TRENDS IN ANTIDEPRESSANT UTILIZATION, AND ASSOCIATED LABOR MARKET PARTICIPATION AND QUALITY OF LIFE OUTCOMES IN THE UNITED STATES: 2004–2007

Lin HC\(^1\), Erickson S\(^2\), Smith D\(^1\), Bakirzihani R\(^2\)

\(^1\)University of Michigan, Ann Arbor, MI, USA; \(^2\)University of Michigan, College of Pharmacy, Ann Arbor, MI, USA

OBJECTIVES: Innovative antidepressants have been widely adopted. However, the differences in patient factors and antidepressant use, and associated patient physical and mental health status.

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METHODS: A retrospective cross-sectional study was conducted using the 2004–2007 Medical Expenditure Panel Survey (MEPS) database. Proportional hazard duration models were used to examine MDD patient's employment duration.

RESULTS: Cox proportional hazard model showed that, compared to uninsured patients (β = 0.36, P < 0.05). Higher antidepressant adherence was associated with higher MDD-specific drug expenditure (β = 0.01, P < 0.01). Use of innovative antidepressants such as SSRIs and SNRIs was associated with an increase in MDD-specific drug expenditure.

CONCLUSIONS: Differences in antidepressant adherence and health care spending across patient factors could have important policy implications for drug formulasaries and health disparities. Solutions for gaps between optimal mental health care for patient mental health caused by systematic differences in sociological factors need to be well tailored.

We need policy makers to be engaged in designing effective policy interventions to improve patient medication adherence, and to fund cost-effectiveness studies to improve patient outcomes and in turn, reduce associated health expenditure.

A SHORT 12-ITEM ZARIT BURDEN INVENTORY FOR THE ASSESSMENT OF DEMENTIA CAREGIVERS AS OBTAINED BY ITEM RESPONSE THEORY

Baillieures A\(^1\), Santos B\(^1\), Gonzalez-Fraile E\(^2\), Muñoz-Hermoso P\(^3\), Dominguez-Pachón A\(^3\), Martín-Carrasco M\(^4\)

\(^1\)University of the Basque Country, UPV/EHU, CIBERSAM, Leioa, Spain; \(^2\)Instituto de Investigaciones Psiquiátricas IRIB, Bilbao, Spain; \(^3\)Hospital Atla Menni, Arrasate-Mondragón, Spain; \(^4\)Clinic Psiquiátrica Padre Menni, Pamplona, Spain

OBJECTIVES: The Zarit Burden Inventory (ZBI) is a 22-item self-report scale frequently used to assess patients’ caregiver burden on several dimensions. As a multi-dimensional instrument the interpretation of its total score is sometimes unclear. Our aim was to obtain a short-ZBI unidimensional scale based on Item Response Theory (IRT) approaches.

METHODS: The validation sample comprised 246 caregivers of patients diagnosed with dementia and recruited for an ongoing multi-center randomized clinical trial on the efficacy of psychosocial interventions (EDUSA-2 trial). The pre-randomization 22-item ZBI was analyzed according to the Samejima’s graded response model to select the more informative items.

The dimensionality of the scale was further tested with Confirmatory Factor Analysis (CFA). Finally, criterion validity was assessed by Receiving Operating Characteristic (ROC) analysis and the Area Under the Curve (AUC) contrasting the short scale total score against the psychological distress criterion evaluated with the General Health Questionnaire 28-item or short-cut ZBI. It covered 87% of the total 22-item ZBI information and showed appropriate item curve characteristics according to the Samejima’s model. The short-ZBI had an internal reliability of 0.89 (Cronbach’s alpha), and was compatible with a unidimensional latent structure for the latent construct (CFI = 0.99, RMSEA = 0.05). According to the GHQ-28 cut-off 131 caregivers (53% of the total sample) could be considered at high risk for developing psychological distress. The discriminant validity of the short-ZBI scale against that criterion was good (AUC = 0.84, 95% CI = 0.79 to 0.89) and not significantly different from the parental 22-item ZBI (p = 0.85).

CONCLUSIONS: We have found good psychometric properties for the short-ZBI scale derived from IRT. Its unidimensionality might be important to enhance its interpretation. Further psychometric studies, mainly on its sensitivity to change are now warranted.
METHODS: Patient relevant endpoints of treatment (remission of depression, response to treatment, no relapse, serious adverse events, adverse events, social function, anxiety, pain, cognitive function) were prioritized using pairwise comparisons of these outcomes. In two separate groups, twelve patients and seven experts judged on a 9 point scale the relative importance of pairs of two outcome measures. The geometric mean of these judgments was used to derive weighting factors for the outcome measures (scale 0–1). RESULTS: Of all outcome measures, patients rated response to treatment highest (0.32), while experts rated remission of depression highest (0.48). Adverse events were all rated lower by patients as well as by experts, and diseases specific quality of life domains such as social function (0.11 & 0.09), anxiety (0.12 & 0.05) and cognitive function (0.13 & 0.06) were rated between in. CONCLUSIONS: The most important outcome measures according to the patients are, in order of decreasing importance: response, cognitive function, no anxiety, social function, relapse, no adverse events, and remission. The AHP appears to be suitable in gaining an overview of the importance of patient relevant outcome measures. An additional advantage of AHP is that the group discussions offer insight in the question why the endpoints are important.

