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RESEARCH ARTICLE

VALUE-BASED PRICING IN MALAYSIA'S HEALTHCARE: A STAKEHOLDER ANALYSIS

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ABSTRACT

BACKGROUND:

High pharmaceutical price is a dilemma. Value-based pricing (VBP) is suggested to be the potential solution to this problem. However, in Malaysia, VBP does not receive favorable response from the industry players. Therefore, in this study we would like to examine the position of various stakeholders on this issue.

METHODS:

The PolicyMaker tool is used to evaluate the position and interest of the various stakeholders. Next, we assess the factors that might contribute to the policy success or failure using Kingdon's multiple stream approach.

RESULTS:

We found that VBP received positive response from the stakeholders with some request for amendments. There was unanimity among the stakeholdersabout introducing medications that do not improve patient outcomes is counterproductive, therefore the problem has been articulated adequately. The policy was sufficiently explained with the publication of the guidelines. Continuous engagement between the government and the private sector plays a major role. Strong political will also contributed to the success.

CONCLUSION:

Our findings showed that VBP implementation is successful due to strategic engagement and strong support from the government and the private sectors.

KEYWORDS

value based pricing, pharmaceutical policy, price regulation, stakeholder analysis

INTRODUCTION

Globally, high pharmaceutical prices has become a dilemma. This conundrum arises from the tension between the need to encourage novel treatments through high product pricing while also protecting consumers and taxpayers from the financial burden of paying for such high costs. In recent years, this topic has become more widespread among the public and the medical fraternities.

One of the potential solutions for this is value-based pricing (VBP). VBP utilized the cost-effectiveness analysis in order to decide which drug and treatment to incorporate into daily practice. VBP ensures that the price of the drug is aligned with the benefits received [1]. Several countries had adopted this strategy namely, Italy, Spain and France. In United States, The Centers for Medicare and Medicaid Services had proposed incorporation of value-based purchasing strategy in 2016, but the plan was cancelled late [2]. However, VBP remains a topic for debate between the stakeholders.

There are two important entities in the Malaysian Ministry of Health (MOH) which are involved in the implementation of VBP in Malaysia, namely the Malaysia Health Technology Assessment Section (MaHTAS) and Formulary Management Branch of the Pharmacy Practice & Development Division (PPDD).

MaHTAS is a vital structure in the MOH. Founded in August 1995 and funded by the federal government, MaHTAS is established under the Medical Development Division, MOH, which also makes it as the first formal health technology assessment (HTA) program in Asia. The primary role of MaHTAS is to assess programs, technologies, procedures, drugs, medical devices and treatments, on issues of safety, cost and effectiveness. It incorporates research evidences, collaborates with local and international stakeholders as well as producing transparent and relevant reports [3].

The second organization is the Formulary Management Branch of Pharmacy Practice & Development Division (PPDD). PPDD is vital as they oversee new drug incorporation into the Ministry of Health Medicine Formulary (MOHMF), modify existing drug specifications or remove existing drugs from the list. Thus, the PPDD role is crucial as they determine what treatments Malaysians will get. Through an extensive literature research and appraisal, PPDD assess about 60 drugs annually with half of them as as full assessments (mini-HTA), evaluating their safety, cost and cost-effectiveness [4].

These two organizations reflect the rising disposition towards the incorporation of economic consideration when devising a new health policy. MOH has also published two guidelines in 2012 and 2019 on pharmacoeconomic analysis studies.

However, VBP does not receive favourable response from the pharmaceutical industry. The Pharmaceutical Association of Malaysia (PhAMA) has argued that cost-effectiveness analysis (CEA) should not be the sole metric to decide which drug to incorporate into the Malaysia Drug formulary. Instead, they suggested that Multi Criteria Decision analysis should be used in order to give a better picture on the overall effectiveness of a drug [5].

In this study, we conducted a stakeholder analysis to assess the position and interests of various stakeholders on the issue. We also used Kingdon's multiple stream approach [6][cite] to contextualize the factors that might affect the success or failure of VBP.

