OBSTETRICS

Reduction of severe maternal morbidity from hemorrhage using a state perinatal quality collaborative

Elliott K. Main, MD; Valerie Cape, BA; Anisha Abreo, MPH; Julie Vasher, DNP, RNC-OB, CNS; Amanda Woods, MA; Andrew Carpenter, BA; Jeffrey B. Gould, MD, MPH

BACKGROUND: Obstetric hemorrhage is the leading cause of severe maternal morbidity and of preventable maternal mortality in the United States. The California Maternal Quality Care Collaborative developed a comprehensive quality improvement tool kit for hemorrhage based on the national patient safety bundle for obstetric hemorrhage and noted promising results in pilot implementation projects.

OBJECTIVE: We sought to determine whether these safety tools can be scaled up to reduce severe maternal morbidity in women with obstetric hemorrhage using a large maternal quality collaborative.

STUDY DESIGN: We report on 99 collaborative hospitals (256,541 annual births) using a before-and-after model with 48 noncollaborative comparison hospitals (81,089 annual births) used to detect any systemic trends. Both groups participated in the California Maternal Data Center providing baseline and rapid-cycle data. Baseline period was the 48 months from January 2011 through December 2014. The collaborative started in January 2015 and the postintervention period was the 6 months from October 2015 through March 2016. We modified the Institute for Healthcare Improvement collaborative model for achieving breakthrough improvement to include the mentor model whereby 20 pairs of nurse and physician mentors experienced in quality improvement gave additional support to small groups of 6-8 hospitals. The national hemorrhage safety bundle served as the template for quality improvement action. The main outcome measurement was the composite Centers for Disease Control and Prevention severe maternal morbidity measure, for both the target population of women with hemorrhage and the overall delivery population. The rate of adoption of bundle elements was used as an indicator of hospital engagement and intensity.

RESULTS: Compared to baseline period, women with hemorrhage in collaborative hospitals experienced a 20.8% reduction in severe maternal morbidity while women in comparison hospitals had a 1.2% reduction ($P < .0001$). Women in hospitals with prior hemorrhage collaborative experience experienced an even larger 28.6% reduction. Fewer mothers with transfusions accounted for two thirds of the reduction in collaborative hospitals and fewer procedures and medical complications, the remainder. The rate of severe maternal morbidity among all women in collaborative hospitals was 11.7% lower and women in hospitals with prior hemorrhage collaborative experience had a 17.5% reduction. Improved outcomes for women were noted in all hospital types (regional, medium, small, health maintenance organization, and nonhealth maintenance organization). Overall, 54% of hospitals completed 14 of 17 bundle elements, 76% reported regular unit-based drills, and 65% reported regular posthemorrhage debriefs. Higher rate of bundle adoption was associated with improvement of maternal morbidity only in hospitals with high initial rates of severe maternal morbidity.

CONCLUSION: We used an innovative collaborative quality improvement approach (mentor model) to scale up implementation of the national hemorrhage bundle. Participation in the collaborative was strongly associated with reductions in severe maternal morbidity among hemorrhage patients. Women in hospitals in their second collaborative had an even greater reduction in morbidity than those approaching the bundle for the first time, reinforcing the concept that quality improvement is a long-term and cumulative process.

Key words: hemorrhage, maternal morbidity, outcomes, quality collaboratives, quality improvement, safety, safety bundles

Introduction

Obstetric hemorrhage is the most common cause of maternal mortality in the world[1] and remains the cause of maternal mortality in the United States that has the greatest chance of preventability.[2,3] Recent evidence indicates that the rate of obstetric hemorrhage is increasing in the United States[4] and hemorrhage is by far the most frequent cause of severe maternal morbidity.[5,6] Therefore, it has been the focus of worldwide research to find new treatments. But perhaps more importantly, there has also been an effort to better establish, disseminate, and implement a structured team approach for the care of a mother with hemorrhage. In California, a multidisciplinary task force developed a quality improvement tool kit of best practices and implementation strategies.[7] This approach has been shown to be of benefit in individual hospitals[8] and a health system[9] and was one of the foundations for the National Partnership for Maternal Safety Consensus Bundle for Obstetric Hemorrhage.[10] In the current project we seek to determine if this approach can reduce severe maternal morbidity from obstetric hemorrhage when scaled up to include >100 hospitals with a broad range of sizes and affiliations that collectively care for >250,000 births each year. The project aims to improve response to obstetric hemorrhage so that fewer mothers (both those with hemorrhage and overall) experience transfusions, major procedures, or serious medical complications.

