Society for Maternal-Fetal Medicine
High-risk pregnancy experts

SMFM Special Report

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# Quality measures in high-risk pregnancies: Executive Summary of a Cooperative Workshop of the Society for Maternal-Fetal Medicine, National Institute of Child Health and Human Development, and the American College of Obstetricians and Gynecologists

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Providers perceive current obstetric quality measures as imperfect and insufficient. Our organizations convened a "Quality Measures in High-Risk Pregnancies Workshop." The goals were to (1) review the current landscape regarding quality measures in obstetric conditions with increased risk for adverse maternal or fetal outcomes, (2) evaluate the available evidence for management of common obstetric conditions to identify those that may drive the highest impact on outcomes, quality, and value, (3) propose measures for high-risk obstetric conditions that reflect enhanced quality and efficiency, and (4) identify current research gaps, improve methods of data collection, and recommend means of change.

The healthcare system is undergoing a major transformative change. In response to the provisions instituted under the Patient Protection and Affordable Care Act, there has been heightened impetus to control costs, increase coverage, and improve quality. Even before the enactment of the Patient Protection and Affordable Care Act, organizations have been working on issues of quality improvement. Most efforts thus far have focused on areas of cost and quality within populations covered by Medicare, which is an uncommon source of insurance coverage among obstetric patients, who are typically covered by either Medicaid or private insurers.

Meanwhile, obstetric providers have grown increasingly frustrated with quality measures that poorly represent true provider and hospital quality.[1,2] Many obstetric providers perceive these measures as being fraught with inadequate risk adjustment, unclear attribution of care, burdensome data collection, and limited evidence that these measures result in actual quality improvement. Providers desire a healthcare system as described in the Institute of Medicine's "Crossing the Quality Chasm" that is patient-centered, efficient, efficacious, equitable, safe, and timely.[3] Accordingly, current efforts must therefore focus on how to encourage participation, cooperation, and collaborative advancement of all parties in the new "5 Ps of obstetrics" (patient, provider, programmer, payer, and place of service) in the development and implementation of ideal quality measures.

The current United States healthcare system appears to deliver health care at high cost with mediocre results. In 2013, 17.1% of the United States gross domestic product was spent on health care, which is a percentage 50% above that spent by France (the next highest spender at 11.6% of gross domestic product) and almost double that of the United Kingdom at 8.8% of gross domestic product.[4] Our excess expenditures appear to be due in part to high use of diagnostic imaging and pharmaceutical costs.[5,6] Despite these extraordinary overall costs, the United States has inferior outcomes in comparison to other high-income nations on several measures of population health that include life expectancy, maternal mortality rate, infant mortality rate, and the incidence of chronic diseases.[7-9] These statistics have spurred leaders throughout the entire healthcare community to address quality and value.

Evaluations of quality of care typically are classified via three types of measures: structure, process, or outcome:

Structural measures refer to the characteristics of the care provider or the place where the care is given. For the provider, these characteristics may include certification or educational background. Place or setting characteristics include structural elements, such as the presence and maintenance of equipment or staffing at a site of care. Structural measures are typically easier to capture than other types of measures and remain relatively stable; hence, they are often used by licensing and accrediting organizations. The assumption underlying structural quality measures is

that enhancing structural elements at healthcare sites improves care. Although structural standards and improvements do not ensure quality, the lack of key structural elements may increase the difficulty of providing and sustaining high-quality care.

Process measures focus on the series of events that take place during an episode of care and depend on the appropriateness of care, proficiency of providers, and timely provision of services. Process measures assume that appropriate care is more likely to result in excellent outcomes.

Outcome measures evaluate whether healthcare goals were realized. Most outcome measures focus on the health status of the patient but can broadly include costs of care or patient satisfaction. Concerns regarding outcome measures often revolve around incorrect attribution of care and inadequate risk adjustment for factors beyond provider control, such as patient characteristics that predispose them to worse outcomes. At best, providers only control the process, which impacts but does not guarantee superior outcomes.

None of the three categories of quality measures is considered inherently or continuously superior to another, and some investigators suggest that a simultaneous examination of measurements of different types allows a greater understanding of the quality environment.

On February 3-4, 2016, the Society for Maternal-Fetal Medicine (SMFM), National Institute of Child Health and Human Development, and American College of Obstetricians and Gynecologists (ACOG) convened a "Quality Measures in High-Risk Pregnancies Workshop." The goals were to (1) review the current landscape regarding quality measures in obstetric conditions with increased risk for adverse maternal or fetal outcomes, (2) evaluate the available evidence for management of common obstetric conditions to identify those that may drive the highest impact on outcomes, quality, and value, (3) propose measures for high-risk obstetric conditions that reflect enhanced quality and efficiency, and (4) identify current research gaps, improve methods of data collection, and recommend means of change.

## Workshop Design

A workshop director and co-director were chosen by the SMFM leadership, and a steering committee was created to discuss the general topics and themes for production of quality measures for high-risk pregnancies. The committee held a series of conference calls during which topics to be considered at the workshop were chosen based on prevalence, increased level of maternal and fetal risk, existing variation in care, heightened economic burden, and primacy of the patient. Topics to be reviewed in breakout sessions at the workshop were chosen by the steering committee. Two facilitators per topic were chosen by the directors to assist in discussion of each topic. Clinical content experts were identified to review relevant evidence for clinical conditions to be examined within each topic. A series of conference calls were conducted before the workshop with the group facilitators, clinical experts, and directors. Call participants reviewed the framework for measuring quality and methods for review, and criteria for selection of appropriate indicators were outlined. For each subtopic, a content expert was chosen to perform a literature review and to lead the presentation of potential quality measures at the workshop. The group facilitators were charged with facilitating attendee participation during the workshop breakout sessions and to moderate discussion among workshop attendees regarding specific quality measure recommendations for each subtopic. Facilitators subsequently presented a summary of their respective breakout sessions to the entire group of workshop attendees for discussion and revision.

The workshop preceded the 36th Annual Pregnancy Meeting of the Society for Maternal-Fetal Medicine. Attendance at the workshop was free, voluntary, multidisciplinary, and open. The workshop concluded with a discussion regarding current research, informational and personnel or organizational gaps, specific recommendations for research, and requirements in the future to enhance quality metrics for high-risk obstetrics and to improve future maternal healthcare quality. The measures recommended in this summary should continue to be evaluated, vetted, validated, and examined according to rigorous standards of measure development outlined by major organizations, including the Agency for Healthcare Research Quality and/or National Quality Forum.

## Results

The steering committee selected the following topics and subtopics for discussion at the workshop:

1. Preterm birth (screening and prevention, treatment, neonatal care)
2. Cesarean delivery (cesarean birth rate measures, vaginal birth after cesarean [VBAC], infectious complications)
3. Hypertension and preeclampsia (hypertensive crisis, magnesium sulfate prophylaxis, low-dose aspirin utilization, and postpartum follow-up)
4. Hospital emergencies (venous thromboembolism [VTE], obstetric hemorrhage, and maternal sepsis)
5. Outpatient care (obstetric ultrasonography and genetic testing)
6. Information gaps and future research

In the following sections, we present a brief overview of the topics, the quality measures discussed, and the measures that were recommended for further consideration. Table 1 lists the main measures discussed and the criteria used for recommendation for further consideration: importance, scientific acceptability, usability, and feasibility. Table 2 lists the 14 proposed measures that were

**TABLE 1**
**Principal workshop-proposed measures for participant consideration as a quality measure: rationale for inclusion or exclusion**

| Proposed measures | Importance | Scientific acceptability | Usability | Feasibility | Recommended for further consideration or development |
|---|---|---|---|---|---|
| Preterm birth prevention (outpatient) | | | | | |
| Universal TVCL screening | Yes<br>Preterm birth occurs in 10% of pregnancies and is the leading cause of neonatal morbidity and death. | Yes<br>Identification of patients with short cervix ≤2.0 cm would provide opportunities for treatment. | Yes<br>Assists with medical decision-making. | Unclear<br>Difficult to abstract data from outpatient electronic health records | No |
| Primary TVCL vs transabdominal cervical length screening | Yes<br>Preterm birth occurs in 10% of pregnancies and is the leading cause of neonatal morbidity and death. | Yes<br>TVCL is the most accepted method. | Yes<br>Assists with medical decision-making. | Unclear<br>Study of training programs suggests variation in use of transabdominal vs transvaginal training for screening and some instances where transabdominal cervical length is adequate. | No |
| TVCL screening by Cervical Length Education and Review—certified sonographer | Unclear<br>Studies suggest standardized training and certification improves outcomes in other areas, but this has not been specifically evaluated for transvaginal ultrasound scans. | Yes<br>Short cervix is associated with increased risk preterm delivery; treatment and standardized training is available; there is no clear consensus about high-risk screening vs population screening. | Unclear<br>Perinatal Quality Foundation has database for status of sonographers and providers via the Cervical Length Education and Review program. | Unclear<br>Provider-level measure (not institutional); even with training, there are concerns about measurement reliability; access to outpatient records for data collection is not widely available. | No |
| Vaginal progesterone for women with short cervix ≤2.0 cm and <24 weeks of gestation and no history of spontaneous preterm birth | Yes<br>Preterm birth occurs in 10% of pregnancies and is the leading cause of neonatal morbidity and death. | Yes<br>Studies suggest treatment is associated with reduction in preterm birth and is supported by ACOG and SMFM. | Yes<br>Measure of effective treatment and can monitor for under- or over-utilization. | Unclear<br>Provider-level measure would need to be done voluntarily or at the health plan level (eg, prescriptions for progesterone) that are linked to ultrasound findings. | No |
| Intramuscular progestins for women with history of spontaneous preterm birth at 20—36 6/7 weeks of gestation | Yes<br>Preterm birth occurs in 10% of pregnancies and is the leading cause of neonatal morbidity and death. | Yes<br>History of preterm birth is a significant risk factor for recurrence; studies indicate prophylaxis is associated with reduction in recurrent preterm birth; prophylaxis is supported by ACOG and SMFM. | Yes<br>Measure of effective treatment that can monitor for under- or over-utilization. | No<br>Requires linkage with vital statistics data and insurance data for prescriptions | No |

