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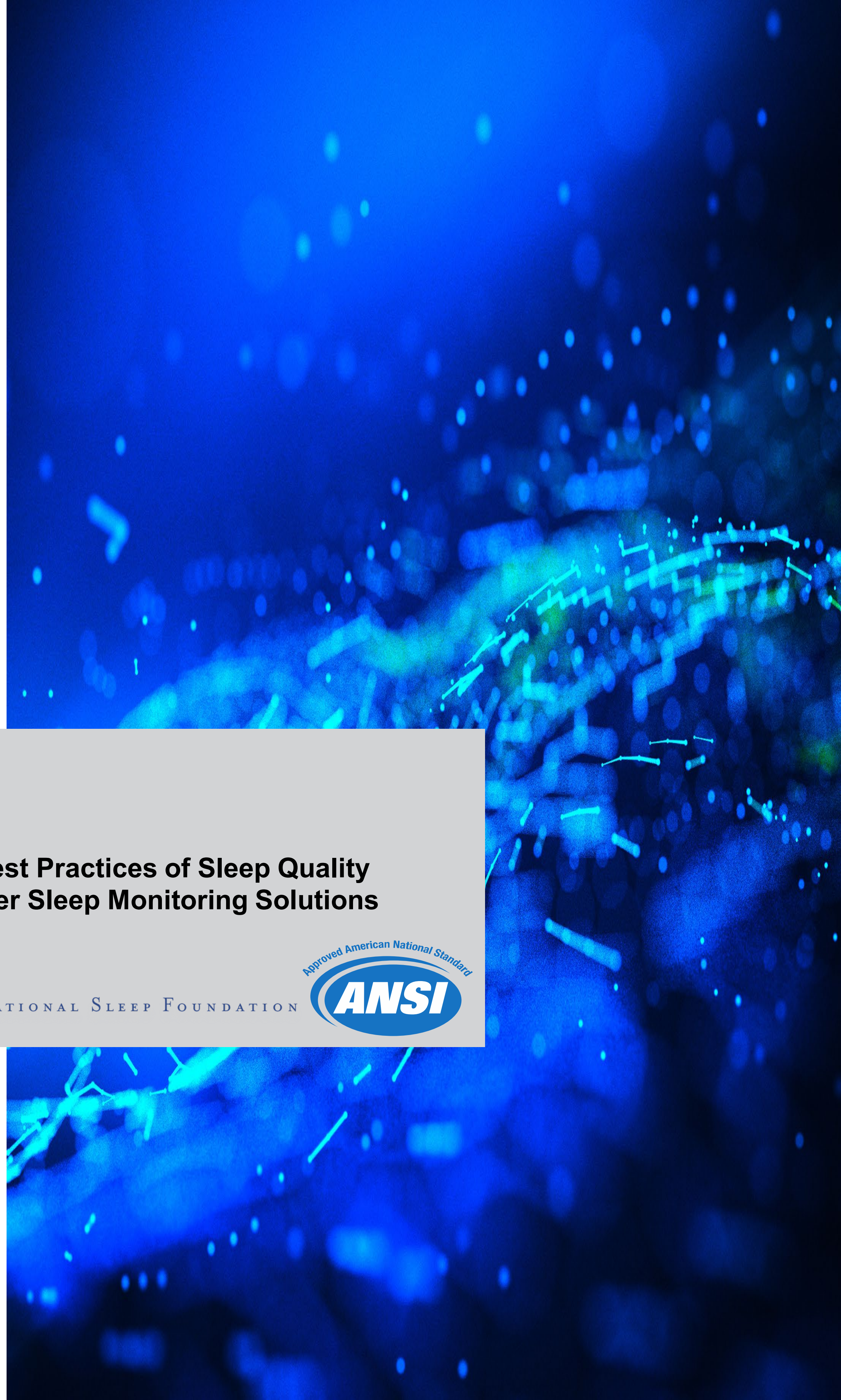

ANSI/CTA Standard

Recommendations and Best Practices of Sleep Quality Determination in Consumer Sleep Monitoring Solutions

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NOTICE

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FORWARD

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Recommendations and Best Practices of Sleep Quality Determination in Consumer Sleep Monitoring Solutions

1 SCOPE

This document will address recommendations and best practices for the recording and reporting of sleep quality by consumer sleep monitoring solutions.

