial incentives?</li> <li>• How does the information system/EHR (Epic) help or hinder the implementation process?</li> </ul>
<b>Concept/Construct<sup>1</sup>: Capacity for organizational change</b>	



Questions	Probes
20. What kind of oversight is there for this program? 21. What leadership or management support is needed to assist you or your colleagues in implementation? In your opinion, is this available, and do clinicians know how to access it? 22. How much of a priority is bundle implementation compared with other initiatives and activities going on in your setting? 23. How useful is monitoring and feedback? Is it available? 24. What does successful implementation mean to you? How would you measure it? 25. What aspects of bundle implementation have gone very successfully? 26. What are challenges to bundle implementation that you are facing currently, or still facing? 27. If you compare [SITE] with other places, are there any significant differences or similarities that you notice in the implementation process? 28. If you could change anything about the implementation process, what would you like to be different?	<ul style="list-style-type: none"> <li>• Is the style of leadership being used helpful?</li> <li>• Who supports bundle implementation and who doesn't (or supports it less)?</li> <li>• What kind of follow-up or tracking is being done?</li> <li>• Are there specific aspects or people at [SITE] that have been very influential?</li> <li>• Are there specific aspects of [SITE] make this process challenging?</li> <li>• What do you think it would take to make that (change) happen?</li> </ul>
<b>Concept/Construct<sup>1</sup>: <i>Social, political, and legal factors</i></b>	
Questions	Probes
29. What is your understanding of why bundles are being encouraged? 30. Are there any payer or funder policies or issues that you're aware of that impact bundle implementation?	<ul style="list-style-type: none"> <li>• Do real or perceived risks of malpractice complaints impact implementation?</li> <li>• Do influential people or groups outside [SITE] impact implementation?</li> </ul>
<b>Concept/Construct<sup>1</sup>: <i>Conclusion</i></b>	
Questions	Probes
31. Is there anything else I didn't ask you about, that you think I should know? 32. Do you have any questions for me?	

Constructs and concepts come from the TICD project:

<http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-8-35>

## CHAPTER FIVE

### **Factors Influencing the Implementation of a Quality Improvement Initiative to Reduce Maternal Morbidity in Michigan: A Mixed Methods Study**

#### **Abstract**

**Purpose:** Rates of obstetric hemorrhage complicating labor, delivery, and the postpartum period continue to increase despite being a leading cause of preventable maternal morbidity. Since 2015, the Alliance for Innovation on Maternal Health’s obstetric hemorrhage patient safety bundle has been initiated across more than 80 hospitals in Michigan. However, little is known about the optimal context, resources, and processes responsible for “successful” implementation of a bundle. Our objective was to systematically identify factors contributing to implementation performance across sites with below- and above-average SMM rates.

**Participants and Methods:** We evaluated patient outcomes associated with bundle implementation in Michigan hospitals in 2019 using a mixed methods explanatory sequential design (quantitative phase followed by qualitative phase). The quantitative phase consisted of an evaluation of patient outcomes using state inpatient records and linked birth certificate data, followed by in-depth qualitative study utilizing semi-structured interviews with stakeholders to characterize implementation context at select sites. Key constructs from the TICD guided the analysis. Qualitative and quantitative data were integrated by identifying content from both datasets to compare, contrast, and synthesize. A final interpretation summarizes how, and to what extent the results from the qualitative and quantitative data contribute to the identification of individual and hospital-level factors that influence bundle implementation.

**Results:** Thematic saturation was reached after 19 interviews with 22 participants representing responsibilities across 30 sites (Nursing leadership (14), OBGYN physicians (6), and quality improvement staff (2)). After adjustment for patient and hospital characteristics, eight hospitals had the highest incidence of SMM in our sample (upper SMM quartile) and eight hospitals were also identified in the lower SMM quartile. In mixed-methods analyses, analysis of TICD codes showed that all participants, regardless of SMM quartile, expressed motivation to implement the bundle with the goal of improving patients' health and save lives. The most frequently coded domains were Individual Health Professional Factors and Incentives and Resources, and there were meaningful differences across domains, with participants reflecting less often on Social, Political, and Legal factors and Patient Factors related to implementation. However, code counts did not differ meaningfully between lower and upper SMM quartiles; Guideline Factors were the only domain where lower SMM quartile hospitals had more codes compared to upper SMM quartile hospitals. Overall, we found that despite significant variation in implementation processes and practices within SMM quartile hospitals, there were ultimately more similarities than differences when comparing lower and upper SMM quartile experiences.

**Conclusion:** Stakeholder perceptions of barriers and facilitators to bundle implementation at hospitals with low or high SMM rates had noteworthy consistencies. These findings suggest that systemic issues such as interprofessional culture or training/educational norms in the medical system may be promising targets for improving implementation performance.

## Introduction

Despite outspending all other countries in per-capita maternity care (\$60 billion annually), maternal death in the United States increased by over 25% from 18.8 in 2000 to 23.8 per 100,000 in 2014, making it one of the only resource rich countries where the rate is increasing, not decreasing.<sup>21,22</sup> This upward trend is also characterized by significant variation across states, with the lowest rate of 4.5 maternal deaths per 100,000 in California, and the highest in Georgia with 46.2 deaths per 100,000.<sup>23</sup>

Factors such as better case ascertainment of maternal deaths at the state level, adverse changes in chronic diseases such as diabetes and pregnancy-related hypertension, insufficient healthcare access (e.g. ability to attend prenatal care visits), and social determinants of health including income, educational attainment, and insurance status have been proposed to explain the wide variation in maternal mortality across states.<sup>24–26</sup>

