# Quality use of medicine in a developing economy: Measures to overcome challenges in the Malaysian healthcare system

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### Abstract

Malaysia inherits a highly subsidized tax-based public healthcare system complemented by a fee-for-service private sector. Population health in Malaysia has considerably improved since independence using a relatively small amount of gross domestic product (~4%). Brain drain of highly specialized personnel, growth in healthcare spending, demographic and disease pattern changes and increase in patients' demands and expectations towards better medical care are exerting pressure on the sustainability of the system to continuously provide efficient and effective services at relatively low cost. Malaysia has adopted and implemented some of the quality use of medicine concepts such as National Essential Medicine List, health technology assessment and promotion of generic medicines in their health policy, but so far the results may not be optimal. Activities to further promote these strategies are needed for successful implementation to achieve more positive and sustained beneficial outcomes. Better strategic planning, management and collaboration between various stakeholders, considering the needs and barriers of the strategies, are important to ensure effective implementation of the strategies. More emphasis should be placed upon more equitable and rational distribution of healthcare resources to cater for rapid urbanization. Additionally, a sustainable health financing structure that is more progressive and does not encourage moral hazard should be established. In conclusion, Malaysia has achieved good outcomes in population health with relatively low financial inputs since independence. However, changes in the overall environment have created issues which would threaten the long-term viability of the healthcare system if not tackled properly. The numbers of internationally trialled strategies could be used to deal with these challenges. In addition, coordinated implementation of these strategies and effective engagement and communication between various stakeholders are necessary to further strengthen the Malaysian healthcare system effectively.

### Keywords

Health system, quality use of medicine, health policy, health planning

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# Introduction

Malaysia comprises 13 states and three federal territories in a land area of 330,803 km<sup>2</sup>. Malaysia has a multicultural population totalling 30.4 million in 2015 with Bumiputeras (i.e. the Malays, the indigenous groups in Sabah and Sarawak, and the aborigines of the Peninsula) accounting for 67.4%, Chinese 24.6\%, Indians 7.3% and others 0.7%.<sup>1</sup> Considering the population demography, Malaysia is a relatively young country where the majority are economically productive with 27.6% of the total population less than 15 years of age and 5.1% more than 65 years of age.<sup>1</sup>

The healthcare services have tremendously improved the health of the population, transforming the country into one of the healthiest countries in the tropics. An indicator of better health outcomes was the increase in life expectancy from 63.1 years (male) and 66.0 years (female) in 1966 to

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72.6 and 77.2 years in 2010, respectively.<sup>2</sup> The increase in life expectancy and other health outcome gains such as improved neonatal, children and maternal mortality rates were largely due to combination of various factors, including the improvement in immunization status, a more equitable social and economic development and better health services.<sup>3</sup> Malaysia could boast these health achievements with an expenditure on healthcare of just 3%-4% of gross domestic product (GDP).<sup>4</sup> However, the Malaysian healthcare system is facing similar challenges faced by other countries in sustaining and providing more equitable and efficient services. This article attempts to describe the current status and challenges of the Malaysian healthcare system and suggests measures to be implemented by various stakeholders to facilitate and improve quality use of medicines (QUMs) in Malaysia.

# Methodology

Databases including EMBASE, PubMed and Ovid were searched for published literature related to the healthcare system for the current review. Initially, the strategy was to identify English language literature from any part of the world that discussed about tax-based healthcare systems. Then, the selection was narrowed down to those especially relevant for the current review. For the initial, broad selection, any literature describing or discussing health frameworks with terms such as 'health system', 'health policy' and 'tax-based system' was included. A snowball sampling technique was then employed to search for more literature from the references of the identified articles.

