



# MALAYSIA'S HEALTH 2004



Ministry of Health Malaysia



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# MALAYSIA'S HEALTH

# 2004

# foreword



Malaysia's Health provides a glimpse of health developments in Malaysia, covering a wide array of topics on healthcare services, population health, health system management as well as research and development in the health sector in Malaysia. This technical report series was started in 1992 and provide the most comprehensive record of health developments in the country, including the private sector.

Malaysia has a mix public-private healthcare system with the Ministry of Health as a major healthcare provider in the public sector. Being the lead agency for health, it provides leadership on matters relating to health, and sets the direction for health development in the country through standards and policy settings; promoting research and development in health; formulating health legislations and their enforcement to protect the health of its population; as well as providing high quality, accessible and affordable primary, secondary and tertiary care services to those who cannot afford private healthcare.

Selected topics in this report provide an account of various initiatives undertaken by the Ministry of Health to improve health of its people, as well as healthcare services in its facilities and the country. These include quality improvements in healthcare provision and patient safety; affordable medicine; disease prevention and control; food quality control and safety; as well as health planning and management. The report on National Health Account gives an interesting insight into the pattern of health expenditures in the country while under the section on Research and Development, Malaysia's role in establishing the Global Hub for Integrated Medicine and Herbal R&D is explained.

It is hoped that this technical report series will continue to provide useful information for health planners and managers; healthcare providers; academicians as well as researchers who seek to study and understand the evolving health scenario of Malaysia in their respective areas of interest.

A handwritten signature in black ink, appearing to read 'Datuk Dr. HJ. Mohd Ismail Bin Merican'.

**DATUK DR. HJ. MOHD ISMAIL BIN MERICAN**  
*Director-General of Health, Malaysia*

# vision

## FOR HEALTH

Malaysia is to be a nation of healthy individuals, families and communities, through a health system that is equitable, affordable, efficient, technological-appropriate, environmentally-adaptable and consumer-friendly, with emphasis on quality, innovation, health promotion and respect of human dignity and which promotes individual responsibility and community participation towards an enhanced quality of life.

# mission

## OF THE MINISTRY OF HEALTH

The mission of the Ministry of Health is to build partnership for health to facilitate and support the people to :

- Attain fully their potential in health.
- Motivate them to appreciate health as valuable asset.
- Take positive action to improve further and sustain their health status to enjoy a better quality of life.

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# 1

## HEALTHCARE SERVICE



# PATIENT SAFETY AND PREVENTABLE ADVERSE EVENTS DUE TO MEDICAL ERRORS

## *SUMMARY*

Medical errors are preventable adverse events that should be minimized by considering the various factors that contribute to the errors, ranging from human error to system faults. The consequences of medical errors can be grave, resulting in pain, suffering, economic and financial loss and worse still, loss of human lives. The Patient Safety Council of Malaysia (PSCoM) was established by the Ministry of Health in January 2003 to promote patient safety in Malaysia with members from government and professional bodies, non-government organizations, the universities and the private sector. A number of strategies have been identified for adoption and three priority areas have been identified for immediate attention, namely : establishing a national data base on patient safety; improving medication safety and lastly, promoting blood transfusion safety.

## **Introduction**

The human body is a very complex being with the same illness manifesting in many different ways and patients with the same illness responding differently with the same treatment due to the many interacting factors. Doctors are also human with varying behaviours even with the same training, working in a very complex healthcare system. Thus, healthcare professionals have to be experienced and discerning to anticipate, detect and manage problems that may arise in managing their patients. However, good patient care is not the sole responsibility of any one person, as often it is a team effort.

The environment under which care is given is also crucial in ensuring prompt, effective, efficient and high quality care is given. Adverse events in patient care can happen and they happen due to a variety of reasons, one of which is weaknesses in the system within the organization. It is therefore essential for healthcare managers to recognize the broader cause of adverse events and manage them proactively to prevent such occurrences.

Preventable Adverse Events have been defined by many expert groups such as the Quality Interagency Task Force and the Harvard Review of Medical Practice as:

*Preventable  
adverse event*

*“injuries caused by medical management (rather than the underlying disease or condition of the patient) that prolonged admission or produced disability at the time of discharge”*

### **Incidence of medical errors**

The Harvard Study of Medical Practice, which is the benchmark for estimating the extent of medical injuries occurring in in-patient hospitals, involved a review of the medical charts of 30,121 patients admitted to 51 acute care hospitals in New York State in 1984. It found that adverse events occurred in 3.7% of admissions, 69% of which were deemed to be preventable, that is, synonymous with medical errors.

*Harvard study  
of Medical  
Practice*

The Study of Quality in Australian Health Care, which was a population-based study modeled on the Harvard study found that adverse events occurred in 16.6% of admissions and 51% of them were considered to have been preventable. Since then, a number of other countries such as the United Kingdom, Canada and New Zealand have conducted studies to determine the extent of preventable adverse events in their countries.

*Quality in  
Australian  
Health Care*

In addition, the World Health Organisation Patient Safety Alliance is also conducting an international collaboration among selected developing countries to determine the epidemiology of preventable adverse events in these countries.

The cost of medical errors can be substantial, not only in terms of financial costs, but also other human costs such as lost productivity, pain and suffering as well as loss of confidence in the health care system. Patients injured as a result of a medical error spend longer time in hospital and have higher hospital costs. For example, in the Harvard study of adverse drug events, the extra cost associated with an event (preventable and non-preventable) was US \$2,595 and the length of stay was increased by 2.2 days. However, among preventable adverse drug events, the excess cost was \$4 685 and the length of stay was increased by 4.6 days. The cost of adverse drug events for a 700 bed teaching hospital in the United States was estimated to be USD\$5.6m a year.

*Cost of medical  
errors*

Comparatively, little is known about the prevalence of medical error outside hospitals. In both the Harvard study and the Australian study, 8-9% of adverse events occurred in a doctor's office, 2-3% at home, and 1-2% in nursing homes. In the Australian study, about 25% of the adverse events occurring among outpatients caused permanent disability or death, and investigators judged it likely that more than two thirds could have been prevented.

Reported incidence of medical errors is usually an underestimate as some errors do not produce obvious effects either because they were minor or the patients were resilient, and most of all "dead men do not tell tales"

*Incidence of medical errors*

Although researchers regularly publish studies on medical error, adequate epidemiological information is limited to a few institutions, procedures, and specialties as institutions understandably do not wish to have such studies, more so, to have reports on them. Most studies on medical errors are conducted in academic referral centers, the results may not be generalised to community based hospitals and outpatient care facilities. Comparing studies is difficult because research methods are usually not standardised. The lack of agreement about methods and the variable rigor of their application contribute to the variations found in error rates. There is thus a serious need for researchers to use consistent definitions and methods and for collaborative work on measuring error as is being promulgated by the WHO Patient Safety Alliance.

### **Types of medical error**

In both the Harvard study and the Australian study, among in-patients, about 50% of adverse events from medical errors resulted from surgery while the other 50% were from non-surgical treatments. In the Australian study, cognitive errors such as making an incorrect diagnosis or choosing the wrong medication, were more likely to have been preventable and more likely to result in permanent disability than technical errors.

*Cognitive errors*

Errors made were either due to an act of omission or commission. An error of omission is a failure of action such as a missed diagnosis; a delayed evaluation; or a failure to prescribe needed drug treatment. An error of commission is an incorrect action such as administering the wrong drug to the wrong patient at the wrong time. In the Australian study, errors of omission occurred twice as often as errors of commission.

*Error of omission and commission*

## Consequences of medical error

Medical errors sometimes do not cause any obvious harm because it is minor or because the patient is resilient. However, serious error can result in an adverse event such as death, temporary or permanent disability, pain and suffering, patient dissatisfaction, litigation or increased costs.

From a review of the literature on medical errors, there is little evidence to suggest that much medical error is due to “bad apples.” In addition, no specialty is immune to error even though some specialties are more prone to error by being more procedural in nature. Procedural mishaps are common in surgical specialties, perhaps because they are hard to disguise. Mistakes may be more common when the doctor is inexperienced or new and when new techniques are introduced. Trainees, for example, house officers and first year post-graduate residents often err. Misread radiographs and pathology specimens, laboratory errors and mistakes made in administering radiation therapy also threaten the safety of patients.

### *Procedural mishaps*

## Addressing our present attitude towards medical errors

Both the public and healthcare professionals themselves expect medical care provided must be flawless even though it is humanly impossible for zero-error in medical care. The human body is a complex being with variable expressions in illness, even for the same illness. Doctors are also human with varying behaviours even with the same training, working in a very complex healthcare system. Technological advancements in biomedical science have created an expectation of perfection.

### *Magnitude of medical errors*

This expectation creates an environment in which clinicians are reluctant to report their errors. Thus, the precise prevalence and magnitude of medical error is unknown. Patients, who have an understandable need to consider their doctors infallible, have colluded with doctors to deny the existence of error. Universal under-reporting, in turn will undermine our efforts to accurately measure error.

We tend to (and still do) view most health care errors as human errors and attribute them to incompetence, inattention, or attitudinal factors on the part of those identified as committing the errors. As a result, there is a tendency to bestow blame when something goes wrong.

We blame the physician who failed to remember a patient's drug allergy, the surgeon who misplaced a stitch in a bowel anastomosis or the nurse who failed to read the concentration of adrenaline on the vial. This approach has diverted attention from the kind of systematic improvements that could decrease errors. A more productive approach at reducing the incidence of medical errors and adverse events should be adopted. It is time to accept the fact that complex systems such as the health care system are error-prone. This is because many errors are built into existing routines and devices, setting up the unwitting physician and patient for disaster.

*Health care system as a complex system*

In developing a safe practice culture, we must start by developing a just culture - a culture which distinguishes between outright incompetence and genuine mistakes. Only then can a reporting culture be nurtured. The lessons learnt from a reporting culture can be used to develop a learning culture, which in turn will finally develop into a culture of safety.

*Safe practice culture*

Although patients are the first and obvious victims of medical mistakes, doctors and other health care professionals are wounded by the same errors - they are the second victims. Making "a mistake" makes the doctor feel guilty, makes him question his competence and also fear being discovered. He knows that he should "confess", but he dreads the prospect of potential punishment and of the patient's anger. We thus need to be humane about human mistakes. We have to redress the current blaming and non-sympathetic culture (which are an impediment to a learning organization).

*Support mechanisms for healing*

People who have "made mistakes" need sympathy and support. We need to develop support mechanisms for healing to ensure doctors and other health care professionals do not find dysfunctional ways to protect themselves like responding to their own mistakes with anger and projection of blame, and may act defensively or callously and blame or scold the patient or other members of the healthcare team.

### **Managing medical error and preventable adverse events**

There are two approaches to the problem of medical errors. Each approach has its own philosophy of error causation and error management. The two approaches are: Person approach and System approach.

The *Person Approach* has been a long-standing and widespread tradition and focuses on the “unsafe acts” such as errors and procedural violations of individuals at the “sharp end” such as nurses, doctors, pharmacists and surgeons. Unsafe acts are due to individual factors such as forgetfulness, inattention, poor motivation, carelessness, negligence and even recklessness.

### *Person approach*

Counter-measures to reduce error in this approach include to reduce unwanted variability in human behaviour by poster campaigns that cause fear, writing another procedure/adding to existing ones, disciplinary measures, retraining or “naming, blaming and shaming”.

However, this approach has been proven to have serious shortcomings and is ill-suited to the medical domain. This person approach also overlooks two important features of human error, that is, often the best people make the worst mistakes and mishaps are not random but tend to fall in recurrent patterns, regardless of the people involved. This is because, by focusing on the individual origins of error, it isolates unsafe acts from their *System Context*, that is, the working environmental context.

### **System Approach in managing medical errors**

Research has shown that most medical errors are latent errors, or errors “waiting to happen”, arising from poorly designed processes and systems of care. Over-reliance on memory, denial of the overwhelming evidence linking fatigue to poor performance, “fighting in the cockpit,” and placing look-alike doses of medications next to one another on a cart are classic failures of process and system design. Thus, even though the individual professional is the final pathway by which these errors happen, errors are designed into our systems and are waiting to be made, if not by you, then by the next doctor or nurse.

### *System approach*

The premise of systems approach is that humans are fallible and thus, errors are to be expected, even in the best organizations. Errors are seen as consequences rather than causes and they originate more from “upstream” systemic factors which include recurrent error traps in the workplace and organisational processes that give rise to errors.

### *Premise of system approach*

Counter measures to errors are based on the assumption that while we cannot always change the human condition, we can change the conditions under which humans work. A central idea in the system approach is the concept of system defenses.

When an adverse event occurs, the important issue is not who blundered but how and why did the defenses fail?. In the majority of situations, latent conditions are the cause of an adverse event occurring. Latent conditions are the inevitable “resident pathogens” within the system.

They can translate into error-provoking conditions within the workplace, for example :

- Time pressure
- Understaffing / inadequately trained staff
- Inadequate equipment
- Fatigue
- Inexperience

They can create long-lasting weaknesses in the system’s defenses like :

- untrustworthy alarms and indicators
- unworkable procedures
- design & construction deficiencies

Latent conditions may lie dormant within the system for many years and then combine with active failures to create an accident opportunity. Latent conditions can be identified and remedied before an adverse event occurs and this constitutes pro-active risk management.

The *Systems Approach* to error management is the approach of choice in developing a safe health care system. The Systems approach to error management has 2 components, that is, limit the incidence of dangerous errors (this can never be wholly effective) and create systems that can tolerate the occurrence of errors and contain their damaging effects. Systems can be designed to help prevent errors, make errors detectable/ visible so that they can be intercepted or mitigate the adverse effects of errors when they are not detected or intercepted.

### **Prevention of errors**

In health care, many factors influence the rate of errors. We must look for ways to prevent errors in the “sharp end” of the system – those giving the care as well as the “blunt” end of the system (institutional context + “latent” conditions). This is important in the design of our services and processes. We need to identify certain “incidents” and prevent them.

## Making errors visible

In reality, most errors cannot be reduced to zero. However, the system should aim for “zero harm” to the patient. We must make errors visible to those working in the system so that they can be corrected before they cause harm for example “double checking” - the inspection of doctors’ medication orders by pharmacist; computerised physician order entry system (POE) that checks for drug-drug, drug-dosage, drug-food, drug-allergy, drug-disease interactions and gives alerts to the doctor; or checking of a nurse’s dose calculations by another nurse or computer.

*Zero harm*

## Mitigating the effects of errors

Because not all errors will be intercepted before reaching the patient, we must make preparations (in high-risk areas) when errors go undetected. We thus need processes that quickly reverse or stop the harm caused, for example, antidotes to certain drugs like “narcan” for opiate overdose post-operatively, to be ready at the point of administration.

## Strategies to address the problem of preventable adverse events in Malaysia

In the 1999 Report “To Err is Human”, the *Institute of Medicine* outlined a number of strategies that can be used to start to develop a culture of safety. These strategies are built around the system approach to human error causation and its management in the health care sector. It is believed that these strategies are relevant to us and can be implemented in Malaysia. They include :

*Strategy for change*

- Adopting a *Systems Approach* in managing preventable adverse events. Systems need to be designed to :
  - help prevent errors,
  - make errors detectable/visible so that they can be intercepted,
  - mitigate the adverse effects of errors when they are not detected or intercepted;
- Conducting base-line studies of medical errors in randomly sampled institutions and targeting the goal of 50% reduction of these errors within 5 years;

- Mandating a reporting system for errors such as *Incident Reporting*;
- Analysing the data (“root cause analysis”) to determine the causes of the error/ adverse event;
- Learning from mistakes by the prevention of re-occurrence of the errors;
- Promoting performance standards that emphasise safety;
- Correcting latent conditions that contribute to error for example, long working hours;
- Emphasising the safe use of drugs;
- Encouraging the judicious use of automation / technology;
- Encouraging the simplification of processes where possible;
- Training workforce to recognise and recover errors;
- Providing legal protection for data collected for patient safety & quality improvement purposes;
- Clinical Governance - healthcare leaders and managers to take personal responsibility for the safety of the processes and systems in which medical staff work, declaring error reduction to be an explicit organisational goal;
- Developing greater openness when things go wrong by using effective communication methods, education and support packages as well as developing guidelines to support open disclosure by health care providers to their patients when things go wrong;
- Being humane about mistakes. We need to develop mechanisms for healing to ensure that doctors and other health care professionals do not find dysfunctional ways to protect themselves e.g. responding to their own mistakes with anger and projection of blame, and may act defensively or callously and blame or scold the patient or other members of the healthcare team;

- Creating a culture where we it feels safe to talk about mistakes. A confidential incident reporting system is a step in the right direction;
- Ensuring that organizations are properly accredited and individuals are properly trained as well as credentialed.

### **The Patient Safety Council of Malaysia (PSCoM)**

Malaysia underlined its commitment to Patient Safety and the World Patient Safety Alliance by officially establishing the Patient Safety Council in January 2003 following the recommendations of the Minister of Health to the Cabinet. The Council is chaired by the Director-General of Health Malaysia. Members of the Council comprise representatives from health-related non-governmental organizations (NGO) such as Malaysian Medical Association (MMA), Association of Private Hospitals Malaysia (APHM), Federation of Malaysia Consumer Associations (FOMCA), representatives of Teaching Hospitals and various Divisions in the Ministry of Health as well as prominent members of Malaysian society who have great interest in the health care system and who have been personally appointed by the Hon. Health Minister or the Director General.

### *Patient Safety Council*

The mission of the Patient Safety Council of Malaysia (PSCoM) is to make patient care in Malaysia safer, with a strong focus on Risk Management. The PSCoM will lead national efforts to improve the safety of healthcare, giving emphasis to patient safety by promoting systemic improvements, with a particular focus on minimising the likelihood and adverse effects of medical errors.

Among others, the terms of reference of the Patient Safety Council of Malaysia are :

### *Terms of reference*

- Advise the Hon. Health Minister on national strategies and priority areas for patient (and staff) safety and quality improvement in healthcare;
- Identify issues and areas of concern concerning patient safety and to monitor the performance / outcome in these areas;
- To discuss issues and to develop means to overcome the problems concerning patient safety;
- Recommend strategies to promote patient safety.

Several strategies have been identified for implementation. To implement them, a number of Technical Advisory Committees were appointed. Three such committees have already been established, namely :

- Data and Information Committee
- Medication Safety Committee
- Transfusion Safety Committee

In addition, the services of a technical consultant on patient safety will be utilized under the auspices of the World Health Organisation. The PSCoM is also committed to support the WHO in any global programmes that are organized by this world body to further the cause of patient safety in Malaysia.

## Conclusion

Understanding how and why errors occur are important pre-requisites to the successful management of preventable adverse events due to medical errors. The ultimate goal of error reduction cannot be achieved unless we discard our blaming culture and replace it with a culture of openness, continual learning and safety.

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# PERITONEAL DIALYSIS SERVICE IN MALAYSIA

## SUMMARY

Haemodialysis and Continual Ambulatory Peritoneal Dialysis (CAPD) are two main forms of renal replacement therapy (RRT) for patients with end-stage renal disease (ESRD), constituting 84% and 10% respectively of new patients on RRT in 2004. Haemodialysis treatment is now widely available in public and private hospitals and NGO-run centres. CAPD however, is mainly available in public sector hospitals, 19 out of 31 centres in the country. CAPD was introduced in the country in 1983 but the take up rate has not been high. It was initially offered to patients with concomitant cardiac disease and poor vascular access as a preferred modality but is now provided to others as an alternative. Quality of life for patients on CAPD is better as patients are ambulant, unlike haemodialysis treatment where patients are chair-bound for many hours when on treatment. Complications of peritonitis and lower survival rate were issues initially, but they are now being overcome and CAPD should now be a possible alternative for those who need to be ambulant to continue with their daily activities, especially work.

## Introduction

The management of End Stage Renal Disease (ESRD) poses major challenges to the healthcare system of any country. This is particularly so in developing countries where the major issue is prioritizing limited resources between public health care programs that benefit the community at large, and costly technology-dependant tertiary clinical services such as dialysis. Malaysia, is a developing nation with a population of 25 million and a per capita GDP of US\$4000. It is fortunate in that the country had, from the beginning, invested in establishing a strong primary care system in the country to attain a respectable health status for its population, and can thus afford to spend considerable resources in tertiary clinical services including dialysis.

*ESRD, a costly challenge*

## Incidence of ESRD

The incidence of end-stage renal failure (ESRD) in Malaysia is not known, but a study done more than a decade ago in one region of the country suggested an incidence of 86 cases per million. It is quite likely that this is an underestimate as the treatment rate in some parts of the

country exceeded 120 per million. Further, the incidence in neighboring countries appears to be higher. If trends of treated ESRD in recent years are of any guide, the incidence appears to be increasing amongst the older populations and the diabetics but has stabilized in the younger age groups.

## Renal replacement therapy (RRT)

### *Provision of renal replacement therapy*

Renal replacement therapy (RRT) refers to all forms of treatment modalities offered to patients with end-stage renal disease. Data from the National Renal Registry showed that in the year 2004, there were 2,774 new patients accepted for dialysis (CAPD + Haemodialysis) (Table 1a), giving a treatment rate of 108 per million population (Table 1b).

### *Dialysis treatment rate*

**Table 1a : Incident Patients on Renal Replacement Therapy, 2000-2004**

New	2000		2001		2002		2003		2004	
	n	%	n	%	n	%	n	%	n	%
CAPD	206	10	286	13	308	12	370	14	289	10
Haemodialysis	1,629	82	1,792	80	2,025	81	2,203	81	2,485	84
Transplant	143	7	161	7	168	7	157	6	185	6
<b>All RRT</b>	<b>1,978</b>	<b>100</b>	<b>2,239</b>	<b>100</b>	<b>2,501</b>	<b>100</b>	<b>2,730</b>	<b>100</b>	<b>2,959</b>	<b>100</b>

CAPD = Continuous Ambulatory Peritoneal Dialysis; RRT = Renal Replacement Therapy

**Table 1b : Dialysis Acceptance Rate Per Million Population, 2000-2004**

Treatment	2000	2001	2002	2003	2004
CAPD	9	12	13	15	11
HD	69	75	83	88	97
<b>All Dialysis</b>	<b>78</b>	<b>87</b>	<b>95</b>	<b>103</b>	<b>108</b>

There were 11,767 patients dialyzing on 31<sup>st</sup> Dec 2004 (Table 2a), a prevalence rate of 460 per million (Table 2b). The renal transplantation rate is still low in the country, with a rate of 7 per million population.

The rate of growth of dialysis patients from the year 2000 to 2003 averaged 11%. The rate of growth varied between the different age groups being highest in the older age groups. The age group 65-74 years had on average a growth rate of 21%, while in the age group 0-19 years it was 13% and in the 20-44 years group it was 5.3%.

**Table 2a : Prevalent Patients on Renal Replacement Therapy, 2000-2004**

Prevalence	2000		2001		2002		2003		2004	
	n	%	n	%	n	%	n	%	n	%
CAPD	657	8	767	8	914	9	1,056	9	1,109	8
Haemodialysis	6,036	76	7,065	77	8,179	78	9,328	79	10,658	80
Transplant	1,250	16	1,334	15	1,426	14	1,497	13	1,581	12
<b>All RRT</b>	<b>7,943</b>	<b>100</b>	<b>9,166</b>	<b>100</b>	<b>10,519</b>	<b>100</b>	<b>11,881</b>	<b>100</b>	<b>13,348</b>	<b>100</b>

**Table 2b : Dialysis Prevalence Rate Per Million Population, 2000-2004**

Treatment	2000	2001	2002	2003	2004
CAPD	28	32	37	42	43
HD	257	294	333	372	417
<b>All dialysis</b>	<b>285</b>	<b>326</b>	<b>371</b>	<b>415</b>	<b>460</b>

### *Providers of dialysis treatment*

In the initial years, the government mainly through the Ministry of Health was the main provider of dialysis treatment. As demand for dialysis increased and the government faced competing demands for its limited resources, private sector providers started to develop in the mid 1980s and catered for the more affluent patients or those whose treatment were taken care of by the employers. There was still a substantial number of patients who were not treated.

*Ministry of Health, the initial major provider*

In the early 1990's, a number of non-profit non-governmental organizations (NGOs) started to provide subsidized haemodialysis treatment to patients. These NGOs ranged from dedicated organizations such as the National Kidney Foundation to service clubs such as Rotary clubs and religious organizations. These organizations including the National Kidney Foundation, raise funds from the public and provide subsidized dialysis treatment.

*NGO providers*

From the year 2001, the government provided subsidies to deserving patients treated by these NGO centers. In addition to being a direct provider of dialysis service, the government in recent years contracted out haemodialysis treatment for its pensioners (or their spouses) and those subscribing to its employee social security fund to private for-profit centers.

*Outsourcing haemodialysis treatment for government dependants*

By the year 2003, the NGO centers have become the main provider of dialysis, treating more than one third of haemodialysis patients. The private centers and most of the NGO centers are in the urban areas. The government provides services in both the urban and rural areas and all of its 124 hospitals including the most remote ones will be equipped with haemodialysis units by end of 2005 (Table 3).

*NGOs, main providers by 2003*

**Table 3 : HD Provider in Malaysia by Sector, 2000-2004**

New	2000	2001	2002	2003	2004
Government*	4	8	11	7	22
NGO	5	7	14	8	9
Private	2	11	12	18	23
<b>All</b>	<b>11</b>	<b>26</b>	<b>37</b>	<b>33</b>	<b>54</b>
As 31 <sup>st</sup> Dec	2000	2001	2002	2003	2004
Government*	6	7	8	8	109
NGO	54	61	75	83	91
Private	66	75	83	100	118
<b>All</b>	<b>183</b>	<b>207</b>	<b>240</b>	<b>272</b>	<b>318</b>

\*Government providers include Ministry of Health (MOH), University and Ministry of Defence hospitals

There are only 31 providers of CAPD, 15 of whom are in the Ministry of Health, 3 in the University hospitals and one in an Armed Forces hospital. The number of CAPD patients in NGO or private dialysis centres is negligible. It is perceived that there were more profits to be made from centre haemodialysis than CAPD – a modality of treatment provided mainly by salaried public sector nephrologists (Table 4).

*CAPD providers*

**Table 4 : CAPD Providers in Malaysia, 2000-2004**

New	2000	2001	2002	2003	2004
Government*	4	1	2	0	1
NGO	0	0	1	0	0
Private	0	3	0	0	1
<b>All</b>	<b>4</b>	<b>4</b>	<b>3</b>	<b>0</b>	<b>2</b>

As 31 <sup>st</sup> Dec	2000	2001	2002	2003	2004
Government*	15	16	18	18	19
NGO	0	0	1	1	1
Private	7	10	10	10	11
<b>All</b>	<b>22</b>	<b>26</b>	<b>29</b>	<b>29</b>	<b>31</b>

\*Government providers include Ministry of Health (MOH), University and Ministry of Defence hospitals

### *Funding for Dialysis*

The government remains the major funder for dialysis. It pays directly and fully for almost all of the CAPD patients and more than a third of the haemodialysis patients and partially subsidises a significant proportion of those treated by the NGO centers. The patients in the NGO centers pay about a third of the cost of the treatment, the balance being subsidized by the government or the NGO or both. Patients dialyzing in the private centers pay either out of pocket, through an insurance scheme (very few) or through employee benefits.

### *Cost of Dialysis*

The cost of dialysis varied between various providers. Some provided only the dialysis treatment with no medications or routine laboratory tests while others provided a comprehensive service. In general, the cost of a haemodialysis treatment in the Ministry of Health is RM 169 per session or RM 26,364 per patient per year. This include cost of disposables, laboratory tests, medications, overheads and nephrologists' services. The cost of CAPD fluids and consumables per patient per year is RM 26,322. An economic evaluation showed the cost for HD and CAPD per life year saved was quite similar at RM 33,642 and RM 31,635 respectively.

### *Specialist manpower*

Haemodialysis started in Malaysia in the mid 1960s. It was in the late 1960s and early 1970s that haemodialysis became available on a very limited scale for the treatment of End Stage Renal Failure. Nephrology as a specialty was only formerly established in the Ministry of Health in 1976.

*Establishment of nephrology as a specialty*

In the initial years there were few nephrologists and the general physicians and nurses played important roles in caring for the haemodialysis patients. The initiation of training for nephrologists and renal nurses which began in 1984 helped to develop a pool of specialist manpower which facilitated the growth of dialysis in the country.

*Renal nurses training started in 1984*

Presently there are 61 adult and 8 pediatric nephrologists in the country (a ratio of 2.7 per million population). Another eleven physicians are in the various phases of the three year training program for nephrologists. More than two thirds of the haemodialysis patients, all of the CAPD patients and a majority of the renal transplant patients are being looked after by nephrologists. There has also been training programs for nurses. The current norm for CAPD nurses to patient ratio is 1:25.

*Present status*

### *Development of peritoneal dialysis service*

Continuous ambulatory peritoneal dialysis (CAPD) was introduced in Malaysia in 1983 in a University Hospital and a year later in a public general hospital. Intermittent peritoneal dialysis with a temporary stiff catheter however, was already available since the sixties. The growth of CAPD was less rapid than haemodialysis. Continuous peritoneal dialysis was and still is confined mainly to public and university hospitals.

*CAPD started in 1983*

Presently there are 31 centres providing CAPD services to approximately one thousand patients. This compared with about 318 centres providing haemodialysis treatment to about 11,000 patients.

*31 centres presently*

The first CAPD system introduced was the Travenol (later known as Baxter) spike system with a connection shield. Baxter CAPD systems remained the predominant systems used with patients graduating from the spike to the Ultra violet set (UVXD) to the Ultra set (disconnect) system and later twin bag systems. Presently most of the CAPD patients are on the Baxter's Ultra set system and about 30% are

*Initial CAPD system*

on the Twin bag system. There are also patients on the Fresenius's twin bag system (Andy Disc"). At one time there was also the B Braun's Carex") system, which was a disconnect system, being used. The development of CAPD was facilitated by the availability of automated peritoneal dialysis machines, initially the Pac X cyclor and later the Homechoice. Both were from Baxter. Other peritoneal dialysis machines that were available included those from Gambro, Kimmel and Fresenius.

Automated Peritoneal Dialysis (APD) is practiced on a very limited scale and confined mainly to paediatric patients. There are only about 25 patients on APD presently. The main reason why Automated Peritoneal Dialysis did not expand was the relatively higher cost of the treatment.

*Automated peritoneal dialysis*

### *Initiation of CAPD treatment*

Patients with advanced chronic renal failure (serum creatinine of > 300 mol/L) are usually seen in the pre-dialysis clinic where they are counseled on the various modes of renal replacement therapy. Counseling is done by a team consisting of a nephrologist, dialysis and transplant nurses and a dietitian. Patients with ischaemic heart disease, especially those with compromised left ventricular function, are preferentially offered CAPD. Once a patient has accepted CAPD, he is further assessed by the CAPD nurse and the home environment reviewed. A home visit is carried out if necessary.

*Selection of patients*

Once a decision is made to start dialysis, a Tenckhoff catheter is inserted and training for CAPD commenced. The training is of 7 -14 days duration and is done on a day care basis. It follows a set protocol. In some patients who have impaired vision or limited dexterity a family member is also trained. Once the senior CAPD nurse is satisfied with the patient's ability to do the procedures the patient is allowed to do the procedure at home. A home visit is done soon after to assess the patient in the home environment.

*Guidance and training for patients*

### *CAPD practice*

Patients are seen in the CAPD clinic initially at two weeks and later, at one month interval. A Peritoneal Equilibration Test (PET) and a Kt/V assessment are done one month after the training period. After this initial period they are reviewed every 2-3 month by the nephrologist and the CAPD nurse. Routine blood tests such as the blood counts,

*Closed follow-up*

renal profile and serum proteins are done and reviewed during these visits. They are also seen by the dietician. The CAPD nurse checks the exit sites and reviews with the doctor the dialysis record charts with the doctor.

Most of the patients are on four exchanges a day using a combination of 1.5%, 2.5% and 4.25% Dextrose solutions. The usual volume of each bag is 2.0 litres but some patients may be placed on 2.5 litres bags if indicated. Presently there are no amino acids containing solutions being used because of the high cost. Icodextrin containing solutions are used very occasionally.

Treatment of Peritonitis is based on a set of guidelines which was developed locally and very much based on guidelines published by the International Society of Peritoneal Dialysis.

### *Outcome of CAPD*

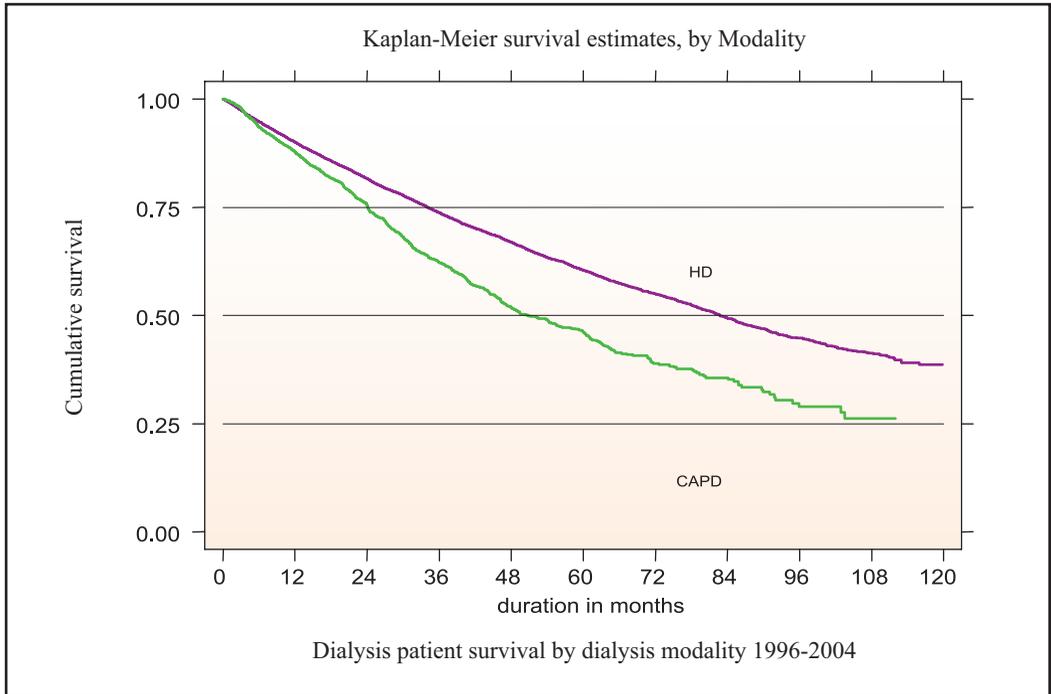
The peritonitis rate has improved with the use of disconnect and the twin bag systems. The peritonitis rate for all systems combined (Disconnect and Twin bags) for both adults and children at Hospital Kuala Lumpur is one episode in 36.3 patient months. The target Kt/V is 2 and the creatinine clearance is 60 litres per week. The technique and patient survival of CAPD patients are shown in the following graphs (**Figures 1 and 2**). Patients have also reported better quality of life with CAPD compared to haemodialysis.

