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

Liling Koh, PhD, BEng(1st Hons)1*, Christoph Glaetzer, Dipl, Kfm1, Shu Chuen Li, PhD, BPharm, MBA2, Meng Zhang, MBA, MSci3

1Janssen, Market Access, Asia Pacific, Singapore; 2Discipline of Pharmacy & Experimental Pharmacology, Faculty of Medicine and Health, School of Biomedical Sciences & Pharmacy, The University of Newcastle, Newcastle, Australia; 3IMS Consulting Group, Greater China, Shanghai, China

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.

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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...
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 outcomes 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.

**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 $C_{C}$ is the cost of the comparator. The x-axis represents the incremental effectiveness of the new intervention, where $E_{N}$ is the effectiveness of the new intervention and $E_{C}$ 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 (DALY) of between 1x gross domestic product (GDP) per capita and 3x 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, 1x GDP per capita would be equal to RMB 60,819 (~US $10,000) and 3x GDP per capita would be equal to RMB 182,457 (~US $29,000). Comparing that to Japan would give 1x GDP per capita of JPY 3,855,054 (~US $32,000) and 3x 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 1x GDP per capita to 3x 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
made in 1995, 2000, and 2006. This would require continuous resource inputs and cooperation from all the stakeholders.

Another interesting point is that to some stakeholders, HTA has been viewed as a budget control tool and the question is whether the implementation of pharmacoeconomic guidelines has successfully kept the drug-spending budget low. The experience in Australia shows that each update of pharmacoeconomic guidelines is followed by a subsequent decrease in Pharmaceutical Beneﬁt Schedule expenditure in the immediate next few years (Fig. 3). After a certain amount of time, however, the Pharmaceutical Beneﬁt Schedule expenditure increases. This example highlights that the role of HTA, like any microeconomic tool, is only one of the many factors that would contribute to overall drug spending. Overall considerations on population health care needs and health outcomes goals would need to be balanced. HTA should be viewed as a tool to achieve this instead of being viewed as a cost-containment tool.

Considerations of Implementing HTA in China

In countries where HTA is used for value assessment of medicines, decisions on HTA at a central level would translate into a funding decision across the country. In China, funding decisions for medicines on the reimbursement drug list lie with regional afﬁliates of the Ministry of Human Resources and Social Security. If HTA were to be implemented, and assuming it would be at a central level, implications for regional budgets would need to be assessed given the great difference in wealth inequity and regional budgets. In addressing the ﬁt-for-purpose question on budgetary control and achieving China’s goals, we need to understand that other countries use HTA as a tool for value assessment and not for budgetary control. As mentioned above, HTA could be used to balance population health needs and health outcome goals. We would like to note, however, that HTA has been mostly used in those countries with higher health care spending, which provides the foundation for effective HTA, that is, greater access and less inequity in health care, greater access to local cost, and quality-of-life data.

IRP as a Tool to Assess “Fair Pricing”

At the most fundamental sense of economics, prices of goods represent their value to consumers. Similarly, the prices of medicines represent their value, of which some aspects are global in nature and some aspects are speciﬁc to the local environment. The global value of a medicine can be thought of as the clinical value and the level of innovation it brings in addressing clinical needs. A medicine’s value in each local country would depend on several factors such as the degree of unmet needs, societal values, evaluation methods, and local competitive environment. IRP is a method used by some countries to guide price determination by first selecting a basket of reference countries.

