OBJECTIVES: Inadequate control over emesis during cancer chemotherapy can adversely affect patient's quality of life, delay the subsequent chemotherapy cycle and may lead to poor adherence to treatment. This study was conducted to assess appropriateness of anti-emetics use in the management of chemotherapy induced nausea and vomiting. **METHODS:** A prospective observational study was conducted for a period of 6 months at private cancer hospital. Medical records of the patients on chemotherapy were reviewed and patients were interviewed to assess the prescribing pattern of anti-emetics and its appropriateness. Chemotherapy regimen and given anti-emetics for each patient were recorded and reviewed with respect to National Comprehensive Cancer Network (NCCN) guidelines for anti-emesis to ensure the appropriateness of drug use. **RESULTS:** Of 346 patients' record reviewed, majority (74%) of them were prescribed with drugs which are highly emetogenic followed by 17% of them with moderately emetogenic and 9% of them with low emetogenic potential. Unlike 30% of patients who were added with NK-1 receptor antagonist (NK1RA) either in oral or intravenous formulation, majority (n=184, 70.76%) of the patients receiving highly emetogenic regimen were placed on combination of 5-HT3 antagonist and corticosteroids without adding NK1RA for prevention of acute and delayed emesis. Majority patients (64%) receiving moderately emetogenic regimen were prescribed with combination of 5-HT3 antagonist and corticosteroids and remaining received combination of metoclopramide with corticosteroids. Most of the patients (82%) receiving low emetogenic regimen were prescribed with combination of metoclopramide and corticosteroids and remaining were prescribed with 5-HT3 antagonist and corticosteroid. Over all, selection of anti-emetic regimen was inappropriate for 32% (n=112) patients. Dosage, frequency and duration of anti-emetic use were inappropriate in 18%, 38% and 8% respectively. **CONCLUSIONS:** Most of the patients received same anti-emetic regimen for highly emetogenic and moderately emetogenic agents. Cost was the limiting factor to choose an appropriate anti-emetic regimen.

INFECTION – Clinical Outcomes Studies

PIN1

NON-INFERIORITY OF ONCE-DAILY COBICISTAT-BOOSTED DARUNAVIR VERSUS RITONAVIR-BOOSTED DARUNAVIR IN HIV-1-INFECTED ADULT PATIENTS: AN ADJUSTED COMPARATIVE ANALYSIS OF POOLED PHASE 3 DATA

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OBJECTIVES: Cobicistat, a CYP3A inhibitor, is a novel, alternative pharmacoenhancer to ritonavir. A fixed-dose combination once-daily formulation that contains darunavir and cobicistat has been developed to simplify dosing and to enhance patient convenience. This analysis compared the virological response of a cobicistat-boosted versus a ritonavir-boosted darunavir QD regimen by testing for non-inferiority. **METHODS:** Patient level data on 800mg QD darunavir treatment from 3 phase 3 trials (GS-216-0130, TMC114-C211, TMC114-C229) were combined for analysis of virological response at Week 48, using the Snapshot algorithm methodology. Patients were HIV-1-infected treatment-naïve or -experienced with no darunavir resistance-associated mutations at baseline. The non-inferiority margin was set at 0.531 on the odds-ratio (OR) scale, which corresponded to a 12% non-inferiority margin on the risk-difference scale, assuming an 80% response rate. Multiple logistic regression was used to adjust for differences in baseline patient characteristics (age, gender, race, baseline CD4+ T-cell counts, baseline HIV-1 RNA, HIV disease status, and previous antiretroviral use) and level of darunavir treatment adherence. A sensitivity analysis was performed on data from patients with viral load<50 copies/mL according to time to loss-of-virological response (TLOVR) algorithm at week 48. **RESULTS:** Treatment with darunavir/cobicistat(800/150mg QD, n=313) was non-inferior to darunavir/ritonavir (800/100mg QD, n=637). Unadjusted virological response rates were 81% and 78%, respectively. The adjusted odds ratio [95% CI] for virological response comparing darunavir/cobicistat with darunavir/ritonavir at week 48 was 0.878 [0.576, 1.339] (Snapshot). The 95% CI lower boundary was above the defined non-inferiority margin. The sensitivity analysis gave similar results: TLOVR OR=0.803 [0.534, 1.208]. **CONCLUSIONS:** This adjusted analysis of pooled phase 3 data of an 800mg once-daily darunavir dose showed that darunavir/cobicistat has non-inferior efficacy compared with darunavir/ritonavir.