### *Continuous Ambulatory Peritoneal Dialysis - issues*

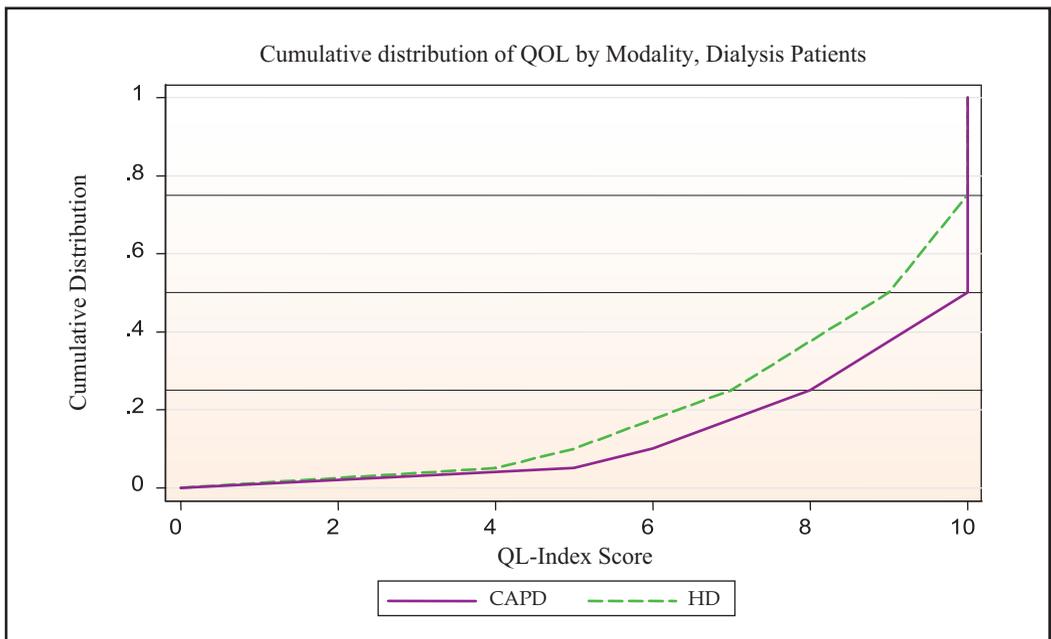
When it was first introduced, CAPD was adopted for patients who cannot be accepted for haemodialysis either because of poor cardiac function or poor vascular access. Not unexpectedly, the survival rate was much poorer compared to haemodialysis. The perception amongst healthcare staff is that it is a treatment of last resort. This perception persists despite a better patient selection system where all patients irrespective of age or co-morbid conditions are given the freedom to choose the dialysis modality. There is also the initial psychological hurdle that has to be overcome i.e. the self care home based nature of CAPD treatment. Many patients are apprehensive initially when empowered to do the treatment themselves.

*Patient  
acceptance*

**Figure 1 : Unadjusted Ten-year Patient Survival by Dialysis Modality, 1996-2004**



**Figure 2 : Cumulative Distribution of QOL-Index Score in Relation to Dialysis Modality, 1997-2004**



Note : QOL – Quality of Life

Another reason for the relative lack of development of CAPD vis-à-vis haemodialysis is cost of CAPD fluids and disposables. Although the cost per life years saved was similar between the two modalities, managers of healthcare programs frequently highlight the higher direct costs of CAPD.

*High cost of  
CAPD fluids*

A good initial placement of the Tenckhoff catheter is essential for CAPD to succeed. The lack of dedicated and committed surgeons for this relatively minor surgery has led to less than optimal catheter survival.

*Tenckhoff  
catheter*

Patient compliance has been good generally. After the initial apprehensions, most patients are happy that they do not have to visit the hospital frequently. There have been no major problems with sanitation as most homes in Malaysia have access to clean water.

*Patient  
compliance*

## Conclusion

CAPD has been available in Malaysia for more than two decades. While outcomes in terms of peritonitis rates have improved considerably and patients have rated CAPD as superior in terms of quality of life when compared to haemodialysis, the treatment has not expanded as rapidly as expected. Efforts to improve the profile of CAPD should be done at all levels including the management, staff and patients.

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# NATIONAL CATARACT SURGERY REGISTRY

## SUMMARY

The National Cataract Surgery Registry (NCSR) established in 2002, yields data on the profile of cataract surgeries and their outcomes. One of the aims in its establishment is to stimulate and facilitate research on cataract management. A descriptive analysis of data collected is presented. Outcome results indicated that there is an increase trend of phacoemulsification as compared to extracapsular cataract extraction (ECCE) as the mode of surgery, and better post-operative refracted vision for phacoemulsification compared to ECCE over the 3 consecutive years.

## Introduction

Cataract surgery is the most common surgery performed in Ophthalmology Departments in hospitals. Outcome of cataract surgery therefore serves as an indicator of the quality of ophthalmic surgical services. It is in this light that the senior ophthalmologists in the Ministry of Health mooted the idea of a National Cataract Surgery Registry (NCSR) and established the project with the help of Clinical Research Centre of MOH in 2002. The participating centres consist of all MOH hospitals, *Terendak Hospital*, *Universiti Sains Malaysia* and *Universiti Kebangsaan Malaysia Hospital*. Till date we have annual reports for the years 2002 to 2004. The Ophthalmology Service is now working on a web-based application, if deem workable, data entry can be done on-line at the respective participating hospitals.

*National  
Cataract  
Surgery  
Registry  
(NCSR)*

## Objectives

The National Cataract Surgery Registry (NCSR) was established in 2002 with the following objectives :

*Objectives of  
NCSR*

- To determine the frequency and distribution of cataract surgery in Malaysia,
- To determine the outcomes, and factors influencing outcomes of cataract surgery, and
- To evaluate cataract surgery services, stimulate and facilitate research on cataract and its management.

A descriptive analysis of data from the registry for the years 2002 to 2004 are presented.

### Registration method

The NCSR collects data on patients who have cataract surgery in a prospective and systematic manner.

The organizational structure of the NCSR consists of sponsors, an advisory committee, a cataract surgery registry unit (CSRU), source data producers (SDP) and target groups/users. Ophthalmology Departments in participating hospitals and the Clinical Research Centre (CRC) of the Ministry of Health (MOH) jointly sponsor the registry. The NCSR is governed by an advisory committee that oversees its operations.

The CSRU is based at the Clinical Research Centre, where collected data are analyzed and reports generated. Source data producers are Departments of Ophthalmology where cataract surgeries are performed. The users or target groups are individuals or institutions to which the regular registry reports are addressed. Data are collected on patient demography, aetiology of cataract, pre-operative visual acuity, pre-existing ocular and systemic co-morbidity, nature of cataract surgery, intra-operative and post-operative complication and visual outcome.

### Initial findings

Data on 48,232 patients from 32 participating centres were collected from 1 January 2002 to 31 December 2004 (**Figure 1**). Detail distribution of workload by participating centres are shown in **Appendix 1**.

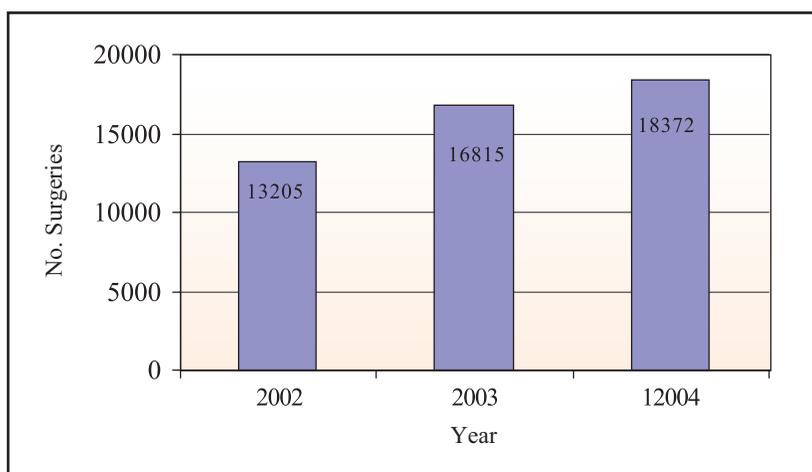
The mean age of patients was 64 years. There were equal numbers of males and females. Seventy percent had first eye cataract surgery. Up to 60% of the patients had medical problems of which hypertension (38%) and diabetes mellitus (31%) were the commonest. Senile cataract was the major cause (93%). One third of the operated eye had pre-existing co-morbidity; the majority being diabetic retinopathy (10%). Seventy six percent of the eyes presenting for cataract surgery had unaided pre-operative visual acuity of 3/60 or worse in 2002 compared to 61% in 2003, 60% in 2004. Based on refracted visual acuity, the proportion was 26% 21% and 26% respectively.

### *Organisation structure*

### *Data collection and processing*

### *Distribution and Patient Profile*

**Figure 1 : No. of Reported Cataract Surgeries in Participating Hospitals, 2002-2004**



Of the 48,232 cataract surgeries performed, extracapsular cataract extraction (ECCE) was the commonest type of surgery performed followed by phacoemulsification (**Figure 2**).

*Practice*

Majority of the patients had intraocular lens (IOL) implantation (97% in 2002, 97% in 2003, 98% in 2004). The materials for IOL implanted are shown in **Figure 3**, the majority being PMMA.

*Pattern*

Most of the surgeries were performed under local anaesthesia - 94% (2002), 93% (2003) and 93% (2004) Among those who had local anaesthesia, subtenon injection was the commonest method - 47% (2002), 52% (2003). And 54% in 2004. However, the use of topical anaesthesia increased slightly from 12% in 2002, 18% in 2003 to 23% in 2004.

### **Cataract surgery outcomes**

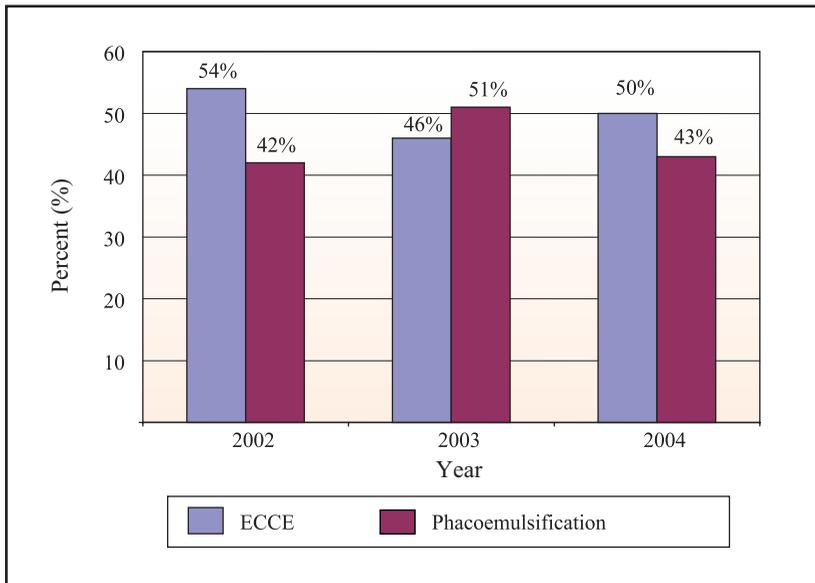
Data on complications showed intra-operative complication in 10% of patients in year 2002 and 2003, 9% in 2004. These were posterior capsular rupture (6% in 2002, 7% in 2003, 5% in 2004), vitreous loss (6% in both 2002 and 2003, 5% in 2004), and zonular dehiscence (2% in all the 3 years). Complication rates were similar in both ECCE and phacoemulsification.

*Intra-operative complication*

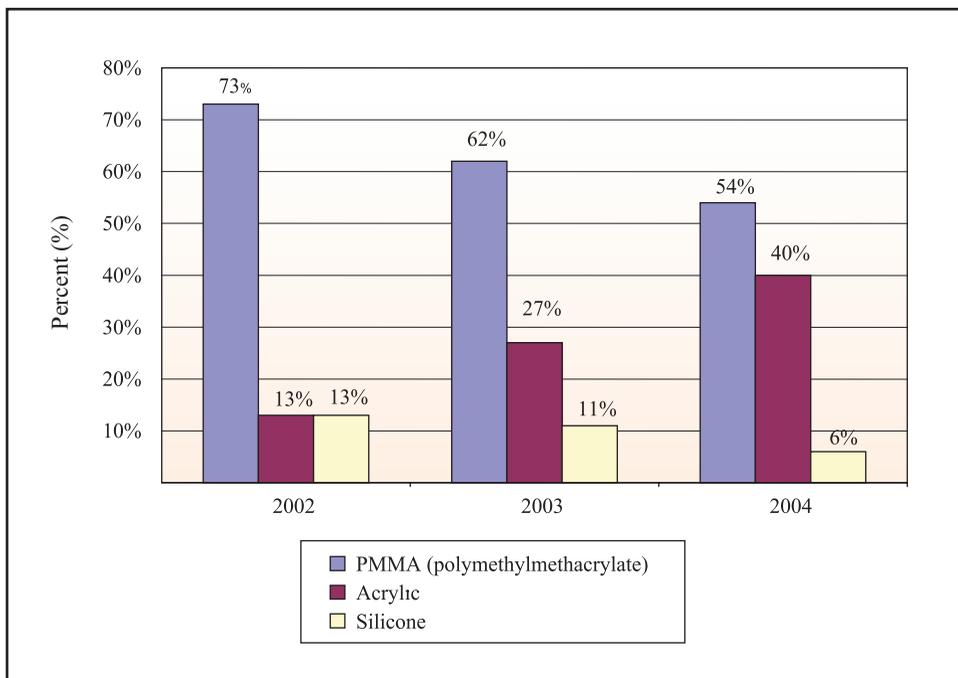
Post-operative refracted vision of 6/12 or better, was achieved in 81% (2002) 82% (2003) and 83% in 2004 for all patients. Of those without ocular co-morbidity, 86% achieved post-operative refracted vision of

*Post-operative refracted vision*

**Figure 2 : Proportion of Type of Cataract Surgery Performed, 2002-2004**

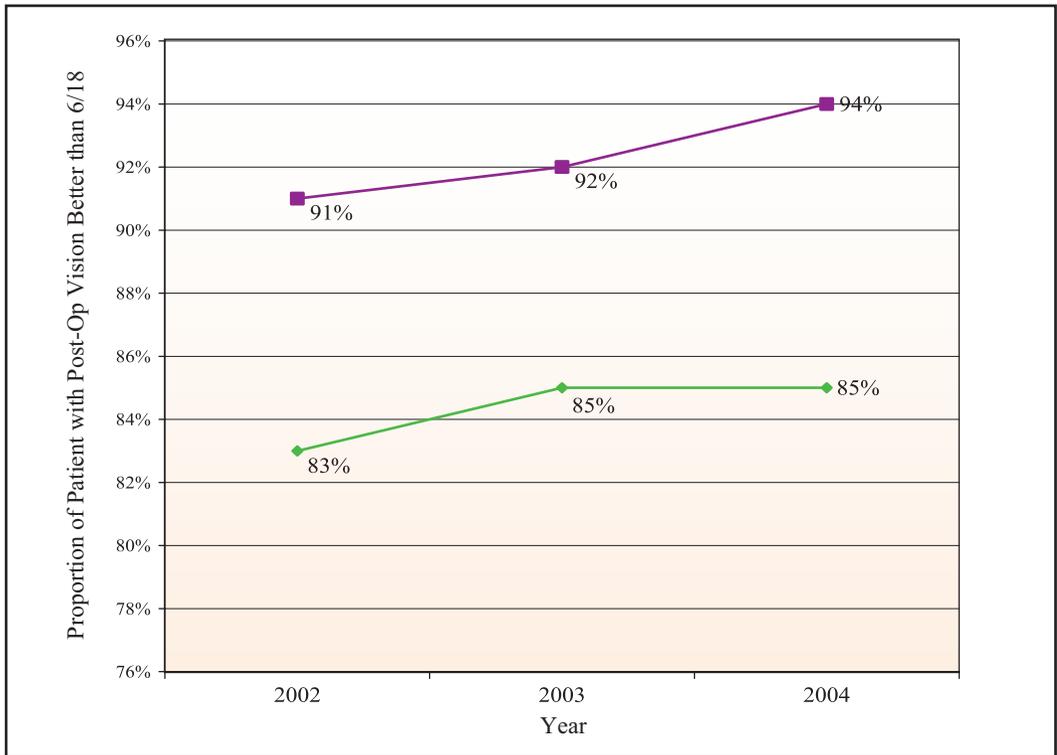


**Figure 3 : Type of Intraocular Lens Materials, 2002-2004**



6/12 or better in 2002, 89% in 2003 and 2004. Overall, patients undergoing phacoemulsification had better post operative refracted vision (6/12 or better) compared to ECCE [phacoemulsification 91% (2002), 92% (2003), 94% (2004); ECCE 83% (2002), 85% (2003), 85% (2004);] (Figure 4).

**Figure 4 : Visual Outcomes of Post-Operative Refracted Vision of 6/12 or Better for ECCE and Phacoemulsification, 2002-2004**



## Discussion

Data collected from NCSR showed the different in distribution of cataract surgery by participating centres, from the minimum number of 120 cases a year to the maximum of 1311 a year in 2004. Factors that affect the number of cataract surgery performed by centres include shortage of human resource, inadequate facilities such as operating time and micro-surgical equipment.

*Factors influencing case load*

Data on surgical practice pattern show the trend in type of surgery performed where there is an increase in phacoemulsification, which is a small incision surgery, compare to ECCE. In terms of outcome,

*Trend in surgical practice pattern*

data show an increase in the proportion of patients with better post-operative visual outcome. However the rate of intra-operative complication is similar over the 2 years.

NCSR findings provided essential data for the monitoring of cataract surgery services and other research areas concerning treatment outcome. With the findings on intra-operative complication, a statistical software programme using Statistical Process Control approach called Cumulative Sum or CUSUM has been developed to be used as an audit tools to monitor occurrence of intra-operative complications and visual outcome on surgeries performed by trainees. Besides research, NCSR annual reports have been published and several papers have been presented at national and international scientific conferences, including a special session on NCSR scheduled for the 20<sup>th</sup> Asia Pacific Academy of Ophthalmology Congress, to be held in Kuala Lumpur from 27 to 31 March 2005.

*Useful outcome  
data generated*

### **Conclusion**

Monitoring cataract surgery service serves as a proxy to assess efficiency and standard of services provided by ophthalmology departments. This is because cataract surgery is the main type of surgery performed. With data for 3 consecutive years, we can see the trend in distribution, practice pattern and outcome.

## Number of Surgery Done by Centre, 2002-2004

Centre	Year 2002		Year 2003		Year 2004	
	No.	%	No.	%	No.	%
All Sites	13,025	100	16,815	100	18,392	100
A	154	1	199	1	167	1
B*	956	7	1,063	6	1,137	6
C	129	1	133	1	120	1
D	27	0.2	1,057	6	816	4
E*	294	2	363	2	315	2
F*	1,079	8	858	5	753	4
G*	422	3	274	2	234	1
H*	737	6	672	4	895	5
I*	1,017	8	1,029	6	1,215	7
J*	519	4	605	4	365	2
K*	1,141	9	943	6	1,125	6
L*	480	4	702	4	889	5
M*	830	6	794	5	906	5
N*	260	2	310	2	300	2
O*	1,009	8	844	5	1,029	6
P*	414	3	552	3	526	3
Q*	429	3	346	2	402	2
R	188	1	263	2	205	1
S*	392	3	619	4	458	2
T*	421	3	395	2	520	3
U*	801	6	699	4	814	4
V*	268	2	395	2	444	2
W	285	2	597	4	632	3
X	70	1	134	1	238	1

Centre	Year 2002		Year 2003		Year 2004	
	No.	%	No.	%	No.	%
Y	42	0.3	87	1	120	1
Z	213	2	619	4	568	3
Aa	37	0.3	167	1	145	1
Ab	Na	Na	980	6	1,311	7
Ac	127	1	539	3	678	4
Ad*	233	2	395	2	190	1
Ae	Na	Na	120	1	Na	Na
Af	Na	Na	62	0.4	20**	0
Ag	Na	Na	Na	Na	630	3
Ah	51	0.4	Na	Na	225	1

Footnote: \*Centre which participated from Jan 2002 To December 2004

\*\* - visiting ophthalmologist to district hospital stop performing cataract surgery

NA= Not available

# MEDICAL ASSISTANTS IN PRIMARY HEALTH CARE SERVICES

## SUMMARY

Medical Assistants (MA) have been a part of the national healthcare system for over 100 years, and have played a significant role in the provision of healthcare services in the country, in particular Primary Health Care. MAs used to manage dispensaries, laboratories, medical records office, medical stores, transport services and even as stewards in hospital kitchens. However, their role in patient care in rural primary care centres have made an invaluable mark in the development of healthcare system in the country. Medical assistants carry out their functions guided by the knowledge and skills acquired during their pre-service training, and this continues with learning from doctors and peers in their places of work. In tandem with developments in primary healthcare service over the last two decades, medical assistants have taken on several expanded and extended roles to provide quality care to patients in comprehensive primary health-care service. Their contribution to health care in Malaysia is significant. As they join other healthcare professionals in facing challenges of the healthcare sector in the new millennium, medical assistants must strive to enhance their competency and professionalism to remain an important member of the healthcare team.

## Introduction

Historically, Primary Health Care is the foundation of the Malaysian healthcare system and has contributed to much of the successes of healthcare system in the country<sup>1</sup>. A major contributing factor to this achievement is the appropriate mix of healthcare providers at the first level of contact. One of the most consistent and committed members of this team is the medical assistant. With the passage of time and the changes in paradigms, the role of the medical assistant in Primary Health Care has become more challenging. This paper presents an overview of medical assistants in Malaysia and highlights their role in Primary Health Care.

*Medical assistants in Primary Health Care*

## Background

Medical assistants have been in the forefront of the health services as a group of male multi-skilled and multifunctional healthcare providers who have been part of the Malaysian healthcare system

*The evolution of medical assistants*

for more than 100 years since 1889. They are trained and equipped with adequate knowledge and skills to serve the public. Initially known as 'dressers', they were recruited by individual State Health Departments in the early days without any specific training. They acquired skills on the job and worked in almost all departments in hospitals as 'jack of all trades'.

In the mid-50s, the male nurse profession was introduced alongside nurses. They were trained together with nurses in the School of Nursing in Johor Baru, Kuala Lumpur and Penang in a three-year programme and were awarded the State Registered Nurse (S.R.N.) certificate upon completion.

Subsequently in 1977, the Hospital Assistants (Registration) Board was established under "Act 180" of Laws of Malaysia<sup>2</sup>. This Board is responsible for the registration of all qualified hospital assistants in Malaysia and for matters connected therewith. In 1982 the nomenclature of "hospital assistants" was changed to "medical assistants" and the level of training upgraded from certificate to diploma level. To maintain a high standard of conduct and professionalism, the Medical Assistants Board introduced a Code of Ethics in 1997<sup>3</sup>.

*Establishment of  
Registration  
Board.*

Currently, the Board functions under the Medical Practices Division of the Ministry of Health with the Director General of Health Malaysia as its Chairman and the Chief Medical Assistant as its Secretary.

### **Role in Primary Health Care**

The medical assistant's role is in line with the Primary Health Care principle, which seeks to balance health needs through optimisation of resources. Medical assistants serve to ensure optimal health status of the population for an enhanced quality of life.

*Trained health  
care providers*

Medical assistants were initially employed to meet the need for support personnel in the provision of medical care. Very often they functioned in the absence of a doctor, and provided much needed care to patients. In a setting where the medical assistant works alongside the doctor, his functions in running the outpatient clinic provides much support to the doctor, enabling him to devote more time to the more complicated cases needing his attention.

To produce medical assistants with good clinical acumen and competence, the MOH introduced a national training curriculum in 1990<sup>4</sup>. In line with growing public awareness and higher expectations in standards of healthcare, the curriculum has been customised to prepare medical assistants who will be able to function effectively as primary care health personnel. In addition, they are competent to serve as assistants to doctors in promotive, preventive, curative and rehabilitative aspects of healthcare in 855 health clinics in Malaysia.

### Before Seventh Malaysia Plan

In the earlier days, medical assistants (MA) managed health clinics in the rural areas, and provided primary healthcare to the community with only occasional visits by medical officers. In the absence of medical officers, the MA in the primary care setting undertook the following clinical functions in direct patient care during and after office hours<sup>5</sup> :

*Multi skill  
and  
multifunctional*

- screening of patients - history taking, conduct of preliminary basic physical examination, carrying out routine clinical laboratory investigations and referring cases to the nearest hospital;
- examination, diagnosis and treatment of simple ailments and performing minor surgical procedures;
- undertaking health education to individual patients, small groups and the community;
- carrying out preventive measures in the form of case detection, disease surveillance, health education, immunisation and notification of communicable diseases;
- documenting appropriate records relating to patients' personal data, patient care, morbidity and mortality;
- providing immediate supportive care for all emergencies, in the form of first aid and resuscitative procedures to revive patients, maintenance of vital signs and making referrals to the nearest hospital;
- providing emergency treatment according to established protocols in the pre-hospital and ambulance service; and
- providing curative care to patients in outpatient units and mobile clinics.

Medical assistants also used to carry out many other functions such as :

- basic laboratory investigations;
- preparation and dispensing of drugs to patients;
- maintenance of inventories of drugs, medical and non-medical equipment and furniture;
- maintenance of buildings, ambulance and other vehicles;
- maintenance of all resuscitative equipments in the out-patient department and ambulance service;
- care for the welfare of clinic staff and their families; and
- execution of leadership role in the health clinic and the local community.

### After Seventh Malaysia Plan

Presently, many new categories of staff like family medicine specialists; medical laboratory technologists and pharmaceutical assistants have been deployed to serve in health clinics. In line with the expanded scope of primary healthcare services, the transfer of outpatient services from hospitals to health clinics and the introduction of family medicine specialists in health clinics, the role of the medical assistant has been expanded and extended. They manage simple and less complex tasks in patient care to enable doctors to devote time for patients with more complex problems. They also do triage of patients to assess who need to be seen by the doctor.

*New roles of  
medical  
assistants*

However, medical assistants still perform many of their traditional roles in Primary Health Care aside their new roles, especially in health clinics in the more rural and remote areas.

In specialised clinics, medical assistants also carry out the following roles to ensure holistic care and quality management of patients at primary care level :

- assessing health status by doing physical examination for early detection of health problems, including screening;
- managing a wide range of clinical conditions, including giving treatment, and making appropriate referrals to doctors;
- continuing treatment initiated by medical officers as required and managing the more stable cases;



**Figure 1 : Medical Assistant examining patient**



**Figure 2 : CPR Training session in progress**

- giving health education and advice to the patient, family, carers and community on healthy lifestyle;
- preparing visit schedules to assess health status of the elderly in the community;
- organising special clinics and making appropriate referrals for further management;
- identifying, suggesting and carrying out preventive and rehabilitative measures;
- organising, coordinating and participating in community-based activities on health promotion and disease prevention;

- providing assistance in epidemiological studies and carrying out research in localised Health System Research; and
- participating in specific activities carried out at the clinic, such as Quality Assurance Programmes.

Their new roles in Primary Health Care are focused within new programmes such as :

- Community Mental Health
- Adolescent Health
- Care of the Elderly
- Occupational Health
- Rehabilitative Services
- Diabetes & Cardiovascular Disease Clinic
- Asthma Clinic
- Quit Smoking Clinic

In the year 2000, only 53.3% of posts for medical officers in primary healthcare facilities were filled. To overcome this gap in healthcare, medical assistants have successfully assumed many additional roles as care givers, decision makers, protectors and client advocates, comforters, communicators, health advocates, call centre managers, counsellors, planners, team players, organisers, controllers and leaders within their level of training, management skills and competencies.

The total number of medical assistants serving in the 859 health clinics in Malaysia is shown in **Table 1**.

Since 1997, the Ministry of Health, had introduced Family Medicine Specialists services and in 2004 out of 859 health clinics only **122 (14.2%)** had the services of Family Medicine Specialists.

The total number of posts and percentage of vacancies for medical officers and medical assistants for the year 2004 in outpatient clinics is presented in **Table 2**. Medical assistants represent the major workforce in outpatient clinics in the absence of medical officers.

Medical assistants are able to fill-in for the shortage of medical officers in Primary Health Care facilities. They attend to the majority of outpatients during and after office hours as shown in **Table 3**.

**Table 1 : The Distribution of Medical Assistants in Primary Health Care Services, 2004**

State	Number of Health Clinics	Number of Medical Assistants
1. Perlis	9	31
2. Kedah	57	155
3. Penang	30	77
4. Perak	79	178
5. Selangor	60	126
6. Federal Territory	15	32
7. Negeri Sembilan	38	97
8. Malacca	27	55
9. Johor	91	175
10. Pahang	63	186
11. Terengganu	43	112
12. Kelantan	55	158
13. Sabah	94	212
14. Sarawak	198	492
<b>Malaysia</b>	<b>859</b>	<b>2,086</b>

Source: Family Health Development Division, Ministry of Health, Malaysia

**Table 2 : Posts and Vacancies for Medical Officers and Medical Assistants, 2004**

Category of Staff	Number of Posts	Number of Posts Filled	Percentage of Vacancies
Medical Officers	1,889	1,008	6%
Medical Assistants	2,256	2,086	9%

Source : Family Health Development Division, MOH

**Table 3 : Workload in Outpatient Clinics, 2004**

Category of Staff	Number of Outpatients Seen		Number of Procedures Done
	During Office Hours	After Office Hours	
Family Medicine Specialists	275,300	196	7,965
Medical Officers	7,915,429	21,361	67,922
Medical Assistants	14,081,891	492,887	2,734,083
<b>Total</b>	<b>22,272,620</b>	<b>514,444</b>	<b>2,809,970</b>

Source : Family Health Development Division, MOH

### Medical assistants in Sabah and Sarawak

Medical assistants in Sabah and Sarawak have important additional roles compared to their counterparts in West Malaysia. The high turnover compounded by the acute shortage of doctors in Primary Health Care services in Sabah and Sarawak have made it necessary, even critical, for medical assistants in these states to acquire extra knowledge, experience and skills to effectively meet the needs of clients.

*Additional roles in Sabah and Sarawak*

Medical assistants in Sabah and Sarawak undergo additional training in dentistry to enable them to perform emergency dental extractions, and in midwifery to enable them to conduct emergency deliveries. They also provide eye care, anaesthesiology service and community clinic management. In addition, they also organise and provide school health services. Medical assistants are involved in flying doctor services to remote villages that are inaccessible by road, river or sea. They play a lead role in village health teams that are accessible by boats on river routes and often by foot on jungle pathways.

In Sarawak, medical assistants are also responsible for the training of village health promoters. This is a unique community-based programme with great emphasis on community participation.

### Flying doctor service in Sabah and Sarawak

Medical Assistants organise and carry out flying doctor services in Sabah and Sarawak, often in the absence of Medical Officers. They provide the following services :

*Medical assistants in Flying Doctor service*

- General patient care (treatment of illnesses)
- Minor surgery and dressing
- Dispensing medicines
- Antenatal Care (Pregnant Mothers) and defaulter tracing
- Child Care including immunization
- Collecting blood films for Malaria detection
- Collecting sputum slides for TB detection
- Imparting basic health education
- Water sanitary examination
- Emergency Medical Evacuation (Medevac)

Flying doctor services in Sabah and Sarawak are carried out mainly by Medical Assistants. The number of patients seen is as shown in **Table 4**.

**Table 4 : Total Number of Patients Seen by Medical Assistants in Flying Doctor Service in Sabah and Sarawak, 2000-2004**

State	2000	2001	2002	2003	2004
Sarawak	61,280	58,396	45,193	52,250	55,061
Sabah	27,096	27,360	29,998	23,660	22,893

Source : Primary Health Care Sections of Sabah & Sarawak



**Figure 3 : Medical Assistant Dispensing Medicine During Flying Doctor Service**

## Medical assistants - equivalents in other countries

The need for supportive healthcare personnel to provide primary, secondary and tertiary care alongside the doctor has seen the emergence of many categories of paramedical healthcare providers all over the world. The medical assistants in Malaysia are a viable alternative, readily available at primary healthcare level around the clock at some convenient location near where most people live. Within this scenario, the primary role of medical assistants has extended and expanded to specific roles, which are becoming increasingly complex.

The nearest equivalent to the medical assistant is the physician's assistant in USA and the 'barefoot doctors' in China. In countries like Singapore, Thailand, Philippines, Saudi Arabia and United Kingdom there are male nurses who perform some of the functions of medical assistants. However, male nurses carry out mainly nursing functions and they have minimum roles in curative services at the primary care level. The successes of medical assistants in Malaysia, as effective healthcare providers at the Primary Health Care level, can be emulated by other developing countries. In fact, Mozambique initiated a three year programme in 1984, to create assistant medical officers (*tecnicos de cirurgia*) to perform fairly advanced surgical procedures in remote areas where consultants were not available.

*Counterparts in other countries*

## Strengthening the role of medical assistants

Although medical assistants have been functioning in rural health clinics for several decades, there are challenges and constraints faced by them in providing quality healthcare. In order to achieve this, the following recommendations are appropriate.

- *Additional and upgrading of posts*

More posts should be created to cater for the demand of medical assistants in primary healthcare services within the Ministry of Health and also in other agencies such as the Department of Social Welfare, Ministry of Youth and Sports, Prisons Department and National Drug Agency. Since primary healthcare has become more complex and specialised, more senior posts need to be created for medical assistants.

*More promotional posts*

- *Upgrading knowledge, skill and competency*

There is a need for medical assistants to have ‘specialised’ skills to perform effectively in their expanded roles in Adolescent Health, Mental Health, Elderly Health, Occupational Health, Rehabilitative Services and Sexual & Reproductive Health, especially reproductive health for men. Their role should be enhanced by upgrading their basic training, and creating degree pathways for specialisation.

*Subspecialties  
and degree  
pathways*

In recognition of their contribution in primary healthcare, medical assistants should be given more opportunities to attend fellowship programmes and courses overseas. This will broaden their knowledge and provide valuable exposure to contemporary healthcare practices in foreign countries to enhance their competencies for the benefit of primary healthcare services.

- *Enhancing professionalism*

For many of the medical assistants posted to rural areas, opportunities to upgrade themselves with new clinical knowledge are limited, leading to professional isolation. Often they are unable to attend courses and seminars because of the lack of staff to relieve them of their duties in rural health clinics. The creation of more posts for medical assistants in primary healthcare will overcome the problem of professional isolation.

*Continuous  
professional  
development*

- *Recognition and incentives*

It is highly recommended that medical assistants be given incentives like critical allowance and call duty allowance in recognition of their important and significant contribution in rural health services.

*Critical service  
incentive  
allowance and  
call allowance*

## **Conclusion**

The provision of continuous, high quality and comprehensive healthcare will be further strengthened through the primary healthcare approach. Medical assistants have been in existence for more than a century, and they play vital roles in the successful implementation of primary healthcare in Malaysia. Although there will be increasing number of doctors in the country, their high turnover rate in the public sector, especially in the more rural areas, will necessitate medical

assistants to continue their definite supportive and gate-keeping roles at primary care level. The effectiveness and impact of medical assistants in primary health care services is well recognised and appreciated by the community at large. They will continue to be key personnel, providing essential supportive roles in preventive, promotive, curative and rehabilitative care in all health clinics of the future. The effectiveness and quality of healthcare provided by medical assistants need to be further enhanced through acquisition of more senior posts, upgrading of their basic and post basic training and continuous professional development.

