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OBJECTIVES: Health policy chances may effect the conducted studies in all fields. Pharmacoeconomics dossiers for the reimbursement applications for new medicines were not mandatory before year 2008. New molecules need to show cost-effectiveness and possible budget effect with their applications for reimbursement to Social Security Institution from 2008. This policy changing may effect pharmacoeconomics and health outcome studies in Turkey. The aim of the study is to evaluate the improvement of pharmacoeconomics and health outcome studies which are specific for Turkey in years. **METHODS:** Database of ISPOR Outcome Research Digest were searched online from the begining of database (1998) to 2011 with the key words "Turkey" and "Turkish". The inclusion criteria were taken as study must be specific for Turkey. Included abstract evaluated for increasing abstract numbers in years, distribution in study topics and diseases areas. **RESULTS:** A total of 108 abstracts were searched from the database; 80 of them were matched with inclusion criteria. First abstracts were published in 2000. There were only one or two abstracts per year until 2008. After year 2008, published abstracts numbers were increased year by year and reached up to 18 per year in 2011. 55% of all abstracts were Cost Studies(CS). It was followed by Health Care Use & Policy Studies(HP) (13.7%) and Conceptual Papers (CP) (8,7%). 15% of all abstracts were Multipl Disease studies. It was followed by Mental Health (15%) and Allergy(12.5%). **CONCLUSIONS:** It was shown that the policy changing in 2008 as to require pharmacoeconomics dossiers in the reimbursement application effected Turkey specific pharmacoeconomic and health outcome studies positively. In other words, pharmaceutical ýndustry and the government started to invest in pharmacoeconomics and health outcome studies after 2008.

PHP142

DRUG SHORTAGES AROUND THE WORLD AND THE UNDERLYING REASONS

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OBJECTIVES: To analyze real occurrences of drug shortages throughout 2010 and 2012 and the underlying reasons. **METHODS:** We conducted a systematic search in the scientific literature, media and public domain on occurrences of drug shortages and the perceived underlying reasons. The type of drug shortages were categorized and considered in context to their impact on access to medicines and health care system efficiency. **RESULTS:** While there were 20 publications of any type around this subject in Pubmed in 1995, the number increased with 34 in the year 2000, 70 in 2005, 99 in 2010, and 128 in 2011. The publications have discussed the health consequences, workarounds, and the health consequences of the workarounds. In February 2012, 110 drugs were listed on the FDA Web site, including at least 14 commonly used cancer chemotherapy drugs. Likewise, drug shortages are reported in many countries around the world including European countries such as Spain, France, UK, Russia, Portugal, Greece, or Rumania. Over the years, the reasons for drug shortages have changed from being predominantly caused by shortages in the active ingredients or insufficient distribution systems to currently often being the consequences of strong cost-containment measures or economic crisis. **CONCLUSIONS:** Drug shortages are increasingly observed over the last decade. Drug shortages can have multiple reasons and are currently often induced by economic or cost-containment reasons, and to misaligned incentives in the supply chain.

PHP143

EXPLORATORY TEST OF STAKEHOLDER THEORY IN THE IMPLEMENTATION PROCESS OF IT-INNOVATIONS IN HOSPITAL CARE

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OBJECTIVES: The main hypothesis in this study is that stakeholders have different preferences concerning IT innovations in hospitals, and these preferences are caused by perceived cost/benefit ratios. This will translate in disagreement between stakeholders on which innovations to implement first, possibly explaining the slow diffusion of innovations in health care. **METHODS:** Analytic Hierarchy Process (AHP) was used to quantify stakeholders positions in their priority of nine IT innovations. These innovations were selected after a systematic literature review and expert interviews. In the AHP, decision criteria related to costs and benefits of the innovations were defined: improvement in efficiency, health gains, satisfaction with care process, and required investments. Stakeholders judged the importance of the decision criteria and prioritized the selected IT innovations according to their expectations of how well the innovations would perform on these decision criteria. **RESULTS:** Sixty-two respondents, including patients, nurses, physicians, managers, health care insurers and policy makers showed significant differences in their expectations about their respective costs and benefits of the innovations, resulting in diverging preferences for the health care innovations. For instance, self tests are one of the most preferred innovations by health care insurers and managers, due to its expected positive impacts on efficiency and health gains. However, physicians, nurses and patients strongly doubt the health gains of self tests, and accordingly rank self tests as the least preferred innovation. **CONCLUSIONS:** We found clear differences in expectations of different stakeholder groups on IT innovations. The differences can be understood from the perspective of costs and benefits per stakeholder for each innovation. This study gives a first quantitative insight in stakeholder differences and presents a novel way to study stakeholder differences. The results may be used by decision makers to include alignment of stakeholder positions in implementation processes.

