Abstracts

cross-cultural validity in an international HIV clinical trial. METHODS: The SDM was included in a Phase IIb/III trial to assess symptoms perceived by HIV-1-infected treatment-naïve patients. The cross-cultural validity of 25 language versions of the SDM was assessed using baseline data of 759 patients from 3 treatment arms, each having received zidovudine and lamivudine in addition to one of the following: maraviroc 300 mg QD, maraviroc 300 mg BID (approved dose for treatmentexperienced patients) and efavirenz 600 mg QD. Given the large number of versions, creating relatively homogeneous cultural groups was necessary for analysis. Seven cultural groups were defined according to language and geographical considerations: European Germanic, Polish, European Romance, Occidental English, American Spanish, Bantu and African Indo-European. The cross-cultural validity of the SDM was assessed by applying ordinal logistic regressions to detect Differential Item Functioning (DIF), and using the STATIS approach, which explores distances between item correlation matrices. RESULTS: Most items did not function differentially between cultural groups: only four symptoms showed DIF (fatigue, fevers, feeling anxious and headache) and the greatest cultural differences were observed for fatigue. The African Indo-European versions of the ASDM presented the highest number of differences from the other versions. With the STATIS approach, the Bantu and European Germanic groups were the furthest from the Occidental English but no clear meaningful difference was found in the expressed symptom pattern across cultural groups. CONCLUSION: Considering the substantial heterogeneity of cultures included in the study, these statistical findings, together with the rigorous methodology applied for the linguistic validation of the questionnaire, support the cross-cultural validity of the SDM. These findings also indicate that culture has a limited impact on the symptoms expressed by HIV-1-positive individuals starting antiretroviral therapy.

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COMPLEMENTARY AND ALTERNATIVE MEDICATION USE AND ADVERSE EVENTS IN HIV-INFECTED PATIENTS Ajugo E¹, Yeh R¹, Wattal R¹, GatheJr J², Sansgiry S¹

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OBJECTIVE: An estimated 29% to 91% of HIV-infected patients use complementary and alternative medications (CAM). The objective was to identify the most commonly used CAM by HIV-infected patients and determine the prevalence of associated adverse events (AEs). METHODS: A single-center, prospective, cross-sectional study was conducted from February to July 2007 via convenient sampling. Inclusion criteria were: HIV-positive adults and using at least one CAM in the prior 12 weeks. Patient information (including demographics, CAM use, concomitant medication use, CAM-related AEs, purchasing behavior) was obtained using self-administered questionnaire and personal interview techniques. This study was approved by the institution's IRB and informed consent was obtained prior to enrollment. Descriptive statistics were performed to evaluate trends and assess AE outcomes (SAS Version 9.0). RESULTS: One hundred individuals participated in the survey, with a response rate of 71.9%. Subjects were 45.0(9.9) mean(SD) years, 70% male, 54% Black, 32% Caucasian, 8% Hispanic, and 2% Asian. Fifty-five percent had a current/previous AIDS diagnosis. Forty-eight different CAM were used, and 96% of respondents were taking concomitant antiretroviral medications. The most common CAM consumed were: cranberry juice (72%), vitamin C (37%), green tea (34%), and garlic (8%). Most respondents (87%) purchased herbal medications on their own, and mostly from the grocery store (56%). Sixty-four percent of respondents

did not inform their providers about CAM use. Fifteen percent experienced AEs that were CAM-related. Nausea and vomiting (33%) were the most frequent AEs reported. Eighty-six percent of subjects experiencing AEs neither consulted their physicians nor stopped using CAM that were thought to cause the AE. **CONCLUSION:** HIV-infected patients frequently use CAM concomitantly with traditional antiretroviral medications. Physicians and pharmacists should document and provide adequate education/counseling regarding CAM, especially for HIVinfected patients, to prevent drug interactions and AEs. More studies are needed regarding CAM utilization, safety, and its economic impact.

PIN42

DESIGNING AND TESTING A HIV-PATIENT SATISFACTION SURVEY FOR A COMPARITIVE ANALYSIS OF MAIL-ORDER PHARMACY VS. COMMUNITY PHARMACY SERVICES

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OBJECTIVE: Designing and testing a reliable and valid survey for comparing HIV patients' satisfaction with services provided by mail order with those provided by a community pharmacy. METHODS: Exploratory cross-sectional design using convenience sample of HIV patients at a University Clinic. The satisfaction scale was developed from previously validated instrument ($\alpha = 0.957 \& \alpha = 0.962$ for factor 1 & 2 respectively). This scale was used for all three settings i.e. mail-order, independent, and chain pharmacies. Practicing pharmacists, graduate students, and pharmacy faculty assessed face and content validity. Clinical pharmacists checked for patient ease of understanding, length, and sensitive items. Students evaluated survey completion time. Faculty members determined ease of understanding, time of completion, research soundness, and objective match. Modifications were made followed by data collection for six-weeks. Reliability tests and item analyses were conducted. Data were entered using SPSS v.15. RESULTS: Forty-seven surveys were completed. Item-objective match ranged from 75-90%. Item means ranged from 2.50 to 4.44 for factor 1 and 2.27 to 4.36 for factor 2 for mail-order, 2.33 to 3.93 and 2.85 to 3.85 for independent, and 3.00 to 4.69 and 3.09 to 4.09 for chain. Response variability for most items were above 0.9 using Factor 'V'. Corrected item-total correlations ranged from 0.484 to 0.902 and 0.606 to 0.907 for factor 1 and 2 respectively for mail-order, 0.577 to 0.965 and 0.858 to 0.960 for independent, and -0.35 to 0.862 and 0.599 to 0.932 for chain. None of the items if deleted would increase alpha. Cronbach's alpha for factor 1 were 0.879 for mail, 0.960 for independent, and 0.803 for chain and for factor 2 were 0.950 for mail, 0.983 for independent, and 0.969 for chain. CONCLU-SION: Analysis indicates good face and content validity, and high reliability. Item analyses indicate items are well written and have good response location, variability, and discrimination.

INFECTION—Health Care Use & Policy Studies

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NATURAL HISTORY OF CHRONIC HCV INFECTION OBTAINED THROUGH INJECTION DRUG USE: A BAYESIAN META-ANALYSIS

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OBJECTIVE: To estimate the rate of progression to cirrhosis for those infected with Chronic Hepatitis C virus (HCV) through