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# Society for Maternal-Fetal Medicine Special Statement: Quality metrics for optimal timing of antenatal corticosteroid administration

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Preterm birth is a leading cause of perinatal morbidity and mortality. Antenatal corticosteroid administration before preterm birth reduces the risks of perinatal death, respiratory morbidity, necrotizing enterocolitis, and intraventricular hemorrhage and reduces the costs of perinatal care. Antenatal corticosteroids are optimally effective when administered within 7 days before preterm birth. However, only 20% to 40% of early preterm infants receive antenatal corticosteroids within 7 days before birth, in part because it is difficult to predict the precise timing of preterm birth. Until 2020, The Joint Commission had a Perinatal Care quality metric measuring the rate of antenatal corticosteroid administration at any time before early preterm birth. This metric incentivized providers to use antenatal corticosteroids liberally. The Joint Commission retired the metric in 2020 after the rate reached more than 97% in The Joint Commission-accredited hospitals. However, metric did not evaluate whether the timing of antenatal corticosteroid administration was optimal, that is, within 7 days of birth. A 2016 multistakeholder Cooperative Workshop recommended the development of a new quality metric to assess the rate of optimally timed antenatal corticosteroids among early preterm births. In this statement, we outline proposed specifications for such a metric and discuss potential uses, advantages, limitations, and barriers. Furthermore, we propose a balancing metric that tracks the percentage of patients treated with antenatal corticosteroids who ultimately give birth at term. We suggest that the use of these new metrics may incentivize more conservative antenatal corticosteroid timing, which could, in turn, lead to meaningfully improved outcomes for preterm neonates.

Key words: betamethasone, dexamethasone, perinatal death, perinatal morbidity, preterm birth, quality improvement

# Introduction

Preterm birth, defined as birth at <37 weeks of gestation, is the leading cause of mortality in infants without major structural anomalies.<sup>1–5</sup> Furthermore, preterm birth accounts for more than one-half of long-term child morbidity.<sup>6,7</sup> Accumulated evidence from more than 25 trials has demonstrated that antenatal corticosteroid administration reduces the risk of respiratory distress syndrome, intraventricular hemorrhage, necrotizing enterocolitis, and perinatal death for preterm neonates<sup>8</sup> and may reduce the risk of early childhood morbidity, such as cerebral palsy.<sup>9</sup> These improved outcomes result in decreased costs to care for preterm newborns.<sup>10–12</sup> No other obstetrical intervention has been shown to have such diverse and consistent benefits for preterm newborns as antenatal corticosteroids.

After the publication of the initial trial showing the benefits of antenatal corticosteroids in 1972,<sup>13</sup> clinical uptake of their administration remained limited for decades.<sup>14–17</sup> In 2013, The Joint Commission (TJC) established a perinatal core quality measure (Perinatal Care Measure 03 [PC-03]) that assessed a hospital's rate of antenatal corticosteroid administration before early preterm births.<sup>18</sup> By 2017, TJC reported that antenatal corticosteroid administration at TJC-accredited hospitals increased steadily from 81.8% of early preterm births in 2012 to 97.8% in 2016.<sup>18</sup> TJC retired the PC-03 measure in 2020, presumably because there was little room for further improvement. Importantly, the numerator of the PC-03 metric included all patients who had antenatal corticosteroids initiated before an early preterm birth without any specification of the timing of initiation, encouraging an aggressive approach to antenatal corticosteroid administration.

Appropriate timing of antenatal corticosteroid administration is challenging in clinical practice. Although neonatal benefits begin to accrue in just a few hours,<sup>8,19–21</sup> outcomes are best when maternal antenatal corticosteroid

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administration occurs 1 to 7 days before birth.<sup>8,21–23</sup> In contrast, if the pregnancy is eventually delivered at term, several studies suggest the association of antenatal corticosteroids with adverse outcomes, including increased rates of neonatal intensive care unit (NICU) admission, small for gestational age, severe childhood morbidity, and childhood mental, neurocognitive, and behavioral disorders.<sup>24–30</sup>

