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All You Need to Know about Infant Formulas

Narrator:
You are listening to this week's medical industry feature on ReachMD. The following segment is sponsored by Perrigo Nutritionals, the largest global manufacturer of store brand infant formulas and one of the world's largest pharmaceutical companies.

Dr. Birnholz:
Although human breast milk is the preferred source of nutrition for infants and is recommended by the American Academy of Pediatrics to be the exclusive source of nutrition for infants for the first 6 months of life, a number of studies have found that by 3 months of age, nearly half of all infants are receiving at least some infant formula. Several experts have ascribed this discrepancy between recommendations and reality, in part, to the changing landscape of today's work force and the logistical challenges involved in maintaining infants exclusively on breast milk. And, in fact, studies have confirmed that today's nursing mothers often are following AAP's recommendations for breastfeeding, making the choice of infant formulas a key clinical consideration for which pediatric practices must be prepared to counsel. What factors should guide our care recommendations to parents, and what do we need to know about infant formulas to make better decisions? We'll be addressing these and other important questions today.

You're listening to ReachMD, and I'm Dr. Matt Birnholz. My three guests today represent a broad spectrum of expertise along the care continuum for infants from neonatology, to gastroenterology and nutrition, to primary care. They are Dr. Frank Greer, neonatologist and Professor Emeritus of Pediatrics at the Wisconsin Perinatal Center at Meriter Hospital in Madison, Wisconsin; Dr. Jenifer R. Lightdale, Division Chief of Pediatric Gastroenterology, Hepatology and Nutrition and Professor of Pediatrics at the University of Massachusetts Medical School; and Dr. Anthony Kovatch, who is a practicing pediatrician in Pittsburgh, currently working at Pediatric Alliance and recipient of a Patients' Choice Award.

Doctors, welcome to the program.

Dr. Lightdale:
Thank you.

Dr. Kovatch:
Thank you.

Dr. Greer:
Thank you, Matt. Thanks for inviting us.

Dr. Lightdale:
Great to have you all with us. So, Dr. Lightdale, let me start with you. How do you counsel when a mother comes to you and asks, “Can I continue breastfeeding?” or, “Can I use formula?”

Dr. Lightdale:
Well, it's a question that does come up often, and I think the first thing I do and I recommend all pediatricians do is to validate, indeed, that breast milk is fantastic, it is great. But especially, if mom is asking, “Can I use formula?” I’m also very quick to validate that breast milk is not the only option out there, and I do believe we need to validate mom's choices, so whatever she chooses, I want to support. And if a person wants to breastfeed, I quickly let them know there are many resources to continue to help people who might be having difficulties with doing that, but I also say, as a doctor and as a gastroenterologist, again, I validate that if for different reasons mom is looking for other options, that that's okay.

This does come up for me quite a bit as a gastroenterologist. I tend to deal with babies who for different reasons aren't tolerating foods that they're having, and that includes breast milk. It's certainly possible a baby is not tolerating breast milk. Often I'm asking mom to make a number of pretty drastic changes to her diet, and when I introduce what's going to be involved, mom may look worried, and I am quick to say, “Listen, it's okay. I'm going to do whatever you want me to do to help you through this. If you want to keep breastfeeding, I'm going to work with you so you can understand what you need to change in your diet,” and then I also say, “Of course, I'm also going to support you if you decide you want to offer formula.”

Dr. Birnholz:
That's great advice, Dr. Lightdale. And before we address the most pressing issues of how and why infant formulas should be recommended in clinical practice for which Dr. Lightdale alluded, we need to better understand what the options are and how they differ. So, Dr. Kovatch, can you take us through the various types of formula available?

Dr. Kovatch:
Yes. In the past 20 or 30 years, there has been a proliferation of formulas available for the infant who is either unable to be breastfed or needs supplemental formula or at some point has to transition from breastfeeding to a formula completely. Let me say at the outset that the Infant Formula Act of 1980 made amendments, with further amendments made in 1986, that these Acts have mandated very strict requirements for any formula that is available over the counter. The addition of DHA and choline in recent years has made all these formulas that are available now even closer to breast milk, and prebiotics and probiotics are probably the most recent additions to all of the formulas.

