Sleep disruption discussion guide

Getting to sleep and staying asleep

This discussion guide will support you in the development and use of the core digital measures of ADRD, while presenting the importance and benefits of employing these measures in research and practice. It also offers considerations that should be assessed when employing a measure in different contexts.

Patient and care partner relevance

- Within the concept of sleep disruption, the meaningful aspects of health most important to people with ADRD and their care partners reflected disturbances involving getting to sleep and staying asleep.

  - In terms of staying asleep, the frequency of wake events, rather than the length of time a person with ADRD was awake, was described as important.

- Sleep disturbance impacts care partners. If the person with ADRD has disrupted sleep, care partners' sleep is impacted, as well as their ability to care both for themselves and the person with ADRD.

- Care must be taken when assessing sleep across the ADRD spectrum due to shifts and changes in the circadian cycle. These considerations and how they inform a measurement strategy for a given intended population should be documented.

- Depending on the stage of ADRD, patients may not be comfortable using wearable technology. Ambient sensors can be a potential alternative in this population, but they may have privacy issues. See V3+ resources to help determine useability of technology.

Use in clinical research as a clinical outcomes assessment (COA) endpoint measure

- Defining the sleep parameters of the chosen technology is important. A more in-depth guide to sleep measurement is available in the DiMe Core Digital Measures of Sleep. This work can help the user choose, specify, and understand the sleep parameters they may need to measure and discuss the importance of sleep measurement with their internal teams.

  - Other sleep disruption measures, such as wake after sleep onset and total napping time, may be useful exploratory endpoints.

- There are many technologies that can be used to assess sleep parameters. Regardless of the type of technology chosen for sleep assessment, support should be offered for the accuracy of parameter estimation in the intended population.

- Time attempting to sleep is a difficult concept to capture algorithmically. Requiring the patient to measure this parameter through a self report, or by wearing/activating the technology only as they initiate a sleep attempt can lead to more reliable estimates.

Use in clinical research as a digital biomarker

- Alongside metrics for patient relevance, sleep data can be used as a digital biomarker of disease stage of predicted progression.
- Some technologies are capable of measuring brain activity. This information can not only be used to estimate the measures presented in this document but can also help the user capture **sleep stage information**.
  - Sleep stage information is less patient-centric, but has the benefit of being highly desirable for the development and use of digital biomarkers of disease onset and progression.
- Where an exploratory COA endpoint may be underpowered to detect group differences in early-phase trials, digital biomarker information can assist with go/no-go decision-making for pivot trial work.

Use in clinical practice

- Measuring patient-relevant concepts in clinical practice can help healthcare providers (HCPs) track the patient journey and can be used as a discussion tool.
  - This approach can help to change the conversation in healthcare and allow individuals to talk with their HCP about aspects of health important to them.
- Outside of medication that is directly indicated for ADRD, sleep monitoring of ADRD patients can lead to behavioral and pharmaceutical interventions to improve sleep. This monitoring can also be reimbursed in some cases.

Importance of metadata

Sleep is a complex interaction of physiological processes that can be disrupted for many reasons. It is important, both for research and clinical practice, to account for different aspects of a patient's life which could also impact their sleep.

- **Existing primary sleep disorders**: Obstructive sleep apnea, rapid eye movement sleep behavior disorder, restless leg syndrome, etc.
- **Ambient temperature**: The ambient temperature of the environment can impact sleep quality.
- **Ambient noise**: The noise in the environment may impact sleep metrics.
- **Existing or new signs or symptoms**: Anxiety and depression symptoms can have an impact on sleep onset latency.
- **Physical activity**: The amount of physical activity in a day can influence nighttime sleep.