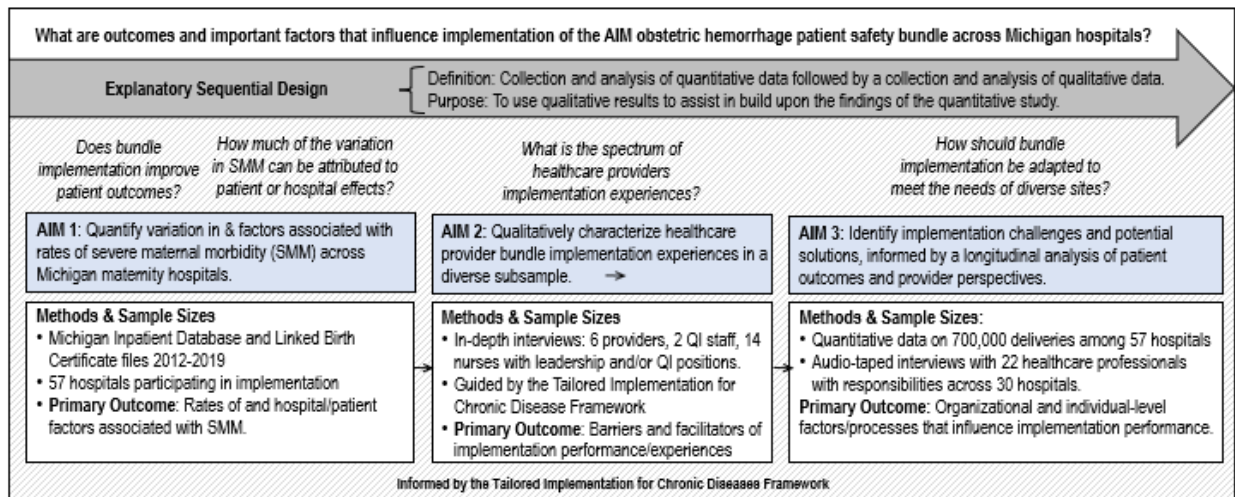
One contributor to this growing problem may be variation in obstetric practice. Hospitals across the United States generally lack a standard approach to managing obstetric emergencies, with adverse events linked to clinician, facility, and system factors such as inadequate training, missed or delayed diagnosis of complications, delayed or ineffective response to obstetric emergencies, or poor communication and coordination. Nationally endorsed collections of evidence-based practices, called patient safety bundles, were introduced to address this complex issue. Bundles provide a structured way of improving the processes of care and include a straightforward set of evidence-based practices that, when performed correctly and reliably, contribute to improved patient outcomes.<sup>74</sup> Standardizing obstetric care with bundles represents an underutilized strategy to improve women’s health, yet little is known about the optimal context, resources, and processes associated with successful implementation.<sup>95–101</sup>

In Michigan, the Alliance for Innovation on Maternal Health’s (AIM) obstetric hemorrhage bundle focuses on the leading and most preventable cause of maternal mortality and morbidity, and is currently being implemented at over 80 hospitals since 2016.<sup>125</sup> This work is focused on understanding experiences of implementation stakeholders and factors that influence implementation of the bundle across Michigan hospitals. We used the TICD to guide our approach.<sup>126</sup> It has seven domains, including detailed individual health professional and organizational domains that outline provider and hospital-level factors that influence implementation. We chose the TICD because it is an implementation science framework based on systematic review of the literature, incorporates 12 prior frameworks, is intended to guide efforts to improve care, and is widely used (>300 citations since 2013). Guided by the TICD, we used an explanatory sequential mixed methods approach to gain a comprehensive understanding of implementation stakeholder perspectives and experiences at the individual and

organizational level, which is critical information for the sustainability of existing initiatives and the future implementation of similar initiatives.

## Methods

Our goal was to understand how, and to what extent the results of quantitative and qualitative data contribute to the identification of individual- and hospital-level factors influencing AIM obstetric hemorrhage patient safety bundle implementation across Michigan hospitals. This sequential explanatory mixed methods investigation consisted of (1) quantitative evaluation of variation in, and factors associated with SMM across Michigan hospitals using the Michigan Inpatient database, and (2) an in-depth qualitative study of the implementation context and experiences at select sites. Finally, a mixed methods analyses was performed to evaluate differences in implementation experiences across select characteristics. A schematic of these research questions, associated aims, and methodology is presented in Figure 14.



**Figure 14.** Schematic of Study Design

### Quantitative Analyses

We conducted a retrospective cross-sectional study of individuals delivering at Michigan hospitals in 2019 using the Michigan Department of Health and Human

Service's resident Inpatient Database and linked Birth Certificate files.<sup>165</sup> This large state database includes demographic characteristics such as age, race, and insurance status, along with patient comorbid conditions, International Classification of Diseases, 9th and 10<sup>th</sup> Revision, Clinical Modification diagnosis, and procedure codes. Information on hospital AIM initiative participation, characteristics, implementation dates, and progress was collected from the MHA's Keystone Center Collaborative database.

The primary outcome of SMM without transfusion during delivery or postpartum hospitalization was identified using the Centers for Disease Control and Prevention's list of indicators.<sup>91,151</sup> The incidence of SMM was calculated using a multivariable multilevel model to better understand patient and hospital specific variation in SMM incidence and its predictors. This multilevel model accounted for patient clustering within each hospital with the inclusion of hospital specific random effects. Predictors included patient age, race (non-Hispanic white, non-Hispanic black, Hispanic, Other non-Hispanic), insurance status (Private, Medicaid, Self-Pay/Other), gestational age at delivery, delivery method (spontaneous vaginal, assisted vaginal, or Cesarean), and hospital size (<500, 500-999, 1000-1999, ≥2000 births). This model was then used to rank identify upper and lower quartile hospitals based on adjusted SMM incidence. Bivariate analysis was performed to compare patient demographic, clinical characteristics, and medical comorbidities. A 95% confidence level was used for all analyses. All data management was performed using SAS version 9.4 (SAS Institute Inc., Cary, N.C.), and analyses performed with Stata (2015, Stata Statistical Software, release 14.1; Stata Corp LP, College Station, TX). This study was approved by the University of Michigan Institutional Review Board (HUM00191708).

### *Qualitative Analyses*

We performed a qualitative study using semi-structured interviews to characterize stakeholder experiences implementing the AIM obstetric hemorrhage bundle in Michigan hospitals. Interviews were conducted with healthcare providers and staff participating in bundle implementation at their site, including nurses, physicians, and quality improvement staff. Participants were recruited from the Michigan AIM

operations committee meetings. This study was determined exempt by the University of Michigan Institutional Review Board (HUM00202266).

The TICD was used to guide qualitative data collection and analysis. This framework was developed as a comprehensive, integrated checklist of determinants of implementation success, reconsolidating across 12 different reviews of implementation determinants.<sup>126</sup> By integrating elements from other commonly used frameworks, e.g., the Consolidated Framework for Implementation Science and the Theoretical Domains Framework, it aims to be an easily used checklist to identify determinants of practice for implementation strategy development and program evaluation.<sup>113,128</sup> As recommended, the TICD's exhaustive checklist of seven domains and 57 associated determinants of practice was reviewed. Importantly, in this study constructs in the TICD that are associated with bundle implementation but are currently unmeasured by available quantitative data were directly explored in the qualitative data analysis.

