FAQ:
Justifying the Inclusion of the Core Digital Measures of Sleep

CORE MEASURES *of* SLEEP

Digital Measures Development

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FAQ: Justifying the Inclusion of the Core Digital Measures of Sleep

This FAQ document is intended for internal discussions to aid the user in justifying the importance of including sleep measures in their research or practice. The information in this document can be used to support decision-making when working with other teams within the user's organization.

Due to the discussion-based presentation of this document, references are not cited through the text, but presented at the end of the document. These references can also be used to support reporting of studies.

Core Measures:

- **Total sleep time**
- **Initial sleep onset latency**
- **Wake after sleep onset**
- **Number of wake events in the primary sleep period**
- **Sleep efficiency**
- **Total napping time**

Total sleep time (TST)

Researchers

Clinicians

Patients

<< Return to Table of Contents

References >>

What is TST? Why is it a core measure?

Total sleep time is the duration of time (hours, minutes, and/or seconds) spent sleeping in the primary sleep period. Total sleep time (TST) is a **core measure** because it is an important indicator of health and mortality. Adequate TST is crucial for maintaining physical and mental well-being, as insufficient sleep duration has been linked to increased all-cause mortality and increased risk for various health issues, such as obesity, cardiovascular disease, impaired immune function, and cognitive deficits.

TST is a key parameter in diagnosing sleep disorders such as insomnia, sleep apnea, and hypersomnia. Researchers use objective methods such as polysomnography (PSG) and actigraphy, along with subjective measures like sleep diaries, to assess TST. Understanding TST helps researchers and clinicians evaluate sleep quality and develop interventions to improve sleep health. Beyond primary sleep disorders, the **relationship between TST and underlying medical conditions** is two-sided: sleep can be affected by many conditions such as pain, shortness of breath, autonomic nervous system disorders, hormonal imbalance, autoimmune and metabolic disorders, and environmental factors such as work schedule or habitat, and inadequate sleep time can exacerbate existing medical conditions. As a general health indicator, **measuring** TST and **comparing** it with the healthy range can reveal a systematically accumulated sleep debt or oversleeping.

Why does TST **matter to researchers?**

Monitoring and assessing treatment efficacy: Measuring TST provides essential baseline data to understand individuals' sleep patterns and identify deviations from healthy sleep norms. By monitoring TST before, during, and after treatment interventions, researchers can assess the effectiveness of therapeutic approaches in improving sleep duration and quality. Assessing TST allows researchers to investigate the long-term effects of interventions on sleep maintenance and to identify potential adverse effects or treatment-related changes in sleep patterns, ultimately informing evidence-based practices for managing sleep disorders and promoting sleep health. TST can also help in determining inclusion or exclusion criteria for relevant studies.

Determining impact on sleep within other disorders: Many disorders have sleep impacts that affect patient health and occur outside the context of traditional sleep disorders. Infectious illnesses (e.g., flu, COVID-19), traumatic brain injuries, respiratory disorders, mental health conditions, neurological disorders, and many other diseases and conditions can have sleep-related symptoms. Understanding a patient's total sleep time can be helpful to understanding non-primary sleep disorders better and influencing therapeutic research pathways.

Why does TST **matter to clinicians**?

Diagnosis: TST is essential for diagnosing various sleep disorders such as insomnia, sleep apnea, and circadian rhythm disorders. Changes in TST may also signal underlying medical or psychiatric comorbidities. For example, persistent insomnia despite treatment may prompt clinicians to evaluate for comorbid conditions such as depression or anxiety, which could be contributing to sleep disturbances.

Clinical management: TST serves as a vital indicator of sleep health and can guide treatment decisions effectively, helping clinicians tailor treatment plans for patients with sleep disturbances. For example, if a patient reports consistently short TST, interventions aimed at improving sleep duration, such as sleep hygiene education or cognitive-behavioral therapy for insomnia (CBT-I), may be recommended. Similarly, in sleep disorders like sleep apnea, interventions such as continuous positive airway pressure (CPAP) therapy aim to enhance TST by reducing nighttime awakenings and improving respiratory function during sleep. After initiating treatment, clinicians can monitor changes in TST over time to assess treatment efficacy and make necessary adjustments.

