12 *Leadership and Governance*

JO. M. MARTINS AND INDRA PATHMANATHAN

12.1 Introduction

This chapter explores the influence of leadership and governance on the development of the health system in Malaysia during the 60 years since independence. Governance refers to 'a wide range of steering and rule-making related functions carried out by governments/decisions makers as they seek to achieve national health policy objectives' (World Health Organization, 2019). It includes the policies and systems structures that facilitate the regular operation of a health system. Leadership has been defined as 'the art of motivating a group of people to act towards achieving a common goal' and includes elements of inspiring and directing (Ward, 2019). This concept has been extended to apply to institutions as leaders (Washington et al., 2008). Leadership occurs at many levels of the system, and its characteristics, development and impact on the health system have been analysed variously (Hartley, 2008; West et al., 2015).

Leadership and governance are strategic elements in a health system (West et al., 2015). Their performance has an impact on:

- the direction and priorities of the system,
- the development and bonding of the various inputs into a coherent set of activities and services, and
- collaboration with relevant public entities and the formation of coalitions with other organisations and civil society in the pursuit of public interest and social welfare.

Leadership and governance are key to planning and implementing activities, evaluating outcomes, and the shifts and corrections needed. By their very nature, they operate in a political and socio-economic context, and outcomes depend on political and social acceptance of objectives and their operational forms. This, in turn, enhances the

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

mobilisation of resources and their application to achieve set goals. They are of greater importance in multi-ethnic societies, such as Malaysia, to minimise tensions arising from differences in perspectives and actual conditions, as well as to create a political framework that can manage the development process in spite of constraints. The development process could either address one set of constraints at a time or follow a more holistic path by addressing a number of related ones simultaneously and benefiting from the synergy of complementary thrusts that enhance outcomes across the system (Pourbohloul & Kieny, 2011).

12.2 The Ministry of Health: Context and Structure

12.2.1 National Governance Context

The Malaysian Constitution provides a federal type of government, with division of powers between the federal and state governments. At the federal level, the legislature consists of a lower House of Representatives, elected through nationwide elections, and a partially appointed Senate. Each state has its own State Assembly elected by statewide elections. The parliamentary type of government has an executive (Cabinet), headed by a prime minister who is a member of the lower house and a number of ministers. The hereditary Malay heads (Sultans) of some states elect from among themselves a monarch (Supreme Ruler) who serves for a fixed term. The monarch has limited powers and follows the advice of the prime minister of the day. The rulers, on the advice of their governments, appoint the members of the independent judiciary, both at federal and state level. While some powers are exclusive to either the federal or the state governments, there are some overlapping areas where powers are conjoint. The federal government has powers concerned with health and the provision of health services and others relevant to health such as the environment, labour and education (Commissioner of Law Revision, 2014), whereas states have powers over land.

Malaysia adopts a holistic approach wherein health policies are formulated and developed within the context of wider major national development policies set by the Prime Minister's Department (PMD) and Cabinet and articulated in various Malaysia Plans. Health professionals in the Ministry of Health (MoH) have the primary

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

responsibility of advising the government on health priorities and formulating health programmes and interventions according to these priorities. Achieving balanced development with greater equity and poverty alleviation has been a national aim, with the reduction of differences between groups of people and regional areas a key priority. Another aspect of priority-setting has been the need to balance health service development with human resources availability and fiscal constraints (Economic Planning Unit, 1991; 2015; Chapters 3–9). National priorities and health needs have evolved as economic and social development took hold with growing urbanisation (Chapter 3). For example, the Eleventh Malaysia Plan (2016–2020) moved priorities from eradicating poverty to improving the living conditions of the 40% of all households that have the lowest income (Economic Planning Unit, 2015). The MoH policies responded accordingly.

12.2.2 MoH Organisational Structure

At federal level, the MoH, headed by a Cabinet-level minister, has two arms. The administrative arm, headed by the Secretary General and staffed by civil servants from the country's general public civil service, is responsible for public service personnel administration, finance and procurement. The health professional arm, headed by the Director General (DG) and staffed by healthcare professionals, focuses on planning, implementing and evaluating service delivery and the wider concerns that affect the health of the community. It appears that areas under the DG's responsibility tend to be concerned with the whole system beyond the health services provided by the MoH, while those under the more direct administration of the Secretary General tend to relate to the provision of services by the MoH and public service administration.

The organisational structure of the MoH follows the conventional separation of public health and community-based services from medical and hospital services, with separate areas of responsibility for research and technical support, including planning, engineering services, the National Institutes of Health, dental care, and pharmaceutical goods and supplies. Each state has a state-level health department responsible for administration and delivering services, and its organisation reflects the conventional separation of public health and community-based services from medical and hospital services (Ministry of

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

Health Malaysia, 1975; 2018). There are smaller administrative entities at district and hospital levels. As described in Chapters 4, 5, 6 and 8, the evolution over the past 60-year period has seen growing professional and managerial competence, beginning at the federal level and gradually trickling down to the district and hospital levels.

12.3 The MoH as an Intersectoral Leader

The MoH is expected to exercise institutional leadership and governance for health. It sets the health agenda and ensures its place in the broader national agenda, sets policies that shape how public and private health sectors operate and interact, creates regulations for health and safety and collaborates internationally for health.

12.3.1 Inter-ministerial Leadership

The MoH is the major source of technical expertise for health. It formulates and administrates health-related legislation and regulations, provides training for nursing and other allied health professional personnel and is the major provider of health services in Malaysia. However, health is dependent not merely on health services but also on what people do and their work and living conditions. Consequently, the MoH often lacks both the direct authority and supervision of substantial areas of relevance to health risks management and their impact on health that fall under the responsibility of other ministries or agencies such as environment, transport or food services. This diversity of authority and responsibilities requires the MoH to provide, at times, leadership and technical support in collaborative approaches with other federal and state agencies and civil society in the pursuit of policies and practices that enhance the health status of Malaysians.

Historically, several other ministries have played influential roles in health development. The PMD plays a major role in developing national policy that guides health policies and translating it into five-year plans with mid-term reviews and longer-term outline perspective plans. This process enables performance evaluation and corrections. The Ministry of Finance addresses fiscal needs from development and operational demands. As MoH revenue amounts to only a small fraction (3% in 2016) of its operational expenditure, it is dependent on the fiscal resources of the federal government through the Ministry of

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

Finance (Ministry of Health Malaysia, 2018; Chapter 9). The role of the Ministry of Education (MoE) has expanded from training medical students to include the training other health professionals. The MoE also administrates a number of university teaching hospitals and has partnered with the MoH in providing health-enhancing services and promoting healthy practices in school-age children. Finally, co-ordination across different levels of government has also been important, with federal, state and local governments sharing responsibilities in areas such as the promotion and maintenance of healthy conditions at a local level, such as the preparation and sale of food in urban areas.

New and emerging challenges to public health have triggered changes in the roles and inter-relationships between ministries. For example, as health concerns related to environmental, occupational or lifestyle issues rise in importance, the corresponding ministries have an increasing responsibility for health. However, there are examples where professional specialisation in the relevant ministries has created gaps in their ability to respond. The MoH has stepped in to address these gaps or ensure proper ownership by other ministries. For example, the professional strength of the agencies concerned with the environment (e.g. the Department of Chemistry) led to a focus on chemistry rather than on bacteriology. In the case of labour, safety concerns focused on risks from mechanical devices and not on exposure to and contamination by biological agents. The MoH supported the relevant ministries in developing the needed expertise.

Although the MoH is the acknowledged leader for issues related to health, in practice, leadership has taken on different forms and has been manifested by different institutions. For example, Chapter 7 provides an example where the MoH provided leadership by facilitating other agencies that had the primary responsibility of providing safe water and sanitation to develop the professional competence required to perform their function adequately. Similar examples are evident in the management of other environmental and occupational health risks (Chapters 4, 6 and 7). As other ministries and agencies acquired greater capacity to address the changing environmental, labour and social scene, the role of the MoH evolved and became a supportive one.

Sometimes leadership is a shared role. For example, universities under the MoE are responsible for the academic training of medical practitioners. However, the MoH, as the leading provider of healthcare, takes the lead in defining the competencies required in the medical

workforce, while the universities take the lead in designing and implementing the curriculum. However, the MoH provides much of the practical training and internship of doctors in its public hospitals and is therefore the final authority to decide whether the new doctor is competent to practice without supervision (Chapter 8). Civil society has also demonstrated leadership in health. Chapter 6 provides examples of situations where non-governmental organisations (NGOs) provided leadership for successful advocacy for national policies and programmes to tackle tuberculosis and HIV/AIDS.

