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# MD ADVISOR

A JOURNAL FOR THE NEW JERSEY MEDICAL COMMUNITY

## SPEAKING HIS MIND ON THE FUTURE OF HEALTHCARE.



SIMON J. SAMAHA, MD  
PRESIDENT & CEO  
SUMMIT MEDICAL GROUP

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THE IN-NETWORK/OUT-OF-NETWORK  
DILEMMA: WE HAVE TO DO BETTER  
Senator Gerald Cardinale

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# An MDAAdvisor interview

with Emily Hamilton, MD, FRCSC, FACOG,  
Mary Veronica Daly, MD, FACOG, and Robert B. Goley

# Shoulder Dystocia: Neither Predictable nor Preventable Not Anymore



*Edited by Theresa Foy DiGeronimo*

Belief that a problem is insurmountable will generally ensure exactly that. A clinical example is found in the tenet that “shoulder dystocia is neither predictable nor preventable.” This belief is often mistakenly applied to a more serious variant—shoulder dystocia with persistent brachial plexus injury. Permanent injuries associated with shoulder dystocia remain one of the top three categories of payments in obstetrical litigation. Payments average a half-million dollars with awards often reaching several million dollars.

Recognizing this clinical and professional liability dilemma, MDAAdvantage™ partnered with PeriGen, specialists in obstetrics risk reduction, to pursue an innovative program designed to enhance the safety of childbirth. As part of this program, MDAAdvantage™ provided its insured physicians with a structured, web-based method for assessing each woman’s individual risk of shoulder dystocia with injury, which in turn was expected to facilitate physician-patient discussions and improve documentation of the mother’s involvement in the birth plan decision-making process. While MDAAdvantage™ considered these features alone of considerable medico-legal benefit, certainly any reduction in the rate of shoulder dystocia and/or associated injury would be an added benefit.

The program, called PeriCALM Shoulder Screen™, helps clinicians identify patients at greatest risk for

shoulder dystocia with brachial plexus injury, numerically estimates that risk and provides documentation of maternal choices regarding delivery options. Three years after the start of this novel program, results are exceeding expectations.

## A MEDICAL DILEMMA

Saying that shoulder dystocia is commonly understood to be unpredictable and unpreventable does not automatically make it easy to defend in a medical malpractice claim. Robert Goley, Senior Vice President of Claims and Risk Management for MDAAdvantage™, explains why this is so by offering this analogy: “When defending a cancer-related medical malpractice claim against a surgeon, for example, no one would accept the argument that precancerous lesions are unpredictable; therefore, all advanced stages of cancer are unpredictable and unpreventable. So, too, with shoulder dystocia. There is a certain illogical inconsistency in the defense that all forms of this condition are unpredictable and hence unpreventable. Although uncomplicated shoulder dystocia is unpredictable using the simple criterion of birthweight, that does not mean that its much more serious cousin, shoulder dystocia with persistent brachial plexus injury, is totally unpredictable using other methods.”

Many branches of medicine today look at combinations of factors, including family history, lifestyle patterns and lab results, in order to predict complex conditions like mortality in intensive care or life expectancy with cancer. In view of these other accomplishments, and when a combination of many shoulder dystocia “red flags” occurs, it is hard to convince a jury that these factors were collectively insignificant.

One of the red flags that makes a case of shoulder dystocia difficult to defend is an incomplete medical record. However, often there is a reason for the poor documentation of this particular medical problem. “Almost everyone is flagged as ‘at-risk’ according to the ACOG list of risk factors,” says Mary Veronica Daly, MD, FACOG,

“The members of our research team began with **clinical intuition** from many years of clinical experience that convinced us that the combination of a short, **heavy** mother with a **large baby** presented a much more worrisome risk of shoulder dystocia than that same baby in a tall, slender mother.”