*SMFM Publications Committee. Quality measures in high-risk pregnancies. Am J Obstet Gynecol 2017.*

*(continued)*

**TABLE 1**
**Principal workshop-proposed measures for participant consideration as a quality measure: rationale for inclusion or exclusion** *(continued)*

| Proposed measures | Importance | Scientific acceptability | Usability | Feasibility | Recommended for further consideration or development |
|---|---|---|---|---|---|
| Cerclage for women with history of spontaneous preterm birth and TVCL <2.5 cm at <24 weeks of gestation | Yes<br>Preterm birth occurs in 10% of pregnancies and is the leading cause of neonatal morbidity and death. | Yes<br>Studies suggest that ultrasound-indicated cerclage in women with a history of spontaneous preterm birth decreases risk of recurrent preterm birth. | Yes<br>Measure of effective treatment that can monitor for under- or over-utilization. | No<br>Requires linkage with vital statistics data and chart abstraction of inpatient and outpatient data | No |
| Preterm birth treatment (inpatient) | | | | | |
| Use of TVCL screening for women with threatened preterm birth (contractions) between 23 0/7 and 33 6/7 weeks of gestation | Yes<br>Threatened preterm birth is common, and determining true labor from false labor is a diagnostic challenge. | Yes<br>Presence of long cervix (≥3.0 cm) is helpful in the determination of who is not at high risk for preterm birth. | Unclear<br>Good for negative predictive value; improves efficiency of care for women at low risk (cervical length, ≥3.0 cm); not as helpful (discriminatory if cervical length is <3.0 cm) with low positive predictive value. | Unclear<br>Chart abstraction required; no standard protocol exists for treatment; main benefit is efficiency for low-risk women. | No |
| Antenatal corticosteroid administration at 24 0/7 to 33 6/7 weeks of gestation | Yes<br>This is the current standard advocated by societies and is the current quality metric. | Yes<br>Absence of timing of steroid administration limits this measure's true effectiveness. | Yes | Yes<br>Currently in use | Yes<br>Continue current measure as balancing measure (Joint Commission PC-03 [Perinatal Care Measure Set-03], National Quality Foundation). |
| Optimal timing of corticosteroids within 7 days of delivery (first or second course) between 24 0/7 and 33 6/7 weeks of gestation | Yes<br>Current variation in performance (only 20% of women receive treatment within 7 days of delivery) | Yes<br>Increased respiratory distress syndrome if exposure is >7 days. | Unclear<br>Data suggest timing better (more reliable) for maternal indications than fetal indications. | Unclear<br>Concern that current success might decrease if clinician waits to try to optimize time; currently, chart abstraction is to dichotomous yes/no; enhanced measure would require date/time of dose and delivery date/time and slightly more intensive chart abstraction. | Yes<br>Develop as an "enhanced measure." |

*SMFM Publications Committee. Quality measures in high-risk pregnancies. Am J Obstet Gynecol 2017.* *(continued)*

**TABLE 1**
**Principal workshop-proposed measures for participant consideration as a quality measure: rationale for inclusion or exclusion** *(continued)*

| Proposed measures | Importance | Scientific acceptability | Usability | Feasibility | Recommended for further consideration or development |
|---|---|---|---|---|---|
| Magnesium sulfate neuroprotection at 24–32 weeks of gestation | Yes<br>Current standard of ACOG and SMFM | Yes<br>Meta-analyses demonstrate decreased moderate-severe cerebral palsy or death. | Unclear<br>Rare outcome, multifactorial causes | Unclear<br>Some concern exists about proper provider attribution. | No |
| NICU accepting VLBW deliveries provide care to an adequate volume of VLBW neonates (>100 VLBW infants per year) | Yes<br>Increased deregionalization in some areas leads to decreased experience and cost, with replication of service and equipment in some centers. | Yes<br>Increased neonatal mortality rates in low- volume NICUs | Yes | Unclear<br>Contradictory financial incentives for delivery and care of VLBW neonate, regardless of outcomes; may harm areas with limited NICUs for immediate transfer. | No |
| VLBW infant delivered at birthing center, level I or II NICU | Yes<br>Measure of poor quality if infant is delivered at birthing center, level I and II NICU; variation because of access or financial incentives | Yes<br>Delivery in level III NICU associated with reduction in neonatal mortality rates. | Yes<br>Differences are clinically meaningful. | Yes<br>Cooperative transfer agreements in effect | Yes<br>Modification of current measure (National Quality Foundation) |
| Hypertension/preeclampsia | | | | | |
| Low-dose aspirin for prevention of preeclampsia | Yes<br>Preeclampsia occurs in 6–8% of pregnancies and is associated with significant maternal neonatal morbidity/death. | Yes<br>Evidence indicates reduction in adverse outcomes, minimal harms; endorsed by ACOG and United States Preventive Services Task Force. | Unclear<br>Needs consensus regarding "at risk" women; ACOG and United States Preventive Services Task Force differ. | Unclear<br>Requires additional data field in inpatient record for electronic medical record abstraction. | Yes<br>As recommended by ACOG Task Force on Hypertension in Pregnancy (Table 2; footnote a). |
| Hypertension/preeclampsia treatment (inpatient) | | | | | |
| Magnesium sulfate for prevention of eclampsia in delivering or postpartum women with preeclampsia with severe features | Yes<br>Significant cause of maternal morbidity and death. | Yes<br>Studies indicate decreased rate of seizures with prophylaxis. | Yes | Yes<br>Chart abstraction or electronic health records | Yes |

*SMFM Publications Committee. Quality measures in high-risk pregnancies. Am J Obstet Gynecol 2017.* *(continued)*

**TABLE 1**
**Principal workshop-proposed measures for participant consideration as a quality measure: rationale for inclusion or exclusion** *(continued)*

| Proposed measures | Importance | Scientific acceptability | Usability | Feasibility | Recommended for further consideration or development |
|---|---|---|---|---|---|
| Treatment of severe sustained and unresolved hypertension in pregnancy within 30 minutes (systolic blood pressure >160 mm Hg or diastolic blood pressure>110 mm Hg) | Yes<br>Elevated blood pressure is a significant cause of maternal morbidity and death. | Yes<br>Studies based on maternal death reviews suggest delay in diagnosis and treatment is associated with increased mortality rates. | Yes<br>Protocols decrease mortality rates from intraventricular hemorrhage. | Yes<br>Standard treatment protocol allows implementation and immediate treatment; may be difficult to abstract data in electronic medical record systems. | Yes<br>Other blood pressure thresholds and time intervals to treatment were also discussed. |
| Documentation of care transition and education after delivery for women with gestational hypertension, preeclampsia, or eclampsia | Yes<br>Elevated blood pressure persists postpartum in 6—34% of women. | Yes<br>Follow-up and treatment, if needed, can reduce morbidity and lifetime risk of subsequent morbidity. | Unclear<br>Documentation of referral at time of discharge vs postpartum visit within 7—14 days with appropriate treatment or referral | Unclear<br>Chart audit for documentation of referral or follow-up evaluation; not linked to outcome; confirmed postpartum visit could be done with administrative data at system level; requires additional specific data field in inpatient record for electronic health record abstraction for referral and education. | Yes<br>Accepted for documented appointment or care transition and patient education before hospital discharge. |
| Cesarean delivery | | | | | |
| Total cesarean delivery rate | Yes<br>Significant variation across hospitals and providers | Unclear<br>No consensus regarding medically indicated cesarean deliveries; variable operative vaginal delivery skills are dependent on clinician experience; needs adjustment for case mix. | Unclear<br>Needs adjustment for case mix for comparisons | Unclear<br>Case mix adjustment could be burdensome. | No |
| Nulliparous, term, singleton, vertex delivery rate | Yes<br>Significant variation across hospitals and providers | Unclear<br>Specified denominator accounts for risk adjustment; significant maternal and neonatal morbidities are associated with cesarean delivery; clinicians are not in agreement about limited exclusions; not sensitive to patient preferences. | Yes<br>May not be adequate for larger-volume hospitals or regional centers with patients at increased risk for cesarean delivery. | Yes<br>Currently being monitored | Yes |