<table>
<thead>
<tr>
<th>Country/region</th>
<th>1x GDP (in local currency)</th>
<th>3x GDP (in local currency)</th>
<th>ICER threshold from empirical evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>RMB 60,819</td>
<td>RMB 182,457</td>
<td>&lt;RMB 40,000</td>
</tr>
<tr>
<td>Thailand</td>
<td>THB 321,552</td>
<td>THB 964,656</td>
<td>THB 120,000</td>
</tr>
<tr>
<td>Japan</td>
<td>JPY 3,855,054</td>
<td>JPY 11,565,162</td>
<td>JPY 5,000,000</td>
</tr>
<tr>
<td>Malaysia</td>
<td>MYR 57,430</td>
<td>MYR 172,290</td>
<td>MYR 19,920–28,500</td>
</tr>
<tr>
<td>Taiwan</td>
<td>NT $1,199,237</td>
<td>NT $3,597,711</td>
<td>NT $ 2,000,000</td>
</tr>
<tr>
<td>Korea</td>
<td>KRW 35,079,558</td>
<td>KRW 105,238,674</td>
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<tr>
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<td>KRW 30,000,000</td>
</tr>
</tbody>
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CE, cost-effectiveness; GDP, gross domestic product; ICER, incremental cost-effectiveness ratio; JPY, Japanese yen; KRW, Korean won; MYR, Malaysian ringgit; NT, New Taiwanese; RMB, renminbi; THB, Thai bhat; WHO, World Health Organization.
and then applying a formula (e.g., average, median, average of lowest three, and lowest) to calculate the reference price. Countries that have implemented IRP include France, Japan, and Taiwan [12]. Each country has its own unique rules on the reference country basket and the method used for price calculation. For example, in France, for medicines that are given a Amélioration du Service Médical Rendu therapeutic rating of I to III, the price will not be lower than the lowest price in force in the four countries that France uses as references, namely, the United Kingdom, Germany, Italy, and Spain, for a period of 5 years starting from inclusion in the reimbursement list. In Japan, after a new drug’s price is determined after using cost comparison or cost plus methodology depending on whether there are appropriate comparators in the market, a price adjustment could be applied by comparing the calculated price to the reference price. The prices may be adjusted upward if they are less than 75% than the average of public prices for the same product in France, Germany, the United Kingdom, and the United States. Prices can also be subject to downward adjustment if they are 150% or more of the average in these same four reference countries. In Taiwan, prices are referenced to the median of A10 countries (the United States, Japan, Germany, the United Kingdom, France, Switzerland, Sweden, Belgium, Canada, and Australia), where the higher the therapeutic gain of a product, the higher percentage of A10 median reference price it would get.

As stated above, a medicine’s price should also reflect value in a local context and the use of IRP would lead to several conceptual issues on the determination of value. First, the reference countries chosen could use different approaches to define local value and price (e.g., HTA systems vs. non-HTA systems). Second, different formulas used to calculate a reference price would lead to different outcomes, thus mixing the picture of the original value assessment. The calculated reference price can be thought of as “importation of other countries” value system into one’s country, and thus does not fairly reflect a drug’s true value in the local environment.

The WHO recommendation is that countries should consider external reference pricing (or IRP) as a method for negotiating or benchmarking the price of medicines. Countries, however, should consider IRP only as part of an overall strategy, in combination with other methods, for setting the price of medicines. In developing an IRP system, the WHO also recommends that countries define transparent methods and processes and that the criteria used to define comparator reference countries should be based on economic status, pharmaceutical pricing systems in place, the publication of actual versus negotiated or concealed prices, exact comparator products supplied, and similar burden of disease [13]. Thus, these considerations need to be applied to any country such as China who wishes to consider IRP.

Considerations for Implementing IRP in China

Drawing from the experience of countries that have implemented IRP, several methodological challenges are apparent. As highlighted by the WHO recommendation, conceptually, similar price levels need to be considered for an “apples-to-apples” comparison (ex-factory price, published list price, negotiated price, etc.). Given that countries have different mark-ups, taxes, and level of reimbursement applied to medicines and the limitation on the type of price information that is available publicly, often what is obtained, however, is an “apple-to-orange” comparison. This is further complicated by the different launch timing of medicines globally, which is due to either regulatory considerations and/or manufacturer’s launch strategy. In China, where innovative drugs face an average of 8 years in access delay versus advanced Western markets [14], the implications on IRP are that medicines are likely to be in a different product lifecycle in the reference country versus China and that currency fluctuations might be occurred.

