OBJECTIVES: Azithromycin has an attractive safety profile in treating or preventing certain bacterial infections. However, there is growing concern that Azithromycin may be associated with increased cardiovascular risk and lead to cardiovascular death in high risk patients. We therefore conducted a meta-analysis of randomized Controlled trials to describe the cardiovascular risk profile of those patients receiving Azithromycin. **METHODS:** The MEDLINE and Cochrane Central Register of Controlled Trials databases were searched from 1991 to September 2013 using specific search terms for English-language trials of comparing high baseline risk of cardiovascular disease patients receiving Azithromycin or placebo and have reported cardiovascular outcomes. Abstracts from major scientific meetings were also reviewed.In the analysis, Methods based on odds ratios (ORs) was used. OR was calculated using a random-effects model (because we assume that the treatment effect in all the included studies are not identical) from the ORs and 95% confidence intervals (CIs) were used for each end point in each study. Statistical heterogeneity scores were assessed with an I^2test. Sensitivity analyses were performed by removing some trials and recalculating the combined ORs for the remaining studies. **RESULTS:** 12 trials randomized a total of 15,588 patients into two groups, treatment and placebo. Treatment effect on any cardiovascular outcome was not significantly different in any of the nine trials. For all trials combined, the pooled odds ratio for mortality was not significantly different [(OR, 0.873; 95% CI, 0.743–1.027), p = 0.102]. No heterogeneity was observed (I^2=0). Similarly, there was no difference in the pooled odds ratio for hospitalization and coronary intervention [(OR, 1.021; 95% CI, 0.882–1.182), p = 0.774, I^2=0%] and [(OR, 0.998; 95% CI, 0.885–1.125), p = 0.982, I^2=0%], respectively. **CONCLUSIONS:** The findings of this systematic review suggest that no significant relationships exist between Azithromycin and risk of cardiovascular events in high risk patients.

PIN23

ANTIMICROBIALS: A MAJOR CLASS OF DRUGS CAUSING ADVERSE DRUG REACTIONS IN THE ICUS OF AN INDIAN PUBLIC TEACHING HOSPITAL

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OBJECTIVES: Patients in the intensive care unit (ICU) have multiorgan dysfunction as well as altered pharmacokinetic parameters. Hence, they are more susceptible to adverse drug reactions (ADRs). The objective of the study was to identify the major class of drugs involved in causing ADRs in ICU patients of an Indian public teaching, tertiary care hospital. **METHODS:** A prospective observational study was conducted in the ICUs of a public teaching hospital. All the relevant data was collected from the patients case records in a standard data collection format and the patients were followed until discharge or transferred from the ICUs. ADRs were identified based on the subjective findings, objective findings and spontaneous reporting. The drugs responsible for causing ADR were identified and classified using Anatomic, Therapeutic and Chemical(ATC) classification. **RESULTS:** The results of this 12 week study were based upon the data obtained from 70 patients(37 males, 33 females). Only 10 patients developed ADRs. The drugs causing ADRs were classified using the ATC classification. This showed that the most common ADR causing drugs belonged to the class of infections and infestations (30%), cardiovascular system(14%), endocrine system(14%), respiratory system (14%) and others (14%), followed by Brain and nervous system (7%), blood and blood forming agents (7%) accounting for least number of ADRs. **CONCLUSIONS:** In this pilot study, Antimicrobials was found to be the most common class of drugs causing ADRs. We studied small number of patients, it is suggested that future large scale studies should be done to further gain insight into the ADRs.