Materials and Methods

Our study plan, the analysis, and this report were designed following the SQUIRE 2.0 standards for quality

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improvement research.[11] For context, the California Maternal Quality Care Collaborative (CMQCC) is a multidisciplinary multistakeholder quality collaborative based at Stanford University since 2006. CMQCC has a long track record of developing quality improvement tool kits comprising best practices, educational tools, and sample protocols, policies, and other implementation aides. Each tool kit was followed by ≥1 multihospital quality collaboratives to test the recommendations and materials. The CMQCC obstetric hemorrhage tool kit was first developed in 2010 and updated in 2015.[7] Two learning collaboratives with 25-30 volunteer California hospitals were undertaken in 2011 and 2013.[12] Subsequent key informant interviews with participants[13] were used to design this statewide implementation project. The collaborative content followed the organization of the National Partnership for Maternal Safety Consensus Bundle for Obstetric Hemorrhage[10] with 4 domains (readiness, recognition and prevention, response, reporting/systems improvement). Each of these domains has a series of recommended bundle elements.

The California Partnership for Maternal Safety (CPMS) collaborative was established by CMQCC, in partnership and collaboration with the California Hospital Association/Hospital Quality Institute, the California district of the American Congress of Obstetricians and Gynecologists, and the California section of the Association of Women's Health, Obstetric and Neonatal Nurses. Invitations to participate in the state quality collaborative to reduce maternal morbidity were sent by each partner to all 245 California hospitals with maternity services. The CPMS collaborative began in January 2015 and lasted for 18 months. In all, 126 hospitals joined the collaborative in a staggered manner over the first 6 months. Of these hospitals, 99 participated in the California Maternal Data Center and this report will focus on these. The Figure describes the stages of hospital participation and analysis. The first year of each hospital's participation was focused on obstetric hemorrhage. Baseline outcome data were collected for the 48 months from January 2011 through December 2014. The postintervention period was considered the last 6 months of the project from October 2015 through March 2016.

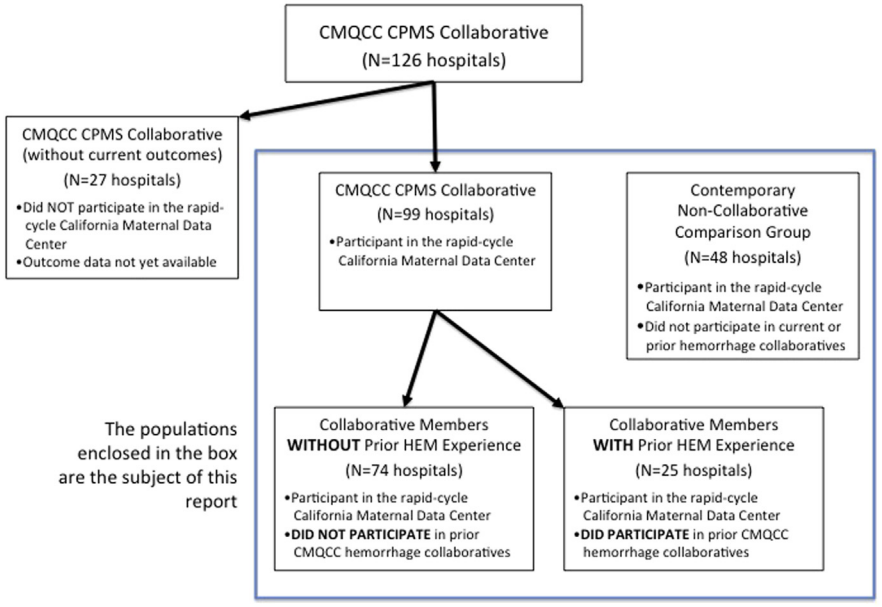
The implementation strategy was similar to our earlier multihospital quality collaboratives and was based on the Institute for Healthcare Improvement (IHI) collaborative model for achieving breakthrough improvement that emphasizes data-driven Plan-Do-Study-Act cycles, community of learning, at least 2 all-participant face-to-face meetings, and monthly check-in telephone calls.[14] We found in our earlier experience with this model that as the number of participating hospitals increased >20 it was increasingly difficult to provide individual attention and the monthly telephone calls became less productive. To scale up to >100 hospitals while still retaining the key attributes of the breakthrough series approach, we used a modified approach. This was the mentor model wherein a physician and nurse pair with maternal quality improvement experience were matched with groups of 5-8 hospitals. The hospital groups were often geographic or system based. The mentors were not from the facilities they supported and served as facilitators leading the monthly telephone calls, providing small group leadership and personal accountability. A CMQCC staff member also supported the mentor groups and attended all telephone calls to coordinate and share lessons and ideas from all the groups. In-person full-day meetings for learning and sharing involving all hospital teams were held toward the beginning and the end of the project. Additionally, hospitals were encouraged to share resources and discussion on a collaborative electronic mailist list/resource sharing service.

