depression (3.5%) was mostly unchanged (Baseline-Wk8; P = 0.059). Clinical depression (patient-reported) was associated with increased bothersomeness of other symptoms (fatigue, loss of appetite, nervousness) at Baseline & Wk8 (P < 0.05). CONCLUSIONS: Patient-reported depression outcomes should be valued during HIV treatment, as more patients who were virologically controlled but experiencing Grade 2 PI/NNRTI-associated side effects self-reported signs of clinical depression than were diagnosed by physicians. Prevalence of clinical depression was reduced following substitution to LPV/r.

ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE MEASURES IN HIV AND AIDS
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OBJECTIVES: The widespread use of highly active antiretroviral therapy (HAART) has greatly prolonged life expectancy in patients with HIV. Therefore, health-related quality of life (HRQoL) has become an increasingly important endpoint in clinical trials to assess interventions for people with HIV. We reviewed the HRQoL measures that have been used in HIV/AIDS since 1990 to establish the most appropriate measures to use in future research and clinical trials. METHODS: A comprehensive, unbiased review of generic and HIV-specific HRQoL measures was conducted using predefined selection criteria. Generic and HIV-specific measures were assessed for practicality (length, administration time and mode). Generic measures were also assessed for their ability to elicit utility data and provide normative values. Measures of HRQoL that were considered practical and were capable of producing utility data and normative values (generic measures) were assessed in detail in terms of their psychometric properties, patient derived content (HIV-specific measures), and use in clinical trials. RESULTS: Two generic measures (Euroqol five Dimension [EQ-5D] and Medical Outcomes Study [MOS] Short Form 36 [SF-36]) and six HIV-specific measures met the initial selection criteria and were reviewed in full. EQ-5D and SF-36 were very similar in terms of the selection criteria and two HIV-specific measures (Functional Assessment of HIV Infection [FAHI] and MOS-HIV) were selected on the basis of their superior psychometric properties. CONCLUSIONS: We recommend using either the EQ-5D with the MOS-HIV, or the SF-36 with the FAHI to assess HRQoL in HIV/AIDS patients when planning future research. Administration of these measures in combination would enable utility scores to be calculated, patient scores to be compared with normative data, and disease-specific HRQoL to be assessed. Future research should concentrate on the sensitivity of the different measures at each stage of infection in patients on HAART.

VALIDATION OF 5-ITEM SYMPTOM SURVEY IN PATIENTS WITH ACUTE BACTERIAL SINUSITIS
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OBJECTIVES: To validate a symptom assessment instrument for patients with acute bacterial sinusitis (ABS). METHODS: Data were obtained from a randomized, double-blind, equivalence study of adults with radiographic evidence of ABS treated with telithromycin 800 mg od for 5 days (n = 159) or moxifloxacin 400 mg od for 10 days (n = 163). A 5-item Acute Sinusitis Daily Symptom Survey (ASDSS) was developed for use in the trial. The five items of the ASDSS (nasal congestion, runny nose, postnasal discharge, thick nasal discharge, and facial pain/pain) used a six-point adjectival scale ranging from zero (“no problem”) to five (“problem as bad as it can be”). Overall ASDSS score was the sum of item responses. Subjects completed the ASDSS daily for the first 17 days of the study. At Visits 1 (Day 1) 2 (Day 3–5), and 4 (Day 17–24), subjects were assessed for quality of life (SF-36, acute form), treatment outcomes (success/failure), and infection-related signs/symptoms. Data were pooled across treatment groups. RESULTS: Survey completion rates ranged from 100% (Day 3) to 79.8% (Day 17). Pearson correlations between the ASDSS items ranged from 0.258 to 0.639. Test-retest intraclass correlation coefficients (ICC) measured over a 5 day interval (Day 1–5) were: nasal congestion (0.681), runny nose (0.612), postnasal discharge (0.689), thick nasal discharge (0.669), and facial pain/pain (0.679). Cronbach’s alpha was 0.788 and test-retest reliability (ICC) of the total score was 0.694. Pearson correlations between ASDSS and the SF-36 scales at Visit 4 ranged from −0.293 (mental health) to −0.496 (vitality). Pearson correlations with the ASDSS at Visit four were 0.599 for major and 0.634 for minor symptoms of infection. Mean ASDSS scores at Visit four were 3.34 for subjects deemed treatment successes and 10.35 for treatment failures (F = 2.60, p < 0.0001). CONCLUSIONS: The ASDSS appears to be a valid symptom assessment instrument for patients with ABS.

