OBSTETRICS

Measuring severe maternal morbidity: validation of potential measures

Elliott K. Main, MD; Anisha Abreo, MPH; Jennifer McNulty, MD; William Gilbert, MD; Colleen McNally, MD; Debra Poeltler, PhD; Katarina Lanner-Cusin, MD; Douglas Fenton, MD; Theresa Gipps, MD; Kathryn Melsop, MS; Naomi Greene, PhD; Jeffrey B. Gould, MD, MPH; Sarah Kilpatrick, PhD, MD

BACKGROUND: Both maternal mortality rate and severe maternal morbidity rate have risen significantly in the United Sates. Recently, the Centers for Disease Control and Prevention introduced International Classification of Diseases, 9th revision, criteria for defining severe maternal morbidity with the use of administrative data sources; however, those criteria have not been validated with the use of chart reviews.

OBJECTIVE: The primary aim of the current study was to validate the Centers for Disease Control and Prevention International Classification of Diseases, 9th revision, criteria for the identification of severe maternal morbidity. This analysis initially required the development of a reproducible set of clinical conditions that were judged to be consistent with severe maternal morbidity to be used as the clinical gold standard for validation. Alternative criteria for severe maternal morbidity were also examined.

STUDY DESIGN: The 67,468 deliveries that occurred during a 12-month period from 16 participating California hospitals were screened initially for severe maternal morbidity with the presence of any of 4 criteria: (1) Centers for Disease Control and Prevention International Classification of Diseases, 9th revision, diagnosis and procedure codes; (2) prolonged postpartum length of stay (>3 standard deviations beyond the mean length of stay for the California population); (3) any maternal intensive care unit admissions (with the use of hospital billing sources); and (4) the administration of any blood product (with the use of transfusion service data). Complete medical records for all screen-positive cases were examined to determine whether they satisfied the criteria for the clinical gold standard (determined by 4 rounds of a modified Delphi technique). Descriptive and statistical analyses that included area under the receiver operating characteristic curve and C-statistic were performed.

RESULTS: The Centers for Disease Control and Prevention International Classification of Diseases, 9th revision, criteria had a reasonably high sensitivity of 0.77 and a positive predictive value of 0.44 with a C-statistic of 0.87. The most important source of false-positive cases were mothers whose only criterion was 1-2 units of blood products. The Centers for Disease Control and Prevention International Classification of Diseases, 9th revision, criteria screen rate ranged from 0.51-2.45% among hospitals. True positive severe maternal morbidity ranged from 0.05-1.13%. When hospitals were grouped by their neonatal intensive care unit level of care, severe maternal morbidity rates were statistically lower at facilities with lower level neonatal intensive care units ($P < .0001$).

CONCLUSION: The Centers for Disease Control and Prevention International Classification of Diseases, 9th revision, criteria can serve as a reasonable administrative metric for measuring severe maternal morbidity at population levels. Caution should be used with the use of these criteria for individual hospitals, because case-mix effects appear to be strong.

Key words: Centers for Disease Control and Prevention, maternal morbidity rate, severe maternal morbidity

Over the last 15 years both maternal mortality and morbidity rates have risen significantly in the United States.[1-3] Despite the increasing rate, maternal mortality remains a rare event and difficult to track in a timely manner. Depending on the definition, severe maternal morbidity occurs 50-100 times more frequently than death and identifies cases that were on a pathway to death.[3-5] A measure of severe maternal morbidity based on administrative data would provide rapid assessments of maternal health at both hospital and population levels and track progress of large-scale care-improvement projects.

Kuklina et al[6] and Geller et al[7] established criteria for identification of "near miss" maternal morbidity at the hospital level focusing on maternal intensive care unit (ICU) admission or transfusion of ≥4 units of any blood product.[6,7] These criteria were validated[8] and proposed for national use for internal hospital quality reviews (with the slight revision of ≥4 units of red blood cells).[9,10] Unfortunately, these criteria are not present in administrative data sets that would prevent their use for population-level assessments. In contrast, investigators at the Centers for Disease Control and Prevention (CDC) used a set of International Classification of Disease, 9th Edition, Clinical Manual (ICD-9 CM) diagnosis and procedure codes that are associated with maternal death to identify potential cases of severe maternal morbidity (referred to as CDC ICD-9 criteria; Table 1).[3-5] However, the accuracy of the CDC ICD-9 criteria in the identification of women with true severe maternal morbidity has not been evaluated with the use of actual patient records. The primary aim of the current study was to validate the CDC ICD-9 criteria in the identification of severe maternal morbidity by reviewing medical records from a large representative sample of cases picked up by the CDC ICD-9 criteria. This analysis required the development of a reproducible set of clinical conditions that were judged

Cite this article as: Main EK, Abreo A, McNulty J, et al. Measuring severe maternal morbidity: validation of potential measures. Am J Obstet Gynecol 2016;214:643.e1-10.

