A United States stillbirth prevention bundle

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The stillbirth rate in the United States is considerably higher than in many countries with similar resources.[1−3] In 2021, the United States stillbirth (loss before birth at ≥20 weeks' gestation) ratio was 5.73 per 1000 births or 1 in 175 pregnancies with 21,000 stillbirths occurring annually.[3] For example, in 2021, the late stillbirth rate (>28 weeks' gestation) in the United States was 2.7 per 1000 births, which is worse than the ratio in 27 other countries.[4] Japan had the lowest rate at 1.6 per 1000 births.[4] Since 1990 (when the stillbirth ratio was 7.49 per 1000 births), the overall United States stillbirth rate decreased by about 26% primarily because of the small decreases in early (<28 week's gestation) mortality.[3] This is a substantially smaller rate of decrease when compared with the rate in other comparable countries; only 35 of 195 countries had a worse rate of decline.[4] These successes in other countries underscore the potential for meaningful reductions in the stillbirth rate in the United States. In addition to relatively high rates of stillbirth, significant disparities exist. In the United States in 2021, the stillbirth rate was 9.89 per 1000 births for non-Hispanic Black individuals in comparison with 4.85 per 1000 births for non-Hispanic White individuals.[3] The rates were also higher for Native Hawaiian and Pacific Islanders (9.87 per 1000 births) and American Indian and Native Alaskans (7.48 per 1000 births).[3]

It seems reasonable and appropriate to investigate if the United States could emulate strategies successfully used in other countries to reduce stillbirth. Some approaches would be difficult to implement because of the differences in healthcare systems. However, several tactics could potentially be adopted in the United States with substantial chance of success. A uniform theme in successful countries is an emphasis on stillbirth prevention. Specific strategies include public awareness campaigns, improved data collection, and the institution of perinatal audits.[5−7] In addition, some countries have implemented care bundles intended to decrease stillbirths. Such bundles include numerous policies, protocols, and strategies.

It is unclear why there has been hesitation to adopt stillbirth bundles in the United States. It may be because of a lack of priority, a lack of proven efficacy of several components, and a concern for the potential to increase morbidity, cost, and anxiety. In addition, bundles can be difficult to assess scientifically. They usually include several elements that are enacted simultaneously. Thus, it is hard to assess which individual components are effective. In addition, they often address rare outcomes. Hence, they are enacted in large populations and do not lend themselves to randomized clinical trials. This leaves suboptimal methods for assessing effectiveness, such as before and after implementation analyses, which are prone to bias. It is often difficult to obtain granular data in large populations, making it cumbersome to assess harm, cost, or other unintended consequences.

Nonetheless, bundles have many attractive features. They are pragmatic and can be adapted to real world conditions. It is not necessary to know precisely which aspects of the bundle are valuable if the net effect is favorable. Bundles can be rapidly implemented in large populations, which is critical for stillbirth rate improvements because prevention measures ideally need to target all pregnancies.

Stillbirth bundles have been successfully implemented in the United Kingdom and Australia. In the United Kingdom, the bundle, termed Saving Babies Lives, focuses on 4 domains, namely smoking cessation, the diagnosis of intrauterine growth restriction, reduced fetal movements, and intrapartum hypoxia.[5,6] Each domain or element has several specific strategic components.[5,6] Recently, outcomes were assessed for 463,630 births in 19 National Health Service sites for 2 years before and after implementation of the bundle.[6] The rates of stillbirth decreased from 4.2 per 1000 births to 3.4 per 1000 births (adjusted relative risk [aRR], 0.80; 95% confidence interval [CI], 0.70−0.91). In addition, the induction of labor increased (aRR, 1.20; 95% CI, 1.18−1.21), emergency cesarean deliveries increased (aRR, 1.10; 95% CI, 1.07−1.12), ultrasounds increased (aRR, 1.25; 95% CI, 1.21−1.28), and the proportion of small for gestational age infants identified increased (aRR, 1.59; 95% CI, 1.32−1.92). The estimated cost of the bundle was 140 British pounds per pregnancy, but authors acknowledge substantial limitations (before and after) in the study design.[6]