The lead author led the study team and conducted semi-structured interviews with participants from November 2020 – March 2022. The interview guide had open-ended questions to elicit participants' experiences, attitudes, and perceptions of bundle implementation in their role(s) or hospital(s). Interviews began with an introduction and rapport building question and then proceeded into the TICD domains, with additional probes regarding barriers and facilitators of implementation. We audio recorded interviews via Zoom, and used MAXQDA (version 20.4.1)<sup>137</sup> to analyze professionally-transcribed interview data and grounded theory techniques for analysis.<sup>171</sup> A qualitative team (EKK, LAM) reviewed transcripts independently and coded the content of each transcript. Because our research design is driven by predetermined theoretical constructs, initial coding was done with a theory-generated template. An inductive approach using open, in vivo coding was also used to identify factors outside of the TICD. After independently coding the initial transcripts, we resolved coding differences through discussion, and repeated this process until we developed a consensus coding template.<sup>138</sup> Themes and patterns were identified and synthesized, using pre-identified theoretical constructs as a guide, as well as new themes as they emerged. Higher order analysis of codes and themes was performed via review and discussion with three qualitative experts (JPW, LKL, CAM).<sup>172</sup> Analysis of patterns by SMM quartile (lower or

upper quartile) – determined from the quantitative analysis - was performed to identify similarities, differences, and trends in how hospitals experienced implementation. Sampling and analysis was continued until theoretical understanding of implementation experiences was reached.<sup>138</sup>

### *Mixed Methods Analyses*

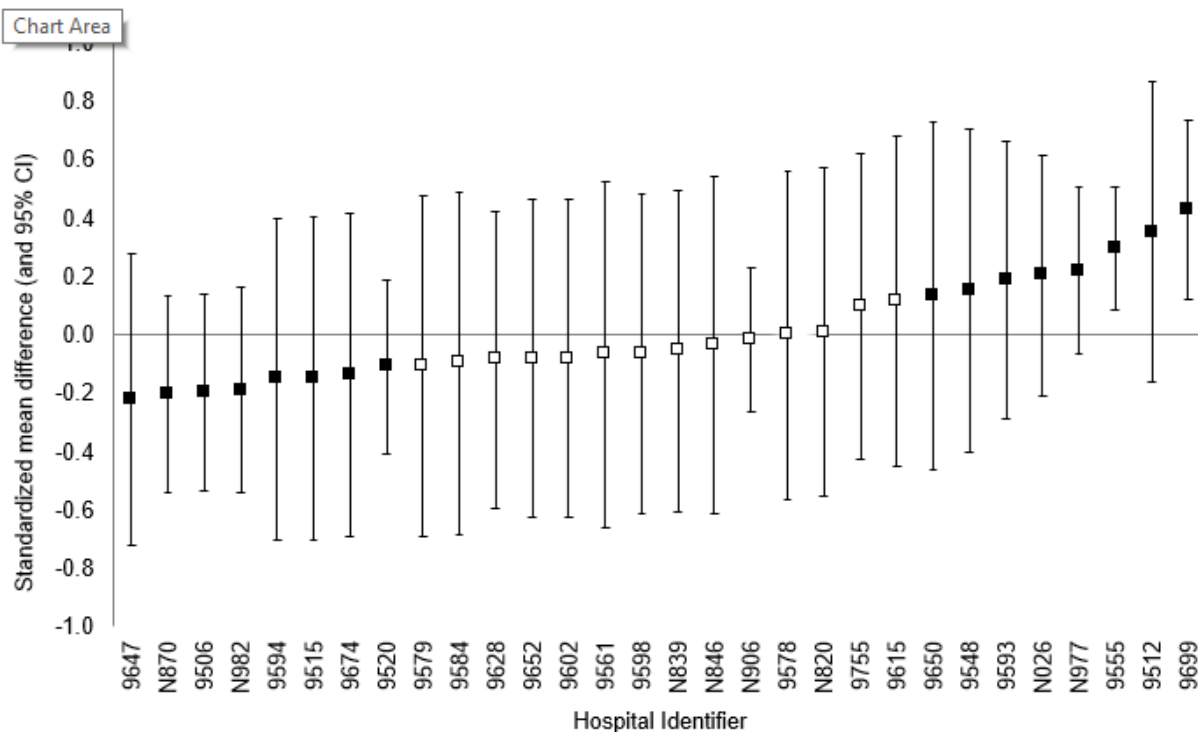
In this explanatory mixed-method design, we expanded the knowledge gained from the quantitative and qualitative analyses by identifying content from both datasets to compare, contrast, and synthesize themes and results. Points of integration occurred at the transition from quantitative to qualitative strands in data collection and sampling, and the results of both strands are integrated at the stage of making inferences from the combined data. First, using a connecting approach<sup>142</sup>, the results from quantitative analysis were used to identify lower and upper SMM quartile hospitals for analysis. Second, using a merging approach<sup>142</sup>, data displays will be created to link major quantitative and qualitative findings to identify points of convergence and divergence. This approach allows us to compare individual-, or hospital-level factors across SMM quartile categories in the form of joint displays. Joint displays are used in mixed methods analyses to provide a structure for the integrated analysis of quantitative and qualitative data and thus can provide new insights.<sup>179</sup> To create the first joint display (Figure 3), we cross-tabulated the number of codes generated within the seven TICD domains (Guideline Factors, Individual Health Professional Factors, Patient Factors, Professional Interactions, Incentives and Resources, Capacity for Organizational Change, and Social, Political, and Legal Factors) by SMM quartile (lower versus upper quartile). A second joint display (Table 2) was created by analyzing codes within the seven TICD domains to identify exemplar quotes demonstrating similarities or differences between low and high SMM quartile groups. Integration of the inferences obtained from these strands of data were presented as theoretical statements referred to as meta-inferences.<sup>180</sup>



## Results

Interview participants included nursing and quality improvement leadership (14), Obstetrician-Gynecologist physicians (6), and quality improvement staff (2), representing responsibilities across 30 hospitals. After ranking these hospitals by their adjusted SMM rate, we observed representation of interviews from hospitals both above and below the mean overall rate (73 (95% CI: 62-85) per 10,000 delivery hospitalizations). There were eight hospitals identified in the upper quartile, meaning that after adjustment for patient and hospital characteristics, these hospitals had the highest incidence of SMM in our sample. Similarly, eight hospitals were also identified in the lower quartile, reflecting the lowest incidence of SMM in our sample. (Figure 15)

**Figure 15.** Caterpillar Plot of the Hospital Effects on SMM, 2019



The 30 hospitals participating in bundle implementation represented in qualitative interviews are ranked from left (lowest) to right (highest) deviation from the overall mean SMM rate. The error bars demonstrate 95% confidence interval. Black boxes indicate hospitals in the lower (left, n = 8) and upper (right, n = 8) quartiles.

Table 5 describes hospital, interview participant, and patient characteristics across hospitals by SMM quartile group. There was equal representation of rural sites and bed size in both quartiles. Overall, upper SMM quartile hospitals had a significantly lower proportion of patients with a prenatal visits in the first trimester (72.5% versus 79.5%,  $p < .001$ ), lower rates of tobacco and alcohol use (11.2% versus 16.7%,  $p < .001$ , and 0.7% versus 2.4%,  $p < .001$ , respectively), lower rates of gestational diabetes (5.3% versus 7.9%,  $p < .001$ ) and chronic hypertension (10.3% versus 11.4%,  $p < .001$ ), and higher rates of prolonged labor (3.9% versus 2.5%,  $p < .001$ ) compared to hospitals in the lower SMM quartile.