0002-9378/$36.00
© 2016 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.ajog.2015.11.004

TABLE 1
Severe maternal morbidity indicators and corresponding International Classification of Diseases, 9th revision, Clinical Modification codes that were developed by the Centers for Disease Control and Prevention[a]

Indicator	Code
Acute myocardial infarction	410.xx
Acute renal failure	584.x, 669.3x
Adult respiratory distress syndrome	518.5, 518.81, 518.82, 518.84,799.1
Amniotic fluid embolism	673.1x
Aneurysm	441.xx
Cardiac arrest/ventricular fibrillation	427.41, 427.42, 427.5
Disseminated intravascular coagulation	286.6, 286.9, 666.3x
Eclampsia	642.6x
Heart failure during procedure or surgery	669.4x, 997.1
Internal injuries of thorax, abdomen, and pelvis	860.xx-869.xx
Intracranial injuries	800.xx, 801.xx, 803.xx, 804.xx, 851.xx-854.xx
Puerperal cerebrovascular disorders	430, 431, 432.x, 433.xx, 434.xx, 436, 437.x, 671.5x, 674.0x, 997.2, 999.2
Pulmonary edema	428.1, 518.4
Severe anesthesia complications	668.0x, 668.1x, 668.2x
Sepsis	038.xx, 995.91, 995.92, 670.2[b]
Shock	669.1x, 785.5x, 995.0, 995.4, 998.0
Sickle cell anemia with crisis	282.62, 282.64, 282.69
Thrombotic embolism	415.1x, 673.0x, 673.2x, 673.3x, 673.8x
International Classification of Diseases, 9th revision, Clinical Modification procedure codes	
Blood transfusion	99.0x
Cardio monitoring	89.6x
Conversion of cardiac rhythm	99.6x
Hysterectomy	68.3x-68.9
Operations on heart and pericardium	35.xx, 36.xx, 37.xx, 39.xx
Temporary tracheostomy	31.1
Ventilation	93.90, 96.01-96.05, 96.7x

[a] Available at: http://www.cdc.gov/reproductivehealth/MaternalInfantHealth/SevereMaternalMorbidity.html (accessed December 15, 2015); [b] One additional code (670.2) has been added to the Severe Maternal Morbidity code set defined by the Centers for Disease Control and is now part of Title V grants applications (available at: http://mchb.hrsa.gov/programs/titlevgrants/fadresource.pdff. Accessed December 15th 2015.

Main et al. Validation of severe maternal morbidity measures. Am J Obstet Gynecol 2016.

to be consistent with severe maternal morbidity and hence used as the clinical gold standard for determination of true severe maternal morbidity. The CDC ICD-9 criteria and "Gold Standard" rates of severe maternal morbidity were then compared among hospital levels of care. A secondary aim was to identify any ICD-9 or procedure code additions or deletions that could improve the CDC ICD-9 criteria.

Methods

Our study sample included all mothers who delivered at >20 weeks of gestation from July 1, 2012, through June 30, 2013, from 16 participating hospitals that were representative of all regions of California (including urban and suburban) and all levels of neonatal intensive care. We intentionally sought a higher representation of regional perinatal centers and hospitals with a greater percentage of African American births to reflect a wide range of cases with severe maternal mortality rates. We used 4 screening strategies initially to identify cases of potential severe maternal morbidity for chart review. These included all mothers with any of the following events: (1) CDC ICD-9 diagnosis and procedure codes, (2) prolonged postpartum length of stay (PPLOS) defined as 3 standard deviations beyond the mean length of stay for the California population (4 days for a vaginal delivery; 6 days for a cesarean delivery), (3) any maternal ICU admissions, and (4) administration of any blood product. The first 2 screening criteria used data from the California Maternal Data Center that linked patient discharge diagnosis data with birth certificate data; the other screening methods (ICU and blood administration) used alternate hospital data sources (chargemaster files, admission discharge transfer files, and blood bank data systems). Only data from the birth admission were analyzed because antenatal and postpartum admissions were more difficult to identify reliably in our data sets.

