Talking Sleep Season 4
Episode 17
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Drs. Louella Amos and Robin Lloyd, Guests

Episode Transcript

DR. SEEMA KHOSLA: Thank you for joining us for Talking Sleep, a podcast of the American Academy of Sleep Medicine. I'm your host, Dr. Seema Khosla, medical director of the North Dakota Center for Sleep in Fargo.

Obstructive sleep apnea can occur at any age, and treating our youngest patients requires some special considerations. Here today to talk with us about these considerations for using CPAP in pediatric populations are Dr. Luella Amos and Dr. Robin Lloyd.

Dr. Amos is a pediatric pulmonologist and sleep specialist at Children's Wisconsin and an associate professor at the Medical College of Wisconsin. And Dr. Lloyd is a pediatric sleep medicine specialist at the Mayo Clinic in Rochester, Minnesota. Thank you both for joining us today.

DR. AMOS: Thank you.

DR. LLOYD: Thank you.

DR. KHOSLA: So, Robin, the AASM recently published a position statement on age and weight considerations for the use of continuous positive airway pressure therapy in pediatric populations. And I have to admit, this surprised me because I did not realize this was an issue. So tell me about this. How did this originate?

DR. LLOYD: Well, back in 2020, it became apparent to the board that a number of the American Academy of Sleep Medicine members were having difficulties getting the PAP supplied to our pediatric populations, the youngest children. And typically this was related to resistance from the durable medical equipment companies. So a survey was sent out back in the spring of 2020 to help enlist more data and try and get an idea of how big of an issue is this and what kind of struggles are people dealing with in this regard.

So they were fortunate enough to receive 121 responses from oh well yes, predominantly pediatric providers. About three quarters of the respond instead over 75% pediatric sleep medicine. And indeed they found that people were having struggles with DME providing the service to our youngest children. Some of the issues that were stated were related to this resistance, were related to weight and lack of FDA approval of the device, as well as age and applying adult OSA guidelines.

So that's kind of how this came about. It was a significant issue that was widespread. The people who are participating in the survey were from all over the country and so it wasn't just in a given region. And it was determined that indeed we needed to have more information put out about this and a position statement was recommended.

DR. KHOSLA: So. So, OK, so what is the FDA approval then for CPAP? Luella, do you know?

DR. AMOS: Absolutely. And so, you know, it's kind of interesting when you look at the literature, there really is no there is no age and weight criteria for PAP in general. But each commercially available machine is FDA approved based on usually weight criteria. There are a couple that have maybe some age requirements, but based on weight, there are some limitations in terms of the patients that can that are, I guess, on label use of these devices.

DR. KHOSLA: So meaning that that you have to be of a certain weight, like you can't be too little?

DR. AMOS: Exactly. Majority are over 30 kilos. There may be machines out there that are 18 or maybe just under 15 or 13 kilos. I know here in the United States we use pounds. So you can kind of think of like 66 pounds versus, you know, maybe about 40 pounds and, and there are some toddlers or younger, you know, elementary school children who would not qualify because of their weight.

DR. KHOSLA: Oh, so that, I mean, that's a pretty high weight. I'm trying to think about my youngest and she must have been like eight before she was 66 pounds.

DR. AMOS: Right. I have a teenager I have a 14 year old. And I don't think it's been that long since he was 66 pounds.

DR. KHOSLA: Oh, so that. OK, so that makes more sense to me for why this even had to be had to be a thing. So then what was the take home message and what was the official position, Robin, on, on using PAP in the people that are sort of outside the FDA guidance.

DR. LLOYD: So after review of what available literature there was, of course there weren't many prospective studies, but rather retrospective studies, case reports, heterogeneous kind of populations. We did determine that in the hands of a clinician who has expertise in evaluating and treating pediatric obstructive sleep apnea, that indeed utilizing PAP for the treatment of obstructive sleep apnea in even the smallest of pediatric populations was safe and effective.

DR. KHOSLA: So it's this. So I'm just flashing back now. I've seen lots of pictures of little babies on CPAP, so was that sort of outside of FDA guidance.

