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Assessing infants' sleep in the home setting: designing rational study approaches

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The methods used for assessing infants' sleep vary widely, and the insights provided by each method are not necessarily interchangeable. Direct physiological measurements are often performed in hospital environments with extensive and controllable instrumentation, whereas at-home assessments have been based on parental questionnaires and diaries or actigraphy measurements. There is a rising need for the establishment of objective at-home methods to improve ecological validity in assessing infant sleep. Here, we review how specific research questions can be aligned with at-home assessment methods, ranging from indirect parental interviews to direct modern measures with unobtrusive sensors (wearables, in-bed sensors, video), and their integrated machine learning -based analytics. We discuss the nature of information available from each method in relation to the physiological or behavioural sleep phenomena. The currently available methods may support disruptive science, including globally harmonized and scaled-up studies across cultures and geographic locations, including fully decentralized developmental research and sleep-focused health care.

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IMPACT:

- The paper raises the practical and scientific need to study infant sleep using methods that are both objective and ecologically valid, thereby supporting the use of direct at-home measurements.
- The paper emphasizes the multifaceted nature of infant sleep, which precludes its assessment as a solitary entity and calls for clear research questions to identify measurable phenomena in sleep-related physiology or behavior
- Presently available research methods for at-home studies are described and compared in relation to their information content, practical utility and caveats
- Various analytic results and sleep metrics are described in relation to the underlying sleep physiology or behavior.
- The overall message emphasizes the need to establish a solid end-to-end waterfall framework in infant sleep research, spanning study questions, sleep phenomena, recording methods, and data analytics.

INTRODUCTION

Sleep is a prominent and spontaneously recurring state of reduced responsiveness, characterized by specific neurophysiological, behavioral, and autonomic patterns. Its regulation involves multidimensional interaction of homeostatic and circadian processes, and it is essential for brain maturation, learning and memory, metabolic regulation, and physical growth[1–3]. Therefore, infant sleep is an essential theme in a wide range of contexts, from everyday parenting and wider societal or work life to pediatric and maternal health issues, as well as in a wide spectrum of developmental studies. The high proportion of time infants spend sleeping implies a significant role for sleep in early development and health[4]. Meanwhile, a range of actual or perceived problems in infant sleep pose significant challenges to parental and societal wellbeing[5]. It is commonly noted that in-lab polysomnography (PSG) is the gold standard in medical sleep assessments, but PSG is not adequate for assessing many infant sleep problems that are experienced in home environments, such as impacts of acute infections and sleep settings, or the sleep effects of daytime experiences[6]. An ecologically relevant sleep assessment should take place in the real-life context—the infant's home. In this review, we propose a rational end-to-end framework for the design and conduct of infant sleep assessments, linking real-world questions to the type of information required, and consequently, to the at-home methodologies best suited for infants.

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There is a larger range of reasons why an infant's sleep is assessed (hereafter, words "assess" and "study" are interchangeable), and one convenient way is to recognize the following three categories: First, sleep disturbances may reflect other illnesses, such as sleep-disordered breathing[7], which require a full polysomnography (PSG) study in a sleep laboratory. Second, sleep problems are reported by a large proportion of parents (30–50%) of typically developing, healthy infants, as well as infants with more complex medical histories, and these cause significant distress and thereby compromise family health. Third, sleep is the dominant behavioral state throughout infancy, making sleep an attractive context in many developmental and pediatric studies. Conversely, measures of sleep may reflect a range of underlying conditions, including malnutrition, maternal health problems, or other biological and environmental influences[5].

Recent technological development has introduced a range of new methods that could be used in infant sleep assessment. The quickest progress has taken place in the field of "self-measurement", with countless consumer products being introduced for at-home assessment of health or other life activities. While some of these purely direct-to-consumer products have been applied in academic and/or health research[8], there is also a growing number of papers introducing scientifically solid and often open-access solutions for infant sleep research[9–12]. Both the consumer-marketed and science-targeted methods share the attraction that direct measurement of a sleeping infant produces mostly observer-independent data. Since these methods provide metrics (e.g., "sleep score") that have a clear name and an exact value, the user may mistakenly assume that the measures are both physiologically meaningful and accurate for application in science or health care contexts[12]. However, numerical precision of the data does not necessarily equal scientific or medical value, and importantly, the consumer systems rarely provide users with access to the recorded "raw data", which would be necessary to assess data quality in the first place. It is unfortunately common that infant sleep studies are performed with methodology that is motivated by clinical or research tradition rather than by the study questions and/or relevant sleep phenomena.

Sleep as an elusive concept

Both everyday and science conversations typically speak of infant sleep as if it was a self-evident concept that allows for a straightforward, holistic handling. However, infant sleep is an inherently multifaceted, biological and behavioral construct without clear operational definitions; therefore, sleep cannot be assessed holistically or with single metrics[13]. For instance, sleep quality (SQ) is a widely used term with a seemingly intuitive meaning that in the infant context typically refers to parental feelings more than the infant's sleep per se. Therefore, the concept SQ remains ill-defined and metaphorical, unless it is grounded to *quantified metrics*, such as sleep duration or fragmentation, and it would be then more appropriate to speak of the given metrics rather than refer to an ill-defined SQ concept. All infant sleep metrics are challenged by the need to recognize different sources of variability (developmental vs physiological vs technical vs true pathology).