METHODOLOGY

DATA

Data were collected from peer-reviewed documents and grey literature from 2000 to 2020 spanning two decades through general web-based searches. Grey literatures consist of reports, working papers, white papers and research outside conventional academic publishing and distribution channels.

DOCUMENTS

Most of the data was gathered through extensive desk review. Keywords used include, "value-based pricing", "pharmaceutical pricing", "cost-effectiveness analysis", the name of specific stakeholders and related queries. Online search also includes newspaper articles, speeches, conference presentation and so forth. We also included social media sites such as Facebook and YouTube in our study.

ANALYSIS

Our analysis was conducted in three steps. First, was to identify stakeholders affected by VBP. Second, was to evaluate the stakeholders' resources, interests and relationships. Third, was to assess the stance and roles taken by the stakeholders.

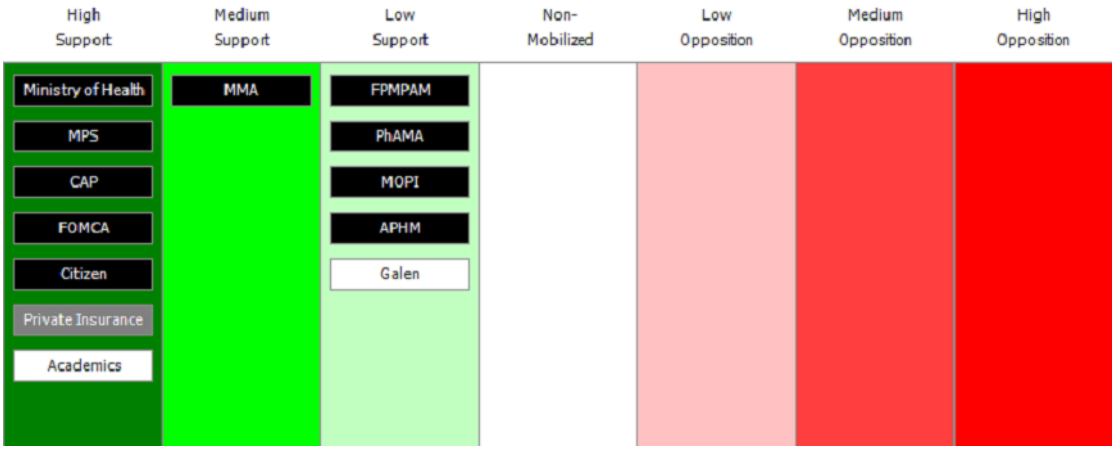
The data collected was then entered into Reich's PolicyMaker software and the software guided the user through each steps [7]. PolicyMaker includes questionnaires to assess stakeholder position (support, oppose, non-mobilized), power (resource available) and the intensity of position (disposition to use available resource). The stakeholders (players) were displayed based on the spectrum from high support, non-mobilized, and

high opposition. A feasibility graph was produced based on three criteria: power, intensity of position and number of mobilized groups. Kingdon's multiple stream analysis [6][[cite] was used to analyse the data and identify the barriers formed by the stakeholders that might influence the policy implementation.

RESULT

In general, the key stakeholders are supportive of the implementation of VBP in Malaysia's healthcare system. We created the Position Map based on the result (Figure 1).

FIGURE 1: BLACK BOXES INDICATE HIGH POWER OF THE STAKEHOLDERS TO INTERVENE, GREY BOXES FOR MEDIUM POWER AND WHITE BOXES FOR LOW POWER



In the PolicyMaker tool, interest is divided into several categories such as financial, ideological, religious and humanitarian. Here we included some of the most prevalent interests.