DR. AMOS: 100%.

DR. KHOSLA: Really? So so this is where my brain is going. So you write a prescription for CPAP and then at what point does it sort of become challenging? Is it the DME? Is it insurance?

DR. AMOS: So the first step is getting the machine from the DME, yes. And often they require kind of a letter or waiver of liability. So parents have to sign this, knowing that they're using kind of off label use of CPAP and so that kind of scares them, of course. And it's just, you know, another step that we have to go through. And then you have insurance behind that to feel comfortable providing or paying for this machine. Now, for the little ones, maybe under 13 kilos or under 30 kilos, certain DMEs are very, very strict and want only a ventilator. Ventilators can

go down 5 kilos or 2.5 kilos depending on the type and so so then you run into that issue and it's very expensive not to mention burden because of the extra requirement to get a ventilator into the home. You have insurance saying, I'm not going to pay for that ventilator. So your parents and these patients ae in limbo between the DME and insurance not being able to get the treatment that they need and just waiting on us to try to write more letters of medical necessity. I don't know, there's a lot of red tape.

DR. KHOSLA: Well, I mean, that just it sounds really kind of onerous. Both sort of on the clinician side. But I mean, imagine being the parent, right? And you've had presumably a sleep study and there's a diagnosis of OSA and then you're having a battle because you either have to be home on a ventilator, which sounds I mean, probably a lot scarier, right, than a CPAP then. And then not knowing about paying that. I mean, I had see this as I live in the adult world, so I had no idea.

DR. LLOYD: Not only is it a financial burden, but also just an access burden. And I think as a result, as you mentioned, it's it's stressful enough, I think having a child who needs special treatments, but also a lot of these kids have special needs at a baseline. And so putting this financial stress as well as limiting the access to the needed, the needed treatment can be very, very hard on the family.

DR. KHOSLA: Wow. And so then for little tiny little kids then so with the position statement, you haven't limited that it can't be used in any population. I think, if I'm understanding this right, it's saying if you understand how to use it in children and you have experienced treating children and sleep-disorder breathing and CPAP, it is completely OK to use it. Or we feel strongly that in those hands it would be OK to use. Is that right?

DR. AMOS: Exactly, yes. That's what the position statement states. I think it's really important. The that caveat, obviously, you're comfortable in your experience of treating pediatric OSA just because there are a lot of nuances that we have to keep in mind. Number one, you got a kind of a mask that fits them can be very different, maybe very small children with complex medical needs may have craniofacial abnormalities. So to keep that in mind. We also have to keep in mind that the frequency of constantly developing structures we have to monitor very closely for maxillary or mandibular intrusion depending on the type of mask use.

One other thing that you know, we've had which we touched on in the in the paper was also the algorithms in the machines that are used to kind of monitor adherence and therapeutic efficacy. Those may not be pediatric, these algorithms through the AHI might be 20, but it's really not, they really are actually getting, you know, efficacious therapy. It's just that they're detecting no airflow when it's just less airflow.

DR. KHOSLA: So I remember I have a friend that's at pediatrics he's actually my go to pediatric sleep person and and he just very casually mentioned this one day and I was like, hang on, what do you mean? And he the way I understood it is that the machine just isn't sensitive enough to figure out that the kid is breathing and using and using the machine and so then it throws off all the adherence and then that sort of leads to, you know, DMEs taking the machine back and sort

of that whole thing and how he has to really ensure that that he is able to document that is actually being utilized.

DR. LLOYD: That's correct. That can be a huge issue. So not just reporting a very high residual apnea-hypopnea index, but also reporting that it's not being utilized. And it's it's interesting because families will say, oh, no, really, I put this on every night. I use it consistently, but and clearly the patient's doing better and awakening more refreshed and and all these things.

So as with anything in pediatrics, it it it it depends on the caregivers input. And so when they're reporting one thing, but yet the machine's reporting something different, that can be a little stressful for everyone involved. And so one of the caveats that we have is that most children are started in a monitored setting, whether it be at the hospital or an attended sleep study setting. And I think that's important so that we can indeed monitor to make sure that the treatment is safe and effective and well-tolerated.