who has practiced full-time obstetrics and gynecology for 27 years in Morris County. “It is unreasonable to expect clinicians to raise the issue of shoulder dystocia—a frightening complication—with almost all mothers who actually have a very remote likelihood of brachial plexus injury.” Shoulder dystocia with persistent brachial plexus injury occurs in approximately 1 out of every 5,000 to 10,000 vaginal births. Daly pointed out that even when risk

factors are identified, it is not clear what should be done. The indications for recommending prophylactic cesarean described in the ACOG guidelines are very stringent. According to this guideline, offering a cesarean to avoid shoulder dystocia is recommended if the baby is thought to weigh more than 9.9 pounds in a mother with diabetes or 11 pounds in a mother without diabetes. Such large babies are found in less than 1 percent of all pregnancies. Even a great majority of women who do go on to have births with persistent injury have babies who weigh less. Therein was a medico-legal dilemma for clinicians—almost all mothers have at least one risk factor; few qualify for elective cesarean, and most injured babies weigh less than the level used to recommend cesarean to avoid shoulder dystocia. Thus in the past, no coherent clinical construct existed within which a practicing obstetrician could address risk factors and appropriately counsel the patient.

Still, the escalating cesarean rates would be expected to reduce the occurrence of shoulder dystocia; however, other underlying factors such as rising rates of maternal obesity continue apace. Maternal obesity is in itself a problem and causes babies to be large for gestational age. This combination is particularly conducive to shoulder dystocia with injury. Cesarean delivery also carries more complications for obese women. Hence, clinicians may be naturally reticent to recommend cesarean with its common complications in order to prevent a potential complication that is so rare they may never see it in their own lifetimes.

Considering these facts, exactly what does a clinician say to a mother with risk factors for shoulder dystocia? It is with little surprise that Steven L. Clark and colleagues found poor documentation in 54 percent of litigated shoulder dystocia cases.<sup>1</sup>

## IDENTIFIED OPTION TO RESOLVE THE MEDICAL DILEMMA

Knowing that shoulder dystocia is an obstetrician’s nightmare, it was a natural focus for PeriGen, Inc. researchers. PeriGen, Inc. is a technology-enabled professional services company specializing in clinical quality improvement and risk reduction in obstetrics. Emily Hamilton,



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PeriCALM Shoulder Screen is a patented, web-based application used in the prenatal period to estimate the risk of shoulder dystocia with brachial plexus injury. It gives physicians what no other tool can: immediate, objective data that helps them reduce the risk of brachial plexus injury. With documentation of recognized risk factors, patient choice of delivery method, and informed consent, Shoulder Screen is the smart support for smart providers.

## Sample Secure PeriCALM Shoulder Screen™ Website

MD, FRCS, FACOG, is an obstetrician gynecologist and Senior Vice President of Clinical Research at PeriGen; she is also the inventor of the PeriCALM Shoulder Screen™ patented technology who well knows the backstory of her invention: “The members of our research team began with clinical intuition from many years of clinical experience that convinced us that the combination of a short, heavy mother with a large baby presented a much more worrisome risk of shoulder dystocia than that same baby in a tall, slender mother. Some simple mathematical functions looked promising, so we went on to use advanced biostatistical methods to determine: 1) what were the most significant factors associated with brachial plexus injury and 2) how those factors could be arranged together so that we could most efficiently differentiate the women who would have the problem from those who would not. How the factors are combined is key—no one before had applied this method to the problem of shoulder dystocia with brachial plexus injury.” Dr. Hamilton notes that the PeriCALM Shoulder Screen™ method helps clinicians identify which mothers are at very high risk and overall detects four to five times more of the persistent injury cases than do the standard methods.

The PeriCALM Shoulder Screen™ Program has four quick steps:

## STEPS

## 4

**Step 1.** A simple checklist applied at 36 weeks identifies which expectant mothers are recommended for further testing. Additional mothers may be tested, if desired.

**Step 2.** Clinicians enter seven common items, such as mother’s height and weight, gestational age and estimated fetal weight, on their own secure PeriCALM Shoulder Screen™ website as shown on Figure 1.

**Step 3.** A risk assessment is then calculated by the application, which provides graphical and numerical estimates of the mother’s risk.

**Step 4.** The website contains specialized consent forms so that a mother can attest to understanding her own risk, the limitations of estimating risk, available



delivery options and her preference for delivery method. A delivery summary template is also available that includes the elements that should be documented when shoulder dystocia occurs.

