OBJECTIVES: To investigate the phenomenon of PPI switching in the acid related disorders treatment in an Italian primary care setting during 2005–2008 (before and after PPIs’ patents expired) and to estimate the costs of health care resources consumptions associated with this phenomenon. METHODS: Retrospective cohort study was performed analyzing data from 127 GPs of Naples in the south of Italy. PPI users for ARD treatment within each study year were selected from source population. Switchers were defined patients changing from one PPI to another within each study year. Multivariate logistic regressions were used to assess the potential predictors of PPI switching and to investigate the factors influencing the direction of the switch. Cost was expressed as Euro 2008 per PPI user. RESULTS: The phenomenon of PPI switching rose from 13.0% in 2005 to 16.7% in 2008 with a peak of 18.8% in 2006. Calendar years, long-term treatments and GERD diagnosis were positive predictors of PPI switching. All years analyzed (2005 2008) were associated with switching to lanograzole while the 2008 year was strongly associated with switching to omeprazole and pantoprazole. Very long-term treatment (>11 pack/years) group accounted for 66.3% of the total primary care cost. Switchers increased primary care costs by 61.1 compared with no switchers, reaching an incremental cost of €13.3 per user-year in the case with more than 1 switch. CONCLUSIONS: In Italy the launch of new generic PPIs in the national market generates the increasing amount of chronic treatments and therapeutic substitution that will probably have had a negative impact on the total saving results, achievable by the introduction of generic products. Policy rules favours generic PPIs prescribing can often influence physicians’ decision to select the appropriate treatment for each patient.

GASTROINTESTINAL DISORDERS – Conceptual Papers & Research on Methods

PGI22

USING DATA ENVELOPMENT ANALYSIS TO ESTABLISH THE EFFICACY AND SAFETY EVALUATION OF DRUGS

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OBJECTIVES: The development and research in pharmaceutical industry has constantly created new listing drugs which provide more therapeutic effect and lower side effects than former drugs, but the price become more expensive. Thus it is crucial to balance the trade-off between medical quality and cost reduction, hospitals have to make the decision-making between the former drugs and the new listing drugs, which have similar therapeutic effectiveness. In this regard, the most primary issue in this research is to establish a more objective and efficient decision-making analysis that consider both effectiveness and cost for the drugs which has the similar therapeutic effect. METHODS: We use data envelopment analysis (DEA) to solve this problem. We screen six critical factors, daily drug expenses, drug profits, side-effect, consumption, patent duration and lead time. Evaluation of relative efficiency of the option with DEA method must be built on the relative performance data of every input or output attributes of each decision-making unit. RESULTS: This study uses four kinds of proton pump inhibitors (PPI) for effectiveness evaluation (the code A, B, C, D drugs to replace its original name), first according to definition of the factors to collect relevant data. We use the DEA method to treat these data, Drug A in the DEA method analysis results is the most effective (6.654E+06), Drug D is the second (4.231E+06), Drug B is the third (2.116E+06) and Drug C is the worst (1.276E+06). CONCLUSIONS: Through this research model, we transfer complex decision-making goals into various measurable or comparable factors that can compare the relative importance. The evaluation result may not let all decision-makers and users to adopt at all. But it is more comprehensive and objective to evaluate the effectiveness of decision-making models than that in the past.

