Preventable Preterm Birth: A Patient Safety Problem
Edward R.B. McCabe, MD, PhD

The US preterm birth (PTB) (<37 completed weeks’ gestation) rate declined from 10.4% in 2007 to 9.6% in 2014 with an intense, multipronged campaign and appeared to be on track to the 8.1% 2020 goal. The rate remained at 9.6% in 2015 and rose to 9.8% in 2016, representing 8000 more infants born preterm in 2016 than 2015 with their associated increased neonatal and lifelong morbidities and infant mortality. Therefore, we need to consider the strategic approach to PTB reduction and more rigorous tactics to address this problem, including developing a culture of safety in the prenatal and perinatal periods encompassing proactive quality assurance. Pregnancy care, including planning and health care, is a complex environment deserving system safety that anticipates and prevents adverse events by identifying precursors that can lead to errors. Approaching error prevention by fostering a culture of safety also involves empowering all caregivers and addressing problems in a nonjudgmental fashion.

Pediatricians must be aware of strategies that will reduce preventable PTBs and become champions for strategic implementation, although many of these issues seem to relate to obstetric practices. Parents may ask their pediatricians for advice during visits before or during pregnancy. Pediatricians, including neonatologists, will see patients with preventable PTBs and should work within their communities to reduce the practices leading to the unnecessary associated morbidity and mortality, always with nonjudgmental approaches consistent with safety culture. Most importantly, the adverse outcomes associated with PTB, including late PTB (34–36 weeks’ gestation), are encountered by our pediatric patients. Therefore, we must be proactive in our communities to prevent these unnecessary adverse outcomes.

Among the 8 risk factors and interventions that prevent PTB, 6 are not under the health care system’s immediate control. Two interventions under the health care system’s control are effective: (1) eliminating elective deliveries before 39 weeks’ gestation and (2) single embryo transfers with assisted reproductive technology (ART) without medical indication for multiple embryo transfers. A woman electively delivered before 39 weeks’ gestation has an increased risk of PTB because of

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Measure 1.6 If multiple embryos are transferred electively to a woman undergoing ART, then there is an increased risk of twins and higher multiples and the associated PTB, morbidity, and infant mortality.

Elective delivery before 39 weeks’ gestation would be expected to result in more late PTBs. The observation that the reduction in PTBs between 2007 and 2014 was greatest among late PTBs compared with births at other gestational ages is consistent with the impact of decreasing elective deliveries before 39 weeks’ gestation. However, there are obstetricians who continue to offer elective deliveries beginning at 37 weeks’ gestation (up to 20% of late PTBs could be the consequence of elective early-term [37–38 weeks’ gestation] deliveries). For those born late preterm (34–36 weeks’ gestation), the infant mortality rate is >3.5 times higher than for infants born term and late term.

One might see changes in the US multiple-birth rate as evidence of improvement because the rate of triplet and higher-order births peaked in 1998 and has declined since then. Data from 1980 to 2014 (Table 1) show that much more needs to be done. Rates for multiple births, twin births, and triplet and higher-order births were higher in 2014 compared with 1980 (Table 1): 1.8-fold, 1.8-fold, and 3.1-fold, respectively. The numbers of multiple births tell stories of infants born at risk for PTB, representing >70 000 additional twin, triplet, and higher-order births in 2014 compared with 1980 (Table 1). Clomid should be considered in twin and other multiple births, although it cannot be quantified because its use is unregulated and unreported. However, the increase in the multiple-birth rate was associated with increased use of ART and multiple embryo transfers, and the decrease in the rate of triplets and higher-order multiples coincided with the release of professional guidelines. Multiple embryo transfers without medical indications result in preventable PTBs. Available data show that achievable reductions in elective deliveries before 39 weeks’ gestation and multiple embryo transfers would have a significant impact on PTBs. These data are estimates based on 2010, when the US PTB rate was 10.0% (because these are estimates and the 2016 PTB rate was 9.8% vs 10.0% in 2010; therefore, the use of these estimates remains appropriate). The total impact of the 8 risk factors and interventions would be −1.76%. The potential impacts of reducing elective deliveries before 39 weeks’ gestation (−0.50%) and multiple embryo transfers (−0.11) are −0.61. Among the interventions and risk factors, only decreasing the pregnancies associated with short interpregnancy interval would have a larger potential impact at −0.69. The remaining 5 would have a total potential impact of −0.46%: 17-hydroxyprogesterone (−0.02%), smoking cessation (−0.02%), and use of low-dose aspirin to reduce preeclampsia (−0.21%). With 3.95 million US births in 2016, the total reduction by the 8 interventions and risk factors (−1.76%) would be 69 520 infants who would be born term rather than preterm. The reduction in elective deliveries before 39 weeks’ gestation and multiple embryo transfers would result in 24 095 of those infants who would be born at term, or 35% of achievable preventable PTBs; therefore, optimization of these 2 interventions would have a significant impact.