PIN2

RELATIONSHIP BETWEEN MICROBIOLOGICAL ERADICATION AND CLINICAL OUTCOME WITH ANTIBIOTIC TREATMENT IN NOSOCOMIAL PNEUMONIA, COMPLICATED URINARY TRACT INFECTION, AND COMPLICATED INTRA-ABDOMINAL INFECTION

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OBJECTIVES: Infections caused by Gram-negative bacteria, including nosocomial pneumonia (NP), complicated urinary tract infections (cUTI), and complicated intra-abdominal infections (cIAI), have been increasing. Although microbiological eradication is on the presumed causal path from antibiotic susceptibility to clinical success, other factors impact clinical success rates as well. This study assessed the relationship between microbiological eradication and clinical outcomes for NP, cUTI, and cIAI based on randomized controlled trial (RCT) evidence. **METHODS:** A systematic literature search identified RCTs (25 NP trials, 10 cUTI, 28 cIAI, and 1 cUTI & cIAI trial) that met the following criteria: Adult patients with cUTI, cIAI, or NP; Gram-negative bacteria present in at least a fraction of the population; treatment including coverage of Gram-negative bacteria; any measure of microbiological eradication and either clinical response, cure or mortality. RCTs with information on both eradication and clinical outcome were selected to estimate their relationship to treatment effects using multivariate meta-analyses. **RESULTS:** Given the variation in analysis populations and timing of outcome assessment across RCTs, a limited number of studies were considered sufficiently similar for meta-analyses. For NP, a positive relationship between microbiological eradication and cure (correlation coefficient of 0.84; 95%CI 0.07, 0.98; 5 studies) and a negative relationship between eradication and mortality (-0.86; 95%CI -0.97, -0.34; 7 studies) were observed. For cIAI, clinical outcome was used as a proxy measure for microbiological eradication, but no correlation with mortality was identified. No relationship was observed for cUTI either. **CONCLUSIONS:** Relationships between treatment effects in terms of eradication and clinical cure and between eradication and mortality were identified for NP. For cIAI and cUTI, the relationship between microbiologic eradication and treatment effects is unclear based on available study level RCT evidence. Given the great variation between studies and several uncertain findings, evaluations using patient level data are recommended.

PIN3

STUDY ON CLINICAL AND IMMUNOLOGICAL OUTCOMES OF ANTIRETROVIRAL THERAPY IN HIV POSITIVE ADULT PATIENTS IN A COMMUNITY CARE HOSPITAL