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# THE FUTURE OF GENERAL MEDICAL PRACTICE IN MALAYSIA

## SUMMARY

'General medical practice' is traditionally taken to mean the ubiquitous non-specialised form of medical care. However, it has evolved to become a medical specialty in its own right, with specialists referred to as Family Medicine Specialists or Primary Care Physicians. General practice, especially in its non-specialised form, is the most accessible of healthcare. Both forms constitute "primary care" and have an important role in achieving "Health for All". Hence, the future of primary care and general practice has to be planned accordingly. There are several challenges faced, but also several opportunities to be harnessed, by the health system in general and by primary care and general practice in particular.

## Introduction

General practice, as the first level and most accessible form of healthcare, has contributed immensely to the health of Malaysians. Today, we recognise 'general practice' as two forms - a truly 'general' non-specialty in medicine, and an accepted specialty in its own right. As a 'non-specialty', general practice is the vocation of many doctors, despite recent growth of medical specialties. The general practitioner treats all ailments that are within his competence, without need for specialised knowledge of any particular organ or system of the human body. In all health systems, non-specialist general practice is the first level of healthcare, exercising a 'gate-keeping' role from where patients requiring specialist care are referred.

General practice has also begun to gain increasing recognition as a specialty in medicine, which appears to be a contradiction of terms. Even though not focusing on a particular organ or system of the human body, general practice as primary medical care has its own body of knowledge, skills and philosophy that, if pursued and studied in depth, becomes a medical specialty in its own right.

The term *Family Medicine Specialists* (FMS) is almost exclusively used in the Ministry of Health (MOH) and universities, while in some other

*Current  
definition of  
'general practice'*

*General practice  
as a specialty in  
medicine*

places they are also called Primary Care Physicians. In the private sector in Malaysia, both terms are used.

For the purpose of this report, general practice shall encompass :

- the *non-specialist* general practitioner (GP) who are almost exclusively in the private sector, and
- the *specialist* primary care physician, who may be in private or public sector.

### General practice as the first level of care

Being the most accessible, general practice ensures healthcare within reasonable costs and therefore is central to achieving equity. It also reduces unnecessary consultation at secondary level or hospitals. Traditionally, the GP as the 'generalist' was the doctor not only of the individual patient, but of the entire family, and served not only as the healer of ills but also as a friend and confidante.

### *The GP and equity*

There are 18191 doctors in the country in 2003. Of these, 8946 or 49% are estimated in the public sector and 9245 or 51% in private practice. Of those in the private sector, a large majority are non-specialist GPs. To date, there are 132 Family Medicine Specialist in the Ministry of Health while another 32 are in the universities that conduct the postgraduate training of these specialists.

### The future of general practice

There are challenges, as well as opportunities, that need to be managed appropriately for the future of general practice. Some of these pertain to the following :

### *The challenges*

- changing disease patterns and profile
- advancing the wellness paradigm
- advances in technology
- changing profile and expectations of the client
- the need to uphold medical ethics
- the organisation and management of general practices
- impending globalisation and the impact on general practice, and
- health sector reforms

## Changing disease pattern and profile

Changing healthcare needs may be attributed largely to changing pattern of diseases, which in turn may be due to change in socio-economic standards, lifestyles, population ageing, and environmental degradation. Non-communicable chronic conditions, especially cardiovascular diseases, diabetes, hypertension, and mental problems are gaining increasing importance. The re-emergence of age-old communicable diseases especially tuberculosis, and emergence of new infections, such as HIV and ebola infections, the Nipah virus outbreak of 1998, and more recently, the SARS and avian flu, are major challenges.

*Changing healthcare needs*

## The Wellness Paradigm

One of the health services goals of the MOH is the shift from illness to wellness with its attendant implications on general practice. This paradigm shift is a critical feature towards attaining health for all, for aspiring towards quality of life, compressing morbidity, and containing costs. Central to this is the role of health promotion and disease prevention as the more important strategy when compared to treatment and rehabilitation. The Healthy Lifestyle Campaign is a major initiative for this.

*Paradigm shift - illness to wellness*

## Advances in technology

The past few decades has witnessed unprecedented advances in information and communication technology including medical technologies. These advances have changed the scenario in healthcare and opened up unbelievable options in diagnostics and treatment modalities.

*Increasing options in healthcare*

## Changing profile and expectations of the client

Patients are better educated, are better off economically and more informed and aware of their rights and the role of their doctors. These have changed their expectations of the health system. While this applies to all forms and levels of care, it is especially relevant to primary care and general practice, which offers first-level care and where first impressions are made.

*Changing consumer profile*

## The organisation and management of general practices

Socio-economic changes and new realities not only affect patient expectations and disease pattern, they also influence the way general practice has evolved. The rise of group practices to replace single general practices has largely been a result of economic forces. The recent surge of Managed Care Organisations (MCOs) and/or Health Management Organisations (HMOs) and the controversies attached to them has major economic impetus and consequences.

### *The changing face of general practice*

## Globalisation and general practice

Globalisation in the context of health has considerable economic and political connotations. The issue of the negative impact of access to life-saving drugs, a provision of the World Trade Organisation (WTO) on intellectual property rights (IPR) as provided under TRIPS (Trade Related Intellectual Property Rights) Agreement, is perhaps the most significant implication of globalisation in healthcare. This has direct consequences on general practice, bringing with it the challenge of how to ensure these life-saving drugs reach the patient through general practice. GPs may need to prescribe very expensive drugs such as anti-retrovirals to treat HIV infected persons.

As regards the modes of globalization and health, there are implications on general medical practice. Due to the tremendous increase in volume, speed and coverage of international travel, agents of infectious diseases will find it easy to cross border; and the general practitioners will need to be competent in management of exotic diseases. Health tourism has clear implication to general practice. Under the mode of movement of natural persons, healthcare providers, including those in general practice will have more opportunities to practice anywhere in the world.

## Health sector reforms and general practice

In the light of changing needs and scenarios, the health system has to respond accordingly, and these responses in themselves pose challenges. There are various possible responses, which can be summed as healthcare 'reforms'. The current system of highly subsidised healthcare by government and a fee-for-service in an almost unregulated private sector is not viable, especially with the overwhelming changes in expensive medical technologies.

## Responses to challenges : optimising opportunities

Appropriate steps need to be taken to meet the challenges and to ensure general practice in the future is strengthened.

To ensure equitable access to first-level care, there has to be adequate numbers of optimally-distributed service providers. The MOH has plans to place at least one Family Medicine Specialist in each of its current 855 clinics. In addition to this, consideration is also to be given to the agreed staffing norms of 1 FMS for 50,000 populations. This implies that by 2020, there should be 696 FMS. Needled to say, this plan can only be implemented in phases (**Table 1**).

*Improving  
access and  
equity*

**Table 1 : Total Numbers and Projections of FMS in Malaysia**

	1997	2000	2005	2010	2015	2020
Number of FMS serving in MOH's facilities	8	73	122	300	450	600
Total Number of FMS in the country	8	80	173	360	520	700

As mentioned, primary care and general practice play a central role in this paradigm shift. General practice has to strengthen its role in health promotion, and disease prevention, while carrying out the functions on treatment and rehabilitation. The MOH is in the process of this implementing and there are implications on infrastructure, human resource and work processes.

*Expanding role  
of general  
practice in the  
wellness  
paradigm*

Quality in healthcare covers a broad range of concerns. With the changing scenario in client expectation, GPs and other primary care providers will need to enhance competencies in both "hard" (technical) and "soft" skills.

*Improving  
quality of GPs  
and primary  
care physicians*

With a plethora of options and technologies in healthcare including in general practice, it is imperative that evidence be the basis of medical practice. The initiative of the MOH to institute health technologies assessment must be fully optimised at all levels of care for patient safety, efficacy, effectiveness, and efficiency.

*Practising  
evidence-based  
medicine*

General practice dealing with undifferentiated diseased conditions has already a wide scope. With changing and expanding needs, such as the consequence of population and socio-economic status and lifestyle, general practice and primary care will continue to expand its scope.

*Expanding the scope of primary care and general practice*

The revolution in ICT can and should be used to advantage in healthcare at all levels including in general practice. The many possibilities of Telehealth can add value to healthcare. The Teleprimary Care (TPC) project of the MOH will need to be expanded from the current pilot areas in Johor and Sarawak, and the future will see its application in the private sector as well.

*Optimising ICT*

Many of the challenges of medical practice require for certain instruments or ‘regulations’ to ensure good medical practice. While some aspects can be regulated by statute, much of good medical practice is influenced by medical ethics. General practice, now and especially in the future, will need to strengthen the principles of medical ethics – non-maleficence, beneficence, respect and justice.

*Strengthening medical ethics*

The current dichotomy within the healthcare system has the weakness of poor coordination and non-integration. There has to be better co-operation between public and private primary care providers. Referral of patients is one familiar area which calls for better linkages; another is the exchange of information, an example being the reporting of notifiable diseases and of service coverage (such as child immunization) by private GPs to the MOH.

*Improving linkages*

In a radical reform of the total health system, it is possible to eliminate the public-private dichotomy. A less radical system may retain this dichotomy but needs to ensure better coordination and harmonization, for example in maintaining quality standards, amount of user fees, provider payment methods, and information sharing among others. It is important that any reform not compromise the first level position of general practice in ensuring geographical and financial access. Any reformed system, therefore, must be better than the current system.

*Protecting general practice in the health reforms*

Primary healthcare and general practice should be actively involved in the use of anti-retroviral therapy procured through the specific mechanisms of the TRIPS. Another aspect of globalisation that the health sector is concerned with is the potential of health tourism. Currently, much attention is focused on hospital care and the

*Managing the implications of globalisation*

Association of Private Hospitals of Malaysia (APHM) has been working closely with the MOH to attract foreign patients. The possibility of GP involvement in primary care needs to be studied for its potential in ambulatory care, risk assessment, and medical screening for foreign patients and tourists.

Soft skill development is crucial the light of changing client expectations, especially to front line worker such as those in general practice. One of the major initiative of the MOH which is consists of caring service, team work and professionalism.

## Conclusion

Primary healthcare provides the most accessible and affordable form of healthcare. There are many challenges faced by the health system in general, and by general practice specifically. The GP and the primary care physician (including the family medicine specialists) must not only be involved with the individual patient, but also with his family, workmates, the community he lives in, and other relevant environment that influences his well-being. The GP and primary care doctor need to expand involvement from curative care into health promotion, disease prevention and rehabilitation. Hence, the GP of the future needs to be well versed in biological determinants of health as well as the psychological, social and cultural perspectives of health.

The GP, thus, provides truly holistic and comprehensive healthcare, accessible to all. The past has laid down the foundations, the present provides opportunities for review in this country, and the future holds many challenges and opportunities for general practice and primary care to continue to be the “driver” of the healthcare system.

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# CLINICAL PHARMACOKINETIC SERVICE: IMPACT ON PATIENT SAFETY

## SUMMARY

The Clinical Pharmacokinetic Service (CPS) is a major component of the Pharmaceutical Services in the country and is critical in ensuring the safe and effective use of medications, particularly those with narrow therapeutic windows. There are currently between 8-14 types of drugs being monitored through the CPS in the Ministry of Health hospitals. Antibiotics are the most common drugs monitored (57.6%), followed by antiepileptic drugs (27.4%). The medical, intensive care and surgical departments are the main users of CPS (78%). Therapeutic confirmation is the main reason for CPS request (75%). Other requests are due to suspected toxicity, non-compliance and poor treatment response. An average of 38% of all the requests needed intervention. For toxicology monitoring of paracetamol over-ingestion, less than 20% of all acetaminophen tests conducted were in the toxic range and required administration of antidote acetylcysteine. With the availability of CPS to ascertain the necessity of instituting antidote therapy in suspected acetaminophen poisoning/overdose, an estimated RM2.7 million were saved for a three year period between 2001-2003.

## Introduction

Since the 1960's and 1970's, pharmacy services in the country have undergone three major phases of development. These include the traditional (distribution) stage, the transitional stage (clinical pharmacy) and now the patient focus stage. Currently, Clinical Pharmacokinetic Service (CPS) forms one of the integral pharmacy activities in more than 70 hospitals in the country. This service has enabled many pharmacists to enter the clinical area of patient care and has proven to be a useful tool in enhancing the pharmaceutical care process<sup>1,2,3,4</sup>.

*Development of  
Clinical  
Pharmacokinetic  
Service (CPS)*

Clinical pharmacokinetics is the process of applying pharmacokinetic principles to individualise dosage regimens of patients needing specific drug products so as to maximise pharmaco-therapeutic effects, and minimise their toxic effects. These drugs are usually associated with the term therapeutic window, where the range between efficacy and toxicity are narrow<sup>5</sup>. Examples of these groups of drugs are the aminoglycoside antibiotics (gentamicin, netilmicin), the typical

*Meaning of CPS*

antiepileptics (phenytoin, carbamazepine) and antiasthmatic agents such as theophylline. A meta-analysis by Reid et al (1989)<sup>6</sup> proved its importance where the service had a significant influence on maintaining drug concentrations within desirable range. It is also found to be especially effective in maintaining serum drug concentrations within the therapeutic range and reducing the proportion of toxic trough concentrations.

CPS specialises on a defined clinical outcome of therapy where pharmacokinetic monitoring is an essential component of pharmaceutical care for selected patients based on their specific pharmacotherapy, disease states and related factors, and treatment goals. Other factors that may affect clinical judgment include age, sex, diet, patho-physiological conditions and concomitant use of other drugs<sup>7</sup>.

*CPS a  
specialized  
service*

Existing literatures on safety of the service support both surrogate endpoints and definitive patients outcomes<sup>8,9,10</sup>. Examples of surrogate endpoint findings include increased patients achieving target concentration, reduced percentage of wastages due to inappropriately drawn or interpreted concentrations, and decreased drug dosages with associated lower hospital cost. Studies evaluating the impact on patient outcomes showed CPS decreases mortality, length of treatment, hospital stay, morbidity and adverse effects from drug therapy<sup>11</sup>.

*CPS for patient  
safety*

### **Roles and function**

The Pharmaceutical Services Division is certain that the Clinical Pharmacokinetic Service is essential towards ensuring not only patient safety but also promoting positive outcomes in therapy.

*Role of clinical  
pharmacist in  
CPS*

CPS describes the clinical pharmacists' critical role<sup>12</sup> as :

- Designing patient-specific drug dosage regimens based on the pharmacokinetic and pharmacologic characteristic of the drug(s);
- Recommending or scheduling measurements of drug concentrations in biological fluids;
- Monitoring and adjusting dosage regimens;
- Evaluating unusual patients responses to drug therapy for possible pharmacokinetic and pharmacologic explanations;
- Communicating patient-specific drug therapy information to health personals either orally or in writing including documentation.

Based on the above complexity nature of the job, it is important that only trained pharmacists are assigned to work in the CPS Unit. Other requirements include the provision of a fulltime pharmacist and pharmacy assistant to conduct analysis of blood samples.

*Trained fulltime pharmacist needed*

Currently, most CPS centers are pharmacy-based, that is, blood samples are analysed by the pharmacy unit and not the hospital laboratory. In Hospital Kuala Lumpur and Hospital Seremban, the laboratory conducts blood sample analysis for TDM. Pharmacy-based CPS centers are aided by pharmacy assistants whose role is to maintain assay quality and quantity.

*Pharmacy-based CPS Centers*

A survey on 13 CPS centers in Malaysia in 2001-2003 showed that 11(84.6%) of the centers have a full-time pharmacist and pharmacy assistant. CPS is available during office hours throughout the year and on limited time for weekends and public holidays. 24-hour service is only for toxicological cases (Table 1).

*Fulltime pharmacist*

**Table 1 : Types of Drugs Monitored in 13 Selected Hospitals 2001-2003**

Hospital	Types of drugs monitored
Hospital Sultanah Aminah, J. Baru	12
Hospital Pulau Pinang	12
Hospital Ipoh	11
Hospital TAR Klang	11
Hospital Kota Bahru	12
Hospital TAA Kuantan	12
Hospital Seremban	14
Hospital Melaka	13
Hospital QE, Kota Kinabalu *	12
Hospital Sg Petani	11
Hospital Umum, Kuching	8
Hospital Kangar *	10
Hospital K.Terengganu	10

*Note : All CPS are run by fulltime pharmacists except hospitals \**

**Table 2** summarises the types of drugs assayed in the surveyed hospitals. The common tests available in these hospitals are the aminoglycoside antibiotics, vancomycin, antiepileptics, digitalis, antiasthmatics and immunosuppressants. Other tests include methotrexate, lithium, salicylate and acetaminophen. Most hospitals also act as the referral center for any request for Therapeutic Drug Monitoring (TDM) or enquiries concerning the monitoring of these drugs.

### *Types of drug assays*

**Table 2 : Types of Drugs Available for Testing at CPS Centers**

Drugs groups	Drug name
Antibiotics	Gentamicin, Amikacin, Netilmicin, Vancomycin
Anti-epileptics	Phenytoin, Carbamazepine, Valproic Acid, Phenobarbitone
Digitalis	Digoxin
Anti-asthmatic	Theophylline
Immunosuppressants	Cyclosporine, Tacrolimus
Others	Methotrexate, Lithium
Toxicological	Paracetamol, Salicylate

### **Impact on health service**

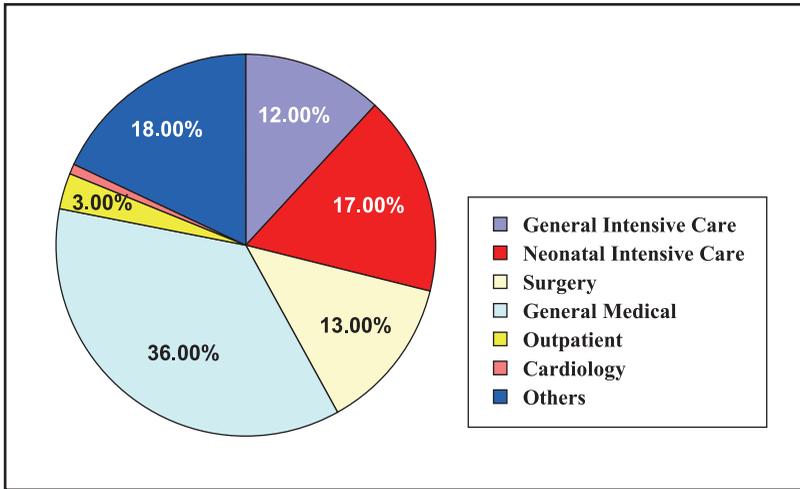
Over the past 20 years, clinical use of CPS has expanded tremendously. In those early years, the primary focus was on the measurement of blood or plasma drug levels. Evaluation of appropriate indications was performed against the background of an increasing awareness of concentration-response relationships of drugs. Currently, the service has developed into evaluating the effectiveness of clinical pharmacokinetic monitoring on overall patient outcome.

### *Impact of CPS*

The acceptance of the CPS in Malaysian hospitals was initially slow in the 1980s but since then, the response has been overwhelming. Request for CPS is mainly from the Medical, Intensive Care and Surgical departments<sup>12</sup> (**Figure 1**). These three departments contributed to almost 78% of all requests of the hospitals. Its impact is further complemented by 18% of total requests from district hospitals and health centers, hence reaffirming the importance of therapeutic drug monitoring and its utilisation in both primary and secondary care setting.

### *Main users of CPS*

**Figure 1 : Number of Cases Requested According to Department**



### Therapeutic Tool

The usefulness of CPS as a treatment tool in health care can be viewed by the increase in the number of cases and the types of requests received. Types of request for CPS can be divided into five main categories (**Table 3**). These are: compliance, therapeutic confirmation, poor or low therapeutic outcome and suspected toxicity. Of these, request for therapeutic confirmation is the highest of the total requisition for the year 2001 to 2003. The request for suspected toxicity, compliance and response are about 25% of the total request from year 2001-2003.

### Clinical use of CPS

**Table 3 : Types of Request for CPS from 2001-2003**

Year	Compliance	Therapeutic confirmation	Suspected Toxicity	Low or poor therapeutic response
2001	2,527	12,110	2,217	1,119
2002	3,383	21,286	4,898	1,878
2003	3,514	25,973	3,790	1,340
<b>Total</b>	<b>9,424</b>	<b>59,369</b>	<b>10,905</b>	<b>4,337</b>
<b>Mean</b>	<b>3,141.3</b>	<b>19,789.7</b>	<b>3,635.0</b>	<b>1,445.7</b>
<b>SD *</b>	<b>536.1</b>	<b>7,051.6</b>	<b>1,347.2</b>	<b>390.4</b>

\* SD = standard deviation

The acceptance of CPS as a tool to ensure patient's safety is clearly demonstrated in **Table 4** and **Figure 2**. CPS clinical role and importance is highlighted by the increase on the average number of recorded cases from 2001 to 2003. Data showed that the overall increase in assays were 36.3% and 41.5% for years 2002 and 2003 respectively. In terms of cases received, the number had risen by 98.3% from year 2001 to 2003. This is an astounding increase of about 16,738 cases over a two year period. These clearly showed that drug blood level monitoring is one of the critical tests used in ensuring appropriateness of drug therapy as well as to minimise toxicity.

*Acceptance of  
CPS as  
therapeutic tool*

Antibiotics are by far the most popular group of drugs requested and tested in most hospitals. This is expected since these are the drugs that are used either in the acute, critical or toxicological cases. The three commonly monitored antibiotics are the aminoglycosides and vancomycin.

*Antibiotic  
monitoring*

The aminoglycoside antibiotics such as gentamicin<sup>14</sup>, amikacin<sup>15</sup> and netilmicin form the most (42.1%) of all drugs tested from 2001 to 2003. Of this group of antibiotics, gentamicin is the most monitored. This is not surprising since antibiotics are critical and important drugs used in empirical, prophylaxis or definitive treatment of various infections. In addition, gentamicin is usually used either singly or in combination as the first line treatment for many infectious diseases in both the paediatric and adult population.

*Aminoglycosides  
monitoring*

Aminoglycosides have long been known to be the commonest cause of drug-induced toxicity. It clinically manifests as non-oliguric renal failure, with a slow rise in serum creatinine and a hypo-osmolar urinary output developing after several days of treatment, and for these reasons routine monitoring is prudent<sup>16</sup>.

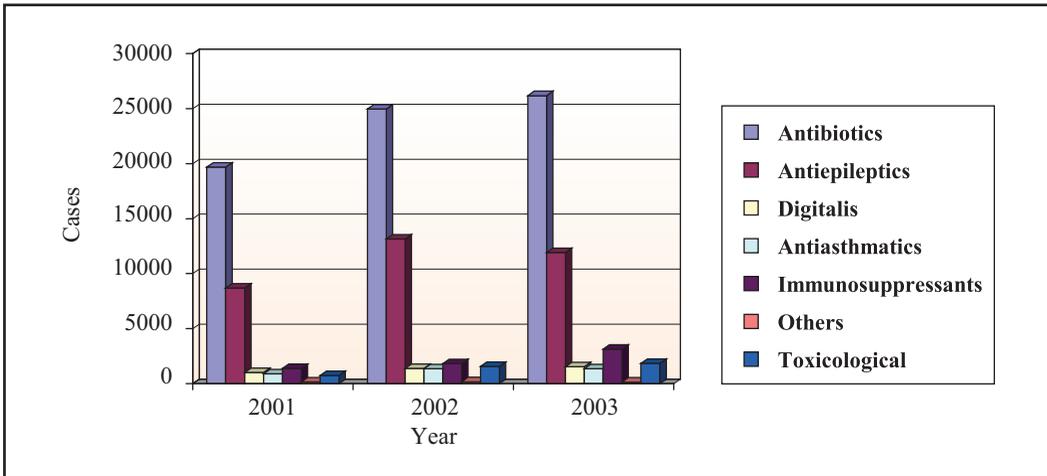
Vancomycin contributes to 14.2% of cases and is effective against gram-positive cocci namely *Staphylococcus aureus* and *Staphylococcus epidermidis*, including both methicillin-susceptible (MSSA & MSSE) and resistant-species (MRSA & MRSE). The significant controversy regarding the efficiency of vancomycin against gram-positive bacteria, potential for misuse and concentration-toxicity relationships, have prompted its controlled use and the need for clinical pharmacokinetic monitoring<sup>17</sup>.

*Vancomycin  
monitoring*

**Table 4 : Types of Assays and Cases Per Day (2001-2003)**

Drugs groups	Drug name	2001	2002	2003	Total assays
Antibiotics (assays per day)	Gentamicin	11,616	13,305	13,655	38,576
	Amikacin	3,691	4,440	4,950	13,081
	Netilmicin	664	991	495	2,150
	Vancomycin	3,720	6,236	7,079	17,035
Anti-epileptics (assays per day)	Phenytoin	3,153	4,804	4,490	12,447
	Carbamazepine	2,362	3,491	2,665	8,518
	Valproic Acid	2,593	4,052	4,056	10,701
	Phenobarbitone	584	806	712	2,102
Digitalis (assays/day)	Digoxin	1,011	1,372	1,530	3,913
Anti-asthmatic (assays per day)	Theophylline	893	1,356	1,355	3,604
Immunosuppressants (assays per day)	Cyclosporine	1,387	1,819	2,830	6,036
	Tacrolimus	0	0	295	295
Others (assays per day)	Methotrexate	72	72	40	184
	Lithium	89	97	97	283
Toxicological (assays per day)	Paracetamol	628	1,392	1,714	3,734
	Salicylate	115	175	134	424
Total assays per year		32,578	44,408	46,097	123,083
% increase (no. of assays) from 2001		-	36.3%	41.5%	
Total cases per year		17,034	32,402	33,772	83,208
% increase (no. of cases) from 2001			90.2%	98.3%	

Figure 2 : Trend of Drugs Tested from 2001-2003



Clinical Pharmacokinetic monitoring of patients on antiepileptic drugs such as phenytoin, carbamazepine, valproic acid and phenobarbitone are important especially since they are generally prescribed to patients as long term therapy. It is recommended to establish maintenance dose and testing for compliance in patients on these drugs. The rationale for CPS is that, therapeutic and toxic effects of these drugs are better correlated to blood concentration and measuring blood concentration may help optimise the dose. For example, with phenytoin there is a point in therapy that varies from patient to patient, where small increments in phenytoin dosage can result in disproportionately large increases in blood concentration. This variation between dosage and blood concentration between individuals are largely due to differences in the saturability of hepatic drug metabolising enzymes<sup>18</sup>.

*Antiepileptic  
drugs  
monitoring*

Theophylline is widely used in the management of both acute and chronic phases of reversible airway obstruction. It has a narrow therapeutic range of 10-20mg/l and blood levels correlate well with both its therapeutic and toxic effects. The clearance of theophylline is affected by variables such as age, smoking, congestive heart failure, other diseases and drug-drug interactions and this necessitates individualised dosage<sup>19</sup>.

*Theophylline  
monitoring*

Digoxin monitoring is common in cases of congestive heart failure and atrial fibrillation. It constitutes 3.3% of all cases in year 2003. It is clinically useful for evaluating compliance in specific populations such as the elderly with potential to develop drug toxicity or for verifying drug toxicity. The reason is that elderly patients are especially prone to enhanced susceptibility to digoxin toxicity where they may show

*Digoxin  
monitoring*

clinical signs of digoxin toxicity despite having digoxin concentrations within the therapeutic range.<sup>20</sup>

Toxicological cases such as acetaminophen and salicylate poisoning are becoming more common in major hospitals. Toxicological cases showed the highest increase of 104% and of which 92% were for suspected acetaminophen over ingestion. These cases presented as acute poisoning and the majority of cases does not require any specific treatment and recover completely without serious complaints. However, without proper verification of actual poisoning, treatment could be rather expensive.

*Acetaminophen and salicylate monitoring*

Patients who undergo solid organ transplant such as kidney or liver, require lifelong immunosuppressive therapy to prevent allograft rejection. CPS provides therapeutic drug monitoring in conjunction with clinical assessment of patients' overall wellbeing. Monitoring of immunosuppressive agents such as cyclosporine and tacrolimus are important to prevent therapeutic failure due to related toxicities and drug-drug, drug-food and drug-disease interactions<sup>21,22</sup>.

*Immuno-suppressive drug monitoring*

### Clinical pharmacist intervention

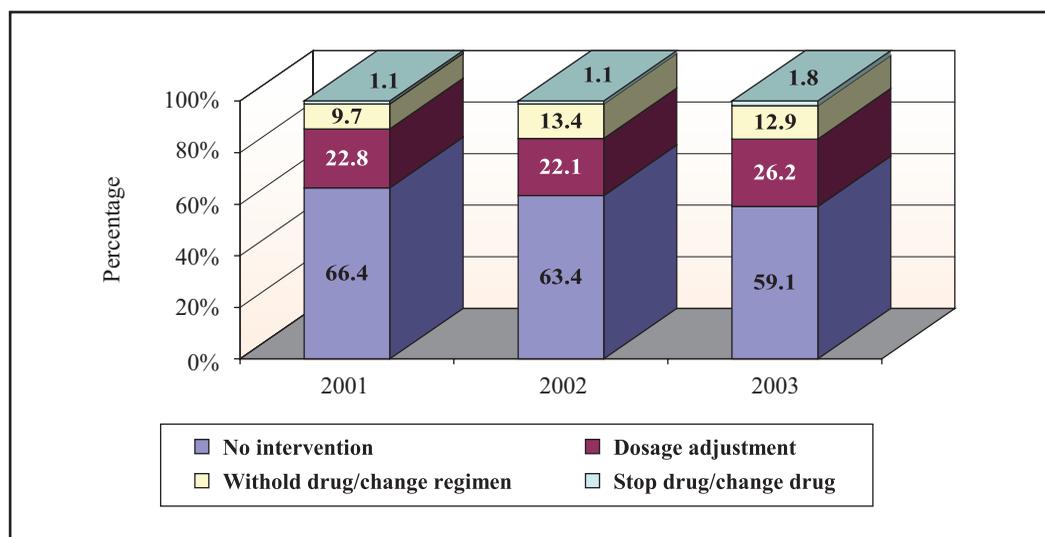
Table 5 and Figure 3 shows the types of interventions from the year 2001 to 2003. The four types of interventions are: dosage adjustment, withhold drug dose and change regimen, stop drug use or change to other drugs. Dosage adjustment includes recommendation of giving loading doses or even changing administration times.

*Clinical Pharmacist interventions*

**Table 5 : Trends of Intervention on Cases Received (2000-2003)**

Year	No interventions (%)	Dosage adjustment (%)	Withhold drug/Change regime (%)	Stop drug/Change drug (%)	Total no. cases
2001	11,466 (66.4%)	3,939 22.8%	1,675 (9.7%)	185 (1.1%)	17,265
2002	18,492 (63.4%)	6,437 22.1%	3,905 (13.4%)	316 (1.1%)	29,150
2003	19,487 (59.2%)	8,617 26.2%	4,252 (12.9%)	588 (1.8%)	32,944
<b>Total</b>	<b>49,446 (12.4%)</b>	<b>(37.7%) 1,089</b>	<b>18,993 (1.4%)</b>	<b>(23.9%) 79,359</b>	<b>9,832</b>

**Figure 3 : Trend of Interventions from 2001 to 2003**



An average of 37.7% of all requests from 2001 to 2003 needed intervention and dosage adjustment accounted for 23.9% of all interventions. The percentage of cases that required interventions increased from 33.6 % (2001) to 40.8 % (2003). Of these, withholding/change and stop drug interventions rose by 32.9% (2001) and 66.4% (2003).

*Dose adjustment intervention*

Intervention of given doses or regimen is critical to achieve maximum therapeutic outcome. It should be stressed that low therapeutic outcome due to inadequate doses can lead to the incidence of resistance for antibiotics or even rejection of organs for kidney transplant patients. As for toxic doses, these usually lead to unwanted side effects or even toxic events that could lead to complications such as acute renal or liver failure. For both these scenario, patients need longer hospital stay, which in turn increase hospital cost and workload.

### **Pharmacoeconomic Impact**

Evidence on the economic benefit of clinical pharmacy services such as general pharmaco-therapeutic monitoring, target drug program, disease management, patient education or cognitive service and pharmacokinetic monitoring has been reviewed by Schumock GT et al 2003<sup>22</sup>. The calculated mean benefit to cost ratios of 1.7:1-17.0:1 (median of 4.68:1) provided continued evidence of positive financial benefits of the clinical pharmacy services.

*Pharmaco-economic impact*

As for the economic benefit of CPS in Malaysian hospitals, **Table 6** summarises the expenditure and workload of running the CPS from year 2001 to 2003. Expenditure for running of blood assays in 2003 rose by 120% from year 2001. Workload (case per day) showed an increase of 37.3% in the same period, but the average cost per case decreased by 3.4% from 2001. This showed that with increase awareness and better promotion of service, the increase in workload had offset the high cost per case. The reasons for rise in cost could be due to the introduction of new drug assay (tacrolimus) and costlier reagents.

**Table 6 : Workload and Cost of CPS by Year, 2001-2003**

Year	Total Cost per year (RM '000)	Cases per year	Average case per day	Average cost per case (RM)
2001	275	17,265	14	20.04
2002	518	29,150	9.41	19.06
2003	556	32,944	9.81	9.37
<b>Total</b>	<b>1,349</b>	<b>79,359</b>	-	-
<b>Mean</b>	<b>449.67</b>		<b>8.78</b>	<b>16.88</b>
<b>SD*</b>	<b>152.45</b>		<b>1.44</b>	<b>2.16</b>

\*SD = standard deviation

An example where CPS can incur cost savings to the healthcare system is the use of acetylcysteine as an antidote for acetaminophen poisoning (**Table 7**). CPS provides evidence for intervention, whether antidote should or should not be given. The figure from year 2001 to 2003 from Hospital Pulau Pinang and Sultanah Aminah Johor Bahru showed that only 17.5% of all acetaminophen tests were in the toxic range which necessitated administration of antidote. Cost savings from reduced usage of antidotes was estimated to be around RM2.7 million for the three year period.

Studies examining the overall pharmaco-economic impact of CPS on the cost of treatment in Malaysia have yet to be initiated. However, published studies have shown that CPS is beneficial in ensuring appropriate patient drug management and cost effectiveness in therapy.