2 REFERENCES

2.1 Normative References

The following standards contain provisions that, through reference in this text, constitute normative provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed here.

2.2 Normative Reference List

1. Ohayon M, Wickwire EM, Hirshkowitz M, Albert SM, Avidan A, Daly FJ, Dauvilliers Y, Ferri R, Fung C, Gozal D, Hazen N, Krystal A, Lichstein K, Mallampalli M, Plazzi G, Rawding R, Scheer FA, Somers V, Vitiello MV. National Sleep Foundation's sleep quality recommendations: first report. Sleep Health. 2017 Feb;3(1):6-19. doi: 10.1016/j.sleh.2016.11.006. Epub 2016 Dec 23. PMID: 28346153. https://pubmed.ncbi.nlm.nih.gov/28346153/.
2. ANSI/CTA/NSF-2052.1-A, Definitions and Characteristics for Wearable Sleep Monitors. September 2022. https://cta.tech/standards.

2.3 Informative References

The following references contain provisions that, through reference in this text, constitute informative provisions of this standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below.

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3 COMPLIANCE NOTATION

CTA defines the following compliance terms for use in its documents:

shall	This word indicates specific provisions that are to be followed strictly (no deviation is permitted).
shall not	This phrase indicates specific provisions that are absolutely prohibited.
should	This word indicates that a certain course of action is preferred but not necessarily required.
should not	This phrase means a certain possibility or course of action is undesirable but not prohibited.
may	This phrase indicates that a certain course of action is optional.

4 DEFINITIONS, SYMBOLS AND ABBREVIATIONS

4.1 Definitions

Regularity of sleep schedule: Variation in bedtime, wake time, or midsleep point may be measured as reflections of regularity of the sleep. These may be measured objectively (e.g., by actigraphy) or subjectively. These may be measured over specific time domains (e.g., night to night, week-day-weekend, week-to-week). There is no single universal metric for sleep regularity.

Regularity of sleep architecture: Variation in sleep macrostructure (e.g., N3 duration), microstructure (e.g., spindle density) or derivable metric (e.g., TST). These shall be measured objectively. These may be measured over specific time domains (e.g., night-to-night, weekday-weekend, week-to-week). There is no single universal metric for sleep architecture regularity.

4.2 Symbols and Abbreviations

EEG Electroencephalogram

REM Rapid Eye Movement

TST Total sleep time

WASO Wake after sleep onset

5 ASSUMPTIONS

The phrase "sleep quality" may refer to the perceived or measured beneficial aspects of sleep. Despite this apparently simplistic view, the concept of sleep quality remains challenging to define operationally, especially since objective metrics and subjective perception may not align. This standard distinguishes objective and subjective perspectives, by using the term sleep quality to refer to objective measurements, and the term sleep satisfaction to refer to the perception of sleep.

Sleep quality and sleep satisfaction are intertwined with sleep quantity but may not be strictly correlated. For example, short sleep duration could impact satisfaction (not to mention daytime performance), even if other metrics of sleep quality are in the normal range. Likewise, adequate sleep duration might not feel satisfying, if not of sufficient quality. Nomenclature referring to sleep satisfaction may span diverse terminology (e.g., deep, restful, refreshing); we do not make distinctions within the overarching concept of perceived satisfaction.

The architecture of sleep over the night can be viewed across a range of granularity. Objective metrics can span the range from high-level variables requiring only binary sleep-wake labels (e.g., onset latency, number of awakenings, WASO, efficiency) or stage architecture (e.g., REM, non-REM stages within sleep), to physiological metrics that depend on certain sensor streams (e.g., spindles, slow waves, or cyclic alternating pattern from EEG; cardiopulmonary coupling from ECG; or even fragmentation indices and rest-active ratios from actigraphy).

