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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Spontaneous Preterm Birth: How Are Clinicians Managing At-Risk Women?

Narrator:
Welcome to CME on ReachMD and the Omnia Education activity, Spontaneous Preterm Birth: How Are Clinicians Managing At-Risk Women?

Your host is Dr. Matt Birnholz. Dr. Birnholz will speak with Dr. Cynthia Gyamfi-Bannerman, Associate Professor of Obstetrics and Gynecology, Director of the Maternal-Fetal Medicine Fellowship Program and Medical Director of the Perinatal Clinics at Columbia University Medical Center in New York, New York. Dr. Cynthia Gyamfi-Bannerman has nothing to disclose.

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In January 2017, after the original release of this activity, The Society for Maternal Fetal Medicine Publications Committee released an SMFM Statement, which is discussed at the end of this activity and covers the choice of progestogen for the prevention of preterm birth in women with singleton pregnancy and prior preterm birth.

Prior to beginning the activity, please be sure to review the learning objectives, or if you're listening to this as a podcast, go to this activity on ReachMD.com/CME on your computer, Smartphone or tablet device.

Dr. Birnholz:
With ACOG changing the definition of preterm birth and the available efficacy and safety data for current progestogen agents, preterm birth is quickly becoming a much more manageable issue for practicing physicians. In today's discussion, we're going to examine the risks and benefits of clinical management options for women at risk for preterm birth as well as understand how term pregnancies versus preterm births are being redefined.

Dr. Gyamfi Bannerman, welcome to the program.

Dr. Gyamfi-Bannerman:
Thanks, thanks for having me.

Dr. Birnholz:
So, as we just mentioned, ACOG recently changed how term pregnancies -- and I want to stress that, term pregnancies -- are defined. What were those specific changes and why were those changes made?
Dr. Gyamfi-Bannerman:
So, ACOG decided to redefine term because previously term had been defined as 37 weeks or greater, but what we noted is that there are increased neonatal morbidities, specifically in both respiratory and nonrespiratory, for infants born from 37 to 38 weeks; so that gestational age window is now called early term, and full term is considered delivery from 39 weeks up to 40 with late term being beyond 41 weeks. But these changes were made to really emphasize that there are increased morbidities if you're born less than 39 weeks gestation.

Dr. Birnholz:
So, on that note, how do we define what constitutes as spontaneous preterm birth, and what's the incidence rate of this issue?

Dr. Gyamfi-Bannerman:
So, in general, preterm birth has been classified as either medically indicated preterm birth or spontaneous preterm birth, and in the category of spontaneous preterm birth, you have preterm labor with intact membrane and then preterm premature rupture of the membrane, and that constitutes about two-thirds of preterm births. So, in the United States, the good news is that the rate of preterm birth has gone down consistently over the last 7 years, but it's still about double the rate of that in other developed nations; and so, currently, the rate of preterm birth is about 11.4%, and you would then estimate that about two-thirds of that is spontaneous preterm birth.

Dr. Birnholz:
Interesting. Why don't we focus then on babies who are born close to term, say 34 to 37 weeks? Are there any significant health risks or issues for these babies given the state of neonatal care today?

Dr. Gyamfi-Bannerman:
Yes, in fact, babies born between 34 and 37 weeks are now called late preterm because of the emphasis on the fact that they are still preterm infants. The lungs, as many obstetricians know, are fully developed after an infant is born and well into childhood, and certainly, respiratory morbidity is higher in a late preterm infant by a significant degree compared to infants born at term; so these morbidities are things that we certainly can't ignore, and really, we should stay away from elective or even soft indications for delivery in that late preterm period.

Dr. Birnholz:
I see. And why don't we take a step back for a second and consider the overall healthcare system? How does spontaneous preterm birth affect the cost of medical care or the financial picture of health services in America?

