IN1

ANTIBIOTIC PRESCRIBING VIA TELEPHONE: HOW OFTEN DOES IT OCCUR?

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OBJECTIVES: Antibiotic prescribing via telephone may be associated with inappropriate antibiotic use and potential bacterial resistance, although limited data exist regarding this practice. The purpose of this analysis was to examine the prevalence and patterns of telephone antibiotic prescribing. METHODS: Patients’ antibiotic prescription data were retrieved from a large, Mid-Atlantic health system outpatient electronic medical record from 2006-2010. Antibiotic prescriptions were categorized as initiated by telephone or office visit and by antibiotic classifications. Antimicrobial use was restricted to azithromycin and ceftriaxone. Data were analyzed to identify patient and pharmacy characteristics associated with antibiotic prescriptions via telephone. RESULTS: Of 447,403 antibiotic prescriptions, 5,103 (1.1%) were written via telephone. When stratified by antibiotic class, ceftriaxone prescriptions occurred most frequently (366/3,572, 10.3%) followed by azithromycin (2,435/21,382, 11.4%). Telephone use was associated with higher median baseline CD4 cell count. CONCLUSIONS: Telephone prescribing is a common practice for antibiotics with a lower cost profile and is associated with high median baseline CD4 cell count.

IN2

COMPARATIVE EFFICACY AT 48 WEEKS OF ATAZANAVIR/RIPTONAVIR VERSUS DURANAVIR/RIPTONAVIR IN TREATMENT NAIVE HIV-1 PATIENTS: A MATCHING ADJUSTED INDIRECT COMPARISON OF RANDOMIZED TRIALS

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OBJECTIVES: No large, randomized head-to-head comparison of atazanavir/riptonavir (ATV/RTV) and darunavir/riptonavir (DRV/RTV) for first-line treatment of HIV-1 is currently available. This study compares the efficacy of ATV/RTV and DRV/RTV at 48 weeks using a matching-adjusted indirect comparison. METHODS: Two similarly designed randomized trials were identified. Individual patient-level data were available for the CASTLE trial comparing ATV/RTV (n=430) vs. lopinavir/rtv (LPV/r) (n=438), each in combination with tenofovir/emtricitabine (TDF/FTC); published summary data were available from the ARTENS trial comparing DRV/RTV (n=343) vs. LPV/r (n=346), each in combination with TDF/FTC. To adjust for cross-trial differences, CASTLE patients were re-weighted to match summary baseline characteristics, and was compared between balanced ATV/RTV and DRV/RTV trial populations after matching. As a negative control, outcomes in the two LPV/r arms were compared. RESULTS: Time to virologic response (HIV-1 RNA <50 copies/mL) occurred in approximately one in eight antibiotic prescriptions and varied by antibiotic class and de novo infection status. The most commonly prescribed antibiotic classes overall with macrolides and quinolones. CONCLUSIONS: Prescribing via telephone occurrence in one in eight antibiotic prescriptions and varied by patient and pharmacy characteristics associated with telephone antibiotic prescribing in this population support the need for further study of its impact on antibiotic resistance.

IN3

THE INFLUENCING OUTCOMES FROM A DYNAMIC TRANSMISSION MODEL FOR VARICELLA VACCINATION TO COST-EFFECTIVENESS ESTIMATES: THE IMPACT OF DIFFERENT ANALYTICAL APPROACHES ON THE RESULTS

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OBJECTIVES: To investigate the varicella vaccine effectiveness and economic evaluation of population-based varicella vaccination using a dynamic transmission model. METHODS: An age-structured SIR (susceptible, infected, recovered) dynamic transmission model was developed to predict the impact of routine infant vaccination on varicella incidence. Individuals transmitted between S and I compartments based on age-of-infection data. Each compartment was stratified into 8 age groups to track individuals as they aged over time. Model parameters included age-specific infection rates from whom (WAIFW) matrix structure, vaccine efficacy, vaccine coverage, costs, QALYs, and demographic data were based on published UK data. The model estimated the incremental cost-effectiveness ratio (ICER) for the vaccination programme using three different approaches: 1) a) cumulatively over time (CumPop), 2) for the entire population for the steady-state year (SSPop), and 3) for the lifetime of the first vaccinated birth cohort (HCRU). Costs and QALYs were discounted at 3% per year. HCRUs were compared for the three analyses. RESULTS: The ICER decreased with decreasing vaccination coverage rates and was 4.7k/QALY at 90% coverage and 11k/QALY at 50% coverage.

PODIUM SESSION III: INFECTION DISEASE OUTCOMES RESEARCH

P1R

FDA ACTIONS AGAINST HEALTH ECONOMIC PROMOTIONS, 2002-2011

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OBJECTIVES: To investigate FDA regulatory actions against drug company’s health economic promotions from 2002 through 2011 to understand the types of economic promotions the Agency considers false or misleading. METHODS: We reviewed all warning letters and notices of violation (“untitled letters”) issued by the FDA’s Division of Drug Marketing Advertising and Communications (DDMAC) to pharmaceutical companies between January 2002 and August 2011. We searched for and analyzed letters containing a violation related to “health economic promotions.” RESULTS: Of 280 DDMAC letters sent to pharmaceutical companies during the study period, 34 (12%) cited an economic violation. The most common type (found in 20 letters) was an unsupported implied claim of cost savings due to work productivity; economic claims containing unsupported statements about effectiveness or safety. We also collected information on other factors, such as the indication involved, and whether the letter referenced Section 501(h) of the Federal Food, Drug, and Cosmetic Act. CONCLUSIONS: Economic claims should be supported with meaningful evidence, regulatory reviews should receive consistent enforcement, and the FDA should remove the cited economic promotion standard from Section 501(h).