**Table 7 : Cost Saving Estimates on Acetylcysteine Usage for the Treatment of Acetaminophen over Ingestion**

No. of cases	Est. use of acetyl-cysteine per case	Cost per 2g/ vial (RM)	Cost of treatment per case (RM)	Total Cost (RM)
2061 (all cases)	45 vials (LD & MD)	35.15/vial	1,581.75	3,259,986 (A)
1700 (non-toxic cases)	9 vials (LD)	35.15/vial	316.35	537,795 (B)
Cost save on acetylcysteine (A-B)				2,722,191

*\*based on 60kg adult and a total of 1470mg/kg(LD) & 17 doses of 70mg/kg (MD)  
MD-Maintenance dose, LD - loading dose<sup>23,24</sup>*

**Table 8 : Cost-effectiveness of Clinical Pharmacokinetic Services**

Year	Reagent kits/100 tests	Estimated cost (RM '000)	Cost/ test (RM)	Unused test	Cost of unused tests (RM '000)	Cost -effectiveness of service
2001	275	275	15.79	4,836	48.36	69.17
2002	518	518	15.48	8,196	81.96	70.87
2003	556	556	14.75	8,221	82.21	74.33
<b>Total</b>	<b>1,349</b>	<b>1,349</b>	-	<b>21,243</b>	<b>212.43</b>	-

Cost-effectiveness of the CPS can be estimated by utilising data on the number of reagents purchased, estimated cost (RM1000 per kit) and the number of unused tests. Overall, the quality of service had improved from 69.2% to 74.3% from the year 2001 to 2003 respectively. However, the values did not include the number of tests used for calibration and control during assaying and thus these values could be under-estimated. Nevertheless, the reduction of unused tests demonstrates that the number of cases per control had increased for every cycle of assaying.

*Cost-effectiveness of CPS*

## Quality Assurance Program (QAP)

The effectiveness and efficiency of CPS towards patient care would not be complete if client's expectation is not met. Currently, the Pharmaceutical Services Division, Ministry of Health has set for monitoring of two indicators related to the clinical pharmacokinetic service<sup>25</sup>. The first indicator states that turn-around time for routine test of all CPS reports must be ready on the same day of request. Secondly, all toxicological cases must be reported within two hours upon receiving the request. To date, most centers have managed to achieve the target with minimal problems.

*Quality assurance for CPS*

Quality studies on client's satisfaction on the service turnaround time showed that most were satisfied with the service<sup>26,27</sup>. However, some studies reported that the turnaround time for some requests can be further shortened and the list of drugs monitored be expanded<sup>28</sup>. Both these requests are being considered based on the feasibility of securing higher-end and more efficient equipments to handle more tests and drug types.

*Client satisfaction on CPS*

The current strategy for improving quality of CPS is to focus on the clinical effectiveness of the service. Effectiveness is not only based on the acceptance of service but also the outcome of intervention. The objective is to ensure that patients will receive the optimum pharmaceutical care. This indicator has yet to be tested and the Pharmaceutical Services Division hopes that continuous quality monitoring will raise the quality of care of patients receiving the service<sup>29</sup>.

## Conclusion

The role of clinical pharmacokinetic service is unquestionably critical, especially for drugs with low therapeutic range. An important aspect of pharmaceutical care of the service is to optimise medication use. CPS is also designed to ensure safe and effective use of medications and increase the probability of desired patient outcome. However, issues concerning its pharmacoeconomic impact need further evaluation, especially those on therapeutic outcome and cost effectiveness.

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# AFFORDABLE MEDICINE : USING GOVERNMENT'S RIGHTS UNDER THE PATENTS ACT 1983

## SUMMARY

Concerns on the high cost of treating HIV/AIDS patients with patented anti-retroviral drugs led to attempts by the Ministry of Health Malaysia (MOH) to obtain discounts from the patent owners. However, poor response from the distributors of the patented drugs led the Ministry to look at other options to reduce costs. The Patents Act (1983) allows the Government, under the threat of public health and national security, to exploit a patent without the permission of the patent owner. Under this provision, the Ministry imported generic versions of patented anti-retroviral drugs from India. This resulted in a simultaneous major price reductions of the patented drugs, and brought down the cost of HIV/AIDS treatments in the country.

## Introduction

**H**IV/AIDS is a much dreaded disease but new developments in drug treatments have given hope to those infected with HIV. Due to the high cost of anti-retroviral drugs, not many infected persons get to be treated. In the 1990s and early 2000, public sector treatment programme for HIV/AIDS only provided Highly Active Anti-retroviral Treatment (HAART) free-of-charge to a small group of patients, namely infected mothers and newborns; healthcare workers infected at work; and patients infected through contaminated blood transfusions. For other patients, they were provided with only one free drug and were required to purchase the other two drugs for the full treatment regime.

*High cost of treatment for HIV/AIDS*

Globally and locally, there has been increasing pressure for governments to improve treatment access to HIV infected persons. Civil society organisations in the country, in particular, the Malaysian AIDS Council, also campaigned for HAART to be made available free-of-charge to all patients.

In July 2001, the Ministry of Health (MOH) acted and called upon drug suppliers within the country to reduce prices on a number of anti-retroviral medicines. Some of these medicines were still under patent protection in Malaysia at that time.

*Call for price reductions*

When the calls failed to produce the desired price reductions, the MOH took steps to consider alternative options. Incidentally around this time, the World Trade Organization (WTO) which met in November 2001, adopted the Doha Declaration which stated that intellectual property rights should not be a hindrance to accessing affordable medicines, especially when there is a threat to public health. This development, coupled with pressure from non-government organisations in the country, added impetus for the government to look for alternative sources of the needed drugs from outside the normal supply system.

*Doha Declaration, Nov. 2001*

### **Importation of generic drugs**

In August 2002, the MOH organised an inter-Ministry workshop to discuss the implications of the Doha Declaration and the legal options opened to the government in terms of accessing affordable anti-retroviral medicines. In November 2002, the MOH submitted a paper to the Cabinet on its plan to import generic versions of anti-retroviral medicines from India, proposing the use of provisions under the Malaysian Patents Act 1983. The Cabinet approved the proposal and on this basis, MOH officials commenced price negotiations in January 2003 with the local agent of the Indian generic drug manufacturer, Cipla.

*Cabinet approval to exercise option*

However, some expressed concern that this move might have negative implications, in particular investment repercussions for the country. Malaysia would be seen to be not respecting intellectual property rights and this raised concerns that foreign investments would be withdrawn. After further deliberations, the Cabinet eventually authorised the MOH to proceed with its proposal in November 2003.

Following this, the Minister of Domestic Trade and Consumer Affairs authorised the company to import generic versions of three anti-retroviral medicines from India for the sole purpose of supplying public hospitals under the powers granted to him under Section 84 of the Malaysian Patents Act 1983.

*Authorisation for Importation of generics from India*

Section 84 of Patents Act 1983, which was amended in May 2002 states :

*Patents Act 1983*

- (1) Notwithstanding anything containing in this Act-
  - (a) where there is national emergency or where the public interest, in particular, national security, nutrition, health

or the development of other vital sectors of the national economy as determined by the Government, so requires; or

- (b) where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive,

the Minister may decide that, even without the agreement of the owner of the patent, a government agency, or a third person designated by the Minister may exploit a patented invention.

The permit further stipulated that importation of the medicines would be subject to the following terms and conditions :

*Terms of permit*

- the authorisation is valid for two years from 1 November 2003;
- the medicines imported shall be in the quantities specified by the Ministry of Health;
- the prices of the medicines shall not exceed the ceiling amount specified by the Ministry of Health;
- the imported medicines shall be labelled with the words “Ministry of Health, Malaysia”;
- the shape, or colour of the tablets or capsules shall be differentiated from the patented product sold in Malaysia; and
- compensation shall be paid to the patent holder(s) within two months of the importation.

The government-use authorisation in Malaysia had been the culmination of a long process of discussion and debate involving close networking of three Ministries. The MOH was responsible for the health and treatment of patients and the people, and thus for procurement of medicines. The administration of intellectual property rights, including patents for medicines, is the responsibility of the Ministry of Domestic Trade and Consumer Affairs while the Ministry of International Trade and Industry is responsible for the negotiations of the WTO agreements in general, including the Trade Related Aspects of Intellectual Property Rights Agreement that also covered patents for medicines.

*Efforts of three Ministries*

The contract for the importation of generic anti-retroviral medicines was finally issued by the MOH in February 2004. These were Didanosine 25 mg and 100 mg tablets, Zidovudine 100 mg capsules and a Lamivudine+Zidovudine fixed-dose combination tablets.

*Contract for importation awarded*

## Cost of treatment

The impending introduction of generic anti-retroviral medicines resulted in a massive price reduction of the patented drugs. The price of the patented Lamivudine+Zidovudine fixed-dose combination came down by 80% from its 2001 price, while the price of Lamivudine dropped by 67% and Zidovudine, by 53%. The price of Didanosine also dropped by 49% and 82% respectively for the 100 mg and 25 mg formulations. The drop in prices may have been an attempt to stop the actual importation of generics when it became clear that the government was serious about exercising its rights.

*Simultaneous drop in price of generics*

With the importation of generics and the drop in price of patented drugs, the monthly cost of treatment was reduced tremendously. The Lamivudine+Zidovudine fixed-dose combination + Efavirenz regime cost RM 1,407 per month in 2001 but in 2004, the monthly cost dropped to RM 446.76 with the use of generic Lamivudine and Zidovudine in combination with patented Efavirenz.

*Reduction in treatment costs*

The lower costs of drugs have now enabled the MOH to provide two drugs free, instead of only one under the previous practice. The patient is now required to buy only one additional drug at a cheaper price than before.

## Compensation

The government rights authorisation left an unresolved issue, that of compensation to be paid to the patent holders. A royalty rate of 4% of the value of the stocks actually delivered (of the generic medicines) was proposed. However, the patent holders showed little interest in accepting or negotiating the proposed remuneration.

*Compensation to patent holders*

## Planning for the future

The use of government rights will expire in November 2005. The MOH has indicated that it is amenable to either engaging in price negotiations with the patent owners or applying for an extension of the government rights authorisation.

*Future options*

Meanwhile, another initiative on the affordability of anti-retrovirals has started. There is a proposal by a local manufacturer to manufacture a 3-in-1 anti-retroviral fixed dose combination of Stavudine +

Lamivudine + Nevirapine for which they have received a voluntary license from the patent holder. MOH is in the midst of negotiating for a suitable price for this product.

### Conclusion

The MOH will continue to safeguard patients' interest by working for cost reduction in the treatment of HIV/AIDS. It is evident that the Cabinet approval to allow for importation of generic drugs under the provision of Section 84 of the Malaysian Patents Act 1983 had achieved the desired effect of causing a parallel drop in price of patented drugs. Further new development for local manufacturing of anti-retroviral drugs is in the pipe line. These new developments has certainly given hope for HIV/AIDS patients in the country, as they buy time and wait upon new breakthroughs for an ultimate cure for this dreadful disease.

*A new hope*

*Chapter*

# 2

## POPULATION HEALTH



# AGEING IN MALAYSIA : RESPONSE OF THE HEALTH SECTOR

## SUMMARY

The lengthening of life expectancy is both a triumph and a challenge. There are important implications on social services, including health of both individual and population ageing. For the health sector to respond appropriately, there is need to assess the magnitude of the phenomenon, as well as to understand the process of human ageing, the concept of “healthy” or “active” ageing and its determinants, the relevant epidemiological features. Finally, the challenges for healthcare for older people need to be recognized, understood and managed. The Malaysian government has formulated a national policy for older persons, and the Ministry of Health has begun to include health of older people in its expanded Primary Health Care Service.

## Introduction

The response of the health sector (and other sectors as well) towards population ageing has to be in the context of the many facets of the Malaysian society, and these include :

*Factors  
determining the  
response of  
health sector*

- Malaysia as a developing country has a clear vision to attain “developed” nation status by the year 2020; and achievements have been made in health and other social sectors that have brought the “triumph” of lengthening the life span.
- Malaysia needs to learn from the experiences of countries that have undergone population ageing, because the triumph of lengthening life is also a challenge.
- The response to population ageing in order to ensure “active ageing” and to truly create a “society for all ages”, needs to involve many determinants for active and healthy ageing are multiple and varied.

In formulating these responses, it is relevant for the health sector to take note of the magnitude of ageing and the health implications; the concept of “healthy” or “active” ageing and the determinants; and some relevant epidemiological features.

## The demographic revolution - magnitude of population ageing

The World Health Organization (WHO) has aptly stated that “Population ageing is one of humanity’s greatest triumphs. It is also one of our greatest challenges”. Worldwide, the fastest rate of growth is in the 60 years and above age group. For developing countries, population ageing has many serious connotations and challenges. For instance, the developed nations of the west “became rich before they became old”, but developing countries today are “becoming old before they become rich”.

*The effect of population ageing*

In 2002, it is estimated that about two thirds of the more than 600 million older persons above the age of 60 in the world were in developing countries. By 2025, about 840 million of the projected 1.2 billion people in this age group (70%) will be in the developing countries. Half of the world’s older persons will be in Asia. Needless to say, health and social policies and perspectives leading to these policies, must take cognisance of this population structure.

Malaysia is a developing country with a relatively young population. In the 50 years since Independence, life expectancy has increased considerably from 55.8 years in 1957, to 70 years (males) and 75 years (females) currently. Taking 60 years old as the cut-off point, there were 1.4 million older persons out of the total population of about 22 million (5.9%) in the year 2000. By the year 2020, this number and proportion is projected to be 3.4 million or 9.9% (Department of Statistic, Malaysia; 2004).

*The life span of Malaysian population*

## Health status of older people in Malaysia

The quality of life and health of older persons provide valuable information to the overall planning of a health programme or service to meet their needs. The health status of older persons has been the subject of several studies by various researchers. Different studies focus on different aspects and use different methodologies. Hence often, the findings are not comparable with one another. The most direct indicator of health status is the proportion of older persons who experience illness in a specified period of time that affected their activity of daily living (ADL).

The ASEAN (Association of South East Asia Nations) study in 1989 showed that the proportion of people aged 60 and above who experienced illness in the past one year for 5 countries were : Indonesia

*Morbidity of the elderly*

(60%), Philippines (46%), Malaysia (45%), Thailand (37%) and Singapore (14%). The same study showed data on good eyesight and hearing, and mobility – proportion of older people who can see well and hear well, and can get around house without difficulty. Malaysians appeared to be relatively handicapped in terms of ability to see well where the proportion is almost twice below the rate of our closest neighbour, Singapore (Table 1).

**Table 1 : Vision, Hearing and Mobility of Older Persons in Five Countries, 1989**

Country	% can hear well	% can see well	% can get around house
Indonesia	42	74	86
Malaysia	33	81	not available
Philippines	23	71	72
Singapore	89	92	91
Thailand	49	79	69

Source : Association of South East Asia Nations Study, 1989

In another study conducted by the Malaysian Medical Association (MMA) in 1997, it showed that 72.4% of elderly felt they were healthy while 31.1% were on some form of medication. The majority of them were living with family members. Yet another health needs study by *Universiti Malaya* (UM) in 1997 showed that a large proportion of older people are mobile and physically active with about 90% of those studied still capable of taking care of themselves while 80% of males and 67% of females could walk uphill or climb stairs. More than 90% of them could eat, dress, bathe and use the toilet without help.

*Morbidity of Malaysian elderly*

### The concept of active ageing and the determinants

If ageing is to be a positive experience, then a longer life must, not only be accompanied by optimal health, but also by their continuing ability to participate in activities of life and the assurance of security in their old age. This philosophy shall guide all perspectives and policies on ageing. This has been the guiding principle on the definition of “active ageing” by the WHO which states that “Active ageing is the process of optimizing opportunities for health, participation and security in order to enhance quality of life as people age”.

*The philosophy of active ageing*

## *Determinants of active ageing*

The term “active ageing” has replaced the previous term “healthy ageing” to connote the continuing participation of older persons in social, economic, cultural, spiritual and civic affairs, not just their ability to be physically active. It also aims to extend healthy life expectancy and quality of life for all people as they age, including those who are not in the best of health, are frail, disabled and in need of care.

An important concept therefore, is that related to autonomy, respect, dignity, independence and self-fulfilment. It shifts the focus from a “needs-based” with a welfare orientation to a “rights-based” approach with a contributory orientation. Another relevant perspective to take note of in ageing policies is that ageing takes place within the context of others – family, friends, work colleagues and society at large – leading to the concepts of inter-dependence and inter-generational solidarity.

Active ageing depends on a variety of factors or determinants that exist in the many sectors of human activity. Much work has gone into adducing the evidence of the role of these factors. WHO has suggested six (6) determinants that interact with one another in determining active aging. Over and above these six, there are two (2) other factors, gender and culture that affect all the six determinants (**Table 2**).

**Table 2 : Determinants of Active Aging**

The six determinants	The two over-arching factors
1. Economic	1. Gender
2. Social	2. Culture
3. Physical Environment	
4. Personal	
5. Behavioural	
6. Health and Social Services	

The economic determinants include income security and work opportunities, as well as social protection. Social protection traditionally comes from the family. With changing family structure that comes with development and urbanisation, this has become an area of increasing concern. Closely related to this is the need to ensure literacy and education of older people, which come under

## *Economic determinants*

social determinants. Another social issue relevant to older people is their risk to abuse and violence, and the need to protect them from such ills.

There are many determinants in the physical environment, not least being safe housing and transport. They also need to be prevented from falls and injuries that occur as a result of poor physical facilities. On personal determinants, it is often seen that longevity, and also the ability to remain well in old age, runs in families which are due to the biological and genetic influences. Personal factors also include psychological attributes such as intelligence and cognitive capacity, and therefore coping ability and styles.

*Physical environment*

The behavioural determinants that influence ageing include tobacco and alcohol use, physical activity, eating habits, oral health, and use of medications. Access to health services also contribute to the way people age. Services must include health promotion and disease prevention, which must be throughout the life course, as well as curative and rehabilitative services.

*Behavioural determinants*

Finally the two cross-cutting determinants are gender and culture which affect ageing to a large extent. How ageing is viewed and also concept of health and illness, are themselves culturally determined, as. These factors influence health seeking behaviour. Reference has been made to family and social support, which have a strong cultural influence as well.

*Gender and Culture*

### **Selected epidemiological features**

Like any public health problem (although ageing is not a disease but a physiological process with important health implications), ageing can be described according to basic epidemiological variables of time, place and person. Besides these variables, three specific epidemiological features deserve mention – the urban-rural trend, cohort perspective and the feminization of ageing.

In terms of the urban-rural differential, the trend of industrialisation has attracted young people to the urban centres where job opportunities are available, leaving behind the older people in the villages. Thus the ratio of older people in rural areas is high where often, they have to fend for themselves. There are also other reasons why the traditional family structure is slowly being eroded. The implications of urban-rural differential on social services including health services are many.

*Urban-rural differential*

From the cohort perspective, the profile of older persons changes with time; those of yesterday were different from those of today and of the future. Education and socio-economic development contribute immensely to this trend.

### *The cohort perspective*

Successive cohorts of older people will be more educated, better-informed, have a higher economic standing, but they will probably have less family support. Their attitudes towards life will also be different, and they will have the desire, the awareness and capacity to avail themselves of newer opportunities.

The feminisation of ageing is another epidemiological feature of relevance in health service planning for older people. Life expectancy at birth tends to favour females over males. If life expectancy at different age groups is analysed, it is also seen that women in general tend to outlive men. This is due to variances in mortality between the sexes at all age groups. Thus there are more widows than widowers. From the biological aspect, which is fraught with social and psychological challenges, menopause has several implications that require appropriate policies and interventions. This perspective is further compounded by the inter-relationship between old age, women's status and poverty. Income insecurity and poverty are common features of old people as well as of women. Thus feminization of ageing brings about increased social burden.

### *Feminisation of ageing*

#### **The life course perspective in active ageing**

To ensure active ageing, interventions that create healthy environment and lifestyles must be at all stages of life, not when people have already entered old age. As people age, non-communicable diseases become the leading causes of morbidity, disability and mortality. These conditions are costly to individuals, families, communities and the nation. Thus there is a strong imperative for these to be prevented or delayed as long as possible, so that as large a proportion of older persons are spared, if not of these diseases, at least of their complications.

#### **A policy for health and ageing : the international impetus**

Interest in population ageing is at a global level. The First World Assembly on Ageing in 1982 provided a major impetus for many countries. Specifically, there was an International Strategy and Plan of Action prepared by the Commission for Social Development of the

United Nations and deliberated at the Second World Assembly on Ageing in Madrid in 2002. It addressed ageing in a very systematic manner, and laid out plans that can be adopted by countries. This United Nations International Strategy and Plan of Action has identified three “priority directions” as follows :

- Development for an ageing world.
- Advancing health and well-being into old age.
- Ensuring enabling and supportive environment.

In this plan, health is expectedly, one of the three priority directions, and it is imperative that it is addressed along with the other factors that determine quality of life of older people, many of which are encompassed in the third priority direction, that is, ensuring enabling and supportive environment.

*The important of creating healthy environment and lifestyles*

The WHO Document “*Active Ageing – A Policy Framework*”, focusing on the aspect of health, has defined the concept of “active ageing” as a central concept. Thus, as defined earlier, “Active ageing is the process of optimising opportunities for health, participation and security in order to enhance quality of life as people age” This policy framework identified three “basic pillars” to ensure active ageing, that is, *Health, Participation and Security*.

Again, as in the UN International Strategy, health is not seen as a stand-alone parameter of active ageing in this Policy Framework. It is abundantly clear that there has to be inter-sectoral responses to an ageing world, with health as one of several concerns. To be fully effective and efficient, inter-sectoral actions need to be integrated and coordinated.

*Global commitments towards ageing*

### **The National Policy on Older Persons /Ageing**

The Malaysian government took a proactive stand and formulated a unified, holistic inter-sectoral National Policy for Older Persons in early 1990’s. The main statement of this policy is “*To ensure the social status, dignity and well-being of older persons as members of the family, society and nation by enabling them to optimize their self-potential, have access to all opportunities and have provision for care and protection*”. This over-arching statement is supported by 3 objectives :

*Malaysia’s commitment*

- To enhance the respect and dignity of older persons in their family, society and nation.

- To improve the potential of older persons so that they can continue to be active and productive in national development, and to create opportunities to assist them to continue to be self-reliance.
- To encourage the establishment and availability of specific facilities to ensure the care and protection of older persons towards enhancing their well-being.

There are several strategies to meet these objectives, and they are encompassed in five areas of concern or principles as follows :

- respect and dignity,
- self-reliance,
- participation,
- care and protection, and
- research and development

The stakeholders carry out the related programmes and activities to reflect these principles and several sectors are relevant including education, employment, recreation, transport, housing, health, social security, media and social support. To ensure a coordinated implementation of this policy there is the National Council at the Department of Social Welfare. For health issues, there is a Council and a National Technical Committee at the Ministry of Health.

### **The responses of the Ministry of Health**

In the health sector, many initiatives have begun. Health services for older people provided by the Ministry of Health encompass health promotion, disease prevention, curative care for illnesses, and rehabilitation. At primary care levels, elderly care is one of the expanded services in Primary Health Care, and almost all of the clinics have begun some components of care for older persons. Training of staff using several modules is an ongoing activity. There is also a module for training of home-carers.

Secondary care at hospitals is an essential component, and hospitals are required to be “elderly friendly”. A few hospitals have begun geriatrics as a specialty service, but needless to say, management of older ill persons necessitates a multi-disciplinary approach, and geriatrics is not practiced in isolation. Rehabilitative services are carried out in hospitals, clinics, ambulatory care centres and even in the community. Home care is another modality, and this has begun to be provided by the Ministry of Health, although NGO’s and private sector are encouraged to complement such services.

Health is only one sector, there are other services provided to older people in the other social sectors, especially from the aspects of welfare and support, employment, recreation, housing, transport and other areas that are of concern to older people. There are professional bodies and societies at both international and national, and even local level that are set up for various aspects of ageing and health. There are also several NGO's concerned with older people, and they are under the umbrella of the National Council for Senior Citizens of Malaysia (NACSCOM). There is a role of the private sector as well, including provision of long term and residential care. The private sector can also play an important role in giving support services especially for ADL, such as the well-known "meals on wheels" projects.

### Challenges and opportunities

One of the most unfortunate negative trends is the mistaken perspective of ageing that takes the form of "ageism". Ageing and the aged are often viewed negatively as a "problem" or a "tolerated burden" that leads to the concepts of dependency and paternalism, and even social discrimination and abuse. This is now changing to the more the more apt concept of ageing being an unavoidable natural phenomenon that, with the right approach and attitudes, can be a positive experience, not only to the older person but to community at large. The slogan "A Society For All Ages" need not be mere lip service, and an unattainable ideal.

*"Ageism"*

One of the most challenging aspects to ensure a new service is procurement of *adequate resources*. Resources used must ensure cost-effectiveness, and any new service must not be at the expense of another service. Participation of older people and policies to ensure their dignity and independence, necessarily have resources implications. But what is important is that older people have rights as the other segments in the community, and society has an obligation towards members of the community including older people. Thus for the policy on active ageing to be fully implemented, there has to be resources for education, housing, health, transport, recreation etcetera.

*Procurement of adequate resources.*

There are still large areas of knowledge gaps in ageing and its implications; knowledge provides evidence for programmes and services. The current high interest in ageing, including in the research component is an opportunity to be optimally used. Professional

*Lack of adequate knowledge*

bodies and societies with the Ministry of Health, universities and the private sector can forge partnerships in the quest for knowledge and evidence.

A feature of any service is the adequacy in terms of scope or range of service, which connotes both quantity and quality. It is important to know “what” to give, and then “how” and “where” and “by who”. Bearing in mind the definition of health that covers physical, mental and social well-being, health and welfare services will have to bring all these on board, the speed depending on the resources available. Health care for older people must incorporate all levels of disease prevention from promotion to specific disease prevention, to early detection, curative care and then to rehabilitation and minimisation of disabilities. Health care systems must add on palliative and end-of-life care especially in terms of ensuring a dignified death.

*Range of services*

Access to health care, while important is not adequate; there has to be the element of acceptability to ensure utilization. Having physical and financial access does not mean effective care; because there are other factors that determine whether the older people will or will not use the service. For the older persons who need hospital or other forms of care, these must be made physically and financially accessible. The Primary Health care service has undergone tremendous expansion and improvement, not only in access, but also in scope and quality of services, and most clinics have begun health care of older persons. One of the factors to determine optimal use of services this is how caring and compassionate the service.

*Accessibility and acceptability to healthcare services*

The challenge of ensuring service integration whether within or among the service providers applies to health of older people as it applies to general health service. In health care, there are many disciplines involved in care for older people, both clinical and non-clinical. In addition, there is more than one level of care that needs to be linked through a referral system. Added to these, there are many choices of providers of care that the older person can access. The many agencies and sectors involved in health and ageing need to work in a more coordinated manner.

*Integration of services*

In the current efforts to reform of the health system, it is important to consider the implications of such reforms on elderly health. There is always the inherent danger of reforms threatening the welfare of the vulnerable groups, such as the poor, women, children and the elderly.

*The effect of reforming of the health systems*

One major reform is health care financing. Whatever forms the new financing system takes, there must be plans and mechanisms to protect and provide the “safety net” for the vulnerable groups including the older members of society.

## Conclusion

Ageing is a natural phenomenon that is inevitable. What is not inevitable however, are the ill healths, discomfort, disability or loss of independence that often accompanies ageing. From the health aspect, the process of ageing can be made a positive experience. This requires many inputs, including an enhancing policy that dispels the negative views of ageism, a strong political commitment to ensure population ageing is accompanied by relevant policies, plans and programs. Malaysia, in undergoing rapid population ageing, has begun to examine the various perspectives of ageing and health in order to plan for a healthier future for the older Malaysians.

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# PREVENTION OF INFECTIOUS DISEASE THROUGH VACCINATION - AN UPDATE

## SUMMARY

The potential public health impact of effective vaccines against vaccine-preventable diseases has been well established. Since the inception of the Expanded Programme on Immunisation (EPI) by WHO, each vaccine has been selected on the basis of safety, effectiveness, reasonable pricing and the ability to combat a childhood disease of significant global public health importance. The six vaccine-preventable diseases originally targeted in 1974 by WHO were tuberculosis, poliomyelitis, diphtheria, pertussis, tetanus and measles. Hepatitis B was added later, and yellow fever was included for countries where this disease is endemic. More recently in 1998, Haemophilus influenzae type B (HiB) vaccine was introduced in 1998. With the introduction of the various national vaccination programmes in Malaysia, an expected real significant decrease in the incidence of specific vaccine-preventable diseases was observed. Currently there are several national childhood vaccination programmes for preventing diseases like tuberculosis, diphtheria, pertussis, neonatal tetanus, acute poliomyelitis, haemophilus influenza type B (HiB), measles, mumps, rubella and hepatitis B providing good seroprotection and maintaining herd immunity at high levels. The next phase would be to either eradicate, eliminate or substantially reduce the targeted vaccine-preventable diseases.

## Introduction

Vaccination is a highly cost-effective and proven public health intervention in infectious disease control. A quarter of a century ago, the deadly smallpox was eradicated as a result of planned global vaccination initiative. Outstanding progress has been made towards the eradication of polio. The 16-year Global Polio Eradication Initiative has reduced the incidence of wild poliovirus cases across the globe by 99% since 1988. Measles mortality has dropped dramatically by 40% since 1999. Neonatal tetanus deaths are on the decline with fewer than 200,000 cases reported in recent years as opposed to over 800,000 in the 1980s.

*Vaccination- a cost effective public health intervention*

Vaccinations avert the deaths of between two to three million children each year and prevent suffering and disability in a most cost effective manner, unlike other interventions like lifestyle change and

*Polio-free certification*

behaviour modifications which are not only time consuming, but also have uncertain outcomes. In response to low vaccination coverage, new initiatives have been launched by international partners to mitigate unacceptable toll of vaccine-preventable diseases especially in developing countries. The current strategy would be to make a case for investment in vaccination by the world community in efforts to globally eradicate or substantially reduce infectious diseases.

As the result of sustained activities under the polio eradication programme, the Western Pacific Region was only the second WHO Region to be declared polio free on 29 October 2000 in Kyoto, Japan. Nevertheless post-certification activities which include high quality reporting of acute flaccid paralysis and high vaccination coverage have to be implemented in this region until global certification is achieved. Strategies are in place to address the current issue of emerging vaccine-preventable diseases.

### **Vaccine-preventable disease control programme in Malaysia**

In Malaysia, there has been a dramatic decrease in the incidence rate of some of the childhood vaccine-preventable diseases over the years, as a result of effective sustained vaccination strategies. (**Table 1 and Figure 1**).

The incidence rates of the childhood vaccine- preventable diseases except for measles, tuberculosis and hepatitis B have reached a satisfactory level that is below 1 per 100,000 population. Nevertheless, some of these diseases have recently shown an increasing trend as a result of re-emergence due to increasing human traffic and the increasing presence of susceptible population groups like the unvaccinated children of illegal immigrant workers, unprotected mobile groups and others. As for poliomyelitis, no cases of indigenous wild poliovirus had been reported since 1984. In order to strengthen the formal surveillance on the occurrence of acute poliomyelitis cases, surveillance of acute flaccid paralysis (AFP) cases were instituted in accordance to the WHO guidelines. The AFP incidence surveillance target of achieving the rate of 1 per 100,000 populations has been achieved over the past three years.

*Childhood  
vaccine-  
preventable  
diseases*

The objectives of the national vaccine-preventable disease programme are :

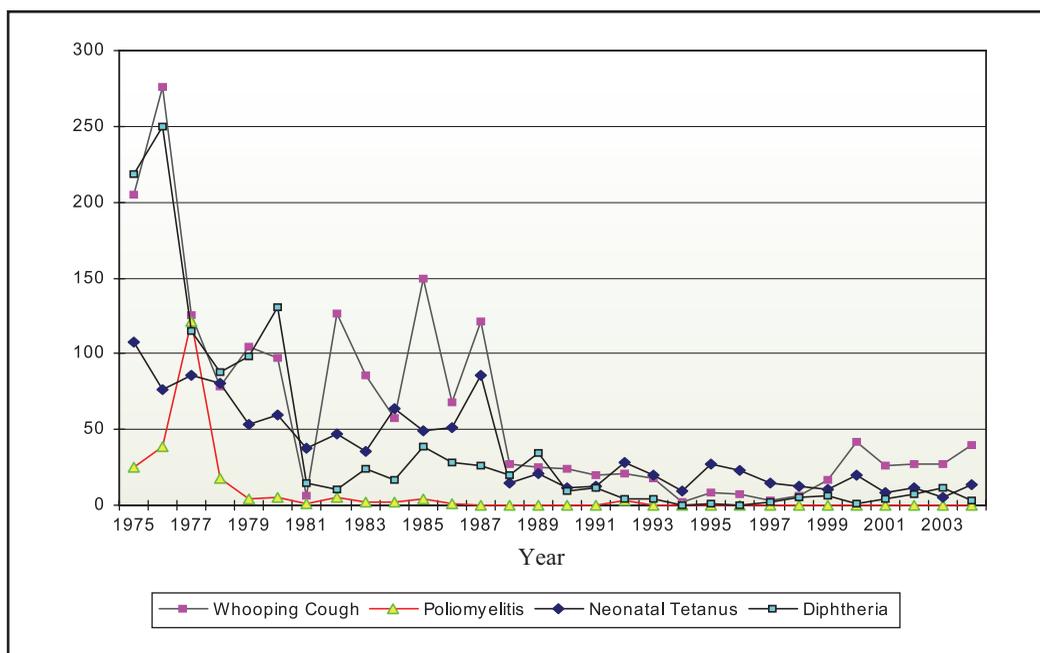
- To reduce mortality and morbidity due to vaccine-preventable diseases (VPD) so that they no longer pose a public health problem.
- To maintain quality surveillance on selected vaccine- preventable diseases.
- To eradicate poliomyelitis, eliminate measles and reduce Hepatitis B by a certain time frame based on WHO's Regional Plan of Action.
- To strategize for complete vaccination coverage especially in high risk population groups and low coverage areas.

**Table 1 : Incidence of Six Vaccine-Preventable Diseases Reported in Malaysia, 1989-2004**

Year	Diphtheria		Whooping Cough		Neonatal Tetanus		Measles		Polio		Hepatitis B	
	Case	IR	Case	IR	Case	IR	Case	IR	Case	IR	Case	IR
1989	35 (6)	0.20	25	0.14	21 (4)	0.12	1,027 (2)	5.87	0	0.00	938 (1)	5.36
1990	9 (1)	0.05	24	0.13	11 (3)	0.06	563	3.13	0	0.00	942	5.24
1991	12 (2)	0.06	20	0.11	13	0.07	275	1.51	0	0.00	724	3.98
1992	4 (1)	0.02	21	0.12	28 (8)	0.15	363	2.01	3	0.02	723	4.00
1993	4	0.02	18	0.09	20	0.10	517 (3)	2.66	0	0.00	576	2.97
1994	0	0.00	12	0.06	9	0.05	346 (1)	1.77	0	0.00	335	1.71
1995	1	0.01	8	0.04	27 (4)	0.13	654 (6)	3.22	0	0.00	551	2.71
1996	0	0.00	7	0.03	23 (3)	0.11	460 (4)	2.17	0	0.00	627	2.96
1997	2 (1)	0.01	3	0.01	15 (1)	0.07	565	2.61	0	0.00	307	1.42
1998	5 (1)	0.02	6	0.03	13 (4)	0.06	483	2.18	0	0.00	5,010 (3)	22.59
1999	6 (1)	0.03	17	0.07	10 (2)	0.04	2,068 (10)	11.48	0	0.00	5,295 (1)	23.31
2000	1 (1)	0.01	42	0.19	20	0.09	6,187 (7)	27.87	0	0.00	2,863 (2)	12.89
2001	4 (4)	0.02	26	0.11	8	0.03	2,207 (4)	9.27	0	0.00	2,926 (3)	12.30
2002	7	0.03	27	0.11	11	0.04	899	3.67	0	0.00	2,706 (1)	11.03
2003	11 (1)	0.04	27	0.11	5	0.02	710 (1)	2.83	0	0.00	2,767 (2)	11.05
2004	3 (1)	0.01	40	0.16	14	0.05	5,729	22.39	0	0.00	1,976 (2)	7.72

Note: Ir - Incidence Rate per 100,000 Population. ( ) - Death

**Figure 1 : Incidence of Selected Childhood Vaccine-Preventable Disease, Malaysia, 1975-2004**



### Pertussis

This is a childhood disease, endemic in certain regions with cyclical outbreaks. The annual incidence of whooping cough is about 30 million infections and rates range from 0.2 to 1,500 per 100,000 population. In most cases, it occurs in young children, where the less than 5 year age group account for 80% of the cases. The mortality rate ranges from 0.4-2% with 300,000 deaths and most deaths (50%) occur in infants. Current epidemiology indicates that due to waning immunity, increasing infections among older children, teenagers and adolescent groups are being seen and this has to be addressed. Adults suffer from chronic coughs caused by pertussis. There is a current concern of vulnerable newborns contracting the infection through exposure to an infected adult.

