Reducing Caregiver Stress From At-Home Infant Monitoring

Results from a survey of Owlet Sock user experiences

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Introduction

The birth of a child brings forth a whirlwind of emotions for parents, from joy and excitement to anxiety and apprehension, especially for those with infants requiring special medical attention. **In recent years, the advent of home monitoring technologies has revolutionized healthcare, allowing for the remote tracking of vital signs and enabling early detection of potential health issues.** One such technology that has been used in home monitoring systems, pulse oximetry, has now become an integral part of routine screening and monitoring of infants and is endorsed by the American Academy of Pediatrics, the American Heart Association, and the United States Department of Health and Human Services.[1] Pulse oximetry is a non-invasive method for measuring blood oxygen saturation level (SpO_2). It involves placing a small sensor on the infant's skin, typically on the foot or hand, that emits light wavelengths to measure oxygen levels. This technology has become increasingly popular for home use, particularly for infants diagnosed with conditions such as congenital heart defects, chronic lung diseases, or apnea of prematurity. **Monitoring oxygen levels at home provides parents with a sense of reassurance and empowerment. It also allows for the early detection of any significant changes in oxygen saturation, potentially preventing serious health complications.** Several case studies have demonstrated that home monitoring can improve survival rates through the timely detection of hypoxic events and hasten the diagnosis of rare diseases such as neuroendocrine cell hyperplasia of infancy[2] or apnea of prematurity.[3] In a 10 year study, Rudd et al. found a 98% survival rate in interstage patients with Norwood stage 1 palliation (S1P) utilizing at-home SpO_2 and weight monitoring, in contrast to the 10-20% mortality associated with unmonitored routine care during the interstage period.[4] In a retrospective cohort study performed by Gélinas et al, an interesting new phenomenon was identified – an increased frequency of home pulse oximetry alarms correlated with increased frequency of desaturation events in the days preceding clinical deterioration, most often due to an upper respiratory tract infection,[5] demonstrating that at-home pulse oximetry can provide alarms before the manifestation of clinical symptoms. These benefits have led some large centers, such as the Apnea Center at Emory University, to consider at-home pulse oximetry monitoring as a valuable tool for patient management,[6] particularly in infant populations with a high risk for sporadic hypoxic episodes.[7,8]

While this technology offers numerous benefits in monitoring the health of these vulnerable infants, it also raises concerns regarding parental anxiety. A false positive alarm, in which alarms occur without a medical reason or due to an overly sensitive system, can contribute to parental stress and anxiety. The consequences of false positive alarms extend beyond the emotional toll on par-

