Use of Maternal Early Warning Trigger tool reduces maternal morbidity

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BACKGROUND: Maternal mortality in the United States has increased unabated for the past 20 years. Maternal morbidity is also affecting an increasingly large number of women in the United States. A number of national and state organizations have recommended the use of maternal early warning tools as a method to combat this problem. There are limited data suggesting that the use of these types of clinical assessment tools can reduce maternal morbidity.

OBJECTIVE: We sought to determine if maternal morbidity could be reduced with the implementation of a clinical pathway-specific Maternal Early Warning Trigger (MEWT) tool.

STUDY DESIGN: The tool was developed internally and prospectively implemented as a pilot project in 6 of 29 hospitals within a large hospital system. The primary goal was early assessment and treatment of patients suspected of clinical deterioration. The tool addressed the 4 most common areas of maternal morbidity: sepsis, cardiopulmonary dysfunction, preeclampsia-hypertension, and hemorrhage. To be considered positive, triggers needed to be sustained for >20 minutes and were defined as severe (single abnormal value): maternal heart rate (HR) >130 beats/min (bpm), respiratory rate >30/min, mean arterial pressure <55 mm Hg, oxygen saturation <90%, or nurse concern; or nonsevere (required 2 abnormal values): temperature >38 or <36°C, blood pressure >160/110 or <85/45 mm Hg, HR >110 or <50 bpm, respiratory rate >24 or <10/min, oxygen saturation <93%, fetal HR >160 bpm, altered mental status, or disproportionate pain. Within each group, recommended management or assessment was also provided. Outcome measures were Centers for Disease Control and Prevention (CDC)-defined severe maternal morbidity, composite maternal morbidity, and intensive care unit (ICU) admissions. Two time intervals were used to analyze the effect of the MEWT tool: a 24-month baseline control period and a 13-month MEWT study period. To determine that the findings noted were not simply changes that would have occurred without the utilization of the early warning tool, we also compared a control population from nonpilot sites during the same baseline and 13-month time periods.

RESULTS: There were 36,832 deliveries at the pilot sites (24,221 pre- and 12,611 post-MEWT testing) and 146,359 at the nonpilot sites (95,718 pre- and 50,641 post-MEWT testing) during the 2 study time periods. Use of the MEWT tool resulted in significant reductions in CDC severe maternal morbidity (P < 0.01) and composite morbidity (P < 0.01). ICU admissions were unchanged. At nonpilot sites CDC severe maternal morbidity, composite morbidity, and ICU admissions were unchanged between baseline and the post-MEWT testing time period.

CONCLUSION: The use of the MEWT tool in this study, designed to address 4 of the most common causes of maternal morbidity, as well as provide assessment and management recommendations, resulted in significant improvement in maternal morbidity. The variation in hospital delivery services at the pilot sites suggests that this maternal early warning tool would be suitable for use in the majority of maternity centers in the United States.

Key words: critical vital signs, maternal decompensation, maternal mortality

Introduction

Maternal mortality in the United States has increased unabated for the past 20 years. Correspondingly, there has also been a simultaneous increase in severe maternal morbidity.1 A number of reasons have been cited for the increase in poor maternal outcome, including the rise in the prevalence of comorbid conditions (obesity, hypertension, and diabetes) and the growing cesarean delivery rate.1,2 State and national review of maternal deaths have suggested that significant improvement could have been made in the care provided to many of the women who died, and many of these cases were potentially preventable events.3-5 The increasing rate of maternal mortality and morbidity has gained widespread recognition and a variety of local, state, and national projects have been designed to address the issue.6,7 One of the proposed methods to reduce both maternal mortality and morbidity has been through the use of clinical tools that would allow early recognition of patients who would likely benefit from more aggressive interventions or transfer to a higher level of care.8,9

A number of proposed identification tools have been designed.9-12 Key elements of any proposed tool must include ease of use, the ability to identify relevant clinical markers of patient deterioration,13 and ideally, guidance for management that ultimately can be shown to reduce maternal morbidity. In Great Britain the modified early obstetric warning system (MEOWS) has been proposed and in the United States the National Council for Patient Safety recently proposed the use of the maternal early warning criteria (MERC).9,10 Although the use of these tools is widely supported, there are no uniform criteria for inclusion or what degree of abnormality should be used to trigger more aggressive intervention,
and neither early warning tool was specifically designed to address the 4 most common causes of maternal morbidity (hemorrhage, preeclampsia, sepsis, and cardiovascular dysfunction). Only the MEOWS has been prospectively tested in a single small study. Neither the MEOWS nor the MERC have been evaluated to determine if their use will result in decreased maternal morbidity. The aim of this study was to prospectively evaluate the use of a pathway-specific Maternal Early Warning Trigger (MEWT) tool and determine if its use was associated with a reduction in maternal morbidity.