Recent studies report uniformly low rates of optimally timed antenatal corticosteroid administration before preterm birth. A population-based study from Canada<sup>31</sup> found that optimally timed antenatal corticosteroid administration (defined as 24 hours to 7 days before birth) for births at 24 to 34 weeks of gestation increased from 10% in 1988-1992 to only 23% in 2008-2012. During this period, suboptimally timed antenatal corticosteroid administration increased from 7% to 34% of births at <34 weeks of gestation; moreover, 52% of patients who received antenatal corticosteroids at <34 weeks of gestation gave birth >2 weeks later,<sup>31</sup> a scenario in which antenatal corticosteroid treatment is unlikely to be beneficial.<sup>8,20,32,33</sup> A single-center study from the United States found that a course of antenatal corticosteroids was given in 93% of births at 24 to 34 weeks of gestation, but the timing of administration was optimal in only 40%.<sup>34</sup> A population-based study from Finland reported that <40% of preterm newborns from 2006 to 2017 received antenatal corticosteroids and that >45% of cases in which a course of antenatal corticosteroids was given eventually gave birth at term.<sup>26</sup> It is intuitive to postulate that incorporating a repeat or "rescue" course of steroids might improve the rate of antenatal corticosteroid administration within 7 days before birth. However, this idea was not confirmed in a study that reported the rate of optimally timed antenatal corticosteroid administration to be similarly low before and after a rescue course became standard practice (26% and 28%, respectively, a nonsignificant difference).35

In summary, an important quality gap exists in our current use of antenatal corticosteroids. TJC's PC-03 metric incentivized providers to give antenatal corticosteroids liberally. Therefore, most preterm infants are exposed to antenatal corticosteroids, but only 20% to 40% receive them within 1 week of birth. Moreover, it has been suggested that administering antenatal corticosteroids to a fetus who is ultimately born at term may be harmful.

In 2016, a cooperative workshop was convened during the annual meeting of the Society for Maternal-Fetal Medicine (SMFM) to consider quality measures for high-risk pregnancies.<sup>36</sup> The workshop executive summary recommended the development of a new metric reflecting optimally timed antenatal corticosteroid administration. Here, we present measure specifications for the metric proposed by the workshop and discuss advantages, limitations, and potential barriers to its use. Furthermore, we propose and critique a balancing metric that may help to guard against overly aggressive antenatal corticosteroid administration.

## Proposed Primary Quality Metric: Rate of Optimally Timed Antenatal Corticosteroid Administration

The measure specifications for the proposed metric are summarized in Table 1. This metric retrospectively evaluates the percentage of patients with early preterm birth who received antenatal corticosteroids within 7 days before birth.

### Denominator

The denominator is the number of patients giving birth to a live-born infant at 24 0/7 to 33 6/7 weeks of gestation.

#### Numerator

The numerator is the number of patients in the denominator who received at least 1 dose of antenatal corticosteroids within 6 to 168 hours (7 days) before birth. Only the initial course or first "rescue" course is counted.

#### Metric

The metric is the ratio, numerator divided by denominator, expressed as a percentage. The theoretical ideal rate is 100%.

#### Strengths and limitations

A critique of the metric is summarized in Table 2. Importantly, previous experience with TJC's now-retired PC-03 metric demonstrates that hospitals are able to obtain and track this proposed metric. Patients who give birth in the desired gestational age window can easily be identified from the labor and delivery electronic health record or NICU system. The administration and timing of antenatal corticosteroids can be extracted from pharmacy data. It may be more difficult to identify antenatal corticosteroids administered before arrival at the birth hospital, for example, in cases of maternal transfer from another facility. In such cases, the time of administration should ideally be documented in the transfer notes from the sending hospital and reflected in the admission notes at the receiving hospital.

The unit of measurement is at the level of individual patients rather than individual newborns to avoid overcounting multifetal pregnancies (eg, double-counting twin pregnancies). We consider a case eligible for the numerator if antenatal corticosteroids were administered within 7 days before the birth of the first infant in a multifetal pregnancy, regardless of the interval between antenatal corticosteroid administration and birth of the last infant.