Early development of sleep physiology

Insights from ontogenetic and phylogenetic studies[14,15] demonstrate that sleep is a spectrum of physiological states, fundamentally orchestrated by neuronal networks in deeper brain structures[16]. These elemental sleep networks direct state-related activities in the "bodily functions" measured with polygraphy signals (e.g., eye movements, respiration, muscle tone, twitching), as well as in the "cortical functions" measured with electroencephalography (EEG) or behavior. In the infant sleep context, it is essential to first recognize how early developmental changes reflect on the information available through different study methods. Both experimental and human studies[17–20] show that bodily functions, such as respiration, eye movements, and muscle tone, are all well developed and observable very early, in the youngest preterm infants. Meanwhile, functional connections between deeper brain (elemental sleep circuits) and cortex develop during the last trimester[21], thus EEG patterns begin to reflect sleep states rather late in ontogeny[22,23]. Independent of the structural and functional organization, there is a much longer time window in the development of ultradian (cycles with a period shorter than 24 h) and circadian sleep rhythms (a.k.a. sleep consolidation[24–26]). The salient ultradian rhythms begin as markedly variable state fluctuation with about 10–30 min cycles in the early preterm infants, and these quasi-periodic cycles increase in length to the commonly observed 60–120 min near term age[27–29]. Meanwhile, the diurnal rhythms (day-active/night-inactive) only begin to emerge postnatally, guided by light exposure and feeding or other care schedules[30], and the clearer day-night rhythms with continuous nighttime sleep and decreasing daytime naps consolidate towards the end of the first year[24,26,31,32] (Fig. 1).

The first critical question in assessing infant sleep: *What is my study question*?

Since each sleep assessment method can only reflect certain aspects of infant sleep, it is critical to determine the study question(s) before selecting an assessment modality. *"If you have a hammer, everything looks like a nail."* In other words, when the methodology is chosen first, it will constrain the breadth of study

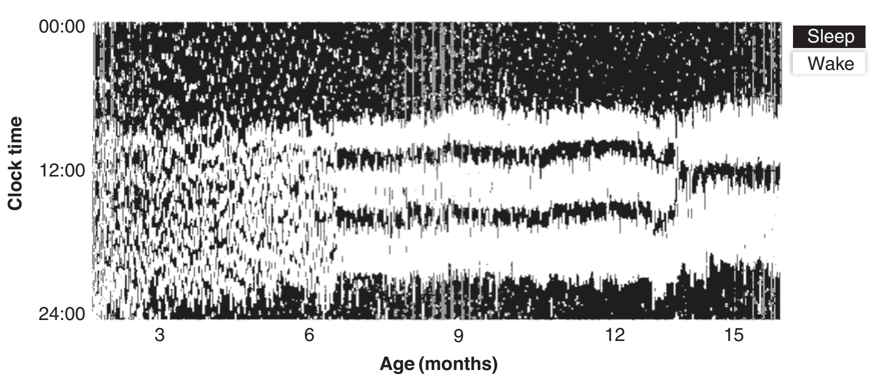

Fig. 1 Consolidation of sleep-wake rhythms. An example case showing daily logging of sleep and wake from 2 to 16 months demonstrates the clear developmental pattern, starting from no apparent rhythmicity until a clear diurnal (day-night) pattern with multiple daytime naps emerging after 6 months of age, with gradual reduction in daily naps during the second year of life. (modified from https://tinyurl.com/wtcyzzeb).

Table 1. Categories of behavioral and physiological phenomena, the needed information, and possible at-home methods.

Study question/Targets	Necessary information	Auxiliary information	Possible at-home solutions	Notes
Parental concern	Interview, diary, questionnaire		Parental diary	Must have parental assessment; subjective and influenced by parents' own well-being and other multiple other factors
Parent-infant interaction	Interview, diary, questionnaire, or dyad recording	interview	Subjective: parental diary objective: dyad measurements	Subjective (diary) vs objective (measurement); these approaches provide distinct information; parental information is likely influenced by parents' own well-being
Activity-rest rhythms	Physical movement activity	Diary	Actigraphy from wrist, ankle, or trunk.Wearable integrated IMU sensor	A full 24/7 assessment requires continuous (wearable) measurement; does not measure sleep per se, is readily confounded by sleep-twitches and external movements (co-sleeping, carrying, transportation)
Sleep structure (sleep architecture, pattern)	Time course of the sleep depth	Diary	Algorithmic analysis of recordings from wearables or sleep mat/pad	Must have measure of sleep depth and/or vigilance state; assessment of temporal structure is usually descriptive; quantitation focuses on discrete states only
Sleep position	Trunk orientation	–	Algorithmic measure of fixed-body accelerometer signal	Must have a direct trunk measure; relies on parental sensor positioning
Sleep-related respiration	Respiration signal	–	Respiration belt; plethysmograph; abdomen-fixed IMU sensor; sleep mat/pad	Must have a direct measure of respiration movements; is contaminated when co-sleeping; sensor attachment is technically challenging at home
Oxygen saturation	Pulse oximeter	–	Pulse oximetry	Artefact sensitivity; interpretation needs contextual sleep information
Heart rate	Heart rhythm		ECG (or pulse oximeter)	Heart rate variability requires high-quality ECG

See the text for further descriptions.

questions. For instance, parental questionnaires can only assess parental perceptions of their infant's sleep, while actigraphy can only assess periods of activity without recognizing sleep per se, and pulse oximetry can only inform about heart rate or oxygen saturation without direct measurement of sleep or breathing. These considerations may sound obvious when openly confronted; however, the rapidly expanding array of methods for assessing sleep underscores the importance of recognizing the specific utility of each methodological approach within specific study contexts.

The second critical question for at-home assessment of infant sleep is: Which *real-life phenomena and behaviors* are relevant to my study question?

