reimbursement decisions. Our objective was to evaluate the lag between a drug’s FDA approval and the publication of the first published CUA evaluating the product. METHODS: We used the FDA’s website to identify newly approved drugs from 2000-2010 (n=342). For each drug, we searched the Tufts Medical Center Cost-Effectiveness Analysis Registry and the NHS Economic Evaluation Database for CUA evaluating the drug, and if we found corresponding CUA, we included drugs with a corresponding CUA in our dataset. When multiple CUA were available, we included the CUA with the earliest publication date. We used multivariate linear regression to determine factors associated with time to CUA publication (years). Independent variables included drug approval year, study funder, i.e., whether the CUA was supported by industry, and whether the FDA assigned the drug priority review status. RESULTS: One hundred and fifty-six (45.6%) drugs in our sample had a corresponding CUA. Average time to CUA publication was 4 years (standard deviation 2.3 years). We divided drug approvals into three time intervals: 2000-2002 (mean time to CUA publication=3.5 SD=2.4), 2003-2006 (mean=3.9, SD=2.0) and 2007-2010 (mean=2.4, SD=0.9). The results for all drugs approved from 2000-2002, time to CUA publication was 1.5 years shorter for drugs approved from 2003-2006 (p<0.001) and 3 years shorter for drugs approved from 2007-2010 (p<0.001). Source of study support and FDA priority review status were strongly associated with time to CUA publication. CONCLUSIONS: FDA-approved drugs with a corresponding CUA, we found a substantial time lag between FDA approval and CUA publication, suggesting that decision-makers are making important drug coverage and reimbursement decisions without published cost-effectiveness evidence available. However, the time to CUA publication appears to have declined over time.

PH12 THE TREND OF PRICE LEVEL FOR ANTI-INFECTIVE DRUGS IN CHINA: AN EMPirical STUDY BASED ON MULTIPLE INDEX METHODS

Ma FE, Wu Y, Zhao SH, Tianjin University, Tianjin, China

OBJECTIVES: To measure the trend of price level for anti-infective drugs in Tianjin, China, using multiple index methods and to explore the influence of price index bias induced by index methods and measurement units. METHODS: Data were extracted from inpatient claims in Tianjin Urban Employee Basic Medical Insurance database from 2006 to 2010. Laspeyres, Paasches, Fisher and chained Fisher index methods were used to measure the price level. Price indices were calculated both at molecule level (defined by active ingredient) and product level (defined by molecule, strength, preparation and manufacturer). Units of quantity and price were defined as per DDD (Defined Daily Dose), per milligram of active ingredient, and per minimum unit separately to calculate the indices. RESULTS: At product level, 367 constantly used products (26% of total 1422 products) were included in unchained indices and 1041 products (73% of total products) were included in chained Fisher index. The results of multiple indices consistently indicated that the price level decreased and the decreasing range indicated by different index methods were from 16% (Laspeyres-unit index at molecule level) to 27% (Laspeyres-DDD index at product level). The price indices at molecule level decreased slower than the counterparts at product level (22% vs. 25% in chained Fisher-DDD index). At molecule level, price indices based on per DDD decreased faster than per mg and per unit (22%, 21% and 18% in chained Fisher). Laspeyres indices decreased slower than Paasches and Fisher indices. We concluded that while the contrary was the case at product level. The results from chained Fisher and unchained counterparts were similar (25% vs. 26% at product level). CONCLUSIONS: The price level of anti-infective drugs decreased heavily in Tianjin, China. The chained indices were similar to the unchained counterparts which suggested that the price of newer and older products decreased at similar rate.

PH13 PERFORMANCE EVALUATION OF THE ESSENTIAL MEDICINES SYSTEM IN CHINA BASED ON DATA ENVELOPMENT ANALYSIS: A CASE STUDY IN SICHUAN PROVINCE

Hu M1, Liao W2, Yang L2, Lin T1
1Sichuan University, Chengdu, China, 2West China Hospital, Sichuan University, Chengdu, China

OBJECTIVES: To establish performance evaluation model of the Essential Medicine System in China based on Data Envelopment Analysis(DEA), evaluate the relative efficiency of essential medicines system and analyze the main problem and impact factors on it. METHODS: 15 counties in Sichuan province were selected by stratified sampling as Decision Making Units(DMU), for each county, 3% primary health care facilities, totally 284 facilities were involved as sample. Questionnaire survey was conducted to collect data of input and output indicators in 2010 and 2011 from sample facilities. 3 input indicators and 4 output indicators were set based on literature review, WHO’s National Drug Policies Monitoring Indicators and experiential principle of DEA. Excel 2007 was used to encode data, DEA 2.1 software was used to conduct CCR and VRS - BCC Data Envelopment Analysis, SPS516 0.6 was used to conduct T-test and multiple linear regression analysis to examine the statistic difference between 2010 and 2011, and the influencing factors of efficiency. RESULTS: For input indicators, the average special funds of Essential Medicine System(x1) in 15 counties was 364,907,000 yuan, while price under the PLS in 2010 was 0.52 million yuan, and the average price was 0.95 million yuan in 2011, the average of the two inputs was 0.65 million yuan. For output indicators, the average number of essential medicines(x2) and drug delivery companies(x3) raised as well. For output indicators, average outpatient cost per visit(y1) and inpatient cost per stay(y2) decreased, meanwhile the outpatient visit times(y3) and discharge number(y4) kept no increasing as expected. The overall efficiency of Essential Medicine System in Sichuan province in two years were in relatively high level(0.908 in 2010 and 0.832 in 2011). Analysis on technical efficiency, scale efficiency and return on scale showed the DEA’s relative efficiency and policy implication for the utilization of input health care resource. CONCLUSIONS: The effectiveness of implementation of Nation Essential Medicine System has been displayed, but health care resource should be adjusted and utilized rationally to improve the overall efficiency.