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OBJECTIVES: Human Immunodeficiency Virus (HIV) has become a chronic manageable disease after the advent of combination antiretroviral therapy (ART). Since launching of ART, the numbers of patients enrolled in to ART are increasing in developing countries like India. In this study we aim to analyze clinical and immunological outcomes of ART in a community care hospital. **METHODS:** A retrospective cohort study was conducted by including 800 ART naive HIV infected adult patients initiated on ART. All patients survived in ART centre at Mysore, India for 12 months from January 2013 to January 2014 were included. Parameters like weight, hemoglobin, WHO clinical stage and CD4 count were collected from medical records before initiation and after completion of 12 months ART. Outcomes of ART were analyzed by paired T- test using SPSS version 21. **RESULTS:** A statistically significant improvement was observed for weight [53.9 (11.9) to 58.2 (32.6) kg; $P = 0.002$] and CD4 count [206.6 (177.4) to 331.1 (220.5); $P = 0.001$] at the end of 12 months of ART treatment. Whereas, marginal improvement in hemoglobin [11.94 (4.3) to 11.98 (5.7) g%; $P = 0.91$] was observed, though it was not statistically significant. Also observed a significant increase in percentage of patients in WHO clinical stage I (64-82%) and decrease in number of patients in stages II (13-14%), III (5-2%) and IV (18-12%). **CONCLUSIONS:** The improvement in weight and CD4 count are indirect parameters of >95% medication adherence and of sustained viral suppression. The optimal outcome would have been all patients in WHO clinical stage I or II and none in III and IV, but in this study 2% and 12% of patients continued to be in stage III and IV respectively. This may be due to development of opportunistic infections such as tuberculosis which is endemic in India.

PIN4

EFFICACY AND HOSPITALIZATION LENGTH OF STAY OF SINGLE DOSE ORITAVANCIN COMPARED TO 7-10 DAYS OF VANCOMYCIN IN PATIENTS WITH ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS IN THE US AND EASTERN EUROPE

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OBJECTIVES: Oritavancin (ORI) is a lipoglycopeptide with bactericidal activity against Gram-positive bacteria including MRSA. This analysis evaluated efficacy and hospital length of stay of ORI for patients with acute bacterial skin and skin structure infections (ABSSSI) who received care in the SOLO program in the US and Eastern Europe. **METHODS:** SOLO I and II were identically-designed comparative, multicenter, double-blind, randomized studies to evaluate the efficacy and health care resource utilization (HRU) of single 1200 mg dose IV ORI versus 7-10 days of twice-daily intravenous (IV) vancomycin (VAN) for the treatment of ABSSSI. SOLO protocols were amended (Amendment 2) to allow outpatient treatment at the investigator's discretion. Efficacy and HRU of treatment were assessed in inpatient and outpatient settings. Efficacy for the European Medicines Agency (EMA) was investigator-assessed clinical cure 7-14 days after end of treatment. HRU endpoints were hospitalization rate and length of stay (LOS) in days if the patient was hospitalized. **RESULTS:** In the combined studies, 1959 patients were in the modified intent-to-treat (mITT) population; 1,172 patients (60%) received a portion of their care in as inpatients; 202 patients were treated in Eastern European countries (EUC: Russian Federation, Romania and Ukraine) and 1,165 were treated in the US. Clinical cure rates were similar for ORI and VAN in both regions (86.1% and 84.2% in EUC, 80.6% and 77.9% in the US. The average LOS (ALOS) in the EUC was longer than in the US (14.9 and 14.7 vs. 6.0 and 6.4 days). **CONCLUSIONS:** Clinical cure rates at PTE were similar between ABSSSI patients who received a single dose of ORI or 7-10 days of VAN in SOLO, but the ALOS in the US was considerably shorter than in Eastern Europe. Using oral or long-acting antibiotic treatments may reduce the numbers of inpatient IV antibiotic administrations, which has been associated with reduced LOS in other studies.

PIN5

RETROSPECTIVE PUBLIC HEALTH IMPACT OF A QUADRIVALENT INFLUENZA VACCINE IN THE UNITED STATES OVER THE PERIOD 2000-2014

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OBJECTIVES: Vaccination has proven to be an efficient preventive strategy against influenza infection. Each year, two genetically distinct influenza B lineages co-circulate. Current trivalent influenza vaccines (TIVs) contain only one influenza B and two influenza A strains, but vaccine mismatch are frequent due to the difficulty to predict which B lineage will predominate during the next epidemic.

