

cation of sufficient time to respond to patients enquiries, consultations (about patient's disease, non-medical treatments, herbal medicines and supplements), arrangement of service stages, honesty in delivery of scarce medicines, waiting time, compliance of number and type of dispensed items with physician prescription, convenience of pharmacy's lobby space and suitable physical space for communication with pharmacy staff. In addition, according to the result of the Friedman test, the most important issue for patients in the study was observation of courtesy and respect by pharmacy staff. Overall satisfaction measured by weighted values (based on priorities identified by participants) of three components of satisfaction (physical space, service quality and staff behavior) was statistically different from satisfaction measured based on common method (3.48 vs. 3.40, p -value < 0.05). **CONCLUSIONS:** Pharmacy customers expect pharmacists to be more involved in providing advice. Also it seems that improvement in design of pharmacies physical space including allocation of an appropriate space for patients to talk with pharmacy staff, specially pharmacist, can increase customer's satisfaction. Observing customers' priorities may have an important influence on interpretation of the results of satisfaction studies and, therefore, on the selection of interventions.

PHP103

CHALLENGES AND FUTURE PROSPECTS OF NURSING WORKFORCE IN GREECE

Skroumpelos A¹, Gialama F², Daglas A³, Skoutelis D³, Pavi E¹, Kyriopoulos J¹

¹National School of Public Health, Athens, Greece, ²National School of Public Health, Athens, Greece, ³Greek Nurses Association, Athens, Greece

OBJECTIVES: Given the financial crisis-driven budget cuts and the experienced shortages in nursing staff, this study aims to identify the factors that have contributed to nurses shortages, the optimum size of nursing staff, the potential improvement of nurses skills and role and the more effective measures to cope with the current circumstances. **METHODS:** Experts from the fields of nursing and hospital management were invited to participate in an expert panel and asked to provide their opinion on the issues concerned with the objectives of the study. **RESULTS:** Of the 32 experts invited 20 (62.5%) accepted to participate. The majority of the panelists argued that the main reasons of nurses' shortages are the lack of workforce planning and the undersupply of nurses. Experts supported that nursing personnel should at least triple (10.5 nurses/1000 population and 2.5 nurses/hospital bed) and the nurses-doctor ratio should change from 0.61 nurses/doctor to 3 - 4 nurse/doctor. Most of the experts argued that more nurses should be university graduates and continuing education programs should be introduced. The substitution of doctors' services from nurses was widely accepted and argued that nurses' role can be expanded to prescribing, to the provision of preventive services, to the management of chronic condition patients and to diagnostic tests interpretation. Finally, in light of reduced health care budgets it was argued that shortages-driven issues could be partially addressed by redistributing the existing personnel according to population and hospitals' needs. **CONCLUSIONS:** The measures suggested for the improvement of nursing services quantity and quality may obscure in the constraints imposed by the current financial crisis. Redistributing the existing personnel can only provide a temporary solution. However, this study stresses the need for an effective workforce planning in order for the health system to guarantee an adequate level of services and equity in access, in times of reduced budgets.

PHP104

A CORRESPONDENCE ANALYSIS OF THE PATIENT'S PERSPECTIVE ON SHARED DECISION MAKING AT THE FAMILY-PHYSICIAN UNIT

Cuziol M¹, Baumgratz TD¹, Battisti R¹, Janini ACR¹, Levy RA², Abreu MM¹

¹Universidade Federal de São Carlos, São Carlos, São Paulo, Brazil, ²Universidade do Estado do Rio de Janeiro, Rio de Janeiro, Rio de Janeiro, Brazil

