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Addressing Information Gaps in Advanced Prenatal Screening: What Your Expecting Patients Need to Know

Narrator:

You are listening to ReachMD. Welcome to this medical industry feature sponsored by Quest Diagnostics. The following program is intended for US healthcare professionals only. Your host is Dr. Matt Birnholz.

Dr. Birnholz:

A new campaign led by the Perinatal Quality Foundation with support from Quest Diagnostics is launching to address information gaps about advanced prenatal tests. In today's discussion we will focus on the goals of this campaign, what clinicians need to know about it, and how it will improve understandings of genetic screening technologies. Joining me today is Dr. Douglas Rabin who is Medical Director of Women's Health and Medical Affairs with Quest Diagnostics and Jean Lea Spitz, Executive Director for the Perinatal Quality Foundation. Dr. Rabin and Ms. Spitz, welcome to ReachMD.

Dr. Rabin:

Thank you.

Ms. Spitz:

Thank you for having me.

Dr. Birnholz:

To start, why don't we move in on the goals of this initiative. Ms. Spitz, from the PQF, maybe you can tell us a little bit about the goals and maybe the mission and visions of PQF?

Ms. Spitz:

The mission of the Perinatal Quality Foundation is to improve the quality of obstetrical care and to facilitate the responsible movement of new advances into obstetrical practice. Our vision for the genetic education program, that we are calling the GEM program, is to ensure that every woman in the United States has access to clear, accurate and unbiased educational resources that will empower her to make informed decisions regarding prenatal testing for herself and her family. There are two elements to the campaign: an educational program and a patient registry. The educational campaign aims to close the knowledge gaps among consumers and healthcare providers about this new generation of highly advanced genetic screening technologies. Through the patient registry women who receive prenatal screening during pregnancy will be able to report results of the confirmatory diagnosis, their satisfaction with their choices and postpartum outcomes. The goal in collecting this data is to enable scientists to use the information in de-identified form to do outcomes research on the predictive value of these tests in the real world. We expect both elements of the campaign to be up and running during 2016, and we are very pleased that Quest Diagnostics, the leader in this field, along with other laboratories shares our vision and is willing to commit to the program to encourage responsible screening.

Dr. Birnholz:

Dr. Rabin, how about from Quest Diagnostics' point of view, what are the goals there?

Dr. Rabin:

Well, I totally agree with Jean in the goals for the educational piece, for the outreach to the patients and for the ultimate registry. We were really excited to have a role in helping the PQF actually put together their RFP and to be involved with initiative at a level to provide the original funding, to be involved with encouraging some other players in the field to be involved as well, and we look at it as an opportunity to improve the quality of non-invasive prenatal screening. I would tell you that Quest Diagnostics has a mission to develop innovative tests like QNatal Advanced which we are calling our non-invasive prenatal screening, but we believe that we have a responsibility to help those who use our testing, both the physicians and the patients, to have insight that will give them information on which they can actually act, and that in order to improve how we do that process we need to have real world data. So the partnership with PQF will allow that to happen. And at this point, we have done over 10,000 tests and we have incredibly exciting results which we are beginning to share with the physicians in the field and with the patients.

Dr. Birnholz:

Excellent, and I will be interested in learning more about that. But, Ms. Spitz, let me turn back to you. You had mentioned knowledge and information gaps about advanced genetic screening technologies, what are the information gaps specifically?

Ms. Spitz:

There are several. One that affects both women and practitioners is results interpretation. How to interpret equivocal results? There is also confusion about the use of cell-free DNA for prenatal screening, that it is a screening and not a diagnostic test. There is confusion about when to send a woman for individualized genetic counseling. There is confusion about the best options to integrate the new test with current screening test, ultrasound and diagnostic testing. And, perhaps most troubling, as demonstrated by Quest in peer-reviewed studies, there is confusion about the test performance characteristics, particularly, the true positive rates, sensitivity specificity in real world situations.

Dr. Birnholz:

And Dr. Rabin, Ms. Spitz just mentioned Quest in this. What's Quest's perspective on this level of information gap?

Dr. Rabin:

PQF and Quest are not the only organizations expressing concerns about the gaps in knowledge. The American College of Obstetricians and Gynecologists and the Society for Maternal Fetal Medicine, published a committee opinion in June, dated for September of 2015 that recognizes the tremendous potential of genetic technology. However, the use of cell-free maternal DNA to screen for fetal aneuploidy is also associated with recommendations that they made. The first, and perhaps the most important, is that referring women who receive an indeterminant or un-interpretable, what we would call a "no-call" test result for genetic counseling and additional invasive testing, is extremely important.

Dr. Birnholz:

Well, you both have hinted at who the information is geared to, but maybe you can get a little bit more specific as to how that information is going to be shared. Ms. Spitz, let's start with you.

Ms. Spitz:

The Perinatal Quality Foundation has implemented similar programs before, and we plan to incorporate lessons learned from these successes into the new program. For example, we sponsor the Nuchal Translucency Quality Review Program that credentials over 6,600 physicians and ultrasonographer participants, and we have collected over 3 million data points in our database related to that program. In this campaign, our goal is to ensure that every woman in the United States has access to clear, accurate and unbiased educational resources and that her health professionals are capable of answering questions that may arise. We believe that women should have multiple options, understand those options, and choose to have tests or not to have tests as best fits her family goals. Under the new program, Perinatal Quality Foundation will develop and cascade various educational materials and tools including a website and probably events and other forums for patients, clinicians and other healthcare providers. The campaign will also educate healthcare providers about the circumstances under which to guide a woman through individual consultation with a genetic counselor. We will have newsletters and updates.