DR. KHOSLA: I think that's a really important a really important point, too, that you have to have that whole support, right? That whole structure where they're initiated, they are observed, they're monitored, they're, everything's tweaked.

DR. AMOS: And Robin, you know, when you touch on a really good point, when you see that you can get their AHI to 1 or zero or 2.2, and then you see the data download saying 15, 20, you can kind of rely on your titration, right? You can say, no we were able to do this and we'll have, you know, and you see that, you know, if it's a certain machine that can ramp up to you're like, they didn't need that. And kind of sort of, you know, I think that titration is essential, especially in the little kids because you can kind of feel confident that you were able to get them to the therapeutic range and, and treat them with, with this pressure, even though the machine says you're not doing a good job.

DR. KHOSLA: So then I imagine you probably have to bring them back in at regular intervals.

DR. LLOYD: Mm hmm.

DR. AMOS: Yeah, sometimes they do.

DR. KHOSLA: So if the adherence is it the same as sort of the adult four hour, 70% of nights Medicare rule?

DR. LLOYD: Well this is kind of, I laugh about it because when you think about children and how much they're sleeping, and so if you take say, you know three or four year old child where you want them sleeping ten, 11, 12 hours a night and then you say oh it's OK if you only use it four hours at a time and that's acceptable compliance. So, so I think there are two different issues. I think there's the insurance recommended compliance and yes, unfortunately it's or fortunately it's extrapolated from the adults sometimes giving those 4 hours is pretty tough. But in actual clinical practice, of course, we like to see the kids using it whenever they're sleeping.

DR. KHOSLA: Yeah, that always, you know, thinking about that, I was like, well, four hours for a kid's sort of expected duration or recommended duration of sleep is, you know, less than half. So it just it's funny, right, how we get stuck on these arbitrary non evidence based numbers.

DR. LLOYD: Right.

DR. KHOSLA: So I really liked in your position statement when you delineated the people, like you didn't just say you have to be a board-certified sleep physician so using myself as an example, I am a board-certified sleep physician. I have no idea how to manage CPAP in a kid. So I love that you included APPs in your statement. You know, you didn't just specifically say this has to be a physician.

DR. AMOS: I think it's really important to include our, I mean, we have a great nurse practitioner at our institution who can manage a lot of our patients with pretty straightforward OSA on PAP therapy. And she's been very instrumental in investigating, you know, adherence issues as well as quality improvement issues. And and, you know, one thing that I think is really important to kind of keep in mind is, you know, when we have to contact the manufacturer to understand why things are different in children.

I kind of go back to the downloads, sorry, I'm kind of perseverating on them, but they, you know, they could show that they're not using them kind of like Robin said. Yeah. Just shutting off because you don't think they're not detecting them because of maybe their tidal volumes or air flow. I'm not quite sure. So we had to make sure that these machines are not shutting off. Like, they're not like turning off and not providing pressure. They're just actually not recording.

DR. KHOSLA: Oh, my gosh. That would be that would be very alarming.

DR. AMOS: Wouldn't it? And then you're like, yeah, this is it is dangerous. And to put on a child if it's shutting off, but it isn't it? It's just not recording, but it's still providing adequate pressure. But you have to kind of show our you know, our nurse practitioner, our regulatory therapists, you know, the people in our lab who had, you know, great experience with children with OSA are able to kind of bring this back to us, you know, the other physicians in the practice to let us know that we are doing the right thing by providing the PAP. We just have to kind of make sure we keep in mind the fact that these machines may not be able to detect them and stop recording their usage.

DR. LLOYD: So I just wanted to add that there was a discussion on the pediatric sleep listserve recently about how people are having more and more nurse practitioners and physician assistants joining their practices. And it was interesting the breadth and depth of of experience and and practice opportunities that the nurse practitioners and physician assistants were providing to the pediatric practices. And so absolutely, I think we need to make sure that that they are included in this this position statement. We felt pretty strongly about that.

DR. KHOSLA: Oh, I love that. So let's take a short break. And when we come back, we'll talk more about using PAP therapy in children. You're listening to Talking Sleep from the American Academy of Sleep Medicine.

