

Safe Motherhood Initiative: Early Impact of Severe Hypertension in Pregnancy Bundle Implementation

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Abstract

Objective To describe the implementation and early results of the American College of Obstetricians and Gynecologists District II Safe Motherhood Initiative's *Severe Hypertension in Pregnancy* bundle on the timely treatment of severe hypertension in New York State obstetric hospitals.

Methods This is a retrospective comparative study of two time periods during voluntary implementation of the *Severe Hypertension in Pregnancy* bundle in New York State's obstetric hospitals. The main outcome measure was the administration of an appropriate antihypertensive agent within 1 hour of the second elevated value for all pregnant or postpartum patients with severe hypertension.

Results Of the 117 obstetric hospitals participating in the Safe Motherhood Initiative, 111 (94.9%) submitted data included in this analysis. During the study period, 80 of the 111 (72.0%) hospitals reported implementing the hypertension bundle. Overall, 2.4% of pregnant women were diagnosed with severe hypertension, and 60 to 65% of patients were treated within an hour of the second elevated value. Although not statistically significant, a greater numbers of patients were treated within an hour of the second elevated value in the second time period compared with the first in most obstetric hospitals (overall 64.8 vs. 60.8%; $p = 0.33$).

Conclusion There were increasing numbers of patients receiving timely treatment of severe hypertension during early implementation of a *Severe Hypertension in Pregnancy* bundle in New York State obstetric hospitals. However, bundle implementation requires significant financial and human resources and the long-term impact on maternal morbidity and mortality in our state remains uncertain.

Keywords

- ▶ severe hypertension
- ▶ bundle implementation
- ▶ safe motherhood
- ▶ timely treatment

* Author names for this group are provided in Appendix A.

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Precis There was a tendency toward more timely treatment of severe hypertension following implementation of a *Severe Hypertension in Pregnancy* bundle in New York obstetric hospitals.

Hypertensive disorders during pregnancy constitute a disproportionate share of preventable maternal mortality and morbidity in the United States.^{1,2} In a series of 28 women who sustained a stroke in association with severe preeclampsia or eclampsia, a delay in treating severe hypertension was found to be a contributing factor in several of the cases.³ Optimal, timely, and well-coordinated efforts to address hypertensive emergencies during pregnancy hold the promise of reducing the morbidity and mortality related to this obstetric emergency.

With this in mind, the American College of Obstetricians and Gynecologists (ACOG) District II (New York) developed a *Severe Hypertension in Pregnancy* bundle (“hypertension bundle”) as part of their Safe Motherhood Initiative, a hospital-based obstetric quality improvement program funded by Merck for Mothers.^{4,5} The hypertension bundle includes algorithms, checklists, posters, and other educational materials on the treatment and prevention of hypertensive emergencies in obstetric patients. In addition to severe hypertension, the Safe Motherhood Initiative includes bundles on venous thromboembolism prophylaxis and the management of obstetric hemorrhage. All resources are available online and for download from ACOG District II’s Web site, www.acogny.org, free of charge, as well as through the Safe Motherhood Initiative app.

Between 2013 and 2015, 117 of the 124 hospitals that have labor and delivery services in New York State agreed to adopt and implement the hypertension bundle. A significant aspect of implementation was the collection of data on the management and outcomes of patients who presented with severe hypertension during pregnancy. This paper details a retrospective comparative study of two time periods early during the implementation phase of the hypertension bundle.

Materials and Methods

Following the voluntary implementation of the *Severe Hypertension in Pregnancy* bundle in New York State’s obstetric hospitals, we performed a retrospective comparative study of two time periods: July to August 2015 (first period) and September to November 2015 (second period). Because of variation in the data collection form prior to July 2015, trends in treatment of hypertensive patients could only be analyzed from July onward.