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**TABLE 1**
**Principal workshop-proposed measures for participant consideration as a quality measure: rationale for inclusion or exclusion** *(continued)*

| Proposed measures | Importance | Scientific acceptability | Usability | Feasibility | Recommended for further consideration or development |
|---|---|---|---|---|---|
| SMFM cesarean delivery rate | Yes<br>Significant variation across hospitals and providers | Unclear<br>Enhanced denominator accounts for more significant risk adjustment; coding not validated across centers; does not account for parity; significant maternal and neonatal morbidities are associated with cesarean delivery. | Yes<br>Allows for a larger population to be measured because of lack of exclusion of multiparous women, which may improve usage; decreased month-to-month variability in smaller hospitals. | Yes<br>However, increases burden of measurement by including more data extraction. | No<br>Not currently recommended, but needs further research; may be better for evaluation of maternal-fetal medicine subspecialists. |
| VBAC/TOLAC<br>1. VBAC rate<br>2. VBAC success | Yes<br>Twelve percent of women have had a previous cesarean delivery and are candidates for VBAC; VBAC success approaches 70% in appropriate candidates. | Yes<br>VBAC rates inversely are correlated with total cesarean rates; repeat cesarean deliveries are associated with increased morbidity over time; VBAC counseling influences uptake of attempted trial of labor. | Unclear<br>VBAC rate depends on access; many hospitals do not meet standards or have chosen not to offer VBAC for risk management reasons; potential for downstream complications if incentivized for VBAC success. | Yes<br>Can use administrative data for VBAC rate and VBAC success rate. | No |
| TOLAC counseling | Yes<br>Accepted by major organizations | Unclear<br>Concern exists about monitoring the content of information for TOLAC counseling. | Unclear<br>TOLAC counseling does not address content, shared decision-making, or language differences. | Unclear<br>Requires extensive chart audit and documentation; dichotomous (yes/no) does not address usability. | No |
| Antibiotic prophylaxis for cesarean delivery | Unclear<br>Possible low incidence of current noncompliance with therapy;<br>no current data was found regarding variation in prophylaxis. | Yes<br>Infection is fourth leading cause of maternal death in the United States; perioperative antibiotics decrease infectious morbidity. | Yes<br>Differences between prophylaxis pre- vs post-incision are clinically meaningful. | Yes<br>Use existing hospital infrastructure for surgical prophylaxis. | Yes |

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**TABLE 1**
**Principal workshop-proposed measures for participant consideration as a quality measure: rationale for inclusion or exclusion** *(continued)*

| Proposed measures | Importance | Scientific acceptability | Usability | Feasibility | Recommended for further consideration or development |
|---|---|---|---|---|---|
| Hospital-based emergencies | | | | | |
| Venous thromboembolism risk assessment | Yes<br>Venous thromboembolism is a leading cause of death in the United States and has significant long-term sequela. | Yes<br>Multiple protocols, evidence addresses primary prevention for patients at increased risk; pregnancy is risk factor, yet no clinical trials: re: prevention in pregnancy. | Unclear<br>International population-based cohort studies demonstrate improved maternal outcomes (decreased mortality rate). | Yes<br>Current infrastructure for risk assessment and monitoring has been implemented widely in hospitals for nonpregnant medical and surgical populations. | Yes<br>All pregnant women should undergo venous thromboembolism risk assessment and receive treatment if at increased risk; recommend tracking of prophylaxis rates, harms (wound infection, heparin-induced thrombocytopenia, hemorrhage) for further analysis. |
| Obstetric hemorrhage (≥4 units transfused) | Yes<br>Obstetric hemorrhage a leading cause of maternal death in United States;<br>significant racial disparity | Yes<br>Death reviews demonstrate that some instances are preventable. | Unclear<br>Concerns about attribution and withholding transfusions because of fear of penalty | Yes<br>Caution regarding regionalized "accreta centers"; consider exclusion of diagnosis of placental invasion abnormalities, clotting abnormalities, trauma, sickle cell disease, amniotic fluid embolus. | No |
| Total packed red blood cells per 1000 deliveries | Yes<br>Obstetric hemorrhage is a leading cause of maternal death in United States;<br>significant racial disparity. | Yes<br>Death reviews demonstrate that some instances are preventable; the benchmark number of transfused units is known (estimated range of 40–60/1000 deliveries). | Yes<br>Relative benchmark known | Yes<br>Caution regarding regionalized "accreta centers"; consider exclusion of diagnosis of placental invasion abnormalities, abruption, trauma, sickle cell disease, amniotic fluid embolus. | Yes |

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**TABLE 1**
**Principal workshop-proposed measures for participant consideration as a quality measure: rationale for inclusion or exclusion** *(continued)*

| Proposed measures | Importance | Scientific acceptability | Usability | Feasibility | Recommended for further consideration or development |
|---|---|---|---|---|---|
| Presence of obstetric hemorrhage protocol | Yes<br>Obstetric hemorrhage is a leading cause of maternal death in United States; significant racial disparity. | Unclear<br>Death reviews demonstrate some instances are preventable; studies that relate to presence of protocols show inconsistent results. | Yes<br>Protocols in place in many larger centers | Yes<br>Ease of measurement | No |
| Sepsis bundle in all hospital systems that perform obstetrics | Yes<br>Fourth leading cause of maternal death and accounts for 5% of maternal intensive care unit admissions. | Yes<br>Sepsis bundle associated with decreased mortality rates. | Yes<br>Early recognition and treatment associated with decreased mortality rate. | Yes<br>But need modified scoring systems to identify pregnant women at increased risk. | Yes<br>Also recommend hospital-based internal quality review for initiation of management protocol and in-person provider evaluation in $<3$ hours from suspicion of diagnosis. |
| Obstetric ultrasonography and genetics | | | | | |
| Accreditation | Yes<br>Many centers with no minimal standards. | Yes<br>Studies demonstrate improved image quality and completeness in accredited units. | Yes | Yes<br>Low cost | Yes |
| Prenatal detection of congenital cardiac anomalies | Yes<br>Cardiac anomalies are the most common major congenital defect; anomalies occur in approximately 1% of births. | Yes<br>One fourth of congenital heart defects require early surgery and management in a tertiary care center. | Yes<br>Knowledge before delivery could impact decision-making and outcomes. | Yes<br>Current postnatal screening programs allow for identification of missed diagnosis and over-diagnosis. | Yes<br>Requires a neonatal $O_2$ saturation screening program. |
| FGR detection | Yes<br>Incidence 5–7% | Yes<br>FGR is associated with significant morbidity and death. | Unclear<br>Several FGR definitions; no treatment options that change course; different management strategies for follow-up evaluation | Unclear<br>Needs consensus agreement on definition and trials to demonstrate effective management protocols with improved outcomes. | No |

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**TABLE 1**
**Principal workshop-proposed measures for participant consideration as a quality measure: rationale for inclusion or exclusion** *(continued)*

| Proposed measures | Importance | Scientific acceptability | Usability | Feasibility | Recommended for further consideration or development |
|---|---|---|---|---|---|
| Doppler assessment of umbilical artery in newborn infants who weigh <5% for gestational age | Yes<br>In agreement with current standard by ACOG and SMFM for use with FGR. | Yes<br>Reduction in mortality rates and morbidity | Yes<br>Knowledge could impact decision-making and outcomes. | Unclear<br>Requires time- consuming chart audits from outpatient and inpatient sites. | No |
| Aneuploidy screening or diagnosis offered to women <24 weeks of gestation at first visit | Yes<br>Current standard by ACOG and SMFM;<br>required for equitable care | Unclear<br>Controversy exists regarding ideal test for high-risk and low-risk women. | Unclear<br>Appropriate counseling is an important component, but quality of counseling cannot be measured easily. | No<br>Would require chart audit of a large majority of pregnant women. | No |
| Percentage of high-risk women with documentation of genetic screening and testing options | Yes<br>Current standard by ACOG and SMFM;<br>required for equitable care | Yes<br>Trials support variations in outcomes based on adequate counseling. | Yes<br>Trials show that counseling leads to changes in test use and patient satisfaction. | No<br>Would require chart audit of a large majority of pregnant patients; components of adequate counseling are unclear. | No |
| Microarray analysis when a diagnostic invasive procedure is performed in the setting of fetal structural anomaly | Yes<br>Current standard of societies | Yes<br>Enhanced detection of abnormality in this setting with microarray | Yes<br>May give important information not seen on routine karyotype; some problems exist with counseling of unknown variants. | Yes<br>Requires chart audit for data abstraction, but numbers would be limited. | Yes |

*ACOG*, American College of Obstetricians and Gynecologists; *FGR*, fetal growth restriction; *NICU*, neonatal intensive care unit; *SMFM*, Society for Maternal-Fetal Medicine; *TOLAC*, trial of labor after cesarean delivery; *TVCL*, transvaginal cervical length; *VBAC*, vaginal birth after cesarean delivery; *VLBW*, very low birthweight.