A key feature of the collaborative was the use of the CMQCC Maternal Data Center for data collection of structure, process, and outcome measures. The maternal data center is a rapid-cycle system that minimizes data collection burden, designed in partnership with state agencies. The data center receives and automatically links birth certificate and hospital discharge diagnosis data files on a monthly basis, 45 days after the end of every month. The data center was used to: (1) collect outcome measures, including a baseline of 48 months; (2) provide a user-friendly interface for structure and process measure collection; and (3) display monthly progress against others in the collaborative. During this study, 147 California hospitals were actively submitting monthly data to the maternal data center. In all, 99 were in the CPMS collaborative and 48 were not. Given long delays and difficulties in data collection among the 25 CPMS collaborative member hospitals not actively participating in the maternal data center, this report is based solely on those 147 hospitals actively reporting (Figure). An important role for the 48 noncollaborative comparison hospitals was to identify whether there were any widespread external trends that could account for changes in severe maternal morbidity.

Outcome measures were designed to be collected automatically using the 2 linked administrative data sets for all hospitals. This allowed for simultaneous and prospective collection of data from the noncollaborative comparison hospitals. A collaborative-specific interface was created in the maternal data center to allow hospital teams to easily enter dates for bundle completion and process measures. In addition, hospital teams could follow their individual progress and compare to other deidentified hospitals in the collaborative. Hospitals were divided for an additional analysis into those that had participated in an earlier hemorrhage CMQCC and those that had not.

We had extensive prior experience with validation of the Centers for Disease Control and Prevention (CDC) measure of severe maternal morbidity among California hospitals[15] and its use for quality improvement projects.[16] This measure is a collection of medical and surgical diagnosis and procedure codes that had an excess association with maternal death (Table 1). We also collaborated with the CDC to revise the definition of severe maternal morbidity

FIGURE
Study flow chart: data analysis pathways



Study flow chart for hemorrhage (HEM) California Maternal Quality Care Collaborative (CMQCC) California Partnership for Maternal Safety (CPMS).

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to include *International Statistical Classification of Diseases, 10th Revision* diagnosis and procedure codes. In that project, preliminary analysis indicated that same-hospital rates of severe maternal morbidity were similar before and after the code transition.

For this collaborative, the main outcome measure was the rate of severe maternal morbidity among our target population: those patients who had a diagnosis of obstetric hemorrhage. A secondary outcome was the rate of severe maternal morbidity among all maternity patients. Obstetric hemorrhage was defined as parturients with *International Statistical Classification of Diseases* versions 9 and 10 diagnosis codes for antepartum or postpartum hemorrhage, placenta previa, abruption placentae, or the procedure code for transfusion. A common issue with administrative data in maternity hospitalizations is undercoding. In our earlier hemorrhage collaboratives we noted that there was a large number of women who received transfusions without a diagnosis code for obstetric hemorrhage. Case reviews found that most of these cases were related to acute blood loss and not preexisting anemia. Therefore, we included in the definition of hemorrhage all parturients who had a procedure code for transfusion without an appropriate hemorrhage diagnosis code unless there was a concurrent diagnosis of sickle cell crisis. We had initially wanted to collect the total number of units of red blood cells transfused to emulate the earlier study of Shields et al[9] but found that most hospitals had significant difficulty in accurately collecting the number of blood units even directly from the blood bank.

Table 2 lists the safety bundle elements used to assess adoption of the bundle. Hospital teams were asked to document the date the bundle element was completed and share with others in their group appropriate protocols and experiences. Progress on bundle adoption was discussed during the monthly mentor telephone check-ins. Additional independent verification of adoption was not performed. Earlier experience indicated that debriefs served as an important feedback loop to support protocol adoption and we initially asked hospital teams to collect the frequency of debriefs following significant hemorrhage. However, this proved challenging given the wide variation in hemorrhage frequency related to hospital size and the logistics of collecting every debrief form so this measure was not uniformly collected. For data accuracy assessments, the rates of hemorrhage and severe maternal morbidity were routinely screened using algorithms for missing values, nonsense values, and outliers. We also tracked the rate of obstetric hemorrhage over time as earlier studies noted an increase in the frequency of coding for hemorrhage with increased surveillance.[9]

To assess whether outcome improvements seen during the collaborative were due to the interventions, we examined whether hospitals that showed improvement had higher rates of bundle element adoption than those that did not show improvement. In all, 25 hospitals had previously participated in 1 of 2 earlier pilot hemorrhage CMQCC. To account for possible confounding we performed a subanalysis of hospitals with and without prior hemorrhage collaborative experience. As the study groups were not randomized, it would be expected that certain hospital characteristics could be overrepresented or underrepresented in the collaborative group. When that was noted, sensitivity analysis was performed by reanalysis once hospitals with that characteristic were removed.