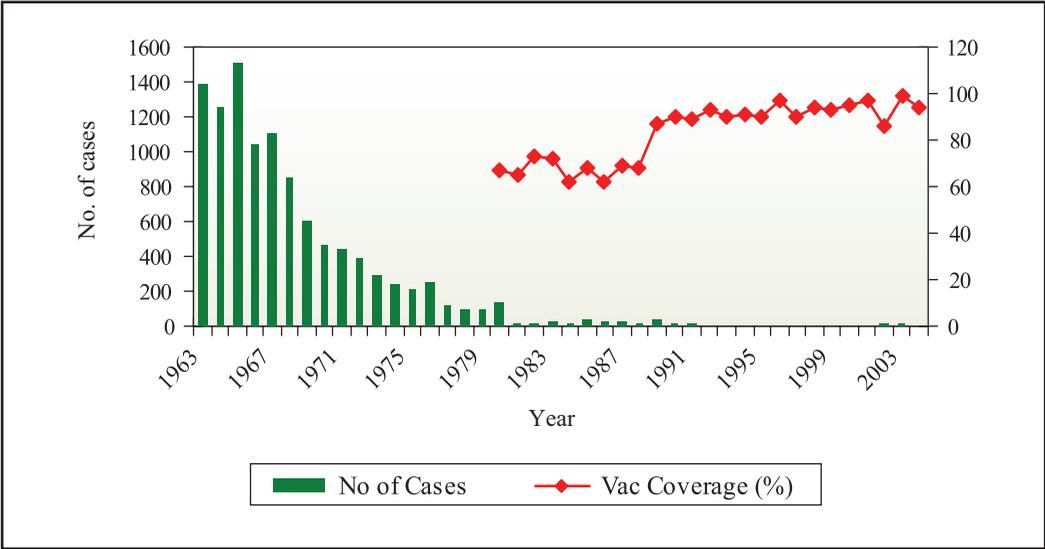
### *Epidemiology of whooping cough*

Due to improved reporting, there has been an increase in the incidence rate of the disease in Malaysia, from a low 0.01/100,000 population in 1997 to 0.15/100,000 population in 2004 (**Figure 2**). For the past 6 years (1999-2004) the number of cases reported has remained at more than 15 cases per year. In 2000 there was a two fold increase in cases to 42 from 17 cases observed in the previous year. The trend then showed a

### *Whooping cough in Malaysia*

decline but another upsurge was seen in 2004 with 40 reported cases. There were no fatalities. All the cases reported were clinically diagnosed. The re-emergence of cases since 1999 and infectious in older age groups has been of current concern.

**Figure 2 : Incidence of Pertussis and Vaccination (DPT3)**



**Tetanus**

This condition as with other infections, has a world wide distribution. The incidence is low in industrialized countries and infection usually follows after sustaining a deep wound or ulcer. This occurs predominantly among inadequately vaccinated elderly adults where in such instance, up to 25% of infected persons may die. The scenario differs in developing countries where the incidence is high (25 per 100,000) and most cases being newborns and young adults who sustain injury. In this situation up to 60% of infected persons may die.

*Epidemiology of tetanus*

In Malaysia, this disease has remained, to a large extent, a much localised problem occurring mainly in specific localities in Sabah. The incidence rate has decreased from 0.13/100,000 in 1995 to 0.05/100,000 in 2004. The trend has showed a steady decline over the years (Figure 1). The low incidence rate of below 0.1/100,000 population has been maintained since 1997. The cases have been mainly occurring among the neonates of foreign mothers who have had no access to proper health care facilities due to socio-cultural and other reasons.

*Neonatal tetanus in Malaysia*

There were no deaths reported in the last 5 years as compared to high case fatality rates of 28.5%, 14.8%, and 30.7% recorded in 1992, 1995, and 1998 respectively. There were 2 reported deaths in 1999. In 2004 a total of 14 cases have been reported out of which 7 were from Sabah, 5 from Sarawak, 1 each from the Federal Territory of Kuala Lumpur and Perlis. Malaysia adheres to WHO's Regional Plan of Action for Neonatal Tetanus Elimination.

## Measles

The WHO Regional Committee for the Western Pacific, during its fifty-fourth session in 2003, resolved to eliminate measles and the Region is continuing to progress towards elimination, with many countries at, or close to elimination. It was agreed that the Regional Director propose 2012 as the target date for regional elimination at the fifty-sixth session in September 2005. This was based on the recommendation of the Measles Task Force which met in July 2004.

In Malaysia, the incidence has been between 1 to 3 per 100,000 population from 1990 except for 3 periods in 1999 where, the incidence recorded was 11.48/100,000 with 10 deaths; 27.87/100,000 the following year with 7 deaths, and 22.39/100,000 in the 2004.

The 2002-2003 period displayed an endemic level picture with upsurge of cases in 2004. The national measles vaccination campaign targeting at the 7 to 15 years old school going age group was conducted successfully in 2004. In addition, action was taken to further reduce existing susceptible groups by providing single dose vaccination to 15 year-olds in secondary schools (Form 3) throughout the country. These are part of the ongoing National Measles Elimination Initiative based on WHO's Plan of Action for Measles Elimination.

## Acute Poliomyelitis

In 1988, the World Health Assembly set 1998 as the goal of worldwide polio eradication. Subsequently, the end of 2005-2010 period proposed as the target period for global certification of the eradication of the disease. Since 1988, WHO has been working with national governments, UNICEF, Rotary International, the Centers for Disease Control and Prevention in Atlanta, USA and a wide array of public and private partners in order to support the ongoing work of eradicating polio from countries where the disease has been endemic. The four principle strategies of polio eradication are routine vaccination

*Global Measles  
Elimination  
Programme*

*Measles in  
Malaysia*

*Global polio  
eradication  
initiative*

of infants; supplementary vaccination through national immunization days (NIDs); high quality surveillance for acute flaccid paralysis (AFP) and mop-up vaccination campaigns.

To date, three WHO Regions including the Western Pacific Region comprising of 37 countries, have been certified polio-free. The Western Pacific Region which includes Malaysia has been declared polio-free on 29 October 2000. The national documentation for the certification of the eradication of polio had been prepared and scrutinised by the Regional Eradication Commission from the 3-4 August 2000 in Manila. The Western Pacific Region was officially declared polio free on 29 October 2000 in an historic meeting in Kyoto, Japan. Nevertheless, high quality AFP case surveillance will be ongoing until global certification. Post certification measures include high quality AFP case surveillance and high vaccination coverage rates and adhere to WHO's Regional Plan of Action and Strategies for Post Certification of Polio Eradication.

### *Polio-free certification*

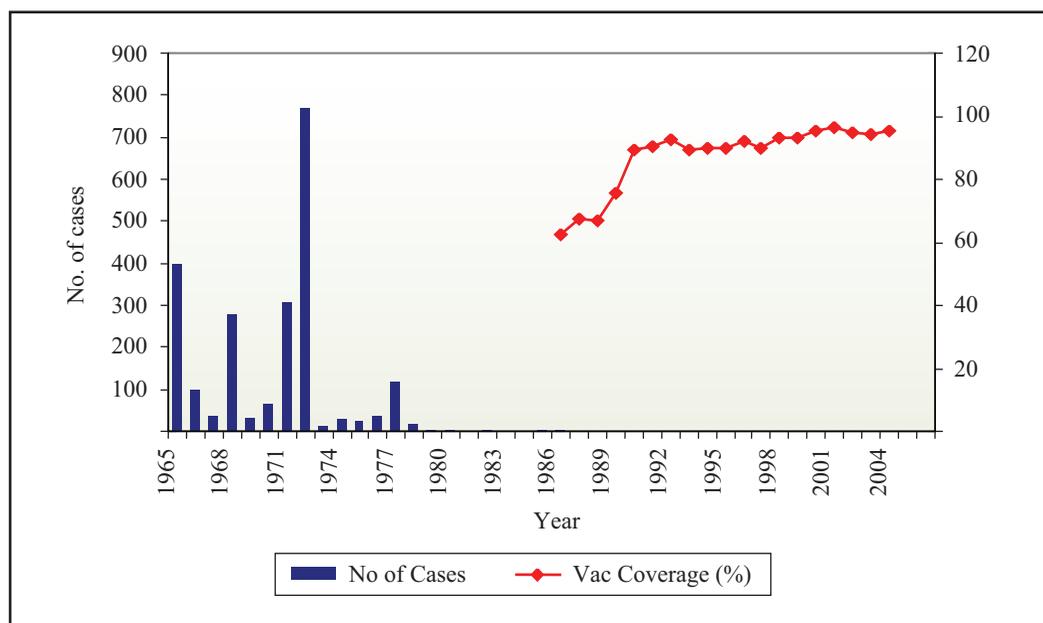
However, due to the persisting prevalence of wild poliovirus cases in the other 3 WHO Regions, specific post certification activities (mainly near-universal polio vaccination coverage and high quality Acute Flaccid Paralysis case surveillance) still need to be maintained in polio-free areas in order that any importation of a wild poliovirus can be managed appropriately with an immediate response mechanism. The target for global certification has been further deferred due to the persisting existence of pockets of wild poliovirus infections. Since the notification of the 3 imported polio cases in 1992, there has been no reported cases of the disease due to wild poliovirus infection since then (**Figure 3**). There is an ongoing acute flaccid paralysis (AFP) surveillance under the National Polio Eradication Programme to detect any case of polio especially those of imported origin. There is also a National Plan of Action for management of imported cases of wild poliovirus.

### *Importation of wild poliovirus*

The national target for AFP cases has been achieved even during the post certification period (2001-2004). Several workshops focused on strengthening AFP surveillance and improving oral polio vaccination coverage among high risk population groups have been conducted over the last few years in order to sustain post certification activities. National annual post-certification activity reports are submitted to the Western Pacific Regional Office as part of the requirements and ongoing efforts to maintain the region polio-free status. This would be continued until global polio-free certification.

### *AFP case surveillance*

**Figure 3 : Incidence of Polio and Vaccination (OPV3) Coverage, Malaysia, 1965-2004**



The National Certification Committee deliberates on major programmed policy matters related to both the National Polio and Measles Eradication Programmes.

### Hepatitis B

Hepatitis B is an important and a priority public health problem especially in the Western Pacific Region, causing approximately 300,000 deaths per year (approximately 22 deaths per 100,000 population). Universal childhood vaccination with three doses of suitable hepatitis B vaccine, with the first dose delivered within 24 hours of birth, is the most effective method of control of Hepatitis B.

### *Epidemiology of Hepatitis B*

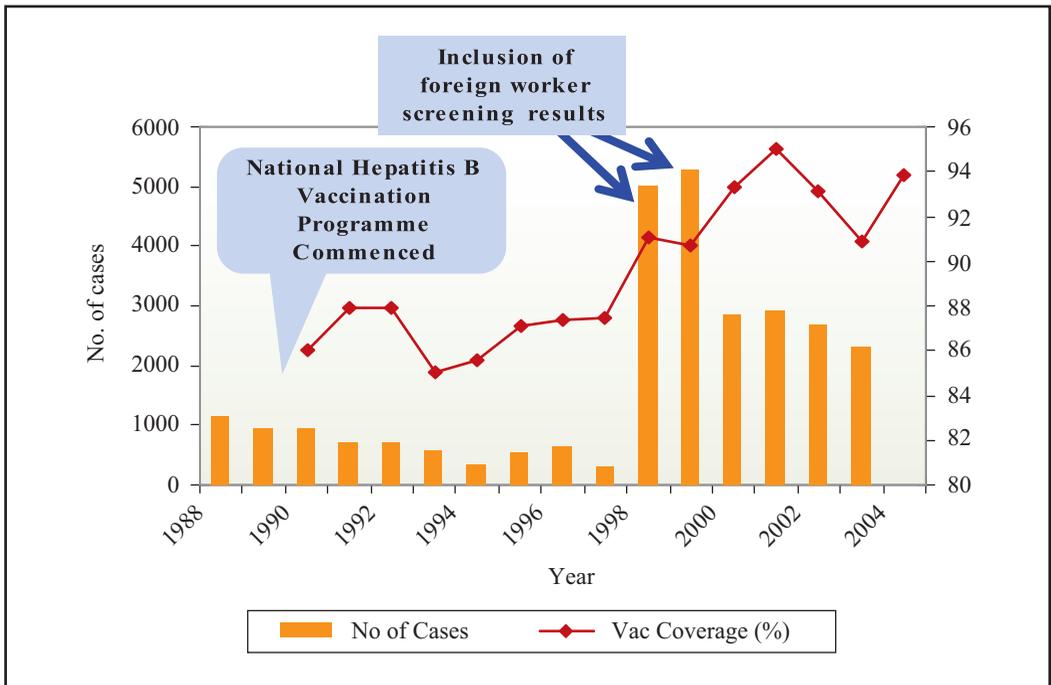
All member states have already endorsed, through the Regional Committee Resolution of September 2003, a Regional goal of <1% HBsAg prevalence in five-year-olds born after the introduction of universal infant hepatitis B vaccination programme. A date to achieve that target has not been set. At the recent Fifteenth Meeting of the Technical Advisory Group (TAG) on EPI and Poliomyelitis Eradication in the Western Pacific Region, the TAG proposed setting the following regional targets of HBsAg prevalence in five-year-olds :

### *Regional reduction targets*

- An interim milestone of <2% HBsAg prevalence in every country by 2012, and
- To establish a regional goal of which HBsAg prevalence to be less than 1% in every country at a set target date.

In Malaysia, there were 1,976 cases of hepatitis B with 2 deaths reported in 2004 (**Figure 5**). Between 1998 and 2004 there has been a downward trend in the number of reported cases. The incidence rate showed a declining trend from 22.59 (5010 cases) in 1998 to 7.72 (1,976 cases) in 2004. The pre-1998 era has incidence rates of below 6.0/100,000 population. From the investigations conducted it appears that the reporting mechanism has improved but it captures both cases with both new and existing infections. The states have provided reports depicting a more accurate disease burden. Surveillance data from the Foreign Worker Medical Screening Programme, indicated that there is a high burden of disease among the foreign workers and other local high risk population groups.

**Figure 5 : Incidence of Hepatitis B and Vaccination (Hep3)**



## Diphtheria

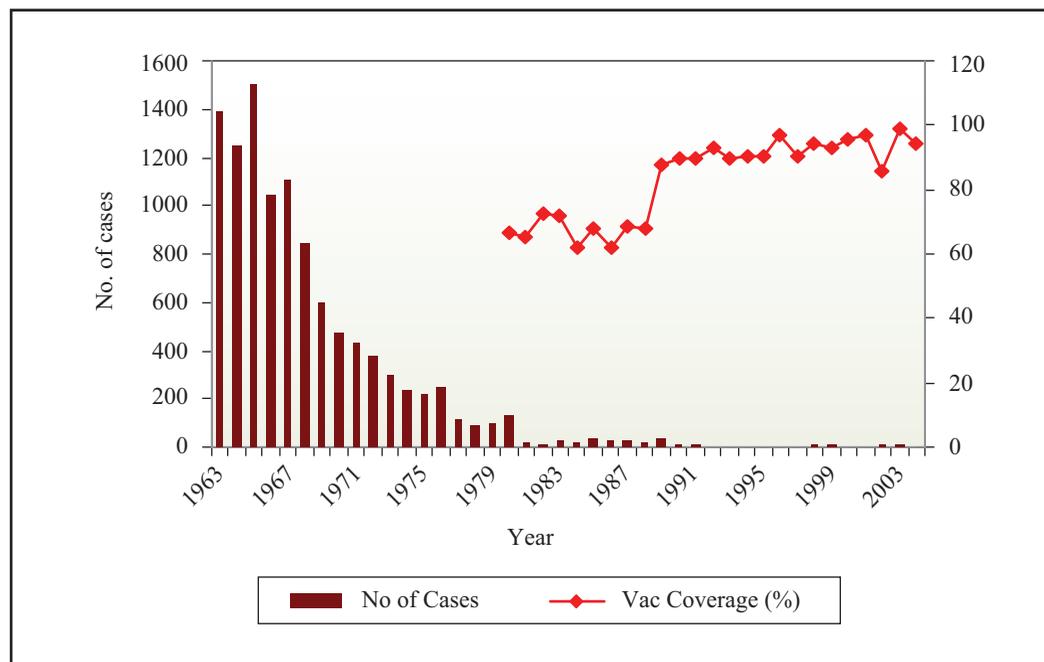
The epidemiology of diphtheria indicates a worldwide distribution. In industrialized countries, it appears to be very rare except in certain parts of Eastern Europe where it appears as skin infections among susceptible adults and has a low mortality rate (1-3%). Whereas in developing countries it is endemic at low levels mainly appearing as respiratory tract infections in persons less than 15 years of age. The mortality though can be as high as 10%.

### *Epidemiology of diphtheria*

There were 3 cases (incidence rate 0.01) of diphtheria in 2004 (Figure 6). From the investigations conducted, it appeared to be well localised and adequately contained. Immediate active measures were taken to detect cases and improve on the effective vaccination of high risk children in the affected and neighbouring localities. No secondary cases were detected. There have been 36 cases with 9 deaths reported in the 1997-2003 period. To counter the re-emergence of this disease, specific surveillance has been strengthened to detect early cases. Measures are also been taken to improve the vaccination coverage of identified high risk children. The resurgence of this disease since 1997 with increasing fatal cases is of concern and various specific strategies have been implemented to urgently address this issue.

### *Diphtheria in Malaysia*

Figure 6 : Incidence of Diphtheria and Vaccination (DPT3), Malaysia, 1963-2004



## Vaccination coverage

The main aim of vaccination is to provide protective efficacy against disease. Factors causing difficulty in providing protection against infection and existence of carriage states are challenges to the implementation of the programme.

### *Role of vaccination*

All vaccines used in the national vaccination programmes are sourced externally. Vaccines are procured through a cyclical tender system and distributed through a privatized entity. This entity is responsible to ensure adequate distribution to all the vaccination outlets throughout the country.

### *Vaccine supply*

Vaccination coverage for children has achieved the targets of Universal Child Immunisation (UCI) (Table 2).

### *Vaccination coverage in Malaysia*

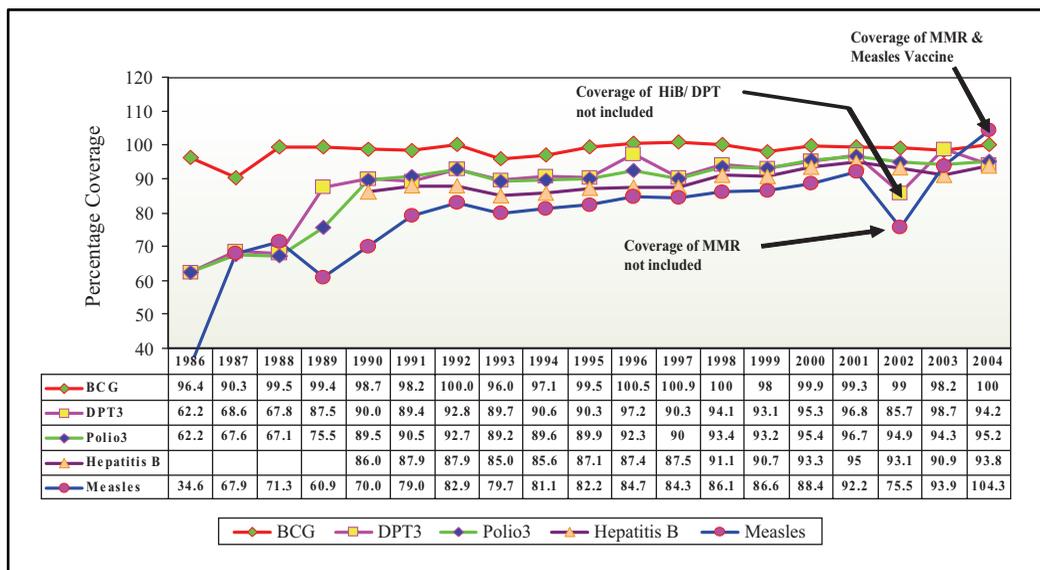
**Table 2 : National Vaccination Programme, Malaysia**

AGE	New Born	1 Month	2 Months	3 Months	5 Months	12 Months	18 Months	Year 1 Primary School (7 yrs)	Form 3 Secondary School (15 yrs)
Type of Vaccination	BCG	Hep B Dose 2	DPT + HiB Dose 1	DPT + HiB Dose 2	DPT + HiB Dose 3	MMR Dose 1	DPT Booster	MMR Booster	Tetanus Booster
	Hep B Dose 1		Polio Dose 1	Polio Dose 2	Polio Dose 3		Polio Booster	DT Booster	
					Hep B Dose 3			Polio Booster	

Reported vaccination coverage for all the vaccine-preventable diseases have sustained reported levels of more than 90% (Figure 7). Vaccination coverage against measles has improved from a low 34.6% in 1986 to 104.3% in 2004. Similarly in 2004, coverage for completed primary series for DPT3 was 94.2% (62.2% in 1986), 95.2% for Oral Polio (OPV3) compared to 62.2% in 1986 and 93.8% for the third dose of Hepatitis B as opposed to only 86% in 1990. In order to further improve vaccination coverage as per requirements adhering to Quality Assurance

Indicators, coverage of 90% or more has been adopted as the minimum standard in 2000. This is in keeping to the recommendations and strategies of EPI, the Mid-Decade Goals for Children and the Millennium Development Goals.

**Figure 7 : EPI National Vaccination Coverage in Malaysia, 1986-2004**



### Activities and achievements

In the area of childhood vaccine-preventable disease control, Malaysia has achieved significant success from the endemic and epidemic situation as recent as in the 70s and the 80s and has reached a current point where we are at the stage of having either eradicated or on the verge of eliminating or having had significantly reduced most of these diseases. This decade has seen dramatic decline in the incidence rates of the major vaccine-preventable diseases. We have to sustain these successes by adopting innovative strategies.

### *Disease control achievement*

### Problems and constraints

Current threat of the emergence and re-emergence of new and old infectious diseases including those which are vaccine-preventable has required modification of strategies of diseases control. The current phenomenon of globalisation has increased the problem of importation of infectious diseases. Preventive and control measures related to imported infections have constraints of implementation

### *Emergence and re-emergence of vaccine-preventable diseases*

of effective measures and contact follow-up. There is thus a constraint in total disease foci elimination thus causing problems of periodic outbreaks of disease. These are the new challenges which have to be faced in the Region.

### **International technical collaboration**

The WHO Technical Advisory Group (TAG) on the Expanded Programme on Immunisation (EPI) and Poliomyelitis Eradication was established in 1991. Its technical guidance was a critical element of the Western Pacific Region's achievement of certification of poliomyelitis-free status on 29 October 2000. In addition to polio-free status, EPI also delivered other important public health benefits to the Region in the form of drastic reduction in infections due to measles, hepatitis B and neonatal tetanus.

### *Role of Technical Advisory Group (TAG)*

### **Programme performance enhancement**

With the formation of the Infectious Disease Surveillance Unit, much better monitoring mechanism are now in place to anticipate and better prepare measures to cope with the real threats posed by the resurgence of some of the vaccine-preventable diseases. There are already plans to sustain and further improve vaccination coverage especially at high risk locality and community levels. The other areas include :

### *Enhancing performance and capability*

- Newer strategies to improve complete vaccination of high risk population groups.
- Intensification of programme strategies for sustaining polio-free status, neonatal tetanus and measles elimination and significant hepatitis B cases reduction.
- Improving quality of surveillance on identified vaccine-preventable diseases.
- Improving training techniques for prevention and control.
- Continuously review and update protocols and guidelines on control of vaccine-preventable diseases.
- Review current vaccination strategies and deliberate newer approaches to challenges posed by the various vaccine-preventable diseases.
- Introduction of new, safe and cost-effective vaccines.

## Areas to be strengthened

In view of the re-emergence of some these vaccine-preventable in countries within the region and in other parts of the world, regional collaboration in the following areas is essential :

*Regional  
technical  
collaboration*

- Surveillance
- Laboratory capability and resource sharing
- Outbreak rapid response
- Research
- Regular exchange of information
- Human resource training
- Vaccine development and
- Collaboration regional emergency preparedness

## Conclusion

Several areas of collaboration and cooperation between the public and private sectors needs to be further strengthened in view of the newer challenges posed by the rapid changes in vaccine-preventable disease scenario. The existing network of communication and consultation should be ongoing so as to serve as an early warning system to prepare the country of any future outbreaks and to be able respond appropriately. The re-emergence of some of the childhood vaccine-preventable disease has to be collectively addressed by all related parties so as to provide appropriate response with maximum impact.

*Future tasking*

Malaysia has achieved great success in greatly reducing the threat posed by these childhood diseases. However, sustained efforts are required to maintain and build upon these successes by further strengthening vaccination services. Attention needs to be given to increasing coverage especially for underserved, hard-to-reach populations and other identified high risk groups; enhancing vaccine-preventable disease surveillance, including laboratory capacity; assuring vaccination safety and potency (addressing cold chains concerns); improving data quality and using data to improve vaccine-preventable disease programme management and improving vaccine security and financial sustainability.

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# NATIONAL CANCER CONTROL PROGRAMME

## SUMMARY

Cancer is among the top 5 killer disease in Malaysia. The National Cancer Control Program is a comprehensive program initiated by the Government to address the growing problem of cancer in Malaysia. The programme involves government and non-governmental organisations. It focuses on activities to decrease morbidity, mortality and improve quality of life among cancer patients. To achieve the objectives, special emphasis is given to the development and reinforcement of programmes that include prevention of cancer in the healthy population and early detection of cases, improved treatment and better accessibility to palliative care among cancer patients.

## Introduction

Non-communicable diseases (NCD) account for almost 60% of deaths in the world and 46% of the global burden of the disease (World Health Report 2001). In the year 2000, the global burden of cancer was estimated by the WHO/UICC to be 10.1 million new cases excluding non-melanocytic skin cancer (NMSC), 6.2 million cancer deaths and 22.4 million people living with cancer. Therefore in 2000, cancer killed more humans than HIV/AIDS, tuberculosis and malaria combined. This also estimates that 43% of cancer deaths worldwide in 2000 were attributable to tobacco use, excesses in dietary habits and infection. Hence, there is an urgent need for worldwide action in primary prevention of cancer by targeting against tobacco use, unhealthy dietary habits, physical inactivity and alcohol abuse.

Early detection and screening of cancer reduces morbidity and mortality. Accessible and affordable screening and diagnostic facilities in cancer detection and treatment should be available to all if not most of the population. Successful cancer treatment increasingly involves multidisciplinary management of the cancer patients using multiple treatment modalities namely surgery, anti-cancer drugs and radiotherapy. Optimal individual treatment plans are designed using evidence based guidelines and protocols.

*Global burden of cancer*

*Early detection of cancer is essential*

## Situational analysis

Although the MOH is responsible for the nation's health, it is not the sole provider of medical and health services in the country. Other agencies within the government complement the role of the MOH. The private sector also contributes to this role and these include the NGOs and support from philanthropist. Medical and health care services are delivered by the Ministry of Health through 117 hospitals, 864 primary healthcare centres and over 1,847 community/rural clinics which are distributed throughout the country. The majority of Malaysians benefit from the highly subsidized medical and health care services provided by the government, while the private sector operates on a fee-for-service basis is found to be too costly to a large proportion of the local population. Hence, at present the provision of health care is dominantly funded through taxation. With time, there would necessarily be upward changes in prices as well as user demand and utilization. Realizing this phenomenon, the Health Ministry has turned to health promotion and disease prevention strategies, which is now rapidly gaining importance.

*Ministry of Health, a major healthcare provider*

## The cancer situation

Cancer remained as one of the five principal causes of national mortality for the past 20 years. In terms of absolute number, annual trends show escalation of cancer cases and similar trends are also seen of annual cancer mortality. Cancer contributed 9.34% of all deaths in 2003 compared to 7.37% in 1975. Based on government hospital statistics, the most commonly diagnosed cancers affecting males are lungs, nasopharynx, mouth, stomach and liver, while amongst females are breast, cervix, lung and stomach. About 60% to 80% of cancers are diagnosed at the late stages of the disease.

*Cancer magnitude*

In Malaysia, numerous cancer prevention and control activities including screening for early detection of cases have been carried out on a regular basis. Facilities for cancer treatment including radiotherapy have improved. Activities and services are carried out quite independently by various agencies under the government as well as by the private sectors including not for profit non-governmental organizations. Services are mainly concentrated at the secondary prevention level. There is a need to increase activities and services targeted at primary prevention, rehabilitation and palliative care. Currently cancer prevention is progressively given due priority in the national cancer program.

*Cancer services*

## Health services at various levels of prevention

The government has always been and will continue to be the main body responsible for carrying out activities in the primary prevention of cancer. These include health education and promotion, related vaccination programmes, enforcement of legislation in relation to cancer risk, and the development of policies positive to human health. The Public Health Department of the MOH in providing the leadership and thrust for the conservation of health in the country and is accountable for most of the cancer prevention and control activities. The Public Health Department consists of the Disease Control Division, Primary Health & Family Development Division, Health Division and the Food Safety and Quality Division.

*Primary  
prevention  
programme*

Health education activities countering cancer risk factors, namely tobacco addiction, food excesses, alcohol abuse, occupational exposure to carcinogens, betel quid consumption and high risk sexual habits, are continually being carried out through the mass media and other channels. These health promotional activities were intensified in 1995, in conjunction with the Healthy Lifestyle Campaign, where the focus is on cancer prevention. In this campaign, the MOH joined hands with other government agencies, NGOs as well as the private sectors. Since 2003, the Healthy Lifestyle Campaigns emphasised on 4 main elements of lifestyle that will address the above risk factors, and these are :

*Health  
promotion and  
education*

- Not smoking
- Healthy eating
- Physical exercising and
- Stress management

Hepatitis B vaccination for newborns became part of the country's Expanded Programme of Immunization in 1989 and is an important long term strategy for the prevention of hepatoma.

*Hepatitis B  
vaccination  
programme*

Legislation to regulate tobacco use, food safety, drugs and chemicals have been in place since 1993, 1985, 1984 and 1952 respectively. Besides the laws vested with the Ministry of Health, other legal measures related to cancer control are within the jurisdiction of the Ministry of Human Resource, Ministry of Science, Technology and Environment, Ministry of Housing and Local Government, as well as the Ministry of Agriculture.

*Tobacco  
control*

Screening services for early detection of cancer are only available for cervical and breast cancers. The Primary Health and Family Development Division of the MOH, together with the National Population and Family Development Board of the Ministry of National Unity and Social Development are major providers of mass cytology screening, particularly for family planning acceptors. Pap smears are also available at private clinics found all over the country.

*Secondary prevention*

Surgery and chemotherapy are presently available at major hospitals in Kuala Lumpur, all state capitals and some large hospitals in the districts. These services are conducted by general surgeons and general physicians in consultation with the oncologist. However, facility for radiotherapy and oncology services is limited. Currently there are 19 centres providing radiotherapy and oncology services of which 5 are government and 14 private. Of the government centres three are under the Ministry of Health. They are located at Hospital Kuala Lumpur, Sarawak General Hospital in Kuching and at Hospital Penang. However, Hospital Penang does not have its own radiotherapy equipment while the facilities at Hospital Kuala Lumpur and at Sarawak General Hospital Kuching require extensive upgrading.

*Cancer treatment*

Palliative care and rehabilitation facilities are available at government hospitals, as an extended service following radiotherapy, radical surgery and chemotherapy and are provided conjointly by oncology, surgical and medical services. Currently however, the Ministry of Health does not provide any form of hospice, domiciliary service or institutional care for palliation. Non-governmental organizations namely Hospice Malaysia and the National Cancer Society of Malaysia (Penang & Sabah branches) provide palliative care services for cancer patients. They are home based programmes, not operational 24 hours and are totally run by volunteer nurses, doctors and lay persons along with 1 or 2 nurses as regular staff. These services are dependent upon public hospitals to manage when care is no longer possible at home. Efforts are currently on the way to establish more hospice programmes in towns of all states in Malaysia.

*Palliative care service*

### **The development of a cancer control programme**

The control of cancer requires the application of scientific knowledge. It is now universally recognised that over one third of cancers are preventable, one third are potentially curable, provided they are diagnosed early in their course, and for the majority of incurable patients the quality of life can be improved by palliative care. Progress

in new cancer treatment has been generally slow, although aided by early detection programmes and improved diagnostic tool. Although treatment has played an important role in keeping cancer deaths in check. However, from the preventive standpoint, it is worth noting that if tobacco attributed lung cancer rates were removed from consideration there would be a decline of about 10% to 15% in total cancer mortality. Thus there is a need for cost-effective intervention programme to address this challenge, and it is imperative that prevention assumes the highest priority in the future of cancer control program.

Although most aspects of cancer control activities are already present in this country, they are carried out in isolation and not coordinated.

### **The Malaysian National Cancer Control Programme (NCCP)**

It is envisaged that by the year 2020, cancer will no longer be a public health problem in Malaysia, where all preventable cancers are effectively prevented; all potentially curable cancers are detected at the early stage and competently treated, thus followed by total recovery, while all terminally ill cancer patients appreciate comfortable pain free life.

#### *The vision*

It is the mission of the NCCP to ensure that all Malaysians must have a factual understanding of cancers; recognize its causes, early signs and symptoms, treatment and possible outcomes. Individuals will be empowered to choose positive lifestyles with regard to tobacco, exercise, diet and other related personal habits. All cancer deaths among the members of the caring Malaysian society will occur within a supportive environment which includes physical, social and psychological environment. Cost-effective, efficient and acceptable facilities and services for prevention and management of all cancers will be made available and accessible. Cooperation and resources from all relevant Government agencies, private sectors, non-government organizations and the community, undertaken as an effective partnership will be harnessed to maximize cancer control efforts.

#### *The mission*

### **Objectives of NCCP**

The general objective of NCCP is to reduce the negative impact of cancer, by decreasing cancer morbidity, mortality and to improve quality of life of cancer patients.