PIN24

HIGHER CD4 AT ART INITIATION PREDICTS GREATER LONG TERM LIKELIHOOD OF CD4 NORMALIZATION

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OBJECTIVES: Higher plasma CD4 cell counts per mm^3 at ART initiation (AI-CD4) improve long-term CD4 responses and survival. Recent data suggest CD4 > 750 is a clinically significant threshold for AIDS-related illness reduction and immune "normalization". We evaluated the effect of AI-CD4 on achieving CD4 >750 and mortality risk. **METHODS:** Among HIV Outpatient Study patients seen during 1996-2012 for three or more years after AI, we analyzed CD4 trajectories and mortality rates per 100 persons-years (MR) by AI-CD4, and the association of AI-CD4 with achieving CD4 >750 ("normalization") using Kaplan-Meier methods and Cox proportional hazards models. **RESULTS:** Of 1327 eligible patients followed a median of 7.9 years, > 85% received HAART ≥ 75% of follow-up time, and 64 died. Higher AI-CD4 was associated with increased median peak CD4 ($p < 0.001$). Maximal CD4 response and benefit plateaued at eight years, but differences by AI-CD4 persisted ($p < 0.001$). Lower crude MRs ($p = 0.005$) and higher CD4 closest to death ($p = 0.013$) were associated with higher AI-CD4. Increases in median CD4 for persons with AI-CD4 < 50 and 50-199 converged by eight years (< 50% achieved CD4 > 750) whereas patients with AI-CD4 > 350 normalized by eight years (> 80% of patients). In multivariable analyses, higher AI-CD4 was the only factor independently associated with achieving CD4 normalization during follow-up. **CONCLUSIONS:** Progressively higher AI-CD4 predicted greater long-term CD4 gains, achieving CD4 normalization, increased crude survival rates, and higher CD4 at death. CD4 gains and chances of reaching CD4 normalization peaked at eight years after AI. Most with AI-CD4 >350 eventually achieved CD4 normalization while less than half with AI-CD4s < 50 and 50-199 did. AI-CD4 ≥ 500 optimized the likelihood of CD4 normalization confirming the hazards of delayed and support AI at CD4 ≥ 500.

INFECTION – Cost Studies

PIN25

PUBLIC AND PRIVATE PAYER PERSPECTIVES ON THE NET COST OF IMPLEMENTATION OF 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE (PCV13) COMPARED WITH 7-VALENT PNEUMOCOCCAL CONJUGATE VACCINE (PCV7) TO IN THE UNITED STATES

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OBJECTIVES: In 2010, the US Advisory Committee on Immunization Practices recommended 7-valent pneumococcal conjugate vaccine (PCV7) be replaced by 13-valent vaccine (PCV13) for routine use in a four-dose series at 2, 4, 6, and 12-15 months of age. Published analyses estimated that PCV13 implementation would be cost-saving in aggregate, but the net economic impact on particular payers is unknown. We disaggregated the expected costs and savings by payer to determine the net costs for public and private payers over a 10-year horizon. **METHODS:** A Markov model was used to simulate vaccination and pneumococcal disease events and their related costs with PCV13 compared to PCV7 from 2010 to 2019. The PCV13 strategy included a one-time catch-up dose in 2010 for children who had completed the PCV7 series. Disease reductions both in vaccinated and other age groups were modeled based on PCV7 efficacy and effectiveness data. Medical costs related to pneumococcal disease were allocated to public (Medicare; Medicaid; military) or private payers using age-specific health care insurance coverage survey data. Vaccine program costs were allocated based on sales data. All costs were measured in 2013 US dollars. **RESULTS:** In the simulation, 40.3 million(M) children participated in routine vaccination while 5.8M received a catch-up dose in the PCV13 strategy. The PCV13 strategy prevented an additional 121,300 cases of invasive pneumococcal disease, 3.3M of pneumonia and 17.6M of acute otitis media compared to PCV7 over 10 years. Public and private payers will pay $3.5 billion(B) and $2.6B, respectively, for the vaccine but accrue $6.1B and $4.2B in overall savings. While the magnitude of savings varied in sensitivity analyses, implementation of PCV13 remained cost-saving for all payers. **CONCLUSIONS:** The currently-recommended PCV13 pediatric program is cost-saving for both public and private payers. Net savings were greater for public payers, despite higher vaccine costs.