The case review team was comprised of 10 obstetric researchers who were experienced in quality reviews, several of whom had specific experience in assessment of severe maternal morbidity. The team first developed a set of consensus clinical conditions to establish a "gold standard" to identify severe maternal morbidity. This process started with previously established criteria that included near miss and organ failure and expanded to severe temporary harm and additional significant procedures.[6,7] We incorporated a patient-orientated view that focused on complications that have significant impact on the woman and her family. Consensus was developed with a modified Delphi method.[11] Some clinical conditions, typically those that were "near miss,"[6] reached immediate consensus, but others required more discussion. To build consistency among

TABLE 2
Gold standard guidelines for severe maternal morbidity with the use of example-driven definitions

Severe maternal morbidity	NOT severe morbidity (insufficient evidence, if this is the only criteria)
Hemorrhage	
Obstetric hemorrhage with ≥4 units of red blood cells transfused	Obstetric hemorrhage with 2-3 units of red blood cells transfused ALONE
Obstetric hemorrhage with 2 units of red blood cells and 2 units of fresh frozen plasma transfused (without other procedures or complications), if not judged to be "over- exuberant" transfusion	Obstetric hemorrhage with 2 units of red blood cells and 2 units of fresh frozen plasma transfused AND judged to be "over-exuberant"
Obstetric hemorrhage with <4 units of blood products transfused and evidence of pulmonary congestion that requires >1 dose of Lasix	Obstetric hemorrhage with <4 units of blood products transfused and evidence of pulmonary edema requiring only 1 dose of Lasix
Obstetric hemorrhage with return to operating room for any major procedure (excludes dilation)	
Any emergency/unplanned peripartum hysterectomy, regardless of number of units transfused (includes all placenta accretas)	Planned peripartum hysterectomy for cancer/neoplasia
Obstetric hemorrhage with uterine artery embolization, regardless of number of units transfused	
Obstetric hemorrhage with uterine balloon or uterine compression suture placed and 2-3 units of blood products transfused	Obstetric hemorrhage with uterine balloon or uterine compression suture placed and ≤1 units of blood products transfused
Obstetric hemorrhage admitted to intensive care unit for invasive monitoring or treatment (either medication or procedure; not just observed overnight)	Any obstetric hemorrhage that went to the intensive care unit for observation only without further treatment
Hypertension/neurologic	
Eclamptic seizure(s) or epileptic seizures that were "status"	
Continuous infusion (intravenous drip) of an antihypertensive medication	
Nonresponsiveness or loss of vision, permanent or temporary (but not momentary), documented in physician's progress notes	
Stroke, coma, intracranial hemorrhage	
Preeclampsia with difficult to control severe hypertension (>160 systolic blood pressure or >110 diastolic blood pressure) that requires multiple intravenous doses and/or persistent ≥48 hours after delivery	Chronic hypertension that drifts up to the severe range and needs postoperative medication dose alteration: preeclampsia blood pressure control with oral medications ≥48 hour after delivery
Liver or subcapsular hematoma or severe liver injury admitted to the intensive care unit (bilirubin >6 or liver enzymes >600)	Abnormal liver function requiring extra prolonged postpartum length of stay, but not in the intensive care unit
Multiple coagulation abnormalities or severe hemolysis, elevated liver enzymes, and low platelet count (HELLP) syndrome	Severe thrombocytopenia (<50,000) alone that does not require a transfusion or intensive care unit admission
Renal	
Diagnosis of acute tubular necrosis or treatment with renal dialysis	Oliguria treated with intravenous fluids (no intensive care unit admission)
Oliguria treated with multiple doses of Lasix	Oliguria treated with 1 dose of intravenous Lasix but no intensive care unit admission
Creatinine ≥2.0 in a woman without preexisting renal disease OR a doubling of the baseline creatinine in a woman with preexisting renal disease	
Sepsis	
Infection with hypotension with multiple liters of intravenous fluid or pressors used (septic shock)	Fever >38.5°F with elevated lactate alone without hypotension
Infection with pulmonary complications such as pulmonary edema or acute respiratory distress syndrome	Fever >38.5°F with presumed chorio/endometritis with elevated pulse but no other cardiovascular signs and normal lactate
	Positive blood culture without other evidence of significant systemic illness

Main et al. Validation of severe maternal morbidity measures. Am J Obstet Gynecol 2016.

(continued)

TABLE 2
Gold standard guidelines for severe maternal morbidity with the use of example-driven definitions *(continued)*

Severe maternal morbidity	NOT severe morbidity (insufficient evidence, if this is the only criteria)
Pulmonary	
Diagnosis of acute respiratory distress syndrome, pulmonary edema, or postoperative pneumonia	Administration of oxygen without a pulmonary diagnosis
Use of a ventilator (with either intubation or noninvasive technique)	
Deep vein thrombosis or pulmonary embolism	
Cardiac	
Preexisting cardiac disease (congenital or acquired) with intensive care unit admission for treatment	Preexisting cardiac disease (congenital or acquired) with intensive care unit admission for observation only
Peripartum cardiomyopathy	Preexisting cardiac disease (congenital or acquired) without intensive care unit admission but on labor and delivery for extra time for observation only
Arrhythmia that requires >1 dose of intravenous medication but not intensive care unit admission	Arrhythmia requiring 1 dose of intravenous medication but no intensive care unit admission
Arrhythmia that requires intensive care unit with further treatments	Arrhythmia that requires intensive care unit observation but no extra treatments
Intensive care unit/invasive monitoring	
Any intensive care unit admission that includes treatment or diagnostic or therapeutic procedure	Intensive care unit admission for observation of hypertension that does NOT require intravenous medications
Central line or pulmonary catheter used to monitor a complication	Intensive care unit admission for observation after general anesthesia
Surgical, bladder, and bowel complications	
Bowel or bladder injury during surgery beyond minor serosal tear	
Small bowel obstruction, with or without surgery during pregnancy/postpartum period	
Prolonged ileus for ≥4 days	Postoperative ileus that resolved without surgery in ≤3 days
Anesthesia complications	
Total spinal anesthesia	Failed spinal that requires general anesthesia
Aspiration pneumonia	Spinal headache treated with a blood patch
Epidural hematoma	