Institutional review board approval was obtained from Stanford University as the study host, and the California Committee for the Protection of Human Subjects for the use of the linked data set. All cases were deidentified fully before clinical data were shared with the study team.

In this before-and-after design, we examined whether the proportion of women with major complications differed in the new time period after the introduction of the hemorrhage quality improvement collaborative. As this is largely a descriptive study, only simple statistics were performed: χ^2 and t tests

TABLE 1
Definitions of severe maternal morbidity (Centers for Disease Control and Prevention) and obstetric hemorrhage

Severe maternal morbidity (CDC)		Obstetric hemorrhage
Diagnoses	Procedures	Diagnoses and procedure
Acute myocardial infarction	Blood transfusion (except for sickle cell disease)	Antepartum hemorrhage
Acute renal failure	Cardio monitoring	Postpartum hemorrhage
Adult respiratory distress syndrome	Conversion of cardiac rhythm	Placenta previa
Amniotic fluid embolism	Hysterectomy	Abruptio placenta
Aneurysm	Operations on heart or pericardium	Blood transfusion (except for sickle cell disease)
Cardiac arrest/ventricular fibrillation	Temporary tracheostomy	
Disseminated intravascular coagulation	Ventilation	
Eclampsia		
Heart failure during procedure or surgery		
Internal injuries of thorax, abdomen, and pelvis		
Intracranial injuries		
Puerperal cerebral vascular disorders		
Pulmonary edema		
Severe anesthesia complications		
Sepsis		
Shock		
Sickle cell anemia with crisis		
Thrombotic embolism		

International Classification of Diseases, Ninth Revision and *International Statistical Classification of Diseases, 10th Revision* codes are available on request and from CDC World Wide Web site: https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html.

CDC, Centers for Disease Control and Prevention.

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were used to assess the significance of rate changes from baseline to intervention periods. All descriptive and statistical analyses were performed using software (SAS, Version 9.3; SAS Institute Inc, Cary, NC).

Results

Table 3 displays hospital characteristics of the 4 study populations described in Table 1: all participating hospitals in the CPMS collaborative; the subsets of those with and without prior hemorrhage collaborative experience; and those in the noncollaborative comparison. While generally comparable, the collaborative group had more hospitals that were under health maintenance organization (HMO) ownership and regional centers comprised a larger proportion of the hospitals with prior hemorrhage collaborative experience. These differences were addressed with sensitivity analyses. The proportions of white and black women were similar but there were more Asians and fewer Hispanic women in the collaborative group of hospitals. Both of those populations historically have similar low rates of severe maternal morbidity so it is unlikely these differences will be meaningful. The proportions of black and non-black women in the collaborative and noncollaborative comparison hospitals remained constant through the study period (data not shown).

Tables 4 and 5 display the main results of the study. Women in hospitals engaged in the hemorrhage CMQCC CPMS experienced a 20.8% reduction in severe maternal morbidity among hemorrhage patients over baseline in a before/after comparison. The second comparison group is women from the 48 California hospitals not participating in the collaborative but for whom we have a complete set of baseline and contemporary outcome data. This group showed a nonsignificant 1.2% reduction over the same time period. We then examined whether prior hemorrhage collaborative experience changed a hospital's response to this collaborative. This subanalysis of the collaborative hospitals is also presented in Table 4. Women in hospitals with prior hemorrhage experience averaged a 28.6% reduction while those without prior experience averaged a 15.4% reduction (both significant changes).

TABLE 2
California Partnership for Maternal Safety collaborative structure measures (N = 17)

Safety bundle elements (dates established or completed were reported)		
Readiness domain	**Recognition and prevention domain**	**Response domain**
Hemorrhage cart/including instruction cards for intrauterine balloons and compression stitches	Assessment of hemorrhage risk (prenatal, admission, and other) (policy with time frames, mechanism for documentation)	Use of unit-standard, stage-based obstetrics hemorrhage emergency management plan with checklists
STAT access to hemorrhage medications (kit or equivalent)	Measurement of cumulative blood loss (formal and as quantitative as possible)	Support program for patients, families, and staff for all significant obstetric hemorrhages
Hemorrhage response team established (anesthesia, blood bank, advanced gynecological surgery, and other services)	Active management of third stage of labor (departmentwide protocol for oxytocin at birth)	Reporting and systems learning domain
Massive transfusion protocols established		Establish culture of huddles to plan for high-risk patients
Emergency release protocol established for O-negative and uncross-matched units of RBC		Postevent debriefing to quickly assess what went well and what could have been improved (agreed upon leader, time frame, with documentation)
Protocol for those who refuse blood products		Multidisciplinary reviews of all serious hemorrhages for system issues
Unit education to protocols		Monitor outcomes and progress in perinatal QI committee
Regular unit-based drills with debriefs for obstetric hemorrhage		