AD BREAK

DR. KHOSLA: Welcome back to Talking Sleep. Today's guests are Dr. Luella Amos and Dr. Robin Lloyd. And we're talking about utilizing CPAP therapy in children.

So we were talking about that residual AHI. And you mentioned some of the inaccuracies. Is the threshold different like do you shoot for an AHI of less than five or an AHI less than two?

DR. AMOS: That's a very good question.

DR. KHOSLA: Or am I poking the bear.

DR. AMOS: Well and you know, the, the criteria so that I get a diagnosis of OSA in children, the AHI is lower than adults. And so, you know, when you look at the literature out there, severity index is different like an AHI of one to five is considered mild, five to ten moderate, greater than ten severe. But if you consider mild OSA as being an AHI of one to five but you cannot order CPAP for someone who doesn't have AHI greater than or you have AHI is less than five, then you're kind of not treating the mild OSA, right. Oh, so it's kind of again it's we're using a lot of adult criteria to provide therapy and to keep the therapy in the home. So it's it's always going to be a discussion just because children are not small adults, they are completely different people.

DR. KHOSLA: OK, so you've hit on something really important, though. I didn't realize that. Like I thought that if a if a child had an obstructive apnea index of one, one and a half, that that satisfies the criteria. And I guess in my brain, I then just assume the next step was straightforward, that, OK, that satisfies our criteria. They have a diagnosis, ergo now we start CPAP. Is that not true?

DR. LLOYD: So that's a great question. And again, this runs into one of the issues that was touched on in the survey and that some of the DMEs utilize adult criterion. And there's so much variability within DME, but we also see variability within an individual DME. And so depending on who you're speaking with that day, you you can really run the gamut of of difficulties.

The other thing that I think is important is, is one of the main reasons we do in-lab sleep studies in kids is not just because of the technical challenges and the stress and burden that it puts on the family, but so much of the diagnosis of sleep apnea is the observation of sleep. So for example, I had a little boy with Down's syndrome who had a, quote, normal, AHI, less than one, but the entire night he was sitting up with his nose, pointed to the air, his neck extremely hyperextended, just trying to open up his airway so clearly his breathing was not normal. And so. Right. And so kids do an awesome job at trying to protect their airway, trying to they wake up to try and to correct. And so I think it's it's a tough thing because when we try and get PAP approved, for kids who have low AHIs, when we know it's the right thing to do, a lot of times we really have to go to bat for them.

But it truly is the right thing to do. So I think Seema, in an ideal world, when you said, hey, you know, if you have an AHI of over one, shouldn't we just be able to get PAP? That that's that's a loaded question. And I think that's that's a big struggle for us.

DR. KHOSLA: Oh, see, I had no idea. And it's so funny, right? Because I know that answer from boards from not from anything practical or always bugging my pediatric sleep, you know, colleagues, you know, and I remember somebody had told me that somebody is a child until they are 17 and 364 days old. And so and that has always stayed in my brain and I never recognized

that there would be a disconnect between the diagnosis then being able to, to offer them effective treatment.

DR. LLOYD: Mm hmm. Yeah.

DR. KHOSLA: So do you think that this position statement will be enough to sway payers?

And I guess and so let me so I'm thinking, you know, we've all kind of suffered in our patients have suffered in the last year and change we have you know, the first we had ventilator shortages and PAP shortages and the recall and now masks and I guess I would think that insurance would want you in the cheapest and most effective modality of treatment. And so pulling ventilators away to treat something that can be treated with CPAP in my in my mind just seems like not the right thing to do.

DR. AMOS: It makes sense, doesn't it, like that you would want to preserve the ventilators for right to use and for no I do hope I do hope it makes a difference. That was the goal. And that's what all the providers on this, they said, you know, this would be amazing if you could put something out to help us out because everyone is working really hard to get therapy to their patients.

And I can confidently say it won't hurt, but will it help? I mean, please, just, you know, in your letters, if you have to write letters of medical necessity, you know, they can quote it just kind of and the feedback would be great to hopefully we can maybe see if there has been a change over the next year or two in terms of getting therapy for the younger and smaller children.

