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The emerging market of smartphone-integrated infant physiologic monitors

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In the past 2 years, a new class of infant physiologic monitors marketed to parents for use in the home has emerged. Smartphone applications (apps) integrated with sensors built into socks, onesies, buttons, leg bands, and diaper clips display infants' respirations, pulse rate, and/or blood oxygen saturation and generate alarms for apnea, tachycardia, bradycardia, and/or desaturation (Table 1). Despite the lack of publicly available evidence supporting their safety, accuracy, effectiveness, or role in the care of well infants, sales of these monitors are brisk and the market is expanding. For example, the makers of the Owlet monitor, a "smart sock" that claims to alert parents if their baby stops breathing,¹ recently reported sales of 40,000 units at \$250 each.²

Advertised role

Consumer infant physiologic monitor websites avoid direct statements that their products treat, diagnose, or prevent disease, yet their advertised role is to alert parents when something is wrong with their infants' cardiorespiratory health. In a video featured on the front page of the Owlet website, the company's CEO states "We can't promise to prevent Sudden Infant Death Syndrome (SIDS) right now, it's an unknown issue but... we believe notifying parents when something's wrong maybe can help."² Contrasting its product to audio monitors, a central focus of Baby Vida's advertising is the question "What sound does your baby make if he or she stops breathing?" suggesting that their sock-based pulse oximeter "*Should* be used every time your baby *could* go to sleep" [emphasis theirs].³ These direct-to-parent advertising strategies may stimulate unnecessary fear, uncertainty, and self-doubt in parents about their abilities to keep their infants safe.

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Indications

There are no medical indications for monitoring healthy infants at home. An American Academy of Pediatrics Policy Statement clearly states “Do not use home cardiorespiratory monitors as a strategy to reduce the risk of Sudden Infant Death Syndrome (SIDS),” noting that there are no data that commercial devices designed to monitor infant vital signs reduce the risk of SIDS.⁴ In select populations, including premature infants at high risk of recurrent apnea, bradycardia, and hypoxemia, physiologic monitoring may be indicated. In those populations, monitoring devices with form factors like those in Table 1 may eventually be of value, but only if their safety, accuracy, and effectiveness are demonstrated.

Regulation

The makers of consumer infant physiologic monitors have avoided Food and Drug Administration (FDA) medical device regulation by stopping just short of claims to prevent SIDS. Two companies reportedly intended to sell their products as medical devices and were planning to pursue FDA approval but later changed their minds because of the time and expense required.⁵

Striking a balance between fostering innovation while exercising regulation in the rapidly expanding mobile medical app market is challenging. The fundamental questions that must be answered about consumer infant physiologic monitors center on their safety, accuracy, and effectiveness. To date, medical apps have a disappointing track record. For example, a recent evaluation of a blood pressure app showed that it falsely reassured nearly 80% of patients with hypertension that their blood pressure was normal.⁶ Like the infant monitor makers, the developers claimed their app was not to be used for medical advice.

There are a few potential paths to establishing the safety, accuracy, and effectiveness of consumer infant monitors. The first is for FDA to step in under existing law. In their 2015 guidance document on mobile medical apps, FDA provides examples of apps that are the focus of their regulatory oversight and include “apps that transform a mobile platform into a regulated medical device” with breathing frequency monitors, apnea monitors, and oximeters among the device types listed.⁷ Based on these regulations, consumer infant physiologic monitors would likely be categorized as FDA Device Class II and be subject to the 510(k) pathway which requires that the makers demonstrate “substantial equivalence” to a legally marketed device.

Alternatively, the clinical research community could evaluate the devices and publish their findings, either independently or in partnership with patient safety organizations or the device companies. Regardless of the approach, the safety, accuracy, and effectiveness of these devices must be evaluated and shared with physicians and parents to allow them to make informed decisions about the use of these products.

Overdiagnosis

Even if one could assume that consumer monitors are highly accurate, the clinical appropriateness of monitoring healthy infants would remain in question. By continuously

monitoring healthy infants, parents will inevitably experience some alarms for conditions that are not life-threatening, including false positive alarms due to motion artifact or other causes, and true positive alarms for events that are not clinically important. It is well-established that healthy infants have occasional oxygen desaturations to below 80% without consequence,^{8,9} placing them at risk of overdiagnosis and harm if these innocuous events generate alarms.

Overdiagnosis occurs when the accurate detection of abnormalities fails to benefit the patient. This is because a single abnormal test—such as a self-resolving desaturation—can trigger a cascade of events. For example, a low pulse oximetry alarm from a consumer monitor could prompt an emergency department visit with blood tests, x-rays, and hospital admission. Rather than reassuring parents, these experiences may generate anxiety and a false assumption that their infant is at risk of dying. These considerations introduce the prospect that using a monitor could indirectly result in harm to infants and their families.

Conclusions

The current market of smartphone apps integrated with sensors that monitor infants' vital signs are innovative and have potential to improve care. However, their performance characteristics are unknown to the public and there are no medical indications for their use. Until they have been thoroughly evaluated and guidelines for use established, the recommendations physicians should give to parents who ask about these products is simple. There is no evidence that consumer infant physiologic monitors are life-saving and there is potential for harm if parents choose to use them. Child and family advocates should make it clear to the FDA and policymakers that regulatory guidance and research evaluating the safety, accuracy, and effectiveness of these products are needed.

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Table 1

Features of consumer infant physiologic monitors with smartphone integration.

	Brand Name					
	Baby Vida	Mimo	MonBaby	Owlet	Snuza Pico	Sproutling
Form Factor	Sock	Onesie	Button	Sock	Diaper clip	Leg band
Pulse Rate	Yes	No	No	Yes	No	Yes
Respiratory Motion	No	Yes	Yes	No	Yes	No
Pulse Oximetry	Yes	No	No	Yes	No	No
Cost	\$150	\$200	\$170	\$250	TBA	\$300