Severe hypertension is defined as a systolic blood pressure ≥ 160 mm Hg or a diastolic blood pressure ≥ 110 mm Hg. The hypertension bundle stipulates that a hypertensive emergency (persistent hypertension) requires treatment if two severe pressures, either systolic or diastolic, are observed more than 15 and less than 60 minutes apart. The severe pressures do not have to be consecutive measure-

ments. The main outcome measure of this comparative study was the administration of specific antihypertensive therapy (labetalol, hydralazine, or oral nifedipine) within 1 hour of the second elevated value for all pregnant or postpartum patients. Secondary outcome measures included maternal death, intracranial hemorrhage, seizures, intensive care unit (ICU) admissions, and transfer to a higher level of care facility.

Participating hospitals were asked to report data on a monthly basis and complete quantitative questionnaires pertaining to the performance of the hypertension bundle within their obstetric unit. Data management included consistency checks to ensure that data being reported were accurate. Hospitals received monthly reports alerting them to any potential inconsistencies in their data and were asked to confirm or update accordingly. For example, if a hospital entered that they had zero hypertensive patients but that four patients were treated, it is likely that they had four patients with severe hypertension and they were asked to correct either the number of hypertensive patients or the number of patients treated. The percentage of deliveries meeting the criteria for a hypertensive emergency was averaged across hospitals stratified by period, according to implementation of the hypertension bundle and by hospital level, as designated through the New York State Department of Health’s perinatal regionalization system. Level 1 hospitals provide care to normal and low-risk pregnant women and newborns and do not operate neonatal ICUs. Level 2 and Level 3 hospitals both operate neonatal ICUs and provide care to patients at low-to-moderate risk to those requiring increasingly complex care, respectively. Regional perinatal centers provide the highest level of care to pregnant women and newborns and operate neonatal ICUs with advanced capabilities.

Trends over time were analyzed within strata, comparing the average percentage of patients with each outcome in the later period (September–November 2015) to the initial period (July–August 2015). Outcomes assessed include the average percentage of patients with a hypertensive emergency, as well as the average percentage of these patients who experienced an intracranial bleed (during pregnancy or postpartum), developed seizures, went to the ICU (or similar unit), and/or were transferred to a higher level of care facility. If a patient had multiple hypertensive emergencies, only data pertaining to the first episode were collected. Furthermore, we examined the rate of treatment with antihypertensive medications (labetalol, hydralazine, or oral nifedipine) within 1 hour of the second elevated blood pressure. Statistical comparisons between time periods were made using the Wald chi-square test.

Finally, the Safe Motherhood Initiative conducted a voluntary qualitative program evaluation survey via a web-based surveying tool in June 2016 following the conclusion of the

first 3 years of the Safe Motherhood Initiative's work. The goal of this survey was twofold: first, to determine, via self-reporting and self-reflection, what stage hospitals were in the implementation process with all three Safe Motherhood Initiative bundles and what challenges they continued to encounter, if any, that may have hindered their implementation efforts; and second, to utilize responses to develop future targeted educational offerings as they relate to the bundles.

Survey questions related to the implementation of the overall bundle, as well as individual components such as the integration of the various checklists and algorithms into routine practice. Open-ended questions regarding the straightforwardness of particular bundle components were also posed. The survey was emailed to all hospital representatives from each of the 117 hospitals several times over the course of summer 2016. More than one response was permitted per hospital since there were multiple individuals, or core team members, who were integral to bundle implementation.

Results

Of the 117 obstetric hospitals participating in ACOG District II's Safe Motherhood Initiative, 111 (94.9%) submitted data included in this analysis. During the study period, 80 of the 111 (72.0%) hospitals reported implementing the hypertension bundle. Overall, 2.4% of pregnant women were diagnosed with severe hypertension, and no difference in this proportion was noted between the two time periods ($p = 0.97$). As expected, a higher proportion of women with severe hypertension were cared for at regional perinatal centers as compared with Level 1, Level 2, and Level 3 hospitals (►Fig. 1).