FINANCIAL INTEREST

Public sector

Stakeholders with financial interest in the public sector aim to optimize their budget utilization by applying VBP in the healthcare system. For example, the MOH have specific divisions to conduct various studies to determine the costs of an intervention or program. Public sector receives limited budget annually and they need to allocate this resource wisely. They also collaborate with local partners such as universities and think tanks, as well as international partners, in order to evaluate the best program for money. Several universities such as Universiti Kebangsaan Malaysia, Universiti Sains Malaysia and Universiti Malaya have integrated casemix system based on Diagnosis Related Group into the hospital setting. Universiti Kebangsaan Malaysia Medical Centre is the first hospital to have fully integrate casemix analysis since July 2002 [8].

Private sectors

This is in contrast with the private sector. Stakeholders with financial interest in the private sector seek to maintain or increase their profits in the market. Generally, the private sectors always stated their support for the application of VBP saying that patient interest is of their utmost importance however, whenever the interest coincide with their profits, they backpedaled. For example, PhAMA initially voiced their full support for VBP and then asked for a few amendments afterward on the methodology of determining cost-effectiveness threshold.

The Association of Private Hospitals Malaysia (APHM) support the application of VBP, and later on added that, the expectation of the public to receive cheap quality healthcare within their vicinity is impossible with the small profits accrued by private hospitals [9]. Some parties do not agree with this claiming that the CEO of a private hospital received RM34 million in remuneration for a particular year [10]. They also reprove this statement arguing that the continuous expansion of the private hospitals both locally and internationally is a proof that the profit is 'exorbitant'.

PhAMA which initially supported the application of VBP withdrew as they were concerned that the sole practice of CEA will restrict the entrance of new innovative drugs into the formulary and therefore, reduced their profits. For example, in the United Kingdom (UK), the willingness-to-pay was set between £GBP 20,000 and 30,000 per Quality Adjusted Life Years (QALYS) [11]. However, many cancer treatments have higher QALYS and therefore were not

reimbursed. PhAMA asserts that using incremental cost-effectiveness ratio (ICER) threshold as the sole criteria for selecting drugs is parochial as it does not account for other factors such as disease severity, unmet needs, target population size and societal cost for CEA. PhAMA instead, suggested that a Multi Decision Criteria Analysis model should be used as it sets weightage to different factors and therefore will be more comprehensive in the decision making [5].

The private insurance industry is generally supportive of any cost containment measure [12]. In 2019, the private insurance sector and Bank Negara Malaysia (BNM) established Medical Cost Containment Task Force (MCCTF) to study the reasons for rising medical insurance premiums. High medical cost will lead to high premiums, which will deter the public from taking private insurance. More co-insurance plans were also suggested to make medical insurance more affordable [13].

IDEOLOGICAL INTEREST

Ideological interest relates to government's role in providing quality healthcare and the population access to better healthcare.

The MOH aims to "assist an individual in achieving and sustaining as well as maintaining a certain level of health status to further facilitate them in leading a productive lifestyle, economically and socially" [14p?]. MOH strong advocavy for VBP is ingrained in its vision to provide the people a quality healthcare that is affordable, efficient and innovative. However, due to budget constraint, this encourages the MOH to explore other avenues which lead to the establishment of National Health Financing Unit in 2009. However, since then, the MOH still has not made a significant move from the general taxation funding system. It has always been to reduce the cost, instead of increasing the income. Besides, the emerging importance of the HTA division in the MOH has shown MOH commitment towards VBP although this effort has been mainly restricted by the lack of data and electronic medical records.

Other stakeholders such as academics have also fully supported the implementation of VBP shown by the growing numbers of CEA studies over the years, increasing from only 2 studies in 2004 to 15 studies in 2017 [15]. Academics have always conducted various seminars and conferences to discuss the importance and application of VBP. One of the foremost universities in this area is Monash University, Australia. Headed by Professor Kenneth Lee, who is widely recognized as one of the pioneers in pharmacoeconomic research in Asia, and also a founding member of the Hong Kong Chapter of the International Society for Pharmacoeconomics and Outcomes Research. Monash University has invited various well-known experts in the pharmacoeconomic area to present as well as organizing health economics workshops and collaborating with the MOH and international universities [16].

