# JCSM Journal of Clinical Sleep Medicine

R E M REM: A PUBLICATION FOR RESIDENTS AND FELLOWS

## MEDIA REVIEW: The Owlet Smart Sock—a "must have" for the baby registry?

Afeerah Malik, MSIII1; Zarmina Ehsan, MD1,2

1School of Medicine, University of Missouri-Kansas City, Kansas City, Missouri; 2Division of Pulmonary and Sleep Medicine, Children's Mercy-Kansas City, Kansas City, Missouri

The Owlet has been voted the "Best Baby Monitor" on multiple leading parenting websites, such as Babycenter.com, What to Expect.com, and the Bump.com. 1-3 It is now featured in the list of "must haves" for baby registries. The Owlet Smart Sock 2 (OSS) is marketed as a device designed to monitor heart rate and oxygen levels. The OSS comes with 3 sizes of fabric socks, a smart sock sensor, a base station, charging cords, and the Owlet app.4 The app for the smartphone lets parents monitor their sleeping baby and receive notifications and alerts throughout the night. There are 5 alerts, of which the Red Alert is the most critical (heart rate is not between 60 and 120 beats/min or oxygen saturation (drops below 80% of the threshold). It is available for \$299.99 on owletcare.com. A recent survey revealed that the majority of parents purchase this for "peace of mind."<sup>5</sup> Although this device can store valuable information on the infants' health, there is concern regarding false alarms, high cost of the device, and excessive reliance on the device. Moreover, marketing these devices for use in otherwise healthy, asymptomatic infants may further exacerbate parental anxiety and worry. Additionally, from the medical provider's standpoint, it is challenging to address any abnormal results in this context.5

There is evolving literature available on this device. A study comparing the OSS and the Baby Vida 2 (another similar baby monitor) to a Food and Drug Administration (FDA)-cleared pulse oximeter (Masimo Radical-7) revealed that the OSS "detected hypoxemia but performed inconsistently" and advised physicians and parents to exercise caution when making medical decisions with OSS data. The authors reported that the sensitivity and specificity of the Owlet for hypoxemia was 88.8% and 85.7%, respectively, and for bradycardia was 0.0% and 100.0%, respectively. Another study on the usage patterns of the OSS reported that clinically significant alerts were clustered. For example, the study found that patients may have 10 alerts within the first day of a respiratory syncytial virus infection, which increases the credibility of the device.<sup>5</sup> These results must be interpreted with caution given that the goldstandard comparative test must be arterial blood gas analysis (albeit with limited feasibility). Although the website claims that the Owlet's sensor accuracy was tested against arterial blood gas measurements and the sensor performed well within industry and regulatory standards for pulse oximetry, when the information is referenced on www.clinicaltrials.gov, we found

that the results, in fact, were returned to the investigator after quality control review. In summary, the device efficacy is low and warrants further study before directing parents to use OSS.

There is certainly a role for home monitors in infants.<sup>6</sup> The most recent committee paper from the American Academy of Pediatrics states that home cardiorespiratory monitors may be considered for "high-risk" premature infants, and infants who are technology-dependent, have unstable airways, or have chronic cardiopulmonary conditions. These monitors may add value in these clinical circumstances by alerting caregivers to signs of respiratory compromise. However, parents must be advised that home cardiorespiratory monitoring has not been proven to prevent sudden unexpected deaths in infants (SIDS/SUID), and pediatric sleep specialists should continue to promote proven practices that decrease the risk of sudden unexpected infant deaths—supine sleep position, safe sleeping environments, room sharing until 1 year of age, and elimination of prenatal and postnatal exposure to tobacco smoke.<sup>7</sup>

As data regarding the OSS evolve, it is important to remember that in comparison to medical devices, commercial devices are extensively marketed and widely accessible and have a growing popularity among parents. However, robust research evidence to support product claims is not mandated. 8-13 On the OSS website, the company explains that the Owlet is not the same as a hospital pulse oximeter, because medical monitors are configured by the baby's medical provider to set thresholds in accordance to the patient's conditions and medical monitors have to go through rigorous testing to get FDA approval. The OSS has relatively conservative thresholds set and should not be used as a replacement for a medical device. Nevertheless, robust prospective studies are needed to assess the utility of the OSS as a medical monitor in select cohorts of infants. As parents become more technology savvy, it is important for sleep providers to stay up to date with new devices on the market and the limitations therein.

### **CITATION**

Malik A, Ehsan Z. Media Review: The Owlet Smart Socka "must have" for the baby registry? J Clin Sleep Med. 2020; 16(5):839-840.

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#### SUBMISSION & CORRESPONDENCE INFORMATION

Submitted for publication April 5, 2019 Submitted in final revised form January 22, 2020 Accepted for publication February 3, 2020

Address correspondence to: Zarmina Ehsan, MD, Division of Pulmonary and Sleep Medicine, Children's Mercy Hospital, 8601 Gillham Road, Kansas City, MO 64106; Tel: (816) 983-6355; Fax: (913) 696-8519; Email: zehsan@cmh.edu.

#### **DISCLOSURE STATEMENT**

All authors have seen and approved the final manuscript. The authors report no conflicts of interest.