In defining this metric, we selected 24 0/7 weeks as the minimum gestational age at birth for inclusion in the denominator. We excluded "periviable" births (before 24 weeks of gestation) because there is no consensus that antenatal corticosteroids should be routinely given for such births. Although antenatal corticosteroids are often given as early as 22 weeks of gestation,<sup>37,38</sup> a practice advisory from the American College of Obstetricians and

Element	Details
Denominator	Number of patients who give birth to a live-born infant at 24 and 0/7 to 33 and 6/7 wks of gestation
Exclusions from denominator	Birth outside of hospital
Numerator	Number of patients in the denominator who received a complete or partial initial course or first "rescue" course of antenatal corticosteroids within 6 to 168 h (7 d) before birth. Timing is based on the first dose of the course.
Exclusions from numerator	Additional "rescue" (repeat) courses of antenatal corticosteroids after the first "rescue" course
Definition of antenatal corticosteroid course	<ul> <li>Complete course of antenatal corticosteroids:</li> <li>Betamethasone 12 mg IM, 2 doses at 24-h intervals</li> <li>Dexamethasone 6 mg IM, 4 doses at 12-h intervalsPartial course of antenatal corticosteroids:</li> <li>Betamethasone 12 mg IM, 1 dose</li> <li>Dexamethasone 6 mg IM, 1 dose</li> <li>Dexamethasone 6 mg IM, 2 or 3 doses at 12-h intervals</li> </ul>
Quality metric	Ratio, numerator divided by denominator, expressed as a percentage
Type of metric	Process
Ideal (perfect) performance	100%
Indicator of improvement	Increasing rate
Unit of attribution	Birth hospital or birthing center
Period of analysis	Measure monthly, report yearly

Gynecologists (ACOG) and SMFM<sup>39</sup> concluded that antenatal corticosteroid administration is not recommended before 22 0/7 weeks of gestation but can be considered at 22 0/7 to 23 6/7 weeks of gestation. Because decisions to proceed with antenatal corticosteroids and neonatal resuscitation may differ by site, clinical scenario, or patient preference, we excluded the periviable period from the metric. This exclusion does not imply that antenatal corticosteroids should not be given, only that this metric will not track their use in births at <24 weeks of gestation. Conversely, at later gestational ages, it may be reasonable for a family to decline neonatal resuscitation in some cases at 24 0/7 to 25 6/7 weeks of gestation or for newborns with major congenital anomalies; antenatal corticosteroids may reasonably be withheld in those cases. A limitation of the metric is that such cases will not qualify for the numerator but will be included in the denominator, resulting in a rate of <100% even though care may be appropriate. However, such cases will likely account for only a small percentage of eligible cases; therefore, their inclusion should have minimal impact on a hospital's overall rate.

We based the metric on antenatal corticosteroid administration before early preterm births (<34 weeks of gestation) and do not consider late preterm births (34 0/7 to 36 6/7 weeks of gestation) despite SMFM's recommendation for antenatal corticosteroids administration before late preterm births in many cases.<sup>40</sup> This decision was, in part, made because the SMFM guidance on antenatal corticosteroid administration for late preterm birth has many exclusions (multifetal pregnancy, pregestational diabetes mellitus, certain maternal medical complications, and previous steroid course) that do not apply to early preterm birth. Tracking and excluding such cases from the denominator would add to the administrative burden of calculating the metric.

We include cases in the numerator only if antenatal corticosteroids are given at least 6 hours before birth because their clinical benefit is almost maximal by that time.<sup>8,21</sup> ACOG recommends initiating antenatal corticosteroids even if it seems likely that birth will occur within 24 hours.<sup>41</sup> The 6-hour lower limit in the numerator will minimize the potential for "gaming" the metric: if no lower limit were specified, clinicians could give the first dose of corticosteroids to an eligible individual at a very short (and ineffective) time (eg, minutes) before delivery to comply with the measure. In contrast, TJC's now-retired PC-03 metric did not have a lower limit, so cases met the numerator criteria even when corticosteroids were given 1 minute before birth when their clinical benefit is unlikely.

Another important limitation of the metric is that rates close to 100% will be virtually impossible to achieve because of the inability to accurately predict which patients might give birth within 7 days. Moreover, it is not possible to accurately predict which patients will not give birth within 7