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**TABLE 2**
**Workshop attendee-recommended new quality measures January 2016: numerator and denominator (when appropriate)**

| Recommended quality measure | Numerator | Denominator |
|---|---|---|
| Optimal antenatal corticosteroid administration | No. of women who delivered liveborn infants between 24 0/7 and 33 6/7 weeks of gestation who received at least 1 dose of corticosteroids within 7 days of delivery; valid only for first or second course | No. of women who delivered liveborn infants between 24 0/7 and 33 6/7 weeks of gestation |
| Delivery of a very low birthweight liveborn infant at appropriate neonatal intensive care unit level of care (for measurement by birth centers and level I or II) | Any liveborn infant at ≥24 weeks and <1500 g delivered at a birth center or a center with a level I or II neonatal intensive care unit whose mother presented and stayed at a center ≥24 hours before delivery | No denominator proposed for consideration as a "serious reportable event," case management category; serious reportable events are considered serious, largely preventable, and harmful clinical events |
| Timely treatment of severe hypertension in pregnancy | No. of pregnant women ≥20 weeks of gestation or postpartum with a sustained and unresolved blood pressure measurement of systolic ≥160 mm Hg or diastolic ≥110 mm Hg who receive an antihypertensive agent within 30 minutes | No. of pregnant women ≥20 weeks gestation or postpartum with a sustained blood pressure measurement of systolic ≥160 mm Hg or diastolic ≥110 mm Hg |
| Low-dose aspirin for prevention of preeclampsia[a] | No. of women who delivered with a history of preeclampsia that required preterm delivery at <34 weeks or preeclampsia in >1 previous pregnancy and who received outpatient daily low-dose aspirin prophylaxis before delivery | No. of women who delivered who had a history of preeclampsia that required preterm delivery at <34 weeks or preeclampsia in >1 previous pregnancy |
| Magnesium sulfate for seizure prophylaxis in preeclampsia with severe features | No. of women who delivered with preeclampsia with severe features who receive magnesium sulfate seizure prophylaxis | No. of women who delivered with preeclampsia with severe features |
| Follow-up evaluation and education of women with gestational hypertension or preeclampsia | No. of women who delivered with a diagnosis of eclampsia, preeclampsia, or gestational hypertension who had combined documented care transition with a primary care provider and documented patient education on future cardiovascular and metabolic complications before hospital discharge | No. of women who delivered with eclampsia, preeclampsia, or gestational hypertension |
| Cesarean delivery rate[b] | No. of cesarean deliveries for nulliparous, term, singleton, vertex pregnancies | Total no. of deliveries for nulliparous, term, singleton, vertex pregnancies |
| Antibiotic prophylaxis for cesarean delivery | No. of women who underwent cesarean delivery and received antibiotics before skin incision | No. of women who underwent cesarean delivery |
| Venous thromboembolism risk assessment | No. of obstetric patients admitted to a hospital from documentation of pregnancy to 6 weeks postpartum who receive a venous thromboembolism assessment within 24 hours of admission | No. of obstetric patients who were admitted to a hospital for >24 hours from documentation of pregnancy to 6 weeks postpartum |
| Blood transfusion in pregnancy (adjust no. per 1000 deliveries) | Total no. of units of red blood cells transfused during pregnancy and immediately postpartum, excluding cases of placental invasion (accreta/increta/percreta), sickle cell disease, trauma, preexisting bleeding disorder, and amniotic fluid embolus | No. of deliveries, excluding cases of placental invasion (accreta/increta/percreta), sickle cell disease, trauma, preexisting bleeding disorder, and amniotic fluid embolus |
| Sepsis identification and treatment | Availability of a protocol for identification and treatment of sepsis in pregnant women: categoric (yes/no) | Not applicable |
| Obstetric ultrasound accreditation | Accreditation per nationally recognized standards that were assessed by a central organization with peer review for practices that perform obstetric ultrasonography; in addition, similarly recognized accreditation for maternal-fetal medicine practices that perform specialized detailed fetal anatomic sonography: categoric (yes/no) | Not applicable |

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**TABLE 2**
**Workshop attendee-recommended new quality measures January 2016: numerator and denominator (when appropriate)** *(continued)*

| Recommended quality measure | Numerator | Denominator |
|---|---|---|
| Detection of clinically significant congenital heart defects | No. of fetuses identified with a cardiac defect on second- or third-trimester ultrasound imaging (excluding echogenic intracardiac focus) in women who delivered at ≥24 0/7 weeks of gestation and whose neonate had a congenital heart defect that was diagnosed before discharge in centers with screening programs with neonatal $O_2$ saturation monitoring | No. of women who had a second or third trimester ultrasound scan and who had an infant delivered at ≥24 0/7 weeks of gestation with a congenital heart defect discovered before discharge in centers with screening programs with neonatal $O_2$ saturation monitoring |
| Microarray analysis in the setting of fetal structural abnormality and performance of a diagnostic invasive procedure | No. of women with a fetal structural abnormality diagnosed on ultrasound imaging at <24 weeks of gestation who underwent a diagnostic invasive procedure for genetic testing (amniocentesis or chorionic villus sampling) and had microarray analysis performed | No. of women with a fetal structural abnormality diagnosed on ultrasound scan at <24 weeks of gestation who had a diagnostic invasive procedure for genetic testing (amniocentesis or chorionic villus sampling) |

*N/A*, not available.

[a] American College of Obstetricians and Gynecologists recommendations for preeclampsia prevention with low-dose aspirin prophylaxis were updated in a practice advisory published in July 2016, after the workshop to include more groups for prophylaxis: history of preeclampsia, multifetal gestation, chronic hypertension, type 1 or 2 diabetes mellitus, renal disease, and autoimmune disease such as lupus or antiphospholipid syndrome (American College of Obstetricians and Gynecologists. Practice Advisory on low-dose aspirin and prevention of preeclampsia: Updated recommendations. July 11, 2016. Available at: http://www.acog.org/About-ACOG/News-Room/Practice-Advisories/Practice-Advisory-Low-Dose-Aspirin-and-Prevention-of-Preeclampsia-Updated-Recommendations. Accessed April 9, 2017); [b] Recent data on the Society for Maternal-Fetal Medicine displays possible improved utility vs nulliparous, term, singleton, vertex rate as a quality measure; further research should be monitored for this quality measure.

*SMFM Publications Committee. Quality measures in high-risk pregnancies. Am J Obstet Gynecol 2017.*

recommended by consensus of the workshop attendees and measurement specifics, as appropriate.

### *Preterm birth*

As the leading cause of neonatal death and disability, preterm birth affects almost 400,000 women in the United States annually. Additionally, preterm birth levies a substantial toll on the healthcare system: a preterm birth costs 12 times more than a term birth in combined maternal and immediate neonatal care.[10] Despite recent decreases in preterm delivery rates, much of which appears to result from quality monitoring efforts that has led to a reduction of late preterm birth, the United States continues to have among the highest preterm birth rates in the developed world.[11,12] Moreover, despite preterm birth rates being a significant public health priority, disparities based on race and ethnicity have persisted for decades.[13] Further reduction in the preterm birth rate is challenging because of the multifactorial cause of preterm labor and the complex epidemiologic condition of idiopathic preterm birth.

***Screening and prevention.*** Efforts to prevent preterm birth are complex and recently have been focused on cervical length measurement and subsequent interventions. Women with a previous spontaneous preterm birth are at increased risk of recurrent preterm birth.[14] Furthermore, short cervical length has long been associated with preterm birth.[15] Evidence suggests that women with a previous preterm birth who have a short cervix (<2.5 cm) demonstrated on transvaginal ultrasound scans benefit from cerclage placement.[16,17] Similarly, randomized trials have supported the efficacy of vaginal progesterone in reducing the incidence of preterm birth in women with a short cervix.[18,19] Universal cervical length screening has been proposed as a means of identifying candidates for treatment to decrease the risk of preterm birth.[20]

The workshop discussed several measures related to cervical length assessment that included identification of candidates for screening (universal vs high risk only), method of cervical length assessment (initial transvaginal sonographic screening vs transabdominal sonographic screening), and training standards for and certification in sonographic cervical length assessment. There is wide variation in the application of cervical length screening, despite continued efforts to develop consensus based on expert opinion regarding routine universal screening vs screening at-risk patients only. This variation is influenced by region, resources, and patient and provider preferences.[21] Although transvaginal cervical length assessment is more accurate than transabdominal assessment, some research suggests improved efficiency based on a strategy of transvaginal evaluation contingent on the findings of transabdominal examination.[22,23] Workshop attendees suspected that, because most practitioners perform initial cervical length screening transvaginally, little variation and only a limited opportunity exists for quality improvement with institution of a specific modality-based quality measure. Outpatient ultrasound reporting systems, which are used to document cervical length assessments, are often

separate from other electronic health record (EHR) systems, which makes data collection difficult. Finally, training in cervical length assessment (and/or specific certification) was considered for inclusion as a structural quality measure but was not recommended because of inadequate current evidence of efficacy. Thus, at this time, the workshop consensus was that no measure related to cervical length assessment could be proposed.

***Treatment.*** Randomized controlled trials and meta-analyses have demonstrated the effectiveness of progestins in decreasing preterm delivery in those women specifically identified to be at increased risk. Studies indicate that daily use of vaginal progesterone in women with a short cervix on transvaginal ultrasound scanning and no history of spontaneous preterm birth or intramuscular 17-OH progesterone injection weekly starting at 16 weeks of pregnancy for women with a history of spontaneous preterm birth are associated with a 30–40% decrease in the rate of preterm birth.[18,19,24] Despite this evidence, workshop attendees verbalized concern about reliability of the required variables, specifically the identification of the denominator (women who are candidates for treatment based on either history or cervical length) and numerator (a reliable method of ascertaining treatment that is not overly burdensome with current EHR limitations). Adequate data collection currently is hindered often by fragmentation within the healthcare system because of limitation of data communication between prenatal providers and obstetric care institutions. New infrastructure for data collection and data abstraction would need to be designed to enable interconnectivity with inpatient and outpatient medical records and vital statistics data. This presently is feasible only in select health systems. Furthermore, barriers that impact acceptance and use of progestins may impede access for patients who are at risk of recurrent preterm birth.[25] Hence, the workshop attendees were unable to agree on measures that involve progesterone administration that could be applied reliably to all practice settings.