Questions that prompt at-home sleep assessments can be grouped by the behavioral and/or physiological phenomena of interest (Table 1). Recognition of the target phenomena is crucial to define what kind of information should be measured, which in turn guides methods selection (Fig. 2), including methods for data collection and analytics, as well as interpretation of the selected metrics in the study context. For instance, direct infant recordings cannot be used to assess sleep quality (SQ) if SQ refers to parental perception. Conversely, parental diaries cannot reliably capture an infant's sleeping position or detailed sleep-wake rhythms in out-of-hospital settings, because human observers cannot provide accurate reports from long-term continuous behavior [33–37].

Parental concerns and parent-infant (dyad) interactions. The most common reason for infants' sleep assessment in the health care setting is parental concerns, with 30–50% of parents reporting issues with their infant's sleep[31,38]. *Sleep diaries* are effective for documenting parental concerns and subjective perceptions, including nighttime interactions and parent-infant interactions (e.g., feeding, nursing), and direct interviews can conveniently extend the diary information. However, parental information is unavoidably subjective and inaccurate for reporting actual sleep durations, nighttime events, or specific aspects of sleeping behavior[34,37]. Direct, simultaneous recordings of the parent-infant dyad can provide significant insights into the parent-infant interaction. For instance, there is often an implicit assumption that the infant awakens the parent, but little is known of the actual delays and likelihoods of one affecting the sleep of the other[39].

Activity-rest periods. The sleep and wake rhythms are seemingly disorganized during the first months of life[24,40], while a clearer diurnal rhythm develops gradually towards the latter half of the first year, with decreasing daytime napping and more consolidated nighttime sleep[24,30]. This is perfectly suited to support an infant's developmental needs, such as feeding and memory consolidation[41], but the clear mismatch with daily rhythms of adults can cause parental distress and concern for sleep problems[38,42]. It is intuitively easy to think that the levels of infants' physical activity would reflect wake and sleep states, and they can be measured at home using convenient wrist- or ankle-worn actigraphy (accelerometer) devices[40,43,44]. However, it is also well known that an actigraphy-based sleep-wake detection in infants is frequently confounded by at least three common daily situations: (i) prolonged calm periods during wakefulness; (ii) developmentally prominent limb and body movements that characterize an infant's sleep (a.k.a. sleep twitches[45,46]); (iii) movement caused by others, such as infant carrying, stroller, or car seat. Therefore, while it has clear capacity to depict periods of activity and rest, actigraphy cannot directly detect sleep.

Sleep structure (sleep architecture/pattern/depth). In addition to sleep duration, it is often important to know the sleep structures, or sleep architecture, that are typically visualized in the sleep labs

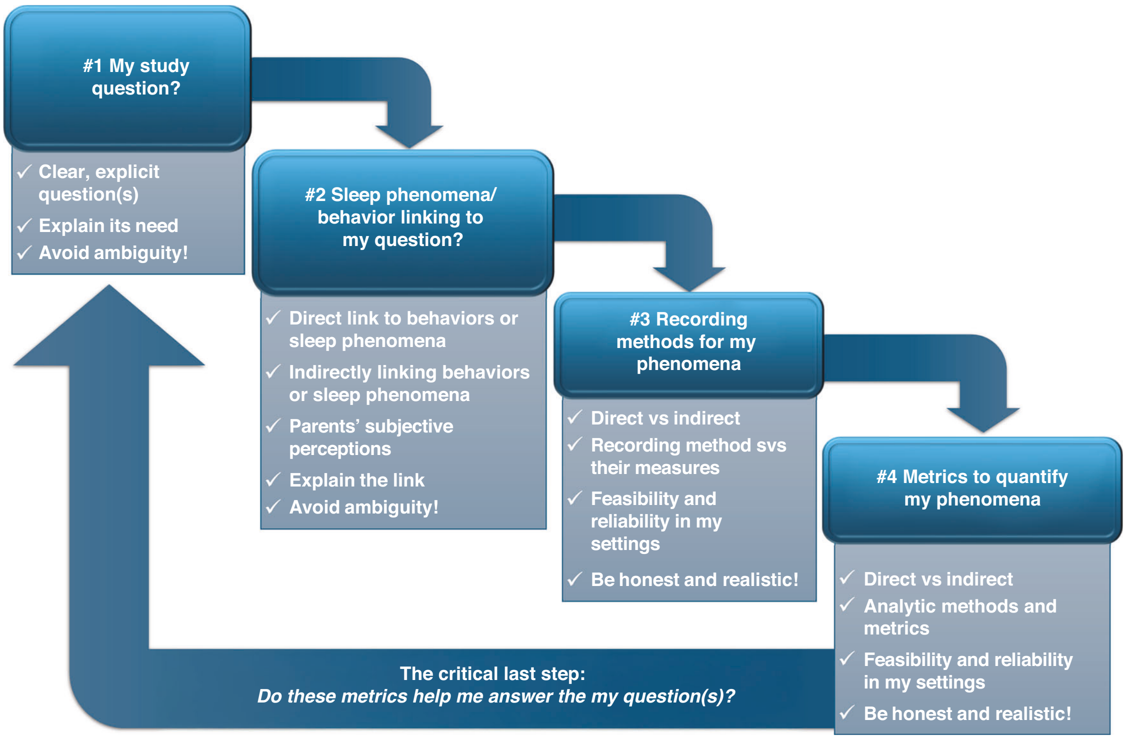

Fig. 2 A rational framework for designing a sleep study. When utilizing sleep assessments, one should always start from the study question (#1) that informs the target phenomena in sleep and/or other behavior (#2), which determines the possible recording methods (#3), and subsequently the study metrics (#4). The ultimate study success is defined by the ability of the chosen metrics to answer the study questions.