Finally, it is important to note that the mere absence of clinical pathology is clearly insufficient to define sleep quality. For the purposes of this guidance, we focus on potential objective metrics relevant to assessing sleep quality, assuming no clinical pathology is present. Likewise, assessing sleep satisfaction also presumes no clinical pathology is present. Subjective-objective disconnects are known to occur in some individuals with diagnose-able abnormalities, such as some sleep apnea patients may have no sleep complaints and wake refreshed, while some chronic insomnia patients may have normal-range objective sleep measurements. Human perception will vary on sleep no matter what the objective outcome is.

6 LITERATURE REVIEW

This section summarizes notable expert reviews on topics of potential relevance to the present standard. The most pertinent of these was the Sleep Quality Consensus Panel commissioned by the National Sleep Foundation regarding indicators of good sleep quality. The recommendations of the panel were published in 2017 [1]. The panel voted after reviewing 277 studies involving objective measures of sleep quality in healthy individuals. Panelists voted on the appropriateness of each indicator for age categories across the lifespan. For adults, the panel indicated quantitative ranges for what is appropriate, inappropriate, or uncertain across key sleep architecture variables, as shown in Table 1. This table is provided for context, based on the consensus of the NSF task force, and is not intended to be a recommendation of the present Standard. Of note, there was less consensus for the importance of particular sleep stages, as indicated by broader ranges being considered of uncertain relevance for sleep quality.

Table 1: Sleep architecture and stages summary for ages >18 years [5]

	Young Adult	Adult	Older adult
Sleep Latency (minutes)	≤30	≤30	≤30
Awakenings >5 min	≤1	≤1	≤2
WASO (minutes)	<20	<20	<30
Efficiency (%)	≥85%	≥85%	≥85%
REM (%)	No Agreement	21-30%	No Agreement
N1 (%)	≤5%	≤5%	No Agreement
N2 (%)	No Agreement	No Agreement	No Agreement
N3 (%)	No Agreement	16-20%	No Agreement
Nap number (per day)	0	No Agreement	No Agreement
Nap frequency (days per week)	0	No Agreement	No Agreement
Nap duration (minutes)	No Agreement	No Agreement	No Agreement

Young adults*, 18-25;* adults, 26-64; older adults, ≥65 years of age [5]. Efficiency is defined here as the Ratio of total sleep time to time in bed.

Recommendations for nap duration and frequency were also discussed by the Panel. Overall, there was insufficient consensus regarding nap-related variables as elements of good sleep quality. Sleep during the daytime is not necessarily equivalent to sleep at night. The number of daily naps, duration of naps, and frequency of naps may be related to sleep quality; however, the specifics of such associations remain vaguely understood. Of note, while nap characteristics may be important indictors or modifiers of sleep quality, information regarding the quality of naps themselves is limited.

Given the admitted uncertainty in regard to demarcating objective criteria for sleep quality, normative values for various sleep metrics can provide additional context for the sleep quality metrics proposed by the 2017 Task Force. Two meta-analyses examined age and sex-related changes in sleep architecture, one in 2004 and one that focused on more recent studies, published in 2019. Neither of these were intended to address quality, but rather focused on normative data, whereas the NSF Task Force focused on quality. Ohayon et al., 2017 [1] found age-related decreases in TST, sleep efficiency, N3, REM sleep, and age-related increases in WASO, N1, and N2. Boulos et al., 2019 [4] found similar age-related reductions in TST (about 10 minutes per decade) and sleep efficiency (about 2% per decade) and increase WASO (about 10 minutes per decade). However, changes in N3 and REM sleep were non-significant with age in Boulos et al., 2019 [4]. The mean values for the entire sample in the Boulos analysis, which included 169 studies of over 5,000 subjects, were: TST 395 minutes; efficiency 85.7%; WASO 48.2; latency 15.4 minutes; N3 20.4%; REM 19.0%. Depending on the age bracket, and whether first night PSG was considered or not, these values may or may not align with what was deemed appropriate for adults and older adults by the NSF task force, a reminder of challenges in addressing seemingly straightforward questions about normative data. As further context in this regard, while both meta-analyses indicated a goal of focusing on healthy (non-clinical) subjects, various sleep pathologies were observed, consistent with well-known data on high rates of undiagnosed conditions.