WILLINGNESS TO PAY FOR PREVENTION AND TREATMENT OF TUBERCULOSIS (TB) IN RURAL NEPAL: A CONTINGENT VALUATION STUDY
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OBJECTIVES: In the mountain kingdom of Nepal, nearly 44,000 new cases of the tuberculosis (TB) appear every year. This study explores community valuation of TB prevention by estimating household and community willingness to pay (WTP) for the prevention of transmission and treatment of TB in the rural areas of mid-Nepal. METHODS: A contingent valuation survey was used to assess individual WTP for specific prevention and treatment interventions for TB. In order to estimate confidence limits in mean WTP and to generate a distribution of WTP for the community, accounting for uncertainty in regression coefficients and variability within the population, a two-dimensional Monte Carlo simulation was also developed. RESULTS: The study results show a mean WTP of $0.81 per month per household (90% CL: $0.43, $1.61) to prevent transmission of TB. However, the mean WTP for TB treatment was estimated to be $2.31 per month (90% CL: $1.32, $3.47) per household. Nearly 22% and 47% of household were not willing to pay for prevention and treatment of TB, respectively. As expected, income positively affected estimates of mean WTP for both TB treatment and prevention. An individual’s familiarity with TB and superstitions significantly negatively influenced WTP for treatment and prevention. Contrary to expectation, WTP for TB treatment and prevention was not influenced by religion and ethnicity in the rural villages of Nepal. In our study, sex and health education do not show any significant affects on WTP for transmission prevention and treatment interventions of TB. CONCLUSIONS: These results show that the majority of the community places a positive value on both prevention and treatment of TB.
WTP provides monetary estimate of over all benefit of TB prevention and treatment program. The study results suggest socio-economic factors and knowledge about TB as major determinants of WTP.

**PIN28**

ASSESSMENT OF BODY CHANGES AND DISTRESS (ABCD) LIPODYSTROPHY QUESTIONNAIRE: CULTURAL ADAPTATION AND PSYCHOMETRIC VALIDATION IN FRENCH

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OBJECTIVES: Lipodystrophy may have a great impact on patients’ quality of life (QoL). Current HIV specific instruments do not measure this impact. We performed a cultural adaptation and psychometric validation in French of a new lipodystrophy specific instrument Assessment of Body Change and Distress (ABCD). METHODS: ABCD consists of three parts: signs of lipodystrophy (6 items), global satisfaction (1 item) and 20 QoL items. Items were generated in US. Our study consisted of two parts: 1) Cultural adaptation; 2) Psychometric validation in a survey in comparison with specific (MOS-HIV) and generic (SF-12) QoL questionnaires. RESULTS: The approach of French patients was to some extent different from US patients, and needed cultural adaptation of several concepts. A total of 155 HIV French outpatients (143 with lipodystrophy) from 2 Parisian hospitals and one general practice were included. Mean age was 43 ± 10 yrs. Mean duration of HAART was 4.5 ± 1.7 yrs. Discriminant validity: QoL scores decreased according to the number of sites with lipodystrophy, ranging from 85 ± 16 (none) to 42 ± 10 (6 sites), p < 0.001, and according to whether patients were thinking about plastic surgery or not, from 68 ± 20 (never) to 33 ± 13 (always), p < 0.001. Internal consistency was high (Cronbach alpha = 0.94). Factorial analysis yielded a 4-factor structure. Convergent validity: the highest correlations were between ABCD QoL and health distress and social dimensions of the MOS-HIV (r > 0.6) and with the mental component of the SF-12 (r = 0.65). CONCLUSIONS: The psychological and social distress related to the body changes must be measured in clinical trials, to make sure that life is not lengthened at the expense of its quality. ABCD questionnaire is a validated questionnaire which can now be used in French.