The Malaysia Pharmaceutical Society (MPS) has organized several forums on VBP. For example, MPS worked with the MOH to organize the 10th National Pharmacy Conference in 2018 to discuss VBP related issues and recent advances in pharmacoeconomic research [17]. MPS encourage patients to obtain prescriptions from their doctors using chemical names instead of brand names as this would allow the patient to choose the medication based on affordability. In 2015, MPS support a petition to classify controlled medication as zero-rated GST [18]. Fundamentally, the Malaysian Organisation of Pharmaceutical Industries (MOPI) is committed to VBP. One of the MOPI's objective is to "ensure that all patients have access to affordable quality medicines" [19][cite p?]. MOPI is committed to promote cost-effective and high-quality pharmaceutical products. The first general principles of MOPI, out of six principles mentioned, was to do all it can to benefit the patients [19]

HUMANITARIAN INTEREST

Stakeholders with humanitarian interest such as the Federation of Malaysian Consumers Associations (FOMCA) seeks to study consumer issues, educate on consumer's rights and advocate for better consumer protection. Established in 1973 in Alor Setar, Kedah, FOMCA has been in the forefront when it comes to consumerism issues. FOMCA works in three phases. In the first phase, FOMCA will organize forums and meetings with the government agencies. In the second phase, FOMCA will write to the press and politicians to assert pressure. The third phase is by collecting petitions from the public [20]. FOMCA seeks to ensure that Malaysian will have the access to affordable and high-quality healthcare. FOMCA suggested that healthcare expenditure should be increased to 7% of GDP, in line with WHO recommendations [21]. Known as the staunch critic for private healthcare sector, FOMCA advocate for better regulation and lower insurance premium to cater for low and middle income consumers [22].

STAKEHOLDER MAPPING: POWER AND POSITION

PolicyMaker tool categorize power into: low, medium and high. Power is characterized by the resource that the stakeholder has, both tangible and intangible. Power is measured by the possession of fiscal, organizational and symbolic resource in order to guide the policy, along with their relationship to the policymaker and media. We showed the power and position of the stakeholders in Table 1.

TABLE 1 1: STAKEHOLDERS' POSITION, INTEREST AND POWER

Stakeholder	Interest	Position	Power
Academics	Professional	High Support	Low
Association of Private Hospitals Malaysia (APHM)	Financial	Low Support	High
Citizen	Financial Ideological	High Support	High
Consumer Association of Penang (CAP)	Humanitarian Ideological	High Support	High
Federation of Private Medical Practitioners' Associations, Malaysia(FPMPAM)	Financial	Low Support	High
Federation of Malaysian Consumers Associations (FOMCA)	Humanitarian Ideological	High Support	High
The Galen Centre for Health and Social Policy	Professional	Low Support	Low
Malaysia Medical Association (MMA)	Financial	Medium Support	High
Malaysian Organisation of Pharmaceutical Industry (MOPI)	Financial	Low Support	High
Malaysian Pharmaceutical Society (MPS)	Financial	High Support	High
Ministry of Health (MOH)	Financial Ideological	High Support	High
Pharmaceutical Association of Malaysia (PhAMA)	Financial	Low Support	High
Private Insurance	Financial	High Support	Medium

The MOH is considered to have high power as they have considerable resources and access to the 'high table'. Their support for VBP enabled them to initiate various VBP programmes and cooperate with numerous institutions. They also provide research grants and funding for health economics studies through National Institute of Health (NIH) and Medical Review and Ethics Committee (MREC). All studies involving MOH facilities must be registered under the National Committee for Clinical Research (NMRR). MOH is responsible for administering several important Acts such as the*Medical Act 1971, Poisons Act 1952 and Mental Health Act 2001*. Conforming to the current technology trend, the MOH is active through social media such as Facebook, Twitter and Telegram, devoted to provide timely, truthful and transparent sources of information.