12.3.2 Leading and Governing Service Delivery in the Public and Private Sectors

The private sector has a significant role in the delivery of healthcare in Malaysia. An important governance question is whether the provision of health services is a public or a private matter and the role of government in its provision and financing. The nature of health services does not make market mechanisms effective to ensure efficiency and social, or even private, satisfaction in meeting health needs. Much of healthcare has the characteristics of what have been termed *public goods*,[1] which makes market competition an inadequate means of achieving efficiency or ensuring equity in their distribution in view of income inequalities and poverty. Further, health services, like education, have attributes that can give them social merit that society needs to determine independently of preferences determined by price and consequently the living standards of more than one generation. Further, the health service 'market' is characterised by commonly designated 'market failures' that preclude assumptions regarding the maximising of consumer utility (or welfare) and efficiency in the allocation of resources and their use. Among other attributes, the health 'market' is characterised by few providers, especially in the case of hospitals, with restrictions to entry due to licensing and other constraints; prices that are sometimes determined by providers or insurers; asymmetry of information between consumers and providers, as the consumer is dependent on the supplier to determine services received; and, as previously mentioned, considerable externalities, especially in the case of infectious diseases. These characteristics of the health services 'market', especially in the case of services provided by the private sector, do not allow the efficient

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

performance of social objectives of consumer sovereignty and efficiency (Martins, 2004).

Thus governance of the health system in Malaysia has to address the balance between public and private provision of services, their relative costs and equity in their distribution. First, the relative scarcity of medical personnel and their concentration in urban centres led to the provision of public sector primary healthcare in rural areas, where most people lived, by allied health personnel. This was a low-cost but effective delivery of basic healthcare. Complemented by environmental services, it contributed to improved equity in access to health services (Chapters 3, 4 and 8).

As medical personnel became more abundant and people more urbanised, with easier geographical access to both public and private health services, the provision of lower-cost public services still played the important function of benchmarking the price of private services, keeping private fees in check. However, to retain medical personnel, the governance of public services had to keep the remuneration of medical personnel in the public sector at an acceptable level (Chapters 8 and 9). These balancing efforts have kept total health expenditure in Malaysia at the middle level of 4.0% of the gross domestic product (GDP) in 2014, compared with its neighbouring countries – 6.5% in Thailand, 4.9% in Singapore and 2.8% in Indonesia (Ministry of Health Malaysia, 2017) – and added about 15 years to the life expectancy of Malaysians (Chapters 3 and 9).

The governance of health services raises some potential conflicts of interest for the MoH. An obvious one is that the MoH is both a regulator and a provider of services. This governance issue is only partly addressed by the establishment of state administrations of public sector health services that are accountable and subjected to oversight by the central administration of the MoH. However, the MoH is, in turn, subjected to oversight by agencies in the PMD and the Ministry of Finance.

In addition, a number of governance issues arise from the government-stated interest in the promotion of the private sector in general and private health services in particular. The government has nominated health as one of the National Key Economic Areas. Although a number of economic activities are included, such as the production of pharmaceutical and medical devices, with some emphasis on their economic and export value, an area more directly related to health

services is medical tourism (Prime Minister's Department, 2017). The Malaysian government has promoted medical tourism since the late 1990s (Ormond et al., 2014; Chandran et al., 2017). It is fostered by the Malaysia Healthcare Travel Council (MHTC), an initiative of the Ministry of Finance. The council's membership also includes the ministries of relevance to tourism, the MoH, and other agencies such as the Association of Private Hospitals of Malaysia (Malaysia Healthcare Travel Council, 2020). There is no obvious evidence of the direct relevance of medical tourism to the health of Malaysians, as its objective is an economic one. This is reflected in the absence of any apparent reference to medical tourism in the annual reports of the MoH (e.g. Ministry of Health Malaysia, 2018). There is not much specific information on the value of medical tourism and its contribution to economic activity. An estimate by the MHTC for 2017 of the value of medical tourism was that it represented the equivalent of about 0.1% of the value of Malaysia's exports in that year (Malaysia Healthcare Travel Council, 2017; Malaysia External Trade Development Corporation, 2018).

However, this economic interest has led to pressure on the MoH to reduce the regulatory burden on private health services in its administration of the Private Healthcare Facilities and Services Act. In this context, a study mandated under the Tenth Malaysia Plan to modernise business regulations conducted a regulatory review with the aim of reducing unnecessary regulatory burdens on private hospitals (Malaysia Productivity Corporation, 2014a). The review focused on the private hospital sector, as this is deemed a high-value-added, high-knowledge-based and growing sector. It found that regulations covering private hospitals were excessively prescriptive and made several recommendations for reducing the regulatory burden. It is noteworthy that the annual report of the same agency – related to the Ministry of International Trade and Industry – for 2013–2014 mentions rising costs and innovation as the major issues to be addressed by private hospitals and makes no mention of the burden of regulations (Malaysia Productivity Corporation, 2014b).

The regulation of medical personnel has been an important point of consistency across the public and private health sectors. Health services are dependent on the competence of medical, nursing and other professional personnel. Malaysia uses the mechanism of licensing via statutory bodies to manage these standards of practice, and this process has

evolved and became more comprehensive over time (Chapter 8). For example, the Nurses Act 1950 provided for a Nursing Board to supervise the training and registration of nurses and oversight of their practice (Chong et al., 2011). The Medical Act 1973 gave the Malaysian Medical Council the authority to evaluate the qualifications of medical practitioners and their registration (Malaysian Medical Council, 2018). This was important because of the past shortages and recruitment from countries with varied training and degrees of competence. The licensing and/or registration of other health professions has continued over the years to ensure appropriate and safe professional practice (e.g. Allied Health Professions Act 2016) (Lim, 2016).

12.3.3 Regulations for Health and Safety

In the health sector, Malaysia uses regulation and licensing for two major purposes. The first is to manage threats to community health arising from the spread of disease or deleterious elements in the environment in which people live. The second is to protect the community from fraudulent or potentially harmful practices by healthcare providers or through the sale of medical and food products. The regulations give legal authority to various agencies for their enforcement, with sanctions for their infringement.

Initial regulatory activity by the MoH addressed infectious disease (Chapter 6), medical personnel (Section 12.3.2) and medical products (Chapter 12). In later years, however, as urbanisation and industrialisation increased the health risks of water supply contamination, changes to the Constitution allowed the federal government and the MoH to play a greater role in water supplies and sewerage and their regulation (Water Services Industry Act 2006) (Wahab, 2011; Pidgeon, 2012). The MoH plays an active role in the National Drinking Water Quality Surveillance Programme (Ministry of Health Malaysia, 1998). The growth in the commercialisation of food supplies, including international trade, has added to health risks in food supply and consumption, leading to the strengthening of the Food Act 1983 and its regulations.

Most Malaysians are of working age and are employed in a wide range of activities with varied degrees of health risk and disability risk. Consequently, occupational safety is a major factor in the maintenance of health. The Occupational Safety and Health Act 1994 aims at maintaining safe working conditions and applies sanctions for adverse

practices. Although the administration of related regulations and surveillance lies with the Ministry of Labour, the MoH remains concerned about the surveillance of occupational diseases in order to identify the causes and sources that can direct remedial action, in addition to the promotion of the health of the large labour force in health services (Ministry of Health Malaysia, 2018).

Malaysia has used health legislation and regulation sparingly, perhaps in part due to limitations in institutional bandwidth and capacity. The lead time for enacting and enforcing new legislation is lengthy, taking five or more years for food legislation, for example. This indicates the complexity of the processes, which include stakeholder engagement, legal expertise and availability to draft the legislation, and developing the enforcement capacity and mechanisms for implementation. Such capacity might require financial resources, digital monitoring, laboratory services, the establishment of procedures and guidelines, and the training of enforcement and prosecution staff. In addition, the nature of the imperatives for legislation influenced political will and support, which in turn influenced the priority of enacting and implementing legislation effectively and the system capacity to do so.

Table 12.1 illustrates this through contrasting examples of the development of legislation to safeguard against hazards in food, where strong foreign trade imperatives proved much stronger than domestic imperatives that involved balancing health concerns against the growth of local food services.

While it is important to allow sufficient time to garner stakeholder support and build system capacity, long lead times in developing legislation and regulation can be detrimental. A problem may develop in the intervening period, resulting in the need for repeated re-drafting of legislation. It weakens governance capacity and engenders frustration among groups experiencing negative impact and among enforcement authorities. An example from Case Study 5.1 in Chapter 5 is the long delay in enacting legislation to govern the behaviour of third-party agencies that serve as intermediaries between employers and healthcare providers for their employees.