DR. KHOSLA: So does this affect then the decision making process in terms of do you offer surgery versus PAP?

DR. LLOYD: So in general, we look at PAP for kids who have either residual sleep apnea after surgical intervention or if surgery is not preferred so people don't want to have their child undergo surgery or if for some reason the child is not a surgical candidate.

DR. KHOSLA: OK. So then this isn't necessarily you know, I'm trying to think about how in my mind if now this option is sort of off the table, what are you left with? Right. We don't use oral appliances in children. You know, we always want to do the sort of kindest, gentlest, least invasive thing first. And I imagine, you know, just thinking back to my days of of pulmonary medicine and home ventilators, there is a lot more to like a home ventilator than a PAP device.

DR. LLOYD: Hmm. Absolutely. So that's why we're we're hopeful that this will be helpful for people. And I think having the support of the American Academy of Sleep Medicine saying, hey, this is a safe and it is an effective treatment based on all the literature that we have available this this this can be used in a safe and effective way, if managed appropriately in the right hands. And so, you know, let us do it. And so so that's our hope.

DR. KHOSLA: So do you do you know why they didn't it was not approved for kids under 66 pounds? Was it just sort of what the trial was or I mean why?

DR. AMOS: You bring up a really another worry because we we as a group the task force learned a lot ourselves. You know we've got we do know how to treat patients with you know with with PAP therapy but what are these issues and how did they come about. How did they get authorized and started to learn about the FDA approval process. And so to not sound too nerdy.

DR. KHOSLA: Nerd away. Go ahead. Let's let's learn.

DR. AMOS: So, PAP devices, commercially available PAP devices are considered class two medical devices. And they go through what we call a 510 K process for approval through the FDA. And so through this process, they essentially just have to show that they have an indication to use the same characteristics, safety and efficacy as a predicate device. So predicate device means a device is already approved for use to treat OSA.

And so they you know, when you kind of look back at those predicate devices, a lot of the weight and age criteria were based on bench studies rather than actually directly studying it on various stages or weights. And so, you know, they they were determined to be safe in efficacy, efficacious or effective. But then, you know, kind of looking beyond those age and weight, we're not really on the radar or specifically done. And so we realized, you know, not only is there a paucity of literature about the use of PAP therapy in children, you know, in a randomized controlled setting, but that was not needed for FDA approval of these machines. And so you're kind of looking at machines that have sort of perpetuated that use age and weight criteria to get them kind of approved and used.

DR. KHOSLA: Well, yeah, it's not like they tested it in little kids and then said, oh, this is not a good thing. It's just it's always just based on whatever the predicate device was. Right?

DR. LLOYD: Correct.

DR. AMOS: Yeah. And even when you look at the studies, looking at the very small children young children, they don't really actually mention the device either. You know, we tried to look into what kind of devices we were using. And so then they just a said CPAP so we still don't know, you know, they they tested it. But is it, you know, what machine was it? We don't know, huh? There's a lot of resistance needed in this area for sure.

DR. KHOSLA: Isn't it funny when you sort of start scratching the surface.

DR. AMOS: You know, to find out things, things yeah. Yeah.

DR. KHOSLA: Well, when you learn about the whole process, like the FDA thing, right. And and even now we're learning, right, with the with our masks and the mask recall and the magnets on the mask and the warning. And, you know, this whole process has to be in place. And, you know, this likely is because of the Phillips recall and you know, digging in deeper and, and that sort of thing. But, yeah, it just seems like I mean, for me, obviously, no idea that this was ever an issue. So hats off to you guys for battling this for so long. And so to me, it just seems like there's this great opportunity for somebody to come out and say, hey, this is something that we've tested in children and this is our FDA clearance and here's our new machine.