QI, quality improvement; *RBC*, red blood cells; *STAT*, immediate.
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Table 5 shows a similar analysis but this time for severe maternal morbidity excluding transfusion codes among women with an obstetric hemorrhage. The pattern of results is identical to that noted for the original analysis but at rates approximately one third of that for the full measure. This indicates that both transfusions and major medical complications decreased among hemorrhage patients in the collaborative group but not in the noncollaborative comparison group.

The differences in the hospital populations noted in Table 3 prompted us to perform a sensitivity analysis to determine if these facility factors contributed to the improvements noted in the whole population. It could be hypothesized that regional centers and HMO facilities may have greater resources and hence improve at a quicker pace. Results are shown in Table 6. Removal of the 11 regional centers and subsequently the 29 HMO-owned facilities did not change the findings. This suggests that all types of hospitals improved at similar rates. An additional subanalysis found that 13 of 14 (92.8%) hospitals with <1000 annual births showed improvement over baseline, while 68% of 1000-<2000 and 66% of ≥2000 annual birth hospitals showed improvement ($P < .05$ small vs medium and large hospitals).

The rates of severe maternal morbidity among all women giving birth (as opposed to the target population of women with an obstetric hemorrhage) is shown in Table 7. As expected, the rates in the total population are lower and the percent decrease is lower than that for the focused target population of only women with obstetric hemorrhage. However, the same pattern of improvement is noted with greater improvement among women who delivered at collaborative hospitals with prior collaborative experience. Table 7 also presents the actual rates of obstetric hemorrhage as defined in Table 1. The rate of hemorrhage increased among women in collaborative hospitals from 5.9-6.7%, an increase of 13.3%. This may account for a portion of the improvement by "diluting the denominator" if all of the new cases of hemorrhage were mild. However, in recent years, there has been an increase in women with previas, accretes, and long inductions, all strong risk factors for severe hemorrhage. An exploratory analysis of the group with the most improvement (women delivering at collaborative hospitals with prior hemorrhage collaborative experience) and holding as the denominator the same rate of hemorrhage as they had in the baseline period, found that the percent reduction of severe maternal morbidity changes at most from 28.6% (without adjustment) to 22.9%.

Overall, 54% of hospitals completed 14 of 17 bundle elements, 76% reported regular unit-based drills, and 65% reported regular posthemorrhage debriefs. We attempted to correlate the intensity of collaboration participation with improved outcomes (reduced severe maternal morbidity). There was no overall difference in bundle adoption between those hospitals that improved their SMM hemorrhage rates and those

TABLE 3
Characteristics for hospitals that participated in collaborative and for hospitals in control group

Hospital characteristic	All hospitals in CMQCC CPMS N = 99 (column %)	In collaborative and without prior hemorrhage collaborative experience N = 74 (column %)	In collaborative and with prior hemorrhage collaborative experience N = 25 (column %)	Comparison group: hospitals not in CMQCC CPMS and no prior hemorrhage collaborative experience N = 48 (column %)	Significance testing collaborative prior experience vs no prior experience	Significance testing collaborative vs comparison group
2015 Birth volume					$P = .2327$	$P = .0052$
<1000	14 (14.1)	12 (16.22)	2 (8)	18 (37.5)		
1000–<2000	32 (32.3)	26 (35.14)	6 (24)	10 (20.8)		
≥2000	53 (53.5)	36 (48.65)	17 (68)	20 (41.67)		
Hospital system					$P = .2613$	$P = .8357$
Yes	79 (79.80)	61 (82.43)	18 (72)	39 (81.25)		
No	20 (20)	13 (17.47)	7 (28)	9 (18.75)		
Hospital type, ownership					$P = .1908$	$P < .0001$
County and district	10 (10.1)	7 (9.5)	3 (12.0)	6 (12.5)		
Investor	10 (10.1)	9 (12.2)	1 (4.0)	4 (8.3)		
Nonprofit corporation	48 (48.5)	36 (48.6)	12 (48.0)	38 (79.2)		
HMO	29 (29.3)	22 (29.7)	7 (28.0)	0		
University	2 (2.0)	0	2 (8.0)	0		
NICU level					$P < .0001$	$P = .3211$
Basic	23 (23.2)	21 (28.4)	2 (8.0)	15 (31.3)		
Intermediate	25 (25.2)	21 (28.4)	4 (16.0)	12 (25)		
Community	41 (41.4)	31 (41.9)	10 (40.0)	20 (41.7)		
Regional	10 (10.1)	1 (1.6)	9 (36.0)	1 (2.1)		
Race/ethnicity					$P < .0001$	$P < .0001$
White	79,313 (30.9)	51,706 (30.4)	27,607 (31.8)	22,869 (28.2)		
Black	13,762 (5.4)	7470 (4.4)	6292 (7.3)	4546 (5.6)		
Hispanic	108,178 (42.2)	75,165 (44.3)	33,013 (38.1)	44,046 (54.3)		
Asian/Pacific Islander	45,720 (17.8)	29,620 (17.4)	16,100 (18.6)	7931 (9.8)		
Other	9568 (3.7)	5853 (3.4)	3715 (4.3)	1697 (2.1)		
Total women	256,541	169,814	86,727	81,089		

