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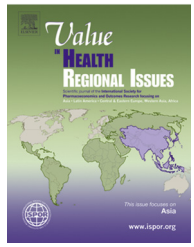

Health Technology Assessment, International Reference Pricing, and Budget Control Tools from China's Perspective: What Are the Current Developments and Future Considerations?

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ABSTRACT

Background: China is investing considerably in health care reforms to address issues in its health care system. An example is access to innovative drugs, which remains challenging because it is largely dependent on patient self-pay. Recognizing this, the government has invested considerably in its basic medical insurance. As health care expenditure increases, there are growing concerns on budget control. Several health policy tools have been discussed recently such as health technology assessment, international reference pricing, and hospital budget control tools, which can be viewed as addressing the affordability concerns of the government budget. China has also listed her health outcomes goals in "Healthy China 2020" initiative. **Objectives:** This article aimed to discuss the "fit-for-purpose" of these tools to address budget concerns and support China in reaching her health outcomes goals. **Methods:** The findings are informed by a panel discussion at ISPOR Asia Pacific 2014, literature review, and authors' experience. This review looks at the current developments in China and the considerations and implications for using these tools by drawing experiences from countries where they are used. **Results:** These tools are generally used in countries with advanced health care systems. China's health care spending is still below that of countries with advanced health care systems and below World Health Organization recommendation. **Conclusions:** China has not yet reached the "critical mass" necessary for the effective use of these tools. As China continues its health care reforms, increase in health care spending to balance the health needs of the population would be key.

Keywords: China, HTA, health technology assessment, international reference pricing.

Introduction

Since 2009, China has intensified its efforts in health care reforms to address key issues in its health care system. Current issues in health care include inequity in health care conditions across regions and high financial burden for patients. Key health indicators place China at a lever similar to that of developing countries [1]. The introduction of innovative medicines has improved health outcomes considerably all over the world in the last two decades. A key challenge involving patient access to innovative drugs, however, is the high financial burden on the patient because there is limited public funding. Innovative drug access is thus affected by patient affordability and willingness to pay (WTP). An example is the use of biologics for the treatment of immunology diseases, for which there is limited public funding and patients' WTP is dependent on the severity of the disease [2,3].

As part of health care reforms, China has invested in expanding the basic medical insurance (BMI) population coverage. From 2000 to 2012, population coverage under the BMI has increased approximately 30 times, and as of 2012, more than 95% of China's residents have BMI coverage [4]. This has been achieved by investing government funds, increasing from RMB 33 billion (~US $5 billion) in 2004 to RMB 387 billion (~US $63 billion) in 2012. With increasing health care expenditure, this has led to growing concerns regarding budget management. Health aspirations for China have also been stated in "Healthy China 2020" initiative, in which key outcome goals include achieving health targets similar to those of middle-income countries and reducing inequity between regions [5].

As part of health care reforms, several health policy tools have been explored in recent years. This article looks specifically at three policy tools that are likely to have an effect on access to innovative drugs—health technology assessment (HTA), international

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reference pricing (IRP), and budget control tools—and all three which have been widely discussed.

Current Status of HTA, IRP, and Budget Control Tools Implementation in China

HTA is used in many markets to control rising health care costs and to help decide on the allocation of health care resources. As health care costs in China increase, the government has expressed an interest in this. HTA is currently not implemented at a national scale in China to evaluate pricing and access to drugs despite the fact that China pharmacoeconomic guidelines have been published, with the most recent update in 2011 [6]. IRP has been used as a tool by the National Development and Reform Commission for price control. In 2012, the National Development and Reform Commission requested manufacturers to submit international reference prices as a way to establish whether fair pricing is done in China. This has subsequently resulted in price cuts for certain drugs. Implementation of IRP in China, however, is unlike other advanced countries (e.g. Japan, Taiwan) where there is a systematic review of drug prices of reference markets at launch and price adjustments are made accordingly.

The analysis of these three tools show that even though the government has expressed interest or has implemented these tools on a small scale, widespread systemic implementation of these tools is not yet present to our knowledge.

Although the current status of these tools is known, we feel that discussion on barriers to the wide-scale implementation of these tools in China is missing and also that a broader policy discussion on whether these tools would achieve long-term health outcomes goals of China [1].