12.3.4 International Collaboration

As with most developing countries, the development of Malaysia's health system has had some external support, specifically from the

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

Table 12.1 *Differing imperatives influenced the system behaviour in formulating health legislation*

	Characteristics of the imperatives for legislation	Lead time for formulation of legislation and preparatory activities
Example No. 1: **Legislation to safeguard the public against health hazards and fraud and to ensure hygiene and sanitary practices in the preparation and sale of food** • Food Act 1983 • Food Regulations 1985 • Food Hygiene Regulations 2009	The domestic market was the target, with public health as the imperative, i.e.: • Malaysian public exposed to health hazards • Malaysian stakeholder support was required • Malaysian enforcement capacity had to be strengthened	**Lead time: 5 years** During the interval: • Support garnered through the gradual enforcement of a code of practice • Staff numbers and competence developed for monitoring and enforcement • Laboratory services strengthened
Example No. 2: **Legislation to ensure that the quality of fish and fishery products exported to the European Union (EU) meet EU requirements and certifications** • Food Regulations 2009 *(Issuance of Health Certificate for Export of Fish and Fish Product to the European Union)*	The EU was the target market, with trade as the imperative, i.e.: In June 2008, the European Commission de-listed all Malaysian fish and fishery processing establishments at Malaysia's request to avoid an EU ban on imports of Malaysian fish and fishery products valued at RM 600 million per year	**Lead time: 2 years** During the interval, Malaysia: • Enacted legislation equivalent to EU requirement • Strengthened the capacity of competent authorities through organisational re-structuring and recruiting additional staff • Increased the financial allocation

• Fisheries Regulations 2009 *(Quality Control of Fish for Export to the European Union)* • Fish Marketing Regulations 2010 • Fisheries Development Authority of Malaysia Regulations 2010 *(Recognition of Fish Landing Site for Fish Export to European Union)*	*Outcomes:* May 2009: Malaysia resumed exports to the EU of fish and fishery products processed from local aquaculture and imported raw materials September 2010: Malaysia resumed exports of fishery products processed from local capture fishery raw materials	• Provided official guarantees of the control of exports of fishery products along the supply chain to meet EU requirements

multilaterals. The World Health Organization (WHO) has been a source of technical advice on the management and prevention of both communicable and non-communicable diseases as well as health personnel training and the organisation of community- and hospital-based services. Malaysia has also collaborated with international financial institutions such as the Asian Development Bank and the World Bank. International support for the Malaysian health system has been predominantly technical in nature, with limited financial support, to cover some infrastructure development rather than for the delivery of programmes. As discussed in Chapter 6, the limited reliance on international financial support contributed to the ability of the MoH to design programmes based on national priorities and directions, integrating new initiatives into existing ones rather than developing parallel initiatives according to external priorities.

The activities of the Institute for Medical Research (Chapter 6) include early examples of Malaysia's international collaboration on research into tropical disease control and professional training for countries in the region (Ministry of Health Malaysia, 1980). A more recent example is the establishment of the ASEAN Risk Assessment Centre for Food Safety (ARAC) to foster collaboration among Association of Southeast Asian Nations (ASEAN) members to improve food safety (Ministry of Health Malaysia, 2018).

The wide range of Malaysia's engagement in international collaboration comprises the continuing contributions of the WHO Collaborating Regional Centre for Research and Training in Tropical Diseases and Nutrition, and the Collaborating Centre for Ecology, Taxonomy and Control of Vectors of Malaria, Filariasis and Dengue, as well as collaboration in health systems research, among others (World Health Organization, 2002; Barraclough & Phua, 2007; Ministry of Health Malaysia, 2018). Other areas of international collaboration involve co-operation with and support of ASEAN countries on a range of health concerns (Barraclough & Phua, 2007). In addition to food safety, these activities include the control of infectious diseases and oral health, as well as other ASEAN clusters of co-operation on issues such as healthcare coverage and access, human resources and health technology assessment (Ministry of Health Malaysia, 2018).

12.4 Leadership in the Public Health Sector

In addition to exercising intersectoral leadership, the MoH has also needed to provide leadership and governance in the public health system. This includes establishing visions and programmes, evaluating performance, ensuring accountability, addressing systemic issues and developing leadership.

12.4.1 Vision and Programme Setting

The national priorities set by the PMD and the Cabinet and articulated in various Malaysia Plans guide health priorities. For example, a major national aim was to achieve balanced development with greater equity, particularly between urban and rural areas, and poverty alleviation (Chapter 3). Top leadership in the MoH contributed to the ability of the health sector to translate national goals into a health sector vision and inculcate basic values that characterised the delivery of health services in both the public and private sectors. An example of the contribution of personal leadership is, for example, the leadership of the Health DG in the 1970s, who translated the Alma Ata vision for primary healthcare into the Malaysian context, as described in Chapter 4. In later eras, successive DGs translated the national emphasis on improving quality of service into a systematic nationwide programme and culture in the public sector health services, as illustrated in Chapter 5. Leaders demonstrated their commitment to collaborating with peers across organisational boundaries and recognising leadership qualities in their subordinate staff and supporting them. Box 12.1 illustrates how persons occupying top positions in the MoH at various times viewed their own contributions to leadership.

Box 12.1 Reflection on leadership in Malaysia's health sector

'Many factors that influence health are outside the purview of the MoH. Leaders in the Ministry of Health must be able to interact with leaders in other sectors to advocate on health issues.'

'They have to be informative, persuasive and proactive. Leaders should monitor performance of the organisation and insist on evaluating interventions.'

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

'We have excellent leaders at various levels. For example, I remember a director in Hospital Kota Tinggi who was a quiet, humble person but inspired great teamwork. I respect him.'

'Resisting political pressure is an essential characteristic of leaders. For example, one MB overruled construction of a septic tank by refusing to approve land. Another diverted funds to his own interest group for building a private hospital.'

Tan Sri Abu Bakar Suleiman Director General Health, Malaysia, 1991–2001

'The Minister of Health should advocate rather than be an administrator. I am very proud of my success in advocating and convincing the PM against approving "kiddie packs" of cigarettes.'

'Politicians know that providing healthcare is an easy credit point with their electorate. Hence they will always push for items for which they can claim credit.'

Dato Seri Dr S. Subramaniam Minister of Health, Malaysia, 2013–2018

'A leader needs to be knowledgeable. I am a lawyer who had to make myself knowledgeable about health issues.'

'I was fortunate to have a highly competent DG in Tan Sri Abu Bakar. We had an excellent partnership.'

'My proudest achievement is that I managed to influence the culture in the MoH. During my tenure, we began the tradition of inviting stakeholder views and having regular consultations. This increased the prestige of the MoH. My ministry was recognised as the leader on health topics.'

Dato Chua Jui Meng *Minister of Health, Malaysia*, 1995–2004

'Leadership should be both a top-down and a bottom-up process: leaders need to listen, anticipate and innovate.'

'Leaders in the MoH need to manage the perceptions of the public.'

'We need to embrace technology and use it innovatively to improve healthcare.'

'Communication strategy is important. For example, we now focus on the non-smoker rather than the smoker!'

Datuk Dr Noor Hisham Abdullah *Director General Health, Malaysia*, 2013–present[2]

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

Leadership also emerged at various levels of the MoH organisation in response to specific challenges, as illustrated in the example of the introduction of the human papillomavirus (HPV) vaccination programme (Table 12.2). Leadership has also emerged from the private sector health service. For example, it was a general practitioner (GP) from the private sector who spearheaded the development of family medicine as a speciality (Rajakumar, 1984).

Most health system programming has been concerned with the organisation of services in the public sector in accordance with national priorities, as detailed in the previous chapters. The health requirements programming in Malaysia follows a top-down and bottom-up approach with a reiterative consultative process that involves a wide variety of officers at national, state, district and hospital levels. MoH programme directors in the various divisions and institutions raise and discuss issues, while similar processes occur at state level. This process involves reviewing and assessing health conditions and trends in Malaysia and identifying the driving factors in order to formulate responses. Current programmes are evaluated, with changes planned to meet evolving circumstances (e.g. Ministry of Health Malaysia, 2012; 2018). Proposed programmes and projects are also evaluated, and those involving large expenditures undergo further assessment for compatibility with development budget estimates. They are submitted for review and approval to the Economic Planning Unit in the PMD for financing and implementation during the period of the proposed Malaysia Plan (Suleiman & Jegathesan, 2000; Ministry of Health Malaysia, 2018).

Issues and priorities identified at the national level are cascaded down to state and district level, which in turn identify local issues and merge them into the national framework and cascade them up to national level for review by a committee of senior managers, with the Division of Planning as the secretariat. This has the advantage of considering perceived major national issues in conjunction with the benefit of emerging local conditions and constraints. In addition, it is a mechanism for developing leadership and governance skills at various levels of the MoH system. However, this process may lead to delays between the identification of health risks and the implementation of responses, such as in the case of dengue and diabetes control (Institute for Public Health, 2015).

Table 12.2 *Illustrative features of leadership during Malaysia's experience in introducing HPV immunisation*

Context	Organisational leadership by MoH	Personal leadership examples
Rapid increase in HPV vaccination in adolescent girls, 2011–2016	1. Established and sustained mechanisms for collaboration with related agencies and departments. An example is the Joint School Health Committees at national and state level. This: a. facilitated institutional memory, b. enabled continuity of dialogue despite changes in personnel, and c. provided a safe and respected space for dialogue between stakeholders. 2. Partner agencies and the public perceived the MoH as a trusted source for technical leadership. Recognition by professional and international agencies contributed to this trust. 3. Within the MoH system, there was strong leadership at national, state and district level.	1. There was mutual respect for the roles and responsibilities of partner agencies. 2. Staff in various managerial positions had the ability to assume differing leadership roles that were appropriate and relevant to their position. For example, at national level, leaders provided a vision and established a culture of collaboration, while at the operational levels, leaders were supportive and responsible to their staff and clients. 3. Leaders displayed the ability to listen to and be heard by stakeholders, for example, the 360-degree process of 'listen–act–provide feedback'.

