Standardized rationale for the use of the Core Digital Measures of ADRD

Quick Links

- **Core Measures Selection**: use this section to specify the core digital measures you are including in your work
- **Background Information**: use this section to offer your reader a background on the development of the core digital measures
- **Specification of the Core Digital Measures**: use these selections to evidence your operationalization of the core digital measures in line with the ontologies and terminologies
    - Visuospatial Memory
    - Expressive Communication
    - Sleep Disturbance
    - Non-sedentary Behaviour

Note: Please ensure that you correct the tense for your own purposes.

Template text:

Core measures selection

This work's operationalization of relevant metrics for patient and care partners will follow the DATAcc by DiMe's Core Digital Measures of ADRD specifications. Specifically, the following core measures will be included:

[Delete any of the below measures that you are not using]

- Visuospatial memory: Remembering where things are
- Expressive communication: Speech fluency and word finding
- Sleep disturbance: Getting to sleep and staying asleep
- Non-sedentary behavior: Keeping active, staying mobile

For the measurement of [insert core measure], this work will use [insert name of technology].

Background information

[Use the following text as an introduction to the rationale behind selecting the core measures set]

The DATAcc by DiMe's Core Digital Measures of ADRD was devised to standardize the conduct and reporting of person-centered ADRD research and practice using sensor-based digital health technology. The project was driven by a pre-competitive group of experts, including digital health technology developers, pharmaceutical industry representatives, and academics. The selection of the Core Digital Measures of ADRD was based on a systematic literature review of qualitative evidence of patient- and care partner-relevant concepts of interest relating to ADRD; a landscape analysis of available technology and its maturity; a multi-national mixed-methods study assessing meaningful aspects of health across people with ADRD, their care partners and healthcare professionals; and a modified Delphi process including experts from research and clinical backgrounds (manuscript in development). The concepts that arose from the mixed methods study were key in the selection of the patient-relevant concepts for inclusion in the set of Core Digital Measures, to ensure that they were relevant across diagnosis, stage, and culture. This study included people with ADRD and their care partners, representing a range of physician-confirmed diagnoses (mild cognitive impairment (MCI)/prodromal-AD, mild dementia due to Alzheimer's disease, moderate to severe dementia due to Alzheimer's disease, vascular dementia, Lewy body dementia, frontotemporal dementia) hailing from a range of countries (United States, Spain, Japan, China, Bulgaria, and Ghana).

The primary output of the Core Digital Measures of ADRD project was the creation of ontologies and terminologies for four measures that allow researchers to transparently specify the parameters they will use in the operationalization of measurement. The four Core Digital Measures of ADRD represent concepts that are broadly relevant across the spectrum of dementia:

- Visuospatial memory: Remembering where things are
- Expressive communication: Speech fluency and word finding
- Sleep disturbance: Getting to sleep and staying asleep
- Non-sedentary behavior: Keeping active, staying mobile

Specification of and deviations from the Core Digital Measures of ADRD

[The ontologies and terminologies offer room for further specification of/or deviation from the core measures. Use the following sections to highlight specifics on your chosen measurement technology, or deviations you have made.]

If you are using the digital measure **Visuospatial memory**, use this page to help specify your approach for active task data collection.

"Visuospatial memory: Remembering where things are" was selected as a core measure based on participant feedback in the mixed methods study. This feedback showed that these concepts were highly ranked areas of importance related to functional daily living. In the qualitative feedback received, participants expressed how forgetting the location of items in their vicinity was not only something that they actively did not want to see decline in, but also expressed the difficulty it would bring to their day-to-day life if this ability declined further.

Task

The task selected for the measurement of Visuospatial memory: Remembering where things are is a [description of task]. This task was chosen specifically for the study population because [rationale, including the diagnosis and stage of the disease in the intended population].

The task contains [X] number of assessments completed daily at [X frequency, e.g., days, days per week] prior to [situation, e.g., each clinic visit]. The number of assessments and the frequency of assessment were chosen to [accomplish X aim, e.g., increase reliability of the measurement estimate (citation; link to any appendix details of reference, etc.)]. For each of the assessments, standardized stimuli have been produced, resulting in [X] standardized stimuli [citation; link to any appendix details of a reference, etc.]. [Describe the repetition of stimuli, e.g., for a place-and-find task will participants place different stimuli each day, and if so, what's the impact?]. Each assessment will start [description of assessment beginning, e.g., with the presentation of a stimuli, presentation of the assessment objective, etc.] and end [description of assessment ending, e.g., once that participant makes a response or 180 seconds have elapsed]. [Where appropriate for delayed recall tasks:] There is a delay of [X time; or specify that recall will occur after an intermittent task] between the presentation of the assessment stimuli and the recall period. [Where appropriate:] A successful assessment is defined as [e.g., retrieving the correct object in virtual space, selecting the correct object on the screen, etc.].

