Validation of the SAGE-SR: A Self-Report Diagnostic Assessment Based on the DSM-5 and SCID Designed to Improve the Signal-to-Noise-Ratio in Clinical Trials

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Background
Accurate characterization of patients entering clinical trials is essential if we are to improve the signal-to-noise ratio in CNS clinical trials. Patient characterization starts with a diagnostic assessment and an assessment of symptom severity. The Structured Clinical Interview for DSM-5 Disorders (SCID) represents the “gold standard” assessment for psychiatric diagnoses. The web-based version of the SCID, the NetSCID-5 Research Version (RV) covers 66 disorders and episodes with an average interview time of 102 minutes. The NetSCID-5 Clinician Version (CV) takes an average time of 64 minutes per interview, and it is an abbreviated version of the RV covering the most common disorders and episodes with an additional 16 screener questions for other disorders. The NetSCID-5 Clinical Trials Version (CT) is the name used for the customized version of the RV that can be used in FDA clinical trials, which require specific diagnostic groups. The NetSCID products are the web-based version of the “gold standard” in behavioral health diagnostics; however, clinicians should receive 8-16 hours of training to achieve high interrater reliability and the study protocol must allow for administration time. The NetSCID would ideally be used for making an official diagnosis once patients have been briefly screened and there is a high probability they will be a participant in any given trial. Another diagnostic instrument, the Mini International Neuropsychiatric Interview (MINI), requires on average 30 minutes for administration. The MINI covers 28 disorders and is widely used in FDA clinical trials, but it is generally not considered as accurate as the SCID. When compared to the NetSCID, the MINI has no report feature, no easy way to electronically navigate back and forth between sections, it does not save data that was previously answered if you change an answer and then change the answer back again, and it does not contain ICD-10 codes. These instruments require a trained clinician for administration. To date, no comprehensive self-report behavioral health diagnostic assessment has been developed with sufficient rigor to use in clinical trials.

Objective
To develop and validate a rigorous self-report diagnostic assessment based on DSM-5 and ICD-10 diagnostic criteria that can be used to accurately identify any of 31 standard behavioral health diagnoses and mood episodes, to facilitate screening for eligibility to participate in FDA clinical trials, and to generate a searchable database with granular information on symptom severity.

Methods
The item development and validation process included an expert panel, four clinical sites, and a control population. An expert panel iteratively developed items based on the exact individual symptoms, time-frames, and clustering described in the DSM-5 and the Structured Clinical Interview for DSM-5 Disorders (SCID-SR). Items were tested using cognitive interviewing (CI) with a total of 50 participants in three rounds. Items that gave rise to any confusion were re-written and re-tested iteratively with CI until all items were clearly understood in the final round of CI items were placed into a computer adaptive instrument according to DSM-5 diagnostic logic, and a branching pattern was developed to eliminate non-contributing items during each assessment. The resulting SAGE-SR was administered to 44 public sector clinical participants and 84 non-clinical controls.

Results
We successfully developed and validated 661 items covering the exact symptoms, time frames, and clustering criteria for the 31 most common DSM-5 diagnoses and episodes. The resulting computer adaptive program ran smoothly and was well liked by the majority of study participants. A clinical report was successfully generated after each assessment. For non-clinical controls the assessment took 14 minutes (SD=6.8) to administer. For public sector behavioral health patients, the SAGE-SR took 24 minutes (SD=12.5) to administer.

Conclusion
The SAGE-SR is a brief self-report diagnostic assessment that can be used to efficiently screen large populations. Because the SAGE-SR is a self-report assessment, the same assessment can also be administered by a clinician or lay person with minimal training. The SAGE-SR can be used to generate individual clinical reports, but it also generates a database that can be searched to identify individuals who might be appropriate for participation in specific clinical trials. Because the SAGE-SR database includes a detailed library of symptoms and severity, it can be administered at multiple time points to track response to intervention over time and identify improvement in specific symptom clusters, as well as identify and characterize sub-populations that have a robust response to a clinical intervention. The SAGE-SR could bring efficiency, accuracy, and rigor to clinical trials. With the inclusion of the most appropriate participants for a clinical trial, the signal-to-noise-ratio will be improved.

Citations