### TABLE 2

# Critique of quality metric on optimally timed antenatal corticosteroid administration

Critique	Details	
Rationale	Antenatal corticosteroid administration reduces neonatal morbidity and mortality if given within 7 d of early preterm birth but not if given $>7$ d before birth.	
Current typical performance	20%-40%	
Maximum realistic, achievable performance (benchmark)	Unknown, likely in 60%—80% range	
Potential to stratify	Can be stratified by race and ethnicity, payer type, preterm birth phenotype (eg, spontaneous vs indicated), provider, or provider group	
Feasibility of data collection	<ul> <li>Experience with TJC's PC-03 demonstrates that hospitals can capture and report relevant data.</li> <li>Antenatal corticosteroid administration (numerator) is easily captured from pharmacy data.</li> <li>Denominator is easily captured from delivery log or NICU census. Timing requires simple calculation comparing pharmacy data and delivery data.</li> </ul>	
Potential barriers to data collection	Antenatal corticosteroids given at another facility within 7 d must be captured manually. Previous courses of antenatal corticosteroids may be difficult to capture.	
Potential unintended consequences	<ul> <li>Missed antenatal corticosteroid administration when there is clinical uncertainty regarding the likelihood of delivery within 7 d</li> <li>May encourage administration in fetuses not intended for resuscitation for whom antenatal corticosteroids are unlikely to have clinical benefit</li> </ul>	
Limitations	<ul> <li>Paucity of evidence that hospitals can improve performance</li> <li>Lack of ability to accurately predict birth within 7 d</li> </ul>	

days so that antenatal corticosteroids can be withheld. Although it might be tempting to try to "game" the metric by giving antenatal corticosteroids every week until 33 weeks of gestation to patients at high risk of early preterm birth, the ACOG guidance recommends a maximum of 1 repeat course because multiple courses have been associated with impaired fetal growth.<sup>41</sup> For this reason, we exclude patients who receive more than 1 repeat course of corticosteroids from the numerator.

# Proposed Balancing Metric: Rate of Term Birth Among Patients Given Antenatal Corticosteroids

Because antenatal corticosteroids are only beneficial if birth occurs within a week and because there is potential long-term harm if birth occurs at term after preterm corticosteroid administration,<sup>24–30</sup> facilities are encouraged to track the percentage of patients who are given corticosteroids and then give birth at term. The measure specifications for the proposed balancing metric are summarized in Table 3. This metric begins with a cohort of patients who receive antenatal corticosteroids and prospectively evaluates the proportion who give birth at term.

### Denominator

The denominator is the number of patients given one or more doses of antenatal corticosteroids at the facility or in preparation for maternal transport to the facility.

# **Numerator**

The numerator is the number of patients in the denominator who give birth at 37 weeks of gestation or later.

### Metric

The metric is the ratio, numerator divided by denominator, expressed as a percentage. The theoretical ideal rate is 0%.

# **Strengths and limitations**

A critique of the balancing metric is summarized in Table 4. Like the primary metric for optimally timed antenatal corticosteroid administration, this balancing metric may also be tracked using delivery and pharmacy records. Some manual medical record review may be needed to capture patients who receive their initial dose of antenatal corticosteroids at another facility before transport to determine which cases qualify for the denominator. Some manual follow-up may be needed to ascertain gestational age at birth for patients who are discharged undelivered and then give birth at other facilities.

This metric is intended to discourage clinicians from overusing antenatal corticosteroids as a means to improve the rate of the primary metric (ie, optimally timed antenatal corticosteroid administration). Because emerging evidence suggests potential negative effects of antenatal corticosteroids on infants born at term,<sup>24–30</sup> we believe this balancing metric will help

#### TABLE 3

# Measure specification for balancing metric: rate of term births among patients treated with antenatal corticosteroids

Element	Details	
Denominator	Number of patients treated with 1 or more doses of antenatal corticosteroids at the facility or in preparation for maternal transport to the facility	
Exclusions from denominator	Patients treated with betamethasone or dexamethasone for reasons other than an increased risk of preterm birth	
Numerator	Number of patients in the denominator who gave birth at term	
Exclusions from numerator	None	
Definition of antenatal corticosteroids	Betamethasone 12 mg IM or dexamethasone 6 mg IM	
Proposed quality metric	Ratio, numerator divided by denominator, expressed as a percentage	
Type of metric	Process	
Ideal (perfect) performance	0%	
Indicator of improvement	Decreasing rate	
Unit of attribution	Birth hospital or birthing center	
Period of analysis	Measure monthly, report yearly	
IM, intramuscular. Society for Maternal-Fetal Medicine. Quality metrics for	optimal timing of antenatal corticosteroid administration. Am J Obstet Gynecol 2022.	

clinicians think critically about the patients who should receive this treatment. However, an important consequence may be that clinicians may withhold antenatal corticosteroids in cases where they may be beneficial. In other words, in striving to improve the balancing metric, clinicians may miss cases in which antenatal corticosteroids could have been provided in advance for early preterm birth.

