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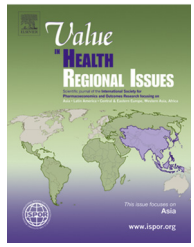

Revisit What Is Next for Pharmacoeconomics and Outcomes Research in Asia

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ABSTRACT

As part of the global trend to address the constrained resources for population health care coverage, the concepts of pharmacoeconomics (PE) and health technology assessment (HTA) have been introduced to Asia in the last decade. Medicines are just one of numerous types of innovative technologies developed to address unmet medical need. Many of these medicines receive a great deal of attention because of their potential impact on limited health care budgets. There are a few key challenges for using PE and HTA in making informed decisions regarding the value of a given new health care technology in an Asian country. These challenges include 1) recognizing the multidimensional aspects of PE and HTA, which can include both health care and political considerations; 2) involving stakeholders (with a focus on patients) in decision making; 3) balancing short- and long-term overall benefits of innovative medicines; and 4) giving consideration to specific local cultural and health care characteristics.

Keywords: Asia, health care, HTA, innovative technologies, patients, pharmaceuticals, pharmacoeconomics, population.

Introduction

In 2004, Doherty et al. [1] evaluated the early evolution of pharmacoeconomics (PE) in Asia, including China, Japan, South Korea, Hong Kong, Taiwan, and Singapore. On the basis of their assessments, the authors proposed that controlling health care expenditure and increasing the efficient use of limited health care resources were the two most important reasons for applying PE to health care in Asia. The authors predicted that the need for PE in Asian health care would result in more academic studies and consequently increased numbers of publications on this subject, which would enhance appreciation for the use of PE in Asia. In these authors' view, this trend would be so even in the absence of formal processes for evaluating PE in these countries.

Over the last 8 years since the Doherty et al. article was published, there has been a rapid advancement in the understanding and implementation of PE in Asia. This is evidenced by many published research articles on the topic. In addition, there have been many important events related to PE development in the region, including the establishment of National Evidence-based Healthcare Collaborating Agency [2,3], which acts as one of the resources providing information on health economics to support decision making on pharmaceutical reimbursement by Health Insurance Review Agency in South Korea [4]. In Taiwan, a health technology assessment (HTA) group has been established within the Center of Drug Evaluations to evaluate pharmaceutical pricing and reimbursement submission and HTA has been included as part of the National Act of 2nd Generation of Healthcare Insurance Reform [5]. In China, PE guidelines have been published [6] and there is ongoing active academic research on HTA [7]. In addition, a group of scholars from mainland China, Taiwan, and Hong Kong created the Greater China (Huaxia) Forum on Health Economics. In Japan, there is a plan to conduct a pilot HTA program by the Ministry of Health, Labor and Welfare [8]. The creation of International Society of Pharmacoeconomics and Outcomes Research Asia Consortium has greatly fostered the development of PE in the region. After 8 years since the landmark article by Doherty et al., PE activities and research are found in more Asian countries than the originally mentioned in their article, such as Thailand, Malaysia, India, Indonesia, and the Philippines [9].

The economy in Asia and the global advancement of innovative medicines have played an important role in pushing the PE development in the region. In the last two decades, there has been greater economic growth in Asia than in other parts of the world. In 2011, health care expenditure as a percentage of gross domestic product (GDP) was quite high across all Asian countries, with Japan and South Korea having the highest proportion of GDP

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(9.6% and 6.9%, respectively) [10]. Health care costs represent a significant proportion of the GDP, indicating the significant efforts being made by the public sector to provide health care coverage to citizens in these countries. This effort also likely reflects increased demands on health care due to aging populations, evolution of disease patterns, and access to improved health technologies. One particular pressure on health care costs is the increased number of potential medicines being developed worldwide. For example, a global statistics showed that by 2011, the number of new medicines under clinical development ranged from 96 for antiviral treatments (hepatitis B virus [HBV], hepatitis C virus [HCV] and HIV) to 1527 for various tumors [11]. Although not every candidate was or will be successfully developed, a good number are anticipated to eventually reach Asian markets. Approvals of these new medicines certainly put pressure on limited health care resources in these Asian countries.

To revisit the question of "what is next for pharmacoeconomics in Asia" that Doherty et al. asked 8 years ago, this article discusses key challenges in adopting innovative technologies, including 1) multidimensional feature of applying PE, 2) stakeholders' involvement, 3) patients' role, 4) focus on overall benefit, and 5) local adaptation of PE. Among all the challenges, the critical point will be how the core value of these innovative medicines should be evaluated in different Asian health care systems.