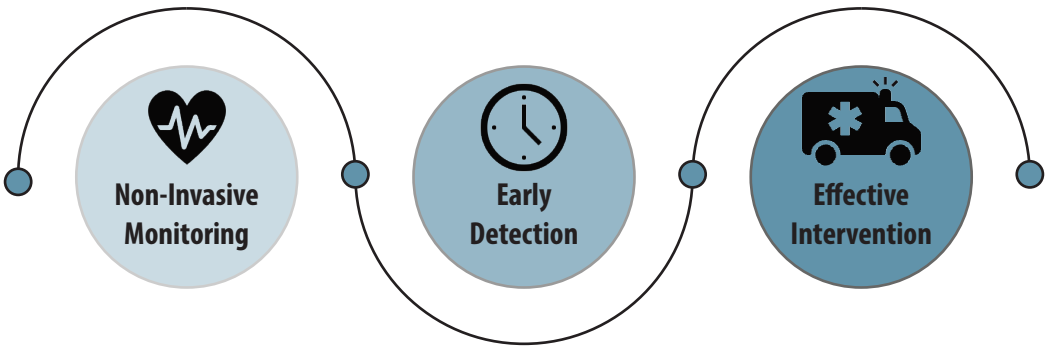

Figure 1. Benefits of at-home pulse oximetry monitoring in babies

ents. Healthcare facilities, already grappling with limited resources and personnel, bear the brunt of the burden. Each false alarm requires follow-up evaluations, often involving visits to emergency departments or pediatric clinics. These visits consume valuable time and resources, diverting attention away from patients who genuinely require medical intervention. Furthermore, false positive alarms can contribute to "alarm fatigue", desensitizing caregivers and leading to delayed responses to genuine emergencies. In a study on alarm burden in infants with moderate to severe bronchopulmonary dysplasia, typical post discharge settings for home pulse oximeters carried a median alarm frequency of 23 events in an 8-hour period.[9] Concerns have arisen that such untenable alarm burden would impact adherence to home monitoring plans.[9] **Therefore, it is critical that at-home pulse oximeters are designed to maintain a balance between triggering alarms for medical events requiring intervention while minimizing false positives to mitigate the risk of parental anxiety and unnecessary medical visits.** Considering these risks, the FDA began regulating pulse oximeters for their accuracy and sensitivity. To meet FDA standards, at-home pulse oximeters must demonstrate their accuracy is not affected by variable factors like peripheral perfusion, different skin pigmentation, probe placement, and patient movements. These rigorous testing protocols reduce the risk of "alarm hazards" that were considered the number one health technology hazard by the ECRI Institute in 2015. The burden of minimizing these risks is even greater for over-the-counter pulse oximetry monitors, which present a different set of challenges. Typically, parents who have chosen to use the Owlet Smart Sock (Owlet Sock) to monitor their babies have lost or known someone who has lost a baby due to Sudden Unexpected Infant Death, have a child with a breathing problem or heart condition, or are "digital natives" who rapidly utilize the latest advancements in technology to ensure the best care for their infant.[3] In all three cases, parents are looking for peace of mind, and a continuous monitoring system reassures them that their baby is safe. No matter what reason motivates pulse oximetry monitoring for their child, having a reliable and accurate device is essential for infant safety. Thus, using an FDA-cleared device is essential to ensure parental peace of mind.[10]

While home pulse oximetry monitoring offers valuable benefits for infants with respiratory or cardiac conditions, the full utility of this technology can only be realized by minimizing the negative effects of false positive alarms. Device manufacturers, regulators, and healthcare providers can ensure efficient resource allocation and patient safety by educating parents, improving technology, and implementing clear guidelines. To that end, tracking user experience data provides manufacturers with unique insights into the benefits and limitations of their devices in a real-world setting.

The Owlet Experience

Pioneering at-home monitoring, Owlet Baby Care, Inc. addresses this unfulfilled user need by creating two medical devices that offer continuous home monitoring incorporating technology that optimizes the accuracy of pulse rate and SpO_2 readings but minimizes excessive alarming, thereby reducing caregiver anxiety. BabySat™ and Dream Sock® are both FDA-cleared pulse oximetry systems enabling continuous at-home SpO_2 and pulse rate monitoring via a PPG sensor embedded within a wearable sock. BabySat and Dream Sock are designed to notify caregivers with light and sound if their child's readings are out of the normal range. Red notifications (alarms) indicate that the baby's heart rate or oxygen levels have left the preset zones. BabySat and Dream Sock are the first medically-cleared iterations of Owlet products, both having received FDA clearance in 2023. The design of both Dream Sock and BabySat are based upon the Owlet Sock, an over-the-counter infant monitor. Considered to be similar devices per the criteria set forth in the European Union Medical Device Coordination Group Guidance (MDCG 2020-5), these products share a commonality of technology which allows the utilization of Owlet Sock post-market data to help identify relevant and specified clinical outcome parameters for the intended clinical benefits of Owlet's medical devices. Post-market Owlet Sock data collected by Owlet shows that a large percentage of parents who utilized the Owlet Sock for at-home pulse oximetry monitoring experience less anxiety and followed safe sleep practices (Table 1).[3] Moreover, 61% of parent-reported red alarms were confirmed as clinically significant after verification with a healthcare provider (Table 2).[3]

Table 1. Parental Outcomes Utilizing the Owlet Sock[3]

Caregiver Outcomes (n=5125)	Respondents (%)
Following Safe Sleep Guidelines	82
Better Quality Sleep	94
Less Anxiety	96

Table 2. Self-reported Conditions Identified After an Owlet Sock Alert[3]