THE SUBJECTIVE WELL-BEING UNDER NEUROLEPTIC SCALE SHORT FORM (SWN-K20) AND THE SF-36 AS QUALITY OF LIFE MEASURES IN SCHIZOPHRENIC PATIENTS
Sanjuan J1, Pernas F2, Martin J3, Diaz T4, Bilbostegos J5
1University of Valencia, CIBERSAM, Valencia, Spain; 2Parc Sanitari Joan de Deu, CIBERSAM, Sant Boi de Llobregat, Spain; 3AstraZeneca, Madrid, Spain; 4AstraZeneca, Zaventem, Brussels, Belgium; 5University of the Basque Country, UPV/EHU, CIBERSAM, Lezo, Spain

OBJECTIVES: Outcomes research in patients with schizophrenia should take into account the subjective interpretation of the mood and physical changes accompanying medication. Those changes influence the behavioural response to treatment and ultimately the patient’s clinical outcome as mediated by his treatment compliance. Our aim was to assess the relationship between a specific well-being measure, the SWN-K20 that presents a general and 5 specific measurement subdomains (mental functioning, social integration, emotional regulation, physical functioning, and self-control), and the 9 domains of the SF-36 v1 as a general quality of life measure. METHODS: The validation sample for this study comprised 97 patients diagnosed with schizophrenia and who were rated as clinically stable at the moment of the study (1 week test-retest intraclass correlation coefficient for clinical symptoms = 0.96). The patients were recruited from a multicenter psychometric trial to validate the SWN-K20 in Spanish. The associations between the domains of the SWN-K20 and the SF-36 were evaluated by the Spearman’s rank correlation test. RESULTS: All correlations among domains were positive and most were statistically significant (p < 0.05). As expected the bodily pain domain of the SF-36 presented the lower correlations with the SWN-K20 (rho range of 0.10 to 0.25), whereas the other 7 domains correlated significantly with the SWN-K20 (rho range of 0.49 to 0.60, all p < 0.001). Overall the largest correlations were obtained between the SWN-K20 and the SF-36 domains of general health (rho = 0.53), mental health (rho = 0.60), and vitality (rho = 0.54). CONCLUSIONS: The positive but nevertheless moderate correlations observed between a specific well-being scale, as the SWN-K20, and a general quality of life scale, as the SF-36, supports the inclusion of specific and diagnose-tailored instruments for outcome assessments of patients with schizophrenia.

INNOVATIONS IN COMBINING PATIENT REPORTED OUTCOMES WITH COGNITIVE TESTING DATA TO STREAMLINE AND LEVERAGE REAL-TIME DATA COLLECTION
Curry C
Pfizer Corporation, Boston, MA, USA

OBJECTIVES: Understand features of an electronic device that allow a marked improvement in the quality of collected data; the importance of improved data quality leading to enhanced patient safety and drug labeling, populations best suited for paired PRO and cognitive measurement technologies; important practical considerations for implementation in clinical trials including training and compliance; the potential for using real-time parallel data for adverse event safety monitoring. METHODS: This session will review ePRO and biomarker technology for parallel data collection. The ePRO will emphasize advantages, disadvantages, execution, and ways to leverage these data. The session will review PRO and cognitive testing technologies, including comparisons of devices that combine physiologic measures with a patient interface with systems that use separate PRO input and biometric devices. RESULTS: Assessing the user’s ability to enhance or prohibit reduction of cognitive processing efficiency is an emerging study in the pharmaceutical industry. Case studies examine how the use of cognitive function tests in combination with ePRO can enhance the data collection so drug effects otherwise unidentified can be determined. The speaker will discuss the future of ePRO combined with biometric measurements as a standard of clinical research. CONCLUSIONS: Clinical trial endpoints can involve collection of physiologic and patient-reported outcome data; a combination of subjective and objective data. Electronic forms of information capture assure trial efficiencies including edit checks and a shorter time to database lock. ePRO provides time-stamped, legible and complete data from subjects. Biometric devices capture the physiological measurements. Typically, cognitive data have been collected from patients separately from PRO data during clinical trials, increasing reported burden and risk of error such as transposing manually entering data. The use of ePRO and biometric devices, evolution of data transmission technology, and greater technologic sophistication of providers, provide an opportunity for parallel electronic data capture, simultaneously capturing and transmitting physiologic and PRO parameters in clinical studies.