Source: Buang et al., 2018.

12.4.2 Data and Evaluation

Governance is first and foremost about achieving results. Monitoring is crucial for identifying constraints encountered in the short term and the attainment of outcomes in the longer term. Reliable and relevant health information is essential in the performance of this governance function (Chapter 10), and relevant follow-up action is a critical partner to monitoring and evaluation. Monitoring and evaluation could be considered necessary but are not sufficient conditions of progress. For example, there has been a lag between monitoring and action in the incidence of dengue. Infectious diseases monitoring has shown a substantial rise in the incidence of dengue since 2000. Although case fatality rates declined due to medical treatment, preventive action lagged and incidence rates were 10 times higher in 2016 than in 2000 (Ministry of Health Malaysia, 2018). Malaysia's systematic planning and evaluation of health development uses information from regular population censuses and comprehensive registration of vital statistics that identifies the population groups most at risk and what degree of progress, or otherwise, has been made over time. Another strength has been the wider people-centred development approach that focused on poverty and human capital, including health, with the collection of data on living conditions (e.g. Department of Statistics, 1959) that identified the population groups most at risk. These were complemented by the registration of health professionals, inventories of health facilities and health service activity information, especially in the public sector, which provided most services. However, it was their analysis in relation to the population that provided the basis for evaluating the results and relative progress. The National Institutes of Health provide research and programme evaluation studies that contribute to the information database. Requests for many of the National Institutes of Health studies come from the MoH, and therefore have a direct link to decision-making.

The evaluation of data and the use of the findings for management purposes demonstrated the importance of health information and research, creating a feedback loop that has led to further investments and improvements in data quality and relevance. In early times, data collection and processing was often carried out by manual methods, before the wider use of computers and what became known as IT (information technology). The substantial investment in the use of IT

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

in managing health services has improved the storage of, access to and analysis of a wide range of health information for monitoring and evaluating progress (Ministry of Health Malaysia, 2005; 2018; Chapter 10). However, it is important to note that improved data collection alone does not guarantee health improvements. The substantial IT thrust has coincided with an increase in the incidence of some non-communicable diseases (e.g. diabetes) during the 2000s and 2010s, stagnation of infant and maternal mortality rates and slower improvements in life expectancy (Chapter 3). Effective ways of understanding and using data to meet these new health challenges need to be developed.

The governance of the health system entails assessment of the current and emerging technologies and practices to evaluate effectiveness, relevance to local conditions and efficient provision. In earlier years, Malaysia depended largely on expertise from international agencies such as the WHO to inform the selection and use of technologies. Examples are the very early adoption of a list of essential drugs and the selection of vaccines to be included in universal childhood immunisation programmes. However, as the complexity of health technology increased and new hospitals were built based on external expertise, technology assessment and use in the Malaysian context became more imperative (Sivalal, 2009; Roza et al., 2019). The MoH established a section for assessing new technologies and reviewing current ones (Malaysian Health Technology Assessment Section, or MaHTAS), and its process relies on systematic reviews of intelligence gathered from other reliable sources and its own evaluation (Ministry of Health Malaysia, 2018). The outputs inform the development of clinical practice guidelines and the purchase of costly technology or medical products by the MoH (Chapter 5). Other examples of the evaluation and use of findings include the assessment of the cost-effectiveness of some of its services, such as neonatal intensive care and diagnostic imaging services, and the effectiveness and improvement of clinical services such as renal dialysis and cataract surgery (Ministry of Health Malaysia, 2002; 2005; Chapter 5). Another example is the evaluation of services that have been outsourced, such as hospital laundry and cleaning services, where the performance of contractual services is a regular feature and has shown increased levels of contractual compliance (Chapter 7).

12.4.3 Accountability

Accountability is an essential feature of governance, although the concept is difficult to define. Accountability involves reporting the actions taken to another who is in a position to assess their appropriateness (Mulgan, 2000). Accountability processes are learning opportunities for corrective action or appropriate shifts. In the Malaysian health system, accountability takes place at different levels and several forms. For example, compliance with rules and regulations, or spending within set budgets, is a form of accountability. Another example is the accountability of professional and other standards of healthcare practice exercised by professionals to their respective statutory registration boards, as described previously. On a different level, accountability is concerned with enhancing the performance and responsiveness of a health service to health conditions and the expectations of the public. This happens on a personal level, through complaints either via official pipelines or the mass media. Alternatively, accountability to the public can occur through political channels.

Several institutional mechanisms support accountability in the health sector. Performance reviews of the various programmes and services take place within the MoH system in a quasi-hierarchical manner, from single service units to state and national level. Accountability of performance and responsiveness to health needs also takes place during the preparation for each five-year Malaysia Plan and their mid-term reviews (Ministry of Health Malaysia, 2012; 2018), reviewed by the PMD and Cabinet. In turn, the Cabinet is accountable to parliament and it to the electorate. At micro and intermediate level, accountability to the public occurs through the mass media, whereby the MoH monitors and reviews every complaint appearing in news media. MoH procedures require a response to the complaint or appropriate remedial action.

Non-regulatory mechanisms can also promote accountability, as seen in the surveillance of practice and follow-up remedial action, particularly in the public sector (Chapters 4, 5 and 7). Examples include the Quality Assurance Programme (QAP) established in the MoH in 1985 that provided leadership to foster service quality (Ministry of Health Malaysia, 1998; 2018); the adoption of the International Organisation of Standardisation (ISO) (9001 version) Quality Management System (QMP) in accordance with government policy (Hashim & Ibrahim, 2016; Ministry of Health Malaysia, 2018); and the establishment of the Malaysian Society for Quality in Health

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

(MSQH), which provides voluntary accreditation for public and private hospitals using national standards to assess the level of performance through external review and encourages continuous improvement of practice (Malaysian Society for Quality in Health, 2019). Most MoH hospitals have been accredited (Ministry of Health Malaysia, 2018), as have many in the private sector (Aziz & Azizan, 2013). The evolution from regulatory to non-regulatory mechanisms reflects the tacit acknowledgement that regulation is suited only to weed out extreme cases of poor quality (the 'bad apples'). Continuing improvement of the systems-wide quality of healthcare requires systems-wide incentives, including monitoring and feedback, professional and managerial human resources competencies and the development of an organisational culture that values quality.

A systemic challenge to accountability in the public health system is that the MoH is simultaneously the regulator and the provider of public health services in Malaysia. One illustrative example of potential conflict is that all the regulatory boards that govern health professionals have the DG of the MoH as chairperson and the respective programme director as secretary. However, the DG and the respective directors are also the heads of the respective services provided by the MoH, thereby posing a challenge to preserving the principles of accountability.

12.4.4 Structural Challenges and Governance Responses

The divisions of expertise and responsibility necessary for a functional health system also tend to foster the development of silos. The MoH employs task forces and committees that cut across divisions to mitigate this problem. The task forces deal with issues that require time-limited activities, while the joint or national committees deal with issues that require continuing collaboration. Changing demands on the health system have dictated different responses. For example, when maternal and child health were the focus, obstetricians and paediatricians from hospitals joined public health professionals in committees for the investigation of maternal deaths. As the focus moved to non-communicable diseases and emerging infectious diseases, a plethora of other committees and task forces combined the talents of clinicians, epidemiologists, laboratory specialties and healthcare managers to develop national strategies or action plans, as illustrated in Chapters 5 and 6.

Box 12.2 System observations: attempts to bridge silos

The observations of short-term task forces and long-term committees formed to foster cross-division co-operation within the MoH demonstrate the difficulty of sustaining lateral engagement. In the absence of tangible and high-priority goals, the regular system structure and work priorities dominate. It also shows the importance of informal systems (e.g. institutional memory and personal relationships) that are not reflected in an organisational chart. Health systems need both formal and informal linkages to facilitate communication and counteract the tendency toward silos.

Anecdotal evidence suggests that task forces that had to produce tangible products within short timeframes were very successful, as evidenced in the examples in the chapter on disease control (Chapter 6). Committees that had continuing responsibilities over time, such as the MoH/MoE joint committee for school health, tended to become lethargic or dormant until energised periodically by having to respond to new leadership or focus on a new challenge, as seen in the example of introducing the HPV vaccine for schoolgirls. Nonetheless, these committees appear to foster institutional memory that can facilitate rapid and effective collaboration across divisions (Buang et al., 2018).