Condition (n=48)	No. of Respondents (n)
Respiratory Syncytial Virus	23
Supraventricular Tachycardia	7
Breathing Disturbance	7
Airway Obstruction	5
Congenital Heart Defect	5
Apnea	3

Motivation for This Study

Owlet submitted two monitoring devices to the FDA for clearance: BabySat*, a prescription pulse oximetry monitoring system for infants who require additional at-home ongoing monitoring, and Dream Sock£, an over-the-counter pulse oximetry device for healthy infants. Both devices were FDA-cleared for home use in 2023. While Owlet made a concerted effort to involve their products' end users in the design process, a significant concern with infant SpO_2 home monitoring systems is that their use will stimulate unnecessary anxiety in caregivers.[10,11] Owlet conducted this study to provide an evaluation of this identified risk of caregiver anxiety while using a wearable home SpO_2 monitor on their infant, and a baseline reference for ongoing regulatory requirements for post-market surveillance to ensure the safety and efficacy of BabySat and Dream Sock. We performed a survey of 4,000 Owlet Sock users in the United Kingdom (UK), Canada, and Australia to determine:

1. If red alarms related to SpO_2 and Pulse Rate readings from an over-the-counter Owlet infant monitor increase anxiety in caregivers.

2. If red alarms related to SpO_2 and Pulse Rate readings from an over-the-counter Owlet infant monitor increase healthcare utilization.

Materials and Methods

Owlet Sock User Survey

We surveyed 4,000 Owlet Sock users in the UK, Canada, and Australia who were active between January and February 2022, and received a total of 707 responses. Baseline characteristics of the survey cohort are provided in Table 3.

Effect of Owlet Sock Red Alarms on Caregiver Anxiety

A subgroup of respondents whose children had no baseline medical condition (n=547) were evaluated. We compared survey responses to the question: "To what extent does having an Owlet Sock on your child(ren) INCREASE or DECREASE your level of ANXIETY?" between respondents who had not received a red alarm and those who had received a red alarm. Respondents selected a value between 1 (decrease in anxiety) – 5 (increase in anxiety), with 3 representing no change in anxiety. Significant differences were assessed by Chi-Square test.

Table 3. Owlet Sock User Survey Demographic Information

	Response	Respondents (%)
Race	Caucasian	81
	Asian	4
	Indigenous	3.6
	Hispanic/Latino	2.5
	Black	0.4
	Other	5.9
	Declined	5
Environment	Suburban	50.6
	Urban	28
	Rural	21.4
Number of Children Monitored with OSS	1	4.6
	2	1.7
	3	85
Household Income	≥$100,000	70

Effect of Owlet Sock Red Alarms on Healthcare Utilization

The rate of red alarms, the rate of caregivers seeking medical advice after a red alarm, and the use of emergency services after a red alarm in all respondents (n=707) was quantified. In a subgroup of respondents whose children had no pre-existing condition, we compared the percentage of respondents who utilized a pediatrician, telehealth, urgent care, or emergency services between respondents who had not received a red alarm and those who had received a red alarm.

Results

Effect of Owlet Sock Red alarms on Caregiver Anxiety

Out of 547 respondents, 69% (n=377) reported that they had not received any red alarm. Most caregivers in both groups reported that usage of the Owlet Sock decreased anxiety (no red alarm, 94%; red alarm, 91%; Figure 2A,B). We found that experiencing a red alarm had no significant impact on caregiver anxiety (Chi-Square = 1.375, p = 0.241).