PIN26

BUDGET IMPACT ANALYSIS OF DOLUTEGRAVIR IN THE TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN ONTARIO, CANADA

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OBJECTIVES: To estimate the budgetary impact of adding dolutegravir to the Ontario Drug Benefit Formulary (ODBF) for a three-year period for the treatment of HIV infection in adults and children (≥12 years of age). **METHODS:** Three discrete populations were considered: treatment-naïve (TN) patients staying on their first line, TN switchers (assumed switches within the first 6 months of antiretroviral therapy (ART) initiation) and treatment-experienced (TE) patients. Epidemiology data were obtained from published sources. Ontario-specific data and analysis from the IMS Brogan Database were used to estimate the proportion of patients who were treated and covered by the ODBF, proportions of patients remaining on their first regimen after ART initiation over time, comparators and historical market share data. ART drug costs were calculated based on the dosage of each regimen component from the respective product monographs and unit costs from the ODBF. The budget impact was calculated for the whole HIV population and separately for each population. Sensitivity analyses were conducted on five key input parameters. **RESULTS:** Out of the 12 comparators, dolutegravir-containing regimens were assumed to take market shares from 6 regimens: Atripla, Truvada/Prezista/Norvir, Truvada/Isentress, Truvada/Reyataz/Norvir, Kivexa/Isentress and Stribild. Adding dolutegravir to the list of reimbursed ARTs on the ODBF will result in incremental savings in each of the three years following the listing date of $2,717,585, $5,181,704, and $8,040,076 for a total savings of $15,939,365. The analysis was somewhat sensitive to assumptions made regarding HIV incidence and prevalence and the proportion treated with drug benefits. Based on the accuracy of the assumptions made in this analysis, the total savings to the budget over a three-year period may range between $12,751,492 and $19,127,238. **CONCLUSIONS:** The addition of adding dolutegravir to the ODBF will result in a significant net savings through the displacement of more expensive regimens in Ontario.

PIN27

'DE-ESCALATION' USING MICAFUNGIN FOR THE TREATMENT OF SYSTEMIC *CANDIDA* INFECTION: BUDGET IMPACT IN FRANCE AND GERMANY

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OBJECTIVES: The prevalence of systemic *Candida* infection (SCI) caused by non-albicans species, which display greater resistance to azole antifungal agents, is increasing. Treatment with broad-spectrum antifungal agents, such as echinocandins, with subsequent switch to fluconazole if isolates are shown to be sensitive ('de-escalation') is recommended by treatment guidelines. We developed a model to assess the budget impact of the de-escalation strategy in France and Germany. **METHODS:** The budget impact of initial micafungin treatment in a de-escalation strategy versus fluconazole in an escalation strategy was modelled using decision analysis based on data from relevant studies and a cost-effectiveness analysis. Duration of appropriate treatment was 14 days, meaning that treatment outcome was assessed after 14 days, or 17 days if fluconazole had to be switched once fluconazole sensitivity was known (after 3 days of therapy). Clinical success was defined as resolution or reduction of all signs, symptoms and radiographic abnormalities associated with SCI at treatment end. **RESULTS:** In France and Germany, the incidence of SCI was estimated at 28

and 38/100,000 population/year, respectively. In both countries, the most common isolates were *C. albicans*, *C. parapsilosis* and *C. glabrata*. In patients with fluconazole-resistant isolates, de-escalation resulted in higher cure and survival rates than escalation, with cost savings of €6,880/patient treated in France and €2,007/patient treated in Germany. Regardless of fluconazole sensitivity, de-escalation resulted in higher rates of cure and survival than escalation; these benefits were associated with an additional cost of €687 and €1,237 per patient treated in France and Germany, respectively. **CONCLUSIONS:** Across all patient groups, de-escalation from micafungin improved clinical outcome and survival. This was particularly marked in patients with fluconazole-resistant SCI, in whom de-escalation from micafungin was cost-saving. Increased costs with de-escalation in the overall population are limited and offset by improvement in survival using this strategy.

PIN28

BUDGETARY IMPACT TO A UNITED STATES HEALTH PLAN OF ADOPTING SIMEPREVIR (SMV) IN COMBINATION WITH PEGINTERFERON ALFA+RIBAVIRIN (PR) FOR THE TREATMENT OF GENOTYPE 1 (G1) CHRONIC HEPATITIS C (CHC) INFECTION

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OBJECTIVES: Economic evaluations of CHC therapies may be important from health plans' perspectives. **METHODS:** A budget impact model compared annual CHC therapy cost before and after SMV+PR adoption for a hypothetical 1,000,000 member plan. The proportion treated for CHC was derived from various publications. Base case analyses assumed Current state market share (MS) within treatment-naïve and -experienced populations was equally allocated between telaprevir+PR and boceprevir+PR while SMV+PR MS was 0%; Future MS was 45%, 45%, and 10%, respectively. CHC therapy costs were estimated based on dosing and administration data from US prescribing information and 12/2013 wholesale acquisition costs (assumed 82 kg person). Population allocation by prior response, disease severity, and treatment duration used trials data. Drug-only costs per member per month (PMPM) and per treated CHC member (PTM) were estimated. Sustained virologic response (SVR) absolute values from trials were used to report annual cost per SVR. **RESULTS:** The model suggested 234 G1 CHC members treated annually. Total health plan's budget (drug-only costs) was estimated at $1.82 PMPM before and after SMV+PR adoption (incremental cost -$0.001 PMPM). Annual total costs were $93,311 PTM in Current state and $93,271 PTM in Future (incremental cost -$40 PTM). The model calculated the health plan's annual cost per SVR as $147,105 in Current state and $144,261 in Future for total (treatment-naïve and -experienced) population. Sensitivity analyses doubling or halving the CHC population and increasing SMV+PR MS to 15% or 20% resulted in incremental PMPM drug-only costs of $-0.002 or $0.000 and -$0.001 or -$0.002, respectively. **CONCLUSIONS:** Modelled drug-only costs results suggest that SMV+PR adoption had an incremental impact to a U.S. health plan budget of -$0.001 PMPM (sensitivity analysis ranged -$0.002-$0.000 PMPM). When the base case considered drug costs plus outcomes, this resulted in a health plan's total annual cost per SVR decrease of $2,844.