A safer baby bundle was introduced in Victoria, Australia in 2019 and is now being implemented throughout the country.[7] Components of the bundle include smoking cessation in pregnancy, screening for (and management of) intrauterine growth restriction (IGR), awareness of and intervention for decreased fetal movement, awareness of safe

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maternal sleeping positions, and the optimal timing of delivery for pregnancies at increased risk for stillbirth.[7]

Importantly, bundles represent an attempt by the medical system to do the best we can given our current knowledge base. There is often debate when treating individual patients about only using well proven tests, therapies, and interventions or offering the best available options when proven strategies are lacking. This always should be performed using the framework of shared decision-making, and it is something that clinicians subconsciously do every day. Along with a critical need to perform high-quality research to discover new strategies and to prove or disprove the efficacy of current ones, there is an ethical obligation to do the best we can with the information that we have. Of course, there is also an obligation to do more good than harm and to be cost-effective.

It is noteworthy that the United States has adopted numerous bundles intended to decrease maternal morbidity and mortality. These bundles focus on hemorrhage, hypertension, cardiac disease, thromboembolism, narcotic use disorder, maternal mental health, postpartum care, and sepsis.[8−16] Another bundle provides a conceptual framework to reduce disparities in maternal safety and peripartum health.[17] These bundles were developed on the basis of expert opinion. Although considerable efforts were made to only provide guidelines based on high-quality evidence, this was not always possible. In many cases, recommendations within these bundles lack clear supporting evidence; indications and protocols for pharmacologic thromboprophylaxis after cesarean delivery serve as a good example.[9] Several authorities have questioned the efficacy of these protocols and whether the benefits justify the harms.[18,19]

Of course, it requires additional data and research to determine the optimal approach for venous thromboembolism prevention after cesarean delivery. Nonetheless, all bundles, including the one for thromboembolism prevention, were thoughtful, developed by multidisciplinary teams, and were good-faith attempts at making the best policies based on currently available information. In each case, it is imperative to assess all favorable and unfavorable effects of the bundles and to revise them accordingly. This is currently ongoing in the United Kingdom and Australia with stillbirth bundles.[6,7]

Much of the impetus that inspired maternal safety bundles was publicity and recognition that the United States rate of maternal mortality was unacceptably high and unacceptably inequitable. Synergy developed among advocacy groups, media, clinicians, researchers, and public health officials spurred a positive feedback loop of public awareness campaigns, education for parents and providers, improved care, research, policies, etc. The same issues are pertinent to stillbirth, but the United States has been slower to respond with similar urgency. This relative lack of action has caused many parents to experience stillbirth, and stillbirth advocates feel frustrated and like they are not being heard. These feelings have been consistently and eloquently voiced by the perinatal loss community, including in a series of talks in recent meetings of the Stillbirth Working Group of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Council.[20]

We propose that it is past time for the United States to implement a bundle intended to reduce stillbirths and stillbirth inequities. There is still a need for research to discover novel approaches to stillbirth reduction. However, there also is an imperative to do the best we can now with what we know today. We need not adopt all elements included in existing stillbirth bundles, and there should be an emphasis on components with compelling evidence. For some elements, existing guidelines could be used with emphasis on education and implementation. It is also important to use careful messaging with public health campaigns to balance the need for patient education and empowerment while not increasing guilt, trauma, and self-blame. The process for developing a stillbirth bundle could be like that enacted for bundles on maternal safety or those used to develop other best practice recommendations. It would be authored by a multidisciplinary group of experts and have input from stakeholders, including parents, advocacy groups, and clinicians. For success, it would require vetting and endorsement by organizations such as the American College of Obstetricians and Gynecologists, the Society for Maternal-Fetal Medicine, and health departments. As with other bundles, prospective data would be collected on the stillbirth rates, interventions, medical and emotional benefits and harms, and costs. Bundles would be continuously modified as appropriate based on new data, including ongoing research. Meanwhile, more than 57 babies are dying each day in the United States. ■

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