While Research on PE Is Technical, Application of the PE Assessment Tools Takes Place in a Multidimensional Plane, Including Public Policy and Political

Bootman et al. [12] defined PE as "description and analysis of the costs of drugs to the health care system and the society". O'Donnell et al. [13] defined HTA as "a form of policy research that examines short and long-term consequences of the application of a health-care technology". The Health Technology Assessment International Association definition for HTA is "the systematic evaluation of properties, effects or other impacts of health care interventions" [14]. Based on these varied definitions, HTA can be viewed as broadly related to health care in general and can involve strategies and more aspects; PE is applied health economics in the narrower area in pharmaceuticals. Regardless of the definitions, the successful use of PE or HTA requires a high degree of subject-specific knowledge. Discussions among PE experts, however, can become so technical that they may not consider other important dimensions of PE such as the implication of PE on public policy decisions. Therefore, for reason of simplicity, "PE" is used because this article mainly focuses on medicines.

When talking about PE for pharmaceuticals, in economics theory, we are talking about opportunity costs, always making trade-offs between different options. For example, allocating a resource to one disease area makes it unavailable for use in other disease areas. Similarly, if a resource is used for the health care sector, it cannot be used for education or housing. In daily life, policymakers always make these trade-offs by prioritizing the use of limited resources. Providing resources to care for one or two individuals is typically a technical decision; however, deciding the use of limited public resources to care for the health of a country's populations is certainly a political decision that is likely highly politically charged.

In addition, setting up a proper legal framework to provide legal positions for the application of PE is important, and can also be quite political. Recent examples from Europe are the process by which requirements of cost-effectiveness analysis were incorporated into the Social Security Law in France, and similarly in Spain, the Royal Decree Law addressed the issue of cost-effectiveness analysis (CEA) for reimbursing new medications [15,16]. Another example with a long history in the legal framework is found in Australia where Pharmaceutical Benefits Advisory Committees were set up in 1950 s [17]. This is important for at least two reasons: first, ensuring transparency in the PE process for all stakeholders; second, denying access to innovative technologies, especially those developed in other countries, could have an impact on trade treaties between countries. Therefore, the use of PE to assist decisions on drug reimbursement can go beyond the health care sector. Unless one has the legal framework moving in the right direction, one cannot properly implement PE evaluations in technical areas, such as setting up guidelines or criteria in conducting PE assessments.

Involvement in Decision Making Should Be Inclusive for All Stakeholders

Because the use of PE is very complex, assessment of innovative technologies by these approaches certainly should involve not only experts on PE and policymakers but also other stakeholders. These stakeholders would comprise health care providers, patients and patient groups, and the pharmaceutical industry. Involvement of these stakeholders provides different perspectives that will contribute to the overall evolution of PE evaluations. Currently, Taiwan and South Korea are actively engaging experts in PE and clinicians (physicians and pharmacists) together with government decision makers in their PE assessments. Later, other stakeholders, such as patient groups, become involved in this process. However, both these countries are lagging in their active integration of pharmaceutical industry representatives (the source of the clinical trial and PE data) into the process.

Two important considerations should be kept in mind in regard to stakeholder involvement. The first is that having a dialogue does not mean that there has to be agreement at all times and active discussion is a key part of the process of implementing PE. The second is the importance of early engagement of all stakeholders, something that is necessary for sufficient consultation prior to making final decisions. In the political world, especially with Asian cultures, it is important to keep in mind that once a decision is made, it may take a very long time to amend that decision. Active and early engagement, therefore, is key to the successful use of PE evaluations in decision making.

Keeping Patients in Mind Is Critical for Adopting Innovative Technologies

The use of PE normally involves technical experts because it is a complex, multidisciplinary science. Keeping the patient in mind, however, is important for any decision making that involves PE evaluations. A policy decision is always made at the population level; therefore, when PE assessments are conducted, every analysis could impact a patient's life. In other words, we are not only talking about numbers but also giving information that will support a decision that would significantly impact patients in our care.

It is well known that in medical practice the flow of information is usually asymmetrical between clinicians and patients. The hallmark of a traditional medical practice model is that clinicians make most of the decisions for patients. In part, to overcome this one-sided flow of information, in 2009, US Congress authorized the creation of an institute called the Patient-Centered Outcomes Research Institute, which is a non-physician source of information for patients [18]. The goal of this institute is to provide the best available evidence so that patients can make informed decisions. Active patient engagement is even regarded as the "blockbuster drug of the century,"