PIN29

A DYNAMIC HEALTH ECONOMICS APP: THE BUDGET IMPACT OF ADOPTING THE RECENTLY FDA APPROVED HEPATITIS C THERAPY, SOFOSBUVIR TO A UNITED STATES FORMULARY

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OBJECTIVES: The objective of this study was to design an app to estimate the budget impact of the adoption of Sofosbuvir, a new antiviral hepatitis C (HCV) therapy to a formulary in the U.S. **METHODS:** The pharmacy budget impact to a formulary was defined as the difference between the cost "with Sofosbuvir" and the cost "without Sofosbuvir" for the treatment of the eligible chronically infected HCV population. The model takes the following into account: number of HCV infected persons, percent chronically infected, percent diagnosed, percent diagnosed and treated with triple therapy, percent covered by insurance, and drug costs. The app may be used to estimate the budget impact of the adoption of Sofosbuvir to either a commercial or Medicare/Medicaid formulary in each state of the U.S. and in the U.S. overall and may be used with iPad, iPhone, other tablets, laptops, and desktops. **RESULTS:** In 2013 in the U.S., 4,008,572 persons were estimated to be chronically infected with HCV. At a default of 3% of those diagnosed with chronic HCV being treated with triple therapy, and with Sofosbuvir having 15% of the market share the total pharmacy budget impact was estimated at $11.3 million annually (before adoption: $1,877 million vs. after adoption: $1,888 million) among those commercially insured in the US. This represents a relative increase of 0.6% ($0.005 per member per month (PMPM)). Among those who are Medicaid/Medicare insured the budget impact was estimated at $5.8 million, also a relative increase of 0.6%. **CONCLUSIONS:** Based on current treatment practices of HCV infected persons, the budget impact of adding Sofosbuvir to a U.S. commercial or government health plan formulary is low ($0.005 PMPM). The impact of increasing HCV screening and treatment rate and the potential reduction of medical costs due to Sofosbuvir's >90% sustained virological response will require future studies.

PIN30

ECONOMIC IMPACT OF VACCINATION WITH 10-VALENT VERSUS 13-VALENT PNEUMOCOCCAL CONJUGATED VACCINES IN COLOMBIA

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OBJECTIVES: Infections produced by *Streptococcus pneumoniae* have an important impact on worldwide health due the high burden of disease they generate; these diseases are a public health priority in Colombia. The aim of this study was to estimate the difference of cases and costs from serotype coverage of pneumococcal conjugated vaccines of 10 and 13 serotypes (PCV10 and PCV13, respectively) in population under 5 years old in Colombia. **METHODS:** A deterministic model was built for a cohort of children born in 2011. The probabilities of incidence, mortality and sequelae of pneumonia, meningitis, sepsis, and acute otitis media and clinical effectiveness of PCV10 and PCV13 for this population, were determined through a systematic literature review. Vaccination scheme 2+1 was included, herd effect of 42% and population coverage of 84.09% was assumed for both vaccines. The differences between the evaluated vaccines were estimated in terms of opportunity costs and net profit. The study was conducted from the perspective of third-party payers and a time horizon of 5 years. Costs were expressed in 2012 USD (exchange rate US$1 = $1798.23 COP). **RESULTS:** A cohort of 652,611 children was assumed. Model showed a higher protection with PCV13 in comparison to PCV10. With PCV13 a difference of 98 prevented deaths for meningitis, pneumonia and sepsis was observed. The opportunity cost of having used PCV10 instead of PCV13 was US$20,090,913 in the 5 year follow-up (US$4,018,183 per year). Costs related to disease not covered by PCV10 are between an annual average of US$4,087,138 to $4,373,597; 82% due to lost productivity associated with premature death, 12% to cases of disease and a lower percentage to sequelae. **CONCLUSIONS:** PCV13 prevents a greater number of deaths and consequences associated with pneumococcal infection compared to PCV10, resulting in a considerable economic impact measured in number of productive years for Colombia.