Recently licensed quadrivalent influenza vaccines (QIVs) containing a strain from each B lineage should address these issues, but their impact still needs to be estimated. Our study assesses retrospectively what would have been the public health benefit of routinely vaccinating the US population with QIV instead of TIV. **METHODS:** We developed a dynamic compartmental model able to account for interactions between influenza B lineages (natural or vaccine-induced). The model simulates influenza dynamics for the period 2000-2014, to account for the long-term impact of infection and vaccination. Age-structured population dynamics, vaccine efficacy (VE) per strain, and weekly ramp-up of vaccination coverage are modelled. Sensitivity analyses were performed on VE, duration of immunity, levels of vaccine-induced cross-protection between B strains. **RESULTS:** Assuming a cross-protection of 70% of the matched VE, the model predicts that QIV would have prevented on average 15% more B-lineages cases. Elderly people (65+yo) and young seniors (50-64yo) benefit the most from QIV with 21% and 18% reduction of B cases respectively in those age groups. Reducing the cross-protection estimate of the matched VE to 50%, 30%, and 0% improves the relative benefit of QIV to 25%, 30%, and 34% fewer B cases in the US. **CONCLUSIONS:** Using a realistic retrospective framework, with real-life vaccine mismatch, our analysis shows that routine vaccination with QIV has the potential to substantially reduce the number of influenza infections, even with relatively conservative estimates of TIV induced cross-protection.

PIN6

IMPACT OF HPV-VACCINATION: HEALTH GAINS FOR FEMALE POPULATION IN ITALY

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OBJECTIVES: Human Papillomavirus (HPV) is the primum movens both in the etiopathogenesis of invasive cervical cancer and in other neoplastic malignant and benign lesions. HPV vaccination was implemented in Italy since 2008. The aim of this study is to evaluate the burden of HPV-related diseases and the effect of current HPV-vaccination strategy in Italy. **METHODS:** A multistate morbidity mortality model was developed in order to estimate the infection process on a theoretical cohort of Italian women. The conceptual Markov process was adapted considering the data available in national and international literature. 7 states (Health, Genital Warts, Grade 1 and Grade 2/3 cervical intraepithelial neoplasia, Cervical Cancer, Death for Cervical Cancer and death for other cause) and 18 transition probabilities were considered. A 5-years incidence rate class was extrapolated and Rogers and Ledent method transformation was used to convert rates into probabilities. Vaccination efficacy was carried out by literature modelling review and based to the coverage rate of the two anti-HPV vaccines available in Italy. Life expectancy (e_x), Quality Adjusted Life Years (QALYs), Disability Adjusted Life Years (DALYs) and Attributable risk (AR) were estimated for no intervention and vaccination strategies scenarios. **RESULTS:** The preliminary results show that for a theoretical cohort of 100,000 Italian women the e_0 is equal to 84.31 years. With the present HPV vaccination strategy the e_0 increase to 84.36 (+0.05) years. However, considering the HPV-related diseases altogether, the QALYs increase from 83.9 for no intervention to 84.1 for Vaccine prevention approach (+0.2QALYs). DALYs decrease of 0.6 thanks to Vaccination (2 DALYs for no intervention cohort vs 1.4 DALYs lived for vaccinated cohort). AR is equal to 0.08 and 0.29 for population and not vaccinated respectively. **CONCLUSIONS:** The model demonstrates that, if we consider different HPV-related diseases, Italian HPV vaccination strategy has significantly effect on health gains for female population.

