

OBJECTIVES: To provide real-world evaluations of newer direct-acting antivirals (DAAs) in CHC patients from large US payer perspectives. **METHODS:** Medical and pharmacy claims linked to lab data from the Humana Database were analyzed for Medicare Advantage or commercially-insured adults with ≥ 2 CHC claims (ICD-9 070.44; 070.54) who received therapy containing SMV and/or SOF through June 2014; those with HIV were excluded. Patients were grouped based on most common regimens in the data: SMV/SOF, SMV/SOF/ribavirin (RBV), SOF/RBV, or SOF/interferon (IFN)/RBV; <3% received other regimens. Baseline (BL) demographics and clinical characteristics (e.g., claims-based cirrhosis or end stage liver disease [ESLD], FIB-4 scores) were described and post-treatment time measured. Methods to control for treatment selection bias were not performed, and comparative analyses were not conducted. **RESULTS:** There were 715 CHC patients who received therapy with SMV/SOF (n=184), SMV/SOF/RBV (n=37), SOF/RBV (n=269) or SOF/IFN/RBV (n=225); mean age was between 60-62 years; 58%, 68%, 62% and 70% were male; most (85%, 78%, 81% and 80%) had Medicare. For SMV/SOF, SMV/SOF/RBV, SOF/RBV, and SOF/IFN/RBV groups, BL cirrhosis was present in 27%, 27%, 17%, and 24% of patients and ESLD in 48%, 38%, 27%, and 12% of patients, respectively. Slightly over half in each cohort had calculable FIB-4 scores, of which, 56%, 54%, 34% and 35%, respectively, had scores > 3.25 . Among those with genotype data, 100% (78/78) SMV/SOF, 94.7% (18/19) SMV/SOF/RBV, 24.4% (29/119) SOF/RBV and 95.8% (92/96) SOF/IFN/RBV were genotype 1. Using prior claims history, 10%, 19%, 12% and 17% of respective cohorts were treatment-experienced. Less than half of each cohort had post-treatment data ≥ 1 week. **CONCLUSIONS:** This analysis of CHC patients predominantly insured through Medicare found that the majority of those who received SMV/SOF +/- RBV had either cirrhosis or ESLD claims prior to therapy and, based on lab data, over half had FIB-4 scores > 3.25 .

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SPENDING ON HEPATITIS C ANTIVIRALS IN THE UNITED STATES, 2008-2014

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OBJECTIVES: New Hepatitis C (HCV) antivirals have been shown to be highly effective with minimal side effects. These medications are costly and have raised significant concern from insurers, policymakers, advocacy groups, and patients about affordability. However, little is known about the impact of new HCV antiviral expenditures. The objective of this study was to describe HCV antiviral expenditures by agent, year, and healthcare sector in the US. **METHODS:** HCV antiviral (interferon/ribavirin, telaprevir, simeprevir, sofosbuvir, boceprevir) expenditures from 10/1/2008-9/30/2014 were obtained from the IMS Health® National Sales Perspectives database. This dataset represents a near-census view of US medication purchases. Expenditures were totaled by drug, sector, and year (defined as 10/1-9/30). Growth was calculated as the % increase compared to the previous year/period. **RESULTS:** A total of \$12.2 billion in HCV drugs were purchased from 10/2008-9/2014, 70.2% in 2014. HCV antiviral expenditures increased 10,880% over the six-years. Expenditures decreased by \$7.8 million in 10/2012-9/2013 as compared to 10/2011-9/2012 (-41% growth). While the majority of expenditures in 10/2008-9/2010 were for interferons, this shifted to telaprevir in 10/2010-9/2013 and sofosbuvir in 10/2013-9/2014. Sofosbuvir was 55% of HCV drug expenditures over the study period and 78% in 10/2013-9/2014. By sector, mail order (59%) and retail (27%) pharmacies were associated with the majority of expenditures. **CONCLUSIONS:** New HCV antivirals are driving the increased expenditures for this class. Decreased expenditures in 10/2012-9/2013 may have been secondary to delaying HCV treatment until new therapies received FDA-approval ("warehousing"). With continued drug development and approval of HCV therapies, expenditures are expected to continue to increase, barring actions by payers that may impede this trend. Medication policies guiding HCV treatment should focus on safety and efficacy while balancing the long-term costs of HCV. With the majority of expenditures originating from outpatient pharmacies, pharmacists are an essential partner to ensure appropriate use.

INFECTION – CLINICAL OUTCOMES STUDIES

PIN1

ANALYSIS OF ADVERSE DRUG REACTIONS DURING PHARMACOTHERAPEUTIC FOLLOW-UP OF HIV+ PATIENTS

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OBJECTIVES: Adverse Drug Reactions (ADR) are one of the main problems related to antiretroviral (ARV) therapy and often result in decreased adherence and therapeutic failure. This study aimed to analyze the ADR that manifested during the Pharmacotherapeutic Monitoring (AFT) of HIV+ patients. **METHODS:** This was a longitudinal study carried out in accordance to the Dader Method of pharmaceutical care, which monitored 100 HIV+ patients in a center of medical specialties in Fortaleza-CE-Brazil, from November/2008 to January/2012. Data were collected from individual pharmacotherapeutic follow-up forms. The ADRs were classified according to causality as "definite, probable, possible, conditional and non-related" and gravity as "mild, moderate, severe and fatal", using the World Health Organization (2002) method. **RESULTS:** Of the reported RAM (n = 267), the two most affected systems by ADR were the gastrointestinal tract (n = 117, ex. diarrhea, nausea and vomiting) and the nervous system (n = 101, ex. dizziness, nightmares and delusions). As for the classes of ARVs that were involved with ADR, the Nucleoside Reverse-Transcriptase Inhibitors (n = 113), followed by inhibitors non-Nucleoside Reverse-Transcriptase inhibitors (n=73) observations and protease inhibitors (n = 49), were the most frequent. With regard to causality, 80.9% of RAM (n = 216) were classified as possible and 19.1% as probable (n = 51). As for gravity, 85% (n = 176) were mild and 15% (n = 40) moderate. **CONCLUSIONS:** Data ratified that ARVs are triggers of ADR and its use need to be continually followed through

a systematic monitoring, as in pharmaceutical care services, seeking to promote safety of pharmacotherapy.