**Materials and Methods**

The data collected for this study were from an approved ongoing clinical patient safety monitoring program and are part of the hospital system’s continuous quality improvement process. Use of the deidentified data for this study has a system institutional review board exemption. This study was initiated as a quality review project to determine if maternal morbidity might be reduced with the utilization of a maternal early warning tool in a group of maternity patients admitted to the intensive care unit (ICU). Data from the review of the ICU admissions and basic elements of other reported early warning tools provided the basis for the development of the MEWT tool used in this study. The tool was designed to address 4 main etiologies of maternal morbidity: sepsis, cardiovascular dysfunction, severe preeclampsia-hypertension, and severe hemorrhage. We also included recommended clinical evaluation and treatment guidelines related to each of these 4 focus areas (Figure). These recommendations were designed to accomplish 5 main goals. First, expedite treatment for suspected sepsis similar to those recommended in the Surviving Sepsis Campaign in patients with an abnormal temperature and/or triggers. Second, provide basic recommendations for evaluation of patients who likely had cardiovascular dysfunction. Third, ensure early treatment of critically elevated blood pressure (BPs) and use of magnesium sulfate, as outlined by the American Congress of Obstetrics and Gynecology (ACOG) and the California Maternal Quality Care Collaborative (CMQCC). Fourth, suggest that other cardiovascular...
Disorders may be present when BP and other triggers were present. Fifth, alert nursing staff and providers that individuals with abnormal bleeding and abnormal symptoms or vitals signs should be escalated to stage 3 of our system hemorrhage protocol. Final refinement of our tool occurred after review and comment from our system perinatal clinical consensus group.

Like other reported maternal early warning tools, ours had 2 levels of activation. In most settings, the patient was required to have 2 abnormal values and these had to be sustained for >20 minutes to trigger the early warning tool. The 2-trigger, nonsevere activation points included: maternal temperature >38 or <36°C, BP <85 mm Hg systolic or <45 mm Hg diastolic, maternal heart rate (HR) >110 or <50 beats/min (bpm), respiratory rate >24 or <10/min, oxygen saturation <93%, altered mental status, or disproportionate pain. Fetal HR >160 bpm was also used as 1 of the 2 triggers within the infection/sepsis pathway. If there was an abnormal temperature serving as a single trigger, the nurse was instructed to notify the physician, but following the recommended sepsis pathway (antibiotics, blood cultures, and laboratory assessment) was not requested. For the hypertension pathway, physician notification occurred with BP >155 mm Hg systolic or >105 diastolic. Intervention with BP medication, magnesium sulfate, and laboratory assessment occurred at BPs of >160 mm Hg systolic or >110 diastolic mm Hg per national and CMQCC guidelines. The hypertension pathway was not considered activated until there was an elevated BP associated with other symptoms or triggers. Severe or single abnormal triggers included: HR >130 bpm, respiratory rate >30/min, mean arterial pressure <55 mm Hg, oxygen saturation <90%, or if the nurse was clinically uncomfortable with the patient’s status.

Six of 29 maternity centers participated as pilot hospitals. These 6 pilot sites have a combined delivery volume of about 1000 births per month. Data were collected weekly and summarized at the system perinatal safety office. Weekly telephone calls with each site’s perinatal safety nurse and physician “champions” were conducted throughout the project. Primary outcome data were Centers for Disease Control and Prevention (CDC)-defined severe maternal morbidity and composite maternal morbidity. Composite maternal morbidity included CDC criteria with the addition of hemorrhage (>500 mL after vaginal delivery and 1000 mL after cesarean delivery without transfusion), dilation and curettage, or ICU admission. ICU admission was included as a criterion because it was uncertain if this would decrease due to a significant reduction in severe maternal morbidity or increase as an unintended consequence of earlier recognition of potential serious maternal decompensation that may have resulted in more ICU admissions. Other outcome data included the screening rate for each hospital, the screen positive or alert rate for each pathway that was triggered, whether the clinical pathway was followed, and timeliness of provider responses. The rates of maternal sepsis, eclampsia, maternal hemorrhage without transfusion, hemorrhage with transfusion, hysterectomy, and dilation and curettage were also collected.