Maternal deaths related to hypertension were rare, with no deaths in the first period and two in the second period—one of which occurred in a Level 3 hospital and one in a regional perinatal center ($p = 0.34$). This represented a maternal mortality rate related to hypertension of 2.4 per 100,000 live births during the study period. Level 1 hospitals that did not implement the hypertension bundle reported the highest proportion of patients with severe hypertension that experienced an

intracranial bleed during pregnancy (2%). However, this was not significant in comparison to hospitals that did implement the bundle ($p = 0.88$). Similarly, regional perinatal centers that did not implement the bundle reported the highest proportion of intracranial hemorrhages during the 6-week postpartum period (0.9%), though again this was not significant in comparison to the hospitals that did implement ($p = 0.42$). While the overall proportion of patients with persistent hypertension who experienced seizures was relatively stable in the first and second periods, at 1.5 and 1.2%, respectively ($p = 0.74$), there was a higher proportion of deliveries with seizures reported in Level 1 hospitals regardless of bundle implementation (4.5 vs. 4.0% with and without implementation, respectively; $p = 0.80$) (►Fig. 2). There was a tendency for more ICU admissions to occur because of persistent hypertension-related indications in the second period, as compared with the first (3 vs. 1.3%, respectively; $p = 0.12$) (►Fig. 3). Similarly, a greater proportion of patients with severe hypertension were transferred to a higher level of care in the second period, as compared with the first (1.9 vs. 2.2%; $p = 0.82$). The difference was most evident in Level 1 hospitals that had implemented the hypertension bundle, increasing from 2.3 to 5.0% ($p = 0.48$).

Although 60 to 65% of patients with persistent hypertension were treated within 1 hour of the second elevated value, there was a tendency for greater numbers of patients being treated in a timely fashion in the second time period compared with the first (64.8 vs. 60.8%; $p = 0.33$). While not statistically significant, this was observed across most levels of care hospitals regardless of bundle implementation (►Fig. 4). Of those women with persistent hypertension that were not treated, over half had another hypertensive emergency (54.5% in first period vs. 57.6% in second period; $p = 0.46$). This risk for another hypertensive episode among untreated patients remained substantial in all hospitals (►Fig. 5).

Finally, hospitals were surveyed about which elements of the bundles were implemented at their institution (►Fig. 6). Responses were received from 45 of the 117 (38%) participating hospitals, and in some cases, there was more than one response per hospital ($n = 54$). Of the respondents, 41% were

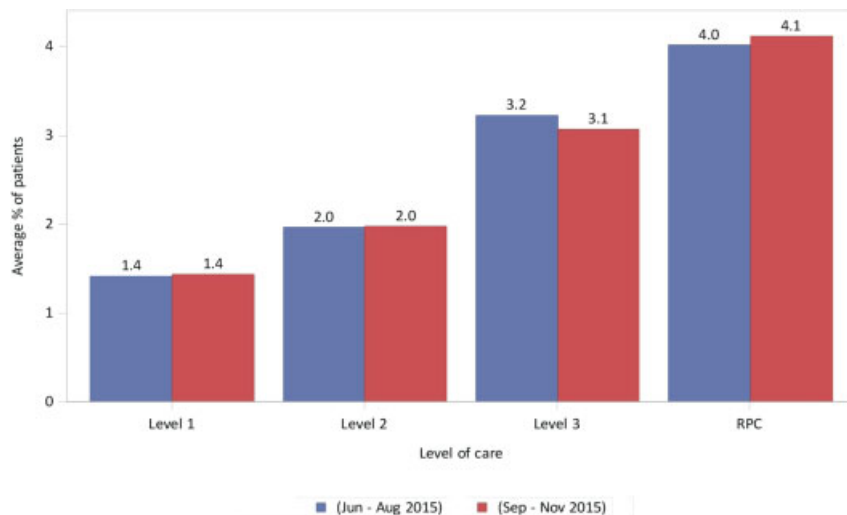


Fig. 1 Proportion of patients with severe hypertension in New York State obstetric hospitals by level of care between the two time periods.

