

# Enhancing Obstetric Safety Through Best Practices

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## Abstract

The pregnancy-related mortality rate in the US exceeds that of other developed nations and is marked by significant disparities in outcome by race. This article reviews the evidence supporting the implementation of a variety of best practices designed to reduce maternal mortality. Evidence from maternal mortality review committees suggests that delays in diagnosis, delays in initiation of treatment and use of ineffective treatments contribute to preventable cases of maternal death. We review several protocols for maternal warning signs that have been used successfully to facilitate early identification and intervention. Care bundles, a collection of best practices, have been developed and implemented to address several maternal emergencies. We review the evidence that supports reduction in adverse outcomes with consistent implementation of obstetric hemorrhage and severe hypertension bundles in a collaborative, team-based setting. The article concludes with suggestions for the future.

**Keywords:** MEWT, obstetric care bundle, obstetric safety, maternal mortality, severe maternal morbidity

## Background

**T**HE TURN OF this century brought a significant transition in health care delivery through the creation of care bundles. These bundles afforded providers with opportunities to develop and apply robust evidenced-based medicine and build resources to perform quality and performance assessments to ensure the provision of a minimum standard of care for all patients. The Institute for Healthcare Improvement (IHI) defines an evidence-based care bundle as a “structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices that, when performed collectively and reliably, have been proven to improve patient outcomes.”<sup>1</sup>

Over the past 2 decades, care bundles have evolved into an important tool in implementing interventions proven to prevent morbidity and mortality, particularly in the intensive care unit (ICU) environment.<sup>2</sup> Recently, these efforts have expanded into obstetrical care, with the National Partnership for Maternal Safety establishing several patient safety bundles that address the leading causes of preventable maternal morbidity

and mortality (MMM).<sup>3</sup> The goal of the bundles is not to develop new guidelines, but rather to organize existing information and tools “in a manner that is easily, consistently, and universally implemented.”<sup>3</sup>

Since 2013, the Council on Patient Safety in Women’s Health Care and the Alliance for Innovation on Maternal Health (AIM) Program developed 10 patient safety bundles targeting maternal health—including maternal venous thromboembolism, obstetric hemorrhage, and severe hypertension in pregnancy<sup>4</sup>; postpartum care basics for maternal safety; and safe reduction of primary cesarean birth.<sup>5</sup>

The Joint Commission, the agency responsible for hospital accreditation in the United States, also established a Perinatal Care Services Certification for health care settings focused on prenatal and postpartum care through a series of core measures using performance measurements that contain established perinatal care bundle elements.<sup>6</sup>

According to the IHI, bundles contribute to improved outcomes by ensuring reliably delivered evidence-based care; promoting team collaboration; and enabling organizations and

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health care teams to systematically approach a redesign of their processes through bundle implementation to improve the reliability of care processes.<sup>7</sup> Limited research exists to support the claim that improvements in patient safety result directly from the implementation of care bundles.<sup>8</sup>

This article provides a review of evidence supporting the implementation of a variety of tools and care bundles, focusing on identification of maternal early warning signs, obstetric hemorrhage, and severe hypertension.

### Early Warning Sign Tools

A recent report from the Centers for Disease Control and Prevention (CDC) combined data from 14 Maternal Mortality Review Committees (MMRCs) from 2008 to 2017. Across all races or ethnicities, 65.8% of all pregnancy-related deaths were deemed preventable. The preventability ranged from 61.8% for Hispanic women to 63.0% for non-Hispanic Black women and 68.2% for non-Hispanic White women.<sup>9</sup> The MMRCs assessed the contributing factors to each death and identified that delays in both diagnosis and effective treatment accounted for approximately one-third of identified provider-related contributing factors for hemorrhagic deaths and ~20% of identified provider-related contributing factors for deaths resulting from hypertensive diseases.<sup>10</sup>

These data suggest early recognition and intervention represent key components in the prevention of maternal death, thus prompting tool development aimed at identifying maternal early warning signs, which could be applied to promote earlier medical intervention. Despite implementation of early warning systems in other specialties, the physiologic changes occurring throughout pregnancy, childbirth, and the postpartum period—as well as the small number of conditions responsible for most maternal death—required the development of unique systems.