Sleep duration may be conceptualized as independent of objective sleep quality, while subjective perception of sleep (e.g., feeling upon awakening) may be influenced by sleep duration. Sleep duration recommendations were proposed by a National Sleep Foundation (NSF) multidisciplinary expert panel in 2015 [5][6]. Using a modified RAND evaluation and voting process, the task force concluded that range of appropriate sleep duration exists across multiple age groups, including 7-9 hours for adults and 7-8 hours for older adults (65+). The task force included an additional category of "may be appropriate", which indicated a range of possible appropriate sleep durations surrounding the range given as "recommended", to account for the large individual variability in sleep duration. The expert panel noted that "excess or restricted sleep duration may produce or result from serious problems that affect health and well-being." Importantly, the panel also reported that "sleep duration represents only one sleep dimension; other sleep features such as sleep depth, quality, and timing also characterize overall sleep health."

The AASM also published sleep duration recommendations [7], similarly using a RAND voting strategy like the NSF expert panel. Results and recommendations were quite consistent with the NSF expert panel. The AASM task force concluded that adults (ages 18 to 60) should sleep 7 or more hours per night to "promote optimal health". In the accompanying literature review and methodology paper [8], the authors emphasize that duration is the best studied and most easily accessible metric, compared to the other facets; they excluded literature focused on non-duration dimensions, including sleep quality. The limitations section calls out that measures of duration do not capture other facets of sleep, including sleep quality.

From an individual perspective, sleep duration may figure prominently in how refreshing or satisfying sleep feels (i.e., qualitative perspective). For example, while the expert reviews discussed above provide consensus opinions about sleep quality and duration, treating these two topics distinctly, they also recognized the constellation of factors important for a holistic view of sleep health, and how intertwined factors like duration and quality are from the individual perspective.

In certain situations, a given pattern of wakefulness could be appropriate by one standard and inappropriate by another. Consider someone in bed for 8 hours, zero sleep latency (for simplicity), a single 60-minute awakening would be appropriate by "# of awakenings" and by efficiency (%), but inappropriate by WASO.

6.1 Alternative Terms Used for Sleep Quality

From Ohayon et al., 2017 [1], the following terms were used in the systematic review process. This list is not comprehensive of all terms, but highlights the diversity of nomenclature in this space:

- Sleep quality
- Sleep efficiency
- Restorative sleep
- Sleep consolidation
- Restful sleep
- Efficient sleep
- Refreshing sleep
- High-value sleep
- High-grade sleep
- Satisfactory sleep
- Sleep depth
- Deep sleep.

6.2 Objective Sleep Quality Overview

As mentioned above, objective sleep quality can be considered across a range of potential indicators. The panel considered a non-exhaustive list of 12 topics of potential indicators of sleep quality:

- Sleep continuity variables: sleep latency, awakenings >5 minutes, wake after sleep onset, sleep efficiency)
- Sleep architecture variables: REM sleep, N1 sleep, N2 sleep, N3 sleep, arousals
- Nap variables: naps per 24 hours, nap duration, and days per week with at least one nap.

The core indicators of continuity (and naps) can be derived from binary sleep-wake determinations, which is common to commercial sleep trackers. The sleep architecture variables that involve stages require a REM and non-REM classifier, which is present in some consumer sleep trackers, often with some collapsing of non-REM sub-stages. For example, N1 and N2 are often combined as “light”, if a tracker reports three sleep stages (REM, light, deep). Alternatively, a single non-REM state may be reported that collapses all three sub-stages if a tracker reports two sleep stages (REM, non-REM). Arousals are traditionally defined based on EEG (occipital and central leads), which is less commonly found in consumer products, although autonomic arousals are recognized (e.g., in the prescription diagnostic devices using peripheral tonometry).

