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Title: The Electronic Self-Report of the C-SSRS (eC-SSRS) Shows Sensitive & Reliable Performance, Reducing Burden on Subjects & Sites

Methodological question: How does the tablet version of the ecssrs perform in use with respect to subject and site burden and followup on reports by sites? Will that work.

Abstract

Introduction (Aims): With the substantial global burden imposed by suicide, it is paramount to utilize tools for measuring suicidal ideation and behavior (SIB) that are of the utmost sensitivity and reliability. The Columbia Suicide Severity Rating Scale (C-SSRS) (interviewer completed) and electronic C-SSRS (eC-SSRS) (self-report) are sourced by the FDA in the SIB Industry Guidance as recommended assessments since they directly classify into 11 preferred [Columbia Classification Algorithm for Suicide Assessment (C-CASA)] categories for measurement of SIB. The eC-SSRS has been shown to have more reports of lifetime SIB (21.1%) than the C-SSRS (15.5%) (Hesdorffer et al, 2013), which may be due to increased patient candor/comfort in disclosing SIB events and severity via a self-reporting medium. The original interactive voice response (IVR) eC-SSRS and a newer tablet eC-SSRS were shown to be equivalent. This study reports parameters of performance of the tablet-based eC-SSRS.

Methods: Over 2,000 subjects in a trial for substance abuse disorder completed the tablet-based eC-SSRS assessment, resulting in over 13,000 administrations using the tablet device. Data from lifetime and since last contact (SLC) versions of the eC-SSRS were analyzed, including the time for subjects to complete the assessment. The response times of site staff to view and acknowledge receipt of the report was also assessed.

Results: Data from the tablet version of the e-CSSRS showed that positive SIB reports were more prevalent in Lifetime (5.4%) than Since Last Contact (0.1%) assessments ($p < 0.0001$). There was a minimal burden for patients to complete the eC-SSRS on tablets with mean $\pm$ standard deviation completion times of 1.94 ± 2.38 minutes for the lifetime and 0.86 ± 1.28 minutes for the SLC versions, respectively. The completion times for patients who scored positive for SIB were 6.49 ± 5.38 minutes and for patients who scored negative for SIB were 0.90 ± 1.29 minutes on the tablet eC-SSRS. With branching logic programmed onto devices, patients responding positively for SIB are asked additional questions and hence appropriately demonstrate longer completion times than patients responding negatively for SIB. Site staff acknowledged all eC-SSRS reports with 99.8% of reports acknowledged within 30 minutes from patient completion.

Conclusions: Overall, these findings demonstrate that the eC-SSRS tablet version has sensitive and reliable performance. Positive scores (0.6%) were identified out of ~13,000 administrations with minimal burden on site staff and rapid acknowledgment of reports by site staff. Subject completion times are short and reflect the number of questions needed to accurately complete this FDA Guidance-recommended SIB assessment. The eC-SSRS represents a powerful methodology for rigorous assessment of SIB using a tool in which patient candor is maximized through self-report. The C-SSRS is sensitive and effective for measuring both efficacy (Ionescu, et al, 2016) and safety and its use has been shown to reduce suicidal ideation and behavior (serious adverse events) through prospective systemic monitoring. These assessment attributes combined with the performance data described herein for the eC-SSRS illustrate that its use enables streamlining of study conduct, reduces site/subject burden, improves care delivery, and optimizes services utilization.

Disclosures: Drs. Durand, Yamamoto, and Dallabrida and Ms. Lima & Mr. Christopher are employees of ERT. Dr. Yershova is an employee of Columbia University/New York State Psychiatric Institute.

References

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