PIN31

ECONOMIC EVALUATION OF FIDAXOMICIN COMPARED WITH VANCOMYCIN IN THE TREATMENT OF CLOSTRIDIUM DIFFICILE INFECTION

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OBJECTIVES: Two Phase 3 clinical trials in patients with *Clostridium difficile*infection (CDI) showed fidaxomicin to be non-inferior to vancomycin in terms of clinical cure, but superior in terms of recurrence. In a pooled, modified intention-to-treat analysis of 962 patients, recurrence rates at 28 days were 26.0% (vancomycin), and 14.1% (fidaxomicin) (p<0.001) [Crook, et al, 2012]. This analysis aimed to evaluate the cost-effectiveness and budget impact of fidaxomicin compared with vancomycin from the perspective of the National Health Service in England. **METHODS:** A Markov model was developed with 10-day cycle length, capturing clinical cure, first and subsequent recurrence, and treatment outcomes within 1-year. Six patient sub-groups were analysed: patients with (a) severe CDI; (b) a first recurrence; (c) cancer; (d) aged ≥65 years; (e) renal impairment; and (f) receiving concomitant antibiotics. Model inputs were derived from published literature and an expert panel. **RESULTS:** Total costs per patient were lower with fidaxomicin than vancomycin for recurrent CDI (£16 535 vs. £16 926), cancer patients (£14 430 vs. £15 373) and patients aged ≥65 (£14 062 vs. £14 715). Fidaxomicin was associated with higher quality-adjusted life years (QALYs) than vancomycin for all patient groups and was a dominant option for these three sub-groups. Fidaxomicin was cost-effective at an implicit incremental cost-effectiveness ratio (ICER) threshold of £20 000 per QALY gained for severe CDI (ICER = £16 529) and patients with renal impairment (ICER = £16 693). The annual budget impact of fidaxomicin compared with vancomycin would be a saving of approximately £2 500 per patient for the six patient sub-groups combined. **CONCLUSIONS:** Fidaxomicin is likely to be a dominant treatment option, when compared to vancomycin, for patients with recurrent CDI, cancer or those aged ≥65, and is likely to be cost-effective at a £20 000 threshold for severe CDI and patients with renal impairment.

PIN32

FINANCIAL ANALYSIS OF A VACCINATION CAMPAIGN USING 13 VALENT PNEUMOCOCCAL CONJUGATED VACCINE (PCV13) WITH EMPLOYERS

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OBJECTIVES: This study evaluates the ROI (return on investment) for a PCV13 vaccination with campaign by corporations for individuals who are 50+ years old. **METHODS:** A budget impact analysis was developed considering vaccination costs, pneumococcal disease events, and productivity loss from employee absence due to sickness or death. Clinical events were calculated using a Markov model with individual-level simulation considering a cohort of 1.000 employees and an annual discount rate of 5%.Only the portion of employees more than 50 years of age was considered. (21% according to Brazilian Institute for Geography and Statistics, IBGE). Absence days due to health events were retrieved from national labor legislations. Average wage was retrieved from IBGE 2013. Return on Investment was calculated as the time until savings from the cost of productivity gains exceeds investment in a vaccination program. **RESULTS:** A campaign for 206 employees 50+ years old cost BRL 31.724 and in the first 2 years the return will be BRL 15.449 due to reduction in events and absenteeism and one fewer death. The ROI will be in 4,17 years. **CONCLUSIONS:** In addition to decreasing productivity loss, death, and additional treatment cost, a pneumococcal vaccination campaign for employees over 50 years old yields a positive return on investment.

PIN33

TOTAL HOSPITALIZATION COST AND LENGTH OF HOSPITAL STAY FOR PATIENTS WITH CARBAPENEM-RESISTANT VERSUS CARBAPENEM-SENSITIVE INFECTIONS IN A TERTIARY CARE HOSPITAL

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OBJECTIVES: To find out the average cost of hospitalization and length of hospital stay for patients infected with carbapenem-resistant bacteria and compare it with