Advancing Sleep Research: New Core Digital Measures & Resources

WEBINAR
Wednesday, April 24
11 am - 12 pm ET

CORE MEASURES of SLEEP

Digital Measures Development

DATAcc
Digital Health Measurement Collaborative Community

by DIME
Welcome & Housekeeping
Opening Remarks from NSF
Background of Project
Panel: Resources in Action
Fireside chat: The importance of sleep staging
Panel: The possibilities for and importance of the out of lab assessment of sleep
Fireside chat: The real world impact of digital sleep measurement
But first, housekeeping

- Please note: **today’s session is being recorded**
  - Slides and recording will be available on DiMe’s webinar page after the session
- To ask a question for discussion during live Q&A, please
  - Type your question into the chat box

*** Participants are not permitted to transcribe this webinar, violators will be removed from the session.***
Agenda

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Advancing Sleep Research: New Core Digital Measures & Resources

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Joe Dzierzewski
Vice President, Research and Scientific Affairs
National Sleep Foundation
National Sleep Foundation

Joseph Dzierzewski, PhD
Vice President
Research & Scientific Affairs
NSF Serves the Public through its Sleep Health Mission and Goals

The National Sleep Foundation is dedicated to improving health and well-being through sleep education and advocacy.

- Sleep health is accepted as a crucial measure of overall health.
- The natural sleep/wake process is understood as the basis for healthy sleep.
- Community, infrastructure, and environments respect sleep health.
- Sleep science and insight are rapidly incorporated into accessible health products and services.
Sleep is Critical for Health and Performance

• Sleep is a fundamental part of our lives, strongly linked to brain and mental health, heart health, obesity, diabetes, immune function, and other public health priorities

• Sleep health and safety for wellness, selfcare, or medical conditions is in focus for the public, clinicians, industry, and policy makers

• Important to include NSF’s guidelines and standards in new targeted resources for consistency across use cases
NSF Published Research and Guidelines
Setting the Standards

Translate science, data, and insights into recommendations for healthy sleep behaviors

Consensus guidelines
- Sleep duration
- Drowsy driving
- Sleep satisfaction
- Sleep quality
- Polyphasic sleep
- Sleep timing
Existing Standards Inform Multiple Use Cases
Consistent Sleep Measures Across Use Cases

1. Guidelines and standards exist
2. Consistency in application is key for progress
3. DiMe Core Measures of Sleep is a great example of appropriate application to expanded use cases
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**Background of Project**

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Sleep disturbance greatly impacts quality of life and it’s often the first indicator of a larger issue. Let’s measure it the right way.

Source: Sleep
We have our measures

Core Digital Measures of Sleep

- Total Sleep Time
- Initial Sleep Onset Latency
- Wake After Sleep Onset
- Number of Wake Events
- Sleep Efficiency
- Total Napping Time

Emerging Digital Measures of Sleep

- Sleep Regularity Index
- Symptomatology Impact on Sleep
Core Digital Measure of Sleep: Total sleep time (Duration)

**Also known as:** true sleep time, time spent sleeping  
**Type:** Duration of time  
**Definition:** The duration of time spent sleeping in the primary sleep period

![Diagram of sleep stages and definitions]

**Primary sleep period label**

**Label definition**

A label for each epoch between:
- The first sleep onset label with a time attempting to sleep label 1
- The final sleep offset label with a time attempting to sleep label 1

The final sleep offset is not included in the definition.

Where the time attempting to sleep label is not available, the in bed label can be used in its place. This substitution should be clearly noted.

**Why is this important?**

The primary sleep period label differentiates from the asleep label, as any sleep period can include brief periods of waking, provided the individual falls back asleep.

The primary sleep period label can therefore be used in conjunction with other labels and derived variables to determine, for example, the number of awakenings or the length of awakenings during the sleep period. It also allows the user to derive measures of other sensor-based symptomatology or activity occurring during the sleep period.

**Derived variables**

- **Primary sleep period start time**
  - **Variable definition:** The timestamp of the first epoch with the primary sleep period label.

- **Primary sleep period end time**
  - **Variable definition:** The timestamp of the final epoch with the primary sleep period label.

- **Primary sleep period duration**
  - **Definition:** A time duration (seconds) calculated as the difference between the primary sleep period start and end times.
Our conceptual model was the basis for our digital core measures selection.
We have resources for everyone!

Clinical researchers  Clinician & healthcare decision makers  DHT developers
Checklists and evidence report forms

Comprehensive Checklist and Report Form for Core Digital Measures of Sleep: **Total napping time**

This checklist and report form is intended for you if you are conducting studies employing a digital health technology (DHT) to measure total napping time (TNT).

