PHPB2 THE DA VINCI SURGICAL SYSTEM: A RAPID REVIEW OF THE CLINICAL AND ECONOMIC EVIDENCE TO INFORM DECISION-MAKING

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OBJECTIVES: Da Vinci Surgical System (DVSS) is the most widely studied surgical robot in recent years, which is developed to assist surgeons performing surgical procedures. However, it is associated with high capital and operating costs. Given its limitations, a review of clinical and economic evidence is necessary for decision-makers. We conducted a rapid review to evaluate the clinical and cost-effectiveness of DVSS compared with open procedures and laparoscopic procedures, in conjunction with a comprehensive search of electronic databases (EMBASE, PubMed, Cochrane Library, Aviation Industry Corporation of China, Cochrane Library, China, 4Nuclear Industry 416 Hospital, Chengdu, China, 1Wuhan University, Wuhan, China).

RESULTS: After an initial screen of 272 studies, 18 studies (n=45,516) were selected for meeting inclusion criteria: 3 studies with 32,499 patients were health economic analyses; 15 were randomized controlled trials and 15 included patients were systematic reviews. The clinical and cost-effectiveness of DVSS was varied between diseases. Overall, DVSS was shown to be associated with a reduction in operative time, length of hospital stay, blood loss, and transverse rate compared with open and laparoscopic surgery on prostatectomy, nephrectomy, and hysterectomy colorectal surgery. DVSS was more expensive than open and laparoscopic surgery for the cost of acquiring, operating, and maintaining the robotic techniques. Most economic studies showed no significant difference was found in cost-effectiveness of DVSS compared with open. CONCLUSIONS: DVSS may have an impact on several clinical outcomes. However, the evidence was limited to systematic review and health economic analyses. Furthermore, the cost of DVSS is higher than open and laparoscopic surgery. Taking all of this evidence together, decisions about the robot-assisted surgery need to be made carefully.

PHPB3 THE PERFORMANCE OF THE PRAGMATIC STRATEGY TO BRING IN PHARMACOECONOMIC EVIDENCE FOR DRUGS REIMBURSEMENT DECISIONS IN TAIWAN

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OBJECTIVES: Local pharmacoeconomic evidence was seldom included in the manufacturers' new drugs submission in Taiwan before. A series of pragmatic strategies were proposed to encourage the presentation of local cost-effectiveness assessment (CEA) evidence in the dossiers. This study aims at examining the performance of these strategies. METHODS: An incentive of mark-up for conducting local CEA studies has been implemented to encourage local manufacturers to submit new CEA evidence for new drugs reimbursement application. The National Institute of Health Technology Assessment (NIHTA) has started to use a self-developed checklist to assess the quality of the local CEA evidence presented in the dossiers. The appraisal committee would then decide the extent of mark-up based on the assessment results. Three epochs were defined as (1) before mark-up epoch: 2008-2009 (No Mark-up Epoch), (2) mark-up without checklist epoch: 2010-the mid-2012 (No Checklist Epoch), and (3) mark-up with checklist epoch (Checklist Epoch): mid-2012 till 2013. The number and the quality of local CEA evidence identified from the dossiers submitted by the manufacturers in the three epochs were compared. RESULTS: In the No Mark-up epoch, none local CEA evidence has been presented in the dossiers. However, 5 and 7 local CEA studies have been identified from the dossiers in the Mark-up epoch and the Checklist epoch, respectively. None out of the 5 local CEA studies has received the mark-up, nevertheless, 6 out of the 7 local CEA studies have received 1% to 5% mark-up for the reimbursement price. CONCLUSIONS: The pragmatic strategy seems an effective approach to encourage the manufacturers to present local CEA evidence in the dossiers, which could improve the quality of decision making. In addition, the capacity of conducting local CEA studies has been gradually established.