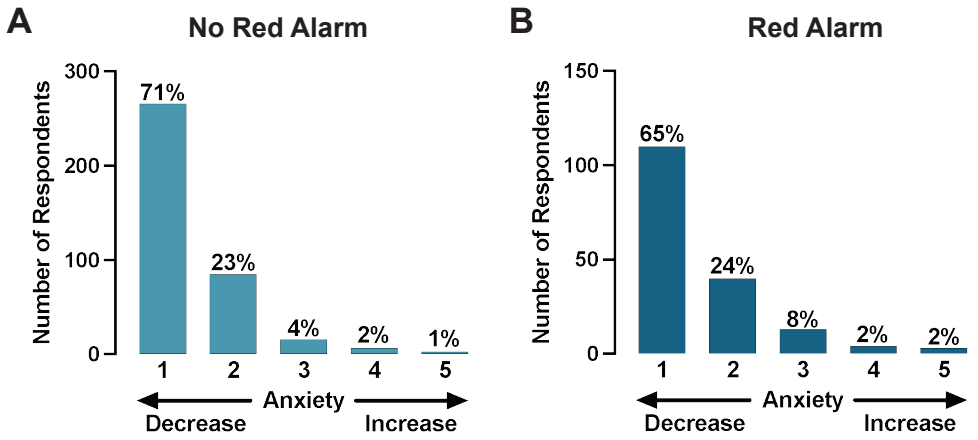

Figure 2. Responses of Owlet Sock users to the survey question: "To what extent does having an Owlet Sock on your child(ren) INCREASE or DECREASE your level of ANXIETY?", in caregivers who had not (A) or who had (B) received a red alarm. Respondents selected a value between 1 (decrease in anxiety) – 5 (increase in anxiety), with 3 representing no change in anxiety.

Effect of Owlet Sock Red Alarms on Caregiver Anxiety

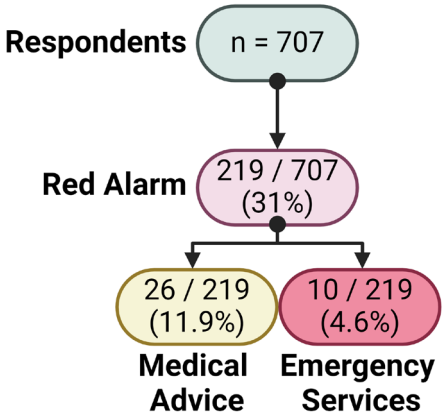

Figure 3. Self-reported healthcare utilization of Owlet Sock users in the UK, Canada, and Australia.

219 (31%) of respondents reported receiving a red alarm related to vital sign abnormalities. Of these 219 respondents, 26 (11.9%) sought medical advice after receiving red alarms, and 10 (4.6%) of these respondents reported utilizing emergency services (Figure 3). 63% of the users who utilized emergency services reported receiving a medical diagnosis that was directly related to the alarm

We found no significant difference in healthcare utilization rate across all encounter types (pediatrician visit, telehealth, urgent care, or emergency room) between Owlet Sock users who had received a red alarm and those who had not (Figure 4). Moreover, we found no significant difference in the proportion of Owlet Sock users reporting a high (≥ 3) number of medical encounters, and the number of users reporting 3 or more medical encounters was rare in both groups (Figure 4).

Conclusions

While at-home pulse oximetry is a valuable tool for monitoring the health of babies with medical conditions, it can also be a source of anxiety for caregivers, and false positive or nuisance alarms could have a negative impact. The reliance on technology for monitoring can foster a sense of dependency and a fear of malfunction. Parents may become overly concerned about the accuracy and reliability of the pulse oximeter, constantly checking and rechecking readings for validation. This dependency on technology can exacerbate anxiety, as any perceived discrepancy or malfunction may lead to doubts about the infant's well-being and the effectiveness of monitoring. These risks can be even more pronounced for parents who have an otherwise healthy infant and have decided to use a home monitor for peace of mind. Therefore, it is a major consideration for device companies that develop pulse oximeters to have a thoughtful approach to how their products perform in the home environment. Prevention of oversensitive alarming can minimize the levels of stress, and produce a higher proportion of alarms which are clinically actionable.

Here, we have presented data from a real-world post market survey of Owlet Sock users to determine how red alarms impact anxiety and healthcare utilization. We found that red alarms from an Owlet over-the-counter infant monitor did not increase anxiety or lead to the overutilization of healthcare resources. Moreover, nearly all the caregivers using the Owlet Sock reported a decreased level of anxiety independent of red alarm status, and most caregivers who utilized emergency services after a red alarm reported that the alarm directly led to a medical diagnosis. These findings suggest that the design of the Owlet alarm algorithm provides highly actionable information to parents, minimizes false alarms, and does not increase parental anxiety. This approach to optimizing the positive predictive value of red alarms was applied to both BabySat and Dream Sock, devices intended for the home environment. In this setting, the balance between accurate detection of events and limiting oversensitive alarms is a goal we believe is essential to minimize alarm fatigue and prevent nonadherence to monitoring protocols prescribed by physicians. The data presented suggests that the design of Owlet alarm logic for its FDA-cleared devices can achieve this balance for home caregivers, a group that is essential to the success of technologies designed for monitoring outside a clinical setting.

