OBJECTIVES: Health policy changes may affect the conducted studies in all fields. Pharmacoeconomics dossiers for the reimbursement applications for new medicines before year 2008 seem to be better. New molecules need to show cost-effectiveness and possible budget effect with their applications for reimbursement to the Social Security Institution from 2008. This policy change may affect pharmacoeconomics and health outcome studies in Turkey. The aim of the study is to evaluate the changes in the pharmacoeconomics dossiers in the reimbursement application from Turkey. The inclusion criteria were taken as study must be published after year 2008. The abstracts were evaluated for increasing abstracts 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 2009. 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 Multi 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 effectuated Turkey specific pharmacoeconomic and health outcome studies positively. In other words, pharmacological industry 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 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, 173 in 2010 and 70 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 consequence of strong cost-containment measures, or alignment of stakeholder positions in implementation processes. 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 views. 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. Respondents assigned converging preferences depending on the innovation, 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. These 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 Ethics Committee of Istanbul Medical Faculty 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 nephrology 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 potential in 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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1National Institute for Health and Clinical Excellence (NICE) health technology assessment (HTA) decisions (HTA inSite) to 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 may be important to approach this evidence and re-submissions in the future 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, 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 in 10 (mean = 4) and in 5 (mean = 4) of 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 = 68). After interview, 22% (8/36) of instructors noted insufficient of hours dedicated to PE. CONCLUSIONS: The majority of Pharmacy schools