

No Small Commitment

With help from Ann Halbower MD, of the Pulmonary Department at Children’s Hospital Colorado, Aurora, CO, the mission to serve the smallest sleep apnea patients with CPAP masks is gaining momentum.

Marketing new CPAP units to a burgeoning adult patient population takes a lot of time, money, and energy. In this highly competitive environment, it’s no wonder that pediatric devices have received relatively short shrift over the last decade.

Not all manufacturers, however, have ignored the “small” market. California-based ResMed got the ball rolling 7 years ago with its Mirage Kidsta mask, a unit cleared by the FDA for children 7 years of age or more than 40 pounds.

Based on the Mirage platform, the Kidsta combined dual-wall cushion technology in an attempt to fashion a comfortable mask for smaller faces. In 2010, the Mirage Micro for Kids took the technology yet another step forward. From there, the evolution has continued thanks to advocates such as Ann Halbower, MD.

With passion and knowledge built up over more than two decades as a board certified physician in pediatric pulmonology and sleep medicine, Halbower has made her voice heard even in the halls of Congress. “I have screamed about this for 20 years,” says Halbower, an associate professor of pediatrics in the Children’s Hospital Colorado Sleep Center, affiliated with the University of Colorado, Denver School of Medicine. “I worked with the American Academy of Pediatrics to develop and push for the Pediatric Medical Device Safety and Improvement Act of 2007, and that bill was passed for us to improve and facilitate development of pediatric medical devices.”

Since then, the FDA has approved CPAP usage for children as young as two years. Working with many sources to help these younger kids under the FDA ruling, engineers at ResMed developed a new mask. Recently launched, the Pixi pediatric mask is designed from the ground up specifically for kids, and is not simply a “sized down” adult mask.

Meeting an Unmet Need

Officials at ResMed believe it is important to address the unmet needs of the pediatric population. “With our pediatric line, our goal is to provide a solution for a group that is often neglected,” says Bernadette McBrearty, Vice President – SDB SBU at ResMed. “We pride ourselves on taking in market feedback to develop products that meet people’s needs while providing viable long-term solutions. Our pediatrics line is part of that.”

Despite widespread perception in the industry that pediatrics is not a lucrative market, Halbower is convinced that investment in pediatrics makes good clinical and financial sense. In a wide-ranging conversation with Sleep Diagnosis & Therapy, she expressed enthusiasm for ResMed’s commitment while making an impassioned plea for more pediatric sleep apnea awareness in the medical community.



Pixi pediatric mask

Are you pleased with the FDA’s level of awareness when it comes to devices that treat pediatric sleep apnea?

Ann Halbower, MD, associate professor of pediatrics, University of Colorado, and Director of Pediatric Sleep Research at the Children’s Hospital Colorado Sleep Center: We still do not have approval for kids younger than two. That is a huge problem, because that is where I see the largest unmet need.

Why did you lobby for the Pediatric Medical Device Safety and Improvement Act of 2007?

We found that there were too many children using devices off label, or using adult devices that were not made for, or studied with, children’s safety and efficacy in mind. I have been working since 2004 directly on trying to improve the availability of medical devices, specifically for sleep apnea in kids.

I have been working with device companies, the American Academy of pediatrics, and I worked with the American Thoracic Society to develop the legislation. For me, it seems a very slow process. We know that these devices are available overseas, but they are not as available in the United States.

It costs too much for premarket approval in the United States for companies to consider going through the FDA process. I am very happy that ResMed has agreed to develop some of these devices for smaller people. There is a huge market, and a huge unmet need in children who are infants to toddlers. We have zero devices available for them that are FDA approved for home use. I think that device companies would be very surprised at how often those devices would be used if they were available. Infants and toddlers often just need a device to get them by until they grow out of a problem.

How would you characterize the current awareness of pediatric sleep apnea among general practitioners and the public in general?

Unfortunately, pediatric obstructive sleep apnea is really a public health problem that is unrecognized. We know that 10% to 16% of children will habitually snore. Out of a population of children, at least 2% to 3% have frank apnea.

What is the level of awareness among fellow pediatricians?