Dr. Birnholz:

That's excellent information and I want to scale back to a million dollar question, just to move forward, and that is: Why is the program necessary? And I will leave that open to both of you. Why don't we start with Ms. Spitz and then Dr. Rabin you can jump in.

Ms. Spitz:

It is necessary because we need to provide accurate and up to date information but we need to collect the data to promote research on the performance of these non-invasive prenatal screenings.

Dr. Rabin:

I totally agree with Jean. Let me add, that what's critical about determining the quality of the tests is to actually understand what its positive predictive value is and its negative predictive value. And the only way to know that among all the patients being screened is through a registry. We felt that the PQF is really the most up-to-date and best talented and capable through prior history to have the resources to get this done

Dr. Birnholz:

So, Dr. Rabin, clearly Quest is interested in this program for a number of reasons that you just highlighted and outlined for me. Are there any other reasons why Quest would really want to gear up and get interested and move in on this program?

Dr. Rabin:

As the world leader in diagnostic information services, it is important that--the main customer we have are physicians and the patients who receive our genetic testing, also understand that we endeavor to be the world leader in education and information delivery to those same clients. We hope that patients and physicians understand that when we provide a test we want them to be comfortable with it, to understand what they are getting and to make a decision that actually informs them across the spectrum of questions they may have. Now this is important because we serve approximately one-third to one-half of American adults and physicians and hospitals at some point in their history and medical care in the United States. We launched QNatal Advanced, which we call our non-invasive prenatal screening test, in 2015, actually in May. And what it does is it offers the non-invasive prenatal screening component to our comprehensive suite of fetal testing options. Well, historically, we have done maternal serum screening. We have done OB panels. We have looked at patients at their alpha-fetoprotein. We have combined with the PQF Nuchal Translucency in first trimester screening. We have done later trimester screening. We have screened CVS and amniocentesis. We now have developed a test that allows us to screen more directly and specifically for trisomy 21, 18, and 13 and for micro deletions and fetal sex.

Dr. Birnholz:

So, Dr. Rabin, clearly, there is an indication for all high-risk pregnancies, but do you think non-invasive prenatal screens should also be used on average-risk women?

Dr. Rabin:

What one of the advantages of the non-invasive prenatal screen is, is that it can be offered at 10 weeks and so, this segues into your question, how I feel about low risk? So, when I am talking about target audience that the American College of Obstetricians and Gynecologists believes should be offered screening and every pregnant patient should be offered screening at a level where she feels comfortable, that woman, you know, chooses. I think that the advanced and non-invasive prenatal screening and, I believe, with the registry data that we will develop which will give us more information about positive and negative predictive value, that the screening test will become a standard for women who want to have insight about their pregnancies. And that, yes, the low-risk group is an absolutely appropriate area. I believe, in addition, that because of the high quality of the testing, as it evolves to improve its ability to be on target with positive predictive value and, for example, with the QNatal Advanced, we are demonstrating very high positive predictive value at this point but we are waiting for more data to add to that information base.

Dr. Birnholz:

So, then, the obvious next question is: What are the next steps? Ms. Spitz, why don't we start with you on what you think the next steps are here?

Ms. Spitz:

The educational program and patient registry are expected to be launched in 2016. We are very excited that Quest Diagnostics along with other labs shares our vision to promote responsible screening and has made a commitment to the program as a funding supporter through a grant.

Dr. Rabin:

Our participation in the campaign will be part of our program of informing physicians and informing patients and I believe that the ultimate goal for us is to advance the cause of responsible screening for women and for physicians and really to encourage the reporting of outcomes data.

Dr. Birnholz:

All right, well, before we wrap up today, any closing comments for our listeners? Ms. Spitz?

Ms. Spitz:

I just want to say that the Perinatal Quality Foundation, its volunteers, board members and staff are really looking forward to working on this program because we think there is such a need and that education leads to satisfaction. We want women in the US to have the education they need to choose the option that is best for them or to choose no test. So, we are committed to this project. We are excited about this project and we appreciate the support that Quest has provided.

Dr. Birnholz:

Dr. Rabin.

Dr. Rabin:

Well, you know, I want to thank Jean for the opportunity to get to work with her. I believe that it is a real great opportunity for patients and women in this country and that one of the goals that we have Quest is to create opportunities to choose an action based on insight. And in this case, this is diagnostic insight that will help patients understand what's going on in their pregnancy. Now, there are keys to that, that I think are critical. Number one, and really this underscores why we are working with PQF to make sure that this educational piece is available to the patients and to the physicians providing our test. Number one, it is a screen only and even with current guidelines that's not going to change and with advanced guidelines that's not going to change. Number two, understanding how tests perform in real world situations, helps physicians—unfortunately—to protect themselves from misinformation, it helps them provide—fortunately—for patients to understand what kind of testing they are getting and it is truly important, and ultimately, it is critical for practitioners to feel comfortable with the data that we provide them in the context of what's the total real world experience. I believe the partnership with PQF and the direction that Quest is taking to provide the best assays, the best diagnosis and the best education really will serve physicians and patients in an excellent way.

Dr. Birnholz:

Well, with that, I very much want to thank Dr. Rabin and Ms. Spitz for their time today. We have been talking about a new campaign to improve understandings of genetic screening technologies and the unique collaboration between the Perinatal Quality Foundation and Quest Diagnostics to make that happen. Again, Dr. Rabin and Ms. Spitz, thanks so much.

Ms. Spitz:

Thank you.

Dr. Rabin:

Thank you.

Narrator:

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