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## Quality Care in the Delivery Room: Can the Use of Fetal Fibronectin (fFN) Help Meet Quality Standards?

Announcer:

This is CME on ReachMD! The following activity, titled *Quality Care in the Delivery Room: Can the Use of Fetal Fibronectin Help Meet Quality Standards?* is provided in partnership with Omnia Education and supported by an educational grant from Hologic, Inc.

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Your host is Dr. Jennifer Caudle.

Dr. Caudle:

Preterm birth, defined as birth before 37 weeks gestation, continues to be a significant public health issue. Approximately, 1 in 10 infants are born preterm, and about 70% of these are spontaneous onset. The annual cost to the health care system is nearly \$70 billion, and on average, \$33,000 per infant, which is nearly 10 times the cost of a full-time delivery.

This is CME on ReachMD, and I'm Dr. Jennifer Caudle, your host. Joining me today to focus on the emerging approaches to reducing the medical and personal impacts of preterm birth are Drs. Michael S. Ruma and Michael G. Ross. Dr. Ruma is a Maternal-Fetal Medicine Specialist at Perinatal Associates of New Mexico in Albuquerque, and Dr. Ross is a Distinguished Professor of Obstetrics and Gynecology and Public Health at the David Geffen School of Medicine and Fielding School of Public Health at UCLA-Los Angeles.

Dr. Ruma and Dr. Ross, welcome to the program.

Dr. Ruma:

Thanks so much for having us.

Dr. Ross:

Thanks.

Dr. Caudle:

Absolutely. Well, I'm excited that you're both here. So, to start, I spoke initially of the medical costs surrounding preterm birth, but clearly, this issue carries much more than just a medical cost alone. So, Dr. Ruma, I'd like to start with you. Can you give us an overview of the health and developmental issues that we frequently face with preterm infants?

Dr. Ruma:

Yes, this is no small problem. We have nearly 4 million pregnant women having babies in the United States on an annual basis, and approximately, 10% of these pregnant ladies are going to go into labor early and deliver preterm infants, and the majority of those are spontaneous. And as you mentioned, this costs our country an inordinate amount of money. It not only has an economic cost and an economic burden, but it also has a significant impact on the child as well as the family.

With that said, these infants face both short- and long-term conditions. Kind of immediate things that face the child are respiratory distress issues that will lead the child to be admitted to the neonatal intensive care unit, potentially placed on oxygen in different forms—nasal cannula, mask, and worse yet, intubated. These children have other complications, such as infection, infections in their intestine called necrotizing enterocolitis, which can require surgical intervention, and long-term complications

that are often due to complications such as bleeding in the brain or intraventricular hemorrhage. These short-term complications and immediate hospital stays lead to long-term complications as well. Of the surviving preterm infants, upwards of 15% of them will require at least 3 hospitalizations in the first 5 years of life, and they go on to have trouble in school with neurocognitive delay, motor deficits, severe things such as cerebral palsy. And it's not confined simply to school. It can also be at home with behavioral and psychological problems as well. These preterm infants, the ones that actually do survive and go on later in life, they have higher rates of asthma, impairment in the way they grow, and things in adulthood like hypertension and insulin resistance, so obviously a very large issue that our country faces, and the individual, the infant, and the family faces.

Dr. Caudle:

I think you've done an excellent job of really kind of taking us through what the possible short- and long-term sequelae of preterm births are. And you're right, it is quite astounding.

Dr. Ross, now that we have sort of a better understanding of the potential short- and long-term impacts of preterm birth—we have this groundwork—what tools are available to help physicians screen patients who may be at risk, increased risk, rather, for experiencing a preterm birth?