PIN7

EFFECTS AND SAFETY OF CEFTRIAXONE VERSUS LEVOFLOXACIN IN TREATING COMMUNITY-ACQUIRED PNEUMONIA: A SYSYTEMATIC REVIEW

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OBJECTIVES: To evaluate the efficacy and safety of ceftriaxone and levofloxacin in treating community-acquired pneumonia and provide references for clinical application. **METHODS:** This was a systematic review. Data were collected from literature (randomized controlled trails) published from January 2003 to January 2014 through searching databases both at home and abroad, such as CNKI, WanFang Data, VIP, PubMed, Science Direct, Springer, Ovid, Wiley-Blackwell and The Cochrane Library (Issue1, 2014). Both qualitative analysis and quantitative analysis were conducted. Quantitative analysis (meta-analysis) was performed by RevMan 5.2. **RESULTS:** Nine studies were included, involving 2233 patients. Of these, six studies (553 patients) met meta-analysis criteria. The results of meta-analysis were clinical effective rates (RR=0.90, 95%CI, P=0.002), and adverse events rates (RR=0.70, 95%CI, P=0.22). The result of qualitative description as follows: one prospective, randomized study showed success rate were 89% in the ceftriaxone group and 96% in the levofloxacin group; one multicenter retrospective study showed the mortality of the two groups were 3.1% and 2.0%, the length of hospital stay (LOS) were 5.5±3.5 days and 4.8±2.9 days respectively, with no significant difference found between groups; the other retrospective study showed ceftriaxone could shorten LOS since it had a trend toward earlier switch to oral therapy. **CONCLUSIONS:** In general, current evidence shows that the efficacy for the treatment of community-acquired pneumonia of levofloxacin is superior to ceftriaxone, there were no significant difference in the incidence of adverse reaction.

PIN8

FIDAXOMICIN THERAPY FOR PATIENTS WITH CLOSTRIDIUM DIFFICILE INFECTION: A SYSTEMATIC LITERATURE REVIEW AND META-ANALYSIS

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OBJECTIVES: C. difficile is the leading cause of antibiotic associated infectious nosocomial diarrhoea. A limited number of new pharmaceutical products have been developed and registered in past decades for the treatment of C. difficile infection. The main aim of this systematic review was to analyse and compare the clinical efficacy and safety of metronidazole, vancomycin and fidaxomicin in the therapy of C. difficile infection. **METHODS:** Systematic review and meta-analysis of the literature using Bayesian mixed treatment comparison. **RESULTS:** Nine studies were included in the mixed-treatment comparison. Our meta-analysis showed that clinical cure was more likely with fidaxomicin compared to vancomycin and metronidazole, however the differences were not significant. (odds ratios [95% CI]: fidaxomicin vs. vancomycin 1.19 [0.82-1.66]; vancomycin vs. metronidazole 1.69 [0.93-2.82] and fidaxomicin vs. metronidazole 2.00 [0.99-3.66]). Fidaxomicin therapy was significantly more efficacious than vancomycin and metronidazole in endpoints of recurrence (odds ratios [95% CI]: fidaxomicin vs. vancomycin 0.47 [0.33-0.65]; vancomycin vs. metronidazole 0.91 [0.44-1.69] and fidaxomicin vs. metronidazole 0.43 [0.19-0.85]) and sustained cure (odds ratios [95% CI]: fidaxomicin vs. vancomycin 1.77 [1.35-2.28]; vancomycin vs. metronidazole 1.49 [0.92-2.30]; and fidaxomicin vs. metronidazole 2.64 [1.50-4.35]. There was no significant difference between fidaxomicin, vancomycin and metronidazole in safety endpoints. **CONCLUSIONS:** Fidaxomicin was the most efficacious therapeutic alternative in lowering the rate of recurrent C. difficile infections.

PIN9

MIXED TREATMENT COMPARISONS TO COMPARE SIMEPREVIR WITH BOCEPREVIR AND TELAPREVIR IN COMBINATION WITH PEG-INTERFERON ALPHA AND RIBAVIRIN (PR) IN PATIENTS INFECTED WITH GENOTYPE 1 HEPATITIS C VIRUS (HCV)