Initial sleep onset latency (ISOL)

Researchers

Clinicians

Patients

<< Return to Table of Contents

References >>

What is ISOL? Why is it a core measure?

Initial sleep onset latency is the duration of time an individual takes to first achieve sleep after intending to sleep. Prolonged ISOL disrupts the continuity of sleep and contributes to daytime sleepiness, impaired cognitive function, mood disturbances, and decreased quality of life. Measuring ISOL provides valuable insights into diagnosing and monitoring sleep disorders, assessing treatment efficacy, and predicting health outcomes.

Initial Sleep onset latency is considered a **core measure** due to its fundamental role in characterizing sleep initiation and quality. ISOL provides a quantifiable indicator of sleep initiation, offering researchers and clinicians precise insights into sleep health and quality and enhancing the reliability and validity of sleep assessments.

Why does ISOL **matter to researchers?**

SOL serves as a crucial metric for **studying various sleep disorders, evaluating treatment efficacy, and identifying potential risk factors** for adverse health outcomes. For example, SOL is a criterion for diagnosis of narcolepsy and an endpoint for narcolepsy type 1 (NT1) trials, as incorporated in the Multiple Sleep Latency Test (MSLT) and the Maintenance of Wakefulness Test (MWT).

- **Evaluating treatment efficacy:** By measuring ISOL, researchers can assess the effectiveness of interventions such as cognitive-behavioral therapy for insomnia (CBT-I) or pharmacological treatments in improving sleep initiation and overall sleep architecture.
- **Contribute to body of knowledge on sleep disorders and other conditions:** ISOL data contribute to our understanding of the underlying mechanisms of sleep disorders and inform the development of novel therapeutic approaches for a variety of conditions with sleep impacts.

Why does ISOL **matter to clinicians**?

Clinicians rely on ISOL measurements to **diagnose sleep disorders, monitor treatment progress, and tailor interventions to meet individual patient needs.**

Diagnosis: Elevated ISOL is a common feature across different sleep disorders, including insomnia, sleep apnea, and circadian rhythm disorders. Prolonged ISOL is a common complaint among patients seeking help for sleep-related problems, and its assessment is integral to the diagnostic criteria for insomnia

Clinical management: By leveraging digital modalities to capture ISOL, clinicians can gather longitudinal data, track treatment responses, and personalize interventions that address the specific sleep difficulties and underlying factors contributing to sleep onset difficulties. Timely identification and management of ISOL abnormalities are essential for improving patient outcomes and promoting better sleep health. Some health conditions, such as sleep disorders, neurological disorders, or chronic pain conditions, can prolong sleep onset latency. Identifying prolonged sleep onset latency may prompt further investigation into underlying health issues that require management to prevent adverse health outcomes associated with these conditions. Some medications, particularly those affecting the central nervous system, may interfere with sleep onset latency. Monitoring changes in sleep onset latency can help identify potential side effects of medications that may impact sleep quality and overall health.

Wake after sleep onset (WASO)

Researchers Clinicians Patients

<< Return to Table of Contents

References >>

What is WASO? Why is it a core measure?

Wake after sleep onset is the total duration of time spent awake in the Primary Sleep Period. In other words, it refers to the total amount of time an individual spends awake after initially falling asleep and before finally waking up for the day.

Wake after sleep onset (WASO) is a **core measure** because it provides valuable insights into the quality of sleep and sleep continuity. High levels of WASO are indicative of **fragmented sleep**, which can lead to daytime sleepiness, impaired cognitive function, and overall reduced quality of life. By monitoring WASO, clinicians and researchers can assess the effectiveness of interventions aimed at improving sleep quality and identify underlying sleep disorders. High levels of WASO are associated with various negative health outcomes, including cardiovascular disease, depression, and decreased immune function. Tracking WASO alongside other sleep parameters is crucial for comprehensive sleep evaluation and management.

Why does WASO **matter to researchers**?

WASO is a versatile measure in clinical research, providing valuable information about sleep quality, its impact on health outcomes, treatment efficacy, and potential avenues for intervention and improvement.

Diagnostic criterion: WASO is often used as a diagnostic criterion for sleep disorders. Elevated levels of WASO can indicate sleep fragmentation, a hallmark of insomnia. Researchers may use WASO thresholds to categorize participants into different diagnostic groups or to assess the severity of sleep disturbances.