### **Next Steps**

We designed the metrics to be measured at the level of the hospital or birthing center and reported annually. Hospitals

#### TABLE 4

# Critique of the balancing metric: rate of term births among patients treated with antenatal corticosteroids

Critique	Details	
Rationale	If birth occurs at term, there is no known benefit attributable to receiving antenatal corticosteroids, and there are suggestions of harm.	
Current typical performance	40%-60%	
Minimum realistic, achievable performance (benchmark)	Unknown, likely in the 20%-30% range	
Potential to stratify	Can be stratified by race and ethnicity, payer type, and other demographics	
Feasibility of data collection	<ul> <li>Experience with TJC's PC-03 demonstrates that hospitals can capture and report relevant data.</li> <li>Antenatal corticosteroid administration (denominator) is easily captured from pharmacy data.</li> <li>Numerator is easily captured from delivery log unless the patient is discharged undelivered and ultimately delivers elsewhere.</li> </ul>	
Potential barriers to data collection	Need for manual tracking of antenatal corticosteroids administered at sending facility or births at any other facility	
Potential unintended consequences	Missed antenatal corticosteroids dosing in the setting of clinical uncertainty; likely more missed antenatal corticosteroids doses in the late preterm period	
Limitations	Lack of evidence that performance can be improved Lack of ability to accurately predict preterm birth	
PC-03, perinatal core measure 03; TJC, The Joi Society for Maternal-Fetal Medicine. Quality	nt Commission. • metrics for optimal timing of antenatal corticosteroid administration. Am J Obstet Gynecol 2022.	

BOX Five possible scenarios of antenatal corticosteroid administration before early preterm birth (<34 weeks of gestation)				
No.	If timing of antenatal corticosteroid administration is	The result is		
1	Too late	No antenatal corticosteroids are given		
2	Too late	Birth occurs $<$ 6 h after initial steroid dose or first rescue dose		
3	Acceptable <sup>a</sup>	Birth occurs 6–24 h after initial steroid dose or first rescue dose		
4	Optimal <sup>a</sup>	Birth occurs $1-7$ d after initial steroid dose or first rescue dose		
5	Too early	Birth occurs $>7$ d after initial steroid dose or first rescue dose		

<sup>a</sup> Included in the numerator of metric (Table 1).

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and birthing centers will have more incentives to track the primary metric and improve performance if measures must be reported to an accrediting body, such as TJC, or a reporting organization, such as the Leapfrog Group. SMFM hopes to engage with these organizations to evaluate the merits of including this new metric in their measure suites. However, even in the absence of any reporting requirement, we encourage hospitals to track the metrics to assess their need to improve the timing of antenatal corticosteroid administration and to start quality improvement efforts.

A good starting point for facilities tracking these metrics is to recognize that 5 distinct scenarios are possible regarding the timing of antenatal corticosteroid administration before early preterm birth, as summarized in the Box. Of these, only 2 are tracked in our main quality metric (acceptable timing and optimal timing). It will be most useful for facilities to track the number of cases falling into each category to inform quality improvement activities. If there are high rates of corticosteroids being administered too early, too late, or not at all, specific focus can be directed in these areas.

Although the metrics are designed to be tracked at the facility level, quality improvement activities will likely require stratification based on the indication for preterm birth, provider or provider group, maternal race and ethnicity, and other demographics. Systematic collection and analysis of these extra data would likely inform best practices, identify clinical scenarios most amenable to improvement, and identify knowledge gaps for future research. The SMFM Informatics Committee has liaisons with major electronic health records systems vendors. Tracking of these metrics and relevant ancillary data can be automated, at least in part, if the vendors can build them into their software systems.