Main et al. Validation of severe maternal morbidity measures. Am J Obstet Gynecol 2016.

reviewers, we created a series of 30 case scenarios to explore borderline situations. After team discussion, if consensus was not reached, the investigators constructed pro and con arguments and potential principles to guide the next round of deliberations. The clinical team went through 4 rounds of the Delphi process before reaching consensus on all case scenarios and completing the final version of the Gold Standard Severe Maternal Morbidity Case Review Guidelines (Table 2). During chart review, if severe maternal morbidity categorization was still not clear-cut, the case was discussed during weekly research-team phone calls, and assignment was made by consensus. At the time of chart review, investigators were blinded to the ICD-9 diagnosis codes but were provided the number of units of blood that had been transfused (derived from blood bank data), the procedures that occurred during the hospital admission, and the number of days spent in the ICU. Cases identified by these gold standard criteria are referred to as "true positives."

Internal review board approvals were obtained from Stanford University as the overall study host, each participating hospital for chart reviews, 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. All descriptive and statistical analyses, which included area under the receiver operating characteristic curve and C-statistic were performed using SAS software (version 9.3; SAS Institute Inc, Cary, NC).

Results

The study population consisted of 67,468 deliveries, which represented

15% of California's births during the study period. The 16 hospitals ranged in delivery volume from 1500 to >7000 annual births. The demographic profile of the study population compared with the entire state is shown in Table 3. Other than geographic distribution, we were not seeking to draw a representative sample of California births but rather to identify more women from regional centers and hospitals with higher African American populations.

Of the 67,468 deliveries, 1313 (1.95%) were screen positive for potential severe maternal morbidity by 1 of the 4 screening criteria; the distribution and overlaps are shown in Figure 1, A. Approximately one-half of the cases (n = 668; 51%) were identified by >1 screening method. The screen-positive rate that used only the CDC ICD-9 criteria was 1.28% of mothers (n = 862). The proportion of screen-positive cases that were ultimately deemed true positive after review of charts was 491 of 1313 (37.4%). The rate of true-positive severe maternal morbidity as defined by the gold standard was 0.73% (491/67,468 deliveries). The distribution and overlaps among screening criteria in the identification of cases that were deemed to meet gold standard guidelines for severe maternal morbidity is presented in Figure 1, B.

Unlike the CDC, we did not exclude cases with a total length of stay of <3 days recorded in the hospital discharge file. In our cases with suspected severe maternal morbidity and a short hospital length of stay, chart review revealed that the error was nearly always in the dates of admission or discharge rather than in the morbidity codes.

Criteria for 15 potential screening measures were tested for their ability to predict true-positive severe maternal morbidity with the use of sensitivity, specificity, positive-predictive value, negative-predictive value, area under the receiver operating characteristic curve, and C-statistic (Table 4). The specificity and negative-predictive values for all proposed metrics were extremely high, as would be expected given the low incidence of severe maternal morbidity. The sensitivity and positive predictive value varied among the 15 potential measures. Among the measure criteria that were based on administrative data alone, the CDC ICD-9 criteria had a reasonably high sensitivity of 0.77 and a positive-predictive value of 0.44, with a C-statistic of 0.87. Models are considered reasonable when the C-statistic

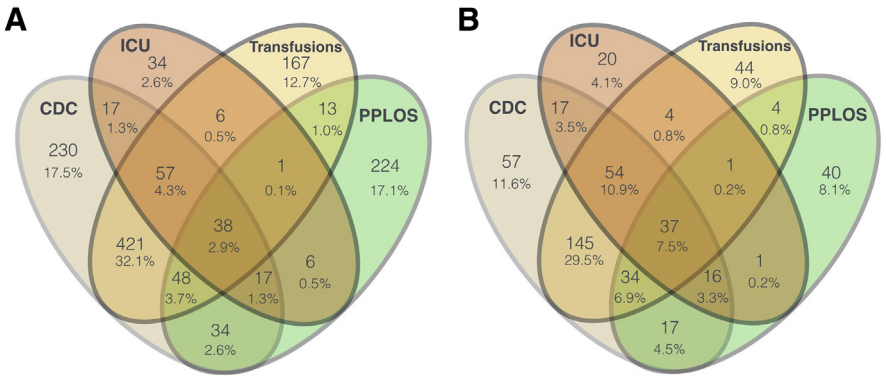
TABLE 3
Demographic profile of study sample compared with the entire state[a]

