BR provided a statistically significant reduction in overall hospitalisations rates and costs versus placebo + BR. Reductions in hospitalisation time indicate significant savings to the health care system and clinical benefit to the patients.

INFECTION – Patient-Reported Outcomes Studies

PIN66

SPILLOVER ADHERENCE EFFECTS OF FIXED-DOSE COMBINATION HIV THERAPY

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OBJECTIVES: Fixed-dose combination (FDC) products consisting of ≥2 antiretrovirals in one tablet improve adherence compared to the same agents taken separately. The impact of FDC products on adherence to other regimen components has not been assessed. We used pharmacy records to evaluate whether an FDC product improves HIV patients' adherence to a 3rd regimen agent. **METHODS:** Data from 1997–2005 were taken from IHCIS Managed Care Benchmark Database, a national sample of 30 health plans covering ~38M lives. We compared adherence to the 3rd regimen component among patients with ≥1 pharmacy claim for the FDC Epzicom (abacavir sulfate 600 mg + lamivudine 300 mg) versus 2 NRTIs as separate pills (SP). Adherence was measured as the medication possession ratio (MPR). Multivariate logistic regression compared treatment groups based on the likelihood of achieving ≥95% adherence, with sensitivity analyses across other adherence thresholds. Multivariate linear regression assessed the effect of treatment group on MPR as a continuous variable. Covariates included age, gender, insurance payer type, year of study drug initiation, presence of mental health and substance abuse disorders, and 3rd agent class. **RESULTS:** The sample consisted of 650 FDC and 1947 SP patients. Unadjusted mean adherence to the 3rd agent was higher in the FDC than the SP group (0.92 vs 0.85; $p < 0.0001$). Adjusting for covariates, FDC patients were 48% and 39% more likely to achieve 95% and 90% adherence to the 3rd agent, respectively ($p < 0.05$ for each). These results did not hold for other MPR specifications. **CONCLUSIONS:** For patients enrolled in managed care plans, use of an FDC appears to substantially improve adherence to a 3rd agent and the likelihood of achieving the accepted standard for adherence to HIV therapy of 95%. FDCs may improve overall adherence by increasing adherence to both the backbone and the 3rd component of the regimen.

PIN67

QUALITY OF LIFE AND HEALTH CARE UTILIZATION BURDEN OF HCV-INFECTED PATIENTS IN EUROPE

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OBJECTIVES: This study is to assess the hepatitis C (HCV) burdens on health-related quality of life (HRQoL) and resource utilization in Europe. **METHODS:** Data from 2006 to 2008 National Health and Wellness Survey (NHWS) in France, Germany, Italy, Spain, and UK were applied. Responders were representative adults. Those with self-reported hepatitis C were categorized as cases. Propensity-matched non-hepatitis survey responders were selected as controls based on country, gender, age, education, employment, and year of survey. HRQoL was collected from both SF-8/SF-12 and Work Productivity Activity Impairment (WPAI) standard instruments. The numbers of physician and emergency room (ER) visits were also collected. Conditional logistic regression was applied controlling for AIDS/HIV status, health status measured by the Charlson Index less hepatitis C, marital status, smoking status, alcohol consumption, and body mass index. **RESULTS:** The final sample included 864 cases and 864 closely matched controls. Sixty-one percent were male with mean age of 49.8 years. HCV patients reported significantly impaired HRQoL scores on both SF-8/SF-12 mental score and physical score ($P < 0.01$). Work productivity was also reported lower for cases although not statistically significant due to limited number of employed patients. In the six months prior to the survey, HCV patients, compared to controls, were significantly more likely to have an ER visit (OR = 1.497, 95%CI: 1.092–2.051), significantly more likely to visit an internist (OR = 2.297, 95%CI: 1.413–3.736), gastroenterologist (OR = 1.997, 95%CI: 1.285–3.104), nephrologist (OR = 3.149, 95%CI: 1.142–8.682), or other medical specialist (OR = 1.434, 95%CI: 1.054–2.050). Overall HCV patients reported 2.34 more medical visits than controls (95%CI: 1.1613–3.5315) in the past six months. **CONCLUSIONS:** HCV infected patients in Europe reported significantly lower HRQoL than non-HCV infected subjects, and were more likely to have ER and physician visits.

