**GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies**

**PGI29**

### PPI GENERAL PRACTITIONERS' PRESCRIBING IN THE TREATMENT OF ACID-RELATED DISORDERS: THE IMPACT OF GENERIC PPI LAUNCH INTO THE PHARMACEUTICAL MARKET IN ITALY

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**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 consumption 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 (*versus* 2005) were associated with switching to lansoprazole 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 €133.1 per user-year in the case with more than 1 switch. **CONCLUSIONS:** In Italy the launch of 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 savings on PPIs, achievable by the introduction of generic products. Policy rules favouring generic PPIs prescribing can often influence physicians' decision to select the appropriate treatment for each patient.

**PGI30**

### ASSESSMENT OF FEASIBILITY OF THE METHODOLOGICAL APPROACH DESCRIBED IN THE MODEL FOR THE REGULATION OF REIMBURSEMENT PRICES IN GERMANY

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**OBJECTIVES:** The generic drug market within the statutory health insurance (SHI) in Germany is affected by price regulations like fixed amounts or rebats. Legal amendments led to an increasing importance of price discounts with uncertain impact on pharmaceutical supply of the patients. To assure a justifiable price for the pharmaceutical companies and high quality a model has been developed by the Federal Association of Medicines Manufacturers e. V. (BAH) for the regulation of reimbursement prices, e.g. cost-benefit based price corridors. Aim of the study is to test the described methods for feasibility. **METHODS:** The prior published methods for the development of reimbursement price corridors are applied and tested for feasibility by use of the indication Gastroesophageal Reflux Disease (GERD). The methods intend the derivation of one or more corridors following a defined decision algorithm based on primary and secondary benefit criteria. Therefore a systematic assessment of benefits of proton pump inhibitors (PPIs), H2-Blockers and sucralfat is the foundation of further decisions concerning the number of corridors to consider. Several methodical approaches for the definition of height of each corridor are tested. **RESULTS:** PPIs are more effective than H2-Blocker or sucralfat concerning primary benefit endpoints. The assessment is based on secondary literature for financial and time reasons that will be relevant when implementing the model in real decision problems, too. Based on the results of the benefit assessment two corridors were implemented into the model. The height of each corridor can be derivated by use of angles as well as by other mathematical parameters like mean, quartiles etc. Both approaches show specific limitations. **CONCLUSIONS:** The feasibility of the reported concept can be shown. Several limitations, e.g. assessment of benefits based on secondary literature should be considered. Use of angles or mathematical parameter should be discussed with decision makers before implementation.

**PGI31**

### EVALUATING THE POST OPERATIVE PRESCRIBING PRACTICES FOR APPENDICITIS IN PUBLIC HEALTH FACILITIES IN PAKISTAN

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**OBJECTIVES:** To investigate the pattern of prescribing practices for postoperative appendicitis in public health facilities. **METHODS:** The study population consisted of the largest public hospital Federal Government Services Hospital (Polyclinic) from Punjab, Pakistan; Islamabad. a sample of 100 prescriptions of post operative appendicitis was collected from the public hospital. **RESULTS:** A total of 13.3% prescriptions out of 100 contain 2 drugs, 40% contains 3 drugs, 40 % contains 4 drugs & 6.7% contains 5 dugs. Only 6.7% prescriptions contain drugs prescribed by generic while 93.3% prescriptions were not prescribed by generic name. a total of 3.3% prescriptions contain no antibiotics, 76.6% prescriptions contain 1 antibiotic, while 20% prescriptions contain 2 antibiotics. On the other hand 23.3% prescription does not contain any injection, 10% prescriptions contain 2 injections, 23.3% prescriptions contain 3 injections, while 43.3% prescriptions contain 4 injections. One hundred percent of prescribers suggested that standard treatment guidelines and essential drug list should be available and updated regularly in hospital and must be strictly followed. a total of 33.3% of prescribers think the essential drug list should be properly regulated and updated should by the hospital management, 33.3% prescribers think by Ministry of Health while 33.3% prescribers thinks it is the duty of Hospital pharmacist. This difference was noted with respect to age of the prescriber ($p = 0.020$) in the prescribing practice of physicians in the public health facility. **CONCLUSIONS:** The major reasons for irrational drug use in case of post operative appendicitis were due to polypharmacy, overuse of antibiotics and injection and lack of standard treatment guidelines in the hospital. Thus the extent of irrational drug use in the public sector calls for in-depth investigation of the system factors and motivations that underlying these problems in the practice and the development of interventions that target the causative factors of inappropriate prescribing practice in Pakistan.

**GASTROINTESTINAL DISORDERS – Conceptual Papers & Research on Methods**

**PGI32**

### USING DATA ENVELOPMENT ANALYSIS TO ESTABLISH THE EFFECTIVENESS 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 relatively. In order 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 to solve is to establish a more objective and efficient decision-making analysis that consider both effectiveness and cost for the drugs which have 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 (6.6542E-06), Drug D is the second (4.2381E-06), Drug B is the third (2.1165E-06) and Drug C is the worst (1.2786E-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

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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 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

2002 and £335 million in UK during 2001. **CONCLUSIONS:** Ulipristal appears as effective as levonorgestrel in preventing unintended pregnancies with similar safety profile. Substantial cost-savings can be expected with appropriate awareness programs about emergency contraceptives among women.