Hence, this article aimed to discuss the "fit-for-purpose" of these three policy tools from two dimensions, that is, for budget control and in supporting China in achieving its long-term health outcome goals. This has been done by looking at the current practices of countries where these tools are used and the considerations and the implications for use in China. Figure 1 describes the analysis framework for this article. To understand the implications for China, we must first look at the methodological limitations of these tools, how these tools are used in other countries, and a comparison of the health care systems in those countries versus China.

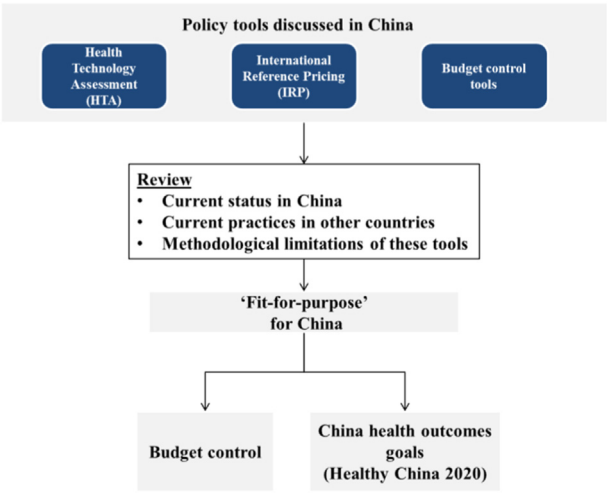

Fig. 1 – Analysis framework for the "fit-for-purpose" of three policy tools (HTA, IRP, budget control tools) in addressing budget control and China's health outcomes goals as stated in "Healthy China 2020" initiative. HTA, health technology assessment; IRP, international reference pricing.

HTA as a Tool for Value Assessment

When deciding on the allocation of health care resources, decision makers are faced with two fundamental questions. The first question is the notion of "value for money"; that is, "Is the new intervention worth the acquisition cost?" The second question is that of affordability, "Are there sufficient resources to fund the new intervention?" With these in mind, we need to look at the role of HTA in countries where it is currently used in addressing these two questions. Using HTA, the first question of value for money is addressed by conducting cost-effectiveness analysis (CEA) and the second question on "affordability" is addressed by conducting budget impact analysis. Because the discussion on HTA has been widely linked to the use of CEA, the concept of CEA and also the challenges in identifying a cost-effectiveness (CE) threshold for decision making are highlighted below.

CE Analysis

In systems in which CEA is applied, an incremental cost-effectiveness ratio (ICER) is calculated and the result can be visualized on a CE plane, as shown in Figure 2. The y-axis represents the incremental cost of the new intervention, where C_N is the cost of the new intervention and C_0 is the cost of the comparator. The x-axis represents the increment effectiveness of the new intervention, where E_N is the effectiveness of the new intervention and E_0 is the effectiveness of the comparator. The CE threshold would decide whether a new intervention is adopted, which can be shown by the slope.

The World Health Organization (WHO) has recommended CE threshold values for a disability-adjusted life-year (or quality-adjusted life-year [QALY]) of between 1× gross domestic product (GDP) per capita and 3× GDP per capita. This would, however, lead to great differences in absolute values for CE thresholds across countries in the Asia Pacific region and even in the same country (Table 1). For example, in China, 1× GDP per capita would be equal to RMB 60,819 (~US $10,000) and 3× GDP per capita would be equal to RMB 182,457 (~US $29,000). Comparing that to Japan would give 1× GDP per capita of JPY 3,855,054 (~US $32,000) and 3× GDP per capita of JPY 11,565,162 (~US $96,000). Empirical studies have been conducted in many Asia-Pacific countries to find a universal ICER threshold using different methodologies for different countries [7–11], and most obtained WTP thresholds for each QALY far lower than the 1× GDP per capita to 3× GDP per capita recommended by the WHO. For example, the ICER threshold from empirical evidence for China is less than RMB 40,000 (~<US $6500). These studies have highlighted the complexity in identifying a universal CE threshold even for a single country or jurisdiction. Besides indicating a threshold much lower than that recommended by the WHO, results from these studies inferred that the WTP for a QALY would be specific for different diseases and patient populations.

Impact of Pharmacoeconomic Guidelines on Pharmaceutical Spending

Given that every country's health care needs and value assessment are unique, to assist in HTA, many countries, for example, Australia, Taiwan, Korea, and Germany, have implemented local pharmacoeconomic guidelines. Guidelines, however, would need to be updated to reflect the country's evolving needs and advancement in HTA. Australia is an example where the draft guidelines were first issued in 1992 and official updates were