The intent of IRP could be thought of as an attempt to establish a “fair” price. The use of IRP, however, could create barriers for other approaches that aim to address “fairness” in pricing of medicines. For example, as mentioned earlier, HTA using CEA and CE thresholds determines the society’s WTP for an incremental QALY. The use of IRP in conjunction with HTA diminishes the initial value assessment done by HTA. Another
example is a proposed approach of equity-based tiered pricing that recommends that pricing of medicines be based on a country’s ability to pay (purchasing power) [15]. The equity-based tiered pricing recommends using the gross national income purchasing power parity or the human development index as the basis for determining prices for countries. Equitable prices of countries are then determined by taking price discounts from an anchor point, which can be a country with high gross national income per capita at purchasing power parity (e.g., the United States) or a basket of countries (e.g., basket of Organisation for Economic Co-operation and Development countries). Similarly, IRP would also restrict manufacturer’s ability to apply equity-based tiered pricing concepts.

In countries where IRP is used, IRP tends to follow a value (price) assessment on drugs, for example, after CEA (e.g., Korea) or comparative effectiveness analysis (e.g., Japan). Drug purchasing also tends to be financed from a central budget. IRP can thus be viewed by authorities as an approach to check whether the initial price assessment is fair to maximize purchasing power. In China, although funding decisions for reimbursed drugs are taken at a regional level, an IRP would also be conducted by a different government body at the central level (National Development and Reform Commission). The fragmented stakeholder landscape would also pose challenges in providing a fit-for-purpose for budgetary control. As mentioned earlier, IRP can be viewed as a price negotiation tool and we view it as not fit-for-purpose for supporting China in achieving its health outcomes goals. IRP could, however, discourage manufacturers from exploring innovative pricing strategies as a reward for innovation. In considering that China would like to match its health targets to those of middle-income countries, supporting innovative drug access tailored to China’s disease burden would be critical.

**Budget Control Tools: Current Developments in China**

Budget control tools are used by policymakers and hospital administrators to control increasing health care expenditure. Examples of budget control tools include capitation, in which funding is allocated on the basis of amount per person in the population catchment area, and global budget control, in which there is a fixed budget for hospital expenditure.

In China, increasing health care expenditure is driven by the increase in government funding to BMI. Because of the rising health care expenditure, China is now slowing down the rate of investment in BMI. Government health care expenditure is showing a decline, with the compound annual growth rate from 2004 to 2007 at 44%, from 2008 to 2011 at 15%, and the year-on-year growth rate from 2011 to 2012 at 15%. The government has also rolled out several budget control tools as part of public hospital reforms to control the rising expenditure, for example, budget based on capitation, hospitalization stay, diagnosis related group, and global budget control.

In 2009, Shanghai was chosen as the pilot city for the implementation of global budget control. Under this scheme, an annual sum is allocated to hospitals to fund the cost of drugs. This is based on a fixed proportion of the total budget of the hospital, usually at around 40% to 45% [1]. Hospitals’ budgets are allocated on the basis of revenue history and growth estimation. As a response to managing the budgets, hospitals apply controls on prescriptions and often monthly or quarterly quotas on drugs on the reimbursement drug list to control costs. Some hospitals also remove expensive drugs from the formulary during the year if drug costs are running high and savings are needed.

The implementation of global budget control in Shanghai saw a decrease in growth in total health care expenditure from 16% in 2009 to 12% in 2010 (Fig. 4). The Shanghai pilot was viewed as a success in effectively controlling hospital spending and in 2011 the Shanghai global budget control model was rolled out in many cities around China to all tiers of hospitals. Figure 5

![Fig. 4 – Growth of total health care expenditure in Shanghai from 2007 to 2010. RMB, renminbi.](image)

IMS Analysis of hospital sales growth in 2011 versus 2010 showed that cities that have implemented global budget control showed lower growth than did cities that have not. However, the average expenditure on in-hospital stay and outpatient visits did not change remarkably. There was a strong shift in the sales of nonreimbursed, fully patient self-pay medicines. Because reimbursed drugs are restricted by global budget control, there was a drop in the prescription of reimbursed drugs as hospitals approached their quotas. This indicates access issues for reimbursed drugs. The phenomenon described above shows that physician-prescribing behavior is greatly affected by hospital guidelines. Hence, any guidelines would need to balance not only medical resources but also patients’ needs, which would need to be disease specific.