**PIH2**

### PEDIATRIC INTENSIVE CARE UNIT (PICU) ADMISSIONS FOR RESPIRATORY SYNCYTIAL VIRUS (RSV) 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 morbidities. **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 IFA test, culture, or PCR. Data was collected on baseline demographics, underlying disease, criteria for hospitalization, type of respiratory illness and management, complications and palivizumab prophylaxis. Group 1 patients (≤2 years) were compared to Group 2 (>2–18 years). **RESULTS:** A total of 181 patients were admitted with RSV infection over 7 years. Group 1 (n = 152); 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; 75.7% 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 prophylaxis. 1 death was attributed to RSV infection. **CONCLUSIONS:** Majority of admissions comprised infants ≤2 years of age. 63.3% were ≥36 weeks gestation without underlying disease and in total 88.4% would not qualify for prophylaxis. Current Canadian RSV prophylaxis guidelines have significantly impacted PICU admission rates in high-risk infants.

**PIH3**

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

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**OBJECTIVES:** Glutamine, although abundant in human tissue, can become conditionally essential in clinical conditions with hyper-catabolism and glutathione depletion (burns, pancreatic necrosis, surgical complications), but has not been added to parenteral nutrition solutions for a long time, for its alleged non-essentiality and the low solubility and stability in aqueous solutions, which have been solved by conjugation with alanine. In 2002 a meta-analysis of available trials conducted with alanylglutamine dipeptide revealed significant reductions of mortality, infections and ICU length of stay. Since then, data from other trials have become available. Aim of the present study is to update the treatment effect estimates by means of a series of Bayesian random effects models. **METHODS:** We searched EMBASE and Medline for clinical trials of standard total parenteral nutrition (TPN) vs. TPN + parenteral alanylglutamine in critically ill patients reporting hospital mortality, relative ICU-incident infection rate, and relative hospital length of stay. For each outcome, a series of Bayesian random effects models was specified, in which the treatment effect observed in the individual trials is assumed to be drawn from a common distribution and expressed as a relative risk or duration. **RESULTS:** Outcomes from 15 trials and 781 patients were retrieved. The main models, i.e. simple hierarchy random effects models with neutral priors, estimate a relative mortality of 0.70 (95% CrI: 0.46–0.97), a relative infection rate of 0.71 (95% CrI: 0.49–0.97), and a relative length of stay of 0.91 (95% CrI: 0.76–1.00). Secondary analyses indicated some heterogeneity in the magnitude and reliability of the benefits in sub-groups of the wider critically ill patient population. The incorporation of prior knowledge leads to significantly more precise estimates and permits to obtain comfortable reliability even on subgroup-specific treatment effects estimates. **CONCLUSIONS:** In conclusion, the available evidence supports a highly credible beneficial effect of alanylglutamine on mortality, infections and hospital length of stay in ICU-admitted critically ill patients.

**PIH4**

### COMPARING THE MODEL PREDICTED VACCINE IMPACT AGAINST ROTAVIRUS HOSPITALIZATION WITH OBSERVED DATA IN BELGIUM

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**OBJECTIVES:** In reimbursement files models estimate the events avoided over time with new interventions. Simulations are performed in the absence of long-term observational data. In this study observed hospitalization data prior- and post-rotavirus vaccination in Belgium were compared to predicted (i.e. modeled) results after 1,2 and 3 years. **METHODS:** A Markov cohort model estimated over time the number of hospitalizations potentially avoided with rotavirus vaccination in Belgium. We adjusted the model to the observed vaccine coverage and to Rotarix™ vaccine efficacy from clinical trials. The obtained modeling results were compared with observed data collected from 9 Belgian hospitals (2 years pre- and 3 consecutive years post-vaccination). The outcomes of both studies are expressed as a percentual decrease in hospitalizations for 2 age-groups (<2 and <5 years old), after each year post-vaccination. The differences are presented in absolute and relative (%) differences for each subsequent year post-vaccine launch. **RESULTS:** The observed data provided slightly better outcomes than the modeled results. After 1 year the absolute difference in decrease of hospitalizations between observed and modeled data was 3% (11%) for both age-groups. After 2 years the absolute differences were 3.5% (6%) and 6% (12%) for the 2 y and 5 y age-group respectively. In the last observation year the absolute differences were respectively 2.8% (4%) and 9.3% (13%). **CONCLUSIONS:** Compared with the observed data the model estimates are conservative. The more favorable observational results are explained by the indirect vaccine effect on non-vaccinated age-groups which is not captured by the static model. The relatively better model fit in the <2 y old with increasing time is explained by the accumulated vaccine impact over time: from 26% (1st year) to 68% (3rd year). *Rotarix* is a trademark of the GlaxoSmithKline group of companies.

**PIH5**

### 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 1334 pregnant women and 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, leonurus and eleutherococcus) 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 fo 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:** Pregnant women in Belarus are active consumers of medicines (vitamins, microcells, herbal drugs, bioadditives) themselves and with doctors' prescription. The widespread use of medicines indicates an increased need for documentation and education about the safety of medicines in the course of pregnancy. Application of these medications creates additional financial burden (in addition to necessary medicines and products), and it does not necessarily positively influence health. Educational programs for pharmacists, doctors and pregnant women are necessary for improvement of drug administration.

**PIH6**

### IMPACT OF ROTAVIRUS VACCINATION ON ACUTE GASTROENTERITIS RELATED EMERGENCY ROOM VISITS IN CHILDREN ≤FIVE YEARS OLD IN BELGIUM

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**OBJECTIVES:** Belgium 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 = 412/3,699). After insignificant change to 10.5% during the 1st year after vaccine introduction (N = 208/1,977), this proportion significantly 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 are the most commonly used treatments. Their use also declined after vaccine introduction. **CONCLUSIONS:** A significant 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.