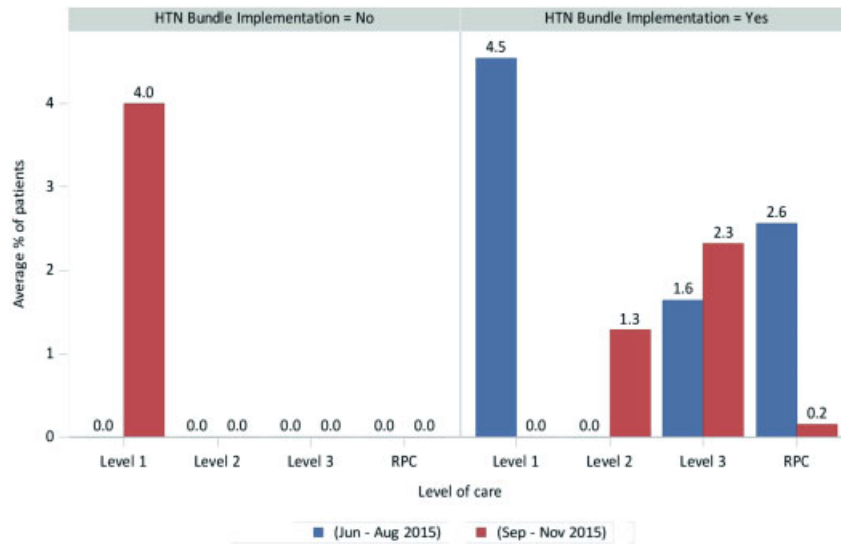


Fig. 2 Proportion of patients with severe hypertension that developed seizures, stratified by bundle implementation, at New York State obstetrics hospitals by level of care between the two time periods.

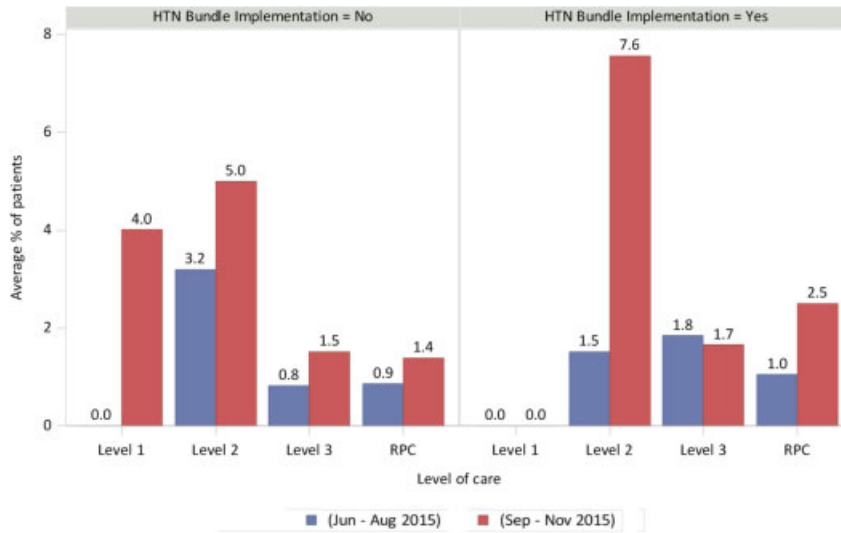


Fig. 3 Proportion of patients with severe hypertension that were admitted to the ICU or similar unit, stratified by bundle implementation, at New York State obstetrics hospitals by level of care between the two time periods.

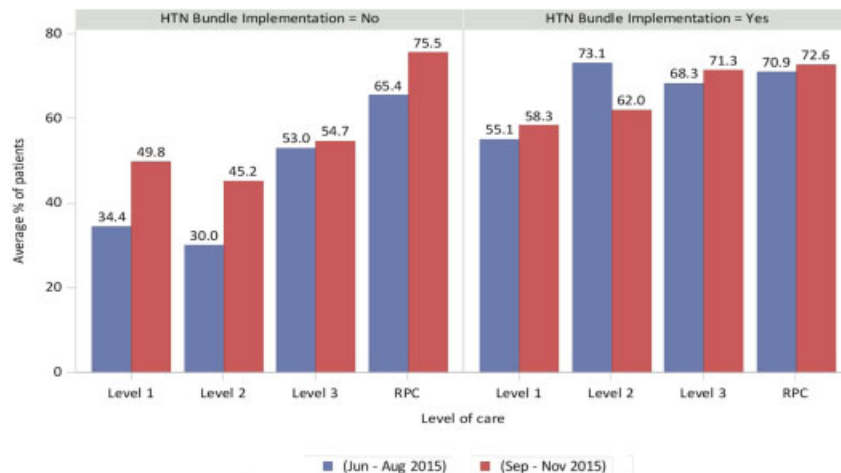


Fig. 4 Proportion of patients with severe hypertension that were treated within 1 hour of the second elevated value, stratified by bundle implementation, at New York State obstetrics hospitals by level of care between the two time periods.