using hypnograms generated through sleep stage scoring[22,23]. Some studies have reported neurodevelopmental correlates of specific sleep stages[47]. However, the hypnograms can also be extended to provide a comprehensive 24/7 assessment of biological rhythms (a.k.a. circadian-ultradian rhythms or interactions)[24]. Noting that vigilance state fluctuations require concerted efforts of brain-wide networks[16], it is easy to accept that an age-typical sleep structure provides a general measure of brain health. A physiologically sound alternative to the conventional discretized hypnograms[23] is to measure and visualize sleep structure as a continuous sleep depth trend (see also hypnodensity)[48,49] that fluctuates between vigilance state extremes, waking and deep sleep, respectively (Fig. 3). Such trends can be generated with machine learning classifiers using physiological signals from wearable or in-bed sensors[9,48–51]. Importantly, such trend outputs can support very robust and direct comparisons between different at-home methods without using the conventional in-lab benchmarks[52]. The most important physiological parameter for sleep depth assessment is respiration regularity[10,51,53,54] that may be supplemented with less specific measures of body movements and cardiac cycle.

Respiration, oxygen saturation, and heart rate during sleep. Respiratory control instability (a.k.a. periodic breathing) during sleep is common in infants irrespective of other medical conditions[55–57]. Parents may be concerned about their infant's irregular breathing, while clinicians may want to treat and follow infants who show apnoea with oxygen desaturation, a common finding among infants born prematurely or with other medical complications[56,58,59]. Diagnostic assessment of sleep-related breathing disorders requires medically validated respiration belt or plethysmograph (part of a standard PSG montage) and substantial expertise in usage, hence making them unfeasible for at-home studies. However, respiration rate and its variability can be measured out-of-lab in several ways, such as: (i) a wearable system with a gyroscope sensor attached at a standard location on the lower abdomen[49,60], (ii) pressure-sensitive sleep mats[49–51], or (iii) remote surveillance by radar or camera technologies[61]. Recent advances in computational methods have enabled the indirect measurement of respiratory activity using electrocardiogram (ECG; cardiorespiratory coupling[62]), but these metrics are not stable enough for at-home assessment of an infant's respiration. Pulse oximetry with cloth-attached sensors has become popular in several consumer products[12]. These devices typically suffer from false alerts that may heighten parental stress and could lead to unnecessary contacts to health care providers. Heart rate can be intuitively appealing and readily measurable in sleeping infants using pulse oximetry or ECG; however, current evidence does not demonstrate clear health benefits from routine home recording of infant heart rate. More elaborate measures of heart rate variability (HRV) have been used in many scientific studies[63,64]; however, reliable HRV assessment requires high-quality ECG recordings that maintain consistent electrode-skin contact – a practical challenge for prolonged at-home studies. Taken together, these measurements can be feasible in infants during calm sleep, but the frequent technical issues with data quality (e.g., unstable skin contact, movement) lead to substantial losses of recorded data that are not good enough for medical or scientific purposes.

Sleep position. Infant body position during sleep and wakefulness has become interesting in health research in several ways: (i) promoting supine sleeping with "back-to-sleep" campaigns reduced the incidence of sudden infant death syndrome (SIDS)[65], (ii) sleep position has significant effects on respiration, including apnea[58,66], and (iii) the "tummy time" campaigns for placing infants prone during wakefulness aim to facilitate neurodevelopment[67,68]. Monitoring infant sleep position is typically done visually by parents[68,69], which is obviously unreliable as soon as the infant learns to roll over[36]. Instead, infant body position and the changes across nighttime, or 24/7, can be quantified reliably