Characteristic	Study sample, n (%)	Statewide, n (%)
Total	67,468 (100)	474,411 (100)
Race/ethnicity		
White	22,937 (34.00)	131,584 (27.74)
Latina	22,657 (33.58)	231,568 (48.81)
Asian	9,050 (13.41)	55,707 (11.74)
African American	4,935 (7.31)	27,234 (5.74)
Pacific Islander	2,439 (3.62)	15,493 (3.27)
Native Indian	242 (0.36)	2,122 (0.45)
Other	59 (0.09)	358 (0.08)
Refused/unknown/missing	5,149 (7.63)	10,345 (2.18)
Prepregnancy body mass index		
Underweight (<18.5 kg/m^2)	2,777 (4.12)	17,684 (3.73)
Normal (18.5-24.9 kg/m^2)	32,864 (48.71)	197,702 (41.67)
Overweight (25.0-29.9 kg/m^2)	14,118 (20.93)	127,711 (29.62)
Obese I (30.0-34.9 kg/m^2)	6,555 (9.72)	61,876 (13.04)
Obese II (35.0-39.9 kg/m^2)	2,699 (4.00)	27,594 (5.82)
Obese III (≥40 kg/m^2)	1,642 (2.43)	16,740 (3.53)
Missing	6,813 (10.1)	25,104 (5.29)
Insurance		
Medicaid	25,497 (37.79)	222,772 (46.96)
Private	30,517 (45.23)	227,493 (47.95)
Self-pay	8,261 (12.24)	14,385 (3.03)
Other (including government)[b]	3,181 (4.71)	9,772 (2.05)
Missing	12 (0.02)	39 (0.01)
Hospital neonatal intensive care unit level[c]		
Regional	22,942 (34.00)	57,942 (12.21)
Community	30,832 (45.70)	238,382 (50.25)
Intermediate	12,107 (17.94)	89,990 (18.97)
Basic	1,587 (2.35)	87,397 (18.42)
Missing		700 (0.15)
Hospital geographic location: California		
Southern	40,750 (60.40)	274,150 (57.79)
Central	6,101 (9.04)	50,705 (10.69)
Northern	20,617 (30.56)	149,556 (31.52)

[a] July 1, 2012, to June 30, 2013; [b] Other insurance includes other government insurance, other indigent insurance, county indigent programs, Worker's insurance, or other payers; [c] Hospital neonatal intensive care unit levels are designated by California Children's Services.

Main et al. Validation of severe maternal morbidity measures. Am J Obstet Gynecol 2016.

FIGURE
Contribution of each screening criteria for the screen positive and true positive populations



A, Overlapping contributions of each screening criteria for the Screen-Positive population (n = 1313 patients) that then underwent chart review. **B,** Overlapping contributions of each screening criteria for the final True Positive population (n = 491 patients). The 4 criteria included the Centers for Disease Control and Prevention, which made identification from administrative data using International Classification of Diseases, 9th revision, codes; intensive care units, which were identified from hospital supplied intensive care unit admission data; transfusions, which were identified from hospital-supplied blood bank data; and prolonged postpartum length of stay (≥4 days for vaginal deliveries; ≥6 days for cesarean deliveries). The *off-white* portion indicates Centers for Disease Control and Prevention information; the *orange* portion indicates intensive care unit admissions; the *yellow* portion indicates blood-bank documented transfusions; and the *light green* portion indicates prolonged postpartum length of stay.

CDC, Centers for Disease Control and Prevention; *ICU*, intensive care unit; *PPLOS*, prolonged postpartum length of stay.

Main et al. Validation of severe maternal morbidity measures. Am J Obstet Gynecol 2016.

is >0.7 and strong if is >0.8. Adding PPLOS improved the sensitivity to 0.86 (C-statistic, 0.92) but reduced the positive predictive value to 0.38. Postpartum length-of-stay calculations require a data-set that is linked to birth records, which limits its utility. Several measure criteria that combined the CDC ICD-9 criteria with hospital supplemental data had higher levels of sensitivity, but at the cost of an increase in false-positive results.