Scoring

The data collected as part of this task include [list out the data elements, e.g., participant response to task, reaction time to task, etc. For any algorithmic derivation of data elements or features, provide citations or references of supporting evidence for the procedure and algorithms used to derive them from the data. Where many features are collected/derived, the data can be tabulated]. This data will be used to create participant scores on the task. The scores at an assessment level consist of a [describe the feature or features used, e.g., the reaction time of a correct response]. The scoring at a task level is defined as [explain the scoring, e.g., the average of all assessment-level reaction time responses, the sum of correct assessments, a multi-feature score consisting of the following elements/features selected because...]. The use of these scoring methods has been shown to have evidence of reliability, validity, and ability to detect change in the intended population [describe and provide citations. Explain where this study will use the data to fill evidentiary gaps, and reference a citation for or append the associated analysis plan for this generation activity].

If you are using the digital measure **Expressive communication**, use this page to help specify your approach for active task data collection.

"Expressive communication: Speech fluency and word finding" was selected as a core measure based on participant feedback in the mixed methods study showing that these concepts were highly ranked areas of importance within communication that related to the ability to continue to express oneself clearly. In the qualitative feedback received, participants expressed how not being able to find the correct word was intrinsically linked to feelings of verbal fluency. The participants expressed their frustration with this experience and how they wanted to be able to continue to recall words in order to feel at ease and avoid awkward situations.

Task

The task selected for the measurement of Expressive communication: Speech fluency and word finding is a [description of task]. This task was chosen specifically for the study population because [rationale, including the diagnosis and stage of the disease in the intended population].

The task contains [X] number of assessments completed daily for [X frequency, e.g., days, days per week] prior to [situation, e.g., each clinic visit]. The number of assessments and the frequency of assessment were chosen to [accomplish X aim, e.g., increase reliability of the measurement estimate (citation; link to any appendix details of reference, etc.)]. For each of the assessments, standardized stimuli have been produced, resulting in [X] standardized stimuli [citation; link to any appendix details of reference, etc.]. [Describe the repetition of stimuli, e.g., for the picture description task, do participants get the same stimuli repeated within the same assessment period, and if so, what's the impact?]. Each assessment will start [description of assessment beginning, e.g., with the presentation of a stimuli, presentation of the assessment objective, etc.] and end [description of assessment ending, e.g,. once that participant makes a response or 180 seconds have elapsed]. [Where appropriate:] A successful assessment is defined as [e.g., describing the presented stimuli in a way consistent with the list of acceptable words].

Scoring

The data collected as part of this task include [list out the data elements, e.g., participant response to task; reaction time; lexicosyntactic, acoustic, or semantic features collected or derived during the task. For any algorithmic derivation of data elements or features, provide citations or references of supporting evidence for the procedure and algorithms used to derive them from the audio data. Where many features are collected/derived, the data can be tabulated]. This data will be used to create participant scores on the task. The scores consist of a [single element/feature score, multi-element/feature score] defined as [explain the scoring, e.g., the average of the reaction time of all correct assessments, the number of correct assessments, the ratio of filled and unfilled pauses to total time spent describing the stimuli, semantic depth of the description, a multi-feature score consisting of the following elements/features selected because...]. The use of these scoring methods has been shown to have evidence of reliability, validity, and ability to detect change in the intended population [describe and provide citations. Explain where this study will use the data to fill evidentiary

gaps, explain that this is the case, and reference a citation for or append the associated analysis plan for this generation activity].

If you are using the digital measure **Sleep disturbance**, use this page to help specify your approach for active task data collection.

[Core measures of sleep in ADRD were adapted from the DiMe Core Digital Measures of Sleep. Please refer to the wealth of source documentation in that work for deeper information and specifications where necessary]

"Sleep Disturbance: Getting to sleep and staying asleep" was selected as a core measure based on participant feedback in the mixed methods study showing that of all the sleep disturbance issues experienced by people with ADRD and their care partners, these were ranked as areas of importance. In the qualitative feedback received, participants expressed how these elements of sleep disturbance were among the most pervasive that impacted their sleep experience and had a follow-up impact on their ability to function the following day. This area particularly impacted care partners' own health and their ability to care for the person with ADRD, and was a source of anxiety for the patient and care partners alike.