The Maternal Early Warning Trigger (MEWT) tool, a two-tiered tool designed to identify abnormal vital signs and provide evidence-based clinical management actions in response to the trigger, exemplifies such a system.<sup>11</sup> This tool addressed four of the most common causes of MMM: sepsis, cardiopulmonary dysfunction, hypertension–preeclampsia, and hemorrhage. The MEWT was implemented in 6 of 29 hospitals within a large hospital system, and the results were compared with a control population from nonparticipating system hospitals during the same baseline and 13-month study period. During the two study periods, 36,832 deliveries occurred at the pilot sites (24,221 pre-MEWT testing and 12,611 post-MEWT testing) and 146,359 occurred at the control sites (95,718 pre-MEWT testing and 50,641 post-MEWT testing). The use of MEWT resulted in significant reductions in CDC-defined severe maternal morbidity (SMM) ( $p < 0.01$ ) and composite morbidity ( $p < 0.01$ ), whereas ICU admissions remained unchanged. At the control sites, however, the same outcomes remained unchanged between baseline and post-MEWT testing time periods.

Two other commonly used tools include the Modified Early Obstetric Warning System (MEOWS), developed and implemented in the United Kingdom<sup>12</sup> and the Maternal Early Warning Criteria developed by the National Partnership for Maternal Safety.<sup>13</sup>

Successful implementation of the early warnings systems requires administrative and leadership support; dedication of resources; improved coordination between nurses, providers,

and ancillary staff; optimization of information technology; effective education; evaluation of and change in hospital culture and practices; and support in provider decision making. Evolving outcomes data on systems suggest that maternal risk may be reduced. To effectively reduce maternal risk, early warning systems that capture deterioration from a broad range of conditions may be required, in addition to bundles tailored for such specific conditions as hemorrhage, thromboembolism, and hypertension.<sup>14</sup>

Further research is needed to improve predictive models and validate that evidence-based, maternity-specific early warning systems that are implemented in the general maternity population reduce MMM.

### Care Bundles

Some of the challenges facing the implementation of tools aimed at improving maternal outcomes during pregnancy, childbirth, and post partum include the need for coordination and communication among clinical care providers (*e.g.*, nurses, midwives, physicians, ancillary staff, *etc.*). In other specialty areas, the implementation of evidence-based care bundles demonstrates the proven success of standardized, evidence-based clinical practice.

### Obstetric Hemorrhage Bundles

Obstetric hemorrhage is the leading cause of maternal mortality worldwide.<sup>15</sup> In 2018, hemorrhage and placenta previa accounted for 4.6% of U.S. maternal deaths from direct obstetric causes in the United States.<sup>16</sup> Although many hospitals implemented postpartum hemorrhage (PPH) protocols, evidence has not supported that the mere presence of these protocols reduces the overall PPH rate.<sup>17</sup> Proponents of PPH bundles argue that this is related to the lack of protocol implementation, also known as the “implementation gap,” in other conditions.<sup>18,19</sup> Among existing PPH bundles, the California Maternal Quality of Care Collaborative (CMQCC) and AIM PPH bundles have demonstrated the most success.<sup>20</sup> Both bundles focus on four key domains: preparedness (readiness) of units for PPH; recognition of PPH when it occurs; response that includes utilization of a stage-based protocol; and finally, data tracking (reporting) and systems-based learning components.

CMQCC's published data show that PPH bundle implementation resulted in a decrease in blood product use (16.7 units/month preprotocol vs. 6.3 units/month postprotocol,  $p < 0.1$ ) and a 64% decrease in disseminated intravascular coagulation ( $p = 0.06$ ).<sup>21</sup> In the postimplementation phase, more patients were treated successfully in phase 1 of the treatment protocol and did not progress to stage 2 (one-third preprotocol vs. 82% postprotocol,  $p = 0.2$ ). Importantly, the unit staff's (physician and nurse) perception of the response and cohesion of the team also significantly improved ( $p > 0.1$ ). Their bundle implementation model encompassed significant team training and simulation that included bundle components, such as the presence and training on the use of a PPH cart, stratification of hemorrhage risk, quantitative measurement of blood loss, early uterotonic use, and a staged-based response to hemorrhage, including early response from medical staff.

The CMQCC implemented an additional comprehensive toolkit for PPH based on the AIM national hemorrhage safety bundle in 99 hospitals around California, representing 256,541 annual births.<sup>22</sup> They paired 20 nurse and physician

mentors experienced in quality improvement (QI) to provide additional support to small groups of six to eight hospitals by using a modification of the IHI Breakthrough Series Learning Collaborative Model. The composite CDC SMM measure for both the target population of women with hemorrhage and the overall delivery population served as the primary outcome. Hospital engagement and intensity were measured by the rate of bundle element adoption. Hospitals in the collaborative research experienced a 20.8% reduction in SMM compared with a 1.2% reduction in control hospitals ( $p > 0.0001$ ), and those participating in the previous PPH project experienced a 28.6% reduction. In this study, 76% of hospitals reported regular unit-based simulation drills, and 65% reported post-hemorrhage debriefs.