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OBJECTIVES: To conduct mixed treatment comparisons (MTC) to compare simeprevir, a new generation NS3/4A protease inhibitor, with boceprevir and telaprevir (all in combination with PR) and with PR alone in treatment-naïve and treatment-experienced genotype 1 HCV infected patients. These MTC results were used to inform the cost-effectiveness model for simeprevir and to prepare submissions to HTA agencies (including NICE). **METHODS:** A Bayesian MTC based on a systematic literature review was conducted. Outcomes of interest included sustained virologic response (SVR) rates, incidence of anaemia and rash and discontinuation due to adverse events (AEs) rates. Networks were based on treatment-, dose- and duration-specific nodes. Q80K-positive patients were excluded from simeprevir arms for the analysis of SVR rates in line with EMA label considerations for simeprevir. Subgroup analyses were conducted to investigate heterogeneity, based on METAVIR scores, sub-genotypes 1a/1b and prior response. **RESULTS:** Simeprevir was associated with higher SVR rates than PR alone in both treatment-naive (OR [95%CrI]: 4.83 [3.50-6.70]) and treatment-experienced patients (ORs: 9.02 [5.54-15.01]) for simeprevir 12+PR 24/48 weeks and 8.73 [5.42-14.19] for simeprevir 12 +PR 48 weeks). Compared to telaprevir and boceprevir, SVR rates tended to be higher for simeprevir with odds-ratios ranging from 1.27 [0.81-2.00] to 2.61 [1.44-4.74] in treatment-naïve and from 1.04 [0.78-1.38] to 1.74 [0.84-3.61] in treatment-experienced patients. In terms of safety, the risks of anaemia and discontinuations due to AEs were lower for simeprevir compared to PR alone, telaprevir and boceprevir. The risk of rash was lower for simeprevir compared to telaprevir, and similar compared to PR alone and boceprevir. **CONCLUSIONS:** This MTC in genotype 1 HCV patients suggests a similar or better efficacy and a better tolerability profile for simeprevir compared to telaprevir and boceprevir both in treatment-naïve and treatment-experienced patients.

PIN11

RESULTS OF COMPARATIVE STUDY OF MACROLIDE GROUP ANTIBIOTICS CONSUMPTION IN UKRAINE, RUSSIA AND KAZAKHSTAN

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OBJECTIVES: Widespread uncontrolled use of antibiotics contributes to the development of microbial resistance. Study of antibiotic consumption by ATC / DDD method in terms of DDDs/1000 inhabitants / day (DID) is one of the ways to control the resistance development rate. Macrolide antibiotics are widely used for treatment of infectious diseases; therefore, their consumption needs control. **METHODS:** Data on packed macrolides consumption in Ukraine, Russia and Kazakhstan, provided by analytical companies researching pharmaceutical market - "Pharmstandard" and IMS Health, has been used for the study. **RESULTS:** Comparing the figures in Ukraine, Russia and Kazakhstan, the largest consumption (in DID) was observed in Russia, Ukraine was in the second place, Kazakhstan was in the third place, during 2010-2012. However, the data were not significantly different; indices were 1.496, 1.445 and 1.356 DID respectively in 2012. The analysis results showed that azithromycin was leading as of consumption in DID in 2010-2012. Every year, the consumption of this preparation increases. Compared to 2010, in 2012 the azithromycin DID consumption index increased for 21.4% and amounted to 0.7931 DID. This means that 5.8% of the population of Ukraine takes one course of azithromycin (5 days) during the year. Growth of azithromycin consumption is associated with its high efficacy. It is accumulated in most tissues and organs, it has the least side effects and provides high compliance; it is used in pediatric practice from an early age. Azithromycin consumption rate in Russia and Kazakhstan increases every year as well. Calculations showed that 2.12% of the population took a course of azithromycin in Russia during 2012; in Kazakhstan, this index equaled 4.59%. **CONCLUSIONS:** The analysis showed that, macrolide antibiotics consumption level in Ukraine, Kazakhstan and Russia within the study period was comparable.

PIN12

TEN YEARS OUTCOMES IN A COHORT OF PATIENTS STARTED ON ANTIRETROVIRAL TREATMENT IN AN URBAN CLINIC IN SUB-SAHARAN AFRICA

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