Now, the standard formulas, which we think of as the regular cow's milk-based formulas, are formulated to be as close to breast milk as possible. Examples would be Enfamil Lipil and Similac Advance. These are the standard formulas for a baby that can tolerate regular cow's milk. These and all formulas come as ready-to-feed, which is the most expensive brand, they come as concentrated liquid, and they also come as powder, which is diluted with regular water. These are the cheapest kind of formula. So, we have 3 different options that are available of the cow's milk formulas.

And over the years -- it's probably always been, but it seems as it's becoming more noticeable now and more detectible now -- babies seem to be developing allergies to the cow's milk protein, so this has brought on an introduction of many of the soy formulas. Examples would be Prosobee or Isomil or Gerber Soy, and these formulas have the soy-based protein as their major protein source, and they are good for babies who are allergic to cow's milk. These formulas are also made to be lactose-free, though they are also valuable in babies that have a problem with lactase deficiency and have problems digesting the lactose in the formula. More formulas are also available now which have the cow's milk protein as well as the elimination of the lactose.

As the years have gone on, formulas were created for babies that had what were called the feeding fussies. These basically involve spitting, constipation and colicky type of symptoms. So formulas were devised that took the cow's milk, regular intact cow's milk protein, and broke it down into what’s called a partially hydrolyzed formula, and these formulas are more tolerable and more digestible than the regular cow's milk formulas. These formulas are not for babies with cow's milk allergy. They are for babies that have primarily problems simply digesting the protein, and they work very well in babies that have constipation, because with the extra particles of the peptides and amino acids, it pulls more water into the stool. Examples of these formulas are Gentlease and Similac Total Comfort.

Additionally, there are formulas now, what are called specialized formulas, which add rice starch to the formula. These are good for babies who need the formula thickened because of problems with spitting. And there are also formulas with higher caloric content like Neosure, which is used for small, premature babies.

Now, the most complicated of the formulas are the protein hydrolysate formulas where the formula is broken down completely into peptides and isolated amino acids, and these are used solely for babies who have the unique problem of cow's milk allergy or babies who have trouble with gastroesophageal reflux. These are formulas that really should only be used at the recommendation of the pediatrician.

And the most important point that I'm going to mention is in this day and age, all the major formulas I mentioned, except for the protein hydrolysate formulas, are available not only in the standard brands like Similac and Enfamil, but they are also available in the store brands. All these formulas must follow the very strict quality control measures to be sure that they are absolutely safe, just like the old, original, standard brand formulas. So I think that any parent who uses the formula from any store should be comfortable that these formulas will meet all the nutritional requirements for their baby.

Dr. Greer:
This is Dr. Greer. That was a really nice summary, Tony, of the formula choices available to parents. I think it's important to point out in a recent review by Susan and Robert Baker at Buffalo Children's Hospital -- I think they're both gastroenterologists -- there are currently

at least 143 formula choices available to parents on the US market, and that's not guaranteed to be complete from their commentary, but I think it's important to point out the choices for parents are somewhat overwhelming when they go to the supermarket.

Dr. Birnholz:
That is a great overview, Dr. Kovatch, and thanks for giving us that rundown of the biochemistry and the formula components. I'm interested in what you mentioned about hydrolyzed proteins, and maybe we can expand on that a little bit more. Dr. Lightdale, can you help us understand hydrolyzed proteins?

Dr. Lightdale:
Absolutely. It is definitely my thing as a pediatric gastroenterologist, and to Dr. Greer's comment, certainly the Bakers are gastroenterologists. I think in GI we are having to understand how the protein plays into the formula. What we know is about 10 to 12% of babies and maybe more -- it's always astounding the numbers in the newer studies -- have difficulty tolerating whatever they are feeding, and the issue is that they're not tolerating well intact molecules of proteins. And I have people imagine in their heads when I'm explaining this in the office a big molecule. You know, I have them actually picture what they think a molecule would look like. And it's those big molecules in whatever they're eating that are the problem. So, breast milk has big molecules of protein and formulas have big molecules of protein, and that could be either cow's milk or soy protein. When you get into hydrolyzed proteins, you've already broken up the molecules into smaller pieces, and that lets the baby tolerate them better. We talk about cow's milk protein intolerance or milk and soy protein intolerance. Really the issue, again, is intact molecules of protein. We know that about 10% offer maybe more of babies have that issue. That's a lot of babies. And it manifests, as Tony says, as fussiness, gassiness. Many of the babies have reflux. Indeed, all recent guidelines now suggest formula changes to a hydrolyzed protein formula or changing mom's diet to get out some proteins from mom's diet if she's breastfeeding. It's really changing the infant's diet that's the better treatment for reflux, much better in randomized controlled trials than medications, and that does solve a lot of problems.