Individual hospital experiences have been varied. For example, the Dignity Health system, with 60,000 annual births and diverse hospital sizes, saw significant improvements in transfusion rates with implementation of a PPH bundle when verifying bundle compliance.<sup>23</sup> The audits included the following: admission PPH risk assessment, blood product crossmatch according to PPH risk, quantitative (not qualitative) blood loss assessment, laboratory results obtained in stages 2 and 3 hemorrhage, more than two uterotonics given without a physician present, and blood product administration per protocol. Each facility's physician and administrative leaders were encouraged to participate in calls and present compliance data. When compliance was less than expected, safety nurses visited the hospitals to provide assistance, including staff education and simulation. The bundle compliance increased from 54% to 80% over this period, during which recognition and correct designation of the stages of hemorrhage also improved and the overall use of blood products decreased (25.9% reduction per 1,000 births in blood product use at 10 months post-implementation).<sup>23</sup> This finding highlights the importance of verification of true implementation and administrative support. Although this group did not specifically comment on the impact of simulation, its contribution to the implementation is notable.

Reversing racial and ethnic disparities remains another critical component for any maternal safety bundle.<sup>24</sup> The CMQCC evaluated its PPH bundle on outcomes stratified by race and ethnicity in a population that was 42% Hispanic, 29% White, 15% Asian, 5% Black, and 7% classified as "other." All populations experienced an overall reduction in SMM during the 6-month period; however, Black women were 23% less likely to experience SMM compared with their baseline rates, which was a larger difference than the overall population after controlling for maternal clinical and socio-demographic factors. Although Black women experienced the greatest reduction, the postintervention rate remained the highest among all racial/ethnic groups (6.9% vs. 5.1%–5.5%). After adjustment for differences in cesarean delivery rates, the racial/ethnic differences in hemorrhage reduction were no longer significant. In addition, anemia was two to six times more likely to occur in Black women than White women and was a strong contributor in transfusion-related morbidity. The authors concluded that reducing variation in clinical care *via* safety bundles improved outcomes overall and reduced racial/ethnic disparities.<sup>24</sup>

The PPH bundles have overall promising results in reducing MMM. The improvement rates noted in some hospitals or states appear to be highly related to bundle

component compliance and the adoption of such factors as mentorship, support from quality team members, and simulation. Future research should identify best strategies for implementation.

### Severe Hypertension Bundles

Hypertensive disorders of pregnancy—including preeclampsia and eclampsia—accounted for 7% of pregnancy-related deaths in the United States during 2011–2016 and also represented a significant disparity (69.8% Black, 43.3% White, and 46.8% Hispanic women).<sup>25</sup> Preeclampsia/eclampsia was the second-leading cause of pregnancy-related deaths in California during a 6-year period (2002–2007).<sup>25</sup> On review of maternal deaths from preeclampsia/eclampsia, the California Pregnancy-Associated Mortality Review found that the chance to alter outcomes was classified as good or strong in 62% of deaths ( $n = 33$  of 53). The greatest QI opportunities were missed diagnosis and ineffective treatment of preeclampsia and related diseases, which occurred in 65% of the cases where women died of preeclampsia/eclampsia sequelae.<sup>26</sup>

The CMQCC developed a toolkit, including the American College of Obstetricians and Gynecologists' severe hypertension treatment guidelines, and collaborated with a group of 23 academic and community institutions to test the toolkit.<sup>27</sup> Before this study, only 41% of sites met the goal of following the treatment guidelines within 1 hour of admission. Treatment recommendations included the use of either intravenous (IV) hydralazine or labetalol, as well as magnesium sulfate, when a patient presented with a sustained blood pressure (BP) of  $\geq 160$  mm Hg systolic and/or  $\geq 110$  mm Hg diastolic. Compliance was assessed with an all-or-nothing metric scoring system based on the number of patients receiving all three components: treatment with IV BP medication within 1 hour of elevated BP, use of magnesium sulfate, and whether the patient received a postpartum follow-up appointment within 2 weeks of discharge. During the 18-month study period, compliance with treatment recommendations increased from 50% to  $>90\%$  ( $p < 0.001$ ); compliance with hydralazine or labetalol use increased by 33.2% from a baseline of 57.1% to 90.3% ( $p < 0.01$ ) during the last 6 months of monitoring; compliance with magnesium sulfate use increased by 10.8% from a baseline of 85.4% to 96.2% ( $p < 0.01$ ); the eclampsia incidence declined by 42.6% ( $1.15 \pm 0.15/1,000$  to  $0.62 \pm 0.09/1,000$  births); and SMM decreased by 16.7% from  $2.4 \pm 0.10\%$  to  $2.0 \pm 0.15\%$  ( $p < 0.01$ ).<sup>27</sup>