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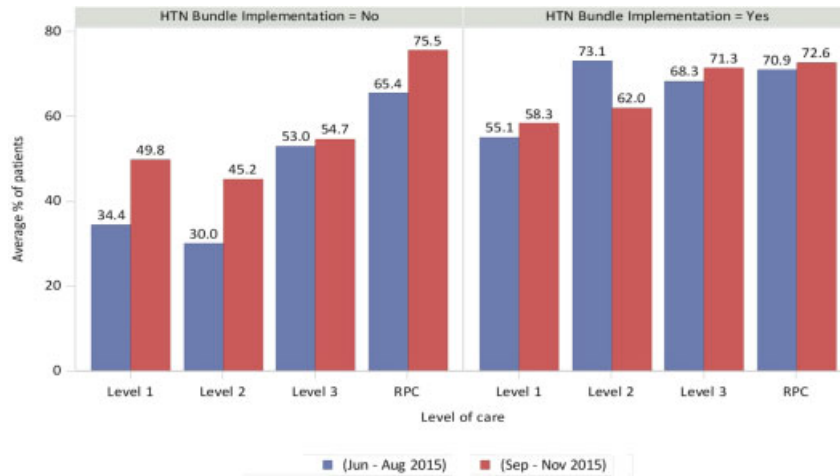


Fig. 5 Proportion of patients with severe hypertension that were not treated and had another episode of severe hypertension, stratified by bundle implementation, at New York State obstetrics hospitals by level of care between the two time periods.