# Current status and challenges of the Malaysian healthcare system

### Healthcare provision

The Malaysian government is integrally involved in providing all levels of healthcare nationally. All citizens basically only have to pay a nominal fee for receiving public health services, while private health providers and facilities are based on fee-for-service models.<sup>5</sup>

Inadequacies in the availability of public health facilities and manpower have led to a proliferation of private health facilities. Private hospitals have grown from 10 in 1980 to 209 in 2013.<sup>3</sup> Inpatient care (77%) is, however, mainly provided by the 143 public hospitals while primary services are predominantly provided by the 6371 private clinics.<sup>3</sup> Urbanization and an increase in national income have significantly impacted the uneven distribution in the healthcare system.<sup>6</sup>

# The brain drain of highly specialized personnel from the public sector

The low level of 0.9 physicians per 1000 population has seriously constrained the capacity in meeting the population's needs in Malaysia.<sup>7,8</sup> The movement of doctors to private hospitals further exacerbated the manpower shortage in public hospitals.<sup>3,9</sup> Consequently, one-third of the total number of physicians who remain in the public sector struggle to provide services for two-thirds of the total number of hospital beds in the country.<sup>10</sup>

The imbalance in the distribution of healthcare resources has a greater negative impact, especially in remote areas.<sup>11</sup> For example, the doctor–population ratio is approximately 0.5 physicians per 1000 population in the rural areas of Sabah and Sarawak, compared to the overall ratio of 0.9 in the rest of Malaysia.<sup>11</sup> Vacancy of medical posts especially in hospitals built with special budget allocations in rural areas, however, adds to allocation and service inefficiency as the facilities do not have the required number of healthcare professionals, especially certain speciality services, required by patients.<sup>9</sup>

### Healthcare expenditure

The increase in the average global healthcare expenditure from 3% of GDP in 1948 to 9.2% in 2010 indicates that healthcare was gaining greater attention in the development of many countries.<sup>4,12</sup> Malaysia which is among the uppermiddle-income countries has followed the global trend where the estimated total health expenditure at 4.4% of GDP in 2010 was in the middle range of the high-income countries in the Asian region.<sup>4</sup> The estimated per capita spending on health in purchasing power parity (PPP) was US\$645 in 2010, slightly higher than the international average of US\$598 for upper-middle-income countries.<sup>4</sup> Sustainability in health financing is a concern, particularly during an economic recession, where an average annual growth rate in health expenditure of about 9% was seen between 2005 and 2010.<sup>3</sup>

Analysis of the Malaysian healthcare expenditure showed that public expenditure has increased almost fivefold in 15 years from RM4317 million in 1997 to RM19 797 million in 2011.<sup>13</sup> The average out-of-pocket spending of 72.2% (as percentage of private expenditure) in 2011 was twice that of high-income countries.<sup>4,9</sup> High out-of-pocket payments will give rise to equity issues and impose higher financial burden on lower income groups which tend to have lower health status and higher health risks.<sup>14</sup>

### Medicine availability and affordability

When it comes to drug pricing, extremely high prices of up to 16 times higher than the international reference prices (IRPs) were found among private retail pharmacies and dispensing doctors.<sup>15</sup> Without any pricing justification, higher mark-ups of up to 316% show an overall lack of pricing policy and suboptimal public sector drug procurement.<sup>16,17</sup> High pharmaceutical prices pose an extra financial burden to the government and patients paying for their own treatments in the private sector.

The issue of affordability of drugs in Malaysia is expected to remain with the total expenditure on pharmaceuticals rising continuously from 6.2% in 1997 to 8.5% in 2011.<sup>13</sup> Availability of new drugs, expansion of public health programmes, increased prescription volume and drug prices are factors associated with increasing drug expenditure.<sup>18</sup>

The government had responded by privatizing the drug procurement and distribution centre in 1994 with the intention to relieve the government's financial and administrative burdens and facilitate national development targets. The centralized drug procurement monopoly has, however, resulted in price hikes of medicines without significant improvements in its distribution system.<sup>18</sup>

Rational drug uses are necessary element of a good health system, and many countries, particularly poor and developing countries, have followed the World Health Organization (WHO) recommendations in the development of a national essential drug lists. The Malaysian National Essential Medicine List (NEML) was derived from the drug formulary for public sector facilities (locally known as the 'Blue Book').<sup>19</sup> The procedure in drug selection and deletion for the formulary is based on the bottom-up approach.<sup>20</sup> The list, however, has been criticized for not being developed rationally based on treatment guidelines and the country's needs.<sup>21,22</sup> Also, the concept of NEML was not adopted for the medicine stocks and procurement even in the central and major regional warehouses of the public sector.<sup>23</sup> These problems lead to a shortage of drugs which eventually affected the credibility and effective operation of the healthcare system.