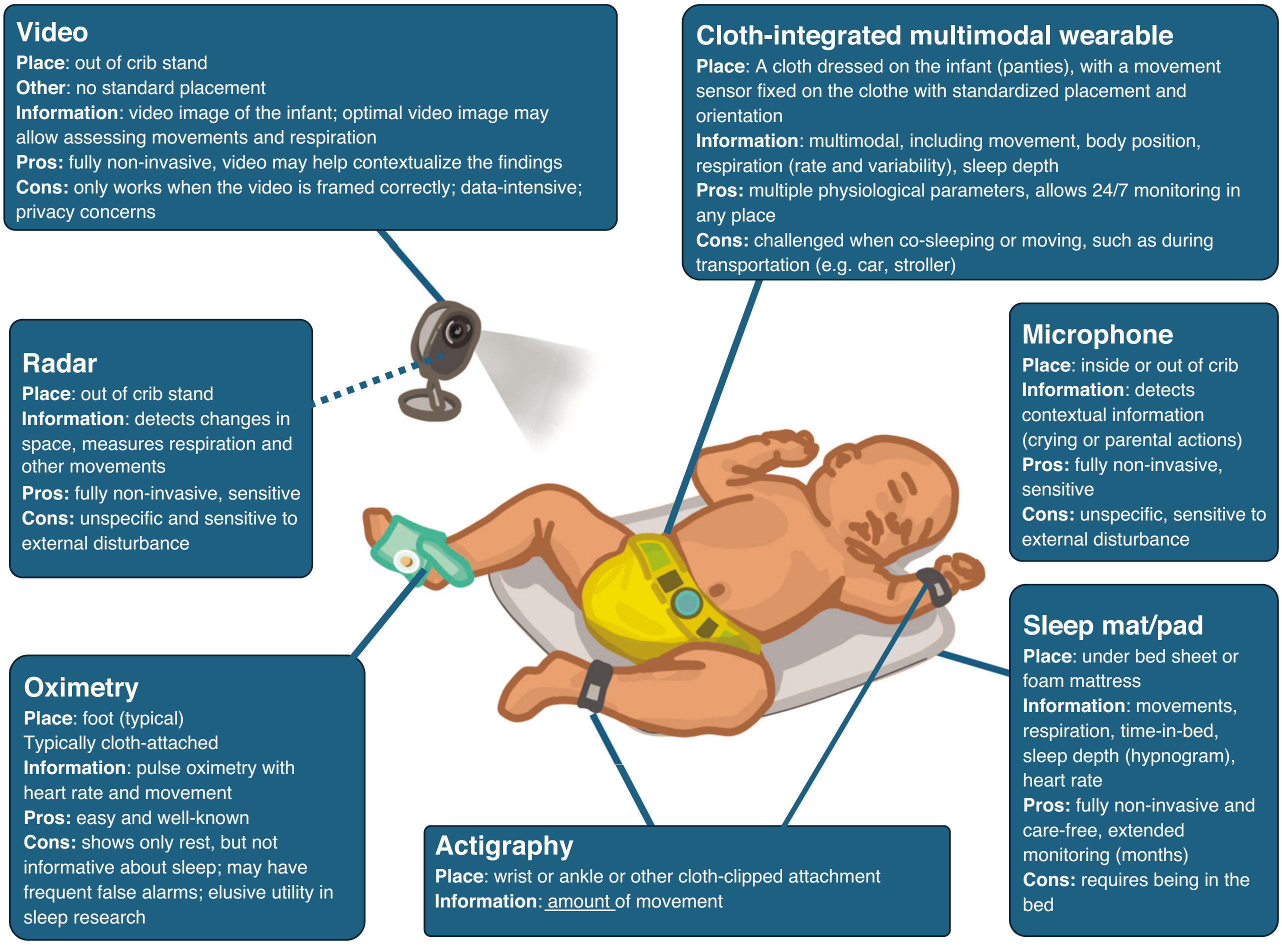

Fig. 3 Methods available for at-home measurements of infants' sleep.

with high temporal accuracy by using an accelerometer sensor with a standardized trunk attachment by belt[36] or wearable garments[49,60].

The third critical question in at-home assessment of infant's sleep: *Which metrics are both feasible and relevant for my study question?*

Modern biomedical studies use statistical analyzes to assess development (or change) over time, differences between groups (or time points), or effects of interventions, environments, and many other factors. All these use cases require quantified sleep metrics. Table 2 presents some of the most common themes or topics that are addressed in infant sleep studies, highlighting the ambiguity of seemingly straightforward questions. The casual usage of general terms (e.g., sleep, sleep patterns, or sleep quality) leads to situations where study questions and scientific conclusions may become detached from the actual measurements and/or analytic results. For instance, usage of the undefined general terms, such as "sleep" or "sleep quality", may misleadingly invite direct comparison of studies using similar terminology but completely different methodology and metrics (e.g., diary vs actigraphy).

Methods for at-home sleep assessment

At-home sleep assessment can be based on parental or measured information. Parental information is always a subjective and indirect report of parents' experience or interpretation of the infant sleep, whereas direct infant measurements can provide objective data, but the information depends on the analytic protocols. Here, it is essential to have a thorough understanding of the promises, pitfalls and caveats of the method, which always consists of a triad: (i) data recording, (ii) data analytics to obtain sleep metrics, and (iii) interpretation of sleep metrics considering both the given data recording and the study questions. For instance: (i) Actigraphy shows physical activity, but it cannot measure sleep per se, or sleep-related behavior; (ii) Interpretation of the same computational sleep metric differs between recording contexts, such as wake after sleep onset during working week vs long holidays; (iii) Wearable methods based on movement sensors cannot reliably detect REM sleep that is characterized by muscle tone and eye movements. Long-form at-home measurements can effectively support context sensitivity, provided the researcher is fully cognizant of them. At-home infant sleep measurements are commonly performed using "wearables", which refers to a wide range of technologies where sensors can be attached to infants' clothing, or placed within or around the infant's cot. Figure 3 summarizes physical modalities that are currently available for such assessments, while Table 3 summarizes their practical feasibility in different use contexts.

Parental information. The most common method for infant sleep assessment is collection of parent-reported information through interviews, structured questionnaires, or sleep diaries. In routine health care settings, the parental interview is typically the first step in assessing the need for further support[4,5]. A real-time *interview* between parent and professional is efficient and flexible, allowing for cultural and contextual adaptation. However, it captures only the parent's subjective perception, which may be influenced by several factors unrelated to the infant, such as parental fatigue, health status, and other daily factors[38]. A growing number of

Table 2. Common topics and questions in infant sleep studies, and the metrics available for such studies.