Data were prospectively collected for 13 months after starting the project (October 2014 through October 2015). Baseline comparative data were derived from the 24-month time period (January 2012 through December 2013). To determine that the findings noted were not simply changes that would have been noted without the utilization of the MEWT tool, we also compared a control population from nonpilot sites during the same 2-year baseline and the 13 months of the MEWT trial. Statistical analysis was carried out using an online tool (Vassarstats.net for comparing 2 independent populations; Richard Lowry, MD, Vassar College, Poughkeepsie, NY). Sensitivity and specificity for pilot site detection of those who required ICU admission was also assessed using an online tool (https://www.medcalc.org; MedCalc, Ostend, Belgium).

Results

During the prospective study period, there were 12,611 deliveries at the MEWT pilot sites and 50,641 at the nonpilot sites. The MEWT sites had delivery volumes that ranged from 860-3000 per year. Non-MEWT site delivery volumes ranged from 150-5000 births annually. During the 2-year baseline there were a total of 119,939 deliveries, 24,221 at the MEWT pilot sites and 95,718 at the nonpilot sites. At the pilot sites MEWT screening occurred in 11,399 (93.4%) of the patients. The frequency of a positive screen was 2.3% (260/11,399). The most common abnormal severe single triggers were maternal HR >130 bpm (0.6% of patients) and the nursing staff being clinically uncomfortable with the patient’s status (0.1% of patients). In the nonsevere group the most common positive findings were maternal HR >110 bpm (1.51% of patients), temperature >38°C (1.5% of patients), fetal HR >160 bpm (0.9% of patients), and respiratory rate >24 or <10/min (0.15% of patients). Low oxygen saturation (<93% and <90%), respiratory rate >30/min, mean arterial pressure <55 mmHg, and altered mental status were seen infrequently (<0.1% of patients). In 82.3% of cases, the physician intervention occurred in <60 minutes. The frequency of physicians following the recommended clinical pathway was high (83.1%).

During the study period there were 47 (3.7/1000 births) patients admitted to the ICU at the MEWT pilot sites. In all, 32 were screened and 15 were not screened. Reasons for no screening included direct ICU transfers from other facilities (n = 2), planned direct ICU admission postdelivery for known medical conditions (n = 3), direct admission from the operating room or immediate post surgery recovery (n = 5), direct admission from the emergency department (n = 4), and 1 patient with hemorrhage was not screened. Of 32 patients who were screened, 31 were screen positive and 1 was screen negative. Of the screened population, the sensitivity for ICU admission was 96.9%, specificity was 99.9%, positive predictive value of 12.0%, and negative predictive value of 99.99%. The distribution of ICU admission was: 38% sepsis, 6% cardiopulmonary dysfunction, 15%
hypertension, 31% hemorrhage, and 6% other (Table 1). During the 13-month pilot time period there was a 5.5% nonsignificant increase in the rate of ICU admission at MEWT pilot sites (P = .8) and an 8% nonsignificant decrease at nonpilot sites (P = .4).

We noted a significant reduction in both CDC-defined severe maternal morbidity (−18.4%, P = .01) and composite maternal morbidity (−13.6%, P = .01) when comparing baseline and after implementation of the MEWT tool. When the same baseline time period and 13-month MEWT trial time were compared at nonpilot sites, there was no change in CDC-defined severe maternal morbidity (P = .6) and no change in the rate of composite morbidity (P = .9). When the 6 MEWT pilot sites were compared to 23 nonpilots sites there was a significantly lower rate of CDC-defined severe maternal morbidity (P < .01) and composite maternal morbidity (P < .01) (Table 2).