DR. AMOS: Hmm. Yeah, I think so. I think we also discovered certain parameters that would be nice to specify in those studies, too, because you know, we used a lot of BMI mentioned, you know, like, OK, body mass index, but not necessarily the weight. So we kind of couldn't figure out, you know, how much your children weigh in some of these studies. So it would be nice to kind of really look, you know, hold down on this on these questions that that if they are, I think, sort of hurdles in getting the machines, the patients, that we actually address these specific parameters that DMEs are looking for, insurance is looking for and really kind of I guess, prove or disprove that they're working at these younger and smaller children.

DR. LLOYD: And I think beyond age and weight, the clinical history is so important, too, because we know that certain populations are absolutely more prone to having sleep apnea and have special craniofacial issues that that put them at higher risk. And so I think looking at the age, the weight, the clinical history, the type of device, the the interface, the treatment outcomes, I think is going to be very important. And, you know, as they say, the proof is in the pudding. And so if if we are able to indeed help prevent deleterious consequences of untreated sleep apnea in children with various clinical backgrounds, I think that's just such a crucial thing going forward.

DR. KHOSLA: Well, and Robin, you raise such an important point that is not you know, and we've said this forever, right? It's not all AHI but just that visual of of that of that little kid trying to keep his airway open, open and contorting his position in an effort to do that. And obviously that is something he learned over years. And to have to be able to explain that in a way that somebody reading through the medical record would understand. Right. And to communicate then with the DME and the payer.

DR. LLOYD: Correct? And do you worry about I mean, certainly if someone has mouth breathing and their mouth is gaping open and, and over many years, they can have changes in their dental arch. And what does that mean for the long term risk and their craniofacial structures? So absolutely, these are all such important considerations and I think definitely, as Louella mentioned, something we need to look at further in a prospective fashion. But we're certainly hopeful that this position will statement this position statement will help us going forward.

DR. KHOSLA: Well, I hope somebody takes that on. So and he is then I wonder if that would also address the low flow issue in the sense of, you know, the ability to detect events with better accuracy. You know, I wonder if if that would be able to be addressed at the same time, that.

DR. AMOS: Yeah, exactly. I think, you know, we specifically looked at this in certain patients because we knew that, number one, certain patients who use them all night but the adherence status that they weren't using it. And they could not they could not remove the mask and like because they have such complex medical needs that they can't remove it. And so I feel like they woke up with it on their face and the machines as they were using it. So we asked them, we looked into it and then again, our staff was able to contact the manufacturer or that representative from the manufacturer just to find out are we going to hurt our children by putting this machine on the market, seeing that they're not using it and they're like, no, it is working. It's just not

recording. So, yes, and I think it's there's a lot to be done. And I don't think you can you know, I don't think we can not look into it enough. You know, I can compare the hard data, which is really like watching the child on the machine and then looking at what the the data download shows that would be pretty useful information as well.

DR. KHOSLA: Wow. So any final thoughts?

DR. AMOS: I think it's very important to recognize everyone on the task force because they were amazing and very efficient, very hard working. We're all so passionate about this, and we all were excited just to get this done. Not completed, but, you know, to get this out there. And so I think it's important to recognize all of us in and I'll name them right now. So we have Olufunke Afolabi-Brown. I just love her name so I have to say it a couple of times. Dominic Gault who I think is Dominic Gault is your great resource. Robin is here and talking with us. Moshe Prero, and of course, Dr. Carol Rosen. And we had amazing AASM staff working with us and getting us, you know, getting us together with our meetings and keeping us in line. And we have Sherene Thomas as well as Uzma Kazmi. I think it's really important to recognize everyone on the task force to put this together. And I think we're making a big difference.

DR. KHOSLA: What a good group. Robin, how about you? Any final thoughts?

DR. LLOYD: I agree with what Luella said. This was an amazing group, very enthusiastic, very passionate. And I hope that this work can be continued forward and and just help with improving outcomes in our our youngest population with challenging obstructive sleep apnea issues.

DR. KHOSLA: Well, thank you so much for explaining these issues around CPAP treatment. for children and really affirming the safety of PAP therapy in children.

DR. AMOS: Thanks so much, Seema.

DR. LLOYD: Thank you.

DR. KHOSLA: To help your little ones get adjusted to using CPAP, the AASM has created a CPAP desensitization video for children. We will leave a link to this in the show notes.

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