***Corticosteroids.*** Currently, administration of corticosteroids for women at risk for delivery at 24–33 6/7 weeks of gestation is a quality measure published by the Joint Commission (PC [Perinatal Care]-03) and has achieved a high percentage of implementation. However, timing of corticosteroid administration is an important factor that has been overlooked in the Joint Commission's current quality metric. Maximum benefit of corticosteroids as shown by a reduction in intubation or respiratory support is achieved when the first dose of corticosteroids is administered within 2–7 days of delivery.[26,27] Despite this evidence, only 20% of women receive these medications within this optimal period.[28] Antenatal corticosteroid administration is timed more ideally when the indication for preterm delivery is for maternal conditions rather than for fetal indications or spontaneous labor.[29,30] Although determination of the timing of corticosteroid administration is complex and often affected by the clinical scenario, the attendees recommended the measure of corticosteroid administration within 7 days of a preterm delivery.

The workshop attendees expressed concern that overall corticosteroid administration might decrease if the current quality measure of any administration before preterm birth is changed to indicate the timing of administration. Conceptually, balancing measures are used to examine whether design improvements in one part of a system lead to problems in other areas of care. Hence, workshop attendees suggested the continuation of the current measure (Joint Commission PC-03) for any administration as a balancing measure in addition to this new enhanced quality metric.

Another concern raised was how to properly integrate the judicious administration of multiple courses of steroids within the newly quantified metric. Serial courses of corticosteroids have been associated with a reduction in birthweight, an increase in the number of small-for-gestational-age infants, and decreased head circumference.[31-33] Conversely, a single rescue course of corticosteroids has been linked to significant reduction in the incidence of respiratory distress syndrome, need for surfactant therapy, and composite morbidity when administered to women with intact membranes at <34 0/7 weeks of gestation.[34] The American College of Obstetricians and Gynecologists recommends the limitation of corticosteroid administration to 2 courses.[35] Workshop attendees agreed that the new quality measure of corticosteroid treatment within 7 days of delivery should be limited to women who receive only their first or second course to account for ideal administration.

***Magnesium sulfate.*** Magnesium sulfate has been shown to prevent moderate-to-severe cerebral palsy or death when administered to women at high risk for delivery at <32 weeks of gestation.[36,37] The American College of Obstetricians and Gynecologists and SMFM support magnesium sulfate use for neuroprotection and released a patient safety checklist for proper administration.[38,39] Although deemed of high clinical importance, workshop attendees were concerned with data accuracy and burden of data abstraction regarding timing of administration and delivery. Because of these concerns, this measure was not recommended.

***Delivery at appropriate neonatal intensive care unit level of care.*** Research has identified an association between outcomes for very low birthweight (VLBW) infants and the level of care of the neonatal intensive care unit (NICU) at the delivering hospital.[40,41] For this reason, the proportion of newborn infants who weigh <1500 g who were delivered at hospitals with the appropriate level of neonatal care was also considered as a quality measure. The neonatal death rate is reduced by 3.4% with care at a large-volume NICU compared with lower volume centers, with a number needed to treat of 30 neonates to prevent a single death of a VLBW infant.[42] Despite these data, multiple factors have led to deregionalization and proliferation of NICU beds, which include increasing availability of technology,

community-based physician competition among neonatology subspecialists, and increasing favorability of Medicaid reimbursement because of shrinking commercial insurer payments.[43] The workshop attendees discussed a measure that would consider NICU volume but were unable to recommend it because of multiple factors that would limit its implementation, which include issues of proper attribution at the provider level vs hospital level and current financial pressures, which potentially reward the presence of NICU facilities and admissions. This makes the possible implementation of this measure difficult. There was universal agreement that intended delivery of a viable VLBW infant at a birthing center or a hospital with a level I or II NICU is suboptimal. Hence, workshop attendees recommended measurement of delivery of a viable VLBW infant at a birthing center or level I or II center in contrast to the preferred optimal delivery at a level III or IV NICU.

### *Summary of recommended measures for preterm birth.*

1. Antenatal corticosteroids initiated within 7 days of delivery to patients who delivered between 24 and 33 6/7 weeks of gestation
   Balancing measure: Any administration of antenatal corticosteroids to patients delivering between 24 and 33 6/7 weeks of gestation (continuation of Joint Commission quality measure PC-03)
2. Delivery of a viable liveborn VLBW infant at appropriate NICU level of care

## *Hypertension and preeclampsia*

Preeclampsia is one of the leading causes of maternal and neonatal morbidity and death worldwide.[44] Notably, the importance of quality care is signified by the reduction in complications that has occurred over the last several decades because of improvements in access to maternity care and effective management of this condition.[45]

***Hypertensive crisis.*** Treatment of severe hypertension in pregnancy is an example of a protocol that clearly has improved outcomes. Use of an order set with automatic and rapid treatment for patients with a defined blood pressure elevation (systolic $\geq$160 mm Hg or diastolic $\geq$110 mm Hg) has resulted in the elimination of death from intracranial hemorrhage over a 5-year period that encompassed >1,256,000 deliveries.[46] The notable improvement in outcomes with this protocol led the workshop attendees to recommend a quality measure of the percentage of pregnant and postpartum women with sustained and unresolved blood pressure (systolic $\geq$160 mm Hg or diastolic $\geq$110 mm Hg) who receive treatment with an antihypertensive agent within 30 minutes of blood pressure elevation.

***Magnesium sulfate seizure prophylaxis.*** The Magpie Trial showed a 58% reduction in the relative risk of eclampsia with magnesium sulfate treatment, with a number needed to treat of 63 to prevent a single case of eclampsia in women with preeclampsia with severe features.[47] Use of magnesium sulfate for cases of preeclampsia with severe features targets women at the greatest risk of eclampsia.[48] Adopting magnesium sulfate seizure prophylaxis in preeclampsia with severe features as a quality measure is facilitated by the ease of abstraction from coding and EHR documentation. Because of the benefit of treatment and ease of measurement, a quality measure that would assess the percentage of women with preeclampsia with severe features who are receiving magnesium sulfate for seizure prophylaxis was recommended. The recommendation noted earlier should not be construed as a recommendation to defer the use of magnesium sulfate prophylaxis in cases of preeclampsia without severe features but instead as an acknowledgement of the need for prophylaxis in the clear majority of women with preeclampsia with severe features.

***Low-dose aspirin.*** Prevention of hypertensive disease of pregnancy is the preferred approach and has been the subject of multiple trials with low-dose aspirin. The United States Preventive Services Task Force has released guidelines for use of low-dose aspirin to prevent preeclampsia, which increase use of this therapy by expansion of the patients whose condition is categorized at elevated risk for the development of this disorder.[49] In contrast, ACOG endorses a more restrained approach by recommending low-dose aspirin use for women with a medical history of early-onset preeclampsia and required preterm delivery at <34 0/7 weeks of gestation or who experienced preeclampsia in >1 previous pregnancy.[50] Although the two sets of guidelines differ in the range of historic factors that require prophylaxis, both statements recommend the use of low-dose aspirin in at least some cases. Considering the somewhat conflicting nature of the guidelines at the time of the workshop, attendees suggested adoption of the more conservative ACOG recommendation of low-dose aspirin prophylaxis in pregnant women with a history of preeclampsia that required delivery at <34 weeks of gestation or preeclampsia in >1 previous pregnancy.

***Postpartum care of patients with preeclampsia.*** Gestational hypertension and preeclampsia are associated with an increased long-term risk of cardiovascular disease. The risks of stroke, coronary artery disease, and peripheral artery disease are doubled in women who are diagnosed with preeclampsia; evidence of increased disease risk can be seen in as few as 8 years after a preeclampsia diagnosis.[51,52] Incidence of subsequent hypertension is also tripled, and the rate of diabetes mellitus has been observed to almost double in patients with a history of preeclampsia or gestational hypertension.[53,54] The identification of pregnancy complications as a window to future disease is an opportunity to affect women's health beyond pregnancy. Documentation at the time of discharge for postpartum follow-up by a primary care provider for care transition and documentation of patient education of risks of future cardiovascular and metabolic disease was recommended as a combined quality

measure for women with gestational hypertension, preeclampsia, or eclampsia.

### *Summary of recommended measures for hypertension and preeclampsia.*

1. Proportion of pregnant women with sustained and unresolved blood pressure (systolic ≥160 or diastolic ≥110) who receive an antihypertensive agent within 30 minutes of continued blood pressure elevation
2. Proportion of women with a history of preeclampsia that required delivery at <34 weeks of gestation or with a history of multiple pregnancies with preeclampsia who receive low-dose aspirin antepartum
3. Proportion of women who delivered with preeclampsia with severe features who receive magnesium sulfate for seizure prophylaxis
4. Proportion of postpartum women with a current diagnosis of gestational hypertension, preeclampsia, or eclampsia who have documented care transition with a primary care provider and documented patient education on future cardiovascular and metabolic complications before hospital discharge

## *Cesarean delivery*

Cesarean delivery is the most common inpatient operation in the United States, yet rates and indications for this procedure vary widely among physicians, hospitals, and regions.[55,56] Several quality measures for this common procedure were considered: cesarean delivery rate, VBAC rate, trial of labor after cesarean (TOLAC) counseling, and administration of preoperative antibiotics.