PHP144

ECONOMIC EFFECT OF CLINICAL TRIALS FOR TURKEY

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OBJECTIVES: Clinical studies are the main drivers of innovation in drug research. Pharmaceutical companies invest 15-20% of their revenue to clinical research for developing new treatments. Due the high investment opportunities, countries take actions to obtain the maximum share from global clinical studies market. Turkey has a good potential due the geological location. The aim of the study is to show possible economic effect of clinical studies to Turkey. **METHODS:** Application documents/files for the Ethic Committee of Istanbul Medical Facultyy were examined from 2006 to 2010. Studies sponsored by pharmaceutical companies were included. Pharmaceutical companies estimated budgets were accounted. Distribution of different disease areas of the studies and budgets were evaluated. **RESULTS:** Total number of applications for clinical studies have risen from 177 to 252 from 2006 to 2010. All industry sponsored clinical trials were reported as 184 for the given timeline. Approved sponsored pharmaceutical trials estimated total budget was € 859 million and Istanbul Medical Faculty could take € 59 million of all estimated budget in given timeline. Average cost for per clinical trial and per patient were calculated as € 467k and € 5k for Turkey. The highest estimated budget was hold by cardiological trials with € 61 million, followed by oncology and norology with € 59 million for the given timeline. **CONCLUSIONS:** It was shown that clinical trials may have a great impact to Turkey's economy. If Turkey may increase new launched trials, this is an opportunity for Turkey to take extra investment. Because these number are below the potential of pharmaceutical trials investment amounts when compared total pharmaceutical market. In addition, it is needed to account possible effects to reimbursement agencies. Due the potential impact of clinical studies for Turkey, decision and policy makers need to take action to improve clinical studies in Turkey.

PHP145

USING AN EVIDENCE DATABASE OF PREVIOUS NICE HTA DECISIONS TO MAXIMISE RE-REVIEW STRATEGY

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OBJECTIVES: To use a database of previous National Institute for Health and Clinical Excellence (NICE) health technology assessment (HTA) decisions (HTA inSite)1to understand the impact of four clinical evidence scenarios on the outcome of NICE technology appraisals (TAs). **METHODS:** We identified published NICE TAs containing evidence applicable to the following scenarios: 1) Efficacy data with a non-significant but positive trend; 2) Surrogate endpoints used in place of real endpoints; 3) Composite endpoints where statistical significance was driven by some, but not all, of the individual components; and 4) Efficacy data from observational studies. For each scenario, multiple submissions and re-submissions were identified using HTA inSite. The analysis focused on the evidence submitted, the final decision and critique by NICE, and any changes in approach by the manufacturer at re-submission. **RESULTS:** Clear patterns emerged for each scenario. For example NICE accepted data from surrogate endpoints (scenario 2) in all of the 4 submissions analysed. This was due to support by clinical experts and a clear rationale for the surrogates as established markers of efficacy. Observational data (scenario 4) were accepted in the absence of randomised controlled trials (RCTs), or in addition to RCTs where long-term or country-specific evidence was required. However, it was important to acknowledge and report any potential bias associated with the design of observational studies. **CONCLUSIONS:** An evaluated database can be used to understand the impact of any clinical evidence scenario on NICE decisions. The results can be used to inform submission strategy and assess decision outcome risk.

PHP146

PHARMACOECONOMIC EDUCATION FOR PHARMACY STUDENTS IN THE RUSSIAN FEDERATION

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OBJECTIVES: One priority for improving Russian health care is the optimization of health care resource use. Pharmacoeconomic (PE) methods allow economic evaluation of pharmaceutical products and services. The objective of this study was to investigate the extent of PE education in 2012 across pharmacy schools/departments in Russia. **METHODS:** A survey was e-mailed to 47 pharmacy schools listed on the federal educational portal www.edu.ru. Follow-up phone calls were made to non-respondents. Questions were used to determine: whether PE topics were taught and under what discipline, whether it was a required (base) or elective (variable) course, the number of academic hours dedicated to PE, the number of students in the course, topics covered, resources used, an opinion of the instructor on the sufficiency of the number of hours devoted to PE, and suggestions on PE education improvement in pharmacy schools. **RESULTS:** Forty-three schools replied to the survey (91.5% response rate). PE education was offered at 35 (81%) schools of pharmacy: in 25 (58%) schools PE topics were covered under required (base) course with median number of hours 3 (range 0.5-10, mean=4) and in 10 (23%) schools PE topics were covered under elective (variable) course with median number of hours 31 (range 16-54, mean=32). Eight (19%) pharmacy schools did not teach PE. The median numbers of students taking PE were 36 (range 12-220, mean=42) and 53 (range 24-350, mean=86) for required (base) and elective (variable) courses respectively. The majority of the instructors 22(63%) noted insufficiency of hours dedicated to PE. **CONCLUSIONS:** The majority of Pharmacy schools

provide PE education, however the number of hours is sufficiently greater for schools with an elective (variable) course in PE. In addition, results pertaining to the opinions of key educators on the insufficiency of number of hours devoted to PE-related topics and on enhancing PE education should be noted.