PIN68

PSYCHOMETRIC EVALUATION OF THE FUNCTIONAL ASSESSMENT OF HIV INFECTION (FAHI) QUESTIONNAIRE IN TWO CLINICAL PROGRAMMES

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OBJECTIVES: To evaluate the psychometric properties of the Functional Assessment of Human Immunodeficiency Virus Infection (FAHI) questionnaire, a 47-item disease-specific instrument evaluating Health-Related Quality of Life (HRQL) in Human Immunodeficiency Virus (HIV) patients, and show its usefulness for the evaluation of new antiretroviral therapy. **METHODS: Treatment-experienced HIV patients included** in two independent clinical programmes completed the self-administered FAHI questionnaire at Baseline and after 24 weeks of treatment. The FAHI questionnaire includes five scales (physical well-being, emotional well-being, functional and global well-being, social well-being, cognitive functioning) and a total score, with higher scores indicating better HRQL. Psychometric properties of the FAHI questionnaire were assessed independently in both trial populations (N = 565, 1096). A range of minimal important differences (MID) was provided using anchor-based and distribution-based methods. The link between HRQL and biological endpoints was explored by regression analysis. **RESULTS: Internal consistency reliability was good, with** Cronbach's alphas ranging from 0.72 to 0.94. Most items met both convergent and discriminant validity criteria, demonstrating good construct validity of the scores. Clinical validity was demonstrated by better FAHI scores, indicating better HRQL for patients in earlier HIV stages. Changes in scores were significantly linked to the change in EQ-5D score, demonstrating their responsiveness. MID ranged from 3.2 to 14 for the FAHI Total score. Regression analyses between the FAHI Total score and CD4 cell count and viral load showed a poor relationships between HRQL and biological parameters (r-square <3%). **CONCLUSIONS: The FAHI questionnaire demonstrated** robust psychometric properties in two independent clinical trial populations. The assessment of HRQL enabled the detection of changes in patients' health status not revealed by traditional clinical parameters of efficacy.

PIN69

A PATIENT SATISFACTION QUESTIONNAIRE FOR ASSESSING PHARMACEUTICAL CARE SERVICES IN NIGERIAN HIV CLINICS

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OBJECTIVES: To develop and validate a questionnaire for assessing patient satisfaction with pharmaceutical care received in Nigerian HIV clinics. **METHODS:** Questionnaire's items were selected from similar published studies and designed as 5-point Likert response scale. Face and content validity, feasibility, factorial validity, reliability, discriminant and convergent validity were evaluated. The instrument's feasiblity was assessed in a secondary health care facility (St. Charles Borromeo Hospital Onitsha) and validated in a tertiary health care facility (University of Nigeria Teaching Hospital Enugu). Factor analysis used principal components and varimax rotation. Reliability was established using internal consistency with Cronbach's alpha. Convergent and discriminant validity were determined using Spearman's rho correlation. **RESULTS:** A self-administered questionnaire with 16 items, 5-point Likert response scale and demographic questions was designed. Questionnaire evaluates cumulative experience of patients with comprehensive pharmaceutical care practice in pharmacies of HIV clinics. Seventy questionnaires were collected for pilot test while four hundred questionnaires were retrieved for the validity test. Factor analysis resulted in four factors: relationship, patient counseling, drug information and patient care, with a cumulative variance of 56.7%. Cronbach's alpha for the whole questionnaire was 0.85, and 0.81, 0.66, 0.67 and 0.72 for the 4 factors, respectively. Four items used for convergent and discriminant validity showed convergence between the related items and variance between the unrelated items. **CONCLUSIONS:** The questionnaire developed can be a reliable and valid instrument to assess patient satisfaction with pharmaceutical care in HIV clinics in Nigeria. Further research is needed to re-validate the instrument.

PIN70

PERCEPTION AND ACCEPTANCE OF INTRADERMAL INFLUENZA VACCINE MEASURED BY THE VACCINEE'S PERCEPTION OF INJECTION (VAPI©) QUESTIONNAIRE

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OBJECTIVES: During the clinical development of a new intradermal influenza vaccine given using a microinjection system, in parallel with the conventional evaluation of vaccine reactogenicity, perception and acceptability of injection site reactions (ISR) were assessed using the VAPI© self-administered questionnaire developed and validated as previously described (Chevat et al, Health and Quality of Life Outcomes 2009, 7:21). **METHODS: The questionnaire was specifically developed and validated** according to recommended methods to assess vaccinees' perception of ISR. It was completed 21 days after intradermal or intramuscular vaccination by elderly and non-elderly participants in two European, randomised, controlled, phase 3 trials. It was divided into 4 dimensions: "bother" (6 items), "arm movement" (4 items), "sleep" (4 items), "acceptability" (2 items), and 5 individual items: anxiety before and after vaccination, bother by pain during injection, satisfaction with injection system and willingness to be vaccinated again. Scores range from 1 to 5 (1 being the most favourable opinion). **RESULTS: Of the 5,562 trial participants, 5,305 returned the questionnaire** with at least one item completed. Mean scores were low (≤1.68 in non-elderly, ≤1.48 in elderly) in both vaccine groups, indicating that ISR did not bother participants or affect their sleep or arm movement (at least 75% were not at all affected). In the ID group, among those who answered the questions, 96% of non-elderly and 97% of elderly participants considered ISR caused by vaccination as being "totally" or "very" acceptable; 96% of both non-elderly and elderly participants were "very satisfied" or "satisfied" with the injection system; and 85% of non-elderly and 89% of elderly participants wanted to be vaccinated again. **CONCLUSIONS: ISR were** well accepted by participants, and were generally not a cause for concern. The level of satisfaction of the participants with the injection system was high, as was the willingness to be vaccinated again.