Topic or theme in sleep studies	Possible questions	Nature of sleep metrics	Comments
1. Sleep and development:	a. How do sleep patterns change as an infant grows? b. What is the typical sleep cycle for infants at different ages? c. How does sleep correlate to neurodevelopment? d. How much sleep does an infant need?	a. The "pattern" is arbitrary as a general concept, because "patterns" can be characterized in unlimited number of ways. b. The concept of a sleep cycle must be specified (wake-N3-wake?) c. "Sleep" is a multifaceted behavior, not a single entity.d. The amount of sleep could be measured by mutually unrelated ways: total duration, proportions or total durations of specific sleep states (e.g., N3), number of sleep cycles, ratio of night-time vs daytime sleep, etc.	a. The "pattern" must be explicitly defined. Also, there must be solid evidence for the physiological meaning and stability of this "pattern" over the whole developmental window. b. The concept "sleep cycle" is not uniform, and the variability of sleep cycles maybe more relevant and informative. c. It is unhelpful and confusing to label any single metric as "sleep". Instead, the study should always discuss a specific metric of sleep, recognizing the mismatch with any other study using different metrics. d. See above. It is only possible to quantify specific aspects of sleep.
2. Sleep environment:	How does room temperature, lights, noise, music etc affect infant sleep?	See above 1. b–d	See above 1. b–d
3. Feeding and sleep:	a. How does feeding (breastfeeding vs. formula) impact sleep patterns? b. What is the relationship between nighttime feeding and sleep quality?	a. See above 1a. b. See below 6	a. See above 1a. b. See below 6
4. Health and sleep:	a. How do health issues, such as teething or illness, affect sleep? b. How does sleep affect overall infant health and development?	a. See above 1c. b. See above 1c-d	a. See above 1c. b. See above 1c-d
5. Cultural and Parental Practices:	a. How do cultural differences influence infant sleep practices? b. What impact do parenting styles have on sleep habits? c. How does co-sleeping or sleep training affect infant sleep?	a-b. No infant metrics, because "sleep practice" or "sleep habit" do not relate to sleep of the infant c. This relates to both infant and the dyad. For infant sleep alone, see 1a-d above.	c. Note that this relates to infant-parent (dyad) interaction. Therefore, contextualization with A detailed diary is minimal, and a direct co-registration would be optimal.
6. Sleep quality in infants:	What is the sleep quality in situation X, Y, Z?	No metric exists. The concept "sleep quality" is more metaphorical than actual.	Neither sleep nor quality has a clear and distinct description to support developing such metrics. However, an indefinite number of features can be claimed for such a role. See also 1.c above

structured sleep questionnaires have been developed to provide standardized, quantifiable measures of infant sleep suitable for statistical analyzes[70]. Nightly *sleep diaries* may provide a somewhat more direct account of certain sleep-related behaviors, such as the overall sleep duration or feeding times. However, interviews, questionnaires and diaries all rely on parental perception, and there is a significant discordance between parental diary entries and direct measures of infant movements[34,35,37]. A sleeping parent cannot reliably report behaviors that do not disturb their own sleep (e.g., self-soothing), and parents often have difficulty accurately estimating the timing or duration of sleep interruptions[34,37]. Taken together, parent-dependent assessment methods are well suited to research questions concerning parental experience, but they offer limited and indirect insight into sleep from the infant's physiological perspective.

Actigraphy. Recording movements of the wrist or ankle with an accelerometer sensor ("actigraphy") has been used for decades in both academic research and clinical work-up, and there are well-established protocols for both recordings and subsequent analyzes[43]. Actigraphy data can depict the timing of active waking and less active rest[33,35], supporting its use for assessing ultradian and circadian "activity-rest" periodicity. Use of actigraphy in infant sleep studies assumes that moving infants are awake and non-moving infants are asleep, which is perhaps sound enough for detecting longer rest epochs as likely sleep, and conversely, longer activity epochs as likely awakenings. However, it is essential to remember that actigraphy quantifies limb movements rather than sleep, and such data is significantly confounded by two common infant behaviors: First, some infants may habitually stay in a calm waking state for extended periods of time, which biases sleep duration estimates. Second, all sleeping infants exhibit neurodevelopmentally essential limb movements (a.k.a. sleep twitches)[45], which readily confound actigraphy-based assessments of sleep and arousals. Additionally, actigraphy cannot differentiate between the infant's own and external movements, such as parents' movements during co-sleeping or transportation in a stroller. These uncertainties can be partly mitigated with analytic thresholds, such as considering arousals only when the infant moves excessively for several minutes[43]. However, such analytic choices pose a significant compromise to the real-world (ecological) validity of actigraphy when assessing issues like sleep fragmentation that causes parental concerns[71].

Sleep mat/pad. Sleep-related body movements can be measured efficiently with a movement-sensitive piezo-element that is placed under the bed mattress ("mat/pad"). The first such solutions became available in the late 1970s, but recent development of sensors, data logistics, and signal processing have expanded their usage. The mat/pad sensors do not directly touch the subject,

Table 3. Comparison of infant sleep assessment methods.

A	Cloth-integrated IMU wearable (multimodal information)	Actigraphy	Microphone	EEG	Sleep diary	Mattress /pad	Video-PSG	PSG
At-home compatible (~ecologically relevant)	X	X	X		X	X	X	
Easy to measure	X	X	X			X		
Parental compliance	X	X	(X)		X	X	X	
Unrestricted movements	X	X	X		X			
Low disruption	X		X			X		X
Many parameters	X		X					X
Sleep structure	X			X		X	?	X
Measure of sleep	X			X	X	X	X	X
Measure of sleep environment			X		X		X	
B								
Academic research	X	X	X	X	X	X	X	X
Multicultural studies	X	X	X					
International studies	X	X	X		X			
Special health care	X	X		X	X	X	X	X
Population health	X	X			X			
Low income regions	X	X	X		X			

A) Technical comparison. B) Utility in different use contexts. Notably, the special health care context is variable and the methods' utility differs between contexts, which can span across well-child clinics, behavioral sleep clinics, sleep therapists, and specialized pediatric care. The Low income region context refers to developing countries and/or geographically dispersed settings, where resource-intensive methods are not available, and the sleep assessments need to be decentralized and readily scalable.

making them particularly attractive for at-home measurements. Currently available sensors may support reliable estimation of several sleep-related physiological measures, such as body movements, rate and variability of respiration, or even heart rate in adults (a.k.a. cardioballistogram)[10,50,72]. A combination of such measures with modern machine learning approaches can support reliable sleep depth/state assessments in infants[10,52]. The principal limitation of mat/pad systems is that accurate recording is feasible only when the infant sleeps in their personal bed, since these systems cannot reliably differentiate infant movements from those of a co-sleeping parent. Consequently, sleep diaries are essential to support the analysis of mixed sleeping arrangements.