This is highlighted when an international survey found low availability of 15 selected generic medicines particularly in the public sector.<sup>24</sup> This could be due to factors such as suboptimal product inclusion and poor compliance to the national medicine lists, inadequate funding, lack of incentive for maintaining stocks, inaccurate utilization forecasts, inefficient distribution systems and leakage of medicine for private resale.<sup>24</sup> The problems of medicine availability in the public sector and high private sector prices increase equity issues as patients are forced to purchase from the private sector.<sup>17</sup>

As a measure to facilitate affordability of medicines, many countries have regulated the price of essential medicines.<sup>22</sup> In Malaysia, there are only monitoring system for medicine prices with no pricing regulations implemented for manufacturers, distributors and retailers.<sup>22</sup>

# Demographic shift, disease pattern transition and urbanization

Fertility rate in Malaysia has fallen to 2.1 births per woman in 2012 from 4.9 births per woman in 1970. The proportion of the population below 15 years of age had also fallen to 31.8%, while those aged above 65 years had been increasing.<sup>3</sup> An ageing population is usually a consequence of a country passing into the final stage of demographic transition when sustained drops in fertility occur.<sup>25</sup> This will have an impact on healthcare expenditure as levels of health spending have been shown to be considerably higher for the aged than for younger groups in every country.

The convergence between the principal diseases of the developing and industrial countries occurred for the first time in 1998 when the global burden of chronic diseases overtook infectious diseases.<sup>26</sup> The shift of mortality from communicable to non-communicable diseases is more pronounced in Malaysia than neighbouring countries, except Singapore.<sup>4</sup> The ongoing nature of treatment and the frequent need for a more costly combination of therapies would cause management of chronic disease unaffordable for large proportions of the population.

Industrialization has made Malaysia the second most urbanized country in South East Asia with the overall increase in the urban population from 26.8% in 1970 to 71% in 2010.<sup>1,3,27</sup> Urban congestion has stronger association with improper urban planning and ineffectual policy implementation than inadequate space or increasing urbanization rate. Most Malaysian cities are unable to satisfy the increased demand for housing, urban and health services due to rapid urbanization.<sup>28</sup>

The previous focus of the health policy in Malaysia to allocate resources proportionally to rural areas has led to overcrowding at metropolitan hospitals while underutilization of small district hospitals.<sup>9,29–33</sup> This is apparent when a midterm review of the Fourth Malaysian Plan reported that the bed occupancy rate for the Pekan District Hospital (a small district hospital) went as low as 26.1% compared to 89.1% at the Kuala Lumpur General Hospital, the largest hospital in the country.<sup>9</sup> A large number of private hospitals and clinics in Kuala Lumpur have partially alleviated the problem. Health planning, therefore, should consider the population shift and channel the resources appropriately to more densely populated urban areas.

### Consumer demands and expectations

Changes in disease and demographic patterns, and better standards of living have impacted patient perceptions and expectations of health, leading to increased demand for medical care. Resource constraints complicate access to expensive and sophisticated treatment in many developing countries including Malaysia. The congestion of metropolitan public hospitals is a result of the population competing for a limited number of personnel and advanced technologies in small district hospitals. This consequently leads to greater admission and treatment rates in private facilities.<sup>9</sup> The private outpatient attendances have shown a large increase (191.4%) from 1985 to 1996 although the median charge per day was 100 times higher than in the public hospitals.<sup>9</sup>

The competitive health-seeking behaviour could also lead to irrational use of healthcare by the patients and providers leading to overcrowding, reduced consultation time, high prescribing levels and low levels of understanding of patient problems at public health facilities.<sup>34</sup> The government's policy of mainly subsidizing the poor and civil servants, coupled with the opportunity for queue jumping by those who can afford to pay for the services, further added to problems of inefficiency and equity.<sup>9</sup> Sustaining the system will hence become more difficult due to these aggregated problems.