PH14 DIFFERENT EVIDENCE REQUIREMENTS COMPARING THE AUTHORIZATION AND REIMBURSEMENT PROCESSES OF HIGH-RISK MEDICAL DEVICES – THE EUROPEAN SITUATION

Krueger L1, Jävers SM2, Hilgmann M3, Wild C4
1Hamburg, Germany, 2Maasrode, The Netherlands, 3Ludwig-Boltzmann Institute for Health Technology Assessment, Vienna, Austria

OBJECTIVES: In the last decade awareness has been raised due to unsafe and dangerous medical devices entering the European market, putting patient safety at stake. Consequently, evidence requirements may not be enough to ensure a high-quality and safe provision of medical devices in Europe. This research aims at exploring the authorization and reimbursement processes and the associated evidence requirements comparing four high-risk regions Europe, United States, Australia and Canada. METHODS: First, we performed a literature search about the authorization and reimbursement in the four high-risk regions. Second, seven high-risk medical devices and the current authorization and reimbursement status were assessed. Information was extracted from publicly available summaries, from PubMed, and from the clinical trial database (clinicaltrials.gov), supplemented by the worldwide web. RESULTS: The evidence required for the authorization and reimbursement processes varies across the four high-risk regions. All seven devices have been authorized in Europe, three in Australia, one in the United States, and one in Canada. Currently none of the seven devices is recommended for reimbursement in the four high-risk regions. CONCLUSIONS: Looking at the difference in evidence requirements, more harmonization, transparency and specific guidelines are needed worldwide for the authorization and reimbursement of high-risk medical devices to ensure a high-quality and safe provision.

PH15 OVERVIEW OF EXTERNAL REFERENCE PRICING SYSTEMS IN EUROPE

Semmelot R1, Urbiniati D2, Recher Y2, Kerdil A3, Toumi M4
1Creativ-Ceutical, Paris, France, 2Creativ-Ceutical, Luxembourg, Luxembourg, 3Creativ-Ceutical, London, UK, 4University Claude Bernard Lyon 1, Lyon, France

OBJECTIVES: ERP is one of most common cost-containment tools used to reduce prices in price-patient pharmaceuticals in the European Union Member States (MS). The objective of this project was to provide an overview of ERP systems, both on processes and potential issues related to ERP systems in 31 European countries (EU MS, Norway, Iceland, Switzerland and Liechtenstein). We present the findings of the Survey ERP Project (http://www.erp-project.eu). METHODS: A systematic structured literature review and consultation of representatives of competent authorities and international organizations were conducted to identify and characterize the use of ERP, to describe its impacts on the prices of pharmaceuticals and to discuss possible cross-country coordination issues in EU MS. RESULTS: All selected countries apply ERP except the UK and Sweden and 23 countries use ERP as main systematic criterion. ERP is based on legislated pricing rules or reference levels of prices. In most countries, ERP is applied either to all marketed drugs or to specific categories of medicines, mainly used for publicly reimbursed medicines. The number of reference countries included in the basket varies from 1 to 31. There is a great variation in calculation methods used to compute the price: 15 countries use average price, 7 countries use the lowest price, and 7 countries use other calculation methods. Among reported limitations of ERP application are reliable sources of price information, price heterogeneity, market access and reimbursement. Spill-over effects on other countries and downward price convergence have often been argued leading to pricing strategies from pharmaceutical companies. CONCLUSIONS: While ERP is widely used in Europe, processes and available price information vary from one country to another that may limit ERP application. Moreover, ERP spill-over effect is a major concern of pharmaceutical firms leading to implementation of the so-called “launch sequence strategies”.

PH16 THE ANALYSIS OF THE DRUG REIMBURSEMENT DECISIONS BEFORE AND AFTER THE POSITIVE LIST SYSTEM IN SOUTH KOREA

Hwang JM1, Jung S2, Yang BM3, Lee HY1, Kwon YH2, Park MH3, Bae EY4
1Seoul National University, Seoul, South Korea, 2Institute of Health and Environment, Seoul, South Korea, 3Health Insurance Review and Assessment Service, Seoul, South Korea, 4Cheongju National University, Cheongju, South Korea

OBJECTIVES: In Korea, the positive list system (PLS) was introduced in 2007 to ensure the good value for money in pharmaceutical expenditure. This study aims to investigate factors that are most influential in reimbursement decisions under the PLS. METHODS: To assess the 5 years operations and compare the results before and after the PLS, we analyzed the drug prices submitted from the companies, the reimbursement decisions made by Pharmaceutical Benefit Coverage Assessment Committee (PBCAC). We extracted data from published evaluation reports, PBCAC meeting minutes, and internal documents of Health Insurance Review and Assessment Service. RESULTS: Under the PLS, 71% of submitted drugs were recommended for reimbursement during January 2007- April 2012. For submissions demonstrated superiority or non-inferiority in clinical benefit, 79% of submissions were decided to be reimbursed. However, submissions with inferiority or uncertainties in clinical benefit were rejected regardless of the price. Comparing the pre-PLS period, the relative price increased 3.8% before the PLS, whereas the negotiated price was 85% of the relative price. The probability of recommendation was high when ICER was under the GDP per capita, nevertheless submissions with low uncertainty and products for severe diseases or rare diseases were recommended for reimbursement despite ICER was high. CONCLUSIONS: This study confirmed clinical benefit was the main driver of the reimbursement decision making. The PLS showed a cost-effectiveness driven system. Consequently, the uncertainty of evidence and reimbursement in other countries were also considered in the reimbursement decision making process. In addition, the drug prices were reduced a little after PLS introduced compared to those under the negative list system.