Wearables with body-standardized IMU sensors. Integration of movement sensors (a.k.a. inertial movement unit (IMU) sensors) into everyday clothing supports standardized measurements[49,60] (Fig. 4), which is critical for reliable capture of specific sleep-related behaviors[49]. For instance, combining in-sensor computation with high-fidelity triaxial IMU sensors can convert one IMU sensor to a multimodal device for reliable tracking of several physiological parameters in real-world environments[60] for up to several weeks. One example of such multimodal infant wearable is NAPPA (NAPping Pants)[49] where a single IMU sensor is fixed on the mid waistline to compute and store physiological sleep-related parameters (movement, body position, respiration rate and variability) for multiple purposes, such as: (1) assessment of sleep structure as sleep depth trends ("hypnogram") disclose actual sleep durations and fragmentation (Fig. 3). (2) recognition of sleep arousals and their relation to parental diaries. (3) accurate measurement of sleep positions and their relation to daytime neurodevelopment[6], or just to measure daytime postures like the recommended "tummy times"[36]. It is important to note here that several consumer products use sensors attached to socks or other infant clothing, but use of non-standardized sensor placements limits their analytic utility only to actigraphy[73]. The key challenge in cloth-based wearable systems with IMU sensors is to have some knowledge of the actual cause of movement. All sensor movement is unquestionably caused by the infant when sleeping alone in a stable place. However, external movements will confound the measurements when the infant is co-sleeping, being carried, or transported (stroller, car). Novel algorithms[74] or multimodal measurements may provide better contextual information, yet it is technically not possible to reliably separate different sources of movements in one sensor signal.

Auto-videosomnography. Recording a synchronized video has been common practice to support clinical PSG review, but recent developments in video recording and analytic methods have enabled the development of auto-videosomnography, a prolonged video-based surveillance and automated assessment of movements, and possibly other sleep behaviors[37,75,76]. It is an attractive option as a visually intuitive and technically non-invasive method, and recent studies have shown its utility in recognizing behavioral sleep characteristics and in clarifying discrepancies between diaries and actigraphy-derived measures[37,75]. While several aspects may be improved by rapid advances in computer-vision technology, it is important to recognize two critical issues that cannot be solved technologically: (1) The most significant non-technical concern is the breach of privacy inherent in proposing at-home video recordings in private bedrooms (or any rooms in a home). In many clinical and research contexts, such privacy concerns may represent a substantial barrier to implementation, even though they may be less restrictive in the case of privately purchased consumer devices. (2) The algorithm cannot infer content that is not in the video recording. All behaviors of interest (e.g., respiration) must be clearly visible in the video image, implying a need for unobstructed visibility from predefined angles and distances. As

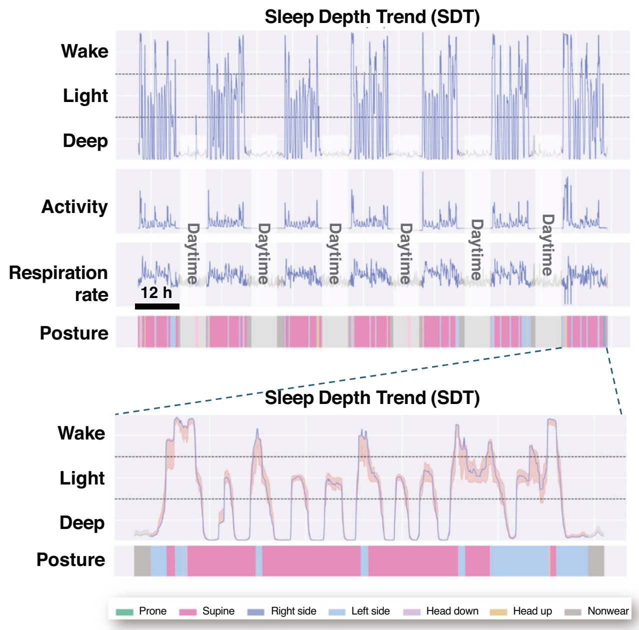

Fig. 4 An example output from a seven-night duration at-home measurement with a cloth-integrated wearable[49]. The standardized IMU sensor placement with in-built signal computation renders the system a multimodal device that simultaneously measures movements, body posture, respiration, and sleep depth trend (SDT). The upper figure shows a full week overview, while the inset below shows one night. Note the gradual changes in the continuous sleep depth (SDT; the shades depict confidence of the predicted sleep depth (blue line)). Note also the salient, infant-typical, relatively rapid and stable cycling between deeper and lighter sleep throughout the night, as well as the less regular waking. Such salient sleep structure ('architecture') requires machine learning-based computation using multimodal data, such as the modalities extracted here from the IMU signal.

bedrooms in family homes are not equipped for studio standards, and infants change their sleeping place and positions throughout the night, there is a continuous need for parents to adjust video recordings. While many video-based infant monitors are available in the consumer market, there is a striking scarcity of practical mobile solutions for setting up such video recordings. Taken together, video-based sleep assessment methods are attractive in consumer markets and for some specific research questions, but there are significant non-technical barriers to their entry into wider use in health care or research.