Dr. Birnholz:
I want to shift gears for a few minutes and talk about the Special Supplemental Nutrition Program for Women, Infants and Children, or WIC, which is clearly an influential factor in how infant formulas are accessed and selected. So, Dr. Lightdale, continuing with you, can you talk about this program and its possible and negative impacts on infant feeding practices nationwide?

Dr. Lightdale:
Well, I would preface that question, if you're going to direct it to me, that it's actually hard for me to give you facts because I would certainly give the disclaimer that I am not a WIC expert, but I have learned a bit about WIC just in trying to help families navigate this incredible issue around choice of formula, especially as I may be prescribing them with new formulas, and I really had some eye-opening experiences as a physician. So really an emotional, I suppose, response I can give you in terms of what I know about WIC is to recognize that the Women and Infants Program that WIC is really a supplemental program, so it's not designed to give a patient everything they need to feed their infant, which I think is the number one fact a lot of physicians don't know. And number two is, at some point, there was a decision made, and I don't know what year it happened, but it was a few years ago, that WIC would really work to support breastfeeding. And in that thought, which is a good thought, they cut down the monthly allotment of formula. So, if a patient is depending on formula through the WIC program, it's being given to them to supplement. It doesn't necessarily give them everything they need to get through the month. And I think anybody who's exclusively formula feeding really needs to be prepared that the WIC allotment in their state is not likely to be everything they're going to need to get through the month, and that was a bit eye-opening for me when I learned about it that way.

I think to that discussion around generic formulas, which Tony talked about, it is important for the families to recognize that even though WIC may hand them a certain brand of formula, they actually don't need to stick with that. They can actually, if they need to supplement their WIC allotment, they can go and get a different formula, so it's certainly possible to get a less expensive formula. They can go to Walmart, buy the Walmart brand; they can go to Target, buy the Target brand. And people need to know that, physicians need to understand that, and they need to understand why people feel that they're running out of formula and what the options are for the family. So, I think validating all of this, making sure people know it's perfectly fine to not necessarily buy exactly the same formula that they're being given from WIC is very important.

Dr. Birnholz:
Dr. Greer, any additional thoughts?

Dr. Greer:
Yes, I appreciate Jenifer's comments. I think it should be pointed out that about 55% of all infants in this country are on the WIC program and that more than half the formula produced in this country by the major formula manufacturers goes to the WIC program itself.

Dr. Birnholz:
I want to consider our fellow colleagues for a moment in all of this. How would we recommend to those colleagues in practice the right questions to ask to make sure that they're addressing this at a well-check visit such as whether or not patients are supplementing or if their child is getting the adequate formula amount? What are your thoughts on that, Dr. Lightdale?

Dr. Lightdale:
Well, I think it is something you really need to elicit from the family, so you need to be asking. Patients really won't volunteer this information, many of them. And I think you need to be prepared, if you elicit the information, which I would encourage everyone to do, how you can help them understand that there are less expensive options for them than just going out and buying the same brand formula that they're getting from WIC. I tend to ask, “Are you receiving enough formula?” or, “Do you have enough formula at home to continue to use it for the whole month?” And a lot of people actually will volunteer, “Well, no, I’m running out.” And then you want to say, “Well, how are you handling that? What do you do when you run out?” And there are, again, lots of ways you can validate their options. So, they can certainly go out and buy the same brand if they want to, but I think it’s also important to say, “Gee, I know those formulas are expensive.” And so in a nonjudgmental way sometimes in a questionnaire, I think you can elicit this information.

I'm not in pediatrics -- I just go to my pediatrician with my own kids -- but I think there are often questionnaires that patients fill out while they're waiting that ask questions like, “Are you using a car seat?” and, “Do you have tobacco at home?” And I think in a similar way, in a nonjudgmental way, it’s okay to ask, “Do you have all the formula that you need?” or, “Are you running out of formula before the end of the month?” It could just be a quick question like that. And then to that end, I also want to find out, “Are you finding yourself, perhaps, conserving formula, giving the baby watered-down formula?” as a lot of people don't recognize dangers involved with not making the formula up the way it's supposed to be made up to get them through the month.