Another challenge is that human resources in the MoH are part of the larger civil service of Malaysia and are governed by the large and rather unwieldy bureaucracy. As such, the MoH has limited flexibility in adjusting employment conditions to the needs of healthcare services. For example, posts and promotion criteria adhere to general civil service rules (Institute of Health Management, 2006). Another example is the prolonged negotiations required to provide special incentives for selected categories to address brain drain to the private sector. This was partly due to concerns that other categories of professionals in the same grade would demand similar incentives, although there was no reason to provide them.

12.4.5 Leadership Development

Although there is no empirical evidence, it is possible to postulate that several factors have contributed to the development of leadership at

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

various levels in the health system. First, the civil service system of career progression requires, as a precondition to promotion, participation in management training programmes that raise awareness of leadership and its functions and the opportunity to bond with fellow officers from other ministries, thereby facilitating future networking. Second, career progression provides officers with the opportunity to occupy leadership positions at successively higher levels in the system (namely district, state and then national levels), thereby providing invaluable experience in communicating and collaborating with other agencies at progressively more complex levels. Third, within the MoH itself, the system requires clinical specialists, who previously focused only on their own patients, to take leadership for their clinical speciality across the state or the whole country. Participating in cross-disciplinary task forces, they acquire leadership competencies. However, to some extent, clinicians are disadvantaged compared to their colleagues in public health, as the latter acquire managerial experience throughout their career, starting from managing district-level entities and progressing to larger entities. In contrast, clinicians acquire exposure to managerial functions relatively later in their career. Fourth, the devolution of decision-making functions in programme formulation, as described above, provides the opportunity for nurturing leadership within the system.

Box 12.3 System observations: systems perspectives on leadership development

It is often easier to describe the role that leadership plays in a health system than it is to identify how a health system produces good leadership. Indeed, the process of grooming and selecting leaders in a health system, especially top leadership, is often not open to documentation and outside scrutiny.

While leadership is indeed critical to the development of a health system, it too is shaped and constrained by health system structures and policies. Health system culture, needs and rules will strongly influence where in the health system leadership can be exercised and what form that leadership takes (e.g. technical, transformational, etc.). In particular, the appropriate devolution of decision-making is important for enabling leadership at all levels and the continuous development of new leaders.

12.5 Conclusions

Health development in Malaysia offers helpful examples of successes and challenges in governance and leadership.

Some of the lessons from successful practice are:

- The formulation and pursuit of national development policies that prioritised social and human advancement and set health development in that wider synergistic context.
- Sage leadership that stimulated the involvement of local leaders, and associated community participation, in socio-economic development, including health improvements.
- The identification of the people most at risk in the population and the organisation of health services to reach out to them in a manner compatible with the limited human and financial resources available.
- Health development policies and priorities that took guidance from macroeconomic policies and that in turn provided feedback that moulded government policies in relation to wellbeing and human development.
- The MoH provided leadership and technical support in areas of significant importance in health improvement that were the more immediate responsibility of other government agencies.
- Periodic review and evaluation of health outcomes and resource gaps led to related resource enhancement and corrections and shifts in direction in response to feedback from information collected and from stakeholders, including the community.
- The use of a comprehensive but incremental approach to health development in response to community demands and political goals. At no stage was there a radical overhaul of the system.

However, there are also some lessons from the persisting challenges, such as:

- How to garner community participation and involvement in health enhancement practices in a changed urban, industrialised and more affluent society.
- The burden of non-communicable diseases prevalent before old age.
- Responses to the ever-rising expectations of the public for more accessible and improved health services in the face of public funding constraints and the high cost of private health services.

- Reconciliation of the political aim of increasing reliance on the private sector with its higher price with the related higher social cost and rising total health expenditure.

A number of questions could be raised in this context:

- Are there applicable lessons from the past, such as how to address health threats arising from activities in other areas?
- Is there a need for a paradigm shift in the provision of health services? What are the critical elements of such a shift and how can stakeholder support for them be garnered?

In line with Malaysia's incremental and consensual approach, these challenges take time to resolve and achieve further enhancements of health. Significant change in the last decade has remained an unrealised goal.

12.6 Key Messages from Malaysia's Experience

12.6.1 What Went Well?

- Despite the highly centralised structure of the healthcare system, it
  - contains both top-down and bottom-up systems for planning, evaluation and implementation,
  - has good internal feedback loops, and
  - has adaptive capacity at implementation level.
- The system promoted and supported leadership development.
- The centralised nature of the system addressed concerns of equity across administrative state boundaries.

12.6.2 What Did Not Go So Well?

- Limited capacity to deal with determinants of health that are under the purview of other sectors.
- Governance structure and inadequate information limited the ability to respond to some social and environmental issues arising from rapid urbanisation, such as:

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

  - health in pockets of urban poverty,
  - the health of marginalised groups, and
  - loss of trust in authority and establishments, giving rise to anti-vaccination movements, etc.
- The combination of the roles of provision and governance of healthcare in the public sector creates the appearance of conflicts of interest, such as:
  - regulation of professional bodies, and
  - governance of private sector healthcare.

12.6.3 Trends and Challenges

- The rapid rate of change of the societal ecosystem and technology presents challenges to governance and leadership.

References

Aziz, A. and Azizan, N. A. (2013). The effectiveness of accreditation assessment for quality improvement in health care: Malaysian private hospital experience. *International Journal of Social Sciences & Education*, 3(4), 990–9.

Barraclough, S. and Phua, K.-L. (2007). Health imperatives in foreign policy: the case of Malaysia. *Bulletin of the World Health Organization*, 85(3), 225–9.

Buang, S. N., Ja'afar, S., Pathmanathan, I. and Saint, V. (2018). Human papillomavirus immunisation of adolescent girls: improving coverage through multisectoral collaboration in Malaysia. *British Medical Journal*, 363, k4602.

Chandran, S. D., Mohamed, A. S. P., Zainuddin, A., Puteh, F. and Azmi, N. A. (2017). Medical tourism: why Malaysia is a preferred destination? *Advanced Science Letters*, 3(8), 7861–4.

Chong, M. C., Sellick, K., Francis, K. and Abdullah, K. L. (2011). What influences Malaysian nurses to participate in continuing professional education activities? *Asian Nursing Research*, 5(1), 38–47.

Commissioner of Law Revision. (2014). *Federal Constitution*. Selangor: International Book Services.

Department of Statistics. (1959). *Household Budget Survey of the Federation of Malaya 1957–58*. Kuala Lumpur: Department of Statistics.

Economic Planning Unit. (1991). *Sixth Malaysia Plan 1991–1995*. Kuala Lumpur: Prime Minister's Department.

Economic Planning Unit. (2015). *Eleventh Malaysia Plan 2016–2020: Anchoring Growth on People*. Putrajaya: Prime Minister's Department.

Hartley, J. M. (2008). *Leadership in Healthcare: A Review of the Literature for Healthcare Professional, Managers and Researchers*. Coventry: Warwick Business School, Institute of Governance & Public Management.

Hashim, F. A. H. and Ibrahim, M. (2016). MS ISO 9001 certification: does it effective and beneficial to MARDI. *International Journal of Business and Management Invention*, *5*(10), 142–51.

Institute of Health Management. (2006). *Health Workforce Development Strategies*. Putrajaya: Ministry of Health Malaysia.

Institute for Public Health. (2015). *National Health and Morbidity Survey 2015. Volume II: Non-communicable Diseases, Risk Factors and Other Health Problems*. Kuala Lumpur: Ministry of Health Malaysia.

Lim, K. G. (2016). *The History of Medicine and Health in Malaysia*. Kuala Lumpur: Lim Kean Ghee.

Malaysia External Trade Development Corporation. (2018). *Top 10 Major Export Products, 2017*. Online article. www.matrade.gov.my/en/28-malaysia-exporters/trade-statistics/3789-top-10-major-export-products-2017

Malaysia Healthcare Travel Council. (2017). *A Million Medical Tourists for Malaysia in 2017*. Online article. www.mhtc.org.my/mhtc/2017/04/24/a-million-medical-tourists-for-malaisia-in2017

Malaysia Healthcare Travel Council. (2020). *About Us*. Online webpage. www.mhtc.org.my/about-us

Malaysian Medical Council. (2018). *Registration Procedures and Guidelines*. Kuala Lumpur: Malaysian Medical Council.

Malaysian Society for Quality in Health (MSQH). 2019. *Overview Hospital Accreditation Programme*. Online webpage. www.msqh.com.my/home/hospital-accreditation-program

Malaysia Productivity Corporation. (2014a). *Reducing Unnecessary Regulatory Burdens on Business: Private Hospitals*. Petaling Jaya: Malaysia Productivity Corporation.

Malaysia Productivity Corporation. (2014b). *MPC 21st Productivity Report 2013/2014*. Petaling Jaya: Malaysia Productivity Corporation.

Martins, J. M. (2004). *Health Financing: An International Perspective*. In M. Courtney and D. Briggs, eds., *Health Care Financial Management*. Marrickville: Elsevier, pp. 23–61.