Pulse oximetry. Pulse oximeters can be used for out-of-hospital monitoring of heart rate and/or oxygen saturation, and they can provide technically reliable recordings during sleep or other calm periods. Several such solutions are available, and they have shown clear commercial potential in consumer markets[12]. While high-quality measures of heart rate or oxygen saturation may co-vary with sleep states, they do not provide sufficiently reliable information to support at-home sleep studies in infants - apart from the breathing disorders that prompt proper hospital studies in any case[77,78]. Therefore, pulse oximeter-based solutions should be viewed as indirect alternatives to actigraphy.

Microphone. Audio recording is a standard feature in consumer-grade baby monitors; however, recording the acoustic scene with a microphone in or near the infant cot may provide significant contextual insights to the bedroom: Infant vocalizations including crying[79], parental vocalizations[80], parent-infant interaction including emotion recognition and affect analysis[81], and a complementary depiction of the night-time active-rest dynamics in terms of auditory activity[80]. Audio analysis can also be used to detect various sources of background noise and thus to make inferences about the sleeping environment[82], which can be used to address various research questions. Akin to pulse oximetry and actigraphy, microphones do not measure sleep per se, and their use should be viewed as indirect auxiliary information to better inform specific research questions.

EEG-based wearables. Electroencephalography supports recognition of sleep states, and several wearable EEG solutions have been introduced for adult use[83]. Since recording good quality EEG signals is difficult from hairy areas, the existing wearable EEG solutions typically use other electrode placements that may still support specific clinical questions, such as quantifying epileptic seizures. For sleep studies, however, it is essential to capture good quality EEG of the posterior dominant rhythm (recognition of wake vs. N1) and the central sleep spindles and slow waves (recognition of N2 and N3, respectively)[23]. In practice, this implies a need to record high-quality EEG from hairy areas, at least from the central and occipital EEG electrodes akin to the conventional PSG setup. Such "ambulatory EEG" is clinically routine in adult patients when technical expertise is available. In infants, however, there are unresolved challenges in recording sufficient EEG signal quality at home. The most critical issue with studying infants in their daily environments is: How can we establish and maintain a mechanically stable skin contact in a wearable EEG solution[84,85]? The wearable EEG headgear (a cap, band, or alike) should firmly affix the electrodes onto the infant's scalp using pressure and/or adhesives, including continuous access to signal quality checks and contact maintenance over a long time in real-life environments. Taken together, long-term infant EEG recordings pose a daily challenge even in dedicated hospital environments[86–88], and there are neither theoretically nor practically feasible solutions for wearable EEG in infants.

How can I choose between consumer products and solutions intended for research or health care use?

There has been a rapid expansion of reasonably priced consumer products for self-monitoring, featuring user-friendly hardware and applications, including forums for further lifestyle support. The technical quality of the underlying sensor hardware between consumer and health care solutions may be comparable, but these products differ significantly in terms of their utility for research or health care: Consumer products are developed for commercial markets, where uptake is driven by user satisfaction in everyday contexts and supported by proprietary algorithms. Generally, consumer products do not provide the user with the recorded raw data, and neither do they share the analytic algorithms used to generate the outputs shown in their customized applications. Moreover, many products retain rights to collect user data for the needs of the device manufacturers.

While these considerations are understandable from a commercial perspective, they create significant challenges when consumer products are used in academic research or health care settings. Most importantly, research and clinical applications require transparency across the entire processing pipeline from signal acquisition to result outputs. Proprietary components within the pathway from raw data to reported results will compromise transparency and replicability, the key aspects of modern science. Two limited exceptions may be considered: First, some medically approved devices may contain partially undisclosed elements, but the full documentation has only been provided to regulatory authorities. Second, some more complex algorithmic outputs, such as automated sleep classifiers, may be validated transparently through published performance metrics and validation studies without publishing the fully trained algorithm (e.g., feature weights or neural network parameters).

Taken together, it is essential to recognize that the drivers, promises and utility differ substantially between consumer products and solutions aimed for research or medical use. The researcher should always ensure sufficient transparency to allow continuity of their research over the coming years, as well as to support comparability of studies across sites that may use different technical solutions.

Concluding dos and don'ts: choose the method for the question, not vice versa

An infant's home is the best, if not the only, ecologically relevant environment to use when assessing sleep for most study questions. Understanding the exact relationship between the three discrete layers - sleep/behavioral phenomena vs recording modalities vs data analysis - lays the foundation for disruptive research with genuine impact. In this light, several don'ts seem obvious, such as: (i) parental questionnaires are inappropriate for studying structure (or quality) of infant sleep (though they are very useful when studying parental experience); (ii) actigraphy methods cannot measure sleep or its depth (though it is a good measure for rest-activity periods); (iii) pulse oximetry – or ECG-based methods do not measure sleep (though they can inform about cardiorespiratory functions during sleep); (iv) wearable methods based on IMU sensors cannot reliably detect REM sleep that is characterized by muscle tone and eye movements; and finally (v) any discrete measures of sleep states (e.g., hypnograms) or metrics derived from brief sleep segments (as in many EEG studies) may poorly represent sleep as it naturally occurs in an individual infant.

Recent technological advances have expanded methodology in at-home sleep assessments, providing reliable, objective, quantitative, harmonized, and widely scalable solutions for many use cases. While past research has often selected methods based on tradition and convention, future research offers both an opportunity and a responsibility to define the full study rationale more explicitly. This process should begin with clearly articulated research questions, which define the sleep/behavior phenomena of interest, and in turn guide. With the advent of new non-invasive technologies and machine learning data analytics, this is an exciting time to engage in infant sleep research; but before embarking on a new study, the researcher is advised to choose the method for the question - not vice versa.

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COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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