Qualitative Analysis of The Content Validity of The Virtual Reality Functional Capacity Assessment Tool (VRFCAT) in Schizophrenia: An FDA-Funded Study

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SUBMISSION DETAILS

What is the Methodological Question Being Addressed? Does the VRFCAT demonstrate acceptable content validity, in terms of its functional relevance as perceived by schizophrenia patients, peer clinicians, and caregivers, to serve as an endpoint in clinical trials?

Introduction FDA has required studies targeting cognitive impairment in schizophrenia to demonstrate functional relevance of any cognitive improvements by using a co-primary measure of functional capacity. The VRFCAT is a performance-based measure that uses a realistic simulated environment to create a series of everyday tasks. FDA recently accepted the VRFCAT into its Clinical Outcome Assessment (COA) Qualification Program as a co-primary measure for schizophrenia. For a full Qualification Package, FDA requires data supporting the COA's content validity, including qualitative evidence that key stakeholders view the measure as relevant and important in the target population. We present preliminary findings from an FDA-funded study designed to obtain qualitative data on the VRFCAT.

Methods First, we convened a panel of academic, industry, and regulatory experts to develop a semi-structured interview to elicit stakeholders' views about (a) the definition of independence and associated behaviors, and (b) the functional relevance of the domains assessed by the VRFCAT (meal planning, transportation, using currency, shopping). Second, individuals from three groups were interviewed: outpatients with schizophrenia (n = 24), family members (n = 12), and peer support specialists (n = 12). The interview contained questions about general perspectives on functional independence and related activities. Representative audiovisual clips depicting the four domains assessed by the VRFCAT were presented, followed by questions about their relevance to independence. Third, a codebook was developed for thematic analyses of transcripts from recorded interviews.

Results Interviews were acquired from the stakeholder subsamples. Preliminary analyses provided confirmation of the relevance of VRFCAT-depicted skills to maintenance of independence, with divergence among stakeholders in perceptions of how the domains relate to independence. Caregivers saw these domains as important for minimizing dependence on the caregiver, whereas peer clinicians saw these functional domains as essential for pursuing higher-order goals (e.g., work). Patients emphasized practical aspects of functional skills, such as the avoidance of theft or loss.

Conclusion Preliminary analyses suggest that key stakeholders view the VRFCAT as assessing four domains that are important for everyday functioning and independence. Incorporating views from multiple stakeholder groups can provide complementary evidence when assessing the content validity of a functional capacity measure in an indication like schizophrenia. Pending further

analyses, the VRFCAT may fulfill FDA's requirement for a valid, reliable, and practical co-primary measure to determine whether new drugs have a meaningful impact on cognition and on the lives of people with schizophrenia.

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Guidelines I have read and understand the Poster Guidelines

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