A strategic approach is known that could prevent PTBs, and professional and regulatory organizations have recommended the implementation of tactics to fulfill this approach. However, implementation remains incomplete, with some practitioners offering and/or patients requesting or accepting elective deliveries before 39 weeks’ gestation and multiple embryo transfers.

On the basis of the evidence of increased neonatal and maternal outcomes risks, hospitals and states developed policies with the intent of reducing deliveries before 39 weeks’ gestation. These policies have included standard operating procedures to prevent elective deliveries before 39 weeks’ gestation in a hospital, a hospital network, or an entire state, referred to as “hard-stop” policies; reduced payments to physicians for elective deliveries before 39 weeks’ gestation by insurers, such as state Medicaid agencies; and educational initiatives. A study of these approaches concluded that “the available evidence…suggests that policies, especially ‘hard stop’ or payment reform, may result in lower EED [early elective delivery or elective

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TABLE 1 Twin, Triplet, and Higher-Order Multiple Births for All Races in 1980 and 2014

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Births</th>
<th>Twin Births</th>
<th>Triplet and Higher-Order Births</th>
<th>Multiple Birth Rate (per 1000 Live Births)</th>
<th>Twin Birth Rate (per 1000 Live Births)</th>
<th>Triplet and Higher-Order Birth Rate (per 100 000 Live Births)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980</td>
<td>3 612 258</td>
<td>68 339</td>
<td>1 357</td>
<td>18.3</td>
<td>18.9</td>
<td>37.0</td>
</tr>
<tr>
<td>2014</td>
<td>3 988 076</td>
<td>135 336</td>
<td>4526</td>
<td>35.1</td>
<td>33.9</td>
<td>113.5</td>
</tr>
</tbody>
</table>

delivery before 39 weeks’ gestation.\(^9\)

The following are examples of tactical approaches used by organizations. One type of hard-stop approach used by some hospitals involves protocols that empower labor-and-delivery staff to notify the charge nurse or head nurse, who will assess the situation and determine if they will approach the on-site expert, such as the physician responsible for the labor-and-delivery unit. Another approach identifies all potentially preventable PTBs, specifically all elective deliveries before 39 weeks’ gestation and all multiple embryo transfers. Then the organization conducts an expert, independent review of each case. With both of these examples, the responsible provider receives feedback in the nonjudgmental fashion appropriate to the safety culture.

Champions are critical for a safety culture. Anyone can be an advocate, and many already are, including parents and patients who are pregnant or considering pregnancy. There should be a partnership between patients and practitioners to consider the safest ways to balance getting pregnant, maintaining pregnancy, and delivering the neonate to optimize pregnancy outcomes. Advocates include parents, patients, and pediatricians and other child health care providers (eg, neonatologists, neonatal nurse practitioners and nurses, obstetric professionals and staff, and patient safety officers). Any advocate should be empowered by the safety culture to approach the appropriate leadership experts in hospitals and health care systems when elective deliveries before 39 weeks’ gestation are scheduled or multiple embryo transfers are identified. These advocates should know that a preventable PTB represents a preventable medical injury and therefore is a patient safety problem and a medical error, according to the Agency for Healthcare Research and Quality.\(^10\)

Avoiding preventable PTB must become part of a health care organization’s safety culture, just like other recognized medical errors. When a preventable medical error occurs, the cause is investigated so that systemic errors can be identified and prevented in the future, and protocols and checklists are updated. Therefore, advocates should work with their health care organizations to urge the same patient safety rigor for preventable PTBs, including robust protocols and checklists; active, standardized monitoring and reporting; and continuous quality improvement. These are valuable components of a safety culture, which will reduce preventable PTB and help more infants get a healthy start in life.

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ABBREVIATIONS

ART: assisted reproductive technology
PTB: preterm birth

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