**Table 5.** Characteristics of Hospitals and Associated Interview Participant and Patient Characteristics by SMM Rate Quartile, 2019

	Total	Lower SMM Quartile	Upper SMM Quartile
	16 hospitals	8 hospitals	8 hospitals
Characteristic <sup>a</sup>	41,843 deliveries	19,929 deliveries	21,914 deliveries
<i>Hospital</i>			
Rural	2 (12.5)	1 (12.5)	1 (12.5)
Bed size			
<500 beds	2 (12.5)	0 (0.0)	2 (25.0)
500-999 beds	5 (31.3)	3 (37.5)	2 (25.0)
1000-1999 beds	1 (6.3)	1 (12.5)	0 (0.0)
2000+ beds	8 (50.0)	4 (50.0)	4 (50.0)
<i>Interview participants</i>			
Role <sup>b</sup>			
Nursing leadership	7	7	6
Obstetrician-gynecologist physician	6	4	3
Quality improvement staff	2	0	2
<i>Demographic</i>			
Age, years <sup>cd</sup>	29.0 (25.0, 33.0)	29.0 (25.0, 33.0)	29.0 (25.0, 33.0)
Race/ethnicity <sup>d</sup>			
Non-Hispanic White	23,716 (64.5)	12,063 (65.1)	11,653 (63.8)
Non-Hispanic Black	6,764 (18.4)	3,226 (17.4)	3,538 (19.4)
Hispanic	3,236 (8.8)	1,339 (7.2)	1,897 (10.4)
Other Non-Hispanic	3,080 (8.4)	1,899 (10.3)	1,181 (6.5)
Body mass index, kg/m <sup>2cd</sup>	26.3 (22.6, 31.6)	26.0 (22.5, 31.3)	26.4 (22.7, 31.8)

<b>Education<sup>d</sup></b>			
Less than high school	4,360 (10.6)	2,155 (10.7)	2,245 (10.5)
High school graduate or GED	9,616 (23.4)	4,512 (22.8)	5,104 (23.9)
Some college, no degree	8,780 (21.4)	4,658 (23.6)	4,122 (19.3)
Associate degree	3,426 (8.3)	1,730 (8.8)	1,696 (8.0)
Bachelor's degree	4,930 (23.1)	4,330 (21.9)	4,930 (23.1)
Master's degree or higher	3,221 (15.1)	2,426 (12.3)	3,221 (15.1)
<b>Source of payment<sup>d</sup></b>			
Private Insurance	24,461 (58.6)	11,491 (57.8)	12,970 (59.4)
Medicaid	16,772 (40.2)	8,121 (40.8)	8,651 (39.6)
Self-pay/other	504 (1.2)	281 (1.4)	223 (1.0)
<b>Pregnancy</b>			
Any prenatal care <sup>d</sup>	39,968 (98.1)	19,006 (98.6)	20,962 (97.6)
Prenatal visit in the first trimester <sup>d</sup>	30,901 (75.8)	15,333 (79.5)	15,568 (72.5)
Prenatal visits, number <sup>cd</sup>	13.0 (10.0, 15.0)	13.0 (11.0, 15.0)	12.0 (10.0, 16.0)
<b>Number of gestations<sup>d</sup></b>			
Single	39,961 (95.5)	19,130 (96.0)	20,831 (95.1)
Twin	1,829 (4.4)	782 (3.9)	1,047 (4.8)
Triplets or more	52 (0.1)	17 (0.1)	35 (0.2)
Gestational age at delivery, weeks <sup>d</sup>	39.0 (38.0, 40.0)	39.0 (38.0, 40.0)	39.0 (37.0, 40.0)
<b>Delivery method<sup>d</sup></b>			
Spontaneous vaginal	26,808 (64.1)	12,618 (63.3)	14,190 (64.8)
Assisted vaginal	1,152 (2.8)	537 (2.7)	615 (2.8)
Cesarean	13,878 (33.2)	6,773 (34.0)	7,105 (32.4)
Obstetric hemorrhage <sup>d</sup>	4,044 (9.7)	1,336 (6.7)	2,708 (12.4)
<b>Risk Factors</b>			
Tobacco use during pregnancy <sup>d</sup>	5,470 (13.8)	3,303 (16.7)	2,437 (11.2)
Alcohol use during pregnancy <sup>d</sup>	626 (1.5)	477 (2.4)	149 (0.7)
Gestational diabetes <sup>d</sup>	2,723 (6.5)	1,574 (7.9)	1,149 (5.3)
Chronic hypertension <sup>d</sup>	4,520 (10.8)	2,276 (11.4)	2,244 (10.3)
Prior preterm birth <sup>d</sup>	1,929 (4.6)	807 (4.1)	1,122 (5.1)
Prior Cesarean delivery	6,583 (15.8)	3,171 (15.9)	3,412 (15.6)
Prolonged labor ( $\geq 20$ hours) <sup>d</sup>	1,335 (3.2)	497 (2.5)	838 (3.9)
Length of stay, days <sup>c</sup>	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)

<sup>a</sup> Data are presented as n (percent) unless otherwise specified.

<sup>b</sup> Data in columns does not necessarily add to the total due to overlap in participant responsibilities across multiple hospitals.

<sup>c</sup> Data are presented as median (interquartile range)

<sup>d</sup> P<.05 for difference using Chi-square or Wilcoxon Rank test where appropriate.

After analysis of TICD codes among interview transcripts, all participants, regardless of SMM quartile, expressed motivation to implement the patient safety bundle with the goal of improving patients' health and save lives. The most frequently coded TICD domains were Individual Health Professional Factors and Incentives and Resources. Code counts differed meaningfully across TICD domains, with participants across all hospitals reflecting less often on Social, Political, and Legal factors and Patient Factors related to implementation. However, code counts did not differ meaningfully between lower and upper SMM quartiles; Guideline Factors were the only domain where lower SMM quartile hospitals had more codes compared to upper SMM quartile hospitals. (Figure 16).

**Figure 16.** Code Counts According to the TICD Domains, Overall, and by SMM Quartile

Domain	Total	Lower SMM Quartile	Upper SMM Quartile
Number of participants interviewed	11	11	15
Guideline Factors	● 10.5	● 11.3	● 10.0
Individual Health Professional Factors	● 16.6	● 15.5	● 17.0
Patient Factors	● 0.9	● 1.0	● 0.6
Professional Interactions	● 9.4	● 9.3	● 10.9
Incentives and Resources	● 13.4	● 11.5	● 14.0
Capacity for Organizational Change	● 10.1	● 9.5	● 10.5
Social, Political, and Legal Factors	● 1.3	● 1.2	● 1.1

NOTE. Because varying numbers of participants were interviewed across SMM quartiles, the code count is shown as the number of mentions per participant.

To further investigate these patterns, representative comments from the TICD domains were cross tabulated across SMM quartile categories, resulting in seven meta-inferences. (Table 6). Overall, we found that despite significant variation in stakeholder processes and practices within SMM quartile hospitals, there were ultimately more similarities than differences when comparing lower and upper SMM quartile implementation experiences defined using TICD domains. There was also overlap

across all TICD domains, reflecting the complexity of factors involved in implementation, and their influence on one another.