OBJECTIVES: This project evaluates the patients' perception about Shared Decision Making in primary attention in a single city. Also identify potential barriers and facilitators for the shared decision making in the clinical practice. **METHODS:** It is a quantitative study. All patients registered for family health care were invited. A questionnaire covering demographic data, multiprofessional team, knowledge of the health-illness and models of patient-physician relationship was developed and validated through a previous pilot study. Statistical analysis was performed through descriptive techniques and multiple correspondence analysis (to test associations among the categories). **RESULTS:** We interviewed 278 patients, 50% Caucasian, 79% female, 24% between 20 and 29 years and 42% with incomplete primary education. Four-one percent are unemployed and have income between one and two minimum wages. Of them, 78% and 78.4% consider the multidisciplinary work very important and its inclusion in the process of treatment, respectively, 71.58% prefer to decide the treatment with the doctor. Most users could not differ types of patient-physician relationship, as paternalistic, shared and informed decisions. A correspondence analysis plot was used to illustrate similarity of multidisciplinary team and shared decision making. Female, mestizo, and age between 30 and 39 years was associated with more willingness to share the decisions with the physician, according to correspondence plot analysis. There was no association between comprehension, decision-making and having a chronic disease or not. The other answers have no association with any category. **CONCLUSIONS:** This study demonstrated that patients on primary care believe that a multi-professional teamwork is important to apply shared decision making on clinical practice. The comprehension about informed, shared and paternalistic decision-making is confused for this sample. Comparative studies between primary care and specialties may assist the implementation of shared decision making, considering peculiarities in both kind of health care.

PHP105

IMPACT OF CLINICAL PHARMACY PROGRAM ON PRESCRIPTION ERRORS IN A LEBANESE INSTITUTION: A COST BENEFIT ANALYSIS

Nasser S¹, Slim M²

¹Lebanese American University, Beirut, Blat, Lebanon, ²Lebanese American University, Byblos, Blat, Lebanon

OBJECTIVES: The minimal role of clinical pharmacists on the medical floors in several health care institutions in Arab countries, had led to the concern of prescription errors. The objectives of this study was to determine if the presence of a clinical pharmacist could be cost beneficial when even limited to avoiding medication transcription errors and unnecessary medication use for the prophylaxis of stress ulcer and deep venous thrombosis. **METHODS:** A total of 1672 medication orders were reviewed to assess the prevalence and type of transcription errors for 255 patients in the internal medicine over a 6-month period between December 2011 and May 2012. Pharmacy interventions were documented by clinical pharmacy students during clinical rounds to determine inappropriate medication use. A cost benefit analysis of introducing a clinical pharmacist on the medical floor was performed. **RESULTS:** A total of 389 (23.3%) transcription errors were identified and classified as 1) failure to transcribe medications from charts into pharmacy orders (39.58%); 2) error in transcribing medications into pharmacy order (33.67%); or 3) errors in medication administrations to patients (26.71%). The benefits of introducing a clinical pharmacist on the medical floor originate from the anticipated reduction of the losses caused by transcription errors, decreased length of hospitalization stay, and reducing unnecessary medication use where a total of \$49,885.5 would be saved which is almost three times the annual salary of a junior pharmacist in Lebanon, and a net benefit of \$13,885.5 could be obtained. **CONCLUSIONS:** The implementation of clinical pharmacy in Lebanese health care institutions is needed to optimize health care clinical outcomes and subsequently minimizing medication errors and economical burdens.

PHP106

IMPACT OF PAYER PERCEPTIONS OF PHARMA COMPANIES ON ACCESS DECISIONS - AN ANALYSIS OF UNPROMPTED EXPRESSIONS IN PAYER INTERVIEWS