**INFECTION (including HIV, CAP)**

**INFECTIONS (including HIV, CAP)—Health Policy**

**PIN29**

ECONOMIC EVALUATION OF MENINGOCOCCAL C VACCINATION PROGRAMMES AND ITS IMPACT ON DECISION MAKING

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OBJECTIVES: Investigate the role economic evaluations played in supporting decision making for meningococcal C conjugate (MCC) vaccination. METHODS: We performed an extensive literature review (PubMed, Embase, HEED, NEED) and contacted experts to identify a) the incidence of meningococcal C disease, and b) economic evaluations for MCC immunisation programmes and their influence on decision making. RESULTS: Data were obtained for Australia, Canada, Israel, the US and 17 European countries. The yearly meningococcal C incidence per 100,000 persons varied between 0.04 (Italy) and 4.91 (Iceland) in 2001. Ten countries have implemented MCC vaccination programmes. In all of them except Greece high meningococcal C incidence was reported between 1999 and 2001 (one year ≥0.8 per 100,000) but economic evaluations were performed in only four. While economic evaluation influenced decision making strongly in Australia, Canada (Quebec) and The Netherlands, its impact was limited in the UK. Of the 11 countries without MCC vaccination programmes, only Portugal and Switzerland conducted economic evaluations. These were performed after the initial decision to not implement MCC vaccination was made, but nonetheless (may) inform subsequent decision making in both countries. All reviewed economic evaluations were modelling studies, each showing that routine childhood MCC vaccination is slightly less effective but much more cost-effective early in the second year of life (about 2500€ to 19,000€ per life-year or QALY gained) than during the first year of life (about 42,400€ to 2.4m€ per additionally gained life-year or QALY compared to immunisation in the second year). The reported results were most sensitive to meningococcal C incidence, vaccine price and specific methodological characteristics. CONCLUSIONS: Only in a minority of investigated countries economic evaluation of MCC vaccination influenced decision making. The divergence and importance of methodological characteristics in the analysed studies demonstrates the need of firmer international guidelines and better adherence to these guidelines.

**PIN30**

FREQUENCY OF POTENTIAL DRUG-DRUG INTERACTIONS WITH TRIAZOLE ANTIFUNGAL USE IN DUTCH HOSPITAL SETTINGS

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Some of the expected adverse drug reactions of the systemic triazole antifungals (fluconazole and itraconazole) can be attributed to drug-drug interactions. OBJECTIVES: To quantify the frequency of concurrent drug use that may cause drug-drug interactions (DDI) with triazole antifungals. METHODS: A retrospective observational study was conducted of adult patients who received systemic triazole treatment in 6 hospitals comprising the PHARMO Inpatient database during 1994–2002. The list of triazole interacting drugs, the severity and effect of interaction was obtained from the Drug-Reax® system and the Drug Interaction Facts. Concomitant use of triazole interacting drugs was identified for each day of systemic triazole treatment. RESULTS: The study cohort comprised 1374 patients with a total of 1522 hospitalizations during which fluconazole (n = 1329) or itraconazole (n = 193) were prescribed. The majority of hospitalizations were for neoplasms (21.6%), respiratory (15.2%) and digestive disease (14.3%). The median duration of triazole treatment was eight days. Among patients receiving fluconazole, 55.3% were prescribed at least one interacting drug (>95% with potential for moderate or severe consequences) with 32.5% of patients receiving more than one interacting drug. The most frequently co-prescribed interacting drugs with fluconazole were haloperidol, digoxin, prednisolone, acenocoumarol and theophylline. Among patients on itraconazole, 65.3% received at least 1 interacting co-prescription (74% moderate or severe), 41% received more than one interacting drug. The most frequently co-prescribed interacting drugs with itraconazole were ranitidine, acenocoumarol, prednisolone, pantoprazole and theophylline. The most frequent occurring effect of the DDI