We did not review all 67,468 deliveries in the study population but instead used 4 very comprehensive screening criteria. To investigate the effect of possible missed cases of severe maternal morbidity in the screen negative population (n = 66,155 deliveries), we added hypothetic false-negative cases at rates from 1 per 10,000 deliveries (an additional 7 cases) up to 1 per 1000 deliveries (an additional 66 cases) to the existing CDC false negatives. The area under the curve C-statistic for the CDC measure did not change appreciably, from 0.88 originally to 0.84 with the addition of 66 hypothetic false-negative cases. Overall screen-positive rates showed considerable variation among the 16 participating hospitals (Table 5). The CDC ICD-9 criteria screen rate ranged from 0.51-2.45% in hospitals. True positive severe maternal morbidity ranged from 0.05-1.13%. When hospitals were grouped by their neonatal intensive care unit level of care, severe maternal morbidity rates were statistically lower at facilities with lower level neonatal ICUs ($P < .0001$; Table 5).

We analyzed whether deletions or additions of specific ICD-9 codes might improve the sensitivity of the CDC ICD-9 criteria. Cases that were identified as true severe maternal morbidity by chart review, but did not have a CDC ICD-9 code, were considered false negatives. No diagnosis codes were identified that would reduce the false negatives without greatly reducing the positive-predictive values. For example, the code "Other immediate postpartum hemorrhage" (666.12) was identified in 30 cases that were judged to be false negative but also in 1373 cases of true negatives. Several ICD9 procedure codes that were used for uterine artery embolization (68.25) and for additional surgeries (54.11, 54.61, 54.19, and 54.91) could be considered as additions. However, these codes accounted for only an additional 13 cases of severe maternal morbidity and would not measurably improve the sensitivity of the CDC ICD-9 criteria.

Cases that met the CDC ICD-9 criteria (Table 1) but were not classified as severe maternal morbidity after chart review with the use of the gold standard definitions were considered false positives. The false-positive diagnosis codes included 1 of the newer additions to the CDC diagnosis code set, "Postpartum coagulation defects, delivered with mention of postpartum complication" (666.32). All 66 cases with this code that did not at least receive a transfusion were judged to not have severe maternal morbidity. Most CDC ICD-9 criteria false-positive cases (n = 293) met the CDC ICD-9 criteria by virtue of a transfusion procedure code; however, on chart review, these cases were discovered to not meet the clinical gold standard criteria for transfusion largely because they had received only 1 or 2 units of blood (Table 2).

Comment

We undertook this study to validate administrative data criteria for their accuracy in the estimation of severe maternal morbidity that could be used to guide improvement efforts. Potential criteria were compared against an expert consensus-derived clinical gold standard. Existing definitions of severe maternal morbidity are vague and include the World Health Organization definition that is a "potentially life-threatening condition" which includes, but is not limited to, a near miss: "a woman who nearly dies but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy."[12] Because these definitions are nonspecific and

TABLE 4
Validation analysis for Centers for Disease Control and Prevention and other potential measures of severe maternal morbidity

Measure criteria	Cases and population rate[a] identified by this measure criterion, n (%)	Sensitivity	Specificity	Positive-predictive value	Negative-predictive value	Area under receiver operating characteristic curve C-statistic
True positives after chart review	491 (0.73)					
Measures based on administrative data alone						
Centers for Disease Control and Prevention (2012 specifications)	862 (1.28)	0.77	0.99	0.44	0.99	0.88
Centers for Disease Control and Prevention less transfusion International Classification of Diseases, 9th revision, codes	456 (0.68)	0.53	0.99	0.57	0.99	0.76
Prolonged postpartum length of stay	381 (0.56)	0.32	0.99	0.39	0.99	0.65
Any of Centers for Disease Control and Prevention, prolonged postpartum length of stay	1106 (1.64)	0.86	0.99	0.38	0.99	0.92
Measures based on supplemental hospital-supplied data alone						
Intensive care unit admissions	176 (0.26)	0.31	1.000	0.85	0.99	0.65
Massive transfusions (≥4 units any blood product using blood bank data)	245 (0.36)	0.61	1.000	0.88	0.99	0.73
Massive transfusions (≥4 units packed red blood cells with the use of blood bank data)	188 (0.28)	0.52	1.000	0.88	0.99	0.68
Measures based on combinations of administrative and supplemental data						
Any of Centers for Disease Control and Prevention, intensive care unit	909 (1.35)	0.82	0.99	0.44	0.99	0.92
Any of Centers for Disease Control and Prevention, prolonged postpartum length of stay, intensive care unit	1146 (1.70)	0.91	0.99	0.39	0.99	0.94
Any of Centers for Disease Control and Prevention less transfusion International Classification of Diseases, 9th revision, codes and adding massive transfusions (≥4 units any blood product with the use of blood bank data)	579 (0.86)	0.76	0.99	0.64	0.99	0.87
Any of Centers for Disease Control and Prevention less transfusion International Classification of Diseases, 9th revision, codes and adding massive transfusions (≥4 packed red blood cells with the use of blood bank data)	540 (0.80)	0.67	0.99	0.62	0.99	0.84

Main et al. Validation of severe maternal morbidity measures. Am J Obstet Gynecol 2016.