Ruppert A, Petrie N, King Z, Plata A, Rao N

IMS Consulting Group, Cambridge, UK

OBJECTIVES: As payer decisions become increasingly evidence based, a key question is whether payer on national/regional level are impacted by company perceptions when assessing evidence and making decisions. To identify what perceptions payers have, if and how these impact their decisions and what differences exist across stakeholders and companies, we analysed unprompted expressions of perceptions obtained from interviews performed with national/regional payers. **METHODS:** We analysed 543 national/regional payer interviews, performed for 100 projects by IMSCG 2008-2011 in Europe, including 900 quotes with unprompted expressions compressed in 1900 buzz-words. Interviews were screened for quotes reflecting perceptions of pharma unrelated to research objectives. Only unprompted expressions were extracted and buzz-words created that compressed expressed perceptions into single words/phrases. Half of the quotes expressed perceptions of specific companies. Analysis of the impact of perception on payer decisions was based on 5% of overall quotes containing that link. Buzz-words were valued, ranked according to occurrence and categorized into perception causes (reputation, interaction, employees, portfolio and research). Payers validated approach and outcomes. **RESULTS:** Perceptions are predominantly caused by company reputation and interaction, with national payers more influenced by reputation, regional by pharma interactions. Differences exist between portfolio versus employee perception, the former predominant in national, the latter in regional payers. While 60% of buzz-words were positive, results differ with national payers being significantly more critical towards industry than regional. The industry perception was more negative than perceptions expressed for individual companies. Perceptions directly impacting payer decisions were all negatively motivated by reputation, interactions and product perceptions ('me-too'), predominantly impacting access. **CONCLUSIONS:** Payers are influenced by company perceptions, which impact their decisions. Negative industry perceptions can be changed by companies; focus should be on national payers as regional have more positive perceptions already. Changing negative perceptions of company reputation, collaboration experience and employees' qualifications might avoid negative impact on access decisions.

PHP107

EXPERTS' VIEWS ON THE INTRODUCTION OF A MONOPSONY IN HEALTH CARE SERVICES IN GREECE

Skroumpelos A, Zavras D, Pavi E, Kyriopoulos J

National School of Public Health, Athens, Greece

OBJECTIVES: In light of the financial crisis, the largest social insurance funds were merged. This study aims to investigate the possibilities of a monopsony and to propose alternative methods for the new fund to allocate resources and to reimburse physicians. **METHODS:** A structured questionnaire concerned with the potentials of the new initiative, the resource allocation method and the physicians' reimbursement methods was constructed. An interdisciplinary expert panel was assembled and asked to provide its opinion on the above issues. **RESULTS:** A total of 66.7% of the experts supported the monopsonistic character of the fund unlike 33.3% who preferred a bilateral monopoly structure. However, expert's opinion on the potential of the fund to control expenditure and reduce cost of time and prices was not clear, while the majority argued that the fund can hardly guarantee adequate quality services. 68.2% agreed on the introduction of regional global budgets and the majority argued that the parameters to calculate the budget should be the region's population, the female, the birth, the elderly and the chronic condition patient rates and the standard mortality ratio. The introduction of an internal

market and capitation reimbursement for general practitioners and pediatricians were widely accepted. Incentive payments for both the above specialties were approved and determined according to the home visits for the pediatricians and according to the number of the enrolled elderly and chronic condition patients, the carry out of screening and the home visits for the general practitioners. Per-item reimbursement for specialists was weakly supported. The introduction of an internal market along with global budgets and incentive payments was argued that could control expenditure and supplier-induced demand, and improve equity in access and outcomes. **CONCLUSIONS:** Experts argue that a public monopoly in Greece can hardly guarantee efficiency and effectiveness, unless included in a wider reform framework of prospective payments, market-like mechanisms and financial incentives.

PHP108

EARLY ACCESS PROGRAMMES (EAPs): REVIEW OF NON- EUROPEAN SYSTEM

Urbinati D¹, Toumi M²

¹Creativ-Ceutical, Luxembourg, ²University Claude Bernard Lyon 1, Lyon, France

OBJECTIVES: Early Access Programmes (EAPs) provide the possibility of making medicines that address an unmet medical need available to patients before regulatory approval from the competent authorities. Market Access includes market development activities and patient access strategy, EAPs can positively impact both areas. The aim of this review is to consider, compile and describe the main EAPs available in Non-European Countries. **METHODS:** We conducted a review and performed a mapping of EAPs systems that exists in Europe. We searched existing literature in Embase, National Health Systems Website, ISPOR conference websites and Internet. In the countries where information were more scattered we directly contacted regulatory agencies and clinicians familiar with the local EAP regulations and practices. **RESULTS:** We described the practical implications surrounding the regulatory framework for EAPs, the key stakeholders involved in EAP decision-making and administration, the timeliness for EAPs approval, and the key factors for success. Many countries do not have an EAP in place and compassionate use is the only route to market for unregistered or investigational products. This is the case for Russia, Turkey, South Korea, Israel, India, and Brazil. The markets where EAP are more developed and sales are possible are: South Africa, Canada and Australia. **CONCLUSIONS:** This project made specific recommendations on the most favourable countries, based on the ease of setting up such a programme and the potential revenue that could result.