Dr. Birnholz:
Let's stick with that idea of dangers. Can you elaborate on the dangers here?

Dr. Lightdale:
Well, so I think this does come up. You'll find people will say, “Well, the last can I’m just careful,” and they may be diluting formula, and they may not recognize the big dangers with diluting formula. The number one danger that’s sort of immediately in my mind is the baby is not getting enough calories, and so they may not grow the way they’re supposed to, but there are, certainly, other even scarier issues to start worrying about. So, you may cause a baby, certainly, over time to become undernourished. You may find that they’re not growing because they’re giving them 18 calorie-per-ounce formula as opposed to 20 calorie-per-ounce formula. And, of course, there are also concerns around water intoxication, and that can have electrolyte imbalance. So, you do need to be asking about what the family is doing to handle the inadequate amount of formula they're being given.

Dr. Birnholz:
So, let me pose a hypothetical then. Let's say that you've asked these questions and it becomes clear that the patient is stretching the formula. How do we then counsel that patient, especially in a manner that's productive and not condescending or judgmental, as you alluded to as a risk of counseling before?

Dr. Lightdale:
Well, I think if you're able to point to the growth curve and notice that the baby is lagging, it's possible to then turn to the family and say, “Gee, can we think about how the baby may not be getting enough calories? It sounds like you’re giving adequate volume, but let’s think about how you’re making the formula. Are you using the directions on the back of the can to make the formula exactly the way it’s supposed to be made?” A lot of people don’t know that some formulas are made by putting powder in first and then adding water. Some formulas you put the water in first and then add the powder. So, you really want to look at the back of the can. We can do that together. And you don’t want the bay by to get too much water. You can say to the person, “They can have abnormalities in their electrolytes. We can have problems from that.” People need to hear that. And then you say, “Okay, how can I help? What’s going on?” And again, as a doctor, in the end I want them to feel comfortable saying, “Well, formula is very expensive, so I don’t want to go out and buy it.” And again, that gives me an opportunity to remind them that there are 140 choices plus that Dr. Greer alluded to earlier. I mean, there are many options, and there are certainly less expensive options, so if you’re finding the formula too expensive, there are generics. There are store brand formulas that we can help orient you to.

Dr. Birnholz:
Well, for those who are just tuning in, you're listening to this week's medical industry feature on ReachMD, and I'm Dr. Matt Birnholz. I'm joined today by pediatrics experts Drs. Frank Greer, Jenifer Lightdale and Anthony Kovatch, and we're discussing Advanced Perspectives on Nutrition for Today's Newborn.

Dr. Greer, let's return to the problem of formula stretching. I understand that there were some research studies conducted to better

understand the extent of this issue, so can you take us through some of these studies and whether their observations and results reflect what you see in your own practice?

Dr. Greer:
Well, as you say, I'm more or less an academic, and I think Tony and Jenifer both alluded to the fact that a lot of the information we have on formula stretching is anecdotal from children being admitted for failure to thrive, etc., etc., who clearly weren't suffering from food insecurity, so there really are relatively few studies that look at this. And the one published, recently published study, was from Cincinnati Children's Hospital, which they used that questionnaire that Jenifer alluded to, that initial office survey before a clinic visit, and they inserted some questions in there which got at the food insecurity issue. I think it's important to point out that of the 150 or so patients that were involved in this study, 81% were on the WIC program, 64% were receiving SNAP, what we used to call food stamps, and over half the patients were receiving both WIC and SNAP food benefits. And what they found in that study was about 1 out of 6 patients were stretching the formula in some way. This could be adding water and, more likely, making a substitute for the formula itself, either juice or a fruit drink or something like that, which, of course, is very concerning.

Dr. Birnholz:
Thanks, Dr. Greer. So, Dr. Kovatch, how then should clinicians manage the formula challenges that Dr. Greer talked about when cost is a known issue for parents?

Dr. Kovatch:
I think that many of the younger parents who are having their first babies are probably quite financially strapped. All you have to do is listen to some of the political debates these days to realize that the financial situation of many of the young people is strained, so we try to take that into account, I'd say, more than ever before.

