







Expressive communication discussion guide



Speech fluency and word-finding

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

- Expressive communication is a high-level concept. People with ADRD and their care partners reported fluency of speech and word-finding to be important.
 - A researcher/developer should consider and document how closely the selected task relates to naturalistic behavior.
- Assessing an individual's speech through tasks can be done in various ways. Here we recommend a recording of speech that is driven by standardized stimuli.
 - Standardized stimuli are often context-dependent, and the culture the assessment is taking place within needs to be considered.

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

- Evidence must be provided that the task and the interpretation of its output is appropriate for the intended ADRD population.
 - For example, when using the picture description task, some features may be more appropriate for detecting the earliest stages of non-amnesiac mild cognitive impairment (MCI) than others.
 - The cultural neutrality of task stimuli should be considered where appropriate, as well as the algorithms used for feature derivation from audio recordings.
- Although speed and accuracy metrics are commonly used in the psycholinguistic literature, other scores for individuals can be created from single features or a combination of multiple features derived from the audio data.
 - There is no community consensus on other metrics. For example, the standardized number of pauses or the semantic depth of a response to an open-ended picture description can relate to word-finding difficulty and speech fluency.
 - Alternatively, many elements could be combined into a potentially more sensitive metric representing expressive communication, e.g., creating a fluency score.



- Being prepared with evidence for sensitivity and interpretability of multi-feature scores and how these can benefit the research outcome will allow for more fluid discussions with internal research teams and external bodies (such as regulators).
 - Having this evidence in an easy-to-explain manner can help overcome barriers for adoption in research.

Use in clinical research as a digital biomarker

- Alongside metrics for patient relevance, speech-based tasks can result in hundreds of possible vocal features.
- These features can be used as a digital biomarker of disease stage of predicted progression.
- Where an exploratory COA endpoint may be underpowered to detect group differences in early-phase trials:
 - Digital biomarker information may help with the selection of patients for trial inclusion,
 - Digital biomarker information can assist with go/no-go decision-making for pivot trial work, and
 - Early phase, under-powered COA-based data collected in early phase work can help calculate the sample size needed in larger trials.

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.
- Longitudinal within-person assessments are <u>sensitive to changes in ADRD over</u> <u>time</u>.
- Where normed data exist for a general population, scores can be presented as deviations from the normed sample.
- As a biomarker, speech is emerging as a very early predictor of later cognitive decline. Speech biomarkers <u>can aid in the screening of patients</u> and could aid in the screening of individuals with ADRD for further assessment.

Importance of metadata

- Anxiety and depression are heavily studied conditions in the field of speech analytics. If this information is collected, it can be used to control for the impact of these symptoms and lead to more interpretable results.
 - In research, metadata should be selected and used as covariates in analyses to control for these factors.



- In clinical practice, taking these factors into account can help the clinician appraise the patient's expressive communication score and score trajectory.
- Other important metadata to consider in research includes technology type and model, scoring algorithm, and software versioning.
 - These elements can impact the results of the task, particularly if they vary between individuals or within-individual over time.