Other potential indicators of sleep quality beyond those reported in Ohayon et al., 2017 [1] include EEG patterns (such as arousals, spindles, slow waves, and cyclic alternating pattern), autonomic patterns (such as cardiopulmonary coupling analysis of ECG signals), and likely heretofore undiscovered patterns.

Regarding consumer applications reporting sleep quality "scores", overall, there is an underdeveloped evidence base guiding particular scores for meaningful outcomes or contexts; plus, approaches to calculating scores currently is not standardized across product developers. It would, therefore, be appropriate to provide detail regarding composition of the score, or to reference its validity, performance testing results and/or contexts, to best allow for interpretation and usefulness.

6.3 Age Specific Factors on Sleep Quality Assessment

Age groups will have an impact on the assessment and reference for sleep quality. Ohayon et al., 2017 [1] considered nine age categories across the lifespan.

Within each age category there may be other factors that also have impacts. This may be especially true for the categories which may encompass adolescence, pregnancy, caregiving, menopause, and other developmental, biological, physiological, and social changes expected across the lifespan. Such contextual considerations are outside the scope of this standard. However, the age group which the device has been tested for should be clearly stated.

6.3.1 Children

Ohayon et al., 2017 [1] divided childhood into five categories: infants, toddlers, pre-schoolers, school-aged children, and teenagers, as above. Consensus recommendations for quality sleep latency and efficiency did not differ across these categories, with appropriate values of <30 minutes and >85%, respectively (and inappropriate amounts of ≥46 minutes and <75%, respectively). The appropriate number of awakenings of >5 minutes was 0-1 across all categories, while the inappropriate number was ≥4 for all groups but teens, which was ≥3. WASO was only defined for preschoolers and older, with the appropriate level being ≤20 minutes for all three categories, while inappropriate levels were >50 minutes (preschoolers and teens) and >40 minutes (school age children).

As for stage percentages, too much N1 (>20%) and N2 (>80%) were considered inappropriate. Less than 5% N1 was considered appropriate for school-aged and teens, while there was no appropriate level of N2 across categories. Inappropriate N3% was similar across categories at ≤10%, except teens with ≤5%; appropriate levels of N3 were only given for school age and teens, and only for the range of 20-25%. Insufficient REM% was considered inappropriate for newborns (<20%), infants through pre-schoolers (<10%), and teens (<10%), and was otherwise "uncertain" except for >40% being appropriate for newborns.

6.3.2 Adults

Across the three categories of adults (young adult, adult, and older adult), the main pattern involved leniency of what was appropriate for binary sleep-wake patterns, where it was felt to be appropriate to have somewhat more WASO and more awakenings, while the appropriate levels for latency and efficiency were the same across these categories. Likewise, levels deemed inappropriate were somewhat larger for older adults for sleep latency, while WASO was uncertain (no inappropriate bound), and the sleep efficiency inappropriate bound was only changed (to a lower level) for young adults. Specific patterns called out are summarized in the prior section.

6.4 Sleep Satisfaction Overview

Self-assessments of sleep can be considered in two broad categories: a gestalt sense of typical or usual sleep (as may occur in epidemiology surveys), versus one or more specific nights (as may occur in studies employing a sleep diary). Within each category, there are a variety of methods to interrogate sleep that differ in terminology, in style (e.g., multiple choice text, ordinal rating scales), and in administration (e.g., administered, guided, self-completed).

Subjective sleep satisfaction and objective sleep quality are not necessarily the same. Tracking apps involving subjective sleep ratings need not resolve this challenge, as providing a method to track subjective sleep ratings may itself provide data of interest for users to peruse.

7 DEFINITIONS

The terms below are defined in ANSI/CTA/NSF-2052.1-A [2] unless otherwise noted.