***Cesarean delivery rate.*** The overall cesarean delivery rate does not measure quality because simple procedure frequency does not consider the case mix of the population being evaluated. Current assessment has focused on subpopulations with particular characteristics that are accessed readily from medical records in an effort to evaluate populations relatively homogenous in risk to bring objectivity to this measure. In discerning the factors that define these subpopulations, attention should be given to the ease of ascertaining the relevant data, reliability of the documentation and coding, frequency of their presence and magnitude of the causal effect on cesarean delivery, and their ability to reflect predelivery characteristics exclusively without contamination by postdelivery developments. Parity, for example, has a large effect on cesarean delivery rates because of its prevalence and attributable impact. Other prevalent factors that affect cesarean delivery rates and have been used to create more comparably measurable subpopulations are gestational age, fetal presentation, and presence of multiple gestations. Consideration of these factors have led to the creation of the "nulliparous, term, singleton, and vertex (NTSV) cesarean delivery rate." Although measurement of the NTSV cesarean delivery rate focuses on a smaller population, this subgroup is still sufficiently large, possesses seemingly ample variation in outcome, and carries implications regarding route of delivery and maternal morbidity in future pregnancies.[57]

The NTSV rate has been criticized because it does not exclude all conditions that are clinically significant and preclude vaginal delivery, such as placenta previa, nor does it consider other maternal or fetal conditions that may lead to a higher rate of cesarean delivery. In comparison, a cesarean delivery rate developed by SMFM restricts the population by the exclusion of patients with additional risk factors that may lead to cesarean delivery.[58] However, workshop attendees expressed concern that, because of the low frequency of these diagnoses in most low-risk centers, the use of the SMFM cesarean delivery rate instead of the NTSV rate would be of limited advantage. Use of coding data may also affect accuracy and reliability of the SMFM cesarean delivery rate, because coding data has been shown to be unreliable in other obstetric scenarios.[59,60] In addition, the SMFM cesarean delivery rate does not account for the effects of parity. The California Maternal Data Center found a 4-fold difference in multiparous vs NTSV cesarean delivery rates.[61] Because workshop attendees agreed that nulliparity should be considered a risk factor for cesarean delivery, measurement of the NTSV rate was considered preferable and recommended as a quality measure.

Nevertheless, the SMFM cesarean delivery rate recently has been shown to compare favorably on several aspects to the NTSV rate, including lower month-to-month variability, which may be particularly important for use as a quality metric in hospitals with lower delivery volume.[62] Recent efforts directing payment based on NTSV rates without consideration of the unintended consequences for the mother or infant have created concern.[63,64] For this reason, some workshop attendees suggested that the SMFM cesarean delivery rate may also provide an improved gauge for maternal-fetal medicine subspecialists or regional referral centers and called for further investigation to validate which cesarean delivery rate would provide the most representative assessment of quality.

***Vaginal birth after cesarean delivery and trial of labor after cesarean delivery.*** Scheduled repeat cesarean deliveries have become a major contributor to the overall cesarean delivery rate in the last decade.[65] Successful VBAC is associated with fewer immediate and long-term complications compared with a scheduled repeat cesarean delivery. Models that have examined cost and quality of life have shown dramatic savings of $164.2 million dollars and an improvement of 500 quality-adjusted life years per 100,000 women with VBAC success rates as low as 47.2%.[66]

Despite these benefits, concerns regarding possible unintended consequences of the use of the VBAC rate as a quality measure prevented its adoption. For example, many hospitals in the United States perform <1000 deliveries per year. These low-volume centers may not have the staff or

experience to respond quickly in emergent scenarios associated with TOLAC, such as uterine rupture. In these low-volume hospitals without adequate resources, not performing TOLAC may be a better approach for optimal quality of care. An additional concern about the use of the VBAC rate as a quality measure is that it may not solely measure provider and facility performance but may also reflect patient preference and demographic factors that are associated with the choice of the procedure, such as maternal age, payer, and race, rather than actual quality.[67,68] Workshop attendees also expressed concern that linking incentives to successful VBAC rates may influence provider behavior and result in missed signs of uterine rupture or slowed responses to adverse events. Furthermore, because of the rare occurrence of uterine rupture (0.7–0.9%),[69] only the largest centers may have more than a few instances of uterine rupture annually. The small sample size at smaller institutions may not yield meaningful results with which to draw conclusions about adverse effects of TOLAC or quality and may instead reflect chance.

To decrease cesarean delivery rates, some experts have called for more consistent and meaningful counseling regarding TOLAC. Hence, counseling for TOLAC has been suggested as a quality measure. However, multiple factors limit the use of TOLAC counseling as an adequate measure. Tracking the provision of counseling without evaluation of the content of the discussion does not assess the quality of counseling. The quality of counseling would be difficult to assess from administrative data because it depends on factors such as the information presented, discussion in the proper language for the patient, and whether counseling was appropriate for the patient's health literacy level. Additionally, specific elements of counseling relevant to improved outcomes have not been established. Finally, assessment of chart documentation regarding TOLAC counseling has shown that patients who currently receive counseling had no increased knowledge of the risks and benefits, which is a finding that limits its use as an effective quality measure.[70]

***Indications for cesarean delivery.*** Workshop attendees also considered quality measures to assess the appropriateness of cesarean delivery by evaluating some of the most common indications. The SMFM–ACOG Obstetric Care Consensus document, "Safe Prevention of the Primary Cesarean Delivery," includes recommendations for the appropriate length of time for diagnosis of prolonged latent phase, arrest of dilation, or failure to descend.[71] Arrest of labor accounts for 35% of all primary cesarean deliveries and 41% of primary cesarean deliveries in nulliparous women. In primigravid women, 42.6% of cesarean deliveries for failure to progress were performed at <6 cm cervical dilation; 15% of cesarean deliveries for failure to descend were performed at <2 hours in the second stage of labor.[72] Twenty-three percent of all primary cesarean deliveries are related to the treatment of patients with nonreassuring fetal heart rate patterns[73]; however, in one tertiary care center, ACOG recommendations regarding the use of scalp stimulation, acoustic stimulation, tocolytic agents, or amnioinfusion when indicated were implemented only in a limited manner.[74] Although the ACOG–SMFM Obstetric Care Consensus document recommends tracking the rate of cesarean delivery for nonreassuring fetal heart rate, it does so only for purposes of providing individual physician feedback.[71] The consensus of the workshop attendees was that the requirement for extensive chart review, lack of adjustment for case mix, and poor predictive capability and ambiguity of fetal heart tracing interpretation limits current widespread use of these measures for quality improvement outside of the previously established guidelines. Additionally, concerns were raised regarding unintended consequences of using rates of cesarean delivery because of nonreassuring fetal heart rate and possible unintended delay in delivery.

***Antibiotic prophylaxis.*** Puerperal infection and sepsis is the fourth leading cause of maternal death in the United States. It is responsible for 11.6% of maternal deaths after a live birth and contributes significantly to increasing healthcare costs.[75] Antibiotic prophylaxis for cesarean delivery reduces infection rates and its associated morbidity from endometritis, wound infection, and other complications by approximately 60% while also decreasing the length of hospital stay and overall treatment cost.[76,77] Compared with the historical approach of administering antibiotic prophylaxis after cord clamping, administration before skin incision has been shown to provide superior outcomes.[78] Workshop attendees therefore recommended the proportion of women who undergo cesarean deliveries who receive preincision antibiotic prophylaxis as a quality measure.

***Summary of recommended measures for cesarean delivery.***

1. Cesarean delivery rate in NTSV patients
2. Proportion of women with cesarean deliveries who receive antibiotics before skin incision

## Hospital-based emergencies

Because of concerns regarding excessive rates of maternal mortality and morbidity and persistent healthcare disparities within the United States, the workshop evaluated opportunities for monitoring the quality of care that is provided during obstetric hospital-based emergency scenarios, which included VTE, obstetric hemorrhage, and sepsis.

***Venous thromboembolism.*** VTE is one of the leading causes of pregnancy-related death in the United States.[79] Beyond death, VTE also can trigger long-term sequelae that include recurrent VTE, postthrombotic syndrome, lung damage, and cardiovascular compromise. Postthrombotic syndrome alone has an estimated additional cost of $7000 per year per case in the United States.[80] Because of the morbidity and mortality rates associated with VTE, primary

prevention with pharmacologic or mechanical methods is recommended for women at increased risk.