PHP109

PRACTICE CHANGE IN ITALIAN COMMUNITY PHARMACY: AN ANALYSIS OF MANAGERIAL IMPLICATION

Vagnoni E¹, Heidari M²

¹University of Ferrara, Ferrara, Italy, ²University of Ferrara, Ferrara, Ferrara, Italy

OBJECTIVES: The national government is repositioning the Community Pharmacies (CP) in the national health service, through definition of different: mix of services, relation with other health care actors, and range of objectives to achieve. Considering the contextual factors, the paper aims at analyzing the managerial implication for CP. For this purpose the CPs' director strategic attitude and the structure of the information system are investigated. **METHODS:** The paper is based on literature review and on a survey conducted among a national sample of 695 community pharmacies (CP). Data were collected through a questionnaire organized in both open questions and closed questions (Likert scale 1-7). Data were analyzed according to descriptive statistics to support the qualitative study approach. The SPSS program was used. **RESULTS:** Respondents have limited awareness of the different actions that the national and regional contexts implement regard to the CP. Although, the mix of services provided is heterogeneous and not widely consistent with the aims of the government reform (2009 law decree), there is a positive willingness to extend the professional role. Increasing the mix of services provided is perceived a strategic action (m=5,09), services are delivered even if the contribution to the CP's revenues is very low (m=2,62). The information system allows the monitoring of the overall financial results (m=5,33), while its relevance decreases with regard to the CP's cost structure (m=4,5) and to the specific service/business area's contribution to the general results (m=4,18). **CONCLUSIONS:** The study suggests that CP's directors haven't developed an effective strategic orientation yet. The actual information system is not able to support them to manage the changes. As long as CPs' director develop a strategic orientation, they could act as agent of change.

PHP110

GAINING REIMBURSEMENT OF ORPHAN PRODUCTS IN EUROPE: CHALLENGES DUE TO WIDE VARIATIONS IN EVIDENCE REQUIREMENTS AND PROCESSES

Heron L¹, Laurenson S¹, Costello J¹, Anderl C², Knosp J²

¹Adelphi Values, Bollington, Cheshire, UK, ²Santen GmbH, Germering, Germany

OBJECTIVES: Understand country-specific evidence requirements for the national reimbursement of orphan products (disease prevalence: <5/10,000) in the UK, France, Spain, Italy and Germany. **METHODS:** Qualitative research identified guidelines for reimbursement submission from each national reimbursement body. 1–5 orphan product appraisals per country were also reviewed to gain insight into the application of guidelines. Findings are based only on review of the guidelines and selected appraisals. **RESULTS:** The markets studied do not have reimbursement processes specifically for orphan products, however special considerations exist. For example, while direct comparator trials are the preferred sources of clinical evidence for non-orphan products, in certain instances reimbursement of orphan products has been granted based on placebo-controlled trials accompanied by indirect treatment comparisons. In England, exemptions are made only for orphan products which extend survival in patients with short life expectancies. In

Scotland, 62% of decisions on orphan indications have been negative, mostly due to a lack of robust economic evidence. In Italy, access to orphan products is encouraged and 94% of those launched are reimbursed: a lower benefit-risk ratio and evidence outside randomized controlled trials is accepted for orphan products. In France, orphan products benefit from fast-track procedures; however no special evidence considerations are acknowledged. Under AM-NutzenV in Germany, the medical benefit of orphan products is considered confirmed through the marketing authorisation; thus orphan submissions require a limited submission document. Whilst no national practices for orphan products exist in Spain, some regions implement risk-sharing agreements. **CONCLUSIONS:** Whilst reimbursement bodies recognize data limitations and provide special considerations for orphan products, processes are not explicit and requirements vary, leading to uncertainty in the reimbursement evidence requirements. It is therefore important to engage with appropriate reimbursement bodies to fully determine their specific requirements and modify one's submission to demonstrate an orphan product's ability to meet payers' needs.