# Discussion and recommendations: improving the healthcare system through QUM concept

WHO has defined QUM as, 'patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community'.<sup>35</sup> Effective QUM management could have significant positive effects in a patient's clinical outcomes as well as improving the organization of the healthcare system.

QUM strategy nevertheless is often neglected in the developing countries leading to an inexcusable essential medicine shortage, an ineffective supply and distribution system and irrational use of medicines. Irrational practices such as high prevalence of antibiotics use (up to 92%) for the treatment of common cold especially in rural clinics in Malaysia could lead to increases in the incidence of antibiotic resistance or even fatal anaphylactic reactions.<sup>36</sup> Consequently, the populations have to bear the burden of high health expenditure, resources wastage and failure to prevent morbidity and mortality.<sup>35</sup>

Various QUM strategies ranging from education, managerial, economical and regulatory approaches have been implemented from the individual organizational level to the highest level of policy making in many countries.<sup>35</sup> Malaysia has followed these approaches by including the QUM strategies in the National Medicines Policy in order to overcome the healthcare challenges.<sup>19</sup>

An essential component of QUM is the ability of each health professional to play the role that they are trained for such that one health professional complements another towards the care of the patient. Malaysia has a dispensing market, that is, the doctor is allowed to supply (and charge for) medicines to patients seen at their clinic. This practice began during a time when there were very few pharmacists, but there are sufficient numbers of pharmacists now. While it is generally acknowledged that the separation of dispensing and prescribing will contribute towards QUM, the dismantling and changing of an entrenched system and practice that involves the income of healthcare professionals is a significant challenge. Therefore, such a change will not only involve an increased understanding of the complementary roles of doctors, pharmacists and dentists and other healthcare professionals but also political will, a revised healthcare financing mechanism and a determination to provide the best for the patient.

### Promotion and education

A National Medicine Use Survey (2013) reported that many Malaysians have problems in understanding the proper use of medicines, differentiating between trade and generic names, and a lack of awareness on the possible side effects and interactions of medications.<sup>37</sup> Various stakeholders have initiated efforts in the development of special programmes such as national project on the Quality Use of Medicine-Consumers (QUM-C) to educate consumers on rational medicine use. However, isolated programmes of similar approaches have failed universally in many countries.<sup>38</sup> Hence, there is a need to develop targeted and coordinated educational programmes.

*Public health programmes.* A relatively small investment in public preventive health services such as immunizations has successfully brought down the incidences of infectious disease since the early 19th century. More than 90% immunization coverage of infants and children in Malaysia has reduced hepatitis B, measles, diphtheria and pertussis infections, and furthermore, it has gained recognition as a polio-free country since 2000.<sup>3,39</sup>

Most researchers agree that changes in individual's lifestyle such as smoking habits, dietary intake and physical inactivity in their early years have a significant impact on reducing the risk of non-communicable diseases in later life. Hence, policy makers in the developing countries should aggressively develop health promotion policies as the ageing population is still at an early stage.<sup>25,40</sup> A comprehensive and integrated approach to reduce all major non-communicable risk factors with the involvement of political/community leadership, intersectoral partnerships, community mobilization and strengthening the health system is crucial as traditional approaches of targeting a single disease are inadequate.<sup>41</sup>

Malaysia's involvement with the WHO Framework Convention on Tobacco Control and the Control of Tobacco Products Regulation (1993) had an impact on smoking habits of the population.<sup>5</sup> Capacity building as well as new healthy guidelines to assist individuals and communities to achieve and maintain optimal health status could further improve population health.<sup>5</sup>

Effective engagement and communication between healthcare professionals and patients in choosing treatment modalities help to improve intermediate outcomes without increasing financial inputs. It improves patient adherence and treatment knowledge, but the long-term reduction in mortality has not been seen.<sup>38,42–44</sup> Other studies showed that implementing intervention programmes to improve rational prescribing could reduce the prescription volume, have positive changes in health outcomes and reduce hospital admissions.<sup>42,44–46</sup> Likewise, early findings of a phased pilot project in four Malaysian states showed an abundance of unused medication at patients' homes, improper storage of medication and consumption of traditional herbs, leading to various adverse drug events and disease complications.<sup>47</sup> A more comprehensive and relevant cost-effectiveness study is needed for implementation of these programmes in other parts of Malaysia, as it is resource intensive.<sup>44</sup>

