enact more stringent price controls. The purpose of this study is to provide empirical evidence on how price regulations in the OECD affected the adoption speed of new patent-protected pharmaceutical technologies during 1999-2008. **METHODS:** We use discrete time duration modelling with parametric and semi-parametric duration dependence to examine how price expectations shape the probability of launch, controlling for competition, market size expectations, firm and molecule heterogeneity across the major OECD markets during 1999-2008. A sub-sample analysis including only EU countries also investigates the impact of price interdependencies and potential firm strategies in launch and pricing decisions. **RESULTS:** The empirical analysis suggests there is a statistically significant and robust price and market size effect in the adoption of new pharmaceutical technologies. A unit increase in the log expected launch price and the log of expected market size increases the probability of launch by 0.003 and 0.002 respectively. Concentrated therapeutic subgroups, reflecting market crowding constitutes a significant barrier to entry. Sub-sample findings from the EU market suggest strategic firm behaviour with firms delaying launch in low-priced markets and attempts to maintain price differentials across interdependent markets to a minimum due to price complementarities. Firm economies of scale and the therapeutic importance of innovations are other important drivers of early adoption. **CONCLUSIONS:** A significant and robust price and market size effect is observed in the likelihood of new pharmaceutical adoption. Price regulations slow down pharmaceutical adoption on a global scale and may impose welfare losses, particularly when the innovations that are delayed are cost-effective from a societal perspective. Due to scale advantages observed in international roll-out strategies, price controls may increase incentives for mergers and acquisitions, further increasing concentration levels and barriers to entry.

PHP22

ARE HOSPITAL MEDICINES PRICES INFLUENCED BY DISCOUNTS AND REBATES?

Vogler S[1], Zimmermann N[1], Leopold C[1], Habl C[1], Mazag J[2]
[1]*Gesundheit Österreich GmbH / Austrian Health Institute, Vienna, Austria,* [2]*State Institute for Drug Control (ŠÚKL),, Bratislava, Slovak Republic*

OBJECTIVES: To understand the role of discounts/rebates impacting medicines prices in hospitals. **METHODS:** Qualitative survey with competent authorities and hospital pharmacists about purchasing strategies for hospital medicines with all EU Member States and two further European countries (Norway, Turkey) Price survey (study visits) of 12 active ingredients in 25 hospitals in Austria, the The Netherlands, Norway, Portugal, Slovakia. **RESULTS:** Of a total of 27 European countries, 25 countries reported about the practice of discounts and/or rebates (ex-post price reductions). The range of the discounts varied among the countries and with regard to the products. Apart from Italy with mandatory discounts to the NHS, discounts were always commercial and as such usually kept confidential. Free-cost medicines (i.e. medicines provided without payment) were reported to be a practice in six countries, whereas it is legally forbidden in another six countries. In Austria, the The Netherlands, Portugal, and Slovakia discounts were granted in individual negotiations between suppliers and hospitals for some of the surveyed products (e.g., for cardiovascular medicines where generics were available; however no discounts for all oncology medicines of the sample). In Norway, discounts played no role since medicines were tendered centrally. In Austria and Slovakia medicines were provided cost-free to some/all hospitals (only in the indication of cardiovascular treatment). In Portugal, unit prices of nearly € 0.00 were surveyed for a few cardiovascular medicines attributable to rebates. **CONCLUSIONS:** In the in-patient sector, confidential discounts, and, to a lesser extent, rebates and cost-free medicines are common in some countries. Discounts are more likely to be provided where there are (off-patent) therapeutic alternatives available. Large discounts and cost-free provision appear to be a practice for "strategic products" which account for high volume and expenditure in the out-patient sector.

PHP23

ORPHAN DRUG ACCESS IN MEDICARE PLANS IN THE UNITED STATES

Sepulveda B, Doyle J
Quintiles, Hawthorne, NY, USA

OBJECTIVES: The increase in premium-priced orphan drugs coupled with health care budget constraints will pressure managed care plans to consider restricting market access. Coverage and reimbursement of ten FDA-designated orphan drugs (ceramide, alglucerase, modafinil, lamotrigine, laronidase, nitisinone, alpha-glucosidase, galsulfase, idursulfase, bosentan) were analyzed for ten popular Medicare PDP (AARP, Cigna, CVS Caremark, Humana, Medco, RxAmerica, EmblemHealth, UniCare, WellCare, FirstHealth. **METHODS:** Formulary tier structure, out-of-pocket costs (OPC), monthly retail costs and utilization restrictions (UR)—pre-authorization (PA), quantity limits (QL) and step therapy (ST)—were obtained from CMS (www.medicare.gov). UR were assigned point values reflecting most to least restrictive—PA, 3; ST, 2; QL, 1; 6 possible points per drug per plan unless excluded from formulary. OPC is the percentage of the drugs' costs paid by patients—an average of deductible, initial, gap, and catastrophic OPC. Disease incidences were obtained from a variety of sources. **RESULTS:** Monthly retail prices ranged from $19.56 (lamotrigine; generic) to $5,946.37 (bosentan). The drugs excluded from the most formularies were alglucerase and myozyme (3 each). Lamotrigine, the least expensive drug, had the highest OPC as a percentage of its retail price (57.58%) on average among the plans; however, this may be because of its low retail price. Bosentan had the lowest OPC (36.48%). There was no correlation between drug price and UR points (r2=0.030). There were a slight positive correlation between disease incidence and drug price (r2=0.219) and between disease incidence and OPC (r2=0.380). There were slight negative correlations between a drug's UR points and its OPC percentage (r2=0.163) and between its retail price and OPC (r2=0.423). **CONCLUSIONS:** URs on orphan drugs were prevalent in Medicare plans, with patients bearing 40-60% of the OPC. The extent of restrictions was not proportional to the drugs' price, suggesting that more research is warranted to investigate the factors related to orphan drug access.