- Fragmentation
  - Number of awakenings (B.11)
  - Number of brief awakenings (B.12)
  - Awakening rate per hour (B.13)
  - Sleep fragmentation rate (B.14)
  - Sleep-wake fragmentation (E.2)
  - Latency to sleep onset (C.3)
- Duration – including beginning/end of sleep
  - Total TATS Duration (A.5)
  - Sleep duration = Total Sleep Time (B.7)
- Variability
  - Regularity of sleep schedule (defined in section 4.1 of this document)
- Sleep stages

  - REM (D.1)
  - N1 (D.2)
  - N2 (D.3)
  - N3 (D.4)
  - Awake (B.1)
  - Asleep (B.2)
  - Sleep Efficiency Percentage (C.5)

8 SLEEP ASSESMENT METRICS

8.1 Sleep Quality

8.1.1 Recommended Elements

- Wake after sleep onset (B.10)
- Sleep onset latency (C.3)
- Number of awakenings (greater than 5 minutes) (B.11)
- Sleep efficiency (C.5)
- TST (B.7)

8.1.2 Optional Elements

- Sleep timing
  - Sleep-wake schedule regularity (E.1)
  - Bedtime regularity (defined in section 4.1 of this document)
- Sleep content
  - Sleep fragmentation (B.14)
  - Regularity of sleep architecture (defined in section 4.1 of this document)

- Naps - Duration, days per week (frequency), naps per 24 hours (see sections 6 and 9.2 of this document)
    - Sleep-wake fragmentation (E.2)
- Duration of sleep stages:
    - REM (D.8)
    - N1 (D.9)
    - N2 (D.10)
    - N3 (D.11)

ANSI/CTA/NSF-2052.1-A [2] has contemplated longer term sleep/wake since not all aspects of sleep can be captured in single night measures.

8.2 Sleep Satisfaction

8.2.1 Recommended Elements

There are no components required for development work in sleep satisfaction. It is recommended, however, that the tools used and their basis (i.e., performance testing and/or validation) be specified for the user to contextualize the data provided.

8.2.2 Optional Elements

While there is no single agreed upon measure of sleep satisfaction, there are many different questionnaires that have been used to examine this aspect of sleep in a wide variety of populations, including in those with and without documented sleep disorders [9][10][11][12][13][14][15]. As there are no established, direct biological correlates of sleep satisfaction, the validation of these questions is often established using face validity [12] and internal consistency, ideally among a representative sample [12] [15]. When considering use of validated questionnaires to reflect satisfaction, authorized use/ copyright must be considered. Additionally, some tools have been validated as a whole, whereas others are validated question by question. As an example, the PROMIS Sleep Disturbance and Sleep-Related Impairment scales, in which questions have been independently validated, are publicly available in a variety of translations, and have been modified for different population groups (parent-proxy, pediatric). The PROMIS scales provide population-based norms to which individual scores can be compared and indexed. The Sleep Satisfaction Tool, a copyrighted instrument, also provides norms based on a probability-based national sample that was weighted to reflect national demographics. Contextualizing sleep satisfaction with external (e.g., light, noise, environmental temperature) and internal (e.g., stress, anxiety, depression) factors may add additional insight to sleep satisfaction.

9 ASSESSMENT OF SLEEP QUALITY

As mentioned above, sleep quality is not a singular metric, but rather an umbrella term that may be assessed via different perspectives and measurements, and may differ according to context, such as what kind of outcome the measurement(s) are being validated against. Some consumer sleep trackers include features that aim to quantify the concept of sleep quality, either through reporting on previously established indicators or presenting aggregate scores. For example, a tracker might provide a “sleep score” to rate the quality of each night of sleep. In cases where the basis is described, the score may be a composite measure that considered multiple aspects of the night to create the score. The following sections describe recommended approaches to providing users with an assessment involving sleep quality, given the challenges associated with sleep quality described above.