Measurement

To measure initial sleep onset latency, the following parameters will be collected:

- Time attempting to sleep start time (sometimes referred to as "lights out time"): the timestamp associated with the point at which the participant goes to bed and starts their sleep attempt. In this work, this time will be estimated [explain the estimation process, e.g., algorithmically using the TECHNOLOGY. Describe how the algorithm is detecting a sleep attempt, e.g., detecting a reduction in activity for Y minutes or more. The algorithm for estimating the start of a sleep attempt has evidence of analytic validation (describe and provide citation). If you are using a technology that is only used at the point that patients attempt sleep, the device initial wear timestamp can signify the attempting to sleep time].
- Initial sleep onset: the timestamp associated with the point at which the participant first gets to sleep. In this work, this time will be estimated [explain the estimation process, e.g., algorithmically using the TECHNOLOGY. Describe how the algorithm is detecting initial sleep onset, e.g., through the further reduction in activity and a heart rate decrease of X for Y minutes or more. The algorithm for estimating the onset of sleep has evidence of analytic validation (describe and provide citation)].
- [Note: for more detail on the parameterization of sleep parameters, please refer to the DiMe Core Digital Measures of Sleep and the associated Sleep Measurement System.]

Initial sleep onset latency will be calculated as the difference between the timestamps associated with these parameters.

To measure frequency of wake events in the primary sleep period, the following parameters will be collected:

- Initial sleep onset: collected as described above.
- Sleep offset: the timestamp associated with each inferred termination of sleep. In this work, this time will be estimated [explain the estimation process, e.g., algorithmically using the TECHNOLOGY. Describe what the algorithm is doing, e.g., only counting wake events longer than X seconds/minutes. The algorithm for estimating the offset of sleep has evidence of analytic validation (describe and provide citation)].

- Wake event: a label in the dataset for each epoch associated with a sleep onset.
- Total sleep time: as described in the DiMe Core Digital Measures of Sleep.

Frequency of wake events in the primary sleep period will be standardized, calculated as the number of Wake events divided by [variable, e.g., total sleep time, primary sleep period duration].

These measures will be collected for a period of [X days, X days per week] prior to [situation, e.g. each clinic visit] and will be appraised individually.

If you are using the digital measure **Non-sedentary behavior**, use this page to help specify your approach for active task data collection.

[The DiMe Core Digital Measures of Physical Activity include a wealth of additional information that can be used in the creation of important measures in ADRD. The measure presented here is unique to the concerns of the Core Digital Measures of ADRD project; however, additional measures are alluded to in the discussion guide for this measure and could be used as a supplemental measure.]

Although the participant quantitative data in the mixed methods study did not place "Non-sedentary behavior: Being active", staying active as highly as other selected core measures, this measure was included based on the strength of the qualitative data. In the qualitative feedback received, participants expressed how the ability to keep being active was an important long-term goal, and that if this ability worsened, it would lead to a large impact on overall quality of life. People with ADRD reported that a decline in their ability to keep active would result in social isolation, withdrawal, and increased dependence on others. For care partners, they reported that if the person they cared for declined in this area, it would not only increase their own care burden, but fundamentally change the relationship they have with the person they care for. A decline in this area would lead to a change in life circumstances (employment, etc.) alongside a reduction in overall quality of life.

Measurement

As a measure of sedentary behavior, reduced mobility and activity will be measured as a [percentage/ratio] of active time (a sum of all time spent in non-sedentary behavior in the activity window) as a function of the length of the daily active window:

- Non-sedentary behavior duration: Non-sedentary behavior will be defined as the duration of time covered by a series of epoch-level data starting at the point of onset (the first [e.g., epoch in a series of epochs with an activity count greater than X, lasting for at least Y epochs]) to the point of offset (the last [e.g., epoch in a series of epochs with an activity count less than X, lasting for at least Y epochs]). The algorithm for estimating non-sedentary behavior has evidence of analytic validation [describe and provide citation].
- Active time duration: The sum of all behavior recorded by the device as being non-sedentary in the active window.
- Active window duration: The difference between the timestamp of the start and end of the most active [X number, e.g., ten] consecutive hours in the day. [If adjusting for sleep events, state how you intend to deal with nap behavior in the active window. For example]: Time spent sleeping in the active window (e.g., daytime napping) will be excluded from the active window duration for the calculation of the activity ratio/percentage.

These measures will be collected for a period of [X days, X days per week] prior to [situation, e.g., each clinic visit]. A minimum wear time of [X hours per day for Y days per week] will be enforced to ensure the robustness of the collected data [provide rationale and citation].