### Managerial strategies

*Human resources.* Personnel to deliver quality healthcare services is still insufficient in Malaysia although various strategies such as recruiting foreign doctors on contract, increased intake of medical and pharmacy students and utilizing services of retired health personnel have long been implemented.<sup>9</sup> A public–private integration strategy attracted small numbers of private practitioners compared to the high utilization of public doctors in the private sector, although the aim was to benefit both sectors.<sup>5</sup> Nevertheless, exchanging healthcare expertise and knowledge through collaboration between various government agencies, private sector and nongovernmental organizations should still be promoted and strengthened.

Task shifting by increasing reliance on the communitylevel workers is another cost-effective solution to increase access to services in various settings.<sup>7</sup> The establishment of the 1Malaysia clinic has received a good response from the urban poor, reducing hospital congestion and improving access to healthcare.<sup>2,48</sup> Improved training of personnel is, however, needed for the expansion of the services, to resolve issues related to legality, quality of care and timely referral.<sup>11</sup>

Strengthening management of the established public sector ambulatory care (i.e. *klinik kesihatan*) is more costeffective without incurring additional cost of building new facilities. Decentralization of the outpatient departments to the district health centres during the Seventh Malaysia Plan (1996–2000) had expanded the health services at the primary care level to provide efficient services and improve equity and accessibility.<sup>9</sup> The involvement of Family Medical Specialists in health centres for delivering comprehensive health checks and treatment since 1997 has also reduced unnecessary referrals and congestion at specialist clinics in hospitals.<sup>5,9</sup>

NEML and clinical practice guidelines. Numerous medicines have been marketed worldwide to this date, adding to the complexities of choosing the best treatment for an individual patient. Evidence-based decision-making is gradually and increasingly accepted in Asia Pacific countries to support decisions in formulating and funding of health policies to keep a balance between efficacy and costcontainment. The approach in formulating the essential medicine list has also been evolving, changing from expert decision to evidence-based and from cost-comparison to cost-effectiveness evaluation.

The Malaysian NEML is widely accepted in the public sector, while the private sector and teaching hospitals have developed their own formularies individually.<sup>21</sup> The list

needs to be independently derived through collaboration with all stakeholders to improve its transparency, reduce bias and enhance users' confidence to achieve its objectives.

Standardized best practice through implementation of clinical practice guidelines (CPGs) is capable of supporting quality improvements and consistency in healthcare delivery. The development and implementation of CPGs in Malaysia should be properly planned taking into consideration the working condition of healthcare providers, adequacy of facilities, logistic barriers (especially in rural areas) and the capability of local industries.

Use of generic medicine. Appropriate use of generic medicines is cost-effective in bringing down healthcare costs without compromising therapeutic outcomes. Studies have revealed that negative perceptions on the quality of generic medicines among healthcare providers in Malaysia are associated with the lack of knowledge and education.<sup>49-52</sup> Dissemination of information and knowledge concerning the use, price and quality at the patient and healthcare provider level needs to be strategically planned to counter the misconceptions and increase their confidence towards generic medicine use.53-56 No regulations for mandatory prescribing of generic medicines currently exist in Malaysia although health professionals are urged to use generic medicines. Pharmacists in public sector generally substitute generic drugs for brand name products. The use of generic medicines is expected to increase if the regulation on the use of generic names in prescriptions is included in the proposed new Pharmacy Bill.57

### Economical/financial

*Pharmacoeconomic* evaluation. The decision to implement health interventions will be largely dependent on the achievement of positive net health benefits within affordable costs. Many countries have implemented the concept of HTA in the healthcare system such as the Pharmaceutical Benefit Schemes for drug reimbursements in Australia, practice formularies and budget-holding in the United Kingdom, national evidence-based clinical guidelines in Scotland, Positive List System in South Korea and pharmacoeconomic evaluation for drug selection and licensing in Thailand and Taiwan.<sup>38,53,54,56,58</sup>