PHP147
EARLY ACCESS PROGRAMMES (EAPS): REVIEW OF THE EUROPEAN SYSTEM
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OBJECTIVES: Early Access Programmes (EAPs) provide the possibility of making medicines that address an unmet medical need available to patients before regulatory approval of the European Medicine Agency. 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 Europe. **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 timelines 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 Germany, Belgium, Poland, Austria and Switzerland. The markets where EAP are more developed and sales are possible are: France, Spain, UK, Italy, Sweden, Denmark, Portugal, and Norway. **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. At the time, there were several countries where the legal framework was changing (e.g. Austria) and some markets where information was simply not available.

HEALTH CARE USE & POLICY STUDIES - Health Technology Assessment Programs

PHP148
EARLY BENEFIT ASSESSMENT (EBA) IN GERMANY: DIFFERENCES BETWEEN PHARMACEUTICAL COMPANIES' CLAIMS AND IQWIG BENEFIT ASSESSMENTS
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OBJECTIVES: Since January 2011 the new German AMNOG health care reform includes a mandatory EBA for innovative medicines. At time of launch pharmaceutical companies have to submit a benefit dossier which is subsequently evaluated by the Institute for Quality and Efficiency in Health Care (IQWiG). Our aim was to explore differences in companies' benefit claims and the respective IQWiG assessments. **METHODS:** The review includes EBAs that were started in 2011. The Joint Federal Committee's (GBA) webpage was used to obtain the respective companies' benefit claims and IQWiG overall (i.e. aggregated, not on endpoint level) benefit assessments. The GBA's official scale is discriminating six levels of additional benefit versus comparative treatment: 1: major; 2: significant; 3: marginal; 4: not quantifiable; 5: no benefit; 6: less benefit. IQWiG's official evidence categories include: 1: proof; 2: indication; 3: hint. For the purpose of this abstract always the highest benefit level and evidence category claimed/assessed was taken into account. **RESULTS:** Twenty-four EBAs were started in 2011: Tafamidis Meglumin, Telaprevir, Abirateronacetat, Linagliptin, Pirfenidon, Boceprevir, Bromfenac, Ipilimumab, Fampridin, Belimumab, Belatacept, Dexmedetomidin, Cannabis Sativa, Apixaban, Pitavastatin, Retigabin, Aliskiren/Amlodipin, Collagenase, Eribulin, Cabazitaxel, Fingolimod, Regadenoson, Ticacrelor, Olmesartan/Amlodipin/Hydrochlorthiazid. The companies' benefit claims/IQWiG benefit assessments included the benefit level: major in 11/0 EBAs; significant 4/4; marginal 0/3; not quantifiable 1/2; no benefit 1/8; less benefit 0/0. Two Orphan indications were excluded from this analysis; for five drugs no full dossier submissions and/or IQWiG assessments were conducted (Bromfenac; Dexmedetomidin; Pitavastatin; Regadenoson; Olmesartan/Amlodipin/Hydrochlorthiazid) which resulted in a 'no benefit' conclusion by the GBA. Companies claimed a proof in thirteen EBAs. IQWiG acknowledged a proof in three EBAs. **CONCLUSIONS:** Both, evidence and benefit levels show major differences between companies' claims and IQWiG assessments. Most frequently companies claimed a major benefit (11 EBAs) while IQWiG most frequently applied the 'no benefit' category (8 EBAs).