#### *Objectives of NCCP*

There are 7 specific objectives of the NCCP as follow :

- Decrease the prevalence of identified cancer risks factors;
- Reduce the incidence and prevalence of cancer;
- Increase down-staging of likely curable cancers;
- Reduce cancer mortality;
- Minimize physical and social disabilities resulting from cancer;
- Improve the efficacy of palliative care in the country;
- Improve the quality of life of terminally ill cancer patients with regards to comfort and pain relief.

### Strategies

Development of cancer control measures should be an integral part of a comprehensive National Health Plan. The cancer control policy will enrich the total health effort, and mutually be enhanced by the overall scheme. The NCCP should also be integrated within the existing health care systems involving the hospitals, primary care and public health level. The components of NCCP include primary prevention, screening for early detection of cases, efficient treatment and palliative care. However, the NCCP should be justifiably prepared in view of epidemiological and economical consideration.

### Organization and management

It is most essential to provide strong and effective leadership from an early stage in the establishment of a NCCP. Since ideal leadership qualities may not be found in one person, a team may be the more appropriate solution. Individuals should be sought with the qualifications that equip them to induce changes.

Inter-sectoral collaboration is a crucial requisite for a cost-effective NCCP. In cultivating a communication strategy, a wide range of functional coalition should be established, with representation from relevant stakeholders. Stakeholders with interest in sharing potential responsibilities for various aspects of cancer control services and activities should include agencies from the government and private sectors including not for profit non- governmental organisations involved in providing medical and health related services. International linkages should be strengthened and maintained. Two-way communication channels for information exchange and updates on global cancer situation and control measures must be established. Besides the WHO and other relevant

### *Network and linkages*

international bodies, the NCCP Malaysia should also link-up with authorities of similar programmes in other countries, essentially those who are members of ASEAN.

Based on current situation, the government would still continue to be the principal provider and financial supporter of the NCCP, even though the trend now is moving towards privatization. Most primary prevention strategies and cancer monitoring and surveillance activities will remain to be the prerogative and responsibility of the government. However, secondary prevention, cancer treatment, palliation, training and research, can be a shared obligation. Meanwhile, NGOs must maintain fund raising efforts to improve their pool of accessible reserves.

### *Financing*

### **Area of focus in primary prevention**

The real challenge in controlling cancer is more than a reduction in mortality but rather, in reducing the incidence. It is imperative that for the future health care system of Malaysia, cancer prevention is to assume an even higher priority than it does today. Although it is recognised that the effect on primary prevention will only be seen some 20-30 years later, current expenditure on primary prevention even if high right now, will save on the long run upon national economic burden on the treatment and palliative care of cancer patients.

### *Reducing incidence*

With the growing expectations as aspired within the new public health movement, the most appropriate strategy for the NCCP is through adoption of the Ottawa Charter on Health Promotion (1986) to :

### *Ottawa Charter on Health Promotion*

- Build healthy public policy;
- Create supportive environment;
- Strengthen community action;
- Develop personal skills; and
- Reorient health services.

More data and research are required to monitor and provide new information on behavioural changes affecting reduction in cancer risk in the communities. Health facilities at primary care level need to review their services and promote the 5 areas of concerns mentioned above in educating the people.

### *Behavioural changes*

Public health education should be strengthened by getting teachers, community leaders, youth personas and other public icon to be directly involved in delivering messages on cancer risk factor as part of cancer control and prevention programme. As health promotion is a fundamental activity in any cancer prevention programme, the NCCP will target children preferably from 12-year-olds upwards to initiate preventive activities in schools. Therefore, it is important for school and parent-teachers associations to become active partners in the cancer promotion programme.

### *Public health education*

Tobacco consumption is rapidly becoming a serious public health problem in Malaysia. The NHMS II (1996) reported an overall smoking prevalence of 24.8% among those aged 18 years old and above. The gender-specific smoking prevalence for males and females were 49.2% and 3.5% respectively. Repeated surveys suggest an upward trend in smoking prevalence. The increase in tobacco attributed cancer morbidity and mortality rates correlated with increase morbidity and mortality rates from other tobacco associated diseases.

### *Smoking prevalence*

The Control of Tobacco Products Regulations gazetted in 1993 and amended in September 2004 signifies an important milestone for legislative tobacco control in this country. Currently the final draft of Tobacco Act is well on the way to further intensify and complement the current proposed Framework Convention for Tobacco Control (FCTC). Since Malaysia already ratify the FCTC, a global treaty on control of tobacco products, a secretariat committee headed by Ministry of Health will be formed as prerequisite in implementing the provision stated. Under FCTC, various sub-committees which will strongly emphasize on multisectoral participation shall then assume responsibility on further actions taken under the National Tobacco Control Product.

### *Tobacco control*

The most useful method of combating cancer as well as other afflictions induced by viral infections would be the application of an effective vaccine. Although some estimate that viruses could be responsible for as much as 15% of cancers, at present, only immunization against hepatitis B virus (HBV) is possible. The prevalence of HBV infection in Malaysia is high. Promotion of HBV vaccination for infants became a part of the Expanded Programme of Immunization (EPI) in 1989. The effort to prevent primary liver cancer as well as chronic hepatitis will however only be apparent within a span of 30 years. The current activities of HBV vaccination for infants are monitored by Division of Family Health Development, Ministry of Health Malaysia.

### *Hepatitis B vaccination*

Some cancers known to be associated with diet are cancers of the gastrointestinal tract, lung, endometrium, breast, prostate, kidney and bladder. Among the associations with regard to diet and cancer, the common ones are the natural ingredients of food (examples; dietary fat, nitrites, salt, micronutrients and minerals) and the food contaminants & additives.

### *Diet & cancer*

The Food Act gazetted in 1983 signifies an important strategy in controlling food contaminants and additives in the country. Health education and promotion on healthy diet and physical activity is carried out by MOH through its Nutrition Section. Similar activities are carried out also by Health Education & Communication Centre (HECC) of the MOH through the Healthy Lifestyle Campaigns.

### *Food quality control*

Apart from the toxicity of excessive alcohol intake and the tendency of some individuals to become alcoholics, investigation has disclosed long term damage to the nervous system, liver and other organs. Moreover liver cirrhosis is strongly associated with primary liver cancer. Accumulated evidences have also shown that heavy alcohol drinking increases the risk of cancer in the oral cavity, pharynx, larynx and oesophagus. It has synergistic effect with exposure to tobacco.

### *Alcohol consumption*

Betel quid chewing is by far the most important cause of oral cancer. Betel quid usually consists of the leaf of the betel vine, areca nut, gambler, lime and tobacco. In Malaysia, the habit of betel quid chewing is prevalent amongst the Indian community as well as among certain indigenous groups in Sarawak, Sabah and Peninsular Malaysia. Hence, primary prevention of oral cancer should focus upon modifying the habitual use of betel quid in these target groups. The Oral Health Division of MOH as well as HECC has been actively promoting oral health care through various activities.

### *Betel quid chewing*

Occupational exposure to carcinogens is responsible for 5-10% of cancers. Exposure to wider range of carcinogens has increased through the introduction of new physical and chemical processes in industries. At least 11 industrial processes and 17 chemical groups are evidentially associated with carcinogenicity in human beings.

### *Occupational factors*

Sexual practices and reproductive factors may affect the incidence of a number of cancers. Late age at first birth and nulliparity increases the risk of breast cancer while early age at first intercourse and multiple sexual partners are risks factors for cancer of cervix and AIDS.

### *Sexual and reproductive factors*

Treatment of menopause and post menopausal symptoms by oestrogen produced epidemics of endometrial hyperplasia and increased risk of endometrial cancer, where as the administration of diethyl-stilboestrol for treatment of threatened abortion produces vaginal cancer in female offsprings, during the 1970s. There is good evidence that continued use of oestrogen by post menopausal women and oral contraceptive use for prolong period by young women, increase the risks of breast cancer. Nonetheless, they also reduce the chance of developing endometrial and ovarian cancer thus, the cost-benefit of these combined effects, especially when their other benefits are taken into consideration, justifies their continued use.

### **Area of focus in secondary prevention**

If cancer can be diagnosed early in its course, treatment is generally more effective than when it is advanced. It is essential that the NCCP recognize the limitations and benefits of early diagnosis and screening to avoid “high technology” but poor cost-effective approaches, or to avoid methods which are not achieving the needed coverage of the targeted population. It is important to realize that screening programmes should not be introduced unless there is adequate manpower to perform the tests and enough facilities for diagnosis, treat and follow- up of individuals with abnormal test results. In Malaysia, a high proportion (approx. 80%) of relatively curable cancers presents at advanced stages. Thus, “down-staging” by increasing public awareness, combined with prompt and effective therapy, could have a major impact on the disease. The current screening programmes for cancer of breast, cervical and oral should be strengthen and other possible screening programmes such as for colorectal and hepatitis cancer should be taken into consideration.

*Early  
detection*

### **Tertiary prevention (Treatment)**

Recognizing the need to diagnose cancers early so that prompt and adequate treatment can be instituted, there is a need to establish referral system from primary health clinics to various secondary and tertiary care centres. These will ensure appropriate treatment which is easily accessible, affordable and of high quality. The strategy for treatment and management is to detect cancer as early as possible and initiate treatment in a timely fashion.

*Prompt  
treatment*

Surgery and chemotherapy are presently available at major hospitals in Kuala Lumpur, all state capitals and some large hospitals in the district. These services are conducted by general surgeons and general physicians in consultation with the oncologist. However, the number of oncologists in the country is still very low compared to other countries. Currently, there are only 38 clinical oncologists in Malaysia. A total of 10 clinical oncologists practice at MOH hospitals (6 local and 4 contract doctors), 7 oncologists are attached to the universities and 21 are in the private sector.

*Cancer treatment facilities*

Treatment and management of cancer is a multi-disciplinary effort. A holistic approach in cancer treatment is necessary and should incorporate the eradication of cancer cells as well as the alleviation of pain and subsequent rehabilitation of the patient. The traditional approach of planning for services in MOH has not achieved the desired results as far as oncology and radiotherapy is concerned. To overcome the shortcomings and problems in cancer treatment, the existing partnership between Ministry of Health and private sector through the outsourcing of a certain proportion of the treatment should be continued and the present system of radiotherapy and oncology services should be strengthened and upgraded.

*Partnerships with private sector*

Currently Ministry of Health is in the process of establishing The National Cancer Institute. It is envisaged that the setting up the National Cancer Institute (NCI) with state-of-the-art facilities will enable it to take on the role of a centre of excellence providing leadership in treatment of cancer as well as cancer prevention and promotion, cancer research and manpower training in cancer management and treatment in the country.

*Establishment of a National Cancer Institute*

### **Palliative care**

Palliative care in the country currently is handled mostly by charitable organizations and NGOs. There was suggestion that instead there it should be led by the Ministry of Health, although Cancer Control on the whole are shared responsibility between governmental and non-governmental bodies.

*Development of palliative care service*

With the success of the Palliative Care Unit in Hospital Selayang, the Ministry of Health has approved the development of Palliative Medicine as a clinical specialty of its own. Palliative care services will initially (over the first 2 years of the 9<sup>th</sup> MP) be further developed

*Palliative care as a specialty*

regionally at 6 hospitals, namely at Hospital Penang, Hospital Selayang, Hospital Johor Bahru, Hospital Kota Bahru, Hospital Kuching and Hospital Queen Elizabeth, Kota Kinabalu.

This will be followed by the development of palliative care services in all state hospitals over the next 5-10 years and each hospital should have a separate unit which is managed and administrated by a Palliative Medicine Specialist and doctors trained specifically in the field of palliative medicine with recognised and accredited training. Simultaneously, efforts must be made to establish good homecare services within the public health set up and via networking with NGOs so as to create a seamless palliative care service from hospital to the community and back again. Due recognition of Palliative Medicine can be achieved when there are fully trained and accredited palliative medicine physicians.

### **Conclusion**

Cancer, which is presently the third major cause of medically certified deaths in the country will continue to become more and more prominent. Unless positive steps are taken right now, Malaysia may have to face enormous cancer burden in the future. This is due to the rise in the proportion of the elderly, while rapid industrialization in someway contributes to the increase in the extent of the population's exposure to risks of cancer. Therefore, the National Cancer Control Programme must be implemented for combating this disease and this is by involving partners from the medical and health professionals and the public including NGOs.

# INFECTIOUS DISEASE SURVEILLANCE IN MALAYSIA

## SUMMARY

Infectious disease surveillance in Malaysia was started 1971 with 36 infectious diseases required notification under various laws and regulation and was reduced to 26 when Prevention and Control of Infectious Disease Act gazetted in 1988. At present, there are 5 separate infectious disease surveillance systems exist to monitor occurrence of infectious disease in Malaysia namely mandatory notifiable infectious disease surveillance, clinical based surveillance, laboratory based surveillance, disease surveillance by others agencies and community based surveillance. There are many issue and challenges of infectious disease surveillance system. All of this will help to improve system and make the system work.

## Background

Surveillance is defined by the World Health Organization as the 'continuing scrutiny of all aspects of the occurrence and spread of disease that are pertinent to effective control'. It is characterized by 'methods distinguished by their practicability, uniformity and frequently by their rapidity, rather than complete accuracy'. In operational terms, it is the ongoing systematic collection, analysis and interpretation of infectious disease data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know, so as to take the appropriate action.

### *Definition of surveillance*

In Malaysia, infectious disease surveillance system exists at national, state and district levels. Surveillance systems are crucial to the timely and effective detection and management of outbreaks and in assisting in the effective implementation of national policies. The national surveillance system combines some of the data collected from State to provide an overview at a national level. Specific functions of the national surveillance system include :

### *Infectious disease surveillance system in Malaysia*

- detection and management of outbreaks affecting more than one jurisdiction;
- monitoring of the need for and impact of national control programs;

- guidance of national policy development;
- resources allocation; and
- description of the epidemiology of rare diseases.

The article describes the types and mechanism of surveillance systems for the infectious disease control in Malaysia.

## History

Currently infectious diseases that are designated as *notifiable* under the *Prevention and Control of Infectious Disease Act 1988* (PCID) requires mandatory notification as in schedule 1 and 2 of the Act (**Figure 1**).

*Notification of infectious diseases*

Before PCID Act was gazette in 1989, various laws and regulations were used such as the '*Quarantine Enactment dan Prevention of Disease Enactment*' for Alliance States, '*Quarantine and Prevention of Disease Ordinance 1939*' for state of Sabah and Sarawak and '*Quarantine and Prevention of Disease Enactment*' for states of Kelantan, Johor, Terengganu, Kedah dan Perlis.

*State Laws before PCID*

There were 36 types of infectious disease that require notification. When PCID Act was gazette, the number was reduced to 26. The ten diseases dropped were anthrax, meningococcal meningitis, chickenpox, filariasis, leptospiral infections, mumps, ophthalmia neonatorum, puerperal septic abortion, trachoma and yaws.

*List of notifiable infectious disease*

Although Disease Control Programme in the Ministry of Health began in 1961, surveillance of infectious disease was only implemented in 1971 when the Epidemiology Unit was established under the Health Services Division.

*Surveillance activity began in 19*

## Type of surveillance systems

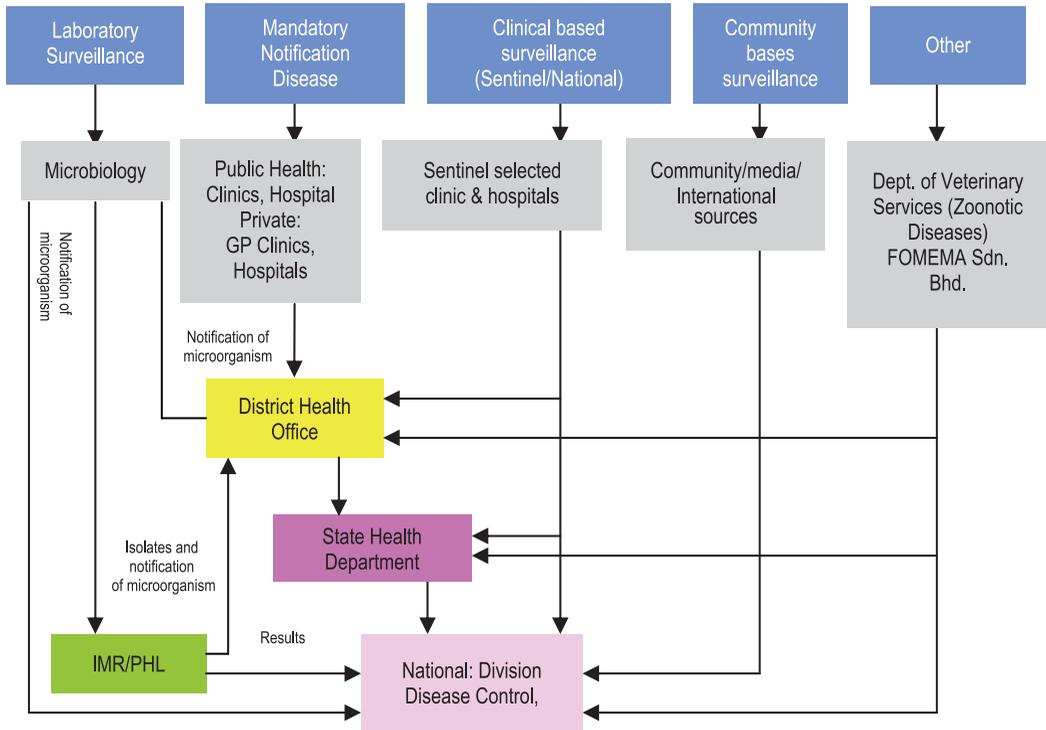
At present, there are five types of surveillance systems implemented in Malaysia for monitoring of infectious disease occurrence. The types and flow of surveillance data and information of each system are shown in **Figure 2**.

**Figure 1 : Prevention and Control of Infectious Disease Act 1988**

FIRST SCHEDULE (Section 2)		
INFECTIOUS DISEASE - Part 1		
1.	Whooping Cough	#
2.	Measles	#
3.	Chancroid	
4.	Dengue Fever and Dengue Haemorrhagic	*
5.	Yellow Fever	*
6.	Diphtheria	*
7.	Dysentery (All types)	#
7A.	Ebola	
8.	Gonococcal Infection (All types)	#
9.	Food Poisoning	*
10.	Cholera	*
11.	Leprosy	#
12.	Malaria	#
12A.	Myocarditis	
13.	Plague	*
14.	Poliomyelitis (Acute)	*
15.	Rabies	*
16.	Relapsing Fever	#
17.	Syphilis (All types)	#
18.	Tetanus (All types)	#
19.	Typhoid and others Salmonoloses	#
20.	Typhus and others Rickettsioses	#
21.	Tuberculosis (All types)	#
22.	Viral Encephalitis	#
23.	Viral Hepatitis	#
24.	Any	#
PART 11		
	Human Immunodeficiency Virus Infection (All types)	#

Note : (\*) - Notification via telephone and follow by written notification (Within 24 hours)  
 (#) - Written notification within one week after diagnosis

**Figure 2 : Types of Surveillance Systems and Mechanism in Malaysia**



Note: IMR - Institute Medical Research  
PHL - Public Health Laboratory

**Mandatory notifiable infectious disease surveillance**

The mandatory notifiable infectious disease surveillance system requires the mandatory notification of 26 infectious diseases under the schedule 1 and 2 of the Prevention and Control of Infectious Disease Act 1988 as shown below. This list is reviewed from time to time. Starting from January 2005, reporting of infectious disease was done electronically using the system called Communicable Disease Control Information System (CDCIS). Before this, reporting was done manually using a prescribed notification form as provided for under the Prevention and Control of Infectious Disease Regulation (notification form) 1993.

*Mandatory notifiable infectious disease*

**Clinical based surveillance**

This system complements the mandatory notifiable disease surveillance system. It is based on syndromic approach to diagnosis for specific infections. The specific infection such as acute flaccid paralysis surveillance is geared for detection of flaccid paralysis of

*Syndromic notification*

recent onset in children under age 15 years (and any suspected poliomyelitis case in person of any age), with prompt virology testing to disprove or confirm poliovirus infection and acute gastroenteritis infection is for early warning or detection of food and water borne disease outbreak. A more comprehensive syndromic based surveillance has been introduced in 2003. Currently, there are 5 conditions notified under the syndromic approach as follows :

- Acute jaundice syndrome
- Acute neurological syndrome
- Acute respiratory syndrome
- Acute dermatological syndrome
- Acute haemorrhagic fever syndrome

### Laboratory based surveillance

Laboratory based surveillance system which monitors the infectious disease agents were introduced in August 2002. This system entails the reporting of certain micro-organisms isolated in all public/private laboratories in Malaysia to the relevant health authorities. Six types of bacteria viz. *V.cholerae*, *H.influenza B*, *Salmonella spp.*, *S typhi/paratyphi*, and *N.meningitides* are being prioritised to be monitored by the participating microbiology laboratories from the Ministry of Health.

*Surveillance of infectious disease agents*

### Disease surveillance by others agencies

This is a surveillance of certain infectious disease that contributes by others agencies, among them is *FOMEMA Sdn. Bhd*, a private company responsible for the screening of specific infectious diseases on foreign workers brought into the country, and reporting them to the Ministry of Health. The Department of Veterinary Services carries out zoonotic disease surveillance in animals, and reports any unusual occurrence to the Ministry of Health as listed below :

*Surveillance by other agencies*

- Rabies
- Nipah Virus Infection
- Avian Influenza
- Japanese Encephalitis
- Vancomycin Resistant Enterococcus
- Bovine Tuberculosis
- Bovine Spongiform Encephalopathy
- Brucellosis

- Anthrax Infection
- Toxoplasmosis
- Leptospirosis
- Bovine Spongiform Encephalopathy

### Community based surveillance

Community based surveillance is the monitoring of rumours/reports on infectious disease from the community and the media (print/electronic) both nationally and international. All rumours, press and media reports are promptly verified at the relevant level to confirm the existent of infectious disease as rumoured or reported.

*Rumour surveillance*

### Issues and challenges

#### *Emerging threats*

There is a need to improve surveillance system in order to recognize emerging threats, both in the community and in hospitals, in a timely manner. The laboratory arm of surveillance must be complemented by hospital and primary care components. More training is needed at all levels - this includes continual professional development for the infectious disease specialists and medical microbiologists.

*Emerging threats*

#### *Coordination*

The contribution and role of general practitioners, infection specialists, microbiology laboratories and public health specialists/agencies to response systems should be defined as clearly as possible and should be either empirically based or derived from scenario-guided. The coordination is factor for success of surveillance systems. This is a challenge to Ministry of Health to play their role as coordinator for the success of infectious disease surveillance system in this country.

*Role of various practitioners*

#### *The role of communications*

One reason a surveillance system may not function at its optimal level is that the people who manage the system is not enough to provide the required information. Communication and efficient flow of essential information is important at all levels.

*Communication and flow of information*

### *Surveillance system evaluation*

Surveillance system allows for timely dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality. Data generated by a public health surveillance system can also be used for program planning and evaluation, and formulating research hypotheses. Therefore surveillance systems should be evaluated periodically, to ensure they are relevant, useful, effective and efficiently run.

*System  
evaluation*

### *Early warning system*

It is often difficult to detect warnings signals on infectious disease outbreaks from raw surveillance data. Thus, reporting of infectious disease must timely and notification data must analyzed in depth for it to function as early warning system to detect outbreaks and to initiate preventive measures. To do this, an efficient, effective and sensitive system is needed. Well trained and educate personnel are needed while use of new technologies such as electronic reporting, geographical information systems and telephone hot-line systems can help to improve the system for early warning.

*Early warning  
system*

### **Conclusion**

Disease surveillance systems evolve in response to changing disease epidemiology and needs of the public health community. In order to meet those needs, a systematic and organized approach to planning, developing, implanting and maintaining surveillance systems is imperative.

The success of a diseases surveillance system is dependent on the quality of the information entered into the system and on the manner of analysis, reporting and dissemination of the information.

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# ENSURING FOOD QUALITY AND SAFETY THROUGH FOOD LABELLING

## SUMMARY

Most food regulations require that every pre-packaged food carry label containing information or particulars about the food. The Government mandates labelling requirements in an effort to ensure meaningful information is provided for the public to make informed choices in food selection. Other reasons include protection of the public against fraud and deception and the promotion of healthy and safe food. As consumers become more knowledgeable about diet and health, they consciously look for nutritious products that fit their healthy lifestyle plan. Consumers want food products labelled with clear meaningful information. Naturally, they make their choices based on the amount of information available to them. They deserve their right to be informed, and to be able to make choices. Nutrition labelling on food packaging provides nutrition information at the point-of-sale. Nutrition labelling enables companies to emphasize the nutritional properties of their products and guide consumers in making better food choices.

## Introduction

The Food Safety and Quality Division of Ministry of Health is the central agency responsible for the food safety programme in Malaysia. The objective of Food Safety and Quality programme is to protect the public against health hazards and fraud, as well as to promote the preparation, handling, distribution, sale and use of food and consumption of safe and quality food. It is also responsible for assuring that foods sold in Malaysia are wholesome and properly labelled. The Food Act 1983 and Food Regulations 1985 are the federal laws governing food products consumed in the country, either produced domestically or imported.

*Food safety programme in Malaysia*

## Importance and purpose of food label

It was estimated that Malaysians spent about RM33 billion on foods in 2001 and processed food accounted for about 32% of the total consumer's expenditure on food. In the coming years, more and more companies will be involved in the processing and packaging of foods. Labelling of foods with catalogue on beautifully designed

packages will be an important tool used by food manufacturers to compete and attract the attention of the growing population towards their products. While the government views this in a positive light, the government also has a social responsibility to protect consumers.

A food label refers to any information given on a food package. It is used by food manufacturers to provide information to assist consumer's choice, to highlight nutritional advantages of their product and to differentiate their product from competitors. This information must be clearly presented in a legible format. The guiding principle is to ensure compliance to the Food Act 1983 and Food Regulations 1985 which require certain essential information to be provided on labels of packaged foods, based on the guiding principles that food are not labelled in a manner that is confusing, false, misleading or deceptive or is likely to create an erroneous impression regarding its character.

### *Legislative requirement*

The objective is to ensure the wholesomeness of food products and to enable the consumer to make an informed choice. Food labelling will make it possible for authorized officers to determine the source of the product in cases of food contamination and food poisoning for product recall. It can also prohibit fraud through misleading labelling by food manufacturers. The food industries also have the responsibility to ensure that the information on the label is factual, truthful and accurate.

The purpose of labelling is to convey information to consumers accurately and clearly, but never to mislead them. The law requires food to be labelled in a manner that serves as an immediate and important source of information about the nature of the particular food purchased. Food labelling is important to all of us consumers as well as to stakeholders in the food industry. The food manufactures or packers should understand the purpose of labelling and its consequence on the potential consumers. Likewise the consumers have the right to know and understand what is on the label in relation to the actual product in the package. Thus information on the label must be in a format that is easily understood by the consumers or target groups. In other words, the manufacturer and the consumer must be able to communicate effectively through food labelling.

### *Purpose of food labelling*

## Codex guidelines on label

The Codex Alimentarius Commission (CAC) commonly referred to simply as 'Codex' is an inter-governmental body created in 1963 to develop international food standards, codes of practice, guidelines and recommendations under the Joint FAO (Food and Agriculture Organisation of the United Nations) / WHO (World Health Organisation) Food Standards Programme.

*Food standards*

The purpose of Codex Alimentarius Commission is to protect the health of consumers, ensure fair practices in the food trade, and promote coordination of all food standards work undertaken by governmental and non-governmental organizations and to facilitate international trade. The Codex Committee on Food labelling is responsible for general text on labelling. Texts nutrition labelling issues are covered by Guidelines on Nutrition Labelling and the Guidelines for Use of Nutrition Claims. The guidelines on Nutrition labelling are based on the principle that no food should be described or presented in a manner that is false, misleading or deceptive for the consumer and that any claims made should be substantiated. Being signatory of the World Trade Organization (WTO) in term of Technical Barrier to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS) Agreements, Malaysia is working seriously at harmonizing its food legislation to be in line with Codex Alimentarius requirements and standards, to facilitate international trade. Malaysia is constantly revising the food laws, regulations and standards so as to be in line with current needs as well as with international requirements

*Purpose of  
Codex*

## Nutrition labelling regulations

Food labelling in Malaysia has undergone significant changes in recent years. As society becomes more knowledgeable and affluent, Malaysian consumers will also be demanding for more information, not only on the nutritional value of foods, but also on ingredients to avoid for various reasons including health and personal nutritional preferences. Today there is increasing concern about maintaining good health and preventing disease through lifestyle modifications. Consumers have the right to informed choices when purchasing food. A balanced diet is a significant element in healthy lifestyle. Nutrition labelling can be seen as an important and easily accessible nutrition education tool for consumer.

*Tool for  
nutrition  
education*

Nutrition labelling regulations have been either voluntary or mandatory in several countries such as United States of America, Australia, Singapore and Thailand. Recognising that nutrition labelling can benefit both the food industries and consumers, the Ministry of Health Malaysia has amended the Food Regulations to include mandatory requirements for nutrition labelling and nutrition claims in 2003. This move was in response to demands from various sectors including health professionals, the food industry and consumers, to incorporate more nutrition information on food labels. The amended nutrition labelling regulations are based on Codex, taking into consideration comments from the industries and consumers.

*Consumer protection*

The regulations cover two main areas. Firstly, the regulations require food industries to label their packaged food products by declaring the energy values, carbohydrate, protein and fat contents for certain common food groups consumed by Malaysians, like bread, cereal and milk. Declaration on vitamins and minerals may also be included if they are present in significant amounts. Besides nutrition labelling requirements, the amended regulations also provide clear requirements on nutrition claims for foods. The regulations lay down provisions pertaining to various nutrient claims. Fraudulent and unsubstantiated claims are prohibited. Four major types of nutrient claims are covered, namely nutrient content claim, nutrient comparative claims, nutrient function claim, and claim for enrichment and fortification.

The primary objective of nutrition labelling is to describe the nutritional qualities of a food product factually and informatively, thereby assisting the consumer in making better food choices when planning their daily meals. Nutrition labelling of food is therefore one of the strategies adopted to assist consumers in adopting healthy dietary practices. Nutrition labelling is equally important to the food industry as labelling provides a means for food manufacturers and retailers to become more aware of the nutritional properties of their products and be encouraged to emphasize these properties to consumers. Food manufacturers have a social responsibility to contribute positively to healthy lifestyle programmes of health authorities. Nutrition labelling provides point-of-sale information intended to help consumers make informed food choices and plan their daily meals.

*Strategy to healthy dietary practices*

## Conclusion

Food safety involves many aspects of scientific, technological, nutritional and legislative principles. But one which can influence the consumer directly is food labelling. Labelling is an important aspect of consumer protection and is one of the areas covered by objectives of Food Safety and Quality Division to protect consumers' health. The fact remains that consumers need more information, and this information should be accurate and relevant so that they can make informed choices. All foods can be considered 'healthful' but prudent selection of 'healthful' foods will contribute most to a well-balanced total dietary approach to health. The ultimate goal of nutrition labelling is to provide concise, understandable and informative labels that will enable consumers to make wise choices.

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# WATER QUALITY AND HEALTH

## SUMMARY

The importance of safe drinking water for health and development has been reflected in the outcomes of many international policy forums, from the International Conference on Primary Health Care (Alma Ata, 1978) to the World Summit on Sustainable Development (Johannesburg, 2002). Under the Millennium Development Goals, countries have committed themselves to achieving inter-related targets for sustainable access to safe drinking water, basic sanitation and reduction in child mortality by 2015<sup>1</sup>. This strategy will lead to better health protection throughout the world. Since the inception of the Ministry of Health National Drinking Water Quality Surveillance Programme in 1983, drinking water quality has improved based on measurements of acute and chronic health parameters.

## Introduction

**W**ater has profound influence on human health. Our body needs water for digestion, absorption, and circulation, transporting nutrients, building tissues, carrying waste and maintaining body temperature. The importance of safe drinking water for health and development has been reflected in the outcomes of many international policy forums, from the International Conference on Primary Health Care (Alma Ata, 1978) to the World Summit on Sustainable Development (Johannesburg, 2002). Under the Millennium Development Goals, countries have committed themselves to achieving inter-related targets for sustainable access to safe drinking water, basic sanitation and reduction in child mortality by 2015<sup>1</sup>. This strategy will lead to better protection for health throughout the world.

*Water and health*

Poor sanitation, industrialisation, land clearance and rapid development without due protection of the environment are found to cause deterioration in the quality of water sources. Poor water quality can cause outbreaks of water-borne infectious diseases and may lead to serious epidemics. It is estimated that about 1.8 million people worldwide die every year from water-related diseases and of these, 90% are children under 5 years of age, mostly from developing countries.

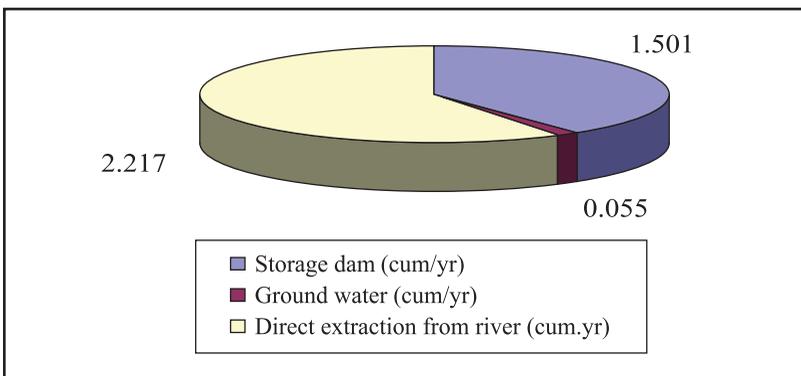
*Water quality and infectious diseases*

## Raw water sources for drinking

In Malaysia, the national average daily consumption of water is 287 litres/capita/day<sup>1</sup>, inclusive of other usage such as bathing, washing and cooking, as well as wastage due to leaking pipes.

Surface water remains the main source of raw water in the country, followed by groundwater and rainwater. According to the Malaysian Water Industry Report 2004, about 98% of Malaysia's potable water supplies are estimated to be derived from surface water (Figure 1).

**Figure 1 : Raw Water Sources for Drinking Water in Malaysia, 2004**



Source : The Malaysian Water Association (MWA) Malaysian Water Industry Guide, 2004

To date, water catchments are not gazetted as protected areas. They are therefore, very susceptible to pollution from industrialisation, and urbanisation. Large scale land clearance for industrial, housing, agriculture, road networks and other developments can also result in pollution of water sources. Added to these problems is the widespread use of pesticides in agricultural schemes located within water catchments. Contamination of water sources from solid waste disposal sites has become increasingly prominent, especially in urban states that generate a lot of waste.

*Problems of raw water quality control*

Effluents from untreated sewage and discharges also contribute to contamination of the raw water supply. The health risk related to water contamination is demonstrated by past outbreaks of water borne-diseases as follows :

*Local outbreaks of water-borne diseases*

- 2,600 cases of gastroenteritis in Seremban (1982)
- 81 cases of infectious hepatitis in Raub (1987)

- 940 cases of infectious hepatitis in Kota Belud (1988)
- 300 cases of typhoid fever in Johor Bahru (1990)
- 1,278 cases of cholera mostly in Penang (1996)

### The National Drinking Water Quality Surveillance Programme (NDWQSP)

To ensure the safety and acceptability of drinking water supplied to consumers, the Ministry of Health (MOH) launched the National Drinking Water Quality Surveillance Programme (NDWQSP) in 1983 with principal objective of NDWQSP is to raise the standard of health of the people by ensuring the safety and acceptability of the drinking water provided to the consumer.