Comment
In this study, we demonstrate that the use of a pathway-specific maternal early warning tool results in significant reductions in both severe maternal morbidity and composite maternal morbidity. These data support the recommendations from The Joint Commission,8 the National Partnership in Women’s Health,9 and others10,11,13 that this type of tool should be used to improve timely assessment and treatment of maternity patients. They are also consistent with others that have reported that maternal early warning tools are, or should be, associated with reduced maternal morbidity.10-12 During the study period, following CMQCC17 and ACOG16 guidelines for management of severe BP as well as recommendations for assessment of suspected sepsis was recommended at all 29 hospitals in the hospital system. Detailed compliance monitoring at nonpilot sites was not carried out for either of these recommendations. The presence of these recommendations likely made it more difficult to show a reduction in severe maternal morbidity at pilot sites relative to nonpilot sites. The reduction in severe maternal morbidity we noted at pilot sites, relative to nonpilot sites, may have actually been greater if we compared the pilot sites to other hospitals without those recommendations in place.

### TABLE 1
Percentage of Maternal Early Warning Trigger positive results of each clinical pathway and intensive care unit admission

<table>
<thead>
<tr>
<th>Clinical pathway</th>
<th>Screened positive (n = 260)</th>
<th>ICU admissions (n = 47)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sepsis</td>
<td>71.4%</td>
<td>38%</td>
</tr>
<tr>
<td>Cardiopulmonary</td>
<td>3.1%</td>
<td>6%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>14.6%</td>
<td>15%</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>7.7%</td>
<td>31%</td>
</tr>
<tr>
<td>Multiple pathways</td>
<td>2.3%</td>
<td></td>
</tr>
<tr>
<td>Pathways follow correctly</td>
<td></td>
<td>82.3%</td>
</tr>
</tbody>
</table>

Physician intervention time points, <30 and <60 min 71.9% and 83.1%

ICU, intensive care unit.


### TABLE 2
Results from pre- and post-Maternal Early Warning Trigger time periods

<table>
<thead>
<tr>
<th></th>
<th>Pre-MEWT</th>
<th>Post-MEWT</th>
<th>Trend</th>
<th>P value</th>
<th>Prenonpilot</th>
<th>Postnonpilot</th>
<th>Trend</th>
<th>P value</th>
<th>Postpilot vs postnonpilot</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliveries</td>
<td>24221</td>
<td>12611</td>
<td></td>
<td></td>
<td>95,718</td>
<td>50,641</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDC-SMM</td>
<td>2.0%</td>
<td>1.6%</td>
<td>↓</td>
<td>&lt;.01</td>
<td>2.4%</td>
<td>2.4%</td>
<td>→</td>
<td>.9</td>
<td>&lt;.01</td>
<td></td>
</tr>
<tr>
<td>Composite morbidity</td>
<td>5.9%</td>
<td>5.1%</td>
<td>↓</td>
<td>&lt;.01</td>
<td>6.2%</td>
<td>6.2%</td>
<td>→</td>
<td>.9</td>
<td>&lt;.01</td>
<td></td>
</tr>
<tr>
<td>Eclampsia/1000a</td>
<td>2.0</td>
<td>0.4</td>
<td>↓</td>
<td>&lt;.01</td>
<td>1.1</td>
<td>1.1</td>
<td>→</td>
<td>.9</td>
<td>&lt;.02</td>
<td>.02</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>2.9%</td>
<td>2.7%</td>
<td>↓</td>
<td>.1</td>
<td>3.2%</td>
<td>3.3%</td>
<td>↑</td>
<td>.5</td>
<td>&lt;.01</td>
<td></td>
</tr>
<tr>
<td>Transfusion</td>
<td>0.7%</td>
<td>0.6%</td>
<td>↓</td>
<td>.5</td>
<td>0.7%</td>
<td>0.8%</td>
<td>↑</td>
<td>.01</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>D&amp;C/1000a</td>
<td>4.1</td>
<td>3.0</td>
<td>↓</td>
<td>.1</td>
<td>3.0</td>
<td>3.8</td>
<td>↑</td>
<td>.02</td>
<td>.2</td>
<td></td>
</tr>
<tr>
<td>Hysterectomy/1000a</td>
<td>0.94</td>
<td>0.63</td>
<td>↓</td>
<td>.3</td>
<td>0.95</td>
<td>0.95</td>
<td>↑</td>
<td>.9</td>
<td>.2</td>
<td>.2</td>
</tr>
<tr>
<td>Sepsis/1000a</td>
<td>0.78</td>
<td>1.3</td>
<td>↑</td>
<td>.14</td>
<td>0.26</td>
<td>0.42</td>
<td>↑</td>
<td>.1</td>
<td></td>
<td>.1</td>
</tr>
</tbody>
</table>

CDC, Centers for Disease Control and Prevention; D&C, dilation and curettage; MEWT, Maternal Early Warning Trigger tool; SMM, severe maternal morbidity.

a Rate given per 1000 deliveries.