KEY BENEFITS OF THE PERICALM SHOULDER SCREEN™<sup>2</sup>

- Assesses risk of shoulder dystocia with injury at or before the onset of labor
- Uses easily available measures
- Enables clinical teams to communicate risk numerically and graphically to patients
- Provides written confirmation of the mother’s participation in decisions about her risk of shoulder dystocia with injury and the planned method of birth

## IMPLEMENTATION OF A SOLUTION

Everyone involved in implementing the PeriCALM Shoulder Screen™ Program was well aware that many research ideas never translate to clinical practice. The decision to move forward resulted in collaboration between PeriGen and MDAdvantage™. In this case study, MDAdvantage™ provided leadership and communicated a clear and definitive change in practice policy to its participating physician insureds. PeriGen provided clinician education and web access to the Program.

“We estimate,” notes Goley, “that more than 50,000 of our insureds’ patients have passed through this process.” The results of this PeriCALM Shoulder Screen™ Program have been extremely positive. In fact, Dr. Daly notes that her experience with the Program to date, as summarized in Table 1, has exceeded expectations in several ways:

- Obstetricians appreciated having an actual numerical estimate of risk so they could explain to a mother

TABLE 1

Rates of Cesarean Delivery (CD) and Shoulder Dystocia (SD) Over Three-Year Period for Physicians Insured by MDAAdvantage™ at Atlantic Health System, New Jersey.

	Year 1	Year 2	Year 3 (YTD)	P
All Births	2721	2372	1414	
Total CD %	1011 (37.2%)	932 (39.3%)	559 (39.5%)	0.095
Primary CD %	571 (21.0%)	534 (22.5%)	265 (18.7%)	0.224
Repeat CD %	440 (16.2%)	398 (16.8%)	294 (20.8%)	<0.001
SD/All Births %	48 (1.8%)	40 (1.7%)	13 (0.9%)	0.056

be quick and easy, inexpensive and readily available. The application performing the risk calculation works over the Internet and hence was simple to deploy and took only a few seconds per test.

The last factor was an effective local steering committee that had the authority and willingness to set clinical practice guidelines.

The next milestone will be the completion of research-in-progress to assess rates of temporary injuries associated with shoulder dystocia. Although these injuries do not tend to have direct legal repercussions, they are an important bellwether for the expected effect on permanent injuries.

#### THE NEXT STEP

The introduction of the PeriCALM Program is just the beginning. "Today," says Dr. Hamilton, "PeriCALM Shoulder Screen™ estimates risks with factors known at the end of pregnancy. Tomorrow, when we have more labor information, it may be possible to update a mother's risk depending upon how her labor has evolved."

Additionally, the PeriCALM Shoulder Screen™ likely will complement simulation training. Many medical institutions use simulation training on delivery techniques and team interactions to ensure that delivery room staff works efficiently to resolve shoulder dystocia expediently and with-

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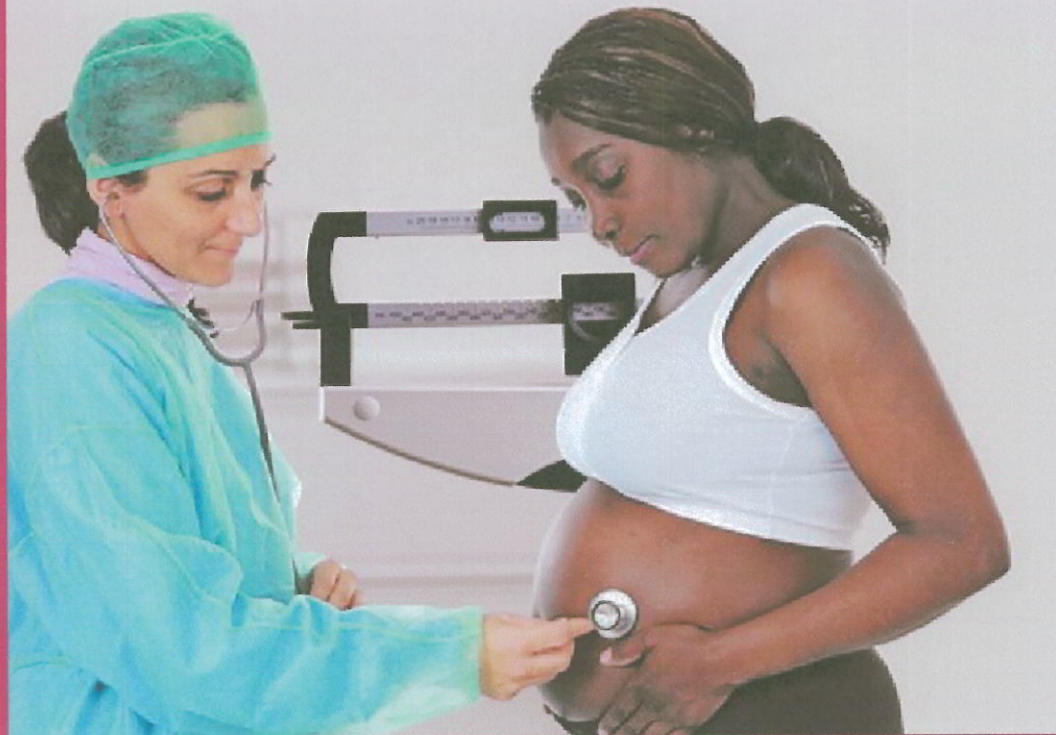