INDIVIDUAL’S HEALTH – Clinical Outcomes Studies

PIH1

EMERGENCY CONTRACEPTION FOR UNINTENDED PREGNANCY: ROLE OF ULIPRISTAL, A NOVEL PROGESTERONE RECEPTOR MODULATOR

Approval A
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OBJECTIVES: Unintended pregnancies represent a global health problem with over 80 million annual pregnancies. These are associated with an increased risk of morbidity and a considerable impact on women’s quality-of-life. Globally, 38% of all pregnancies are unintended resulting in 42 million induced abortions and 34 million unintended births. This corresponds to 43% of all child-births worldwide. A novel drug (“Ulipristal” was introduced in Europe in May 2009 with efficacy beyond 72 hours after unprotected coitus. The objective of this review was to determine the safety and efficacy profile of ulipristal compared to levonorgestrel. METHODS: A number of databases (PUBMED, EMBASE, POPLINE, CENTRAL and clinicaltrials.gov) were searched and the citations screened to identify randomised controlled trials (RCTs) reporting efficacy and safety outcomes of ulipristal. Grey literature was searched to identify the cost associated with unintended pregnancies. Summary-statistics (Random-Effects: DerSimonian-Laird) were used to assess pregnancy and adverse-events outcomes. RESULTS: Seven RCTs were identified and only two reported pregnancy outcomes. In a pooled analyses when compared to levonorgestrel, ulipristal showed better efficacy results in preventing pregnancy following unprotected coitus on day 1 and day 3 (Day 1, RR = 0.435, [95%CI=0.148, 1.279] and Day 3, RR = 0.376, [95%CI=0.110, 1.283]). However, these results were non-significant. Conversely, subgroup analysis showed that if a drug administered on day 2, this trend was reversed with administration of levonorgestrel being associated with fewer pregnancies (RR = 1.309, [95%CI=0.572, 2.996]). The frequency of adverse events like nausea, headache, fatigue and dizziness was similar with both the drugs. Unintended pregnancies were found to be associated with huge costs that amounted up to US$ 5 billion in US during...
PEDIATRIC INTENSIVE CARE UNIT (PICU) ADMISSIONS FOR RESPIRATORY SYNCTIVIRUS INFECTION IN THE ERA OF PALIVIZUMAB PROPHYLAXIS

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OBJECTIVES: To examine the characteristics of patients admitted to PICU with RSV infection following provincial approval of RSV prophylaxis in June 2002. Secondly, to determine if patients had received palivizumab and document incurred morbidity and mortality.

METHODS: A retrospective, hospital medical records review of all PICU admissions for RSV infection from January 1, 2003 to December 31, 2009. RSV infection was identified by ICD codes and cases were confirmed by RSV real-time, culture, or PCR.

RESULTS: Data was collected on baseline demographics, underlying disease, criteria for hospitalization, and complications. Group 1 patients (n=152) had a mean admission age in months (SD); 3.7 (4.4) versus 59.9 (37.7). Majority (79.6%) Group 1 versus only 20.7% Group 2 (n=29) had a mean admission age in months (SD); 3.7 (5.7) versus 59.9 (37.7). Majority (79.6%) Group 1 versus only 20.7% Group 2 (P<0.001) had no underlying disease. 97.4% versus 93.1% were admitted with respiratory distress and most had bronchiolitis; 88.8% versus 55.2% (P<0.001), decreased oxygen saturation; 77% versus 75.9% and inability to maintain intake; 72.7% versus 44.8% (P=0.01). Fifty percent versus 41.3% required mechanical ventilation and 81.6% versus 69.0% received antibiotics. Median days (range) in PICU was 5 (1–73) versus 2 (1–36). Median length of hospital stay days (range) was 9 (1–113) versus 7 (1–64) (P=0.05). The overall RSV positive, PICU hospitalization rate was 5.7%. There were few complications: respiratory (2.8%); concurrent bacterial sepsis (5.5%). Only 3.3% children had received palivizumab. 1 death was attributed to RSV infection.

CONCLUSIONS: Majority of admissions comprised infants ≤2 years of age. 63.3% were 6–24 weeks gestation without underlying disease and in total 9.6% would not qualify for prophylaxis. Current Canadian RSV prophylaxis guidelines have significantly impacted PICU admission rates in high-risk infants.

PARENTERAL ALANYL-GLUTAMINE IN CRITICALLY ILL PATIENTS: A BAYESIAN META-ANALYSIS OF PUBLISHED TRIALS

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OBJECTIVES: To determine if patients had received palivizumab and document incurred morbidity and mortality. METHODS: A retrospective, hospital medical records review of all PICU admissions for RSV infection from January 1, 2003 to December 31, 2009. RSV infection was identified by ICD codes and cases were confirmed by RSV real-time, culture, or PCR.