Ministry of Health Malaysia. (1975). *Annual Report Ministry of Health Malaysia 1973–74*. Kuala Lumpur: Ministry of Health Malaysia.

Ministry of Health Malaysia. (1980). *Annual Report Ministry of Health Malaysia 1980*. Kuala Lumpur: Ministry of Health Malaysia.

Ministry of Health Malaysia. (1998). *Malaysia's Health 1998*. Kuala Lumpur: Ministry of Health Malaysia.
Ministry of Health Malaysia. (2002). *Malaysia's Health 2002*. Putrajaya: Ministry of Health Malaysia.
Ministry of Health Malaysia. (2005). *Malaysia's Health 2005*. Putrajaya: Ministry of Health Malaysia.
Ministry of Health Malaysia. (2012). *Country Health Plan: 10th Malaysia Plan 2011–2015*. Putrajaya: Ministry of Health Malaysia.
Ministry of Health Malaysia. (2017). *Malaysia National Health Accounts: Health Expenditure Report 1997–2015*. Putrajaya: Ministry of Health Malaysia.
Ministry of Health Malaysia. (2018). *Annual Report Ministry of Health Malaysia 2016*. Putrajaya: Ministry of Health Malaysia.
Mulgan, R. (2000). Accountability: an ever-expanding concept? *Public Administration*, 78(3), 555–73.
Ormond, M., Wong, K. M. and Chan, C. K. (2014). Medical tourism in Malaysia: how can we identify and manage its advantages and disadvantages? *Global Health Action*, 7(1). DOI: https://doi.org/10.3402/gha.v7.25201
Pidgeon, M. (2012). Soggy politics making water 'public' in Malaysia. In M. Pidgeon, D. A. McDonald, O. Hoedeman and S. Kishimoto, eds., *Remunicipalisation: Putting Water Back into Public Hands*. Amsterdam: Transnational Institute, pp. 90–104.
Pourbohloul, B. and Kieny, M.-P. (2011). Complex systems analysis: towards holistic approaches to health systems planning and policy. *Bulletin of the World Health Organization*, 89, 241–316. DOI: http://102471/BLT.11.087544
Prime Minister's Department. (2017). *National Transformation Programme Annual Report 2017*. Putrajaya: Prime Minister's Department.
Rajakumar, M. (1984). A proposal for the training of physicians in primary care for the rural areas of Malaysia. *Family Practitioner*, 7(1), 58–61.
Roza, S., Junainah, S., Izzuna, M. M. G. and Nurhami, K. A. R. K. (2019). Health technology assessment in Malaysia: past, present and future. *International Journal of Technology Assessment in Health Care*, 35(6), 446–51.
Sivalal, S. (2009). Health technology assessment in Malaysia. *International Journal of Technology Assessment in Health Care*, 25(Supplement 1), 224–30.
Suleiman, A. B. and Jegathesan, M., eds. (2000). *Health in Malaysia: Achievements and Challenges*. Kuala Lumpur: Ministry of Health Malaysia.

Wahab, N. A. (2011). *Overview of the Water Services Industry in Malaysia*. Putrajaya: Ministry of Energy, Green Technology and Water. Online document. www.mlit.go.jp/common/000135515.pdf

Ward, S. (2019). *What Is Leadership? And Can You Learn to Be a Good Leader?* Online article. www.thebalancesmb.com/leadership-definition-2948275

Washington, M., Boal, K. and Davis, J. (2008). Institutional leadership: past, present, and future. In R. Greenwood, C. Oliver, R. Suddaby and K. Sahlin, eds., *The SAGE Handbook of Organizational Institutionalism*. Thousand Oaks, CA: SAGE, pp. 721–35.

West, M. A., Armit, K., Loewenthal, L., Eckert, R., West, T. and Lee, A. (2015). *Leadership and Leadership Development in Health Care: The Evidence Base*. London: King's Fund, Faculty of Medical Leadership and Management.

World Health Organization. (2002). *Malaysia: Country Cooperation Strategy*. Online document. www.who.int>countries>cooperation_strategy_mys_en

World Health Organization. (2019). *Health Systems Topics: Governance*. Online document. www.who.int/healthsystems/topics/stewardship/en

System Analysis Case Study 12.1: Leadership Enabled Affordable Treatment of Hepatitis C in Malaysia

Chee Han Lim, Faizul Nizam bin Abu Salim and David T. Tan

This case study illustrates the role of leadership in the complex negotiations that resulted in Malaysia obtaining an affordable price for medication for hepatitis C.

Background

Hepatitis C is a liver disease caused by a bloodborne virus (hepatitis C virus, or HCV) and is a major cause of liver cancer. The most common modes of infection are through exposure to small quantities of blood. This may happen through injection drug use, unsafe injection practices, unsafe healthcare, transfusion of unscreened blood and blood products, and sexual practices that lead to exposure to blood. There is currently no effective vaccine against hepatitis C; nevertheless, research in this area is ongoing. Antiviral medicines can cure more than 95% of persons with hepatitis C infection, thereby reducing the risk of death from cirrhosis and liver cancer, but access to diagnosis and treatment is low (World Health Organization, 2019). As the pool of infected persons is large, the risk of spreading the infection is high. The World Health Assembly resolution 63.18 'recognised viral hepatitis as a global public health problem and the need for governments and populations to take action to prevent, diagnose and treat viral hepatitis'.

The HCV disease burden is a major concern in Malaysia. In 2009, the MoH estimated that 453,700 people were living with HCV infection in Malaysia (McDonald et al., 2014) and that there would be a cumulative total of 63,900 HCV-related deaths by 2039 (McDonald et al., 2015). The incidence rate of HCV infection increased from 2.56 per 100,000 population in 2010 to 9.54 per 100,000 population in 2017 (Ministry of Health Malaysia, 2019), with about 2,000–3,000 newly diagnosed patients added to the patient burden every year (Hiebert et al., 2019).

After more than a decade of multiple research initiatives, an effective medicine, sofosbuvir (the generic name), was developed and patented. This drug has cure rates ranging from 30% to 97% (depending on the genotype treated) and has relatively few adverse effects. However, the price of medication in Malaysia for the requisite 12-week treatment

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

was RM 300,000 (US$70,000) (Drugs for Neglected Diseases Initiative, 2017). The high price was a serious barrier to patient access to effective treatment and prevented its inclusion in the MoH drug formulary, thereby making it unavailable to the highly subsidised public sector.

A Conflict of Interest

Malaysia was seriously concerned about the need to manage the pool of infected patients effectively to prevent spread. A conflict situation was emerging between the price dictated by the foreign pharmaceutical company and the Malaysian desire for affordable medication to contain the public health risk of the large pool of patients capable of spreading hepatitis C.

Essential Features of the Conflict Situation

International pharmaceutical companies are for-profit agencies. They justify the high cost of patented drugs by citing the need to recover the costly process of developing new drugs. The World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) granted authority for patenting innovative products to protect the rights of the patent holder. Patents last for a specific number of years (see Box 12-A). Enforcement against violations of intellectual property rights (IPR) are usually through trade sanctions by the patent holder's host country against the violating country.

Gilead Science[3] is the patent holder for sofosbuvir (trade name Sovaldi), and the patent will be valid at least until 2024. Compulsory licensing allowed 11 Indian companies to produce and export a generic version of the medicine at a much lower price to 100 low-income countries, but this arrangement excluded Malaysia because it is an upper-middle-income country.

Price Control Tools: Paradigms and Risks

There is an intuitive and widely held paradigm that affordable medical treatment should be available to all. Such beliefs are reinforced when treatment prices become a barrier to access

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

Box 12-A Essential vocabulary regarding rules governing international trade of medicines

The **WTO** is an international body that deals with the global rules of trade between nations.

TRIPS is an international legal agreement between all the member nations of the WTO. It sets down minimum standards for the regulation by national governments of many forms of intellectual property as applied to nationals of other WTO member nations (World Trade Organization, n.d.).

A **patent** is an exclusive right granted for an invention, which is a product or a process. The patent owner has the exclusive right to prevent others from commercially exploiting the patented invention. Usually the patent lasts for about 20 years. Thus other manufactures cannot produce and market a patented medicine at a lower cost.

Compulsory licensing (an exception granted by the WTO) authorises third parties to produce medicines for government use without authorisation by the patent holder. The intention is to enable low-income countries to access patented drugs by giving them the right to produce generic versions of the drugs. *However*, the national legal process must deem it not anti-competitive and it must be for public health (World Trade Organization, 2018).

Voluntary licensing is an arrangement whereby a patent holder may allow others to manufacture, import and/or distribute its patented drug (Amin, 2017).

The **Medicines Patent Pool** (**MPP**) is a UN-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. The MPP negotiates with patent holders for licences on life-saving medicines for low- and middle-income countries (Medicines Patent Pool, 2019).