Malaysia similarly has established an HTA unit in August 1995 to identify, review, approve and formulate policies, as well as disseminate and implement activities related to health technology. The positive impact from this implementation includes the use of HTA in formulation of national and Ministry of Health (MOH) policies, as the basis for development of CPGs, input into purchasing decisions and regulation of drugs.<sup>56,59</sup>

In Malaysia, barriers in HTA implementation could be divided into issues in producing economic evaluation data and context-related needs. The scarcity of locally produced economic, population and health system data in many developing countries necessitates the adoption of data from other countries.<sup>60</sup> Nevertheless, difference in population factors and health system characteristics as well as dissimilarity in liability and incentives of remuneration will lead to bias which may also be amplified by studies funded by pharmaceutical companies.<sup>60</sup> Hence, locally performed studies are urgently needed for comparisons with other countries, and to ascertain consumption patterns. In terms of context-related needs, Malaysia has progressively trained their healthcare staff and gained experience through international collaboration to overcome the poor understanding of economic evaluation among potential users.<sup>61</sup> Nevertheless, addressing all these philosophical, ethical and social institutional barriers regarding HTA are critical to achieve the aims in financial sustainability, improving equity of access and distributing the budget effectively in Malaysia.

Resource constraints in many developing countries including Malaysia further complicate the issue, as not all cost-effective interventions can be funded. Most European and Middle Eastern countries have regulated the price of essential medicines to control their healthcare budget.<sup>22</sup> The prices for essential and newly listed medicines in Malaysia MOH Drug Formulary are monitored for the negotiation in the procurement process as well as to avoid unforeseen price changes.<sup>62,63</sup> A monitoring-only approach, however, is not effective in controlling the budget without government regulation. The transparency of pricing information such as the international reference pricing (IRP), mark-up and profit controls at dispensing level furthermore will eventually put downward price pressure on the manufacturers, distributors and retailers.<sup>57</sup>

The current approach of voluntary submission of pharmacoeconomic evaluation for new medicines inclusion should be made mandatory,<sup>64</sup> but adequate resources to establish a national centre and regulating body responsible for the evaluation would be necessary. In line with increasing demand for local pharmacoeconomic data, the MOH has recently published guidelines for pharmacoeconomic studies.

# Regulation through a probable National Health Financing System

Regarding the sustainability of the Malaysian healthcare system, the probable National Health Financing Scheme (NHFS) was widely discussed during the midterm review of the Fourth Malaysia Plan (1983).<sup>9</sup>

Factors such as the extent of population coverage, the structure of contribution rates, earnings limit on contributions and contribution shares between employee and employer are important determinants to be decided in the proposed NHFS.<sup>65</sup> The concept of cost sharing and shared responsibility of all citizens according to individual ability to pay (ATP) could be achieved by combining the new NHFS contribution with the government and any third-party funding.<sup>65</sup> Public–private integration in health

financing may lead to greater cohesion and efficiency of healthcare services.<sup>66</sup>

Basic healthcare coverage under a new NHFS could further reduce out-of-pocket payments and increase the individuals' ATP for other healthcare services.<sup>65</sup> Some copayments would reduce moral hazard and promote individuals' responsibility for their own health,<sup>65</sup> but strengthening exemption policy is necessary as copayments will discourage the poor and vulnerable from accessing healthcare services.<sup>65</sup> Theoretically, the shift in financial burden towards the rich will improve the progressivity, thus ensuring the sustainability of universal healthcare funding and enhancing its equity and accessibility.<sup>65</sup>

# Conclusion

Since independence, Malaysia has achieved good outcomes in population health with relatively low financial inputs. But the changes in the environment have created new challenges which exert pressure on the health system to continue to provide effective and efficient services. Many internationally trialled strategies could be used to deal with these challenges. However, besides coordinated implementation of these strategies, effective engagement and communication between various stakeholders is also necessary to allow these strategies to take effect in strengthening the Malaysian healthcare system.

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The views expressed in the submitted article are the authors' own opinions and do not express the views of their official position of the institution or funder.

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