First, Guideline Factors such as the strength of the recommendation and implementation feasibility were reported similarly across lower and upper SMM quartile hospitals. Importantly, these factors were not reported as barriers to implementation, suggesting that the content and structure of the bundle itself was acceptable for most hospitals.

Second, Individual Health Professional Factors such as attitudes towards guidelines in general or intention and motivation, were commonly phrased as barriers to implementation, with participants stressing how challenging behavior and practice change were at their hospital(s). There was wide variation in personal attitudes and behaviors toward quality improvement initiatives, with inertia as the prevailing sentiment to not implement. Experiences between lower and upper SMM quartiles were overall very similar, suggesting that Individual Health Professional Factors may be commonly held among many individuals in medicine or hospitals.

Third, Patient Factors such as knowledge, needs, or preferences were rarely mentioned in the context of implementation. We found that low SMM quartile hospitals may be more amenable, or in a better position to include patient factors into implementation compared to upper SMM quartile hospitals. Alternatively, these results suggest that providers' assumptions of patient needs may be biased, and this domain would be better assessed via patient survey or interview.

Fourth, Professional Factors such as communication and team processes were also well-aligned between lower and upper SMM quartile hospitals. Major barriers to implementation were mentioned by all participants, including the need for multidisciplinary teams and a culture of psychological safety. Upper SMM quartile hospitals more often mentioned geography (rural/urban status), and hospital size as barriers to improving team communication and unit culture.

Fifth, Incentives and Resources, specifically financial and nonfinancial were also similar across lower and upper SMM quartile hospitals, and largely framed as barriers to implementation. Of particular concern were financial incentives to improve engagement and participation, and the impact of COVID-19 staff shortages on the ability for hospitals

to prioritize and sustain these initiatives. The lack of standardized, “real-time” data collection procedures that inform audit and feedback processes were a primary concern for all sites as well. Importantly, the Incentives and Resources factors were the most coded for both groups.

Sixth, Capacity for Organizational Change factors were also similar across both SMM quartile groups. Capable leaders (nurses, providers, or administrators) were often mentioned as critical for implementation success but may not always have the proper skills (or resources) to lead this work.

Lastly, Social, Political, and Legal Factors were also rarely mentioned in this context, however, present insight into the role these factors play at the state level. Both upper and lower SMM quartile hospitals reported instances of malpractice as a driver of implementation, and participants at lower SMM quartile sites indicated integration with advocacy and legislative processes that were not mentioned at upper SMM quartile hospitals. This reflects the limited opportunities for participation in advocacy and policy changes desired for long-term funding for implementation.

**Table 6.** Mixed Methods Analyses Demonstrating Exemplar Quotes and Meta-inferences by TICD Domains and Codes Across SMM Quartiles

TICD Domain	Lower SMM Quartile	Upper SMM Quartile	Meta-Inference
Guideline Factors	"I think it's strong. I think it's evidence-based. It takes into account the team approach that's needed, specifically in OB and in OB emergencies. I find it very straightforward and easy to follow." [PROVIDER]	"I think we had pretty good buy-in, some of the providers had questions because everybody has their own way that they like to treat their patients, but it was really nice because what we were bringing to the table was evidence based practice, that this was proven...." [NURSE]	<b>The bundle and its elements were considered strong and straightforward by all implementing hospitals, and left room for tailoring to individual and team needs.</b>
Individual Health Professional Factors	"It's a big hospital system and it's really hard to move a huge ship like the Titanic in one direction when everybody's doing something different." [NURSE]	"They promised the hospitals... that they could continue doing what they've done in the past. If you become a system, you can't do that because the economies of scale. So it's been a struggle to try to get anything done because the independence of each hospital..." [PROVIDER]	<b>Implementation experiences are associated with variation in personal attitudes towards guidelines in general, intention, and motivational differences that are person and/or site-specific.</b>
Patient Factors	"They [patients] might know it to a small extent, but I don't think they know it to a big extent.... One thing that yes, we probably could improve on is more education for the patients... why we're doing what we're doing and letting them know this is why we're doing what we're doing." [NURSE]	"Now, whether or not a patient and family need to be aware of [hospital] is platinum status in the Michigan AIM collaborative related to obstetric hemorrhage, probably not so much. I mean, if somebody asks, of course." [PROVIDER]	<b>Although patient factors were rarely discussed in the context of implementation, lower SMM quartile hospitals may be more amenable to including patients in this process.</b>
Professional Interactions	...The culture shift that I've seen over the past three to four years. ...when other providers listen to other providers. And nurses listen to other nurses and nurses listen to providers. So, when we have this huge team with all of these different interdisciplinary groups, like quality, safety, risk, physician, nurse, we even have our infection prevention team. [NURSE]	When you go out to these rural places and you have these docs that are kind of isolated, it becomes almost like a fiefdom... The nurses fall in line. When you're in a rural area, you really don't get that exposure like they would... where there's high-risk OB people that you can learn from. So that interaction, that indirect education... is not present. Because of that, even the nurses then suffer. [PROVIDER]	<b>Multidisciplinary teams, stakeholder buy-in, and a culture of safe team communication were factors associated with positive implementation experiences but were rarely achieved. Hospital-level factors such as geography and size may impact feasibility of change.</b>

Incentives and Resources	It's essentially a volunteer program. So until we actually have a true, committed funding and a program manager and a better infrastructure, I don't necessarily believe that we're ever going to get to that 100% participation. And that's going to require funding. It's going to require additional clinician engagement, provider engagement. [PROVIDER]	One of the unique things of... One of the issues with AIM is that as a collaborative, it's purely voluntary. There's no funding for it, and there's no actual reward for participation beyond kudos and doing the right thing. And that's been one of the challenges, for sure. Just getting administration to have any interest in it has been challenging. [PROVIDER]	<b>Upper and lower SMM quartile groups were similarly concerned that reliance on volunteer effort was unsustainable, and experienced similar challenges including staffing shortages, lack of data infrastructure, competition with other hospitals, consistency of training and education, and weighing efficiency versus speed.</b>
Capacity for Organizational Change	We do have a couple of people like myself who have been in the history of what's happening, know the implementation pieces, know the bundle, know the metrics and are constantly helping bring every single hospital together. [NURSE]	Most things seem to be run done by clinical people, by nurses and physicians, instead of by administrators. And there's good and bad parts to that. But I think what we've experienced is that mainly clinical people don't know what the hell they're doing when it comes to project management, so we just flounder and we're unproductive. [PROVIDER]	<b>Capable leaders ("champions") are an essential source of historical knowledge, audit and feedback to teams, and drive prioritization and ownership of bundle elements across all hospitals but need to have the proper skills.</b>
Social, Political, and Legal Factors	We're working on some advocacy pieces through the state and... getting a line item in the budget for our work. So that would require legislation and getting something passed... So that's a very positive thing. [PROVIDER]	We just had some big major payout for a malpractice case... So the corporation said we can't have this anymore. So... we're working with [organization] to develop really a safety program for the whole system, but the starting department is going to be OB. [PROVIDER]	<b>Malpractice cases were a concern for hospitals, and access to opportunities for advocacy or policy changes desired for long-term funding changes for implementation were rare.</b>

<sup>1</sup> Domains come from the TICD project: <http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-8-35>



## Discussion

We performed an in-depth mixed methods assessment of factors associated with bundle implementation from the healthcare provider perspective. We found that despite variation in factors related to implementation within lower and upper SMM quartile hospitals, there were ultimately more similarities than differences when comparing lower and upper SMM quartile implementation experiences. This study is one of the first to use the TICD for guiding data collection, analysis, and interpretation in the context of systems-level bundle implementation experiences. The domains Guideline Factors, Individual Health Professional Factors, Professional Factors, Incentives and Resources, and Capacity for Organizational Change saw alignment in experience across lower and upper SMM quartiles. Small differences between groups were observed in Patient Factors and Social, Political, and Legal Factors, however these were the least frequently mentioned domains.

