

community hospitals as models in areas such as following: to improve efficiency by downsizing the scale of the hospitals, to adopt new marketing strategies, and to change the cost structure of facility operations. **CONCLUSIONS:** Results of this work can be useful for guidance to hospital CEOs and administrators, creditors and bondholders, health care consultants, public finance and public accounting researchers, public policy analysts, and the government; to gain insights of this issue of hospital's economic performance along the above mentioned variables.

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PERFORMANCE INDICATORS OF INTENSIVE CARE IN HUNGARY

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OBJECTIVES: The aim of the study is to show the change in important parameters of intensive care units in Hungary from the year 2000 to 2010. **METHODS:** Data of the analysis was taken from the financial database of the Hungarian National Health Insurance Fund Administration, the only health care agency in Hungary. We analyzed the number of hospital beds at intensive care units, the number of intensive care units, their average bed numbers, market share. **RESULTS:** The Hungarian health care system has had 150-167 intensive care units all over the country. The teaching and some county hospitals had more than one ICU. That meant 1183-1430 beds during the 10 years. We found the highest number of intensive care beds in 2006 (1430) which was significantly decreased in 2007-2008 below 1300 beds. The median range of beds at a typical ICU was between 5-9. The market share of intensive care hospital beds form the total number of acute care hospital beds increased from 1.8 % in 2000 to 2.9 % in 2011. The proportion of day provided with ventilation also significantly increased from 29 % in 2000 to 68 % in 2010. **CONCLUSIONS:** In Hungary the number of the ICUs and the number of the ICUs' bed did not change significantly in the last 10 years. During this period, the rate of the ventilation increased. The Hungarian intensive care units successfully managed to adapt to the changing hospital environment.

Health Care Use & Policy Studies – Health Technology Assessment Programs

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PRELIMINARY ANALYSIS OF THE UNWRITTEN DECISION RULES BEHIND THE FRENCH TRANSPARENCY COMMISSION'S ASSESSMENT OF DRUGS

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OBJECTIVES: Our objective was to analyze the French HTA decision making process of the Transparency Commission (TC) and try to identify unwritten decision rules which influence a drug's SMR and ASMR. **METHODS:** We analyzed the TC database for the years 2005 to 2010, looking at key points of the TC's opinions listed within such as: SMR, ASMR, target population, public health impact, presence of alternatives, orphan drug status, prescription restriction etc. Using a bivariate analysis we compared drugs granted: insufficient SMR versus other SMR; ASMR V versus ASMR IV; ASMR IV versus ASMR I, II and III. **RESULTS:** We found that drugs granted an ASMR V more often had alternatives than drugs with an ASMR IV (89.74% vs. 69.82%, $p < 0.005$), while prescription of drugs with an ASMR IV was more often restricted than for drugs with an ASMR V ($p = 0.01$ for hospital-only prescription and $p < 0.005$ for specialist prescription). The median target population for drugs with an ASMR IV was also smaller than for an ASMR V (15,000 vs. 97,250). On the other hand drugs with an ASMR IV more often had no public health impact than those with an ASMR I-III (55.70% vs. 22.13%, $p < 0.005$). Drugs with a high ASMR had smaller median target population (3,400 vs. 15,000) although there was no difference in orphan drug status between the two groups (9.47% for ASMR IV vs. 14.07% for ASMR I-III, $p = 0.20$). More drugs with ASMR I-III were paediatric medicines (30.04% vs. 14.79%, $p < 0.005$). **CONCLUSIONS:** Further analyses are in progress using additional qualitative criteria extracted from the TC's opinions and using a multivariate analysis. Such information would be critical for the development of TC application dossier.

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CLINICAL AND ECONOMIC EVIDENCE BASES FOR HEALTH TECHNOLOGY ASSESSMENT: A COMPARISON OF THREE JURISDICTIONS

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OBJECTIVES: To understand how different evidence bases may contribute to health technology assessment (HTA) across jurisdictions, we reviewed the evidence considered by three HTA agencies supporting reimbursement recommendations for nine drugs. **METHODS:** We selected nine drugs for which the Canadian Common Drug Review (CDR), the Australian Pharmaceutical Benefits Advisory Committee (PBAC), and the National Institute for Health and Clinical Excellence (NICE) had each provided recent reimbursement recommendations. We reviewed the clinical and economic evidence considered for each decision and evaluated whether different evidence bases could have contributed to different HTA decisions. **RESULTS:** The three HTA agencies agreed (recommended to reimburse) for four drugs and reached different recommendations for five drugs. In both categories, somewhat different evidence bases were used by each agency. For a given drug, different comparators were sometimes considered by different agencies. Even when comparators were common across agencies, there was variability regarding which clinical trials were considered. All agencies considered data from

