



The Hospital + Healthsystem
Association of Pennsylvania

Leading for Better Health

February 21, 2025

The Honorable Dr. Debra Bogen,
Secretary of Health
Pennsylvania Department of Health
Health and Welfare Building
625 Forster Street, 8th Floor West
Harrisburg, PA 17120

Regina M. Hoffman, MBA, BSN, RN, CPPS
Executive Director
Pennsylvania Patient Safety Authority
333 Market Street
Harrisburg, PA 17101

**RE: Draft Recommendations to Mitigate Risk of Harm Related to Shoulder Dystocia
published in 55 Pa.B.888 on Saturday, January 25, 2025**

Dear Secretary Bogen and Ms. Hoffman:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), which represents approximately 235 member hospitals, we appreciate the opportunity to comment on the draft recommendations to mitigate risk of harm related to shoulder dystocia. We understand that these recommendations have been proposed in response to a reported increase in the rates of shoulder dystocia but have significant concerns regarding the reliability and predictive value of the proposed risk assessments and the unintended consequences that could result from recommendations or regulations requiring them.

Risk Assessments

In the draft recommendations, the Pennsylvania Patient Safety Authority (PSA) proposes that hospitals and birth centers develop a policy that would require providers to evaluate any patient who is in labor or who presents for obstetrical-related care within 30 days of their estimated due date for risk of shoulder dystocia and document the results in the patient's chart. Assessments done prior to the onset of labor would be repeated when labor begins. The hospital community appreciates the intent of the recommendation and the desire to mitigate the risk of harm related to shoulder dystocia but would point out that there are several fundamental flaws in this recommendation rendering it inefficacious.

Shoulder dystocia is not predictable or preventable

Clinical subject matter experts working within our member hospitals report that most shoulder dystocia that they encounter in their clinical practice was not predictable – a position also supported by academic and peer-reviewed research and national experts. Commonly referenced risk factors associated with shoulder dystocia include birth weight, gestational diabetes and previous history of shoulder dystocia. Even with early identification of those at risk based on



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one or all of these three factors, it is still very difficult to predict who will have this complication. A 2022 study published in the American Journal of Obstetrics and Gynecology found that 40 percent of the shoulder dystocia cases reviewed, no risk factors were present.¹ Similarly, the American College of Obstetrics and Gynecology, a well-respected expert in the maternal health space, indicates that studies have shown that pre-pregnancy, antepartum, and intrapartum risk factors have extremely poor predictive value for shoulder dystocia.² Clinicians should be prepared to address this complication in all deliveries.

There is no validated tool for evaluating the risk of shoulder dystocia

HAP cannot support a recommendation that risk assessments are conducted on every birthing person if there is no validated tool for clinicians to use. A 2024 study published in the Journal of Personalized Medicine indicates that although there are known risk factors associated with shoulder dystocia, there is no singularly recommended and evidenced based risk assessment tool to identify fetuses at risk and that it has proven impossible to recognize individual cases in practice before they occur during labor.³

Recommendations could unintentionally result in an increase in cesarean deliveries

There is no evidence-based response when “risk factors” for shoulder dystocia are identified in delivering persons. As previously stated, fetal weight isn’t an accurate indicator of risk and basing decisions regarding mode of delivery on fetal weight alone would, according to ACOG, result in a large number of c-sections to prevent a single brachial plexus injury. Unnecessary cesarean births increase the likeliness of complications and run counter to hospital goals for quality improvement and safe patient care.

Simulation training and competency assessments

The draft recommendations propose that hospitals develop policies on training and competency assessments of credentialed providers and staff involved in labor and delivery care and that competency assessments are included in the appointment and reappointment of credentialed providers and or completed biennially. HAP is supportive of a structure that encourages continuing education but seeks clarity on the Agency and the Department’s expectations as they relate to simulation training. For instance, does the Authority see simulation and competency as two separate activities, or is simulation considered a competency assessment?

The hospital community requests that any recommendations around simulation training be flexible enough to account for varying levels of resources at birthing hospitals. Some have expressed concerns regarding the availability and cost of simulation equipment and training

¹ Duewel AM, Doehmen J, Dittkrist L, et al. Antenatal risk score for prediction of shoulder dystocia with focus on fetal ultrasound data. *Am J Obstet Gynecol* 2022;227:753.e1-8

² Shoulder dystocia. Practice Bulletin No. 178. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2017;129:e123–33

³ Tsikouras P, Kotanidou S, Nikolettos K, Kritsotaki N, Bothou A, Andreou S, Nalmpanti T, Chalkia K, Spanakis V, Peitsidis P, et al. Shoulder Dystocia: A Comprehensive Literature Review on Diagnosis, Prevention, Complications, Prognosis, and Management. *Journal of Personalized Medicine*. 2024; 14(6):586



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sessions, particularly if the training will be required every two years in perpetuity. HAP requests that the agencies provide information on online resources that could be used to meet the intent of the recommendations. Finally, birthing hospitals would request that requirements for training and competency not be tied to reappointment. The logistical challenges of tying the two together would be extremely burdensome especially if the goal of biennial training could still be achieved outside of the reappointment process.

Debriefing and documentation

The draft recommendations propose that hospitals develop and implement a policy on debriefing and documentation of all deliveries involving shoulder dystocia. HAP is supportive of this recommendation as hospitals already have debriefing and documentation structures in place and for adverse events. Members of the regulated community have indicated that these activities should not be required to be under the direction of the healthcare facility's Patient Safety Committee and that hospitals should be able to determine the appropriate forum for the recommended debriefs followed by report outs to the PSC. Birthing hospitals also seek clarification on what the term "mitigation" would mean with regards to the policy for debrief.

Recommendations versus regulations

The joint publication of these recommendations on behalf of the PSA and the DOH raises questions and some concern among members of the regulated community regarding the intention of the agencies. HAP is supportive of programs and initiatives that assist member hospitals in their journey to zero harm when the tenants are evidence-based, and the work is collaborative. If the Department of Health intends to recognize these recommendations as regulations, we would expect that they would be submitted to the Independent Regulatory Review Commission and move through the required regulatory review process.

We appreciate your consideration of the regulated community's feedback and stand ready to be good partners in Pennsylvania's quest to improve maternal health outcomes.

Thank you,

Kate McCale, MPH
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