The AIM severe hypertension in pregnancy bundle follows the PPH bundle format, with the four key domains—readiness, recognition, response, and reporting.<sup>4</sup> The Illinois Perinatal Quality Collaborative (ILPQC) engaged hospitals in QI work *via* the Severe Maternal Hypertension Initiative, using the AIM bundle as their framework.<sup>28</sup> Of the 120 possible hospital teams, 110 teams (representing more than 95% of births) participated in the statewide initiative. The ILPQC reported a decrease in SMM in state population-level data over the course of the initiative. Of the 9,818 cases of severe maternal hypertension, the percentage of new-onset severe hypertension cases treated within 60 minutes increased from 41.5% (baseline) to 78.9%, and the percentage of hospitals with 75% to 100% of women treated within 60 minutes increased from 14% to 65%. The percentage of cases

receiving preeclampsia education at discharge increased from 37% to 81%, scheduling follow-up appointments within 10 days of discharge increased from 53% to 75%, and debriefing after an event increased from 2% to 44%.<sup>28,29</sup> These results further support that statewide QI efforts—including collaborative learning, rapid response data, and QI support—can reduce hypertension-related maternal morbidity.

### Next Steps

Although maternal health bundles are a newer innovation, efforts to implement bundles to prevent central line-associated bloodstream infections (CLABSI) and ventilator-associated pneumonia were developed by the IHI in early 2001.<sup>7</sup> The lessons learned from the process of wide application of these patient safety bundles can be applied to the ongoing implementation of maternal health bundles.

Experts studying the impact of CLABSI bundles discovered a high variability in adherence to bundle elements and found that the bundle's positive impact is greatly diminished when all elements of the bundle are not followed.<sup>30</sup> The IHI emphasizes that the bundle should be seen as an “all-or-none” measure.<sup>7</sup> Maternal care bundles, such as the AIM bundles, have been designed with the importance of full compliance in mind. The bundle elements are limited in number and realistically can be accomplished in a variety of settings. Smaller hospitals may need to innovate to ensure that practitioners can access all the needed bundle components at all hours of the day. Simulation, as noted in prior examples, can offer a key opportunity to assess bundle implementation and ensure that success in all bundle components is consistently achievable.

The CLABSI bundles were initially thought of as an ICU intervention; however, central line insertion takes place in many clinical environments, including the emergency department (ED), the operating room, or the general floor. If the teaching and resources required for CLABSI bundle implementation are only available in the ICU, non-ICU patients will lack access to this important intervention. This “lesson learned” can be applied to maternal health bundles by ensuring engagement of an interdisciplinary team during implementation. The interdisciplinary maternal health team may include obstetricians, nurse midwives, nurses, and medical technicians, as well as physicians and nurses from additional specialties and departments. In some hospitals, family physicians may perform some or all deliveries, and their engagement would be critical to success. The ILPQC engaged hospitals in QI work *via* the Severe Maternal Hypertension Initiative by using the AIM bundle as their framework.<sup>28</sup> Some bundles may require customization to meet the unique needs of pregnant patients in the ED, but the flexibility of bundles allows local modification by a multidisciplinary care team.

As bundle development increased in other clinical specialties, some bundles provoked physician backlash. Recent additions to the Surviving Sepsis Campaign and the associated sepsis bundles have met significant physician resistance due to concerns about using poor-quality evidence in guideline creation and excessive industry influence over guideline development.<sup>31</sup> To avoid such backlash, maternal health bundles to date represent established national intervention and treatment guidelines accepted by general consensus in the field.<sup>7</sup>

Although it has not yet been accepted as an AIM bundle, a bundle on maternal mental health has been developed by the Council on Patient Safety in Women's Health Care.<sup>32</sup> Given the significant burden that maternal depression and anxiety pose in both morbidity and mortality, this bundle is critical in improving the health of women and is an excellent example of the need for an interdisciplinary approach to women's health. Screening for mental health conditions can be available in numerous health care settings, including in pediatricians' offices, where young mothers may present more frequently with their newborns and young children than they would present for care themselves, as well as in EDs, where patients who otherwise are not routinely engaged with the medical system may present for care. Interventions that allow providers to recognize and respond to the mental health needs of these women, wherever they present for care, can save lives.

Existing maternal care bundles are based on robust evidence and have been shown to reduce MMM when properly implemented. The future impact of maternal health bundles will depend on successful implementation across all care settings, ongoing buy-in from direct care providers, and interdisciplinary adoption of best practices to reach all women.

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