Dr. Gyamfi-Bannerman:
Spontaneous preterm birth has a huge impact on the cost of care in kind of both health disparities and in the public health burden of healthcare costs because some of these babies are born quite preterm and end up spending months at a time in intensive care units, so these costs are incredibly high, and anything that we can do to decrease the rate of both spontaneous or indicated preterm birth would have a significant impact on public health and on healthcare dollars.

Dr. Birnholz:
And if we turn back to the clinical side again, since that's one of the primary focuses for us, what are the most important risk factors that are associated with spontaneous preterm birth, and are any of them preventable?

Dr. Gyamfi-Bannerman:
So, that's a great question. Having had a history of preterm birth is one of the highest risk factors in terms of having another preterm birth. It sometimes can be difficult for women in their first pregnancy who don't have that history, so another risk factor that we're starting to look at is the length of the cervix. And we know that a cervical length that is shorter in the midtrimester is also correlated with a higher risk of preterm birth. But some other risk factors would be a multiple gestation, the majority of whom actually deliver preterm, and black race and smoking. So, of all of those, really probably smoking would be the only modifiable risk factor.

Dr. Birnholz:
So, Dr. Gyamfi-Bannerman, if a woman has had a prior spontaneous preterm delivery, what can be done to reduce her risk of another preterm birth? And, I guess for that matter, are there any current guidelines from either SMFM or ACOG or both that assist in this regard?

Dr. Gyamfi-Bannerman:
Yes. Women with a prior spontaneous preterm delivery should seek healthcare early in their pregnancy, so they should meet their physician, whether it's an obstetrician or obstetric provider or maternal-fetal medicine specialist in the first trimester to get early care. One of the primary treatments that we use is 17-Hydroxyprogesterone caproate or 17P, and this medication can be injected weekly from about 16 weeks on to about 36 weeks, and it leads to a significant reduction in the rate of recurrent preterm birth. SMFM and ACOG both suggest using progestational agents in women who have had a history of preterm birth. And, in fact, SMFM is developing bundles that relate to preterm birth and specific management strategies for women in this category.

Dr. Birnholz:
So, if we stick with the guidelines for a minute, what do the guidelines have to say about cervical length measurements? Do they differ for a woman who had a preterm birth in a prior pregnancy compared to someone having had her first baby?

Dr. Gyamfi-Bannerman:
They do. So, while a woman is recommended to have cervical length measurements in the setting of having a prior preterm birth, this

recommendation is not yet active for someone who doesn't have that history; so there is some debate in the literature as to whether there should be universal screening for asymptomatic women without a history versus kind of targeted screening, and so SMFM and ACOG have not yet recommended universal cervical length screening in that setting.

Dr. Birnholz:
And I have to ask then, because it comes to mind, sort of an intuitive next question, a lot of what you said makes a lot of intuitive sense, but is it ultimately easy to incorporate current guidelines for reducing preterm birth into the day-to-day practice of obstetrics?

Dr. Gyamfi-Bannerman:
In fact, it is. It's a matter of the provider knowledge base, because there are interventions out there that are relatively easy to access. And if a patient comes in on time for care and starts one of these interventions once they're indicated, it is relatively easy to provide the appropriate care to the patient. Similarly, for most healthcare providers, there is access to maternal-fetal medicine specialists who can also co-manage these patients with the other providers.

Dr. Birnholz:
Excellent. Why don't we then turn to talk about treatment options and focus on that? Now, compounded medications appear to be in the limelight here. Can you tell us a little bit more about this independent approach compared to pharmaceutical manufacturing and whether there are any differences between them as far as safety and efficacy go?

Dr. Gyamfi-Bannerman:
So, the one kind of criticism about compounding pharmacies, in general, is that the regulation for those types of medications is a little bit different and there's potential to have different formulations, different kind of quantities of medication in each dose. The potential does exist. For the most part, when these types of compounded pharmacies have been tested, for the most part it comes out that it's probably similar. But with the availability of an FDA-approved product, at least at the current institution where I am, we have moved towards using that product as the primary product. There are definitely issues with patient access to certain products around the country such that not everyone has similar access to these medications, and there are some people who use this as an alternative, but at least at our institution we do use the FDA-approved formulation.