Outcome measure in clinical trials: In clinical trials evaluating interventions for sleep disorders, WASO serves as an outcome measure to assess the effectiveness of an intervention in reducing sleep fragmentation and improving sleep quality.

Exploring comorbidities: Researchers may examine the relationship between WASO and various health outcomes or comorbid conditions, such as cardiovascular disease, metabolic disorders, mental health conditions (such as depression and anxiety), cognitive function, and overall quality of life.

Facilitate comparative studies: WASO can be compared across different populations, age groups, or clinical conditions to identify differences in sleep quality and patterns of sleep disruption, helping researchers better understand the factors contributing to sleep disturbances and inform targeted interventions.

Why does WASO **matter to clinicians**?

Diagnosis around sleep complaints: WASO provides valuable insights into the quality of a patient's sleep. By assessing WASO, clinicians can identify underlying sleep disturbances and tailor treatment plans accordingly. WASO can aid clinicians in assessing the severity of a patient's sleep disturbance and its impact on daytime functioning. Addressing sleep fragmentation and reducing WASO can help improve patients' daytime functioning and overall quality of life.

Clinical management, sleep disorders: WASO can serve as an objective measure to monitor treatment response and adherence in patients with sleep disorders by assessing changes in WASO over time to ensure patients are benefiting from and following prescribed treatment regimens consistently. Evaluating WASO levels before initiating treatment may help predict how patients will respond to different interventions. Patients with higher baseline WASO levels may require more intensive or targeted treatments to achieve desired outcomes.

Clinical management of other conditions: WASO is associated with a range of physical and mental health conditions. Elevated WASO levels have been linked to an increased risk of cardiovascular disease, metabolic disorders, depression, anxiety, and impaired cognitive function. Addressing sleep fragmentation and reducing WASO may mitigate the risk of these adverse health outcomes and improve overall patient well-being.

Inform lifestyle modification counseling: Clinicians can use WASO data to inform patients about the impact of certain lifestyle factors on sleep quality. By identifying behaviors or environmental factors contributing to elevated WASO, clinicians can recommend appropriate lifestyle modifications to improve sleep hygiene.

Number of wake events in the primary sleep period

Researchers

Clinicians

Patients

<< Return to Table of Contents

References >>

What is number of wake events? Why is it a core measure?

The number of wake events is the total number of wake events in the primary sleep period.

The **number of wake events during the primary sleep period** is a **core measure** because of its pivotal role in **determining sleep continuity and quality.** Sleep continuity refers to the uninterrupted duration of sleep, crucial for achieving restorative rest and cognitive function. Frequent awakenings disrupt this continuity, leading to fragmented sleep patterns that can impair daytime functioning and overall well-being. Assessing wake events during the primary sleep period provides valuable insights into sleep architecture, aiding in the diagnosis of sleep disorders. Monitoring wake events allows clinicians to track treatment efficacy and adjust interventions accordingly to optimize sleep outcomes for individuals. By emphasizing this measure, clinicians can comprehensively evaluate sleep quality and tailor interventions to address specific sleep disturbances, promoting overall health and vitality.

Why does the number of wake events **matter to researchers**?

Better understand sleep disorders: Assessing the number of sleep awakenings provides researchers with crucial information to better understand various sleep pathologies by elucidating patterns, severity, and underlying mechanisms of these disorders, as well as differentiate between sleep disorders.

Assess treatment efficacy and inform therapeutic applications: Monitoring changes in the number of awakenings before and after treatment allows researchers to evaluate the effectiveness of interventions for sleep disorders. This data can provide valuable feedback on treatment efficacy and help refine treatment strategies.

Better understand relationship between sleep disruption and adverse health outcomes: Frequent awakenings have been linked to adverse health outcomes, including cardiovascular disease, metabolic disorders, and cognitive impairment. By further understanding this relationship, researchers can identify individuals at higher risk and develop targeted interventions to mitigate these risks.

Why does the number of wake events **matter to clinicians**?