(continued)

TABLE 4
Validation analysis for Centers for Disease Control and Prevention and other potential measures of severe maternal morbidity *(continued)*

Measure criteria	Cases and population rate[a] identified by this measure criterion, n (%)	Sensitivity	Specificity	Positive-predictive value	Negative-predictive value	Area under receiver operating characteristic curve C-statistic
Any of intensive care unit, massive transfusions (≥4 units any blood product with the use of blood bank data)	340 (0.50)	0.61	0.99	0.88	0.99	0.80
Any of intensive care unit, massive transfusions (≥4 units packed red blood cells with the use of Blood Bank data)	292 (0.43)	0.52	0.99	0.88	0.99	0.76
Any of prolonged postpartum length of stay, intensive care unit, massive transfusions (≥4 units any blood product with the use of blood bank data)	634 (0.94)	0.76	0.99	0.59	0.99	0.87
Any of prolonged postpartum length of stay, intensive care unit, massive transfusions (≥4 units packed red blood cells with the use of blood bank data)	590 (0.87)	0.68	0.99	0.56	0.99	0.83

[a] Total population examined includes 67,468 mothers.

Main et al. Validation of severe maternal morbidity measures. Am J Obstet Gynecol 2016.

hence difficult to compare, we developed a consensus clinical case dictionary using a variety of scenarios. Importantly, we viewed the definition of temporary harm from the viewpoint of the mother and family in addition to the medical team. Abnormal laboratory results without symptoms generally were not considered sufficient to be deemed severe maternal morbidity. Using a modified Delphi technique, 10 investigators were able quickly to arrive at consensus for a set of clinical scenarios that described severe maternal morbidity. This was easier to apply for case review than a general definition and afforded greater reproducibility. However, it should be recognized that maternal morbidity is a continuum and that different study teams may develop differing criteria for the cut-point to define severe morbidity.

The CDC ICD-9 criteria fared well with a good sensitivity (0.77); however, the positive predictive value was average at 0.44. Adding clinical data such as ICU admission or 4 units of blood transfusion improved the accuracy but violated the ability to calculate the measure with the use of the administrative data alone. Transfusions remained the most important driver for severe maternal morbidity, contributing more than one-half of the CDC criteria rate (1.0% with transfusion ICD-9 codes and 0.38% without). However, the ICD-9 code for transfusion does not denote the number of units transfused and so is positive for as little as 1 unit. Our gold standard guidelines required 4 units of packed red blood cells or 2 units in the setting of other procedures (such as embolization, uterine balloon, or compression sutures) to meet the threshold for severe maternal morbidity. Although we judged that transfusion of a single unit of blood would not rise to the level of severe morbidity, one could argue that some women and their families would consider any transfusion to be a sign of a major complication.

Our observed rate of screen-positive severe maternal morbidity that was based on the CDC ICD-9 criteria was 1.28%, which is similar to that previously reported that used a national

TABLE 5
Severe maternal morbidity rates by hospital-level

Hospital level[a]	Facilities/ mothers, n	Severe maternal morbidity rate (expert-panel validated)			Centers for Disease Control and Prevention severe maternal morbidity rate			Centers for Disease Control and Prevention less transfusions severe maternal morbidity rate		
		Mean, %	Range	*P* value	Mean, %	Range	*P* value	Mean, %	Range	*P* value
Basic/intermediate	6/13,694	0.28	0.05–0.48	< .0001	0.87	0.66–1.14	< .0001	0.39	0.21–0.59	< .0001
Community neonatal intensive care unit	6/30,832	0.82	0.2–1.13	Reference	1.22	0.88–1.60	Reference	0.78	0.31–1.26	Reference
Regional neonatal intensive care unit	4/22,942	0.88	0.51–1.07	N/S	1.60	0.51–2.45	< .0001	0.71	0.23–1.08	N/S
All hospitals	16/67,468	0.73	0.05–1.13		1.28	0.51–2.45		0.68	0.21–1.26	

N/S, not significant.

[a] Hospital levels for neonatal intensive care units are designated by California Children's Services.

Main et al. Validation of severe maternal morbidity measures. Am J Obstet Gynecol 2016.

discharge diagnosis data set (1.3%).[3] The wide variation in hospital rates of severe maternal morbidity with the use of either the CDC ICD-9 criteria (0.5-2.45%) or the gold standard true-positive clinical criteria (0.05-1.13%) suggests that case-mix adjustment may be required to compare hospitals. This is expected because most morbidity and mortality measures require risk adjustment. However, even without such adjustment, the measure can be of value to follow a single hospital's progress over time.

Strengths of the study include the large number of cases that underwent screening (67,468) and subsequent physician chart review (1313) to confirm severe morbidity, the use of a Delphi process to establish a consensus gold standard guidelines that define true-positive severe morbidity, the diversity of hospitals that collaborated in the study, the recent time period of the study, and the addition of blood bank data to identify transfusions.