Individual provider-level barriers to implementation were identified. Personal attitudes towards quality improvement guidelines in general and factors influencing intention and motivation to implement such as “saving lives”, or financial gains were frequently mentioned. One explanation for variation in individual level attitudes and behaviors was that the bundle is one the first quality improvement initiatives to frame their strategies as “recommendations” instead of “mandates.” This nuance possibly allows personal opinions and site-specific social or practice norms to be incorporated into an otherwise short conversation.

Organizational level barriers were also identified. Although feedback was perceived as critical for implementation performance, the ability for hospitals to acquire, evaluate, and disseminate “real-time” data regarding SMM or other patient outcomes is severely limited. Additionally, capable leaders in any role were critical for implementation success, but in danger of burnout. Much of the volunteer effort for implementation comes from a few champions, and this role is unsustainable without more formal allocation of time or funding for effort.

This study had several strengths. We used rigorous qualitative methods in sampling, and data collection and analysis. The theoretical basis for this study

increases the likelihood its findings can be clinically translated to effective strategies and interventions. There also were a few study weaknesses. First, the findings should be understood within the context of the timing of the interviews (November 2021 to March 2022) given the continued pressure on healthcare providers due to the COVID-19 pandemic. It is possible that individuals who would otherwise participate in this type of study were not available. Second, consistent with the goals of qualitative purposeful sampling, participants and their affiliated hospitals may not be representative of all Michigan participants or hospitals, but rather reflect characteristics that may underlie variations in implementation.<sup>136</sup> Participant recruitment occurred during MI-AIM operations committee meetings, which may bias representation to more engaged hospitals compared to non-attendees. To address the two previous limitations, sampling and analysis was continued until we reached theoretical saturation of implementation experiences, or until we no longer identified new or disconfirming or confirming data with respect to the original research aim. Third, our study design to compare lower and upper SMM quartile hospital groups may have masked variation across other factors of interest such as urban/rural status or patient population. Future work should explore the interaction of these alternative hypotheses on implementation experiences. Finally, we aimed to understand implementation experiences across a range of roles and hospitals, which limited our ability to probe differences between these factors. However, the data collected in qualitative interviews was sufficiently detailed to provide robust inferences.

Overall, we found that factors influencing implementation as categorized using the TICD domains were more similar than different between hospitals with below-average SMM and above-average SMM rates. Future research should seek to identify areas for intervention within the individual, team, and organizational factors described. A more comprehensive understanding of variation in experiences across these factors will better predict implementation success and will be crucial to providing tailored implementation strategies to improve health outcomes.

## DISCUSSION

This dissertation answers a key question to build knowledge regarding the impact of standardizing reproductive healthcare with patient safety bundles in Michigan: *What are the outcomes and important factors that influence the bundle implementation process across Michigan hospitals?* To answer this, an explanatory sequential mixed methods approach informed by implementation science using the TICD conceptual framework was designed. Three aims served as the basis for the retrospective analysis of the bundle implementation in Michigan hospitals between 2012 and 2019. Variation in, and factors associated with SMM were quantitatively evaluated across Michigan hospitals using the Michigan Inpatient Database and linked Birth Certificate files (Chapter Three). A qualitative study using in-depth semi-structured interviews with implementation stakeholders was then conducted to assess the implementation context at select sites (Chapter Four). Finally, factors contributing to implementation performance across sites with below- and above-average SMM rates were examined by synthesizing the quantitative and qualitative data (Chapter Five).

Chapters three, four, and five present the results of this systematic approach, which illustrates the complexity of the obstetric hemorrhage bundle implementation process in the state. Our findings have consolidated and synthesized the abundant conversations, actions, and data surrounding these efforts, and aided the identification of practical opportunities to improve and sustain bundle implementation activities at many levels. This highlights the power of mixed methods in this context: our qualitative findings give us narrative stories and on-the-ground experiences, while our quantitative findings give us data that illuminate the relationship between patients, providers, hospitals, and implementation outcomes. Together, this information demonstrates that despite efforts to standardize obstetric care across Michigan hospitals with this bundle, variation in patient, provider, and hospital characteristics and context-specific

microenvironments and cultural factors have strong influence on implementation success. Moreover, many of the factors identified as barriers to implementation are systemic to individuals in the medical field or hospital settings, presenting additional challenges. Taken together, variation in implementation performance and experiences across hospitals is related to the specific combination and respective strength of these factors. Bundle implementation is often advertised or understood as a straightforward process, but these results suggest that it may be quite the opposite. The following section outlines the implications of this work on existing and future implementation initiatives, implementation science research, and learning health sciences. Finally, opportunities for future investigation are proposed.

### **Implications for Bundle Implementation**

The results of these analyses inform the ongoing obstetric hemorrhage implementation initiative and provides key insights for hospitals and stakeholders interested in optimizing future implementation. This work presents the first mixed methods evaluation of patient outcomes and provider experiences regarding implementation in Michigan, offering important insights for hospitals that have been participating in implementation since as early as 2016. The methodology outlined in this dissertation and the subsequent results may also be of interest to obstetric hemorrhage bundle implementation initiatives in other states.

Chapter Three presents a retrospective evaluation of births occurring at Michigan hospitals participating in bundle implementation between 2012 and 2019. Importantly, patients with hemorrhage – specifically targeted by this intervention – showed declining rates of SMM in both the pre- and post-implementation periods. This was an important first step to establishing the impact of bundle implementation on patient outcomes across Michigan hospitals. To date, a gold standard for measuring the impact of bundle implementation on patients, implementation stakeholders, or hospitals has not been defined. Therefore, this work provides important information on the appropriate limitations, considerations, and optimal context for the use of SMM as a primary outcome for bundle implementation research.