Other stakeholders such as PhAMA and APHM use media and forums to state their position. Social media such as Facebook and Youtube are also used.

KINGDON'S MULTIPLE STREAM APPROACH

It is necessary to understand what factors lead to the virtually successful implementation of VBP in Malaysia's healthcare system. One of the ways to do this is by applying Kingdon's multiple stream framework. This framework analyses the component or the stream of policy setting process which are the problem, policy and the political stream. This analysis attempt to discover the window of opportunity so that, VBP can be maintained and strengthened as the national agenda.

THE PROBLEM STREAM

To ensure that the problem is solved, the problem needs to be addressed first. The stakeholders agreed that incorporating drugs that do not improve a patient's outcomes is detrimental and a waste of money. There is a consensus amongst stakeholders that integrating VBP into the pharmaceutical pricing is essential. This can be seen through numerous seminars and conferences organized on the issue. Therefore, a proper problem framing has been established on the importance of implementing VBP in the drugs listing and pricing.

Stakeholders with financial interest such as MOH plays vital role in pushing forward the VBP agenda through its divisions and programmes. Academics had been increasing their studies and discussion on this topic, making it a primary issue in the health economics area [15].

Private sectors with financial interest, such as PhAMA and APHM, also generally agreed with the notion although they called for several modifications. The public sector viewed VBP as their responsibility to provide a high-quality healthcare at affordable price to the public, whereas the private sector viewed VBP as their way of conveying their commitment toward patient's care and ultimately, customer's interest.

As a result of the unanimity among public sector, private stakeholders, academics and the NGOs, the implementation of VBP received a favourable response.

THE POLICY STREAM

Policymaking is a complex process, intertwined with various concepts, players and solutions, presented at different stage of the policy cycle [23]. However, the problem must first be identified and then, the solution (policy) can come into play.

The implementation of VBP in the country is still not widespread, yet it is moving in the right direction. The strong agreement among the stakeholders helps this policy to come into light.

The HTA division under the MOH, widely regarded as one of the most important divisions, continuously engaged with stakeholders through seminars, forums and workshops. This continuous engagement is crucial to strengthen the understanding between the stakeholders and improve transparency. The MOH conduct various VBP studies and published several guidelines to help improve the state of VBP in the country. These guidelines help the private sectors and the academics to comprehend the approach that MOH is taking.

Although the MOH does not publish official CEA threshold, the MOH generally agreed to follow WHO recommendations. A study in 2017 found that the CEA threshold estimated for Malaysia is lower than the WHO recommendation [24]. The simple and straightforward nature of the guideline supports unambiguity and helps to frame the solution as acceptable to many [25].

The continuous interests from the academics involving several local universities helps to provide factual evidence on VBP, shown by the increasing number of studies on VBP over the years.

Stakeholders with humanitarian interests like FOMCA, welcome the solution as they had been asking for years that the problem of expensive healthcare, be addressed and thus, VBP implementation is seen as a way to help reduce the cost of healthcare for low- and middle-income groups, especially in the private sector.

The private sector generally agreed with the solution although they asked for a few modifications. PhAMA is concerned that VBP might hinder the entrance of new innovative drugs whereas the private hospital group is concerned that VBP might compromise patients' welfare. Although they have financial interest at stake, the private sector managed to frame the modifications as a way to protect the public's interest.

Coming together, the stakeholders managed to push forward the VBP agenda. The strong policy stream coupled with well-framed problems, helps the implementation of VBP to be successful.

THE POLITICAL STREAM

The establishment of MaHTAS in the 1990s signified the importance of HTA in the country. Progressing towards evidence-based medicine and later on, VBP, the changes of administration continuously uphold the concept of VBP and put it in the centre. Perhaps helped by the previous Prime Minister, Tun Dr. Mahathir bin Mohamad, who was a medical doctor by training, also spearheaded the reform of HTA in the MOH. Political groups, whether they are in the government or in opposition, both support VBP. This can be seen after the fall of Barisan Nasional in 2018 and

subsequently the takeover from the Pakatan Harapan, that the VBP agenda has become more important. This is also encouraged by the commitment from the government to establish Malaysia as an educational hub and therefore invited several reputable universities to get a foothold in Malaysia. Among them is Monash University which is seen at the forefront of VBP implementation.