**Considerations on the Future Developments of Budget Control Tools in China**

As seen above, budget control tools are effective in addressing the fit-for-purpose of budgetary control. Although China is raising concerns on cost expenditure, we note that China’s funding surplus at 8% in 2012 is still lower than the WHO-recommended benchmark of 15% [16]. Budget control tools would also affect reimbursed drugs. Drugs included in the reimbursed drug list have demonstrated their value in addressing the country’s unmet clinical needs. Looking at “Healthy China 2020” goals, which include improving health outcomes and reducing inequity in regional differences, budget control tools cannot be said to be fit-for-purpose. The restriction on the prescription of reimbursed drugs would further increase patients’ financial burden and could lead to greater differences in health inequity because of wealth status.

**Conclusions**

This article attempted to address whether HTA, IRP, and budget control tools address fit-for-purpose of budget control and support China in achieving its health outcomes goals. Experience from Australia shows that HTA should not be viewed as a budget control tool and should be balanced with overall population health needs to achieve health outcomes goals. IRP can be viewed as a tool to establish a fair price, but on its own it does not directly address budget control. IRP could also risk discouraging manufacturers from using innovative strategies to come up with medicines tailored to China’s needs. IRP is thus not fit-for-purpose for helping China establish its health outcomes goals. Although the budget control tool is effective in budget management, the impact on patient access to innovative drugs may be
viewed as negative. As described above, for hospitals under global budget control, if the hospital quota is reached, prescriptions for reimbursed drugs would be stopped and patients will not get access to these drugs. Because universal reimbursement of drugs is currently not yet achieved on a national basis in China, it can be said that drugs on the reimbursed list are deemed to have high clinical value to patients based on the disease profile of patients in China. To recap on China Healthy 2020 goals of improving health targets, patients not being able to access reimbursed drugs under such circumstances would go against China’s goals. Hence, global budget control of medicines could be viewed as not fit-for-purpose for supporting China in achieving its health outcomes goals.

These tools are used in countries with advanced health care systems. On comparing the health care landscape in emerging markets such as China to that in advanced countries, some interesting differences are noted. Looking at the supply side, the pharmaceutical industry remains the manufacturers of drug treatments in both market types, but more regional differences would be seen in the delivery of health care by health care providers due to wealth inequity in regions (e.g., east vs. west regions in China). The demand for health care would be dependent on the disease burden, and in China, this consists of disease burden of both emerging markets (e.g., communicable diseases such as tuberculosis) and that of advanced markets (e.g., noncommunicable diseases such as cancer and cardiovascular diseases). This landscape is different from advanced markets where the disease burden is more skewed toward noncommunicable diseases. For innovative drugs in China, funding is largely patients’ responsibility unlike advanced markets where a higher share of funding comes from government/social security. Thus, the demand for health care in China is also dependent on patients’ ability to pay and WTP. Societal values in terms of priority across diseases would also affect the demand for health care.

China’s health care spending is still below that of advanced health care systems [17] and below the WHO-recommended benchmark [16]. China has not reached the critical mass for the effective use of these tools. As China continues its health care reforms, increase in health care spending to balance population’s health care needs would be key. Other considerations would also need to be taken into account to optimize the health care system in China, for example, efficient delivery of health care. To help China meet its health outcome goals, it is important to create an environment in which all stakeholders collaborate to deliver quality care, provide reward for the research and development of innovative medicines, and improve patient access to innovative drugs.

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