This surveillance programme covers all public water supply systems in the country which includes :

- urban public water supply
- rural public water supply
- privately owned public water supply

The programme consists of four elements, namely: monitoring, sanitary survey, data processing and evaluation, remedial action and institutional examination. In the monitoring activity, water samples are taken at the intake point, treatment plant outlet, and at designated sampling points along the distribution system for analysis. Water sampling is carried out by environmental health assistant officers from the district health departments. The frequency of such tests range from weekly to monthly and quarterly as stipulated in National Standard for Drinking Water Quality (**Appendix 1**).

The monitoring programme covers 3 main aspects of water quality, namely physical, chemical and bacteriological tests. The tests covered are as follows :

Tests	Parameters
Physical	Turbidity, pH, colour, Total Dissolve solids
Chemical	Residual Chlorine(RC), Hardness, Chemical Oxygen Demand (COD), Biological Oxygen Demand(BOD), ammonia, flouride and heavy metals, and others when necessary
Bacteriological	Total coliform and E-coli

*Water quality*

*Surveillance Programme*

The water quality is compared against the *National Standard for Drinking Water Quality (NSDWQ)* which is based on standards from the World Health Organisation (WHO) guidelines (**Appendix 1**). These standards are revised from time to time based on the latest WHO guidelines<sup>3</sup>.

To further ensure the safety and quality of water supplied to the consumer, sanitary survey is conducted yearly. This survey is carried out at the catchments area, treatment plant and distribution systems to identify sources of pollution that could present a health hazard to the consuming public.

### **Agencies involved in ensuring water quality**

Water is a state matter and many agencies are involved in ensuring clean and safe water supply to the public. This varies from state to state. Control of pollution of water sources are governed by the Department of Environment, while treatment and supply of water in some states like Sarawak are still under the Public Works Department (*Jabatan Kerja Raya, JKR*). In Negeri Sembilan, it is the Water Supply Department (*Jabatan Bekalan Air, JBA*) while in Penang and Melaka, they are managed by Water Boards. In Selangor, treatment of raw water is by several private consortiums while another private company, SYABAS (*Syarikat Bekalan Air Selangor*) is responsible for the supply of treated water to the public.

Although there is a national standard for drinking water quality in Malaysia, there are no laws regulating these standards currently. However, for water treatment and supplies involving privatized bodies, the standards are contractual in nature subjected to terms and conditions of the contract with the state government.

### **Raw water quality**

Total coliform bacteria (excluding *E.coli*) occur in both sewage and natural waters. Some of these bacteria are excreted in the faeces of humans and animals, but many coliforms are heterotrophic and able to multiply in water and soil environments.

### **Microbiological contaminants**

In 2004, a total of 18,882 raw water samples were analysed under the monitoring programme for total *coliform*. It was found that 3,281 (17.4%) of the samples having total coliform above the standard sets in National Standards for Drinking Water Quality which is at

5000MPN\*/100ml. The details breakdown by each states as in **Appendix 2**.

\*MPN: Most Probable Number

Chemical oxygen demand (COD) is an indicator for contamination of raw water by oxidized organic and inorganic compounds. COD determines the amount of organic pollutants found in surface water. As indicated in Appendix 2 out of 3200 raw water samples analysed by MOH it was found that 812(25.38%) of these samples were above - permissible levels of COD which is at 10mg/l.

*Organic and inorganic compound*

The presence of higher-than-natural levels of ammonia in raw water is an important indicator of organic contaminant. High ammonia imparts taste and odour problems, as well as decreased chlorine disinfection efficiency during water treatment. Of 15,533 raw water samples tested by MOH in 2004, 170 (1.1%) were found with above-permissible levels of ammonia. Effective aeration and filtration processes are needed during water treatment processes to overcome this problem. The details breakdown by each states as in **Appendix 2**.

### **Treated water quality**

#### *Microbiological quality*

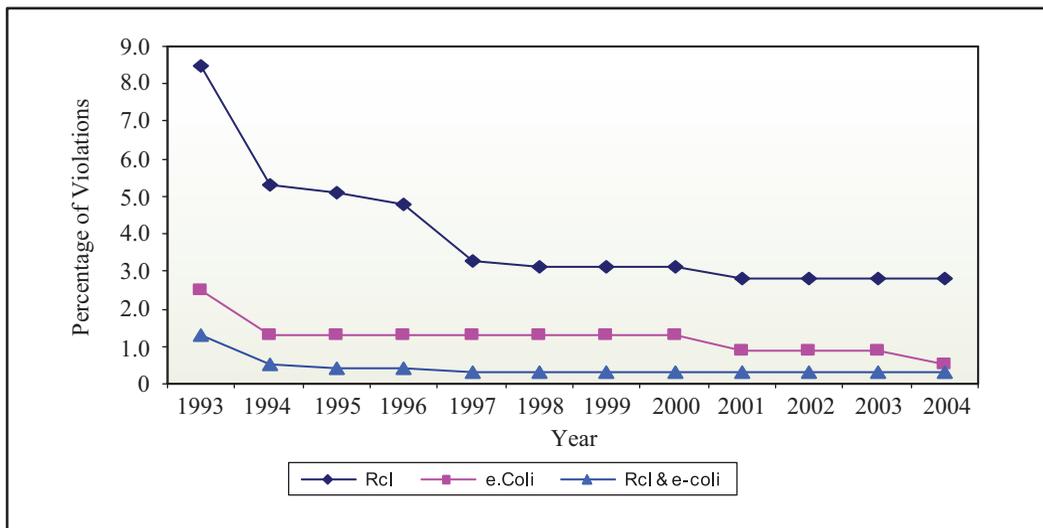
As for treated water, infectious diseases caused by pathogens are the most common and widespread health risk associated with drinking water<sup>2</sup>. There are four types of waterborne pathogens - bacteria, viruses, protozoa and helminthes. These pathogens cause diseases such as cholera, typhoid, dysentery, hepatitis, giardiasis, guinea worm and schistomomiasis. *Coliform* bacteria are common in the environment and are generally not harmful in themselves.

*Microbiological contaminants*

In 2004, more than 90,000 treated water samples from 465 water courses were tested for total *coliform* and *E. coli* nationwide. Of these, 3.4% of the samples tested violated total *coliform* standard (not present in 100 ml water) while there were 0.8% violation for *E. coli* (not present in 100 ml water). (**Appendix 3**).

Over the years, microbiological contaminants (total *coliform* and *E.coli*) in water quality has shown some reduction (**Figure 2**). However, relationship between water quality and water borne diseases could not be conclusively established.

**Figure 2 : Summary of Residual Chlorine, E.coli and Combined Residual Chlorine and E.coli Violations in Malaysia, 1993-2004**



Source : National Drinking Water Quality Surveillance Programme, MOH

### **Residual chlorine**

Chlorine is widely used as a disinfection and oxidation agent in drinking water. It effectively inactivates a wide range of waterborne pathogens as long as it maintains residual level in the water throughout the distribution systems. The minimum level for residual chlorine in drinking water as indicated in the National Drinking Water Quality Guideline (NDWQG) is 0.2 mg/l.

### **Chlorine**

In 2004, of 90,677 treated water samples analysed, 3.3% had chlorine levels below 0.2 mg/l. (**Appendix 3**). These violations were mostly due to shortage of chlorine and electrical supply, especially in remote areas. Relevant water purveyors have been advised to overcome these problems.

### **Combine violation**

Combined violations of residual chlorine and *E. coli* indicate that the treated water is not protected from waterborne pathogens. This violation may be due to improper water treatment processes such as insufficient contact time. In 2004, of 86,884 treated water samples analysed, 0.4% had combined violation. (**Appendix 3**).

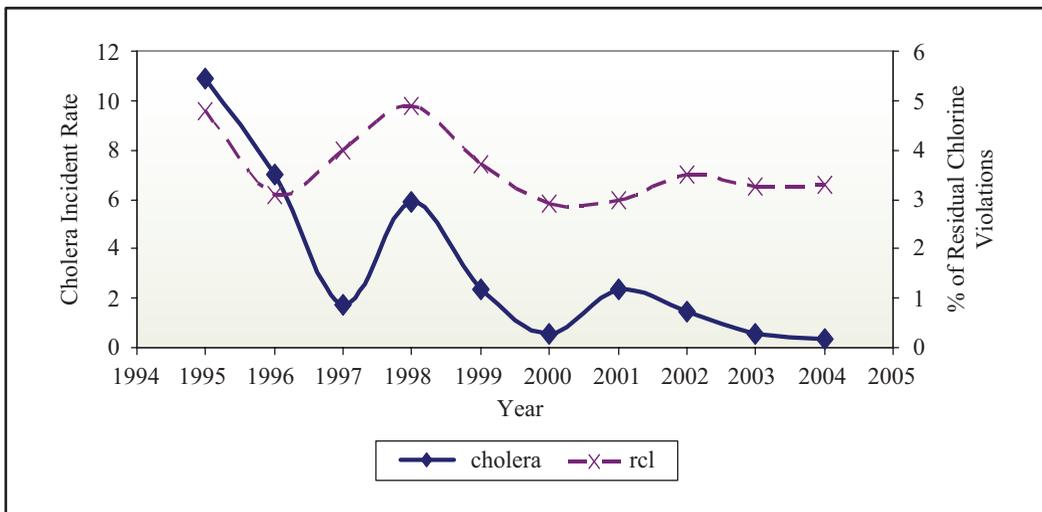
### **Combined Chlorine and E. coli Violations**

## Water quality and health

Cholera is caused by the bacterium *vibrio cholerae* is transmitted via the faecal-oral route; through handling food with contaminated hands, or through eating food or drinking water contaminated by faeces of infected persons. This bacterium has low resistance to chlorine. It has been found that there is a correlation between the numbers of cholera incident rates and residual chlorine violations in drinking water (Figure 3).

### Chlorine-cholera correlation

**Figure 3 : Relationship between Cholera Incident Rate per 100,000 Population and Residual Chlorine Violation in Malaysia, 1995-2004**



Source : Center of Disease Control, MOH  
National Drinking Water Quality Surveillance Programme, MOH

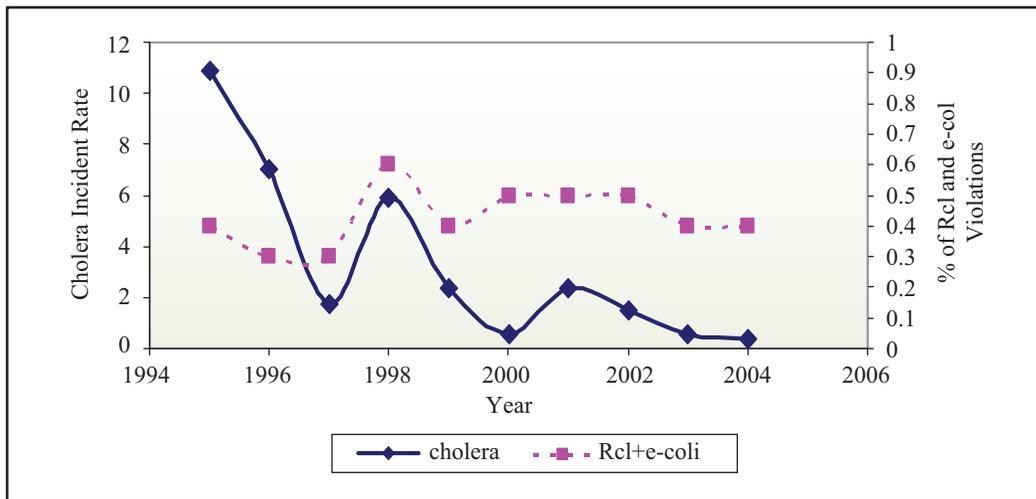
There is also a correlation between combined *E. coli* and residual chlorine violation and cholera incident rates in drinking water (Figure 4).

### Chemical contamination

Chemical contamination of drinking water also have effects on health. Generally, chemical contaminants have chronic health effects such as nitrate, which has been linked to methaemoglobinemia in infants or 'blue baby syndrome', arsenic that have been related to inflamed eyes, skin lesions and various types of cancer. There is also heavy metal contamination to contend with, such as mercury causing Minamata (sometimes called madcat disease in Japan), cadmium causing a painful disease the Japanese call 'Itai-Itai' leading to destruction of bone structures of its victims.

### Chemical contaminants

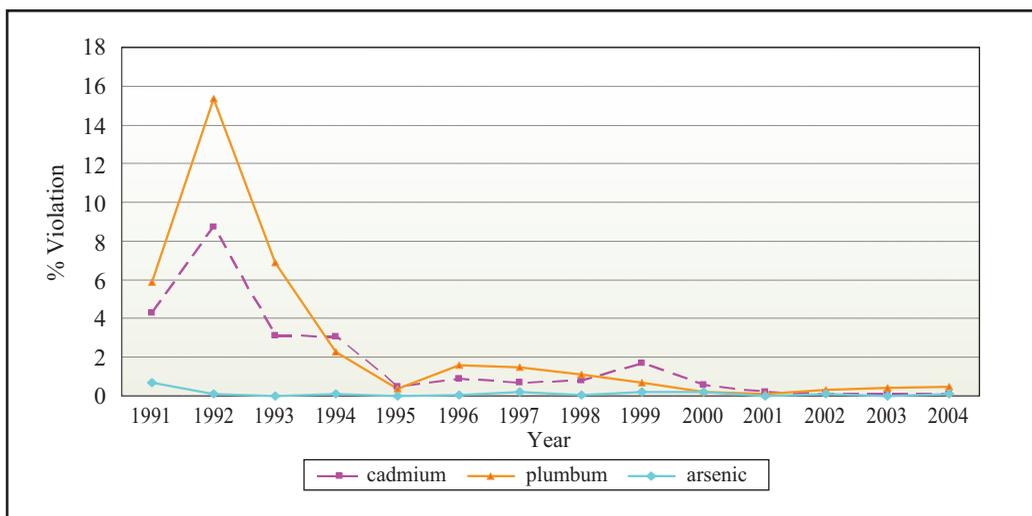
**Figure 4 : Relationship between Cholera Incident Rate per 100,000 Population and Combined Residual Chlorine and E.coli Violations in Malaysia, 1995-2004**



Source : Center of Disease Control, MOH  
National Drinking Water Quality Surveillance Programme, MOH

To ensure drinking water is safe from these chemical contaminants, the National Drinking Water Quality Surveillance Programme (NDWQSP) analyses more than 30 chemical parameters annually. Since the implementation of this programme, the drinking water quality for chronic health effect parameters such as lead, cadmium and arsenic have improved (Figure 5).

**Figure 5 : Chronic Health Effect Parameters for Drinking Water Quality Violations in Malaysia, 1991-2004**



Source : National Drinking Water Quality Surveillance Programme, MOH

## Conclusion

Drinking water quality has improved over the years although the relationship between water quality and waterborne diseases cannot be conclusively established. Nevertheless, increased access to improved water sources has been a powerful factor in improving health and reducing the spread of infectious diseases in Malaysia<sup>4</sup>. Co-operation between water stakeholders is imperative to ensure that the water supplied to public is safe to drink.

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### Drinking Water Quality Standards and Frequency of Monitoring

No.	Parameters	Maximum Acceptable Value	Frequency To Be Monitored				Source Of Reference
		Mg/L (Unless Otherwise Stated)	Water Treatment Plant Outlet	Service Reservoir Outlet	Distribution System	Well/ Spring	
<b>Group I :</b>							
<u>Microbiological</u>							
1.	Total Coliform	Mpn Method/ Membrane	W	W	M	2Y	MAL
2.	<i>E. Coli Or</i> Thermotolerant	Absent In 100ml Sample	W	W	M	2Y	WHO2
<u>Physical</u>							
1.	Turbidity	5 Ntu	W	W	M	2Y	WHO2
2.	Colour	15 Tcu	W	W	M	2Y	WHO2
3.	PH	6.5 – 9.0	W	W	M	2Y	MAL
4.	Free Residual Chlorine	0.2 – 5.0	W	W	M	2Y	WHO1
5.	Combined Residual	Not < 1.0	W	W	M	2Y	Mal1990
<u>Inorganic</u>							
1.	Total Dissolved Solids	1000	M	M	Y/2	2Y	WHO2
2.	Chloride	250	M	M	Y/2	2Y	WHO2
3.	Ammonia	1.5	M	M	Y/2	2Y	WHO2
4.	Nitrate	10	M	M	Y/2	2Y	WHO1
5.	Iron	0.3	M	M	Y/2	2Y	WHO2
6.	Fluoride	0.4 – 0.6	M	M	Y/2	2Y	MAL
7.	Hardness	500	M	M	Y/2	2Y	WHO1
8.	Aluminium	0.2	M	M	Y/2	2Y	WHO2
9.	Manganese	0.1	M	M	Y/2	2Y	WHO2
<b>Group III :</b>							
1.	Mercury (Total)	0.001	Y/4	Y/2	Y	2Y	WHO2
2.	Cadmium	0.003	Y/4	Y/2	Y	2Y	WHO2
3.	Arsenic	0.01	Y/4	Y/2	Y	2Y	WHO2
4.	Cyanide	0.07	Y/4	Y/2	Y	2Y	WHO2
5.	Lead	0.01	Y/4	Y/2	Y	2Y	WHO2

No.	Parameters	Maximum Acceptable Value	Frequency To Be Monitored				Source Of Reference
		Mg/L (Unless Otherwise Stated)	Water Treatment Plant Outlet	Service Reservoir Outlet	Distribution System	Well/Spring	
6.	Chromium	0.05	Y/4	Y/2	Y	2Y	WHO2
7.	Copper	1	Y/4	Y/2	Y	2Y	WHO1
8.	Zinc	3	Y/4	Y/2	Y	2Y	WHO2
9.	Sodium	200	Y/4	Y/2	Y	2Y	WHO2
10.	Sulphate	250	Y/4	Y/2	Y	2Y	WHO2
11.	Chloroform	0.2	Y/4	Y/2	Y	2Y	WHO3
12.	Bromoform	0.1	Y/4	Y/2	Y	2Y	WHO2
13.	Dibromochloro-methane	0.1	Y/4	Y/2	Y	2Y	WHO2
14.	Bromodichloromethane	0.06	Y/4	Y/2	Y	2Y	WHO2
<b>Group IV :</b>							
1.	Aldrin/Dieldrin	0.00003	Y/4	WN	WN	WN	WHO2
2.	DDT	0.002	Y/4	WN	WN	WN	WHO2
3.	Heptachlor & Hepatochlor epoxide	0.00003	Y/4	WN	WN	WN	WHO2
4.	Methoxychlor	0.02	Y/4	WN	WN	WN	WHO2
5.	Lindane (Bhc)	0.002	Y/4	WN	WN	WN	WHO2
6.	Endosulfan	0.03	Y/4	WN	WN	WN	AUS

**Abbreviations :**

- W : Indicates parameters to be monitored at least once a week.  
M : Indicates parameters to be monitored at least once a month.  
Y/2 : Indicates parameters to be monitored at least once in 6 months.  
Y : Indicates parameters to be monitored at least once a year.  
2Y : Indicates parameters to be monitored at least once in 2 years.  
WN : Indicates parameters to be monitored when necessary.  
WHO1 : Indicates WHO Guidelines for Drinking Water Quality 1984.  
WHO2 : Indicates WHO Guidelines for Drinking Water Quality 1993/96.  
WHO3 : Indicates WHO Guidelines for Drinking Water Quality Addendum to Vol.1) 1998.  
MAL : Indicates values adapted for Malaysian conditions.  
AUS : Indicates Australian Drinking Water Quality Guidelines, 1996.  
EEC : Indicates EEC Standard Council Directive (80/778/EEC).  
NZ : Indicates Drinking Water Standards for New Zealand 1995.

Notes : Any toxic substances not listed shall be deemed as not allowable in drinking water.

## Summary of Raw Water Quality in Malaysia by State, 2004

States	Total Coliform Above 5,000			Chemical Oxygen Demand (10)			Ammonia (0.5)		
	A	B	C	A	B	C	A	B	C
Perlis	174	12	6.9%	0	0	0.0%	50	0	0.0%
Penang	775	96	12.4%	134	10	7.5%	139	4	2.9%
Kedah	1,288	220	17.1%	199	47	23.6%	220	2	0.9%
Perak	2,396	28	1.2%	168	0	0.0%	454	3	0.7%
Selangor	1,183	422	35.7%	334	46	13.8%	280	29	10.4%
WP K.Lumpur	87	12	13.8%	16	0	0.0%	15	1	6.7%
WP Putrajaya	0	0	0.0%	0	0	0.0%	0	0	0.0%
N. Sembilan	853	247	29.0%	193	27	14.0%	156	12	7.7%
Malacca	152	54	35.5%	16	0	0.0%	22	0	0.0%
Johore	1,886	991	52.5%	406	220	54.2%	371	15	4.0%
Terengganu	744	39	5.2%	60	11	18.3%	118	1	0.8%
Kelantan	1,102	169	15.3%	145	30	20.7%	246	16	6.5%
Pahang	2,985	429	14.4%	686	59	8.6%	709	8	1.1%
<b>West Malaysia</b>	<b>13,625</b>	<b>2,719</b>	<b>20.0%</b>	<b>2,357</b>	<b>450</b>	<b>19.1%</b>	<b>2,780</b>	<b>91</b>	<b>3.3%</b>
Sarawak	3,902	471	12.1%	701	334	47.6%	711	13	1.8%
Sabah	1,136	91	8.0%	142	28	19.7%	142	1	0.7%
WP Labuan	219	0	0.0%	-	0	0.0%	-	0	0.0%
<b>Malaysia</b>	<b>18,882</b>	<b>3,281</b>	<b>17.4%</b>	<b>3,200</b>	<b>812</b>	<b>25.4%</b>	<b>3,633</b>	<b>105</b>	<b>2.9%</b>

Source : National Drinking Water Quality Surveillance Programme. Annual Report 2004

Note : A = Number Of Samples Analysed  
 B = Number Of Violations  
 C = Percentage Of Violation

Summary of Treated Water Quality in Malaysia by State, 2004

States	Total Coliform			E. Coli			Residual Chlorine			R. Chlorine & E. Coli		
	A	B	C	A	B	C	A	B	C	A	B	C
	Perlis	739	76	10.28	738	3	0.41	738	128	17.34	737	10
Penang	3,418	132	3.86	3,418	16	0.47	3,390	21	0.62	3,390	0	0.00
Kedah	8,137	345	4.24	8,137	103	1.27	8,136	106	1.30	81,35	20	0.25
Perak	9,389	111	1.18	9,389	23	0.24	9,388	48	0.51	9,388	6	0.06
Selangor	8,426	148	1.76	8,426	128	1.52	8,426	247	2.93	8,426	3	0.04
WPUR	1,028	8	0.78	1,028	27	2.63	1,028	1	0.10	1,028	0	0.00
Putrajaya	331	19	5.70	331	0	0.00	331	35	10.50	331	0	0.00
N. Sembilan	4,211	109	2.59	4,211	15	0.36	4,211	85	2.02	4,211	13	0.31
Malacca	2,813	106	3.77	2,800	17	0.61	2,813	119	4.23	2,800	17	0.61
Johore	12,289	145	1.18	12,289	45	0.37	12,144	344	2.83	12,140	0	0.00
Terengganu	5,680	4	0.07	5,680	4	0.07	5,663	60	1.06	5,663	0	0.00
Kelantan	5,082	97	1.91	5,082	23	0.45	5,086	575	11.31	5,082	31	0.61
Pahang	10,765	619	5.75	10,763	112	1.04	10,765	607	5.64	10,763	196	1.82
<b>West Malaysia</b>	<b>72,308</b>	<b>1,919</b>	<b>2.65</b>	<b>72,292</b>	<b>516</b>	<b>0.71</b>	<b>72,119</b>	<b>2,376</b>	<b>3.29</b>	<b>72,094</b>	<b>296</b>	<b>0.41</b>

States	Total Coliform			E. Coli			Residual Chlorine			R. Chlorine & E. Coli		
	A	B	C	A	B	C	A	B	C	A	B	C
Sarawak	12,599	735	5.83	12,596	109	0.87	12,326	152	1.23	10,807	2	0.02
Sabah	5,374	419	7.80	5,347	54	1.01	6,232	469	7.53	3,983	86	2.16
Labuan	0	0	0.00	0	0	0.00	0	0	0.00	0	0	0.00
<b>Malaysia</b>	<b>90,281</b>	<b>3,073</b>	<b>3.40</b>	<b>90,235</b>	<b>679</b>	<b>0.75</b>	<b>90,677</b>	<b>2,997</b>	<b>3.31</b>	<b>86,884</b>	<b>384</b>	<b>0.44</b>

Source : National Drinking Water Quality Surveillance Programme. Annual Report 2004

Note : A = Number Of Samples Analysed

B = Number Of Violations

C = Percentage Of Violation

## PROMOTING BREAST FEEDING

### SUMMARY

Breastfeeding promotion is of utmost importance in the strategy to promote, protect and support optimal child nutrition. Various strategies have been employed in efforts to increase the prevalence and practice of breastfeeding in the country. The Baby-Friendly Hospital Initiative is an important endeavour that helps establish the initiation of breastfeeding from the beginning of an infant's life. Ongoing support for breastfeeding mothers is provided through a network of mother support groups. Marketing of breast milk substitutes which often pose a threat to mothers' enthusiasm for breastfeeding is curtailed through a voluntary Code of Ethics. Continuous advocacy on breastfeeding to various agencies and to the public is undertaken through seminars, forums and also advocacy through the mass media. Training of health staff is carried out through short courses. A multisectoral approach in breastfeeding promotion is crucial to ensuring its long-term success in Malaysia.

### Introduction

**B**reastfeeding promotion, as established in the Ministry of Health's National Plan of Action for Nutrition<sup>1</sup>, is an integral and inseparable part of efforts to promote healthy nutrition, particularly in infants and young children. It is reflective of the commitment to adhere to and support the Global Strategy for Infant and Young Child Feeding<sup>2</sup>, jointly developed by the World Health Organisation and UNICEF which underlines strategies to promote, protect and support appropriate infant and young child feeding. The strategy specifies not only responsibilities of governments, but also of international organisations, non-governmental organisations and other concerned parties.

Malaysia is also a signatory to the Innocenti Declaration<sup>3</sup>, which is reinforced every year. The first Innocenti Declaration was produced and adopted by participants at the WHO/UNICEF policymakers' meeting on "Breastfeeding in the 1990s: A Global Initiative", co-sponsored by the United States Agency for International Development (AID) and the Swedish International Development Authority (SIDA), held at the Spedale degli Innocenti, Florence, Italy, on 30 July - 1 August 1990.

*Breastfeeding,  
an integral part  
of National  
Nutrition Plan*

*Innocenti  
Declaration*

Breastfeeding saves millions of infant lives throughout the world every year. The World Health Organisation confirmed breastfeeding as vital for optimal child health in April 2006. New growth reference standards were agreed upon that refer to breastfeeding as “the biological norm” in international benchmarks for children’s growth. This implies that a lack of breastfeeding presents a risk to the infant and the young child and to health later in life. Breastfed babies suffer fewer incidences of diarrhoea, respiratory and middle ear infections and are less likely to develop allergies. Breast milk provides complete nourishment for an infant from birth up to about six months of age. Apart from its immunological benefits, it is always at the right temperature, needs no sterilisation, costs nothing and almost every mother and baby pair can breastfeed successfully. Breastfeeding promotes emotional bonding between mother and child. There are also health benefits for the mother.

*Breastfeeding,  
vital for optimal  
child health*

It is thus, doubtless that breastfeeding promotion is a fundamental step in the promotion of healthy nutrition. The criticality of the continuous need for this exercise is reflected in data from the WHO Data Bank from 1980-1989 which indicated that there were wide variations in the duration of breast feeding globally. In some countries, there has been a decline in rates for \*exclusive breast feeding, despite the overall satisfactory ever-breastfed rates.

*Exclusive  
breast-feeding is  
desirable*

### **History and rationale of breastfeeding promotion**

In Malaysia, the National Health and Morbidity Survey II (NHMS II)<sup>4</sup>, carried out in 1996, indicated that even though the prevalence of \*ever breastfed was high (88.6%), it did not reflect optimal feeding practices. Findings from the same study showed that only 29% of infants were \*exclusively breastfed and 10% were \*predominantly breastfed. It is, however, noteworthy that the findings of the NHMS II were far more favourable when compared with those of the Malaysian Family Life Survey 2 (MFLS 2)<sup>5</sup> which was conducted in 1988. The MFLS 2 reported very low prevalence of exclusive breastfeeding, and almost all mothers included in the survey were found to give supplementary food and drinks to their infants on a regular basis from the first day of life.

*Prevalence of  
breastfeeding in  
Malaysia*

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#### **Footnote :-**

- \* Ever breastfed - defined as all children less than 2 years who were given breast milk at any time
- \* Predominantly breastfed - defined as all children less than 2 years who are given breast milk as the predominant source of nourishment.
- \* Exclusive breastfeeding - defined as all children less than 2 years who were given only breast milk before the age of 4 months.

## Ongoing strategies

Since 1976, The Ministry of Health of Malaysia has implemented several strategies to promote breastfeeding. Some of these strategies are implemented with the collaboration of non-governmental and voluntary bodies. Consistent with the stance adopted by the World Health Assembly to impose a form of regulation on the promotion and marketing of breast milk substitutes, the Ministry of Health Malaysia officially published the Code of Ethics for Infant Formula Products<sup>6</sup> in 1979. The Code is a voluntary measure, in which companies marketing infant formula products are monitored. The Code of Ethics for Infant Formula Products has undergone 3 revisions in 1983, 1985 and 1995, to further strengthen its provisions in an endeavour to curtail new marketing approaches in the infant formula marketing industry.

The Code provides guidelines for ethical marketing of infant formula products and for health professionals and health personnel in the handling of infant formula promotions targeted at them. Major strides have been taken in the implementation of the Malaysian Code, including legislation of some provisions via the Malaysian Food Regulations (1985)<sup>7</sup>. A whole section of the Food Regulations is devoted to the labelling requirements of infant formula products, including follow-up formula, which is marketed for children aged 6 months and above.

Among the requirements are to display on all infant formula product labels, the statement “Breast Milk is The Best Food For Infants” and the prohibition of any claim of superiority of the product over breast milk. Labels should also not display any picture of human babies, which would serve as an endearing feature on these products.

In 1993, the Ministry of Health Malaysia launched the National Breastfeeding Policy. This followed the signing of the World Declaration on the Survival, Protection and Development of Children by the then Prime Minister in New York in 1990. The original policy stated that : “*All mothers are encouraged to breastfeed their babies exclusively with breast milk for 4 to 6 months of age and thereafter to continue until the child is 2 years old. Complementary foods should be introduced when the baby is 4 to 6 months old.*”

*Collaboration with non-government agencies*

*Ethical marketing of infant formula products*

*Label requirements*

*Launching of National Breast-feeding Policy*

In 1993 too, the Ministry of Health Malaysia adopted the WHO/UNICEF Baby-Friendly Hospital Initiative (BFHI). The BFHI was initiated by governments throughout the world as a spin-off from the joint WHO/UNICEF statement “Protecting, promoting and supporting breastfeeding: the special role of maternity services” which formed one of the bases for the Innocenti Declaration (1990).

*Adoption of WHO/UNICEF Baby Friendly Hospital Initiative(BFHI)*

The BFHI is based upon the “10 Steps to Successful Breastfeeding” (Appendix 1). Implementation of BFHI is carried out through a Hospital Assessment protocol, in which hospitals with maternity care facilities are evaluated for their adherence to the ten steps. Baby-Friendly Hospital Assessors are required to complete the 18-hour Lactation Management Course and the External Assessor Course in order to be competent.

*10 steps to successful breastfeeding*

A typical team of Baby-Friendly Hospital Assessors comprise a medical doctor, a nursing personnel and a public health nutritionist. Hospitals which comply with all the Ten Steps are certified as Baby-Friendly Hospitals. The Baby-Friendly status is valid for a period of two years, after which the said hospital is reassessed for continuous compliance. In March 1998, Malaysia was proudly declared the third country in the world to attain 100% Baby-Friendly accreditation amongst its government hospitals. By the end of 2004, the number of hospitals accredited as Baby-Friendly had grown to 121, including all government hospitals (Table 1).

*BFHI assessors*

**Table 1 : Number of Baby-Friendly Hospitals in Malaysia, 2004**

Year	Number
Government Hospitals	114
Private Hospitals	4
Army Hospitals	2
University Hospitals	1
<b>Total</b>	<b>121</b>

Source : Family Health Development Division, MOH

The Baby-Friendly concept which advocates a supportive environment for pregnant, newly-delivered and lactating mothers in hospitals has been extended to Health Clinics, in adoption of the *The Seven Point Plan for the Protection, Promotion and Support of Breastfeeding in*

*Supportive environment for breastfeeding*

*Community Health Settings* initiated by UNICEF, United Kingdom (**Appendix 2**). Other training and advocacy activities related to breastfeeding promotion include :

- Lactation management courses for state trainers
- Breastfeeding counsellors course
- Mother-to-mother support training for local women with breastfeeding experience
- Short courses for administrators and policy makers on the promotion of breastfeeding
- Seminars on breastfeeding
- Exhibition and counseling on breastfeeding
- Launching of baby-friendly shopping centres

The crux of breastfeeding promotion amongst the public in which the Ministry of Health and its division at state level are involved is the annual World Breastfeeding Week in the first week of August. During this week, all state health departments have their own activities such as exhibitions and public forums on breastfeeding. Breastfeeding is also promoted through the broadcast media as well as the print media, in the form of interviews, talks and articles.

*Annual World Breastfeeding Week*

### **Current highlights**

Recent highlights of the breastfeeding promotion drive include the reformulation of the National Breastfeeding Policy which advocates 6 months of exclusive breastfeeding, as compared to the previous duration of 4 to 6 months. The new policy states that “*All mothers are encouraged to breastfeed their babies exclusively with breast milk for 6 months of age and thereafter to continue until the child is 2 years old. Complementary foods should be introduced when the baby is 6 months old.*” The new policy is in pursuance of World Health Assembly Resolution 58.32<sup>7</sup> based on the findings of the WHO Expert Consultation on optimal duration of exclusive breastfeeding.

*Reformulation of National Breastfeeding policy*

The Ministry of Health has stated its support for the lobby by breastfeeding activists and women’s groups alike, to increase the duration of maternity leave to 84 days from the current 60 days, in line with WHA Resolution 58.32 which calls for a comprehensive national policy, including a legal framework to promote maternity leave and a supportive environment for six months’ exclusive breastfeeding. The ILO Convention on Maternity Protection, which calls for a minimum of 98 days maternity leave is also a major consideration.

*Support for increase in duration of maternity leave*

Guidelines for the establishment of Baby-Friendly Clinics, Monitoring of the Code of Ethics for Infant Formula Products, Mother Support Groups and Lactation Counselling for Health Personnel have been developed.