DISCUSSION

The implementation of VBP is considered as successful. Our analysis used a double pronged approach to study VBP, first with Reich's methodology to understand the stakeholders position and then merged that with the Kingdon's multiple stream framework to evaluate the factors involved in VBP success.

We found that both approaches point to the significant role of the MOH in ensuring that VBP remains a priority. The stakeholder analysis revealed that the MOH have significant power and resources, are highly supportive and continuously engaged with stakeholders to implement VBP. The Kingdon's multiple stream approach demonstrates how cost becomes a major problem resulting in the strong endorsement by the MOH in the policy stream.

WINDOW OF OPPORTUNITY

VBP implementation is still progressing. There are several things that can be improved. First, the inclusion of CEA studies should be made mandatory when submitting dossier for new drug listing. All the drugs in the formulary should continuously be evaluated. Government should invest in digitalising the healthcare system. Electronic medical records need to be used in hospitals and clinics, both in public and private sectors. Hospitals should move from paper-based systems to fully computerized systems. This data then needs to be integrated. Malaysia should emulate the Taiwan Health Care Smart Card system which uses a microcontroller-based card that has various information such as the number of admissions, accumulated medical expenditure, drug allergy history and immunization information [26]. A centralised patient registry should also be set up. The availability of the data will help catapult the integration of VBP into the healthcare system. The presence of real-time data, coupled with longitudinal pharmaco-surveillance, will help to reduce the uncertainties regarding the true safety and effectiveness of the drugwhile at the same time providing leverage in the pricing negotiation process.

FUNDAMENTAL CAUSE OF VBP SUCCESS

This research seeks to understand the interplay between the stakeholders in VBP implementation. We believe that the MOH plays a big role in ensuring VBP success. The MOH utilised its resource efficiently in applying and presenting VBP as the top priority. Conversely, if the MOH is not adamant in putting VBP forward, VBP might succumb to the pressure from the private sectors.

Private sectors also play a major role in VBP implementation. Continuous engagements and clear commitment on the VBP implementation from private sectors contributed to the wide acceptance of the policy by the stakeholders.

VBP was perceived as the way to ensure sustainable healthcare cost in light of increasing spending and budget constraint. VBP is vital in ensuring the benefits received is align with the cost and therefore, optimize the budget provided to the fullest while protecting patients' welfare.

In regard to about budget constraint however, there is still a need for more fiscal allocation for health. The total healthcare expenditure in 2019 is at 4.26% of GDP [27]. This needs to be increased to 7% of GDP as recommended by the WHO. Healthcare in Malaysia is virtually seen as a burden to the government rather than a booster to the economy. This perception needs to be changed as a good healthcare system will provide a healthy generation and a high quality workforce.

Economic concerns, corruption, unemployment, political instability and kleptocracy have always become the priorities, something that are always seen in the news, social media and in daily conversation. Healthcare cost should also have topped this list. More discussion and awareness on the importance of affordable excellent healthcare is needed.

LIMITATIONS

This study has several limitations. We attempt to analyse the problem using Reich's stakeholder analysis and Kingdon's multiple stream approach, which are both recognized scientific methods. However, it is difficult to externalize this study to policy in other countries as this study is a single case study with various unique stakeholders.

There are a lot of stakeholders that might be involved in the current study. However, we only focused on the big and powerful organizations which in itself might be a bias.

This study also only involved publicly available data. This study does not take into account what might happen during private negotiations.

As for public documents, these documents might be available in English, Malay, Mandarin or Tamil. However, our sources of information were only from English and Malay.

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