Dr. Ross:

Great question. Our focus today is on the symptomatic patient. Labor is a process of regular uterine contractions with cervical change or a dilated cervix. Of course, if you have ruptured membranes or significant uterine bleeding, we would consider that premature. However, only 10 to 15% of patients who present at less than 34 weeks meeting the contraction criteria actually deliver within 1 week, so our challenge is to identify the patient in true preterm labor. To do this, we first use clinical symptoms, and a contraction frequency of approximately 1 every 5 minutes is of concern, remembering that many patients in the third trimester will have some frequency of 2 to 4 contractions per hour, most of which are asymptomatic. Patients may have low backache, pressure in the vagina or the pelvis, vaginal discharge or spotting. All of these symptoms are consistent with preterm labor but don't help us terribly in determining is this true preterm labor or, in fact, false labor. So we also rely on cervical dilation. If we get to 3 cm dilated, either as a result of the discharge of an early preterm labor patient or a late presentation of the patient, we're far less likely to be successful in tocolysis and steroid administration, so we have to get to these patients earlier. So we need to focus on the patient with uterine activity and early cervical change. This is the dilemma for us, and this is where fetal fibronectin is going to help. Over-admission of early preterm labor patients is costly. It interrupts their personal lives and incurs risks of medications and unnecessary hospitalization. But undertreatment can result in an untreated preterm delivery.

So let's talk for a minute or introduce fetal fibronectin. Fibronectin is an extracellular matrix protein. It resides at the decidua chorionic membrane interface. And when that interface is disrupted by infection, inflammation, abruption, or even uterine contractions themselves, it's released into the cervicovaginal secretions, and this can be of great value in determining your management for the patient in possible preterm labor.

Dr. Caudle:

Excellent. So, Dr. Ross, let's get back to fetal fibronectin, which you have really just introduced to us. It really seems to have a unique physiologic position and potentially is a useful marker for women in preterm labor that are at increased risk for a preterm birth. So, can you give us a little bit more information on the use of fFN, or fetal fibronectin?

Dr. Ross:

Yes, there have been many, many studies performed as far as the predictive value of fetal fibronectin, and in general, a review of the randomized trials showed that, for patients with delivery within 7 to 10 days of the testing—which is sort of the magic window for this—the sensitivity and specificity were 77 and 83% respectively, so very good results. For prediction of delivery less than 34 weeks or less than 37 weeks, the results were fairly similar—sensitivity levels of 60 to 69%, specificity at 82 to 84%, so very good sensitivity and specificity levels. .

Dr. Caudle:

For those of you that are just tuning in, you're listening to CME on ReachMD. I am your host, Dr. Jennifer Caudle, and I'm talking with Dr. Michael S. Ruma and Dr. Michael G. Ross about approaches to reducing the medical and personal impacts of preterm birth.

So, Dr. Ruma, moving forward, a recent algorithm was presented by Lockwood concerning the use of fetal fibronectin in the management of preterm labor and how it fits into the overall decision tree to assess risk for preterm birth. Can you take us through that algorithm and explain how a physician reaches the decision to either discharge patients or consider next steps?

Dr. Ruma:

Absolutely, Jennifer. Algorithms in medicine are incredibly useful. This is one that emanates from Lockwood. A patient presents with preterm labor. And let's go down the side where the patient is actually less than 34 weeks. And if she's dilated and we do an examination, typically this should start with a sterile speculum exam, and it's clear that she is dilated at least or greater than or equal to 3 cm. True preterm labor, as Dr. Ross had talked about, is very, very likely, and we should admit that patient.

What's a little more confusing is when the patient is 0, 1 or 2 cm, which is incredibly common and one

of the most common dilations that present to triage. What we would suggest and what this algorithm suggests is we should collect a fetal fibronectin, we should conduct a transvaginal ultrasound for cervical length. If the cervical length is under 20 mm, the patient should be considered at high risk for preterm delivery, admitted and tocolysed and given antenatal corticosteroids. For the patient that has a cervical length over 30 mm, then we would consider this patient to be at low risk and proceed with discharge of the patient, reassurance, and follow up in the outpatient setting.

In this equivocal or indeterminate zone, 20 to 30 mm—there are other authors that have talked about 15 to 30 mm—the fibronectin can shine in this area, differentiating low- versus high-risk patients. If the fibronectin is negative, we should believe in the high negative predictive value, trust in that and discharge the patient with the same type of follow-up as the patient with a normal cervical length. If the fibronectin though is positive, that patient should be treated as a high-risk individual, again receiving antenatal corticosteroids for the benefit of the preterm infant as well as tocolysis magnesium sulfate for fetal neuroprotection. And you can see this well elucidated in this algorithm that's available in a variety of different settings.