Clinical decision-making: The assessment of frequent awakenings during the primary sleep period is essential for clinical decision-making processes due to its multifaceted implications for patient health and well-being. Frequent awakenings serve as a cardinal manifestation of sleep disturbances and play a pivotal role in evaluating sleep continuity, quality, and underlying pathologies. Clinicians rely on the analysis of awakening frequency to guide diagnostic evaluations, differentiate between various sleep disorders, and formulate tailored treatment plans. Fragmented sleep can exacerbate existing medical conditions such as hypertension, diabetes, and mood disorders, and is associated with other conditions, such as compromised immune function and neurological and movement disorders.

Care management: Monitoring changes in awakening frequency over time enables clinicians to assess treatment responses, refine therapeutic interventions, and optimize patient outcomes. When gathered longitudinally, this data can provide clinicians with necessary comprehensive insights into patients' sleep patterns, helping them identify potential health risks and implement targeted strategies to improve sleep quality and overall health, which fosters better patient care and management of sleep-related disorders.

Sleep efficiency (SE)

Researchers

Clinicians

Patients

<< Return to Table of Contents

References >>

What is SE? Why is it a core measure?

Sleep efficiency is the **proportion of time spent sleeping when the individual intends to sleep,** and is expressed as a **percentage**.

Sleep efficiency is a **core measure** because it is a **key indicator of sleep continuity and overall sleep health.** A higher sleep efficiency indicates better sleep consolidation and quality, whereas lower sleep efficiency suggests fragmented or disrupted sleep patterns. Research has consistently shown that disturbances in sleep efficiency are associated with various adverse health outcomes, including increased risk of cardiovascular diseases, metabolic disorders, and impaired cognitive function. Therefore, monitoring sleep efficiency is essential for identifying individuals at risk for sleep disorders and implementing appropriate interventions.

Why does sleep efficiency **matter to researchers**?

Quantitative and standardizable outcome measure: In clinical research, sleep efficiency provides a quantitative measure of sleep quality and continuity, allowing researchers to objectively assess the effectiveness of interventions targeting sleep disorders or disturbances by monitoring changes in sleep efficiency before, during, or after the intervention. As a standardized outcome measure, sleep efficiency facilitates comparisons between different studies and interventions, allowing for meta-analyses and systematic reviews to evaluate the overall efficacy of treatments for sleep disorders across multiple studies.

Contribute to body of knowledge between sleep disorders and other adverse health outcomes: Sleep efficiency can help researchers understand the underlying mechanisms of sleep disorders and their impact on health outcomes. For example, studying alterations in sleep efficiency in various populations may shed light on the relationship between sleep disturbances and chronic health conditions such as cardiovascular disease or mood disorders.

Why does sleep efficiency **matter to clinicians**?

Clinical diagnosis: Sleep efficiency provides valuable information for diagnosing sleep disorders such as insomnia, sleep apnea, and circadian rhythm disorders. It helps clinicians assess the severity of sleep disturbances and differentiate between different types of sleep disorders based on patterns of sleep continuity and fragmentation.

Clinical management: Clinicians use sleep efficiency to monitor the effectiveness of interventions for sleep disorders. Changes in sleep efficiency over time can indicate whether treatment is improving sleep quality and continuity. Clinicians turn to published research that reports sleep efficiency data when determining the success of treatments and making evidence-based recommendations for patient care. By monitoring sleep efficiency, clinicians can tailor interventions to address specific sleep disturbances and optimize treatment outcomes for individual patients.

Identify health risk factors: Low sleep efficiency is associated with an increased risk of various adverse health outcomes, including cardiovascular disease, metabolic disorders, cognitive impairment, and mental health disorders. Clinicians can use sleep efficiency as a marker of overall sleep health and to assess patients' risk for developing chronic health conditions.

Total napping time (TNT)

Researchers

Clinicians

Patients

<< Return to Table of Contents

References >>

What is total napping time? Why is it a core measure?

Total napping time is the total duration of time spent sleeping outside of the intended Time Attempting to Sleep period.

Total napping time is a **core measure** because it can be a marker of poor sleep on the prior night or a marker of morbidity and mortality. Excessive daytime napping, particularly when it occurs outside the primary sleep period, has been associated with various health issues such as cardiovascular diseases, metabolic disorders, and cognitive decline. Assessing total napping time outside the primary sleep period in clinical research is crucial for understanding its implications on health outcomes and implementing targeted interventions to mitigate associated risks.

Why does total napping time **matter to researchers**?