PHP111

FACTORS PREDICTING REIMBURSEMENT DECISIONS ON ORPHAN DRUGS IN EIGHT COUNTRIES

Kanters T, Redekop W, Hakkaart L

Erasmus University Rotterdam, Rotterdam, The Netherlands

OBJECTIVES: The number of orphan drugs has increased vastly over the last years. However, the reimbursement of orphan drugs remains a black box. The objective of this study was to examine how much reimbursement decisions are influenced by disease-related and financial aspects of orphan drugs. **METHODS:** We examined publicly available reimbursement decisions for all 11 orphan drugs listed on the Dutch policy rule in eight countries (Australia, Belgium, Canada, England, Ireland, New Zealand, Scotland, and Wales). We examined whether the proportion of positive reimbursement decisions (based on the originally submitted price) depended on number of eligible patients, treatment costs, budget impact or timing of application. Information on these factors were based on the Dutch situation. **RESULTS:** For these 11 orphan drugs, 45 reimbursement decisions were publicly available, of which 12 decisions were positive. In addition, three decisions were positive for only a subgroup of an indication (infantile Pompe disease) and negative for all other patients (late-onset Pompe disease). Furthermore, in two cases the orphan drug was not eligible for reimbursement at the originally submitted price. One decision was deferred to allow additional data collection. The proportion of positive reimbursement decisions decreased as treatment cost per patient increased. A similar relationship was observed between total budget impact and proportion of positive reimbursement decisions. The number of eligible patients did not influence the proportion of positive reimbursement decisions. The proportion of positive decisions was lower for orphan drugs that were added to the policy rule at a later time. **CONCLUSIONS:** The proportion of positive reimbursement decisions is lower for drugs with higher treatment costs or budget impact. Future studies should be conducted with country-specific explanatory factors. Furthermore, future research should not only examine the outcomes of reimbursement decisions, but also study the entire reimbursement process to identify areas of improvement.

PHP112

ESTIMATING THE PROBABILITY OF A FAVORABLE ASSESSMENT OF CLINICAL BENEFITS FOR A NEW DRUG IN GERMANY USING AN MCDA APPROACH

Williams P¹, Mauskopf J¹, Kilburg A², Lebiecki J²

¹RTI Health Solutions, Research Triangle Park, NC, USA, ²RTI Health Solutions, Manchester, UK

OBJECTIVES: To develop a quantitative process to estimate the probability of a favorable assessment of additional clinical benefit for a new drug for a chronic non-life threatening disease in Germany. **METHODS:** A multi-criteria decision process was used that included: selection of 7 German decision makers; pre-workshop questionnaires to identify the most important attributes for the decision and their relative importance; a workshop to develop levels for the most important attributes, map each attribute level to a value function and identify marginal drug profiles (drugs just demonstrating 'additional clinical benefit'); post-workshop estimation of weighted scores for each marginal product based on the estimated values and relative importance of their attribute levels and a logistic regression model to estimate the probability of an 'additional clinical benefit' decision as a function of the weighted scores; post-workshop questionnaire to validate the logistic regression model using participant ratings for some hypothetical products. **RESULTS:** The most important attributes identified for a determination of 'additional clinical benefit' and their relative importance weights (%) were: robustness of clinical evidence (29%); incremental efficacy (19%); unmet need (12%); incremental impact on QOL (10%); availability of alternative treatments (9%); safety of new drug (9%); burden of disease (5%); availability of other country evaluations (4%); budget impact (3%). The attribute levels and relative value for a positive decision (0-1) for the most important attribute, robustness of clinical evidence, were: 'endpoints and/or comparators not relevant to patients' (0); 'clinical endpoints relevant but comparators not relevant needing indirect comparisons' (0.764); and 'all clinical endpoints and comparators relevant for patients and payers' (1). The estimates of the probability of an 'additional clinical benefit' for the hypothetical products using the logistic regression model had 71% positive predictive value and 85% negative predictive value when compared to participant decisions for these hypothetical products. **CONCLUSIONS:** An MCDA process can provide both a qualitative understanding and quantitative estimates of the relative importance, attribute levels, and value scales of different product attributes that influence a decision of 'additional clinical benefit' in Germany.