9.1 Mandatory/Basic Approach

At a minimum, the tracking device shall be transparent in explaining how the sleep quality metric or score is derived [3] and reporting what is the element accuracy of performance. Since the prevailing research, highlighted in the NSF task force position regarding sleep quality [1], indicates that multiple factors contribute to sleep quality, it is likely that most quality metrics will involve some combination of component aspects. In such cases, the minimum requirement would be listing the component inputs and even their relative weighting to generate a composite score if possible. For example, this description should include whether the quality output considers as input data factors such as sleep duration, awakenings, regularity, stages, and/or other quantities. Furthermore, if a novel metric is introduced, beyond the traditional metrics used to describe sleep architecture and stages, this should be described in sufficient detail. From a user perspective, transparency ensures users have some understanding of what contributes to the metric being shown.

9.2 Validation Considerations for Sleep Quality Measurement

The concept of validation for a quality score encompasses a range of perspectives, and types of contextual data included. For example, when considering metrics that contribute to objective sleep quality (as mentioned above in the NSF task force report [1]), the metrics were sub-categorized according to age. Whether or not normative demographic considerations are applied, the components of objective sleep quality can be viewed from the following perspectives.

Sleep quality assessments based on sleep tracker metrics also raise the question of accuracy of the tracker to quantify the underlying physiologic measure. Considering a purely objective sleep measurement perspective, validation would include experimental demonstration that the component metrics going into a sleep quality score are themselves measured accurately with respect to a reference standard [3]. As an example, consider a hypothetical tracker that combines TST, REM percentage, and a heart rate variability (HRV) metric into a composite score, each of these should be shown individually to be accurate measures against a reference ground truth. Accuracy measures provide context for interpretation of quality outputs based upon these building blocks. Uncertainty in the concepts of sleep quality may be compounded by uncertainty in the accuracy of metrics feeding into a quality measure.

A related topic to tracker accuracy involves naps. Naps can reflect a range of physiology and pathophysiology. They can also be intentional or unintentional. For example, naps could indicate excessive sleepiness from insufficient sleep or a common disorder such as untreated sleep apnea or a more rare disorder such as narcolepsy. In some cases, naps can influence subsequent sleep, such as may occur in those with insomnia or irregular sleep habits. Naps can also be part of cultural norms and personal preference. In addition, since they occur at distinct times and are often shorter than the main sleep period, naps could present algorithmic challenges to record accurately.

It should be noted that performance characteristics of a particular sleep tracker for nocturnal sleep may not translate entirely to nap detection or characterization, so ideally, performance characteristics specifically for the nap context should be specified.

Another perspective to consider is that of the impact of sleep quality on daytime performance. In this view, a sleep quality measurement could be assessed against one or more daytime tests of performance, such as reaction time. For example, an experiment might compare overnight sleep quality scores with next-day reaction time in a cohort using both within-subject and group comparison approaches, either in a naturalistic setting of nightly variability, or in a controlled experimental setting. It should be noted that while this type of sleep quality assessment provides distinct context to a quality metric, it also introduces both experimental and interpretation complexity. Performance metrics are diverse, spanning physical, cognitive, emotional, and other domains; a detailed recommendation on such potential approaches is beyond the scope of this standard.

Finally, from a subjective sleep satisfaction standpoint, a sleep quality measurement might be assessed using one or more self-report tools, that is, mapping the quantitative metrics to a qualitative perception of sleep. Such mapping can be performed at the cohort level, if the tool captures sleep satisfaction in general, or at the night-by-night level within-subject, if the tool is appropriate for a repeated measure. For example, the Sleep Satisfaction Tool developed by an NSF task force [12], a 9-item survey, is intended for general satisfaction rather than nightly (e.g., the questions in the survey include terminology like “generally” and “in general”, and also asks about weekend vs weekday nights). Like the question of daytime performance, mapping objective quality to self-reported satisfaction provides context to a sleep score, but achieving this high bar requires more complex experimental approaches. Finally, and separate from potential regulatory oversight, application of these standards may further support product representations and claims about measuring sleep quality and can help consumer perceptions of credibility and utility for a variety of monitoring solutions in a growing marketplace.

Consumer Technology Association Document Improvement Proposal

If in the review or use of this document a potential change is made evident for safety, health or technical reasons, please email your reason/rationale for the recommended change to standards@CTA.tech.

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