(Figure 12-A). This paradigm has been instrumental in creating protections and price control tools, especially for developing countries, such as TRIPS and the Medicines Patent Pool. These tools are

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

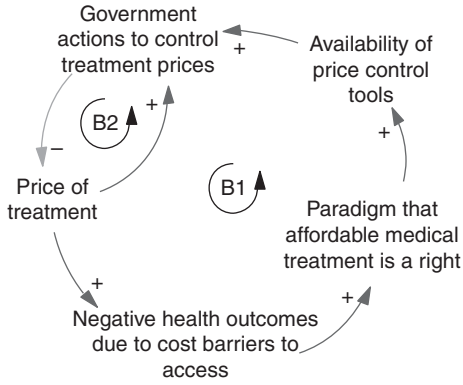

Figure 12-A The paradigm that affordable medical treatment should be a right has led to the creation of tools meant to limit the price of treatment (B1 loop). These tools have provided governments with important leverage to negotiate treatment prices with suppliers (B2 loop).

meant to provide governments with the ability to negotiate and control treatment prices.

There is a competing paradigm, however, that medical treatment is best developed through market mechanisms (Figure 12-B). The private sector has indeed been an important engine for developing new medical products. For those who benefit from these products and the existing system, either medically or monetarily, price control tools may threaten to disincentivise private investment, slowing or even halting the development of new medical products. These actors thus challenge the paradigm of affordable medical treatment as a right. They also advocate trade agreements and IPR that restrict countries' abilities to make use of price control tools.

As a result, government actions to control treatment prices incur risks in the form of political pressure, sanctions, etc., limiting government willingness to take action to reduce treatment prices (Figure 12-C, B4 loop). Using these tools requires political and technical leadership at local and international scale to manage these risks.

The Negotiation Process

Facilitated by the United Nations (UN)-backed Medicine Patents Pool, Malaysia embarked on a nine-month negotiation with the patent

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

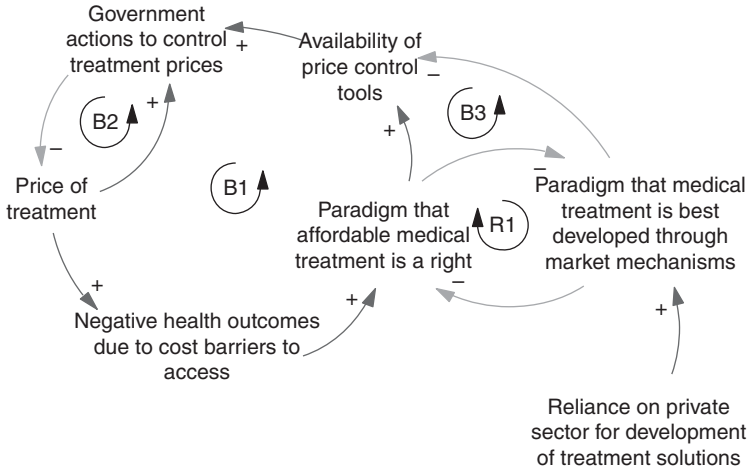

Figure 12-B Reliance on the private sector for developing treatment solutions creates a competing paradigm that distrusts interference with market mechanisms (R1 loop). This paradigm undermines the availability of price control tools (B3 loop).

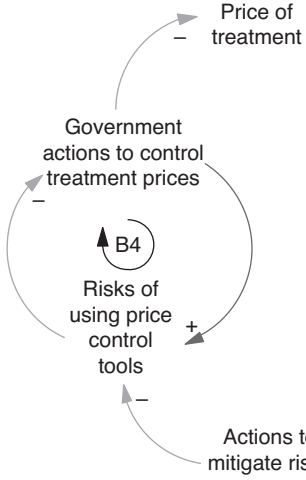

Figure 12-C Advocates for market-driven development of medical products have pushed for trade agreements, IPR protection and the use of political pressure and sanctions that increase the risk of using price control tools to limit government actions to control treatment prices (B4 loop). For governments to successfully utilise these tools, they must take a variety of actions to mitigate against these risks.

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

holder to award voluntary licensing to Malaysia. At the end of this period, the patent holder reduced the quoted price per 12-week treatment per person from US$70,000 to US$12,000. However, Malaysia regarded this as unaffordable.

Therefore, Malaysia decided to explore the route of obtaining compulsory licensing. The country had previous experience in using this route to obtain generic medicines for HIV/AIDS by using a specific clause in TRIPS that specifies flexibility (World Health Organization Regional Office for South-East Asia, 2014). 'The key TRIPS flexibility, as highlighted in the Doha Declaration on TRIPS and Public Health (the Doha Declaration) (World Trade Organization, 2001), is the right of WTO Member States to include in their patent legislation a provision for use without authorization of the patent holder, as provided in Article 31' (Nicol & Owoeye, 2013).

Malaysia already had the Patents Act 1983 (Intellectual Property Corporation of Malaysia, n.d.). The Act authorises the issue of a compulsory licence without agreement of the patent holder in a national emergency, stipulating no sale to others and no commercial exploitation.[4] The major risk in this approach would be retaliation through negative trade sanctions.

Meanwhile, in a parallel development, an Egyptian producer (Pharco Pharmaceuticals) applied through the auspices of the DNDi[5] to Malaysia (and Thailand) to conduct clinical trials of a new combination medication (ravidasvir/sofosbuvir) that promised to be highly effective against several strains of HCV. Being a founder member of the DNDi, the MoH had strong connections with the organisation, and Malaysia had a strong ecosystem for conducting clinical trials.

Learning of this initiative, the patent holder initiated the next phase of consultations and negotiations between various stakeholders. Table 12-A provides a summary of the stakeholders' positions. The patent holder adopted a 'carrot and stick' approach by offering voluntary licensing that also dictated the price of the medicine while simultaneously mobilising trade associations and representatives of the US government to pressure Malaysia against adopting the compulsory licensing route. In response, Malaysia focused on rallying the various domestic players who either feared or supported the compulsory licensing route and on consolidating political, commercial and professional support for whichever route

Table 12-A *Stakeholder concerns and contributions*

Malaysian stakeholders and their key concerns and contributions in the negotiation process	
MoH: Disease Control Division	• Concerned about public health and the need to increase access to care. Provided epidemiological and cost-effectiveness data.
MoH: Pharmacy Division	• Knowledge of drug registration, procurement and international drug pricing. Concerned about ensuring competitive price.
Director General Health	• Established Malaysia's position as solely to address a serious public health concern, namely preventing the spread of infections. Provided repeated assurance that Malaysia would not use it as a precedent for other medicines, such as oncology and rare diseases that could not be regarded as of public health concern.
Ministry of International Trade (MyIPO)	• Responsible for IPR and preserving favourable international trade conditions for the country – concerns about negative trade impact.
Attorney General's Chambers	• Knowledge of provisions and precedents in the national and international legislation. Concern is to ensure that any measure taken has a firm legal basis.
Ministry of Domestic Trade and Consumer Affairs	• Concerned for trade deals, fair price for consumers, protection of competitive practices – ensuring fair trade practice.
Minister of Health, Malaysia	• Concerned that pressing for compulsory licensing would generate negative public image during the upcoming general election, but provided strong support when he realised the price difference and potential savings and health benefit. Worked collaboratively with the Health DG to gain the understanding and support of the prime minister and key colleagues in the Cabinet.
Top political leaders in the Malaysian government (prime minister, deputy prime minister, ministers of domestic trade and consumer affairs, and international trade and industry) and the Deputy Minister of Economic Affairs provided sustained political support for the position advocated by the MoH.	

Table 12-A (*cont.*)

International stakeholders and their concerns and contributions in the negotiation process	
Médecins Sans Frontières (MSF, an independent, private medical aid organisation)	• Concerned about 'finding long-term, sustainable solutions to the lack of essential medicines', they participated in a workshop in Malaysia early in the negotiation process to raise awareness and share ideas on potential solutions.
Third World Network	• Concerned about pricing of and access to affordable DAA (direct-acting antivirals) for treating hepatitis C and finding options available to promote access to these new HCV medicines at an affordable price in Malaysia. Co-organised a national workshop to bring together national stakeholders as well as international experts to exchange information on the national and global situation. The workshop inspired the MoH to take the lead later in pushing for the issuance of compulsory licensing. Provided legal expertise and advice on using TRIPS flexibility for the access to medicine.
DNDi	• Regarding hepatitis C: 'a key challenge: the existing system of biomedical innovation has failed to deliver safe, effective, quality products that are affordable to poor populations'. Business model is 'supportive' and 'engagement is tailored and appropriate to need'.
Gilead Science	• As the patent holder, was anxious to retain its monopolistic position in relation to hepatitis C medication.
The USA – represented by the White House Coordinator for Intellectual Property and the Office of the US Intellectual Property Enforcement Coordinator, and supported by the American–Malaysia Chamber of Commerce (AMCHAM), the US Chamber of Commerce and the Global Innovation Policy Centre	• Concerned about safeguarding the rights of intellectual property owners to ensure future private investment in research and development. • Concern that the use of compulsory licensing for hepatitis C would be a prelude to extending its use to a wide variety of other drugs.