Multiple agencies, including the Agency for Healthcare Research Quality and the National Quality Forum, have evaluated the importance of VTE prophylaxis; however, the Joint Commission excluded the obstetric population from measurement. Within the obstetric population, there has been major disagreement in existing guidelines for prophylaxis. Based on various association guidelines, the percentage of pregnant women who should receive thromboprophylaxis range from 1% from ACOG, to 35% from the American College of Chest Physicians, and to 85% for the Royal College of Obstetricians and Gynaecologists.[81] Such wide variation in recommendations underscores the importance of the evaluation of outcomes and adverse effects of treatment before specific quality measures relating to VTE prophylaxis are made. Nonetheless, because of the increased risk of VTE in the obstetric population, workshop attendees recommended that some form of risk assessment should be performed for all antepartum, delivering, and postpartum patients within 24 hours of admission. Additionally, hospitals should consider monitoring for complications that are associated with pharmacologic prophylaxis, such as wound hematomas, heparin-induced thrombocytopenia, and hemorrhage.

***Obstetric hemorrhage.*** Obstetric hemorrhage is one of the major causes of maternal morbidity and death in the United States.[79] The incidence of obstetric hemorrhage varies greatly and is largely dependent on the criteria used for definition. Transfusion of $\geq$4 units of red blood cells has been used as a definition of severe obstetric hemorrhage and as a component in the definition of severe maternal morbidity.[82] Workshop attendees suggested that misinterpretation of this transfusion threshold as a quality measure or sentinel event has created confusion and concerns of improper attribution and disciplinary action instead of fulfilling its original intent as a trigger for institutional review and a means of fostering an environment of education and a culture of improvement.[83] Workshop attendees also noted that the use of this standard as a quality metric may make providers reluctant to transfuse beyond 3 units of packed red blood cells to thwart possible review. Workshop attendees therefore recommended that this measure exist only as means of internal performance improvement and education.

As an alternative, the total number of packed red blood cells transfused per 1000 delivering women was recommended as a quality measure. This measure is easily identifiable from administrative data and has an expected baseline rate of 40–60 units per 1000 births at >20 weeks of gestation.[84] The final interpretation of this measure should include recognition that hospitals that serve as regional referral centers are expected to have increased transfusion rates in comparison with other sites and that regionalization is important in decreasing maternal morbidity and mortality rates.[85] Ideally, placenta previa, placenta accreta, and other preexisting conditions that highly predispose patients for transfusion (such as trauma, sickle cell disease, amniotic fluid embolus, and preexisting bleeding disorders) should be considered exclusion criteria or factors for risk adjustment in quality measurement.

It has been hypothesized that outcomes of obstetric hemorrhage improve with better preparedness. Despite this hypothesis, one study found that <50% of hospitals have massive transfusion protocols.[86] The use of a standardized protocol for obstetric hemorrhage has been associated with mixed results regarding blood loss and transfusion rates.[87,88] Because most evidence supports rapid treatment to prevent the sequelae of massive obstetric hemorrhage, the workshop attendees recommended that all hospital labor units develop the infrastructure to enable a prompt response to this emergent scenario as part of a coordinated treatment regimen. However, because of mixed results in outcomes, the proposed structural metric of the presence of an obstetric hemorrhage protocol as a quality measure was not recommended by workshop attendees.

***Maternal sepsis.*** The incidence of maternal sepsis in pregnancy is increasing in the United States. Research shows a doubling in the risk of sepsis-associated hospitalizations, an increase in diagnosis of severe sepsis, and similar increases in related deaths over a 10-year period.[89] Currently, maternal sepsis is the fourth leading cause of maternal death in the United States and is responsible for 5% of intensive care unit admissions during pregnancy.[75,90] Complications from sepsis have led to the formulation of management algorithms that are designed to improve early identification and care in nonpregnant populations.[91] Protocols for sepsis management can be initiated through nurse-driven screening programs to expedite delivery of care.[92] Unfortunately, the variables and criteria used for early identification within a nonpregnant population of patients who are at risk for sepsis and systemic inflammatory response syndrome overestimate the risk of morbidity and death for the pregnant patient.[93] A retrospective study has shown that a modified scoring system had high sensitivity, specificity, and negative predictive value for intensive care unit admission and may hold promise for future use in pregnant individuals, but this scoring system has not been validated and explicitly cannot be recommended currently.[94]

Once an individual has been identified to be at risk for sepsis, prompt treatment should be initiated. The components of different sepsis treatment bundles vary, but most protocols include key components such as identification and risk stratification by lactate level, early antibiotic therapy, and rapid administration of fluid therapy within 3 hours of diagnosis.[91,94-97] Because the overall number of obstetric cases with septic complications at individual hospitals remains small, the use of outcome-based measures may be limiting; hence, the recommendation for a general

management bundle protocol rather than specific outcome measures. The presence of a sepsis management bundle has been associated with a 25% decrease in mortality rates, decreased time in intensive care, and decreased lengths of hospital stays in nonpregnant patients.[98] Because of the improved outcomes with early identification and treatment of sepsis, the workshop attendees suggested the use of a sepsis bundle for pregnancy as a structural quality measure for institutions. Initiation of management within 3 hours of the diagnosis of suspected sepsis with a protocol and in-person provider evaluation was also recommended as an important hospital-based measure for internal quality review.

### *Summary of recommended measures for hospital-based emergencies.*

1. Proportion of obstetric patients who undergo VTE risk assessment within 24 hours of hospital admission
2. Measurement of the total number of units of RBCs transfused per 1000 delivery hospital encounters, excluding cases of cases of placental invasion, (accreta/increta/percreta), sickle cell disease, trauma, preexisting bleeding disorder, and amniotic fluid embolus
3. Presence of a protocol for sepsis identification, evaluation, and treatment that includes pregnant patients

### *Outpatient care: ultrasonography and genetics*

Quality measures currently focus almost exclusively on inpatient treatment because of formalized electronic medical record systems that facilitate data collection. However, the clear majority of patient-provider interactions for women with high-risk pregnancies occur within an outpatient setting. Medical decisions and procedures performed in the outpatient setting have tremendous effects on the cost of care and eventual patient outcomes in both the inpatient and outpatient spheres. For these reasons, the workshop considered measures for the ambulatory care setting, specifically for obstetric ultrasonography and genetic testing.

***Ultrasonography.*** In the United States, an average of 4.55 ultrasound examinations are performed for each low-risk pregnancy.[99] The number of obstetric ultrasounds examinations performed per pregnancy varies widely by state, which raises concern that factors other than standardized medical indications may be driving usage.[100] Specialized ultrasound examinations, such as umbilical artery Doppler (current procedural terminology [CPT] 76820) and specialized detailed fetal anatomic sonography (CPT 76811), have high variation in usage,[100,101] but further study is needed to recommend usage thresholds for these procedures. However, eventual quality measures in this area are needed with the goal of reducing unnecessary usage and cost.

***Accreditation.*** A lack of regulatory control within the field of obstetric ultrasound imaging has resulted in variation in quality and a high incidence of misdiagnosis. In the last decade, 40% of practices initially seeking accreditation for obstetric ultrasonography fell below minimal standards and guidelines.[102] Calls for accreditation have received limited attention because the incidence of congenital abnormality is low (approximately 3–5%); hence, even practices that do not meet accreditation standards will not miss abnormalities in the overall majority of patients, which makes it more difficult to make the case for accreditation. Potential benefits of ultrasonography accreditation include identification of weaknesses in practice, acceptance of recognized ultrasonography guidelines, standardization of personnel qualification and education, performance within safety criteria, and requirement of proper reporting and documentation standards. In practices that participate in an accreditation process, use of standardized imaging protocols for specific types of ultrasound examinations have been shown to improve the quality and consistency of images over time.[102] Thus, accreditation by a central body is suggested as a measure of ultrasound quality for all centers that provide obstetric ultrasonography services. Furthermore, accreditation for obstetric ultrasonography and for specialized detailed fetal anatomic sonography (CPT 76811) is recommended for all maternal-fetal medicine practices.

***Fetal anomaly detection.*** The workshop attendees also considered the development of quality indicators for detection of major abnormalities with obstetric ultrasonography. The recognition of major fetal cardiac anomalies has a moderate-to-high rate of misdiagnosis and wide variation in ultrasound detection among sites.[103,104] Congenital heart disease is the leading cause of death from anomalies in the first year of life and affects approximately 1% of all pregnancies.[105,106] Misdiagnosis is also associated with increased neonatal death and longer length of hospital stay.[107,108] Current recommendations call for screening of neonates with pulse oximetry, which may assist in the detection of 29.5% of cases of nonsyndromic congenital heart disease that are currently diagnosed >3 days after birth.[109] Neonatal oxygen saturation monitoring provides a means of hospital-based postnatal detection of congenital heart disease and allows the identification of missed diagnosis in patients with a previous second- or third-trimester ultrasound examination as a quality measure. The percentage of congenital heart defects that are detected before delivery in infants with a prenatal ultrasound examination after the first trimester is recommended as a quality measure. Hospitals should also track individual physician performance as a provider-based quality improvement program.

***Fetal growth restriction.*** Intrauterine fetal growth restriction (FGR) is associated with a 360% increase in the rate of stillbirth and a 130% increase in the rate of neonatal death. Compared with prenatal diagnosis of FGR, lack of detection is associated with a 3-fold increase in fetal acidemia or seizure, neurologic damage, or death.[110] Prenatal detection of FGR allows Doppler assessment of the umbilical artery, which is associated with reductions in labor induction, cesarean delivery, and perinatal death.[111] However, workshop

attendees opted not to recommend a quality metric directed at detection of FGR because of multiple concerns. These include the feasibility of operationalizing ultrasound detection of FGR because of difficulties in postdelivery data capture and follow-up evaluation, poor detection rates of growth restriction by ultrasound scanning, lack of a reasonable consensus threshold for FGR, and coordination of data extraction for inpatient and outpatient sites.