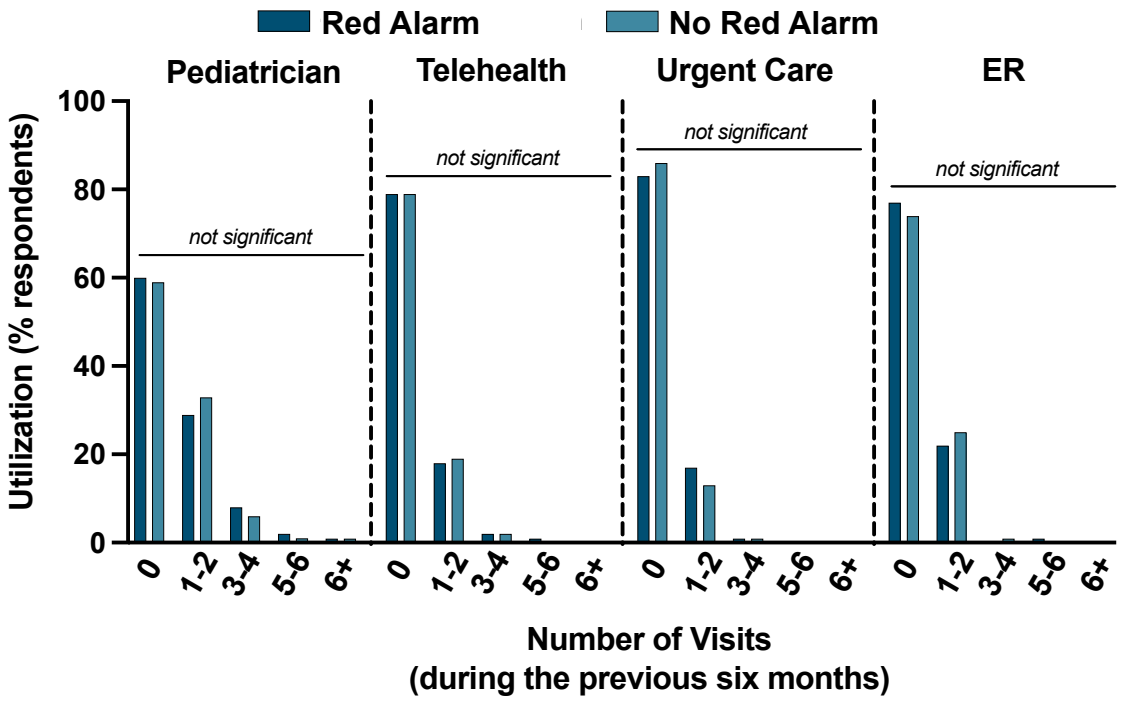

Figure 4. Healthcare utilization in Owlet Sock users with and without a red alarm.

Summary

Based on the data collected, utilization of the OTC Owlet Dream Sock carries little risk of increasing caregiver anxiety or healthcare utilization. For both Dream Sock and BabySat, reducing nuisance and false positive alarm burden is a paramount goal to prevent caregiver alarm fatigue and impacts on infant safety.

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*The BabySat pulse oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and heart rate. It is indicated for spot-checking and/or continuous monitoring of well-perfused patients more than one month old and weighing 6 - 30 lbs in the home environment.

£FDA-cleared Dream Sock features are for healthy babies between ages 1-18 months and weighing 6-30 lbs and is available through an Owlet Dream App update for US customers. CE Marked and UKCA Marked Dream Sock is intended for healthy infants between 0-18 months and 2.5-13.6 kg. Dream Sock is intended to track babies' heart rate and oxygen level and keep parents informed but it is not intended to diagnose, treat or cure any disease or other condition including, but not limited to, Sudden Infant Death Syndrome (SIDS) and/or Respiratory Syncytial Virus (RSV).

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