We recognize that a major knowledge gap exists in our inability to accurately predict which at-risk patients will give birth within 7 days after evaluation. Many factors must be considered, including clinical presentation (contraction frequency, cervical dilation, membrane status, bleeding, severity of hypertensive disorders, or multifetal pregnancy), ultrasound findings (cervical length and amniotic fluid volume), and laboratory findings (fetal fibronectin, blood cell counts, serum chemistry, and urinary protein). The contribution of some of these risk factors, alone and in limited combinations, to the prediction of impending preterm birth has been studied.34,42-53 The prediction of birth within 7 days may be more accurate for patients with hypertensive disorders<sup>34</sup> or prelabor rupture of membranes<sup>51</sup> than for patients with preterm labor. Among patients with preterm labor, short ultrasonographic cervical length, cervical dilation, cervical change, and cervicovaginal fetal fibronectin correlate with the probability of delivery within a few days and may help inform the timing of antenatal corticosteroid administration.42,44,45,50,51 An ultrasonographic short cervix is a predictor of early preterm birth overall but a poor predictor of birth within 7 days in asymptomatic patients.<sup>52,53</sup> However, to the best of our knowledge, there is no validated, comprehensive, quantitative method to synthesize all these factors to estimate the probability of birth within 7 days.

ACOG recommends antenatal corticosteroids for patients "who are at risk of preterm delivery within 7 days"41 but does not quantitate the risk that is sufficiently high to warrant their administration. Should corticosteroids be given if a patient has a 5% risk of birth within a week? What if the risk is 10% or 25%? Although it seems intuitive that there should be a lower threshold for administering antenatal corticosteroid at extremely early gestational ages, statistical modeling suggests that the optimal strategy depends on complex interactions of many variables, including the indication for preterm birth and the gestational age-specific probabilities of reducing perinatal death and severe neonatal morbidity.54 Improved risk prediction would not only facilitate improved timing of antenatal corticosteroid administration but also enhance our overall understanding of the epidemiology and pathophysiology of preterm birth. Thus, to improve our

performance on this metric, we may need new research using high-quality data to improve the prediction of preterm birth. Better prediction tools would support clinicians in making decisions regarding antenatal corticosteroid administration.

Even without new research, it may be possible to improve performance by simply encouraging clinicians to thoughtfully evaluate the actual risk of birth within 7 days before giving corticosteroids to patients whose risk may be fairly low, such as those with an asymptomatic short cervix<sup>52,53</sup> or those with contractions but a long, closed cervix and negative fetal fibronectin test result.<sup>42,50</sup>

Ultimately, we envision that these metrics might be endorsed by the National Quality Forum based on satisfying strict measure evaluation criteria.<sup>55</sup> These include the importance and scientific acceptability, feasibility, usability and use, and evaluation of any related and competing measures. The usability and use criteria require a demonstration that facilities are using the metric and, most importantly, a demonstration that the rate can be improved. To date, we are not aware that any facility has demonstrated that the rate of appropriately timed antenatal corticosteroid administration can be improved from the current 20% to 40%. Although we are confident that the rate is amenable to improvement via tracking and quality improvement processes, the metrics will not satisfy the criteria for endorsement until some facilities show that improvement can be made. Such a demonstration will only be possible if facilities track their actual rate of optimally timed antenatal corticosteroid administration rather than the rate used in TJC's PC-03 metric, which ignored timing. We encourage facilities to develop pilot quality improvement projects to test the assertion that we can do far better than the current 20% to 40% rate of optimally timed antenatal corticosteroid administration before early preterm birth.

### Conclusion

Research and quality improvement efforts are needed to determine how the timing of antenatal corticosteroid administration can be improved for patients at risk of preterm birth while simultaneously minimizing antenatal corticosteroid exposure for patients who ultimately give birth at term. With the success of TJC's PC-03 in making antenatal corticosteroid administration almost universal before early preterm birth, providers and facilities may presume that there is no room to improve. However, in most cases, antenatal corticosteroids are given too early to be beneficial, and many patients who receive antenatal corticosteroids do not give birth until several weeks later when they have no demonstrated benefit. The proposed quality metrics will allow each facility to identify quality gaps and track progress as they take steps to improve corticosteroid timing and neonatal outcomes.

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# **SMFM Special Statement**

SMFM Patient Safety and Quality Committee reviews publications every 36 to 48 months and issues updates as needed. Further details regarding SMFM publications can be found at www.smfm.org/ publications.

SMFM recognizes that obstetrical patients have diverse gender identities and is striving to use gender-inclusive language in all of its publications. SMFM will be using terms such as "pregnant person" and "pregnant individual" instead of "pregnant woman" and will use the singular pronoun "they." When describing study populations used in research, SMFM will use the gender terminology reported by the study investigators.

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