***Genetic counseling and testing.*** Controversy exists regarding quality measures for genetic counseling services. The American College of Medical Genetics states that there are no clear baseline measures that are nationally accepted, user driven, and rigorously developed.[112] Additionally, measurement of quality in prenatal genetic testing is difficult for several reasons: lack of current consensus regarding ideal protocols, rapid changes in testing technologies, and significant variation in testing implementation because of patient preference. Emerging technologies are introduced rapidly, with inadequate studies from a population, health system, or cost-effectiveness perspective. Because fetuses with an anatomic abnormality noted on ultrasound imaging are at a higher risk of chromosomal abnormality, there is general agreement that invasive diagnostic testing is recommended. In women who undergo amniocentesis, other-than-common benign copy number variants are found in 8.1% of women with ultrasound-detected anomalies vs 3.6% of those without ultrasound-detected anomalies.[113] Additionally, a review of several large-scale studies reported clinically significant deletions or duplications in 6.5% of cases with abnormal ultrasound findings, despite these cases having normal karyotypes.[114] Workshop members therefore suggested a quality measure for the performance of chromosomal microarray analysis in the setting of a fetal structural anomaly when invasive diagnostic testing is performed.

### *Summary of recommended measures for outpatient care: ultrasonography and genetics.*

1. Performance accreditation for practices that perform obstetric ultrasound per nationally recognized standards as assessed by a central organization with peer review; performance accreditation within maternal-fetal medicine practices that provide specialized detailed fetal anatomic sonography (CPT 76811) per nationally recognized standards as assessed by a central organization with peer review
2. Rate of prenatal second- and third-trimester ultrasound detection of clinically significant congenital heart defects in centers with neonatal screening programs
3. Proportion of women who receive microarray analysis at the time of diagnostic prenatal testing in the setting of fetal structural abnormality

## *Information gaps and future research*

A major objective for the workshop was to coalesce expert efforts on quality improvement and thereby examine the available evidence, evaluate the current landscape within obstetrics, and develop measures that would drive high impact on outcomes, quality, and value. The workshop organizers understood that many of the proposed quality measures may be difficult to implement initially because of deficiencies in system infrastructure that supports data collection or measurement, lack of integration of electronic records between ambulatory and hospital services, and insufficient provider influence in the fields of quality measurement and informatics. Reviews of maternal deaths have found that a significant proportion of cases may have preventable causes.[115] The Alliance for Innovation on Maternal Health has set a goal to prevent 100,000 cases of severe maternal morbidity and 1000 cases of maternal death over a period of 4 years.[116] Dissemination of patient safety bundles and efforts for quality improvement via efforts led by the California Maternal Quality Care Collaborative have produced a concomitant statewide 60% reduction in maternal mortality rates since 2006.[117] The efforts of state-based perinatal quality collaboratives, which were formed as networks of providers and health professionals, can assist in the improvement of quality care for women and their children. The recent launch of the National Network of Perinatal Quality Collaboratives holds promise as a means for sharing best practices, lessons on implementation, and the formation of an initial infrastructure for networking and support.

The identification and construction of quality measures should move forward under the impetus to provide improvement over punishment. Production of quality measures, which includes those provided by this workshop, must be examined rigorously, and possible balancing measures must be kept in mind to avoid unintended consequences of inappropriate rewards or penalties. Measures should present low burden and affordability to providers and hospitals or outpatient clinics. For actual quality to be measured, more effective measures eventually will require appropriate risk adjustment. The development of measures should connect peers and involved parties as teams to avoid the burden and possible consequences of unnecessary or flawed measure development.

Currently, our inability to obtain sufficient data because of inadequate data systems is a significant limitation to quality measurement efforts. The workshop organizers and attendees understood that many useful quality measures cannot be implemented because of a lack of current system infrastructure and standardized documentation elements. EHRs are omnipresent but frequently lack enhancements that promote meaningful functionality, efficiency, system interoperability, and readily available data abstraction capability. Furthermore, decisions regarding the purchase and implementation of EHR systems frequently are made on the basis of cost, presumed clinical need, and institutional revenue generation, sometimes at the expense of data reporting and analytic capability. Clinicians are entering information geared towards documentation of clinical care rather than data generation and abstraction needs. The

often unstructured information entered by providers provides a comprehensible story for patient care but is inadequate for reporting and data functions. Conversely, structured data entered for the purposes of reporting are often inadequate for use in logical documentation of patient care. In addition, there is a lack of data standardization that makes information dissimilar across individual sites of care.

Current efforts at a standardized medical record system have started with the Medical Quality Improvement Program that is now being implemented at the University of Rochester and a community hospital system. This system is based on similar efforts in anesthesia that have been overseen by the Anesthesia Quality Institute. In the system administered by the Anesthesia Quality Institute, data entry is performed by providers for approximately 20% of all anesthesia cases in the United States. This database supplies provider benchmarks, continuous improvement monitoring, and performance analysis. The Medical Quality Improvement Program seeks to provide a national clinical data registry focused on maternal and neonatal outcomes created by doctors and nurses. Although efforts like the Medical Quality Improvement Program are to be applauded, they are likely to engender resistance for several reasons. Most deliveries take place in hospitals that perform $<$1000 deliveries per year. In addition, these hospitals often use lower quality EHRs, have fewer support personnel, and lack financial resources to assist with implementation, updates, and support.

Clearly, multiple efforts are needed to improve the measurement of obstetric quality. A significant component in this effort would be the formation of a national birth certificate system. The current system of individual state certificates introduces variability in data elements and collection, therefore impeding meaningful progress. A national birth certificate would simplify data entry requirements from EHR vendors and would enable the standardized upload of data entry from both inpatient and outpatient systems. A national birth certificate with standardization of data entry could allow major improvement through linking medication exposures, specific interventions, and obstetric history directly to the care of the woman and neonate. Additionally, it would allow real-time evaluation of these interventions, thereby facilitating and accelerating data collection and evaluation that could immediately improve care, decrease maternal and neonatal morbidity, and save lives.

Current measures to assess patient satisfaction within healthcare systems are generic, flawed, and do not address the specific issues associated with maternity care that account for $>$4 million births and $>$ 20% of all hospital discharges. Consumer Assessment of Healthcare Providers and Systems surveys must address specific pain care issues that are unique to childbirth and provide specificity for pain control in settings of vaginal birth vs cesarean delivery. Current Consumer Assessment of Healthcare Providers and Systems questions focus on care in the last 12 months instead of the episode of maternity care. Survey questions should acknowledge the possible use of advanced practitioners or alternative birthing centers instead of focusing solely on physicians and hospitals. In addition, the availability of the questionnaires in English only prevents a large proportion of the maternity population from being adequately sampled. Hence, a specific Consumer Assessment of Healthcare Providers and Systems survey centered on maternity care for facilities, providers, and health plans is recommended.

To facilitate our attempts at quality improvement, we will need multifaceted efforts. EHR vendors and the major societies in obstetrics will need to work together to improve record usability and efficiency, while incorporating the needs for workflow improvement. A balance will need to be struck between structured data and textual documentation with endorsement of set standards. Further research in quality improvement and informatics is required, and these topics should be part of the standard medical training curriculum. The current gaps stress the need for clinical physician informaticians who can assist with EHR design and data quality improvement to help with quality improvement efforts.

### *Summary of recommended measures for information gaps and future research.*

1. Systematic efforts to develop more physician informaticians in our field who are experts on EHR design, data quality/governance, and quality and performance improvement
2. Development of a national birth certificate system with mandatory data entry from inpatient and outpatient EHR systems
3. Partnership with EHR vendors to meet usability and efficiency needs while incorporating workflows that collect accurate and usable clinical data
4. Strong support of clinical standardization and registry development in obstetrics
5. Research into understanding the proper balance of discrete structured data to textual documentation and endorsement and training to those standards
6. Endorsement of regulatory standards for data quality and governance
7. Initiation of efforts to make quality improvement and informatics a part of the standard training curriculum for students, residents, and fellows (along with training for current faculty)
8. Encouragement of research and publications in quality improvement and informatics
9. Formation and use of specific maternity-care–based Consumer Assessment of Healthcare Providers and Systems surveys for facilities, providers, and health plans

## Comment

This workshop brought together our multiple organizations, clinicians, and researchers to suggest and make progress

towards the realization of meaningful quality measures for high-risk obstetric conditions. In conjunction with applicable providers, we must take a more consistent role in measure development, research, analysis, validation, and refinement. Our hope is that the measures suggested within this document serve a basis for quality assessment and are considered a framework for future validation and inclusion in obstetric quality programs. Research on these and other quality measures is needed to identify ideal quality goals, prevent unintended consequences, and improve risk-specific measure adjustment for measure refinement. Partnerships between providers, patients, EHR vendors, payers, hospital systems, and governmental agencies are needed to provide cost-efficient solutions with the connectivity, interoperability, and mandated information to improve care consistently and provide transparency and accountability. To achieve these goals, the formation of an ongoing task force or committee with commitment to quality measure refinement, validation, research, and reform that involves obstetric providers and major organizations is recommended.

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