Most pediatricians still do not screen for who is snoring and who is not. We still get many children who have had problems and symptoms for many years, but it has gone unrecognized, unchecked, and undiagnosed. It is not until new providers or teachers pick up on the fact that a child is very sleepy or is behaving abnormally.

Are surgical remedies working?

A lot of ENTs get kids with snoring or big tonsils and they operate on them, but there is another unrecognized problem. Adenotonsillectomies really only cure about 50% of all comers when it comes to childhood sleep apnea.

Fifty percent not cured is a large number. How can we make sure these kids don't fall through the cracks?

We used to think that surgery would cure 90%, but so many kids have craniofacial abnormalities or concurrent asthma and allergies, obesity, and all of these things that play a role as to whether you are actually cured at the end of surgery. Almost everybody gets better, but getting all the way down to an AHI of less than one is hard to do.

Are manufacturers doing enough to address the pediatric market?

Device companies have not run with the ball to use that legislative act to enter into markets that still have huge, unmet needs and gaps. Sleep apnea in kids is unrecognized, not screened for, and it is a public health problem because it causes so many other secondary problems. Kids who have sleep apnea generate two and a half times more in health care costs. They tend to have cognitive issues, cardiovascular risk, and they often have superimposed obesity. This can affect their school performance, which can affect their entire economic output in life.

I am putting in my two cents to say that it may look like a small market, but the market is actually pretty huge in the United States. For the new device by ResMed, we tried it on a lot of tiny heads and we found that several tweaks were necessary. I think users will find them helpful, including having the tube come off from the side so it does not obstruct vision. We have very little dead space around the nose so pressure can be delivered without CO₂ retention.

How early should we treat sleep apnea?

We need to recognize sleep apnea and treat it early, even in infants. It is my hope that device companies will help us with that by entering into markets where we do not have devices available.

Why don't pediatricians screen more often for sleep apnea?

I do not think pediatricians recognize the long-term consequences of not treating sleep apnea. We do our best

to train doctors in this, but busy health care providers have 10 minutes to see somebody, and they are trying to get through immunizations, car seat safety, and other concerns. We must remember to screen for snoring, because parents do not often say to doctors, 'My kid is snoring and I think he has a sleep disorder.' Parents do not recognize it as a problem, especially if it has been there a long time. Unless you screen for, it is not going to be picked up.

Other than snoring, what are the different signs of sleep apnea in children?

Gasping, gagging, and labor are more common, but discrete signs of apnea in children are not easy to recognize. Children can have prolonged partial obstruction. They can continue breathing without waking up, but they may be working hard to breathe, while having gas exchange abnormalities.

Kids can have an adult-like phenotype, but they do not always. The younger the child, the more different are the symptoms. If infants have apnea, they may make no noise at all. For those who have a long epiglottis that is almost touching the soft palate, their apnea is silent. Or they may have stridor.

Some children have very large tonsils and adenoids, but sometimes those tonsils and adenoids are so large that they prevent the vibration of snoring.

What are the therapies for severe apnea in infants?

In the United States, our only approved therapy for severe apnea in infants is tracheostomy, and that is a huge burden and a huge health care cost. Families do not have enough home nursing to send these kids home right away. It increases our medical costs enormously, not to mention the morbidity and mortality of kids.

How difficult is it for kids to adjust to CPAP treatment?

They certainly have different issues than adults. First of all, we have all learned that CPAP does not work in children unless the parents have bought into it. It is a teaching program that is required, because you must get the parents to learn why it is important and why it is important to be consistent with the child.

In my sleep program alone, we have more than 520 children on noninvasive ventilation. A clinical psychologist and dedicated respiratory therapist helps to desensitize children to the masks and teach parents appropriate clinical introductory skills for the children. Once again, buy-in from both parents and a lack of fear from the children means more success.

We have more success with little kids, especially special needs kids, then we do with the older teenagers who by now have decided whether they are or are not going to use it. Of course, there are fewer issues that around body image in younger children that can conflict with adherence. It is not easy to sleep with a device on the nose every night, but we find that our compliance is improved if we use a slow introductory process and we actually get the parents to help us with age-appropriate introductory skills.

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