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“The results of this PeriCALM Shoulder Screen™ Program have been **extremely positive.**”



that *her* risk was based on the best available information on *her* combination of factors.

- Even though tested mothers had some risk factors, most had results indicating a very low likelihood of shoulder dystocia with injury. This was reassuring to mothers and their doctors.
- For those with positive results, the conversation was facilitated with the numerical estimates of risk and the graphical displays that allowed the mother to actually see how close or far she was from the norm. Informed consent regarding route of delivery was easily obtained and documented.
- There were no increases in the primary cesarean rates. Although the small group of patients with elevated results had very high cesarean rates overall, this was offset by a tendency for lower section rates in women at risk who had reassuring results from the PeriCALM Shoulder Screen™ test. This observation has been replicated in other hospitals and clinics.<sup>3,4</sup>
- Finally, and most notably, the rate of shoulder dystocia fell by 50 percent as is shown in Table 1.

#### REFLECTIONS ON KEY SUCCESS FACTORS

Many factors contributed to the success of this

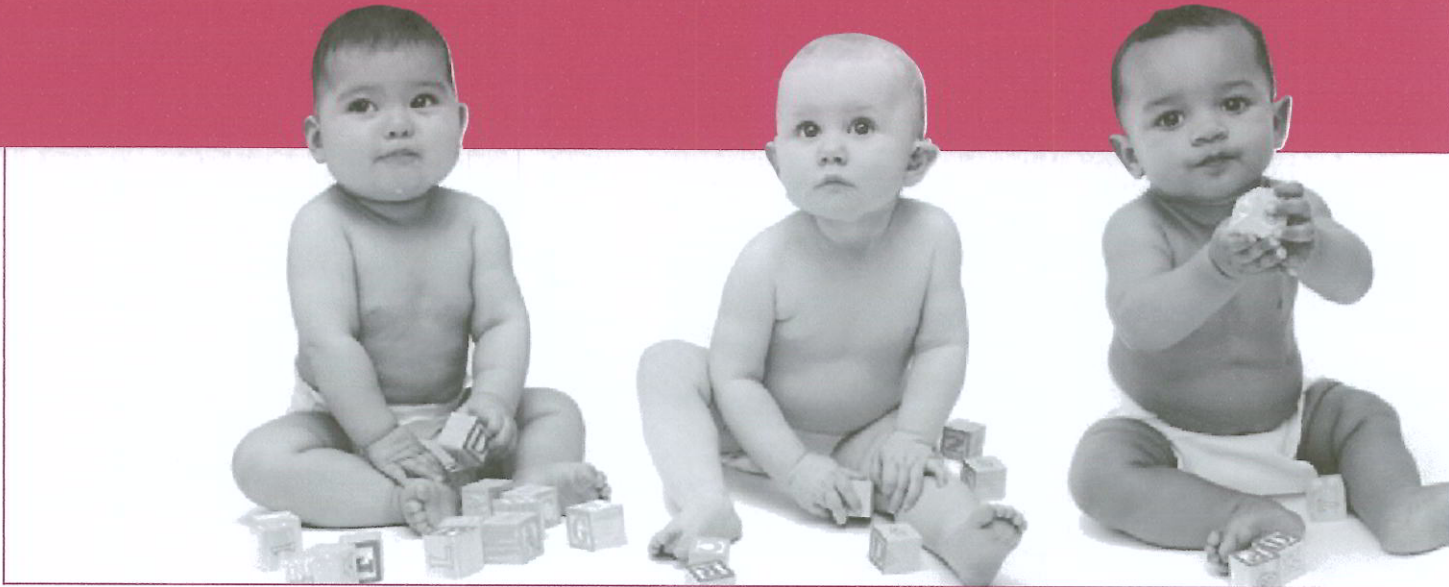
implementation of the PeriCALM Shoulder Screen Program. “The first step to success,” says Goley, “occurred when someone questioned the status quo and was unwilling to accept the assertion that the problem of shoulder dystocia-related injury is insurmountable.”