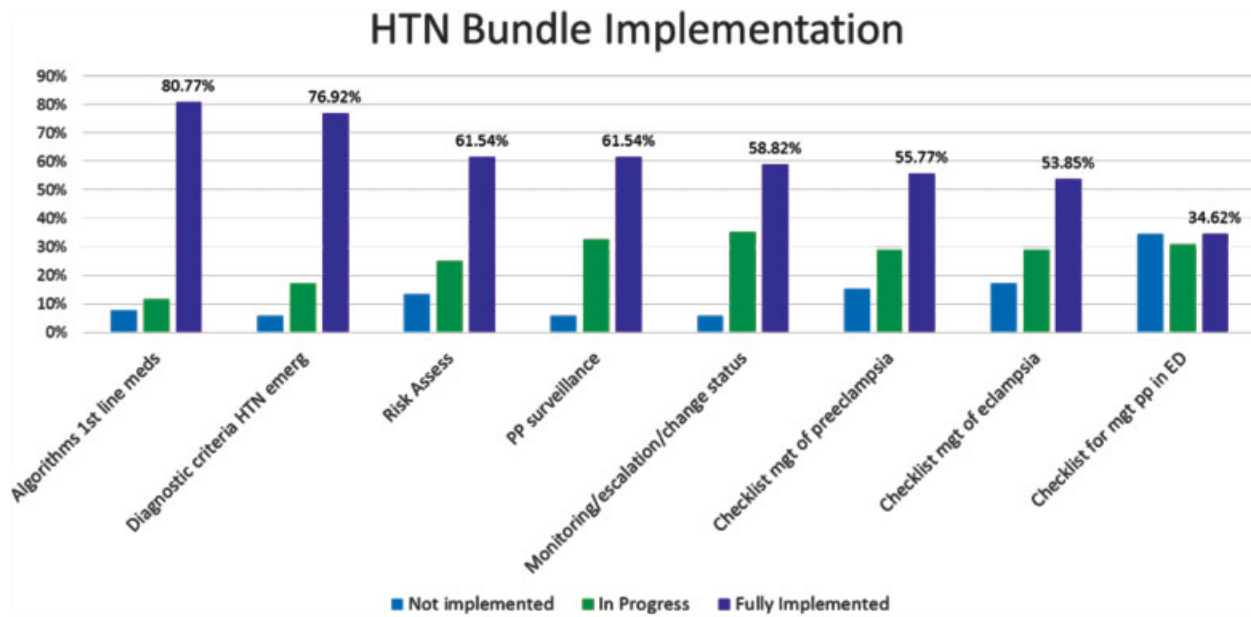


Fig. 6 Implementation of various elements of the *Severe Hypertension in Pregnancy* bundle by participating New York State obstetric hospitals.

from Level 1 hospitals, 24% from Level 2, 17% from Level 3, and 18% from regional perinatal centers. Overall, 63% indicated full implementation of the hypertension bundle; 32% acknowledged they were still in progress; and 5% indicated they had not implemented the bundle at all. Hospitals reported being most successful in implementing the algorithms for first-line treatment of hypertensive emergencies (80%) and standardizing the diagnostic criteria for a hypertensive emergency (77%). They reported the least amount of success with implementing checklists for the management of preeclampsia and its complications, especially in their emergency departments (35%).

Discussion

Despite numerous scientific advances and the availability of high-quality obstetric care, the United States has experi-

enced a rise in maternal mortality of almost 3% since 2000, as compared with a decrease in many countries throughout the world.⁶ New York State's data are equally disturbing with a maternal mortality rate of 29.2 per 100,000 live births in 2008.⁷ From 2006 to 2008, there were 26 maternal deaths due to complications of hypertension, accounting for 23% of all pregnancy-related deaths in the state.⁷

ACOG District II's Safe Motherhood Initiative was cultivated by key stakeholders in response to this potentially preventable crisis and was remarkably successful in that over 90% of New York's obstetric hospitals actively engaged in the process.^{4,8} Development of the various elements of the *Severe Hypertension in Pregnancy* bundle was time-consuming and required significant financial and human resources to complete. From 2013 to 2015, quarterly meetings were held at various locations across New York State to exchange information and ideas, establishing an expanded

communication network among the obstetric hospitals to address challenges in patient care, bundle implementation, and collection of outcome measures.⁸

While hypertensive disorders of pregnancy affect up to 10% of women, the proportion that develop severe-range blood pressures has not been firmly established. In our study, 2.4% of pregnant women were diagnosed with severe hypertension with no significant difference between the two time periods. Early implementation of the *Severe Hypertension in Pregnancy* bundle was not associated with significant changes in outcome measures such as maternal mortality, intracranial hemorrhage, or seizure activity. This was not unexpected given the short time frame of the study and the low incidence of serious adverse events. However, several positive observations between the first and second study periods were made. First, there was a tendency for more ICU admissions to occur because of persistent hypertension-related indications in the second period, as compared with the first. Second, a greater proportion of patients with severe hypertension were transferred to a higher level of care in the second period, as compared with the first, and this difference was most evident in Level 1 hospitals that had implemented the hypertension bundle. While transfer to an ICU or a higher level of care hospital is often interpreted as an adverse outcome, this may reflect the recognition of maternal risk with transfer being a safety measure to allow for appropriate surveillance and care. In contrast to policies that regard ICU admissions and transfers to higher level hospitals as adverse outcomes, we consider this an encouraging effect during the early implementation phase of the *Severe Hypertension in Pregnancy* bundle in New York State. Finally, it was reassuring to observe a higher proportion of patients with persistent, severe hypertension being treated within 1 hour in the second period (64.8%) compared with the first (60.8%). Interestingly, this was observed in the majority of hospitals regardless of whether they had implemented the *Severe Hypertension in Pregnancy* bundle. It is possible that just participating in ACOG District II's Safe Motherhood Initiative quarterly meetings resulted in increased awareness, acceptance, and adoption of treatment recommendations. Promising results have subsequently been observed in other states. For example, the Illinois Perinatal Quality Collaborative maternal hypertension initiative reported an increase in the treatment of severe hypertension within 60 minutes from 48% in July 2016 to 74% in April 2017 (<http://ilpqc.org/hypertension>). We also found that there was a risk of a second severe hypertensive episode in over half of patients that were not treated, underlining the significance of timely treatment as an important intervention that has the potential to reduce maternal morbidity and mortality.