The MEWT tool used in this study differs from both the MEOWS\textsuperscript{10} and more recent MERC\textsuperscript{9} tools because it was designed to identify 4 of the major causes of maternal morbidity: sepsis, cardiovascular dysfunction, severe pre eclampsia-hypertension, and hemorrhage. Other investigators have shown that these 4 entities make up the majority of obstetrical cases that are ultimately admitted to ICU, as well as having high rates of severe maternal morbidity.\textsuperscript{1,2,20} The other major difference between the MEWT tool used in this study and other early warning tools was the inclusion of recommendations for patient assessment and treatment. The tool also served as a reminder to physicians that there could be overlap in clinical pathways and that assessment of multiple pathways may be needed. Following successful clinical pathways has been shown to decrease death from sepsis,\textsuperscript{1,5} reduce morbidity from severe pre eclampsia,\textsuperscript{2,19} and reduce morbidity from hemorrhage.\textsuperscript{18} Delays in recognition, assessment, and treatment are common themes from maternal mortality reviews and well recognized as significant contributors to maternal morbidity.\textsuperscript{5} By using clinical pathways, the authors expected that the MEWT tool would expedite patient assessment and treatment. Physician assessment and intervention occurred in <60 minutes in >80% of the MEWT-positive patients and the clinical pathway was followed in >80% of cases. This finding is consistent with data suggesting that compliance appears to be critical for observing clinical improvement when utilizing standardized practice recommendations.\textsuperscript{22}

Use of maternal early warning or trigger tools have been suggested by many organizations\textsuperscript{6-12} and prospectively validated in a small study from a single center.\textsuperscript{10} The results presented here add to the prospective data suggesting that recommendations for use of maternal early warning systems are correct. There are major obstacles that will need to be overcome before early warning systems are readily adopted. These include maximizing the ease of use by labor and delivery staff,\textsuperscript{13} the alert frequency must be low enough to prevent “alarm fatigue,” and the positive predictive value must be high enough that clinicians associate value with the alert. In this study, the alert frequency was relatively low, about 1 in 50 patients had a positive screen, and of those with a positive screen, 1 in 8 were admitted to the ICU. Whether these values, or those reported by others,\textsuperscript{10} can be improved will require further prospective testing of any early warning system. It should be noted that the use of ICU admissions might not be a good surrogate marker for complications of obstetrical care. We were not able to associate reduced maternal morbidity with a reduction in ICU admissions. This may have been due to the fact that some patients were treated earlier and not admitted to the ICU while other patients were admitted to the ICU due to their positive MEWT tool results.

The most commonly triggered pathway in this study was infection/sepsis. The sepsis component of the MEWT tool was modeled after recommendations from the Survive Sepsis Campaign\textsuperscript{13} with modifications that were thought to be more reflective of maternal-fetal physiology. Of the patients admitted to the ICU with sepsis, all were screen positive. However, with high sensitivity and specificity, there was relatively poor positive predictive value (7.0%). The incidence of sepsis at pilot sites was higher than at our nonpilot sites suggesting that the sepsis component of the MEWT tool may not be as good when generalized to other centers with lower rates of sepsis. These data are consistent with others who have noted poor performance of maternal sepsis screens.\textsuperscript{23,24} Further refinement of maternal sepsis screening will likely be the best way to improve the performance of any maternal early warning system.

In summary, we noted significant reductions in CDC-defined severe maternal morbidity and composite morbidity with the use of a clinical pathway-specific maternal early warning tool. Three components of the tool that make its use favorable are: (1) the alarm frequency was relatively low; (2) there was a reasonably good predictive value for patients who were ultimately admitted to the ICU; and (3) it was tested in hospitals with delivery volumes that varied between 860-3000, suggesting that this tool would be suited for use in the majority of maternity centers in the United States.

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