Trade Associations such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organisation	• Called for Malaysia to be placed on the US Trade Representative's Priority Foreign Countries watch list in its 2018 Special 301 Report.
Eleven Indian companies that operated under compulsory licensing for sofosbuvir	• Collaboration with the patent holder to maintain profit margins.
Pharco Pharmaceuticals (an Egyptian producer)	• Keen to break into a new market (Malaysia and Thailand) with a new product (a pan-genotype combination product of ravidasvir/sofosbuvir).

Box 12-B Relevant quotes

1. Letter to the Honourable Minister of Health dated 10 December 2018 by 74 NGOs: 'we strongly support the Government Use Licence (GU) that offers the Government the best option for urgently procuring HCV treatment at a price that enables MoH to sustainably scale up and make treatment available . . .'
2. MSF support letter to Malaysia dated 11 February 2019: 'we are writing to express our support for the "government use" licence to accelerate the MoH's effort to scale HCV treatment . . .'
3. 26 February 2018, DG of the World Health Organization at the WHO-WIPO-WTO Technical Symposium on Sustainable Development Goals: Innovative technologies to promote healthy lives and wellbeing: 'We must not tolerate systems that put the protection of intellectual property ahead of the protection of health. Patients must always come before patents.'

would enable Malaysia to obtain the medicine at the best competitive price.

Having launched the clinical trials, Malaysia learnt informally that the price of the medication could be much lower than that offered by the patent holder through voluntary licensing. This enabled Malaysia to sustain a strong stand in resisting pressure while bargaining for the best price using the market forces rationale.

After 12 months of intense negotiations, Malaysia adopted compulsory licensing, using its Patents Act, and obtained the medicine at about US$300 for a 12-week treatment, an almost 100% drop from the original treatment prices.

Leadership

This case study analyses leadership using the concepts of leadership as demonstrated by 'the personal qualities of leaders, leadership positions in the organization and social interactions and relationship of the

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

Table 12-B *Leadership characteristics and outcomes*

The leader(s)	Characteristics and source of influence	What they did and evidence of success
Director General of Health, Malaysia	• A dedicated and visionary health professional who believes in teamwork. • Had excellent international and regional contacts in the health sector by virtue of his position.	• Established the purpose and rationale of the exercise. • Mobilised professional resources within the MoH and the Attorney General's Chambers. • Interacted with and obtained active support from international networks (Table 12-A). • Built political support through well-researched messages that recognised the concerns of various stakeholders (Table 12-A). • Recognised the window of opportunity provided by the competing interest of a rival initiative (Table 12-A, Pharco Pharmaceuticals). • Sustained a long negotiation process with a cordial relationship while building and sustaining a strong bargaining position.
Leadership from Malaysian professional resources		
Director, Disease Control Division, MoH	• Health professional who applied knowledge of epidemiology and management to analyse the situation and advise the DG on management options.	• Researched and shared up-to-date knowledge on hepatitis C, its public health implications and options for management. • Supported the DG in creating appropriate messages for various audiences.

Table 12-B (*cont.*)

The leader(s)	Characteristics and source of influence	What they did and evidence of success
Director, Pharmaceutical Division, MoH	• Health professional who applied knowledge of drug registration, procurement and pricing.	• To advise the DG on international pricing and regulations. • Mobilised international networks in the pharmaceutical field.
Legal department of the MoH and Attorney General's Chamber, Malaysia	• Legal professionals who researched domestic laws and international agreements to advise the DG on legally acceptable measures.	Identified: • The flexibility provided in TRIPS (Doha Declaration). • The empowerment provided by the Malaysian Patents Act 1983. Supported the MoH in applying the relevant legal provisions.
MoH Malaysia	• The MoH has credibility and a reputation for technical competence both domestically and internationally.	In particular, Malaysia gained kudos for being the first country to use the flexibilities in the TRIPS (Doha Declaration) to obtain anti-retroviral drugs in 2003.
Malaysian political leadership		
Minister of Health	• Politician with a health background and interest in affordability of healthcare.	• Grasped the complexity of the negotiations. • Used his technical expertise and the credibility of the MoH to obtain sustained support from top political leaders to withstand pressure from international sources mobilised by the patent holder.

leaders … The person, position and process approach to leadership' (Hartley, 2008). Malaysia is a small upper-middle-income country with little political or economic advantage. Therefore, individuals within the Malaysian system served as leaders, using their personal qualities and organisational positions to leverage networks and knowledge bases. Working in collaborative team modes or as individuals, these various leaders steered the MoH and the country through the complex environment of international trade, IPR and conflicts between commercial interests and social goals to reduce the financial barriers to accessing a medical product. Their success is evident, not only in having overcome price barriers but also in setting an example from which other countries sought to benefit.

Systems Lessons

Systems analysis demonstrates how two competing paradigms on healthcare generate conflicting views on acceptable mechanisms for making critical patented medicines affordable. Such conflicts create risks for national governments seeking to ensure access to medicines. This case study shows how innovative leadership can mitigate these risks while intervening for public health purposes.

References

Amin, T. (2017). *Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution to Improving Access to Affordable Medicines?* Online document. https://apps.who.int/medicinedocs/documents/s19793en/s19793en.pdf

Drugs for Neglected Diseases Initiative. (2017). *DNDi Welcomes Malaysia's Move to Secure Access to More Affordable Treatments for Hepatitis C*. Online article. www.dndi.org/2017/media-centre/press-releases/dndi-welcomes-malaysia-move-access-affordable-treatments-hepc

Hartley, J. M. (2008). *Leadership in Healthcare: A Review of the Literature for Healthcare Professional, Managers and Researchers*. Coventry: Warwick Business School, Institute of Governance & Public Management.

Hiebert, L., Hecht, R., Soe-Lin, S., Mohamed, R., Shabaruddin, F. H., Syed Mansor, S. M. et al. (2019).A stepwise approach to a national hepatitis C screening strategy in Malaysia to meet the WHO 2030 targets: proposed strategy, coverage, and costs. *Value in Health Regional Issues*, 18, 112–20. DOI: http://10.1016/j.vhri.2018.12.005

Intellectual Property Corporation of Malaysia (MyIPO). (n.d.). *Laws of Malaysia. Act 291. Patents Act 1983*. Kuala Lumpur: Intellectual Property Corporation of Malaysia.

McDonald, S. A., Mohamed, R., Dahlui, M., Naning, H. and Kamarulzaman, A. (2014). Bridging the data gaps in the epidemiology of hepatitis C virus infection in Malaysia using multi-parameter evidence synthesis. *BMC Infectious Diseases*, 14, 564.

McDonald, S. A., Dahlui, M., Mohamed, R., Naning, H., Shabaruddin, F. H. and Kamarulzaman, A. (2015). Projections of the current and future disease burden of hepatitis C virus infection in Malaysia. *PloS One*, 10 (6), e0128091.

Medicines Patent Pool. (2019). *Who We Are: MPP*. Online webpage. https://medicinespatentpool.org/who-we-are

Ministry of Health Malaysia. (2019). *National Strategic Plan for Hepatitis B and C 2019–2023*. Putrajaya: Disease Control Division, Ministry of Health Malaysia.

Nicol, D. and Owoeye, O. (2013). Using TRIPS flexibilities to facilitate access to medicines. *Bulletin of the World Health Organization*, 91, 533–9.

World Health Organization. (2019). *Fact Sheets: Hepatitis C*. Geneva: World Health Organization.

World Health Organization Regional Office for South-East Asia. (2014). *Access to Affordable Medicines for HIV/AIDS and Hepatitis: The Intellectual Property Rights Context*. Geneva: World Health Organization.

World Trade Organization. (n.d.). *What Is the WTO?* Geneva: World Trade Organization.

World Trade Organization. (2001). *WTO | Ministerial Conferences: Doha 4th Ministerial – TRIPS Declaration*. Geneva: World Trade Organization.

World Trade Organization. (2018). *WTO | Intellectual Property (TRIPS) – TRIPS and Public Health: Compulsory Licensing of Pharmaceuticals and TRIPS*. Geneva: World Trade Organization.

Notes

1. Public goods are those from which consumption by an individual cannot restrict others from benefiting.
2. Interviews conducted by authors during January 2019.
3. Gilead Science is a pharmaceutical company based in the USA.
4. Section 84 of the same Act deals with the rights of the government to exploit a patented invention even without the patent holder's permission, provided there is a national emergency or where the public interest – in particular, national security, nutrition, health or the development of

https://doi.org/10.1017/9781108954846.015 Published online by Cambridge University Press

other vital sectors of the national economy as determined by the government – so requires or a judicial or relevant authority has determined that the manner of exploitation by the patent owner or their licensee is anti-competitive.

5. The DNDi is a collaborative, patients'-needs-driven, non-profit drug research and development organisation that is developing new treatments for neglected diseases.