Dr. Birnholz:
And does this apply to such medications as 17OHPC, clearly produced both by compounding pharmacy, also an FDA-approved product produced by the manufacturer? Any differences there?

Dr. Gyamfi-Bannerman:
Yes, actually, specifically so. And the issue with the compounding pharmacy in New England didn't impact us in any way and certainly was isolated to that particular pharmacy, but it was at that time that we decided to switch our patients from compounded 17OHPC to the FDA-approved product.

Dr. Birnholz:
And what about the FDA's voice in this? Do they have anything in particular to say about using compounded medication for the purpose of trying to reduce recurrent preterm deliveries?

Dr. Gyamfi-Bannerman:
The FDA advocates that if there is an FDA-approved equivalent to the medication that the provider err on the side of using the FDA-approved medication unless there are extenuating circumstances towards which that medication is not available.

Dr. Birnholz:
Now, in the last minute or two of our discussion, Dr. Gyamfi-Bannerman, I want to make sure that we cover any issues that you want to revisit or re-emphasize. Is there anything that we didn't discuss that you would like to impart with our audience?

Dr. Gyamfi-Bannerman:
I think it's important for an obstetric provider to consider that a woman who's had a history of preterm birth, whether it's spontaneous or indicated, because sometimes the interplay of those indications is kind of difficult to separate, they should be seen early, come early for care, and these medications can be initiated early in the second trimester to help decrease the rate of recurrent preterm birth. And certainly, in some areas these patients can be co-managed with maternal-fetal medicine specialists as well.

The SMFM is coming out in the next year with new bundles specific to preterm birth to help guide management and help providers understand what are the appropriate medications to use in these settings but there definitely is treatment and hope for women who have had a history of preterm birth.

Dr. Birnholz:

Well, very nicely put. And with that I very much want to thank Dr. Cynthia Gyamfi-Bannerman for joining me today. We've been talking about prevention and management considerations for preterm birth and the updated definitions and guidelines on this obstetric issue.

Thanks again for your time, Dr. Gyamfi-Bannerman.

Dr. Gyamfi-Bannerman:
Thanks, thanks for having me.

Dr. Birnholz:
In January 2017, after the original release of this activity, The Society for Maternal Fetal Medicine Publications Committee made public an SMFM Statement entitled: The choice of progestogen for the prevention of preterm birth in women with singleton pregnancy and prior preterm birth. This article was made available electronically in the American Journal of Obstetrics and Gynecology.

The purpose of the statement was to reaffirm its 2012 guidance as to the choice of 17 OHPC for women with a singleton gestation and a prior spontaneous preterm birth. The 2012 SMFM guidance no longer recommended the use of vaginal progesterone for women with a previous spontaneous preterm birth, as had been advocated in the 2003 and 2008 guidances. Data from several sources suggest that despite these recommendations, there remains continued underutilization of
17-OHPC for eligible patients.

The rationale for the change from recommending both 17-OHPC and vaginal progesterone were the findings from multiple randomized controlled trials over the past decade. Results from these studies, many of which are noted on this slide, demonstrated either the efficacy of 17-OHPC in women with a singleton gestation and prior spontaneous PTB, or the efficacy of vaginal progesterone in women with sonographic short cervix. Based on available data regarding the lack of benefit of vaginal progesterone in women with a history of prior spontaneous PTB, SMFM recommends continuation of 17-OHPC therapy in women with history of prior spontaneous PTB throughout the pregnancy despite the development of cervical shortening with or without cervical cerclage placement.

In its statement, the SMFM conclusions can be seen in this slide. It reaffirmed the use of 17-OHPC in women with a singleton gestation and a prior spontaneous preterm birth. At the same time, it noted that vaginal progesterone should not be considered a substitute for 17-OHPC in this patient population.

Narrator:
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