One limitation of this study is that the initial screening was first done with administrative data so that, potentially, a few cases of severe maternal morbidity may have escaped identification. However, given the range of cross-checking alternative screenings, it is unlikely that there were many cases of severe morbidity that did not receive any transfusions noted by the blood bank or a PPLOS by hospital discharge data or an ICU admission (by admission/discharge/transfer tracking systems) or a diagnosis or procedure on the CDC criteria list. Another concern is the spread of investigators over a large geographic area that precluded direct inter-reviewer reliability testing. This was addressed by regular group discussions of case synopses and consensus determinations.

In conclusion, we evaluated several different approaches to the measurement of severe maternal morbidity. The CDC ICD-9 criterion is a reasonable population-level measure that is not difficult to calculate. Blood transfusion is a major driver of the ICD-9 criteria because it can include a single unit of blood. Therefore, a significant proportion of these cases did not meet our consensus-developed gold standard criteria for severe maternal morbidity. However, the optimal number of units of blood that should denote severe maternal morbidity remains an important question. Given the facility variation in severe maternal morbidity that was noted, especially between regional and nonregional centers, we recommend that case-mix adjustment be assessed before its use for the comparison of hospitals. Although the previously validated indicators (ICU admission or 4 units of blood) remain the mainstay for the identification of cases for focused multidisciplinary reviews within a facility, the CDC criteria would serve well at the level of a region or a state.[7-10] ■

References

1. Berg CJ, Callaghan WM, Syverson C, Henderson Z. Pregnancy-related mortality in the United States, 1998 to 2005. Obstet Gynecol 2010;116:1302-9.
2. Creanga AA, Berg CJ, Ko JY, et al. Pregnancy-related mortality in the United States, 2006-2010. Obstet Gynecol 2015;125:5-12.
3. Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. Obstet Gynecol 2012;120:1029-36.
4. Callaghan WM, MacKay AP, Berg CJ. Identification of severe maternal morbidity during delivery hospitalizations, United States, 2001-2003. Am J Obstet Gynecol 2008;199:133.e1-8.
5. Kuklina EV, Meikle SF, Jamieson DJ, et al. Severe obstetric morbidity in the United States: 1998–2005. Obstet Gynecol 2009;113:293-9.
6. Geller SE, Rosenberg D, Cox SM, Kilpatrick SJ. Defining a conceptual framework for near-miss maternal morbidity. J Am Med Womens Assoc 2002;57:135-9.
7. Geller SE, Rosenberg D, Cox S, Brown M, Simonson L, Kilpatrick SJ. A scoring system identified near-miss maternal morbidity during pregnancy. J Clin Epidemiol 2004;57:716-20.
8. You WB, Chandrasekaran S, Sullivan J, Grobman W. Validation of a scoring system to identify women with near-miss maternal morbidity. Am J Perinatol 2013;30:21-4.
9. Callaghan WM, Grobman WA, Kilpatrick SJ, Main EK, D'Alton M. Facility-based identification of women with severe maternal morbidity. It

is time to start. Obstet Gynecol 2014;123:978-81.
10. Kilpatrick SJ, Berg C, Bernstein P, et al. Standardized severe maternal morbidity review: rationale and process. Obstet Gynecol 2014;124:361-6.
11. Hsu C, Sandford B. The Delphi technique: making sense of consensus. Practical Assessment, Research & Evaluation 2007;12:1-8.
12. World Health Organization. Evaluating the quality of care for severe pregnancy complications: the WHO near-miss approach for maternal health. Geneva, Switzerland: WHO; 2011.

Author and article information

From California Maternal Quality Care Collaborative, Stanford University, Palo Alto, CA (Drs Main and Gould and Ms Abreo and Ms Melsop; Long Beach Memorial Miller Children's and Women's Hospital, Long Beach, CA (Dr McNulty); Sutter Medical Center, Sacramento, CA (Dr Gilbert); Sharp Mary Birch Hospital for Women & Newborns, San Diego, CA (Drs McNally and Poeltler); Alta Bates Summit Medical Center, Oakland, CA (Dr Lanner-Cusin); Scripps Healthcare, Scripps Memorial Hospital Encinitas, CA (Dr Fenton); Community Regional Medical Center, Fresno, CA (Dr Gipps); Cedars-Sinai Medical Center, Los Angeles, CA (Drs Greene and Kilpatrick).

Received Aug. 17, 2015; revised Oct. 21, 2015; accepted Nov. 5, 2015.

Supported in part by a grant from the Maternal Child Health Bureau through the State of California (DHCS), grant 13-90225, SPO 38996, HRSA, Washington, DC.

The authors report no conflict of interest.

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