There are numerous algorithms in the literature available to review. I think the importance of electing which algorithm and how you're going to approach this is really whether or not the institution that you work in has the availability of 24-hour-a-day, 7-day-a-week transvaginal ultrasound cervical length assessment. And then, also, you have to look at do those individuals that are conducting those ultrasounds—do they actually have the appropriate training to perform that study? If you do not have that available, I do believe that fetal fibronectin still, based on what Dr. Ross has explained to us—very high negative predictive value and a reasonable positive predictive value—that fetal fibronectin should be the diagnostic tool used if transvaginal ultrasound is not available in your institution.

Dr. Caudle:

Dr. Ross, what barriers need to be overcome so the fetal fibronectin algorithm similar to Lockwood's can be widely adopted, and what are the best approaches to overcoming those barriers?

Dr. Ross:

I think the algorithm is excellent. We need all physicians to be educated in the appropriate and optimal use of both fetal fibronectin in conjunction with transvaginal ultrasound and to begin to screen the vast majority of patients with that and can we catch preterm labor early and use these algorithms.

Dr. Ruma:

algorithms in medicine are important. There is a wonderful book written by Dr. Atul Gawande, Checklist Manifesto: How To Get Things Right, written several years ago that really, I think, for every physician that should be required reading to see the benefits of following algorithms and checklists

A very recent study by Sean Blackwell, our current President of the Society of Maternal-Fetal Medicine, which was published in ClinicoEconomics and Outcomes Research just last year, looked at an insurance database, and this insurance database had 23,000-plus pregnant women in it. And as we walk through this paper, we find that we are not triaging patients correctly and that, sadly, of the patients that are discharged home, an incredibly high number of patients actually do go in and deliver spontaneously within 72 hours. In that study, the patients that were discharged home, 1 in 5, or 20% of those patients, delivered within 3 days. And the sad information about our national statistics is that less than 80% of those women actually had any diagnostic tool, including both fibronectin or transvaginal ultrasound, used in that triage visit, and I think this is a statement of where we're at today

Dr. Caudle:

Wonderful. And I appreciate you both commenting on that question. I also want to open the floor now for you both for anything else that you'd like to share with our audience on this subject today. Dr. Ross, maybe we should start with you, and then, Dr. Ruma, if you'd like to chime in.

Dr. Ross:

in addition to the healthcare consequences Dr. Ruma brought up, there are also very important programming effects. If a baby is born preterm, beyond the acute and the long-term pulmonary and gastrointestinal complications, there are approaches where the baby actually has an increased risk of diabetes, obesity, hypertension as an adult, so all the more reason to be vigilant in preventing and treating this disease.

Dr. Caudle:

Absolutely. Dr. Ruma?

Dr. Ruma:

I would just end and try to encourage our listeners and the viewers of this material today to really not take shortcuts with patients. If this was your child, your daughter, your sister, your mom being evaluated with symptoms of preterm labor, which are truly real, we don't want to skip steps. We want to take it a step at a time, use the diagnostic tools that we have available that have just a tremendous amount of research demonstrating how fibronectin can determine whether or not a patient is truly at high or low risk for spontaneous preterm birth, and we should trust in these tools, trust in the research, and use that to make diagnostic decision-making and not guess on what we should do with these individuals.

Dr. Caudle:

Very, very good points from both of you, and I really appreciate, really, everything that you said, and I think what a wonderful way to close about the importance of this issue, but also the importance of using the tools that we have to not underestimate or overlook patients and their symptoms and to make

sure we are treating them appropriately.

We've covered a lot of information today on identifying women presenting with preterm labor who are at a heightened risk for experiencing a preterm birth. I really want to thank you both for helping us better understand the tools available to improve our medical management. Dr. Ruma and Dr. Ross, it was wonderful having you both on the program. Thank you so much for being with us.

Dr. Ruma:

Thank you so much for having me today.

Dr. Ross:

Thank you very much. We really appreciate it.

Announcer:

This has been CME on ReachMD. The preceding program has been provided in partnership with Omnia Education.

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