CMQCC, California Maternal Quality Care Collaborative; *CPMS*, California Partnership for Maternal Safety; *HMO*, health maintenance organization; *NICU*, neonatal intensive care unit.

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TABLE 4
Comparison of severe maternal morbidity among hemorrhage patients in collaborative and noncollaborative hospitals and in collaborative hospitals with and without prior hemorrhage collaborative experience

California hospitals with CMQCC rapid-cycle maternal data center	Hospitals, N	Baseline period (4 y), N/D[a]	Baseline SMM-hemorrhage rate (per 100 hemorrhage cases)	Postintervention period (6 mo), N/D[a]	Postintervention SMM-hemorrhage rate (per 100 hemorrhage cases)	Reduction in SMM-hemorrhage	Significance of reduction from baseline to intervention periods, *P* value
Hospitals in CMQCC CPMS	99	13,037/57,320	22.7	1481/8220	18.0	20.8%	<.0001
Without prior hemorrhage collaborative experience	74	7663/33,691	22.7	952/4951	19.2	15.4%	<.0001
With prior hemorrhage collaborative experience	25	5374/23,629	22.7	529/3269	16.2	28.6%	<.0001
Comparison group: hospitals not in collaborative and no prior CMQCC hemorrhage experience	48	4066/14,227	28.6	452/1601	28.2	1.2%	.7713

CMQCC, California Maternal Quality Care Collaborative; *CPMS*, California Partnership for Maternal Safety; *SMM*, severe maternal morbidity.

[a] Denominators (D) indicate number of hemorrhage cases and numerators (N) indicate number among denominator with SMM.

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that did not. However, this was partly due to inclusion of hospitals that began with low rates of severe maternal morbidity and might have less opportunity to improve. Therefore, we chose to subdivide hospitals based on their starting level of morbidity. We identified hospitals with high rates of severe maternal morbidity among hemorrhage patients as those with a starting rate >1 SD of the mean rate among improved hospitals in the final cohort (22.5 per 100 hemorrhage cases). Table 8 illustrates that those hospitals that started with a high rate and did not show improvement adopted significantly fewer safety bundle elements than those with an initial high rate that did show improvement (56.7% vs 78.2%, $P < .05$). Hospitals that started with low rates did not show this association even though some did show further improvement. These findings suggest that the starting level of morbidity acts as an effect modifier.

The potential for unintended consequences was judged to be low for this project. The collaborative leadership team noted some potential for overtreatment based on possible overdiagnosis. However, the number of women actually receiving a transfusion was lower and there were no reported major drug reactions. Missing data were an issue for several additional collaborative measures including total blood units transfused, prompting us to concentrate on bundle element adoption.

Comment

A major aim of this project was to demonstrate that implementation of maternal safety bundles can be scaled to a very large number of hospitals (99 hospitals caring for 256,541 annual births) that were diverse in size, ownership, and neonatal intensive care unit level, all on limited budget. Severe maternal morbidity was reduced by 20.8% among hemorrhage patients (the target population) and 11.7% among all women giving birth. This is consistent with prior studies indicating that hemorrhage accounts for 50-60% of severe maternal morbidity.[5]

TABLE 5
Comparison of severe maternal morbidity excluding transfusion among hemorrhage patients in collaborative and noncollaborative hospitals and in collaborative hospitals with and without prior hemorrhage collaborative experience