Also in Chapter Three, variation in SMM across hospitals was described. Overall, most hospitals did not have substantively better or worse rates of SMM compared to the average hospital, with only three hospitals having significantly worse rates. This analysis also demonstrated that the variation in SMM was not attributable to hospital factors, suggesting that there were other significant, yet unmeasured factors that may be influencing implementation. We learned that the data contained in both the inpatient claims and birth certificate datasets are insufficient to appropriately identify contextual factors associated with variation in SMM in this context. To address this gap, the qualitative study outlined in Chapter Four was designed.

Chapter Four provides one of the first systematic collections, documentation, and analysis of “real-world” insights, attitudes, and experiences with obstetric hemorrhage bundle implementation. Participants in this study described challenges to bundle implementation at the individual, team, and organizational levels, including time and resource constraints, interprofessional team dynamics, burden of workload, limited personal motivation and incentives to encourage engagement and adherence, and complexity of observing and measuring outcomes. Many participants were proud to recount their experiences addressing or overcoming these challenges as an individual and as a team. However, feelings of frustration and uncertainty regarding future implementation efforts were fueled by the COVID-19 pandemic, adding stress to an already complex process, and undermining the sustainability of implementation.

The findings in Chapter Four highlight areas of significant tension for hospitals and implementation stakeholders to direct their attention and efforts. When planning complex changes in practice, implementation strategies that address potential barriers at the individual, organizational, and social levels are recommended. However, the obstetric hemorrhage bundle does not contain information on why, or how to identify barriers to implementation, nor do they provide resources to educate on or address barriers as they are identified. The “Reduction of Peripartum Racial/Ethnic Disparities” supporting bundle, developed by AIM provides some of the only recommendations and resources for addressing social determinants of disparities in maternal health outcomes. However, this bundle requires equivalent time and resources to implement, and may not address specific cultural needs at hospitals. Participants also expressed frustration at

their lack of training in this area, which indicates a clear opportunity for educational interventions for implementation stakeholders. Identifying and addressing barriers to implementation such as interprofessional communication or cultural issues is a critical step towards healthy collaboration, and ultimately improves integration of bundle elements into care practices.

In Chapters Three and Four, we observed improvement in rates of SMM among patients with hemorrhage, yet factors associated with implementation performance varied widely across individuals and hospital(s). The Chapter Five analysis was designed to systematically identify factors contributing to implementation performance across sites with below- and above-average SMM rates. This comparison provides insight into whether implementation performance is associated with any specific concepts, actions, or patterns that would inform best practices. Overall, we found that despite significant variation in stakeholder experiences within SMM quartile hospitals, there were ultimately more similarities than differences when comparing lower and upper SMM quartile experiences. These findings suggest that regardless of patient outcomes, hospitals and implementation stakeholders have faced similar challenges up until this point in the initiative. This underscores the systemic nature of many of these factors, and on the other hand, the potential for the development of interventions that are broadly applicable and feasible.

It is important to contrast the bundle recommendations to other quality improvement initiatives, such as toolkits or mandates often used in quality improvement. The AIM bundles are disseminated as a package of tools and strategies that are used to facilitate behavior change, yet the items in a toolkit are not prescribed. Rather, the goal is for users to select and specify items from this collection that are evidence-based, have proven effectiveness, and meet the user's aims, resources, and context. We see this reflected in our finding that hospitals have unique implementation experiences in Chapters Four and Five. However, the AIM approach is fundamentally different than many previous initiatives that historically provided more structure, rules, or directives to providers. Our results suggest that perhaps that the latitude provided by the bundles is, at some hospitals a gift, and others, potentially unfamiliar territory. The need for gold standard measurement goals as highlighted in Chapter 3 combined with the lack of

time, resources, or awareness to comprehensively identify potential barriers to implementation, and the absence of stakeholders with the skills or background to lead a less regimented initiative may leave hospitals feeling like they simply don't know where to start. There is great need to develop robust approaches to accurately identify and monitor health systems that need, or desire bundle implementation, and to deliver adaptable and tailored support.

Overall, the results of Chapters Three, Four, and Five demonstrate the complexity of the bundle implementation process between 2012 and 2019 and have provided critical new knowledge for optimizing future implementation endeavors.

### **Implications for Implementation Science**

Implementation science is a new and evolving field, with theory and methodology being developed and updated frequently. These results contribute to the validation and strengthening of theory-informed implementation science research in a few ways. First, we performed one of the first highly systematic and organized assessments of bundle implementation experiences in the setting of labor and delivery based on the TICD, which was specifically developed to guide efforts to improve care. Our findings present an applied example of the utility of this framework in bundle implementation evaluation to guide data collection, analyses, and interpretation at the state level. Second, we expanded upon the TICD's domains and constructs to identify novel codes and themes important to understanding bundle implementation. These results may help to expand the TICD to the labor and delivery setting. Third, these results demonstrate how mixed methods approaches can be well suited to optimizing the results of implementation science research questions. Our findings highlight the power of mixed methods in the context of bundle implementation: our qualitative findings gave us narrative stories and on-the-ground experiences, while our quantitative findings gave us data that illuminate the relationship between patients, hospitals, and implementation outcomes. Moreover, maximizing the integration of data in this way provided relevant, robust, and targeted information to address the study aims. The methodology outlined in this dissertation and the subsequent results may also be of interest to obstetric hemorrhage bundle

implementation initiatives in other states. Using the TICD (and its extensive guidance and supplementary materials) to guide data collection and analyses allows for potential replication or adaptation of this study design to similar initiatives or settings.

### **Implications for Learning Health Science**

As mentioned previously, the five key attributes are crucial to a fully functional LHS: 1) availability of secure, large-scale, routinely-collected patient data; 2) best-practice knowledge derived from these data capable of being computable for translating into clinical practice; 3) multiple simultaneous and continuous learning and health improvement cycles; 4) presence of infrastructures to support learning cycles; 5) identification of stakeholders and experts for establishing learning communities surrounding health-related issues. In Chapter One, we saw that many elements of a functional LHS for bundle implementation were insufficient or missing altogether. The results of this dissertation are unique in that they provide critical new knowledge and information through directly addressing multiple gaps in this cycle as they relate to bundle implementation.

First, Chapter One discussed the lack of quality maternal health data available in Michigan. Indeed, we found that little infrastructure exists at the hospital level to support data collection, management, audit and feedback, or statistical analysis of maternal health data. The results from Chapters 4 and 5 suggest that support in the form of funding or workforce capacity for these activities would benefit many aspects of implementation. Most importantly, routinely collected patient data would inform timely audit and feedback activities within hospitals - often mentioned as a motivator for engagement and would better sustain activities by providing ongoing goals or incentives for stakeholders.

Second, this dissertation lays the groundwork for identifying best-practices in implementation. We have successfully evaluated trends and factors associated with patient outcomes during the implementation period, characterized attitudes and experiences towards bundle implementation, and identified perceived barriers and facilitators to implementation at the provider and system level. For example, these



results show that implementation experiences are surprisingly very similar across diverse hospitals, indicating the impact of issues systemic to medicine on patient outcomes and implementation performance. These are some of the first insights from rigorous quantitative and qualitative analyses and may provide crucial validation or information for implementation stakeholders. Further, these results provide many opportunities for intervention development across the learning health cycle.