The checklist will help you and your team by ensuring that you have identified and collected the necessary details and evidence to support 1) the use of the measure in your target population and 2) the parameterization of the core measure.

Descriptions and evidence (references, parameterization details) relating to each aspect of the core measure are recorded on the following pages.

<table>
<thead>
<tr>
<th>Total napping time as an outcome measure</th>
<th>Description</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Qualitative evidence supporting patient relevance in the target population.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>See: Digital Measures that Matter to Patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. Quantitative evidence of clinical validity in the target population.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>See: The V3 Framework</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Arming you with the evidence you need to make a case for sleep

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

CORE MEASURES of SLEEP

Digital Measures Development

https://datacc.dimesociety.org/core-measures-sleep/
Resources for the general population and for clinicians

Connecting Core Measures: Suggested Recommendations for Interpreting Data

Markers of good sleep health

<table>
<thead>
<tr>
<th>Young adult (18-26 years)</th>
<th>Adult (26-64 years)</th>
<th>Older adult (≥65 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total sleep time</strong></td>
<td>7-9 hours</td>
<td>7-8 hours</td>
</tr>
<tr>
<td><strong>Initial sleep latency</strong></td>
<td>≤ 30 minutes</td>
<td>≤ 30 minutes</td>
</tr>
<tr>
<td><strong>Wake after sleep onset</strong></td>
<td>≤ 20 minutes</td>
<td>≤ 20 minutes</td>
</tr>
<tr>
<td><strong>Number of wake events</strong></td>
<td>≤ 1 awakening</td>
<td>≤ 2 awakenings</td>
</tr>
<tr>
<td><strong>Sleep efficiency</strong></td>
<td>≥ 85%</td>
<td>≥ 85%</td>
</tr>
<tr>
<td><strong>Naps</strong></td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>


Reimbursement for Clinicians: Getting paid for caring for your patients using digital measures of sleep

For the purposes of monitoring, diagnosing, and treating patients with sleep or sleep-related disorders, you as a healthcare provider (HCP) can perform a sleep assessment for your patients. There are several reimbursement avenues available to you for this assessment. However, the specific medical insurance codes for reimbursement and the associated activities need to be in line with guidelines to enable this process.

This document aims to offer you top-level initial guidance on the specifics of the reimbursement process if you wish to use digital health technology measures of sleep, such as the Core Digital Measures of Sleep, when treating your patients.

The full Payment and Coding Toolkit and Quick Start Guide is available should you be looking to adopt remote monitoring.

Remote patient monitoring (RPM) and remote therapeutic monitoring (RTM)

Remote patient monitoring, also called remote physiological monitoring, refers to the use of digital technologies to capture and analyze patients’ physiological data, such as sleep metrics, blood pressure, glucose levels, or lung function.

Remote therapeutic monitoring refers to the use of digital technologies to collect and analyze data, including patient-reported measures, for the purposes of therapy...

Special thanks to Joe and Shannon at NSF for their input into these...
Vendor selection checklist to help you ask the right questions

Checklist:
Essential Questions for DHT Vendor Selection

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What should I ask a DHT vendor?

What is your method of sleep monitoring, and which signals are being recorded and used?
Different technologies can estimate sleep staging using data collected from different sensor-based sources (e.g., EEG, actigraphy, ballistocardiography, etc.). Each technology type has different properties that impact the estimation of sleep staging. Understanding the technology used to collect the data and its strengths and limitations is important for later interpretation of, and confidence in, the arising results.

What granularity of sleep data do you estimate?
The estimations of sleep staging are at the heart of the Core Digital Measures of Sleep. The Core Measures: Sleep Measurement System provides three levels of sleep staging, from coarse grain awake vs asleep, to fine grain N1-N3 and REM staging. The needs will vary based on the context of use and research question employed, so it is important to know the resolution of sleep stage estimation.
All the graphics we produced are available for you to use in your work.
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Michael Kremliovsky
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Moderator
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Farah Hasan
Expert Advisory Board Member and Patient Speaker
Project Sleep

Piper Fromy
Associate Program Director
Digital Medicine Society (DiMe)
Moderator
Join us in our next project as we convene leaders from across the field to **develop the business case** to support the development, adoption, and scale of digital endpoints!

Don’t miss out on our next DATAcc by DiMe project – **scan the QR code** to share your interest and learn more!

Source: [https://pages.insightly.services/digital_endpoints](https://pages.insightly.services/digital_endpoints)
Join us for an upcoming DiME Webinar

The DiMe webinar series hosts leading experts from across a variety of disciplines to discuss critical topics on digital medicine with our community.

Scan the code & learn more about our webinar series and to register for our next event!

Source: DiMe Webinar Series