PHP149
HEALTH TECHNOLOGY ASSESSMENT EVIDENCE CRITERIA: WHAT TYPES OF EVIDENCE SHOULD BE PRESENTED FOR PRODUCTS USED TO SCREEN FOR DISEASE IN THE UNITED STATES?
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OBJECTIVES: Screening technologies are on the forefront of innovation and have an impact on the care of patients in terms of identifying disease and appropriate treatment options at an early stage. As such, screening technologies are of key interest to health technology assessment (HTA) agencies in the United States (US) and abroad. The objective of this research study is to evaluate existing technology assessment standards for screening technologies in order to establish a best practice that may be implemented by US technology assessment organizations to broaden the criteria used in assessments for screening products. **METHODS:** Qualitative interviews involving 12 HTA experts from the US, Canada, and the UK were conducted. The experts represented HTA organizations that were for profit, not for profit, government agencies, private payers, and academic medical centers. While quantitative analysis of the levels of evidence required by HTA organizations for screening products would produce a desirable study design, the findings from the literature review indicated that quantitative evidence does not exist. **RESULTS:** The results of this study indicate that the best practices should include criteria to support screening reliability, sensitivity and specificity; evaluate data to identify appropriate patient populations; reference to the natural course of the disease; consider ethical implications; and the impact of cost. **CONCLUSIONS:** HTA criteria specific to the evaluation of screening products would positively impact HTA stakeholders such as HTA organizations, their clients, patients, as well as technology innovators. Best practices designed to help HTA organizations choose criteria that are focused on screening technologies will help to identify whether relevant patient populations for the technology exist. In so doing, levels of evidence and data requirements would be more transparent to screening technology innovators and patients. Cost should be a part of the assessment to understand the cost and benefit of using the product in specific patient populations for appropriate clinical decision making.

PHP150
SEARCHING FOR A THRESHOLD IN HUNGARY
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OBJECTIVES: Estimating the critical threshold value from previous reimbursement decisions is one of the several methods to determine a cost effectiveness threshold. The methodology is based on analyzing the relationship between the Incremental Cost Effectiveness Ratio (ICER) of the assessed health technologies, and the reimbursement decisions. Our study tries to examine if there is any relationship between cost effectiveness and decision making in Hungary by analyzing data abstracted from HTA appraisals and health economic studies. **METHODS:** The members of the HTA Department examined the submissions containing a cost-utility analysis which were assessed by the Hungarian HTA Office since 2004. We created a database in which we summed up the cost/QALY values of the examined submissions and HTA reports. We analyzed the appraisal determinations of the HTA Committee regarding the assessed submissions in order to examine the likelihood of a positive/negative decision according the level of the assessed pharmaceutical's ICER value. We searched for the technology with the highest ICER value, which got reimbursed. **RESULTS:** We examined 165 submissions which contained a cost-utility analysis that have arrived to our Department. Our results suggest that there is only a weak correlation (r=0,14) between the level of the calculated ICER and the reimbursement decisions. We found, that the highest ICER which resulted a positive reimbursement decision was 9 500 000 HUF/QALY (32 000 EUR). **CONCLUSIONS:** One of the several methods to determine a threshold value is to examine the relationship between previous reimbursement decisions and ICER values calculated in health economic appraisals. However one must take into account, that estimating a threshold value based on prior decisions has limitations, as reimbursement decisions are almost never made based on ICER ratios alone. This could be the main reason our study only showed a weak correlation between the level of calculated ICERs and the outcomes of the determinations.

PHP151
THE INFLUENCE OF PATIENT COMPLIANCE ARGUMENTS IN NICE TECHNOLOGY APPRAISALS
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OBJECTIVES: To identify, using HTAinSite, if and how manufacturers have used improved patient compliance as a value argument for their product in submissions to the National Institute for Health and Clinical Excellence (NICE). We analysed if and how compliance data were presented, how they were received by NICE, and if they were an influential factor in NICE's decision making. **METHODS:** A key phrase search in HTAinSite was used to identify instances of 'compliance' and 'adherence' in manufacturer submissions and NICE technology appraisal (TA) documents. After review for relevance, information was extracted and used to conduct a qualitative analysis. **RESULTS:** Fifteen manufacturer's submissions and 12 TAs reported an improvement in compliance as a value argument for their drug. Factors used to justify improved compliance included improved convenience, a reduction in adverse events, increased treatment choice, and improved route of administration. In 8 of 13 TAs (relating to 11 manufacturer submissions), NICE state that the compliance argument was considered by the Committee. In the remaining 5 TAs, despite inclusion of a compliance argument by manufacturers in their submissions, the Committee made no reference to it in the TA. Interestingly, only three manufacturers explicitly reported evidence supporting their compliance argument; however, the Committee discussed this in all of the associated TAs. The impact of improved compliance on clinical outcomes or cost-effectiveness was frequently not clearly reported by manufacturers or NICE. NICE did not explicitly cite compliance as an influential factor in their final decision in any TAs. **CONCLUSIONS:** The committee are more likely to consider a compliance argument if there is a clear clinical rationale and it is accompanied by supporting data. Although compliance arguments are considered by the Committee, NICE have not explicitly stated to have used them to influence final decisions.

PHP152
THE EARLY BENEFIT ASSESSMENT OF DRUGS THAT ARE LAUNCHED BEFORE 2011