direct, randomized trials, but PBAC and NICE accepted indirect comparisons, whereas CDR did not. Regarding economic outcomes, all NICE decisions made use of cost-effectiveness (mostly cost-utility) analyses, but cost-minimization approaches were considered by CDR and PBAC for several drugs. Overall, NICE provided the most transparent reporting on decision making, and CDR was generally the least transparent of the three. **CONCLUSIONS:** HTA drug decisions across the three countries lack good agreement, and considerable variability exists in the clinical and economic bases considered by CDR, PBAC, and NICE. The reluctance of CDR to accept indirect clinical comparisons, and the propensity of NICE to heed expert advice when analyses were inconclusive may contribute to dissimilar decisions being reached for some drugs. Greater transparency and harmonization of HTA methods have the potential to improve efficiency in health care decision-making, and further research analyzing additional HTA drug decisions is warranted.

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THE COST-EFFECTIVENESS THRESHOLD: THE RESULTS OF A NOVEL LITERATURE REVIEW METHOD

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OBJECTIVES: To review the existing literature on: i) the definition of the threshold ii) debate about its use, theory and value and, iii) robust theoretical methods for its calculation. **METHODS:** The traditional approach for literature searching makes use of key terms and Medical Subject Headings (MeSH) that most accurately capture the range of literature relevant to the piece of work while attempting to minimize irrelevant studies. This process requires a degree of expertise (and luck) as to the terms used, with the potential of missing related but differently specified areas of the literature and anything not captured in search engines. The alternative approach is "pearl growing". This approach uses a pool of relevant papers ("initial pearls") to grow the literature both through references and citations until all relevant papers have been discovered. This approach therefore relies on the expertise of the authors of the published literature rather than the searcher's knowledge of applicable terms. **RESULTS:** The traditional method of searching yielded 34 papers, only 17 of which were deemed relevant. In comparison pearl growing resulted in the identification of 76 relevant papers, including all of the 17 papers identified under the traditional strategy. The focus of many of these papers was to debate the use of a threshold, the theory underlying it or its value. A small number focused on methods for estimating its value, with a large majority using the social willingness-to-pay. **CONCLUSIONS:** The "pearl growing" approach offers a range of benefits over traditional methods, including the identification of papers and distinct sections of the literature not discovered otherwise, although it is limited by the existing software. The cost-effectiveness threshold has been heavily debated, but there exists very little literature that attempts to provide a meaningful estimate of its value or even provide a theoretical framework for its calculation.

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ANALYSIS OF PRICING & REIMBURSEMENT APPROVAL PROCESS FOR NEW DRUGS IN KOREA UNDER NEWLY-INTRODUCED HTA ENVIRONMENT (2007-2010)

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OBJECTIVES: Since 2007, HTA environment has been introduced to evaluate new drugs' pricing & reimbursement in Korea, and PE submission became one of mandatory requirements in HIRA (Health Insurance Review Agency). The objective of this study is to understand the overall process and result under the current environment, and to identify factors in the process which might cause a patient access issue. **METHODS:** We reviewed DREC (Drug Reimbursement Evaluation Committee)'s result reports (n=97) of new products from August 2007 to November 2010, which is open to the public. **RESULTS:** Among total 97 cases, the number of reimbursement decision was 58 (59.8%) at HIRA. The majority of reason for reimbursement decision was lower treatment cost (67.2%). DREC accepted only 12 cases' ICER value for reimbursement decision, 85 decisions were made without PE result data. Although clinical usefulness was improved in 33 cases, non-reimbursement decision was made in 6 cases because cost-effectiveness or PE data was uncertain. Among 39 cases of non-reimbursement decisions, 10 cases accepted WAP (Weighted Average Price) that HIRA suggested. Success rate of price negotiation at NHIC was 68.0%, and took 3.7 months including administrative process from DREC decision to MOHW (Ministry of Health and Welfare)'s final announcement. Average duration for final reimbursement decision was 16.9 months. Approximately 7 more months were necessary for applicant with PE data rather than without PE data (22.0 months vs. 15.0 months). **CONCLUSIONS:** The aim for introducing HTA is to list drugs which prove clinical usefulness and cost effectiveness but this analysis shows that it is difficult to expedite patient access to medicine through a HTA environment in Korea. Alternatives beyond PE evidence are needed for timely patients' access to innovative drugs.

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IS THERE NO OPTIMAL APPROACH FOR ORPHAN DRUGS TO PATIENT ACCESS? RARE DISEASE IS NOT RARE AND NEEDS TO DEVELOP THE NEW PRICING AND REIMBURSEMENT SOLUTION

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