RESULTS: Data was collected on baseline demographics, underlying disease, criteria for hospitalization, and complications. Group 1 patients (n=152) had a mean admission age in months (SD); 3.7 (4.4) versus 59.9 (37.7). Majority (79.6%) Group 1 versus only 20.7% Group 2 (n=29) had a mean admission age in months (SD); 3.7 (5.7) versus 59.9 (37.7). Majority (79.6%) Group 1 versus only 20.7% Group 2 (P<0.001) had no underlying disease. 97.4% versus 93.1% were admitted with respiratory distress and most had bronchiolitis; 88.8% versus 55.2% (P<0.001), decreased oxygen saturation; 77% versus 75.9% and inability to maintain intake; 72.7% versus 44.8% (P=0.01). Fifty percent versus 41.3% required mechanical ventilation and 81.6% versus 69.0% received antibiotics. Median days (range) in PICU was 5 (1–73) versus 2 (1–36). Median length of hospital stay days (range) was 9 (1–113) versus 7 (1–64) (P=0.05). The overall RSV positive, PICU hospitalization rate was 5.7%. There were few complications: respiratory (2.8%); concurrent bacterial sepsis (5.5%). Only 3.3% children had received palivizumab. 1 death was attributed to RSV infection.

CONCLUSIONS: Majority of admissions comprised infants ≤2 years of age. 63.3% were 6–24 weeks gestation without underlying disease and in total 9.6% would not qualify for prophylaxis. Current Canadian RSV prophylaxis guidelines have significantly impacted PICU admission rates in high-risk infants.

PHARMACOEPIDEMIOLOGICAL BURDEN OF PREGNANCY IN BELARUS

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OBJECTIVES: Application of medicines during pregnancy is a challenge of clinical pharmacology. We have analyzed priorities of physicians while choosing medications in the course of various diseases during pregnancy and adherence of pregnant women to the appointed treatment in Belarus. METHODS: It was prospective multi-center cross-sectional epidemiological research. We interviewed 619 physicians with diverse specialties in 6 regions of the country using a structured questionnaire from January to December 2009. All questionnaires have undergone statistical analysis. RESULTS: We found that 34.5% of the pregnant women who took part in questioning have had chronic diseases. Medical products were prescribed for 91.7% (1223) women, a total of 23.8% of them have received more than 5 medical products. Vitamins and drugs with microcells (magnesium, iodine, iron, and calcium), herbal drugs (valerian, lemon and elatericoccus) were in the lead in structure of prescription. 91.8% of the pregnant women took all prescribed medicines. 7.7% (103) women took antibacterial medicines following recommendations of the doctor, a total of 365 women (27.3%) took medicines without prescription (625 cases). Non-prescribed drugs during pregnancy had mostly been recommended by family or friends (24.1% of women) and pharmacists in drugstores (24.1%). CONCLUSIONS: Pregnancy in Belarus is one of the few countries to implement rotavirus vaccination within its universal paediatric immunization programme. This study was designed to measure the impact of rotavirus vaccination on acute gastroenteritis (AGE) related emergency room (ER) visits in children aged ≤5 years in Belgium. METHODS: A retrospective observational study was performed across 11 Belgian participating centres. Each centre provided an anonymised list of all ER visits of children aged ≤5 years during the periods June 2004–May 2006 (pre-vaccine period) and June 2007–May 2009 (post-vaccine). A sample of 7620 ER visits (3699 pre-vaccine; 3921 post-vaccine) was randomly selected from the 180,253 ER visits reported. Patient demographics and information on the reason for ER visit were collected from all randomly selected visits. If the visit was AGE-driven, additional data were collected on vaccination status, symptoms, tests performed, treatment, and visit outcome. RESULTS: The proportion of AGE-driven ER visits was 11% in the 2-year pre-vaccine period (N=AGE-driven visits/Total N ER visits = 412/3,669). After insignifcant change to 10.5% during the 1st year after vaccine introduction (N = 238/2,177), this proportion signifcantly declined to 8.2% (26.6% reduction; p-value<0.001) in the 2nd year (N = 159/1,944), a strong seasonal effect exists in the proportion of AGE-driven ER visits on the total number of ER visits, peaking in February and March. The number of patients who needed to be hospitalised because of AGE declined over time (from a yearly average of 94 pre-vaccine to 62 and then 44 in the 2 consecutive years post vaccine introduction). Oral and IV rehydration were the most commonly used treatments. Their use also declined after vaccine introduction. CONCLUSIONS: A signifcant decline in AGE-driven ER visits and subsequent hospitalizations was observed in Belgium after introduction of a universal mass vaccination program against rotavirus. AGE cases appeared less severe.