Third, these analyses inform a gap in identification of stakeholders and experts for establishing learning communities. The MI-AIM program was appropriately concerned with identifying implementation champions at participating hospitals. Indeed, the results from Chapter Four indicate that champions play a key role in implementation performance. However, we found that most of the work and leadership rests on a few champions, and to complicate matters more, staff shortages and turnover related to the COVID-19 pandemic threaten implementation success and sustainability. These results again suggest a large infrastructural gap in support for implementation. Addressing staff shortages in medicine is ongoing in Michigan, with legislators, national organizations, and hospital stakeholders working on solutions at many levels. These results show the impact that improving workforce capacity could have on adverse events in pregnancy. Chapter Four also identified a critical point in the implementation process: the transition of leadership and ownership of implementation from individual champions to a team or group. This is a concept not recommended in the bundle nor present in any quality improvement practices we are aware of. This transition period may provide interesting opportunities for further study or intervention moving forward.

Overall, the goals of AIM closely align with the concept of an LHS: to efficiently deliver best care practices and generate and apply new knowledge to improve health. Implementation stakeholders have invested significant time and energy towards the goal of creating learning communities, and this dissertation provides a unique evaluation of what has been learned so far in this process.

## Opportunities for Further Research

There are several gaps in our knowledge of the implementation process that follow from our findings and would benefit from further research, including evaluation to extend and further test the recommendations we have presented throughout.

First, the work in Chapter Three treats implementation as a binary option: either implementation is occurring or not occurring at a certain point in time. In practice however, the speed of implementation changes over time, and stops and starts have been documented across AIM-participating hospitals. In addition, the speed of implementation may be tied to the order of elements implemented, which have not yet been well-documented. Further analyses would seek to accurately measure the specific order of implementation practices at specific timepoints and use these variables to identify drivers of performance over time. In addition, detailed measurement of these elements over time and their relationship to patient outcomes or implementation performance may be key indicators to optimize hospital engagement and recruitment activities.

Second, SMM without transfusion was chosen as our primary outcome, selected based on the latest recommendations from the Health Resources and Services Administration, enabling states to make comparisons to national and other state data. This choice was justified in Chapter Two, however, it's worth noting that it differs from previous studies that have used blood transfusion or other patient outcomes as a primary outcome. There is agreement that SMM is an important outcome that merits further study, as it is measured and defined inconsistently across studies utilizing administrative claims and/or birth certificate data. In the case of blood measurement or transfusion, variation in methods of quantification have been well-documented, and indeed were significant barriers to quantitative blood loss implementation as part of the bundle found in Chapter Four. To address these limitations, further research should investigate the impact of implementation on other related or otherwise unrelated patient outcomes. Additionally, longitudinal measurement of individual and team factors such as attitudes, motivation, communication, and workplace culture may be important to understand the "unintended" impacts on stakeholders. These effects were also captured

in Chapter Four and deserve further investigation. Overall, the most accurate and appropriate way to measure the impact of implementation on patients, stakeholders, and systems remains unclear. The results presented here aid in the optimization of these measures and present many opportunities for future research.

Third, the term “implementation performance” has been used throughout this dissertation, however, this term has yet to be defined specifically in any context. This is a critical term to define for a given individual, team, or hospital, yet it’s inherently complicated when discussing integration of evidence-based practices like the bundle. For some, successful implementation may be achieved by “checking boxes”, and to others achievement looks like practices becoming so integrated that they become second nature. These are just a few examples from interview respondents in Chapter Four, when asked to provide their own definition of what “implementation success.” The results of this work begin to point to certain elements that define performance, and these data provide a perfect starting point for further research in this area.

Fourth, this dissertation has approached studying implementation experiences from the provider perspective, however, there may be much to learn from patients. Chapter One discussed racial disparities in reproductive health stemming from factors such as limited access to providers and hospitals, provider biases, and failure of the health care system to listen to African American women’s health concerns. The impact of bundle implementation on these factors and subsequently disparities in patient outcomes is a critical opportunity for further research. Our interviews in Chapter Four rarely mentioned patient perspectives, however, building patient awareness and involvement in these initiatives was seen as a very positive thing. Further research should seek to understand the patient experience of hemorrhage among bundle-participating hospitals and evaluate opportunities for engagement.

## CONCLUSION

Since 2016, over 80 hospitals in Michigan participated in the implementation of the Alliance for Innovation on Maternal Health's obstetric hemorrhage patient safety bundle – addressing the leading and most preventable cause of SMM in the United States. The work presented in this dissertation assesses patient outcomes and factors that influenced the bundle implementation process across Michigan hospitals. An explanatory sequential mixed methods design informed by implementation science using the Tailored Implementation for Chronic Disease conceptual framework served as the basis for this retrospective analysis of bundle implementation in Michigan hospitals between 2012 and 2019. Variation in, and factors associated with SMM were quantitatively evaluated across Michigan hospitals using the Michigan Inpatient Database and linked Birth Certificate files (Chapter Three). A qualitative study using in-depth semi-structured interviews with implementation stakeholders was then conducted to assess implementation experiences and context at select sites (Chapter Four). Finally, factors contributing to implementation performance across hospitals with below- and above-average SMM rates were examined by synthesizing quantitative and qualitative data (Chapter Five).

This dissertation research has many firsts. Chapter Three demonstrates one of the first rigorous quantitative evaluations of patient outcomes surrounding the AIM obstetric hemorrhage bundle at the state level. In Chapter Four, we performed one of the first highly systematic and organized assessments of bundle implementation experiences in the setting of labor and delivery based on the TICD, which was specifically developed to guide efforts to improve care. Importantly, we also expanded upon the framework's domains and constructs to identify novel codes and themes important to understanding bundle implementation. And the study in Chapter Five is one of the first mixed methods analyses of patient outcomes and provider

experiences regarding bundle implementation to use the TICD for guiding data collection, analysis, and interpretation in the context of systems-level implementation. The results of these analyses inform the understanding of bundle implementation outcomes, processes, and experiences across diverse hospitals and provides novel and critical information to shape future bundle implementation planning and strategies. The methodology outlined in this dissertation and the subsequent results may be of significant interest to obstetric hemorrhage bundle implementation initiatives in other states. Subsequent work in this area should address the many gaps identified in the course of this research, including but not limited to understanding the details of implementation processes, the evaluation of the impact of implementation on racial disparities in reproductive health outcomes, the development definitions for implementation success.

It is important to remember that the results and subsequent recommendations herein transcend the academic – they can change and save lives. While some of the barriers to implementation identified require significant investments of time and funding, individuals and teams can begin to make small changes immediately. I hope the contents of this dissertation have motivated you to look at the people and spaces around you - family, friends, home, work, school, community - and identify opportunities to improve care for persons of reproductive age, in whatever capacity you are able.

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