Total napping time provides insights into an individual's overall sleep patterns and habits, beyond just nighttime sleep duration. Understanding how much time individuals spend napping outside their primary sleep period can offer valuable information about their sleep quality, sleep hygiene, and potential sleep disorders.

Sleep disorder indicator: Total napping time outside the primary sleep period serves as an indicator of potential sleep disturbances or disorders. Excessive daytime napping, especially if it occurs irregularly or disrupts nighttime sleep, may suggest underlying issues such as insomnia, sleep apnea, or circadian rhythm disorders. By monitoring total napping time, researchers can identify individuals at risk of these sleep disorders and investigate their impact on various health outcomes.

Relationship to adverse outcomes: Studying total napping time outside the primary sleep period enables researchers to explore its associations with adverse health outcomes. Several studies have linked prolonged daytime napping to increased risks of cardiovascular diseases, metabolic disorders, cognitive decline, and mortality. By including this measure in clinical research, researchers can better understand the relationship between daytime napping habits and various health conditions, thereby informing the development of preventive strategies and interventions.

Why does total napping time **matter to clinicians**?

Clinical diagnosis: Understanding the extent of daytime napping can help identify potential sleep disorders, such as narcolepsy, insomnia, sleep apnea, or circadian rhythm disorders, which may require further evaluation and intervention. Unintended and undesired napping can be a diagnostic criterion.

Clinical management: Monitoring total napping time can aid in evaluating the effectiveness of interventions aimed at improving sleep health and overall health outcomes. For individuals with sleep disorders or chronic health conditions, reducing excessive daytime napping and promoting a more consistent sleep-wake schedule may be an important component of their treatment plan. By tracking changes in daytime napping habits over time, healthcare providers can gauge the impact of interventions and make informed adjustments to optimize patient outcomes.

Identify associated conditions or health risk factors: Total napping time can serve as a marker for underlying health conditions or lifestyle factors that may impact sleep quality and overall well-being. Excessive daytime napping, particularly if it occurs irregularly or disrupts nighttime sleep, may be indicative of health issues such as depression, chronic pain, or medication side effects. By considering daytime napping as part of the clinical assessment, healthcare providers can uncover these potential underlying factors and tailor treatment plans accordingly.

Core Measures of Sleep: Considering what **matters to patients**

In addition to being important health indicators, each core measure can provide important insights into a **patient's daily functioning, experience, and quality of life**.

Total sleep time reflects the amount of restorative sleep patients obtain each night, influencing their energy levels, mood, cognitive performance, and physical well-being. Insufficient TST can lead to daytime sleepiness, fatigue, irritability, and impaired concentration, impacting interpersonal relationships as well as productivity at work or school.

Initial Sleep onset latency: Challenges in falling asleep can lead to frustration, anxiety, and a sense of helplessness. Poor sleep quality resulting from extended ISOL can exacerbate daytime fatigue, impair concentration and memory, and contribute to mood disturbances, hindering daily function and reducing perceived quality of life.

Core Measures of Sleep: Considering what **matters to patients**

Wake after sleep onset directly affects overall well-being and daily functioning. High levels of WASO can have significant implications for daytime functioning, including increased fatigue, impaired cognitive performance, and decreased productivity. Patients may struggle to perform daily tasks or engage in social and occupational activities due to disrupted sleep. WASO has been linked to mental health issues such as depression and anxiety and is associated with physical health problems, including cardiovascular disease, obesity, and metabolic disorders. Increased WASO can exacerbate pain perception and reduce pain tolerance in some individuals.

Number of wake events in the primary sleep period: Disrupted sleep patterns are associated with increased daytime sleepiness, impaired cognitive function, and decreased quality of life. Individuals experiencing frequent awakenings often report feelings of fatigue, irritability, and difficulty concentrating during waking hours. Fragmented sleep can take a psychological toll, contributing to heightened levels of stress, anxiety, and depression.

Core Measures of Sleep: Considering what **matters to patients**

Sleep efficiency: Patients care about the ability to fall asleep and the ability to stay asleep. When these are both impacted, SE suffers and patients feel and report the adverse effects.

Total napping time: Napping is not always a negative experience for patients. However, when napping is undesired (such as for individuals experiencing conditions like narcolepsy or excessive daytime sleepiness) the adverse effects can be frustrating as individuals navigate personal, occupational, and/or social demands.

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