California hospitals with CMQCC rapid-cycle maternal data center	Hospitals, N	Baseline period (4 y), N/D[a]	Baseline SMM-hemorrhage (no transfusion) rate (per 100 hemorrhage cases)	Postintervention period (6 mo), N/D[a]	Postintervention SMM-hemorrhage (no transfusion) rate (per 100 hemorrhage cases)	Reduction in SMM-hemorrhage	Significance of reduction from baseline to intervention periods, *P* value
Hospitals in CMQCC CPMS	99	4036/57,320	7.1	457/8220	5.6	21.1%	<.0001
Without prior hemorrhage collaborative experience	74	2278/33,691	6.8	274/4951	5.5	19.1%	<.0001
With prior hemorrhage collaborative experience	25	1768/23,629	7.5	183/3269	5.6	25.3%	<.0001
Comparison group: hospitals not in collaborative and no prior CMQCC hemorrhage experience	48	1056/14,227	7.4	120/1601	7.5	−1.3%	.7713

CMQCC, California Maternal Quality Care Collaborative; *CPMS*, California Partnership for Maternal Safety; *SMM*, severe maternal morbidity.

[a] Denominators (D) indicate number of hemorrhage cases and numerators (N) indicate number among denominator with SMM without transfusions.

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Randomization for a project of this size would have posed special logistical and ethical difficulties that were far beyond our budget. To partly compensate for lack of randomization, we followed a contemporary noncollaborative comparison group using the same rapid-cycle data collection system to supplement our before-and-after model. The lack of improvement in the comparison population suggests that there were not statewide external factors responsible for the observed reductions in severe maternal morbidity. In addition, the sensitivity analyses indicate that differences in the populations of hospitals were unlikely to affect the results. Indeed, each subgroup showed as robust improvement as the whole population. The significant association between the number of bundle elements adopted and the reduction in morbidity among hospitals that started with high morbidity rates is also supportive.

Two additional findings were not expected. While improvement was noted in hospitals of all sizes, the finding that 92% of small hospitals (<1000 annual births) showed improvement illustrates the important needs of that population and their ability to improve. The other important finding was the persistent observation that hospitals in their second round of collaborative work on hemorrhage did notably better (nearly twice as much improvement) than hospitals in their first collaborative experience. Quality improvement leaders frequently note that it often takes >12 months to fully implement change packages and to adjust physician and staff practice patterns.

Earlier studies have shown similar improvement in single hospitals[8] or with a group of hospitals within a hospital system.[9] In such examples it can be hard to differentiate the effects of a strong leader or the centralized resources of a hospital system from the approach of the intervention project itself. The large number and range of hospitals that engaged and the ability to demonstrate widespread improvement supports the ability to scale up multidisciplinary improvement projects and supports the

TABLE 6
Sensitivity analysis: effects of removal of hospitals that are regional centers or owned by health maintenance organizations on reduction of severe maternal morbidity among hemorrhage patients

California hospitals with CMQCC rapid-cycle maternal data center	Hospitals, N	Baseline SMM-hemorrhage (per 100 hemorrhage cases)	Postintervention SMM-hemorrhage (per 100 hemorrhage cases)	Reduction in SMM-hemorrhage	Significance of reduction, *P* value
Removal of 11 regional centers					
Hospitals in CMQCC CPMS	89	22.4	18.0	19.5%	<.0001
Without prior hemorrhage collaborative experience	73	22.5	19.3	14.2%	<.0001
With prior hemorrhage collaborative experience	16	22.3	14.6	34.8%	<.0001
Comparison group: hospitals not in collaborative and no prior CMQCC experience	47	31.2	30.3	2.8%	.5011
Removal of 29 HMO-owned facilities					
Hospitals in CMQCC CPMS	70	23.7	18.2	23.1%	<.0001
Without prior hemorrhage collaborative experience	52	23.0	19.7	14.3%	<.0001
With prior hemorrhage collaborative experience	18	24.2	17.0	29.7%	<.0001
Comparison group: hospitals not in collaborative and no prior CMQCC experience	48	28.6	28.2	1.2%	.7713

CMQCC, California Maternal Quality Care Collaborative; *CPMS*, California Partnership for Maternal Safety; *HMO*, health maintenance organization; *SMM*, severe maternal morbidity.
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growing role of state-based maternal quality collaboratives.

Limitations of this study include the reliance on administrative data for outcomes. While this may be unavoidable for intervention studies involving >250,000 patients, we took extra steps for validation including case reviews and outlier checks. The immediate feedback of rates and the ability to drill down and review individual cases within the maternal data center all encouraged hospital to engage in their data. The absence of a randomized control group is another limitation but this was a study of the ability to scale up implementation rather than a test of the bundle. While we attempted to standardize the definition of obstetric hemorrhage, that remained a work in progress. The increase in the rate of hemorrhage over the course of the project may have partially contributed to the lower severe morbidity among hemorrhage cases (assuming all of the new cases identified were mild hemorrhages). However, the exploratory analyses suggest that this effect is small. This is supported by improvement in severe maternal morbidity seen among all women in the collaborative. Bundle adoption was self-reported and we did not perform site visits. We did have monthly calls with hospitals that discussed progress on specific bundles. Several process measures could support this question but their analysis is quite complicated and will be the topic of a future report.