PHP24

HOW DOES THE COMMITTEE TO EVALUATE DRUGS (CED) MAKE DECISIONS ABOUT AMBULATORY PHARMACEUTICAL FUNDING IN ONTARIO?

Sim J, Speicher J, Evans G, Mahar AL, Johnson A
Queen's University, Kingston, ON, Canada

OBJECTIVES: Pharmaceutical drug costs represent a large portion of government health care spending. A national standard to regulate the process of public financial reimbursement for drugs does not exist in Canada and variations in practices are evident across the country. The purpose of this study was to provide a comprehensive overview of how drug-funding decisions are made in Ontario. **METHODS:** Access to Ontario's Committee to Evaluate Drugs (CED) meeting minutes (July 2009-July 2010) was granted. A data abstraction form was created based on the framework established by Johnson et al. (2009). For each criterion, importance to the final decision, strength of evidence and quality of evidence were recorded. Two reviewers independently extracted the information and consensus was achieved. **RESULTS:** Forty-four submissions were included. Five main observations: 1) the CED considered certain criteria more frequently than others (e.g., clinical benefit was considered for all decisions, while societal values were discussed less frequently); 2) the relative impact of each criterion on the CED's recommendation varied (e.g., overall clinical benefit, efficacy, value for money, and need had the largest influence); 3) the CED was more likely to discuss the strength of evidence when its recommendation did not support public funding (e.g., the strength of cost evidence was discussed 3 times more often for those drugs not recommended for funding); 4) the frequency with which the CED considered criteria varied according to whether or not the CED believed there was an established need; and 5) the majority of the comments made by the CED about the strength of evidence indicated that the quality of the data was low. **CONCLUSIONS:** This review identified trends in the influence of different criteria involved in the CED's drug assessment process. These results may promote the development and application of a comprehensive, consistent, and transparent framework for reimbursement decision-making.

PHP25

DESIGNING FEASIBLE MODELS FOR AN OPTIMAL PHARMACEUTICAL CONSULTATION PROGRAM USING A SYSTEMATIC REVIEW

Medina-Artom T[1], Bramli S[2], Shavit O[3]
[1]*JDC-Brookdale Institute, Jerusalem, Israel,* [2]*JDC-Brookdale Institue, Jerusalem, Israel,* [3]*The Hebrew University of Jerusalem, Jerusalem , Israel*

BACKGROUND: Pharmaceutical consultation (PC) aims to maximize the successful outcome of a drug treatment. Although its benefits are well documented, several different PC models are implemented in various healthcare settings (HCS) and no optimal model has been identified. **OBJECTIVES:** To analyze the characteristics of PC models most relevant to key clinical, monetary, and social objectives, and to design PC models that optimize them and could be implemented in various HCS and in primary care in Israel. **METHODS:** We systematically reviewed studies of PC programs published from 2000–2010. We analyzed the programs by their organizational characteristics and defined a scale for measuring their success that incorporated the clinical, monetary and social objectives. Their results were then scored accordingly. We calculated the association between each of the key organizational characteristics and the success score to identify the characteristics that maximize the program's success. **RESULTS:** The analysis revealed three core patterns: consultation to patient and physician, patient alone, and physician alone. For each pattern, three feasible models for optimal PC were found. The organizational characteristics of each model included the subject and location of the consultation, target population, consultant's profession, communication method, incentives, duration, financing, and the PC process steps. **CONCLUSIONS:** This method for optimizing a model for PC program could be implemented in a variety of HCS to maximize successful drug treatment reflected in the prevention and control of illnesses, improved clinical outcomes, enhanced well-being of the population and maximum economic benefits. Interviews with a sample of key players in HCS could reveal preferences and benefits, which then will be combined with the results of the previous analysis to optimize a PC program for primary care in Israel and for other HCS.

PHP26

HEALTH OUTCOMES AND ECONOMICS RESEARCH FOR REGENERATIVE MEDICINE AND CELLULAR THERAPIES: LESSONS FROM A MULTI-MARKET HEALTH TECHNOLOGY ASSESSMENT AND REIMBURSEMENT REVIEW

Faulkner EC[1], Fernandez M[2], Spinner DS[1]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*RTI Health Solutions, RTP, NC, USA*

OBJECTIVES: Regenerative medicines, which include cellular and gene therapies, offer to shift the focus of healthcare from one of palliative care to curative treatment. Because these technologies are novel, more complex than standard biopharmaceuticals, and often costly, they are anticipated to face heavy scrutiny for market access and adoption. The objective of this analysis was to evaluate published HTAs and reimbursement policies on regenerative medicines for select global markets, compare them to existing biopharmaceuticals, and evaluate lessons for HEOR and market access planning. **METHODS:** A search of HTAs and reimbursement policies from Australia, Canada, France, Germany, Sweden, the UK (UK) and the United States (US) was conducted to identify reimbursement recommendations and key HEOR considerations for this new field. A review of the literature, including