Disclaimer for Pediatric Home Sleep Studies

Ultimate medical decision making occurs between the patient and their medical provider in the context of full informed consent. Though medical organizations can make clinical recommendations and the FDA can approve products for safety, the implementation of those recommendations and the use of those products for patient care resides with the clinician. For example, the American Academy of Sleep Medicine's position paper on Home Sleep Study usage in pediatrics in 2017 states that, "use of a home sleep apnea test is not recommended for the diagnosis of obstructive sleep apnea in children" due to limited literature comparing home sleep studies to polysomnograms in children. However, the statement also noted that "the ultimate judgment regarding propriety of any specific care must be made by the clinician, in light of the individual circumstances presented by the patient, ***available diagnostic tools, accessible treatment options,*** and resources."

In an article entitled *Opportunities and Unknowns in Adapting Pediatric Sleep Practices to a Pandemic World* in the *Journal of Clinical Sleep Medicine* in 2021, it was acknowledged that "pediatric sleep healthcare providers have long had to use sensible, good practice when clinical circumstances demand creative, patient centered problem-solving. Even in the absence of sufficient data to support, for example a clinical practice guideline, a home sleep study may be a sensible choice for certain individuals in the pediatric age range and in certain circumstances… such as lack of access to sleep centers…" "Time and cost-efficient options include relying entirely on bedside assessment or if testing is needed, considering the use of home sleep studies in adolescents and children on a case-by-case basis, weighing clinical judgment, pretest probability, and potential patient specific limitations of home testing. In selected pediatric patients, a home sleep study could be part of a multistep pathway of diagnostic testing, which starts with home testing and moves to in laboratory testing in cases of negative or failed home sleep studies as is currently done for adults."

It must be recognized that numerous medications and medical devices are never tested by companies or approved by the FDA for use in pediatrics because of the significant added cost. Yet a large percentage of medications are used in the pediatric population based on experience in the adult population. If a pediatric patient had a formal in laboratory sleep study, which is the gold standard for both pediatrics and adults, the CPAP machine utilized to treat the pediatric patient's obstructive sleep apnea would not have been approved by the FDA for use in pediatrics; i.e., the proprietary algorithm in the machine is specifically for adults with apneas lasting 10 seconds. Of note, normative values for the duration of respiratory events in ??? children ages XX-XX is 10 seconds.

The FDA definition of a pediatric patient is age 21 or younger, therefore; includes a very wide range of patients that we would not necessarily consider pediatrics. So, the use of home sleep equipment that has FDA approval for adults in theory could not be use on an 18 year or even a 15-year-old that was the size of an adult.

In considering the usage of home sleep equipment in the pediatric population, one must first take into account whether the patient will keep the equipment on during the night hence not requiring a technologist to monitor the equipment, and signal quality. Some pediatric patients actually might do better in their own home environment so this is not totally based on age. It is critical to take into consideration the expertise of the individual looking at the raw data to determine whether it is interpretable.

Current home sleep study devices all use the same technology including the measurement of airflow from the mouth or nose, the use of appropriately fitting chest and abdominal belts to document chest wall movement, and an oximeter that measures oxygen levels and heart rate. Also included is documentation of sleeping position and snore sensors. Only one device has sought FDA approval in pediatrics in the US. (Of note this device was on the market when the AASM policy statement was made in 2017).

Currently in the Kansas City area there are only 14 pediatric sleep beds at Children's Mercy Hospital to meet the needs of the four-state area. The current wait to get a sleep study is over 9 months. They are attempting to use home sleep study equipment in 18-year-olds. Many adult labs are closing in the Kansas City area. A few remaining labs will perform in-laboratory sleep studies for older adolescents but do not provide home sleep studies for any age of pediatrics. The bottom line is there is a paucity of sleep study testing options for our pediatric patients to meet the demand.

I have actually talked to the American Academy of Sleep Medicine about my concerns. They have reassured me that they are forming a task force to address this issue by reviewing the new data published since 2017 but they will have to make sure they have billing codes and reimbursement in place with insurance companies to move forward. From my stand point, something needs to be done now and even if the AASM officially makes a statement about using home sleep studies in pediatric patients your wait to be seen in the Sleep clinic at CMH will likely still be over 9 months.

With my 20 years of experience reading the raw data of sleep studies and the last 12 years exclusively working as the medical director of the pediatric sleep lab at CMH, I have the

knowledge and experience to determine whether the acquisition of the raw data on any sleep study is adequate enough to allow for an interpretation. Being able to provide a home sleep study for a pediatric patient provides much more information to families than a simple overnight oximetry and will provide families with additional information to make clinical decisions. Young pediatric patients, such as toddlers, typically have low numbers of respiratory events per hour so if they are not demonstrating moderate or severe disease they should be sent for an in-laboratory sleep study. Additionally, those children who are at risk for hypercarbia would also be best studied at a in laboratory facility.

The goal for providing home sleep studies for the underserved pediatric population is solely to provide more information beyond just a simple clinical suspicion for a patient's sleep apnea where there is limited access to any type of analysis and the answer has been to simply wait for an appointment or to see if things improve. This is not acceptable. There is no risk to testing but there is risk to ignoring moderate to severe sleep apnea.

Please discuss the above information with your provider. If you understand and accept the limitations listed above, please sign below.