An earlier large-scale study in France was less successful. Deneux-Tharaux and colleagues led a cluster randomized trial of a package of hemorrhage interventions focused on education efforts in the model of academic detailing.[17] Both intervention and control groups (each arm with 70 hospitals) had similar reductions in rates of postpartum hemorrhage and severe postpartum hemorrhage. Our intervention package involved more comprehensive systems changes, nurse and physician education, and ongoing audits. The focus of our collaborative was to reduce the frequency of severe maternal morbidities from hemorrhage and less on the uncertain potential of preventing the hemorrhage. The hemorrhage safety bundle was vetted by multiple state and national organizations, which aided its adoption. We also used a novel addition to the typical IHI learning collaborative model by breaking the support group down to a smaller size (6-8 hospitals) and assigning a physician-nurse pair to mentor, support, and facilitate their hospital group. Group peer pressure can be an effective tool for improvement projects.[14]

A significant asset for supporting a project of this size on a small budget was the ability to fully utilize the California Maternal Data Center. This World Wide

TABLE 7
Rates of hemorrhage and severe maternal morbidity in entire obstetric population

California hospitals with CMQCC rapid-cycle maternal data center	Hospitals, N	Baseline (per 100 mothers)	Postintervention (per 100 mothers)	Decrease	Significance of reduction, *P* value
Rate of severe maternal morbidity among all obstetric patients					
Hospitals in CMQCC CPMS	99	1.71	1.51	11.7%	<.0001
Without prior hemorrhage collaborative experience	74	1.54	1.40	9.1%	.0030
With prior hemorrhage collaborative experience	25	2.06	1.70	17.5%	<.0001
Comparison group: hospitals not in collaborative and no prior CMQCC experience	48	1.53	1.46	4.5%	.2589
Rate of obstetric hemorrhage (see Table 1 for definition)					
Hospitals in CMQCC CPMS	99	5.9	6.7	−13.3%	<.0001
Without prior hemorrhage collaborative experience	74	5.2	6.1	−16.2%	<.0001
With prior hemorrhage collaborative experience	25	7.2	7.8	−8.6%	<.0001
Comparison group: hospitals not in collaborative and no prior CMQCC experience	48	4.2	4.3	−4.5%	.06

CMQCC, California Maternal Quality Care Collaborative; *CPMS*, California Partnership for Maternal Safety.
Main et al. Reduction of severe maternal morbidity from hemorrhage. Am J Obstet Gynecol 2017.

Web–based rapid-cycle interactive data tool allowed rapid display of outcome, process, and structure measures as part of the normal data flow of the obstetric unit. Having outcome data available for all hospitals within 45 days was a boost that helped to reinforce implementation. Hand-collected data can be very costly and often limits what can be done for quality-improvement projects, especially at the scale of >100 hospitals. This was evident in our project when we sought to collect items that were not standard in the data center—completeness and accuracy declined significantly.

The success of scaling up implementation of the national safety bundle for hemorrhage is promising for our national efforts to reduce maternal morbidity and mortality. Further analysis is underway using both quantitative and qualitative approaches to identify which bundle elements and activities are most important in this journey. ■

TABLE 8
Association between improvement in severe maternal morbidity among hemorrhage patients and percent of hemorrhage bundle elements adopted

Improvement group (CMQCC CPMS active track hospitals, N = 99)	Hospitals, N	Mean hemorrhage bundle elements adopted
Low rate to start and did improve further	28	81.1%
Low rate to start and did not improve further	18	85.6%
High rate to start and did improve	42	78.2%[a]
High rate to start and did not improve	11	56.7%[a]

High rate group was defined as >1SD over mean of severe maternal morbidity among hemorrhage cases in improved hospitals at end of intervention period (22.5 per 100 hemorrhage cases).

CMQCC, California Maternal Quality Care Collaborative; *CPMS*, California Partnership for Maternal Safety.

[a] Significantly different, $P < .05$.

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Author and article information

From the California Maternal Quality Care Collaborative, Division of Neonatal and Developmental Medicine, Stanford University, Palo Alto (Drs Main and Gould, Ms Cape, Ms Abreo, Ms Vasher, and Ms Woods), and Critical Juncture LLC, San Francisco (Mr Carpenter), CA.

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Corresponding author: Elliott K. Main, MD. main@cmqcc.org