I think that one of the major developments in recent years is that the standard brand formulas are less and less involved with their distribution of these formulas in the hospital so that parents may get started on something, but they are not allowed to give out the great amount of samples that they did in the past that would maybe hook a family on a particular formula. And I think most of the younger generation being cost conscious are going to do what they think is right with the pediatrician's recommendation, so if I were to recommend the store brand formulas, I think they would do that without any hesitation just because the people are more savvy than they have been in years past. I'm becoming a little firmer in telling people that these store brand formulas are required to meet the FDA requirements, so you can use whichever one is available at the store that you go to. If they take a particular formula and ask us about it, I think that they should always stay on a formula that they're tolerating well, but if they want to switch to a cheaper formula, there should be absolutely no problems with that.

Dr. Birnholz:
What about addressing parent concerns of potential intolerance caused by switching formulas? How is that done, and is there any proof behind this type of concern?

Dr. Greer:
I would say the proof is in the pudding so to speak, but again, I'm an academic, but I did do three years of general pediatrics in the beginning of my career. I must confess when a parent came into the office and baby was spitting up too much or constipated or diarrhea, whatever, and the parents blamed it on the formula, the first think I would always say is, "Oh, try another…" I would try to say, "Try another formula." And the mother would try another formula, and sure enough it would work and everything turned out great. Now, putting on my hat as a neonatologist, I can see some disadvantages to formula switching. In other words, I'm taking care of a sick term baby or a sick premature baby who clearly has nutritional issues, and hopefully we're using breast milk, but we have to use formula sometimes. The mother will say, "Okay, well I don't want my 28-week baby to receive any cow's milk formula because my last two children have been allergic to cow's milk," which puts restraints on what I can use for a sick premature baby, or a mother will say, "Oh, well, I only feed my baby soy milk because my previous babies are allergic to lactose or lactose intolerant." So, I think that's the one issue I have a problem with with switching formulas, that the parents get a certain misconception from switching to a formula that seems to work and subsequently applying that to all her other infants, which, as I said, restricts my practice somewhat in neonatology over the years to choices which I think are most nutritionally advantageous for an infant and I'm not allowed to use because the parents has these preconceived ideas about cow's milk allergy or lactose intolerance.

Dr. Birnholz:
Interesting perspective from the neonatology side, Dr. Greer. Dr. Lightdale, what about your perspective?

Dr. Lightdale:
The more typical situation of just having one brand of formula and you go out to the store and can you get a different brand that's the

same type of formula but perhaps another name brand or perhaps the store brand question, I personally encourage and tell families that I'm not worried about the baby having intolerance switching between similar types of formula, and that certainly goes between name brand to name brand, name brand to store brand, store brand to name brand, whatever the case may be. I think there really are very minor differences. It's all in whether the baby notices a taste, which is actually a little bit about the baby themselves, how developed is that baby and whether they're going to be a foodie some day.

So, my own advice to patients is just go out and try it cold turkey, see if the babies do just fine. Most babies will have no appreciable differences. Some babies are very discerning, so it's really about the baby's own level of whether they're going to notice the taste. If, obviously, a baby is rejecting it because of taste, I think you may have to teach them to like it, so you may need to sneak it in, perhaps giving a bottle that has 3 ounces of the formula they were used to and 1 ounce of the new formula and then gradually changing those ratios so it becomes the new formula over time. And almost all babies you can get them used to a new formula, again, within that same type of formula.

There is actually a study out there that tried to break this down that did have 3 groups of babies, so they had babies that went from one name brand to another name brand, they had one group that went from a name brand to a store brand, and then they also had a group of babies that got exactly the same formula -- it was just repackaged. So, the blinded study, nobody knew. And the parents certainly aren't tasting these, so they didn't know that there was any difference. And what they really showed was in switching babies you didn't see any differences in burping, spitting up, crying. I mean, they were trying to get at what is tolerance, so irritability, gassiness, and you just didn't see any differences in those groups in those types of symptoms. So, I think babies, from our perspective as adults, are going to do just fine once they switch from one formula to another, again, as long as it's within that same type of formula and you're keeping them in that same category.

Dr. Birnholz:
And with that I very much want to thank my guests, Dr. Frank Greer, Jenifer Lightdale and Anthony Kovatch for joining me today. We've been discussing counseling strategies to help pediatricians and parents select appropriate infant formulas for their newborn.

Doctors, thanks again for your time.

Narrator:
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