The second factor was deciding to move forward with a new approach based on abundant good evidence rather than maintaining the status quo until perfect evidence of effect was obtained. There are no prospective randomized clinical trials on any technique to reduce shoulder dystocia with permanent brachial plexus injury because such trials would require enrollment of 500,000 patients to ensure statistical confidence. Nevertheless, it is possible to gain assurances using other methods. Many insurance groups sent PeriGen data on babies, with and without shoulder dystocia injuries, from different geographical regions throughout the United States. The model performed as expected with very little variation on this retrospective data. Prospective studies, such as the one described here, and peer-reviewed articles on additional studies from different locations collectively also help to build a credible body of evidence.<sup>3-6</sup>

The third factor was ‘logistics.’ Given the excessive demands on clinician time, the actual process needed to




“I believe that one day we will look back at this problem and **wonder why it took us so long to come to a better approach.**”



out injury. According to Dr. Hamilton, the PeriCALM Shoulder Screen™ helps identify the pregnancies with the greatest risk of injury so they can be avoided with cesarean, and simulation training helps to ensure optimal clinical response for the remaining cases. “Together,” says Dr. Hamilton, “these two approaches have great potential to reduce lifelong impairment from shoulder dystocia. I believe that one day we will look back at this problem and wonder why it took us so long to come to a better approach.”

*Emily Hamilton, MD, FRCSC, FACOG, is an obstetrician gynecologist and Senior Vice President of Clinical Research at PeriGen.*

*Mary Veronica Daly, MD, FACOG, a partner in Lifeline Medical Associates, has practiced full-time obstetrics and gynecology for 27 years in Morris County, New Jersey.*

*Robert B. Goley is Senior Vice President, Claims and Risk Management, MDA Advantage™ Insurance Company of New Jersey. *

<sup>1</sup> Clark, S. L., Belfort, M. A., Dildy, G. A., & Meyers, J. A. (2008, December). Reducing obstetric litigation through alterations

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<sup>2</sup> PeriGen. (2011). *PeriCALM Shoulder Screen*. [www.perigen.com/oursolutions/shoulder-screen](http://www.perigen.com/oursolutions/shoulder-screen).

<sup>3</sup> Hamilton, E. F., & Miner, L. (2008, December). Shoulder dystocia with brachial plexus injury: Is it completely unpreventable? *Gynobilis*, 9(3), 12–14.

<sup>4</sup> Lerner, H. M., & Hamilton, E. F. (2007, November). Shoulder dystocia: What if you could see it coming? *Contemporary OB/GYN*, 1–6.

<sup>5</sup> Dyachenko, A., Ciampi, A., Fahey, J., Mighty, H., Oppenheimer, L., & Hamilton, E. F. (2006, December). Prediction of risk for shoulder dystocia with neonatal injury. *American Journal of Obstetrics and Gynecology*, 195(6), 1544–1549.

<sup>6</sup> Hamilton, E. F., Ciampi, A., Dyachenko, A., Lerner, H. M., Miner, L., & Sandmire, H. F. (2008). Is shoulder dystocia with brachial plexus injury preventable? *Fetal and Maternal Medicine Review*, 19, 293–310.