PIN2

ASSESSMENT OF NEPHROTOXICITY AND COST IMPLICATIONS OF COLISTIN THERAPY IN ICU PATIENTS

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OBJECTIVES: To study the risk of nephrotoxicity and the cost of treatment of colistin. **METHODS:** Patients admitted in ICU with resistant bacterial infections and on colistin for at least seven days were included in the study. They were observed for any change in Glomerular filtration rate and the risk of nephrotoxicity according to the RIFLE criteria after the colistin therapy. The GFR values before the initiation of treatment with colistin were compared with that after the end of regimen. The pre and post treatment GFR values were compared using non-parametric Wilcoxon Signed Ranks test. **RESULTS:** A total of 30 patients on colistin were observed during the study. The mean age of the patients was 45.47±16.45. The average APACHE II score was 15.87±5.82. There was no significant difference between the GFR of patients before and after treatment with colistin (p=0.130). The average hospitalization cost was 255245.41±138099.29 and the average cost of colistin therapy was 31638.10±12625.90. **CONCLUSIONS:** This study showed that the nephrotoxic effect of colistin is not significant. There is a need to conduct more studies with a higher sample size to assess the risk of colistin-induced nephrotoxicity. The incidences of nephrotoxicity in the patients studied can be attributed to various other factors such as age, comorbidities etc. The cost of colistin therapy was substantial being more than one-tenth of the total hospitalization cost.

PIN3

ANIDULAFUNGIN IN COMPARISON TO FLUCONAZOLE, AMPHOTERICIN B DEOXYCHOLATE, AMPHOTERICIN B LIPOSOMAL, CASPOFUNGIN AND MICALFUNGIN FOR THE TREATMENT OF INVASIVE CANDIDIASIS AMONG NON-NEUTROPENIC PATIENTS ABOVE 16 YEARS: BAYESIAN MIXED TREATMENT COMPARISON (MTC)

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OBJECTIVES: Invasive candidiasis is an important cause of complication and mortality of inpatient. Anidulafungin as others echinocandins are drugs that have shown clinical relevance in the treatment of invasive candidiasis. This research sought to evaluate the effectiveness and safety of anidulafungin in comparison to fluconazole, amphotericin B deoxycholate, amphotericin B liposomal, caspofungin and micafungin for the treatment of invasive candidiasis among non-neutropenic patients above 16 years. **METHODS:** We performed a systematic review in which were included randomized clinical trials (RCT) evaluating the different drugs to treatment of invasive candidiasis in non-neutropenic patients. It involved in MEDLINE, EMBASE, Cochrane, DARE and LILACS. The quality of evidence and risk of bias of clinical trials were assessed with GRADE tool and Cochrane methodology respectively. We performed a meta-analysis and Bayesian mixed treatment comparison (MTC) to compare the effectiveness and safety of the different considered treatment. The outcomes of effectiveness and safety were global response rate, mortality and occurrence serious event adverse (SEA). **RESULTS:** We included 11 RCT and clinical evidence provided was of moderate quality according to the GRADE system. For global response rate, the MTC displayed that anidulafungin was more effective than fluconazole (OR 2.07 IC95% 1.20- 2.59). In comparison with others drugs, anidulafungin presented similar effectiveness (non-significant statistically differences). In mortality, it presented less proportion of events (29,5% IC95% 18,8-42,0) than other interventions, but it was not statistically different of them. Anidulafungin showed better safety profile than amphotericin B deoxycholate regarding to occurrence of SEA (OR 0.15 IC95% 0.02-0.97). However, there were not significantly statistical differences with amphotericin B liposomal, caspofungin and fluconazole. **CONCLUSIONS:** The MTC found that anidulafungin is more effective than fluconazole and exhibited similar effectiveness than others interventions. With respect to safety profile, anidulafungin was superior to amphotericin B deoxycholate and similar to the others.

PIN5

SERIOUS ADVERSE EVENTS IN CANADIAN CHILDREN RECEIVING PALIVIZUMAB FOR THE PREVENTION OF RESPIRATORY SYNCYTIAL VIRUS INFECTION

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BACKGROUND: A landmark in the prevention of serious respiratory syncytial virus (RSV) infection was established with the release of palivizumab, a recombinant, humanized, genetically-engineered monoclonal antibody. Palivizumab has been deemed safe in clinical trials without major, serious adverse events (SAEs). **OBJECTIVES:** The primary objective of this study is to evaluate the safety and tolerability of palivizumab for RSV infection prophylaxis in high-risk children. **METHODS:** High-risk children prophylaxed against RSV infection were recruited into a prospective, observational, Canadian RSV Evaluation Study of Palivizumab (CARESS) registry with active SAE monitoring from 2008 to 2013. SAE reports were systematically collected and assessed for severity and relationship to palivizumab. Data were analyzed by using Chi-square or Fisher Exact Tests to examine group differences in proportions. **RESULTS:** 13,025 infants were enrolled and received 57,392 injections: premature infants ≤ 35 weeks gestational age (n=8224; 63.1%), children aged <2 years with chronic lung disease (n=978; 7.5%), hemodynamically significant congenital heart disease (n=1442; 11.1%) and pre-existing medical disorders (n=2381; 18.3%). 915 patients were hospitalized for a respiratory