Implementation of the Safe Motherhood Initiative bundles required a varied and dynamic approach, which is why ACOG District II conducted onsite hospital visits and grand rounds, and continues to periodically hold collaborative meetings throughout New York State.^{4,8} These vital in-person opportunities enabled the Safe Motherhood Initiative leadership to respond, in real time, to challenges identified at participating hospitals while providing education to multi-

disciplinary groups of physicians and nurses. Many hospitals encountered challenges to bundle implementation due to lack of time and manpower. In our survey of participating hospitals, only 63% had fully implemented the *Severe Hypertension in Pregnancy* bundle. Of the various elements of the bundle, hospitals reported the highest implementation of the diagnostic criteria of a hypertensive emergency and algorithms for the treatment of severe hypertension. This may, in part, be responsible for a greater proportion of women with persistent, severe hypertension receiving treatment within 1 hour in the second study period.

Hospitals reported they were less successful with implementing checklists for the management of preeclampsia and eclampsia, especially in their emergency departments. Explanations included "checklist fatigue" as well as inconsistencies in local, national, and international guidelines for the management of hypertension in pregnancy.⁹⁻¹¹ A lack of hospital manpower to implement all elements of the bundle likely contributed to the focus being on the diagnostic criteria of severe hypertension and its treatment, elements with the greatest potential to decrease maternal morbidity and mortality on the obstetric service.

Hospitals also reported difficulties in retrieving requested outcome measures due to a lack of personnel, noninterfacing electronic medical records and "provider fatigue." Given that hospitals are already required to collect and submit data for multiple organizations, adding to this burden and convincing local hospital leadership that the ACOG District II's Safe Motherhood Initiative was a priority was sometimes challenging. Extracting data points from diverse, noncommunicating medical records was also problematic and, in some cases, documentation of those data points was lacking. For example, in analyzing the data on patients who met criteria for persistent, severe hypertension, but were not treated, reasons for withholding drug therapy were frequently not found despite Safe Motherhood Initiative's emphasis on physician and nursing documentation. As New York State obstetric hospitals grapple with finite resources, clinician burnout, and dwindling manpower, it is critical to address the lack of inter- and intrahospital alignment of priorities, as it translates into major obstacles for effective bundle adoption.

The observations of this study are limited by its short time frame, comparing two consecutive periods during early implementation of the *Severe Hypertension in Pregnancy* bundle, and the rarity of adverse outcomes such as maternal death, eclampsia, and intracranial hemorrhage during the 6-month study period. Despite our inability to show statistically significant improvement in our outcomes, there was real value derived from ACOG District II's Safe Motherhood Initiative program, focusing the attention of providers across professional specialties, patient safety staff, hospital administration, and policymakers on the leading causes of maternal mortality in New York State. The early findings and challenges of this initiative support a multiinstitutional, multiyear, and, likely, multistate partnership to establish statistical significance for outcome measures resulting from implementation of a *Severe Hypertension in Pregnancy* bundle, ideally nationwide.¹²

In recent years, there have been repeated calls to action to improve maternal outcomes and ACOG District II responded with its Safe Motherhood Initiative, a quality improvement program to reduce preventable pregnancy-related deaths from causes such as hypertension.^{13–15} During the early implementation phase of the *Severe Hypertension in Pregnancy* bundle, there were encouraging reports of more timely treatment of severe hypertension in the majority of participating New York State obstetric hospitals. However, state-wide bundle implementation and sustainability require significant financial and human resources and its long-term impact on maternal morbidity and mortality in our state remains uncertain. While the preliminary observations of this study are promising, there is significant work still to be done to decrease our nation's maternal mortality from hypertension and its complications.

Note

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Conflict of Interest

None.

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Appendix A

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