PHPB4 BENCHMARKING THE IMPACT OF HTA ON NEW MEDICINES DEVELOPMENT AND COVERAGE DECISION MAKING

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OBJECTIVES: To evaluate the impact of HTA on new medicines development and market access of new pharmaceutical products in Australia, Canada, England, France, Germany, Italy, Spain and the USA. METHODS: An annual benchmarking study was developed in collaboration with 9 multinational pharmaceutical companies to establish appropriate development and performance metrics to identify if scientific advice was received, when it was received, from whom and the outcome and specific HTA requirements included into the development process. In addition data were also collected across 8 jurisdictions (Australia, Canada, England, France, Germany, Italy, Spain and the USA) to identify what evidence was submitted, the time it took and what additional evidence was requested. Data on 19 projects that entered phase III and 30 products achieving first world approval from 2009-2012 were analysed. RESULTS: For the phase III projects, 63% received HTA scientific advice, of which 61% occurred during phase II, with company-sponsored advisory boards being the most frequent provider. The main HTA-related requirements included in development were patient-reported outcomes (88%), HTA-acceptable endpoints (74%), and cost-effectiveness analysis (74%). For licensed products, the median time from regulatory submission to reimbursement decision varied from 639 days in Japan and 466 days in Italy. Additional comparators for local HTA submission were requested by all jurisdictions except USA. England and France showed the highest percentage of products being reimbursed as per the regulatory label (50% and 55% respectively). CONCLUSIONS: Companies are actively taking scientific advice and incorporating HTA requirements into their products, although they are still challenged by divergence in HTA process and decision making across jurisdictions. Benchmarking HTA processes at the product level supports companies in driving excellence in risk management and strategic planning.

PHPB5 COMPARISON OF ECONOMIC EVALUATION GUIDELINES BETWEEN JAPAN AND ASIAN COUNTRIES

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OBJECTIVES: The special committee of cost-effectiveness at the Japanese health ministry advisory panel was established in 2012 and the need for economic evaluation guidelines was proposed. The research team funded by the Japanese Ministry of Health, Labor, and Welfare and the guidelines commission for healthcare technologies in 2013. We compared the Japanese guidelines to existing guidelines in other Asian countries and to the NICE guidelines (UK). METHODS: We reviewed the guidelines published in Japan, China, Taiwan, Thailand and South Korea until 2014. Similarities and differences between Japanese guidelines and those from other Asian countries as well as NICE guidelines were identified. RESULTS: Japanese guidelines are mandatory in the UK, South Korea and Thailand, recommended in Taiwan, and optional in China. In Japan, economic evaluations are currently not formally considered in pricing and reimbursement decisions. Japanese guidelines are relatively open, leaving room for decision makers. Guidelines from different countries were broadly consistent in terms of preferred analytical technique (cost-effectiveness analysis), need of systematic reviews of evidence and consideration of effectiveness data as well as efficacy, but varied in terms of primary perspective for estimating costs (third-party payer in Japan), preferred outcome measure (no systematic use of QALYs in Japan, other measures, such as laboratory values, also accepted), preferred methods to derive utility values (generic instruments with scoring algorithm developed in Japan). The sensitivity analysis “when possible”. CONCLUSIONS: This comparative exercise provides an overview of economic evaluation guidelines adopted by 5 Asian countries and UK. The recommendations differed in some aspects, but Japanese guidelines are relatively open, which should facilitate adaptations of models between countries. One of the hurdles for adapting models is likely to be the variability in approaches recommended to obtain utilities.

PHPB6 HEALTH TECHNOLOGY ASSESSMENT IN JAPAN: PRACTICAL IMPLICATIONS BASED ON A COMPARATIVE EXERCISE

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OBJECTIVES: A rapid growth of health technology assessment (HTA) activities for new pharmaceuticals and medical devices in Japan is observed since the mid-1980s. However, Japan lags behind Europe, Australia, and several Asian countries in implementing national HTA regulations. Although it is generally accepted that low health care costs and a good health prevail in Japan, population aging, rising costs of medical technologies and slow economic growth rates necessitate rethinking the current HTA regulations. This study aims to evaluate the history and current situation of the Japanese HTA system, and what Japan needs to do in order to successfully implement national HTA regulations. METHODS: Past and current Japanese HTA regulation are assessed by analysing both English and Japanese publications and legal documents, as well as comparing these with the systems in other Asia-Pacific countries. Australia, South Korea, Taiwan, Thailand. RESULTS: There are historical, social, and biological reasons why Japan has been successful at maintaining the world’s longest life expectancy and the lowest infant mortality at relatively low cost despite the lack of a comprehensive HTA system. How implementation of HTA regulation would be a key lever in the health system in line with the new economic policy introduced by Prime Minister Abe in 2012. Looking at the legal and organisa- tional structures, implementation and performance of their Asia-Pacific counterparts, a comprehensive HTA system for Japan is proposed. CONCLUSIONS: HTA systems have been rapidly developing in the Asia-Pacific over the last decade. Facing the current pressures on the health system, the question is not whether Japan should introduce a comprehensive HTA system but what modifications the existing HTA system should undergo. The experience of other Asia-Pacific countries in implementing national HTA systems can help inform the development of an innovative national HTA system in Japan that could play a central role in the future of Japanese health care.