### Future Goals

The Ministry of Health Malaysia would expect to work closely with other agencies, including the Ministry of Women's Development and Ministry of Human Resources in helping to establish a legal framework for adequate childcare facilities at the workplace. The establishment of support groups on breastfeeding in the community whom mothers can turn to for guidance and counselling will also be strengthened.

*Collaboration  
with other  
agencies*

Planned improvements to the Code of Ethics for Infant Formula Products shall include expansion of the scope and its application to not only infant formula products but also commercially-produced infant foods such as cereals. Provisions for regulating the promotion of feeding bottles, teats and pacifiers, which are also deemed as threats to the maintenance of breastfeeding, will also be incorporated into the revised Code. The improvised Code will also address issues of sponsorship of activities involving Health Professionals for commercial gain. With these improvisations to the Code, it is foreseen that previous shortcomings in the regulation of marketing behaviour in the breast milk substitute industry will be successfully overcome.

*Improvements  
to Code of  
Ethics for Infant  
Formula  
Products*

Advocacy of breastfeeding to various quarters including KEMAS, LPPKN and the Welfare Department will also form the mainstay of future breastfeeding promotion in Malaysia.

### Conclusion

Continuous and multisectoral efforts to promote breastfeeding must be carried out so that the main objective of the National Plan of Action for Nutrition, which is, to ensure the nutritional well being of the population, and, on a larger scale, to fulfil the targets of the Millennium Development Goals are achieved.

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8. World Health Assembly Ninth Plenary Meeting. Resolution 58.32, 2005.

### Ten Steps to Successful Breastfeeding

Every facility providing maternity services and care for newborn infants should :

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within half an hour of birth.
5. Show mothers how to breastfeed, and how to maintain lactation even if they should be separated from their infants.
6. Give newborn infants no food or drink other than breast milk, unless medically indicated.
7. Practise rooming-in - that is, allow mothers and infants to remain together - 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

*Source : Protecting, Promoting and Supporting Breastfeeding: The Special Role of Maternity Services, a joint WHO/UNICEF statement published by the World Health Organisation.*

### Seven Point Plan

#### For the protection, promotion and support of breastfeeding in Community Health Care Settings

All providers of community health care will :

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all staff involved in the care of mothers and babies in the skills necessary to implement the policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Support mothers to initiate and maintain breastfeeding.
5. Encourage exclusive and continued breastfeeding, with appropriately-timed introduction of complementary foods.
6. Provide a welcoming atmosphere for breastfeeding families.
7. Promote co-operation between health care staff, breastfeeding support groups and the local community.

*Chapter*

# 3

## HEALTH SYSTEM MANAGEMENT



# QUALITY INITIATIVES IN THE MINISTRY OF HEALTH

## SUMMARY

The Ministry of Health, guided by the Vision 2020 and Vision for Health strives for continuous quality improvement in the provision of health care for its population. As the main provider of health services, the Ministry of Health emphasises on quality in its agenda. The Quality Assurance Programmes (QAP) and many other quality improvement initiatives have been successfully implemented in the Health Ministry. The Evaluation of Quality Improvement Efforts in the Health Ministry, conducted in 1996, identified strengths, and weaknesses of the implementation of quality improvement efforts. The findings of this evaluation contributed significantly to the development of the Strategic Plan for Quality in Health. Making quality as the driving force for any health system development, developing collaborative partnerships and taking a system approach in managing quality are key issues in consolidating the efforts of improving quality to enhance its institutionalisation and development of quality culture.

## Introduction

Ensuring quality in health is an integral component of a health system. The Ministry of Health (MOH) Malaysia has given a high accord to quality. Many quality improvement efforts (QIE) have been initiated since the 80's within the MOH.

*Priority of the Ministry of Health*

The MOH pioneered the way for Quality Assurance (QA) in 1985 through the formal introduction of the Quality Assurance Programme (QAP). To date, the QAP has been initiated and implemented in 9 health programmes. Under the QAP, two quality assurance approaches have been instituted; the National Indicator Approach (NIA) and the Hospital/District Specific Approach (HSA/DSA). For the NIA, several indicators have been introduced to be used throughout MOH. Below are the summary of the status of implementation of QAP of the various programmes and the number of quality indicators currently in place to monitor improvement in quality (Table 1).

*Quality improvements efforts (QIE) in MOH*

For the HSA/DSA, local QA Committees undertake QA projects to help solve local quality problems. Sharing of quality initiatives are being encouraged through publications in local QA journals/bulletins,

*Sharing and disseminating work on QA/I*

**Table 1 : Status of QA Implementation by Programmes**

Programmes	Year initiated	Awareness	Indicator Development	Implementation	No of indicators developed (updated Dec. 2004)
Patient Care Services	1985	✓	✓	✓	53
Public Health Services	1990	✓	✓	✓	34
Pharmaceutical Services	1990	✓	✓	✓	21
Engineering Services	1990	✓	✓	✓	7
Laboratory Services	1992	✓	✓	✓	25
Oral Health Services	1992	✓	✓	✓	5
Allied Health Training	1997	✓	✓	✓	5
Planning & Development	1998	✓	✓		-
Administration & Finance	2003	✓			-

and presentations at local, national and international conferences/ seminars. The QA Secretariat supports the dissemination of QA initiatives through regular Quality Bulletins, updating the database on QA projects which can be accessed through its website and organising major events such as the biannual QA Conventions and other national meetings. Training activities at national and local levels are carried out to develop critical mass of staff proficient in carrying out quality improvement activities. Emphasis is given towards developing trainers for undertaking and managing quality improvement initiatives. To support training activities, training manuals have been developed and widely circulated.

To date, various quality initiatives have been introduced. Some of these are listed below :

### *Quality Initiatives*

- Clinical/Medical Audit
- Confidential Enquiry into Maternal Death (CEMD) and Perinatal Mortality Review
- Peri-operative Mortality Review (POMR)
- Nosocomial Infection
- Clinical Practice Guidelines (CPG)
- Incident Reporting
- Registry of Diseases
- Corporate Culture
- Quality Control (QC)
- Total Quality Management (TQM)
- Client's Charter
- Innovation
- Quality Control Circle (QCC)
- MS ISO 9000/2000
- Hospital Accreditation
- Other Development Administrative Circulars (PKPA)

The application of quality indicators such as those used by the national QA programme to compare performances, within and between facilities, has also been used by hospitals and organisations in other countries. For example, the Hospital Quality Alliance (HQA) in the United States introduced three major clinical conditions - myocardial infarct, congestive heart failure and pneumonia to monitor improvement of quality in 40 hospitals in the United States. The Veterans Health Administrations (VHA) upon studying continuous improvement activities in eight centres in the US, recommended the establishment of a mechanism for continuous identification and refinement of evidence base practices in its processes. The Australian Council on Healthcare Standards have also used clinical indicators to estimate the national rates over time and to detect where there have been improvement or decline in performance.

### *Use of quality indicators in other health organisations*

### **The way forward**

The Health Ministry has accumulated sufficient amount of experience in designing and implementing quality initiatives through its 2 decades of involvement in quality improvement initiatives. In 1996, an evaluation of the various quality improvement efforts within the MOH was undertaken. The evaluation showed that the success of the

### *1996 QIE evaluation study*

implementation of these efforts had been attributed to the wide dissemination of respective protocols, manuals and guidelines to facilitate the implementation, the identification of prime movers or leaders, strong managerial support, clear top-down directives, presence of awareness or willingness to participate, and the organisation of continuous training programmes.

The findings of this evaluation had been extensively used in developing the '*Strategic Plan for Quality in Health*'. The Plan, published in 1998, contained the mission and policy statements, objectives and 14 broad strategies that provided a framework for specific activities to be operationalised at the various levels of health care.

*Strategic Plan  
for Quality in  
Health*

Weaknesses have also been identified. Being too focused on technical aspects, giving emphasis to theoretical rather than practicality, being less personal and less reflective through our failure to listen, have all been commonly quoted as weaknesses that needs rectification.

To have a greater impact in improving quality and making quality improvement a culture in the Health Ministry, the following consolidation efforts are required :

*Consolidated  
efforts required*

- Quality must be seen as **the driving force** for any health system development. Although accepting that quality can be seen from various perspectives, there is a need to have a holistic view of quality which will drive the development of the health system.
- To expand the coverage of quality initiatives in health sector there is a need to form **collaborative partnerships** between and amongst health care providers (public and private sectors) and other partners such as: consumer groups and associations, individuals, families and communities, non governmental organisations, professional bodies and associations and regional/ international health care organisations.
- **Taking a system-wide approach** in managing quality and not looking at quality initiatives as separate entities (silos). Harmonising the various quality improvement efforts as an integrated entity towards achieving a common goal should always be the priority.

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# MALAYSIAN NATIONAL HEALTH ACCOUNTS (MNHA)

## SUMMARY

The MNHA Project results showed that the total expenditures on health (TEH) in Malaysia was RM 8 billion in 1997 and RM14 billion in 2002, which averages to an annual increment of 11% in TEH. These were equivalent to 2.9% of GDP in 1997 and 3.8% of GDP in 2002. The capita spending on health was RM379 in 1997 and RM555 in 2002. The public: private sector expenditure had shifted from 50:50 to 56:44 ratio of TEH. In 2002, data showed that Ministry of Health, Malaysia (MOH) was the largest source (86%) of health expenditure within the public sector whilst household out-of-pocket accounted for the largest source (74%) in the private sector. Hospital and curative care services accounted for the biggest share of TEH in both the public and private sectors. The largest expenditure within the MOH hospitals, was for inpatient care services (65%).

## Introduction

The National Health Accounts (NHA) is a comprehensive, consistent, comparable, and timely information that constitute a systematic financial resource flow needed for health planning. It describes the flow of funds from various sources of health financing, the payers and purchasers of health and health related services within the health system and the utilization of health services in terms of health providers and functions. By its virtue, NHA comprised of data from both the public and private financing systems. NHA also provides the basis for more specific analysis of policy issues in health care financing to ensure services delivered to the public are equitable, accessible, appropriate and cost effective. Together with the knowledge on disease patterns, dynamic change in technologies, and other health-related matters, the National Health Accounts can assist governments in resource allocation on priority health areas. The importance of NHA in supporting health system governance and decision-making has mooted many countries to set up their own NHA system.

In August 2001, the Government of Malaysia (GOM) with the co-operation of the United Nations Development Programme (UNDP), launched the Malaysian National Health Accounts (MNHA) project. Its main objective was to capture, for the first time, details of the

*Definition of the National Health Accounts*

*Malaysian National Health Accounts (MNHA) project*

national health care expenditures in Malaysia. Two committees, the Steering Committee and the Technical Committee, were set up under this project. The MNHA Project Steering Committee was chaired by the Economic Planning Unit (EPU) of the Prime Minister's Department, with representatives from various government ministries and agencies. The main function of the Steering Committee was to facilitate and monitor the progress of the project. The MNHA Technical Committee chaired by the Director-General of Health, Malaysia endorsed technical decisions and inputs into the project. The secretariat for the MNHA project was the Planning and Development Division of the Ministry of Health, Malaysia. The project was completed in September 2005.

### Malaysian National Health Accounts (MNHA) Framework

There are several methods of analyzing the health accounts of a country. One such method is the System of Health Accounts (SHA) which was published in the year 2000 by the Organization of Economic Co-operation and Development (OECD)<sup>1</sup>. Since then, this system has been adopted by the World Health Organization (WHO) as a basis for international data collection.

The OECD SHA defines the concept of Total Expenditure on Health (TEH). This is a standardized definition on which areas of health spending are to be measured and reported in the TEH of the nation. In the Malaysia National Health Accounts (MNHA) framework, TEH are expenditures from both the public and private sectors which include hospitals, nursing and residential care facilities, ambulatory care facilities, dental clinics, out-patient care centers, retail sale and providers of medical goods, health related services provided by institutions and so forth.

*Total expenditure on health (TEH)*

The SHA (OECD, 2000 Version 1.0) classifies all health system spending using a tri-axial system, known as the International Classification for Health Accounts (ICHA). ICHA categorizes health expenditures by :

*SHA (OECD) classification*

- Sources of financing
- Providers of health services
- Function of health services

The MNHA framework was developed from the SHA (OECD, 2000) classification with some modifications to suit local needs.

*MNHA framework*

In the MNHA context, **sources of financing** included the public sector - consisting of the federal government, state government, local authorities and social security funds and the private sector consisting of private insurance, managed care organizations, out-of-pocket expenditure, non-profit institutions, and private corporations.

*MNHA sources of financing*

**Providers of health services** were categorized as hospitals, nursing and residential care facility providers, ambulatory care providers, retail sale and medical goods providers, public health programme providers, and so on.

*MNHA providers of health services*

**Functions of health services** included core functions of health care (curative care, rehabilitative care, long term nursing care, ancillary services, out-patient medical goods, public health services, health programme administration and health insurance) and health-related functions (personal health education and training, research and development, and so on).

*MNHA functions of health services*

The information for the above three classifications was coded and analysed using the software application called MNHA Business Intelligence Solutions (MBIS). This is the first Malaysian web-based software developed specifically for the project to facilitate health account analysis. The MBIS allows tracking of results and compilation of the estimated data based on the identified classifications to generate meaningful data.

## **Methodology**

Detailed definition of what constitute health expenditure, institutional entities, and specification of the types of desegregation were drawn up based on inputs from documents, committee meetings and consultative advice from both within and outside the Ministry of Health. Both primary and secondary data were used in this analysis.

*MNHA Business Intelligence Solutions (MBIS)*

Primary data were obtained through studies conducted during the MNHA Project period, whereas secondary data from 1997 to 2002 were retrieved through various sources. These data were then coded according to the MNHA classification based on the SHA (OECD, 2000) classification.

*Primary and secondary data collection*

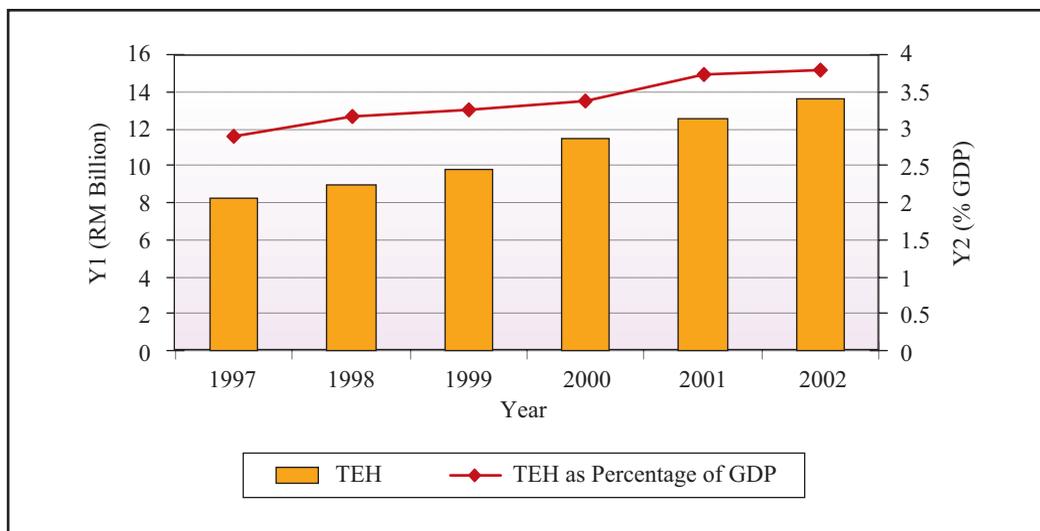
The sets of data from each source were processed differently depending on availability and completion of data. Data analysis was carried out based on the tri-axial MNHA entities of sources, providers and functions. Cross-classification of the entities and its important sub-components allowed further analysis of the national health expenditures. The process of data entry and analysis were carried out using the Microsoft Excel Programme, STATA Version 6.0 and the MNHA Business Intelligence Solutions (MBIS). The initial MNHA data preparation, analysis and coding were done in Microsoft Excel spreadsheets and the resulting text data files were loaded into the MBIS after data cleaning and programme verification using STATA. Although the MBIS allows for detail analysis of the MNHA, this report only highlights important findings, which are of use for future health planning of the country.

**Findings**

The total expenditure on health was RM 8 billion in 1997 and RM 14 billion in 2002. This represented an average increase of 11% increase and equivalent to 2.9% of GDP in 1997 and 3.8% of GDP in 2002 (Figure 1). The overall per capita spending on health was RM 379 (USD 135) in 1997 and RM 555 (USD 146) in 2002.

*Total expenditure on health in 1997-2002*

**Figure 1 : Trend for Total Expenditure on Health (TEH), Malaysia in Nominal Price (Ringgit Malaysia), 1997-2002**

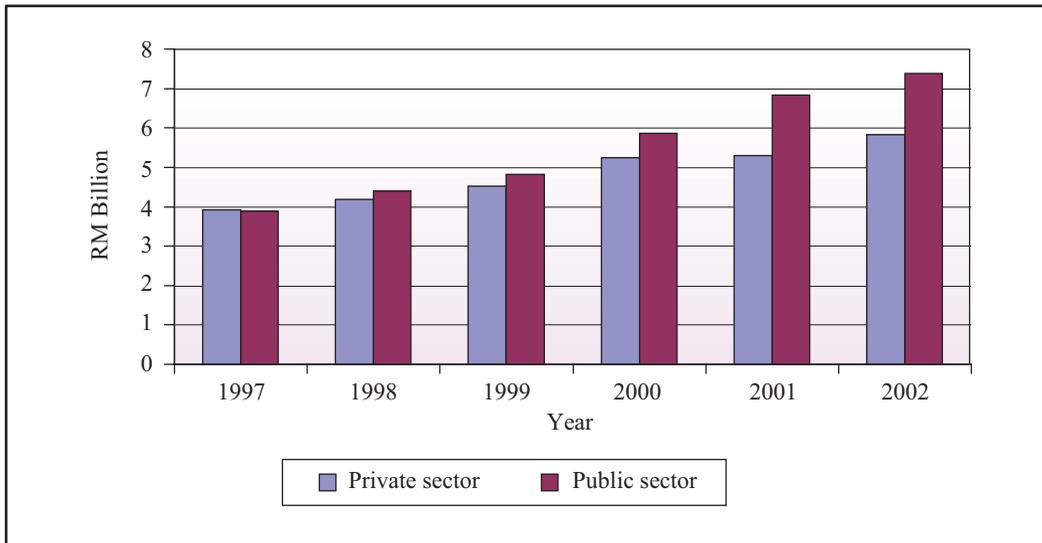


## Health expenditure by sources of financing

In the years from 1997 to 2002, the proportion of public: private sector expenditure increased from 50: 50 to 56: 44 for the total health expenditure (**Figure 2**). In 2002, total public sector health expenditure accounted for 2.1% and total private sector health expenditure accounted for 1.7 % of the GDP.

*Public-private expenditure*

**Figure 2 : Proportion of Public vs Private Health Expenditure (1997-2002) in RM**



Analysis of the sub-components of the 2002 public sector expenditure showed that 86% of the total public sector health expenditures were by the Ministry of Health (MOH), the largest contributor in this sector (**Table 1**). This is a rise from 1997 when the MOH proportion was only 44% of the total expenditure on health. In 2002, the Ministry of Education / Ministry of Higher Education and the Local Authorities were the next largest contributors, accounting for 6% and 5% of respectively of the total public sector health expenditure. Expenditures on health by other public agencies were less than 3% of the total expenditure on health (Statutory Bodies- 2%, Ministry of Defence 1%, Employee Provident Fund (EPF) and Social Security Fund (SOCSO) - less than 1%).

*Sources of financing in public sector*

In the public sector, when the entities of source and provider were cross-classified, hospitals consumed 46% of the public sector expenditures, followed by non-hospital ambulatory care (16%), and provision of public health programmes (10%). In terms of functions of

**Table 1 : Sources of Health Expenditure by the Public Sector (2002)**

MNHA code	Sources of financing in public sector	Ringgit Malaysia (RM million)	Percent (%)
MS1.1.1.1	Ministry of Health (MOH)	6,511	86
MS1.1.1.2	Ministry of Education (MOE) / Ministry of Higher Education (MOHE)	481	6
MS1.1.3	Local authorities	344	5
MS1.1.1.9	Other federal agencies (including statutory bodies)	144	2
MS1.2.1	Employee Provident Funds (EPF)	37	1
MS1.1.1.3	Ministry of Defence (MOD)	36	1
MS1.2.2	Social Security Organization (SOCSCO)	22	*0
MS1.1.2.2	Other state agencies (including statutory bodies)	17	*0
	<b>Total</b>	<b>7,593</b>	<b>100</b>

Note : \*SOCSCO – 0.3%, Other state agencies (including statutory bodies) – 0.2%

health care, curative care services consumed 55% of the public sector expenditure followed by capital formation of health care provider institutions or health facility development at 21%.

The private sector health expenditures were mostly contributed by private household out-of-pocket expenditures (Table 2). In 2002, the household out-of-pocket (excluding personal or family insurance) health expenditure amounted to 74% of the private sector expenditure (or 33% of the TEH). This was followed by contribution from private health insurance which was 13% of the private sector expenditure (or 6% of the TEH). Private corporations (excluding insurance purchased by private corporations for its employees) accounted for 12% of the private sector expenditure (or 5% of the TEH).

In the private sector, just as in the public sector, hospitals consumed 38% of the private sector expenditure followed by non-hospital ambulatory care services consuming 31%. Curative care consumed 65% of the private sector expenditure followed by medical goods

### *Sources of financing in private sector*

**Table 2 : Sources of Financing in the Private Sector (2002)**

MNHA code	Sources of financing in private sector	Ringgit Malaysia (RM million)	Percent (%)
MS2.4	Private household out-of-pocket expenditures	4,443	74
MS2.2	Private insurance enterprises (other than social insurance)	770	13
MS2.6	All Corporations (other than health insurance)	700	12
MS2.3	Private MCO and other similar entities	74	1
MS2.5	Non-profit organisations serving households	39	1
	<b>Total</b>	<b>6,026</b>	<b>100</b>

dispensed to outpatients consuming 23% and health administration and health insurance consuming 6%. Most of the private sector out-of-pocket expenditures, were towards hospitals (39%), followed by providers of ambulatory care of non-hospital setting (30%) while retail sale and other medical goods providers consumed another 30%.

### Health expenditure by providers and functions of health services

The MNHA analysis showed that in 2002, hospitals (both public and private) consumed 43% of the total expenditure on health. This was followed by non-hospital ambulatory care (23%), general health administration and insurance (16%), retail sale and other providers of medical goods (11%), preventive and promotive public health programmes (5%). Health expenditure by other providers was relatively small. The finding showed that 47% of hospital expenditure was from the public sector, mainly the Ministry of Health that amounted to 54% of the total hospital expenditure (Table 3). In-patient cases consumed 66% followed by out-patient at 32%. Daycare services in hospital setting consumed the remaining 2% of the total MOH hospital expenditure. 61% of the ambulatory care expenditure in non-hospital setting was consumed by the private sector whereas 39% was consumed by the public sector.

*Health expenditure by providers and functions of health services for both public and private sectors*

**Table 3 : Cross-classification of Hospital Expenditure and Sources of Health Financing, 2002**

MNHA code	Sources of health financing	Ringgit Malaysia (RM million)	Percent (%)
MS1.1.1.1	Ministry of Health (MOH)	3,159	54
MS2.4	Private household out-of-pocket expenditures	1,718	29
MS2.2	Private insurance enterprises (other than social insurance)	334	6
MS1.1.1.2	Ministry of Education (MOE)	269	5
MS2.6	All Corporations/Private companies (other than health insurance)	248	4
MS1.1.1.9	Other federal agencies (including statutory bodies)	52	1
MS1.2.1	Employee Provident Funds (EPF)	33	1
MS1.1.1.3	Ministry of Defense (MOD)	7	*0
MS1.2.2	Social Security Organization (SOCSO)	3	*0
MS2.3	Private MCO and other similar entities	1	*0
MS2.5	Non-profit organisations serving households	0	*0
MS1.1.3	Local authorities	0	*0
	<b>Total</b>	<b>5,831</b>	<b>100</b>

Note : \*Other state agencies (including statutory bodies) - 0.13%,  
MOD - 0.12%, SOCSO - 0.05%, MCO - 0.02%, NGO - RM 3,830

The trend on total expenditures on health by functions of health services showed that curative care consumed the largest proportion of the total expenditure on health, which accounts to more than 50% of the total expenditure on health throughout 1997 to 2002. In 2002, 59% of total expenditure on health was for curative followed by 12% on capital formation of health care provider institutions which mainly constitute health facility development.

Next was medical goods dispensed to out-patients which consumed 11% of the total expenditure on health. Expenditure funding for education and training of health personnel was only 2% of the total expenditure on health and research and development consuming less than 1% of the total expenditure on health.

When curative care was cross-classified with sources of financing, it was noted that in the year 2002, 51% of curative care expenditure was from the public sector and the remaining 49% from the private sector. When the public sector curative care expenditure was cross-classified with the sources of financing, it was found that for the year 2002, 2% of this sector sources of financing came from the private sector. Whereas when the private sector curative care expenditure was cross-classified with the sources of financing, it was found that 7% of the source of this sector funding came from the public sector.

### *Curative vs preventive*

However, for preventive and promotive public health programmes expenditure, it was found that in 2002, 99% of this portion of expenditure was funded by the public sector. Similarly for training, 72% of the funding came from the public sector of which the Ministry of Health was the largest source of fund.

### **International Comparison**

International comparisons were made with some caution due to variations in boundary definition and in institutional settings of the health system, and the methodologies involved in expenditure analysis across the countries. In making international comparison, expenditure for training was excluded because it is not captured internationally.

### *International comparison*

The MNHA project showed that the health expenditure for the year 2002 was 3.7%\* of GDP. Most Asian countries like Singapore, Thailand, Indonesia, Sri Lanka and others spend an average of 3% - 5% of GDP on health. This is in contrast to most OECD countries that spend an average of 8% - 9% of GDP on health (**Table 4**). However, in terms of health outcomes like life expectancy, maternal mortality and infant mortality, Malaysia is better than many countries of similar socio-economic status. The Malaysian per capita spending in 2002 was USD143\* which was higher than Asian countries like Vietnam, China and Thailand.

**Table 4 : Comparison of Total Expenditure on Health as Percent of GDP in Some Selected Countries**

WHO Member States	Total Expenditure on Health as % Of GDP				
	1998	1999	2000	2001	2002
Bangladesh	3.1	3.2	3.2	3.2	**3.4
Sri Lanka	3.4	3.5	3.6	3.6	**3.6
China	4.8	5.1	5.6	5.7	**5.6
Thailand	3.9	3.7	3.6	3.5	**3.3
Australia	8.7	8.9	9.2	9.3	*9.4
UK	6.9	7.2	7.3	7.5	**7.7
*Malaysia	(MNHA 3.1)	(MNHA 3.2)	(MNHA 3.3)	(MNHA 3.7)	(MNHA 3.7)
Singapore	4.2	4.1	3.6	3.9	4.3
France	9.3	9.3	9.3	9.4	9.7
Germany	10.6	10.6	10.6	10.8	10.9
Philippines	3.5	3.5	3.4	3.23.9	
Japan	7.2	7.4	7.6	7.8	**7.9
United States	13.0	13.0	13.1	13.9	**14.6

Source : World Health Report 2005 (except data for Malaysia is from the MNHA Project) & Asia-Pacific NHA Network Data Correspondents, 2005

Note : • As for Malaysia, for the purpose of international comparison, the training component is excluded for the calculation of MNHA (ie the GDP on health was 3.7% without training, 3.8% with training).  
 • \*\*This data is derived from the Asia-Pacific NHA Network Data Correspondents, 2005.

The Malaysian health expenditure, as in developed countries and most upper-middle income economies, such as UK, Australia and Korea, is predominantly public funded. In 2002, the Malaysian proportion of public expenditure was more than the private expenditure in the ratio of 55:45\*. However, in Asian countries like Singapore, Vietnam and China, the private expenditure exceeded public expenditure.

In 2002, Malaysia spent 44% of the total expenditure on health on hospitals. This is higher than countries like Korea and Australia, which spend more than Malaysia towards providers of ambulatory care services. In the same year, Malaysia spent 60% of the total expenditure on health on curative care.

The most recent available published data shows that majority of the countries spend more than 50% of their total expenditure on health on curative care rather than on preventive and public health care services. In the same year Malaysia spent 7% of the total expenditure on preventive and public health services, which is more than other countries like Korea, Japan and Australia. It is noted that the more developed countries tend to spend less on preventive and promotive public health care services.

## Limitations

The interpretation of results presented in this document should take consideration of some limitations. Currently the design of the MNHA framework does not provide for the distribution of expenditure or the utilization pattern of the expenditure by population groups. In the application of this framework, due to the structural characteristics of the system in this country, it was difficult to draw definite expenditure lines within the health care system based on MNHA classification.

*Caution in interpreting results*

Furthermore, small contributions to the total health expenditure from activities under certain programmes like the environmental health programme expenditure are excluded in the analysis. Logistic limitations include difficulties and delays in data retrieval and analysis since health expenditure data recording is not an institutionalized process. Human resource problems like staff, attrition and turnover were other limitations.

*Exclusions of certain health programmes*

## Recommendations

The MNHA Project has achieved a milestone in the journey towards an improved evidence-based planning process for the Malaysian health sector. The MNHA will enable relevant stakeholders in health to use this planning tool to achieve better allocative efficiency, equity, accessibility and appropriateness in healthcare for the betterment of the healthcare system in the country. The MNHA project identified the need for improvement in the system of accounts used in Malaysian health sector and the need for a better system for generating and managing health data.

*MNHA project, the first step forward*

A mechanism need to be developed to capture health expenditure routinely in a format that can be transformed into three entities, namely, sources, providers and functions of health services. This can be achieved by using the MNHA framework established in this project. However, the framework will need some modification and refinement

*Mechanism to capture health expenditure routinely is needed*

in due time. When utilizing this framework, data flow should not be ad hoc but regular and routine from various identified sources. This may need some changes in the accounting system and perhaps even some impetus via legislation. One such legislation is the Private Healthcare Facilities and Services Act 1998.

The contributions from MNHA will be of importance in planning and managing health services in the country including the proposed National Health Care Financing mechanism.

## Conclusion

The MNHA Project has, for the first time, provided a picture of various health funding and spending patterns across the country. The results show that in 2002, Malaysia spent 3.8% of the GDP on health. The different percentage of distributions of health expenditure, based on the MNHA classification, reflects the various aspects of the structural characteristics of the health care system in this country.

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# HOUSEMAN TRAINING IN MALAYSIA

## SUMMARY

The Medical Act requires all newly qualified graduates to undergo a year of satisfactory housemanship training experience to be eligible to be considered for full registration. Currently, houseman training is conducted in 28 hospitals throughout the country. The training period consists of 3 postings of 4 months each to a medical discipline, a surgical discipline and obstetrics & gynaecology. Over a thousand houseman are registered for training in 2004. The period of apprenticeship under supervision by specialists is aimed at developing clinical skills, as well as molding of attitudes to produce competent doctors who are able to conduct themselves professionally. The process of supervision, monitoring and evaluation are described. Some constraints are encountered in the training of houseman. New initiatives are being proposed to further improve the training of houseman in the country.

### Houseman training hospitals

The Medical Act also provides for the establishment of a Medical Qualifying Board which shall be responsible for accrediting houseman training hospitals. Visits are conducted to potential houseman training centres and an evaluation is made based on the following requirements :

### *Accreditation of houseman training hospitals*

- House Officer postings should be in units with a sufficient senior staff of consultant status to ensure adequate supervision of the work of House Officers;
- The postings should preferably be in the major disciplines which offer breadth and diversity of experience, rather than in narrow or specialized fields. Essentially there must be a core of general experience in medicine and surgery. Recognition of posts in medical, surgical and other specialties is acceptable as long as they make a contribution to good general clinical experience;
- In order to develop a sense of responsibility, House Officers should be given the opportunity to deal with and be responsible under supervision for cases of major and serious character. It is regarded as unsatisfactory that House Officers should hold appointments where their responsibility is only for minor and trivial ailments;

- House Officer posts must be fully residential;
- Hospitals recognized for House Officer training should have suitable pathological, radiological and laboratory facilities.

Based on the above criteria, 28 hospitals have been approved for the training of 1,259 housemen at any one time. The list of hospitals approved for the training till 31 December 2004 is as indicated in **Appendix 1**.

### **Monitoring and evaluation**

The Medical Qualifying Board also monitors and evaluates through administrative channels, the training programme and performances of house officers. This is done through the Housemanship Training Committee which is established in all houseman training hospitals. This committee, consisting of the hospital director and senior specialists, monitors the performance of housemen during the training programme. Only house officers who at the end of general training have acquired an appropriate level of competence and have established good working relationships with patients and colleagues will be signed up for full registration.

*Monitoring and evaluation by Medical Qualifying Board*

While houseman training is for a year, a house officer may be extended due to reasons of poor performance or exceeding stipulated days of leave allowed. Recommendation for extension, particularly relating to professional competency, shall be discussed at the committee for a decision.

*Extension of houseman training for poor performance*

A number of house officers had the tenure of their housemanship extended between 2002 and 2004 as tabulated in **Appendices 2 to 4**. Three house-officers were required to extend their postings in all disciplines in year 2003.

### **Supervision**

Houseman training log books have been developed to monitor the acquisition of specific skills in a more objective manner. The log book has a listing of core procedures which all houseman have to perform, to assist and observe in the various disciplines. The log book also provides guidelines on important topics they need to know and be exposed to.

*Houseman training log book*

The log books are reviewed on a regular basis so that the contents are relevant with current practice, particularly since more procedures are being done on an outpatient basis and some are already not applicable in view of technological changes.

Every house officer should be adequately supervised where :

*Review of log book by supervisor*

- Supervisors must be identified and formally designated as educational supervisors;
- Educational supervisors need to be formally trained on their role as clinical supervisors and counselors so as to assist the housemen in both professional and personal development;
- Regular monitoring and discussion must be conducted to identify early deficiencies in performance;
- Facilitate attendance in educational programme, with at least 4 hours per week scheduled for C.M.E. activities, are facilitated.

Some of the constraints encountered in the training of housemen are :

*Constraints in training*

- Inadequacy of physical facilities.
- Unavailability of adequate numbers of supervisory staff.
- Workload varying from hospital to hospital.
- Lack of objectivity of some supervisors in the evaluation of housemen.
- Inappropriate duties being given to housemen by supervisors.
- Hours of work and frequency of calls by housemen varying too much from center to center and from one period of the year to another.
- Lack of coordination and interest among supervisory staff.
- Poor record keeping by housemen.
- Lack of understanding of the ethical and legal aspects of practice among housemen, for example, doing locum practice.

### **The expectations**

It is expected that all qualified medical officers must have :

*Expected competences after training*

- competence in basic clinical skills,
- competence in certain basic practical procedures,
- competence in basic investigations of a patient,
- competence in basic patient management,
- good communication skills,
- and as such, adherence to good medical practice

It is preferred that every doctor posted to any hospital particularly those without specialist to have the followings :

- ***Have completed 5 basic postings***

Every doctor is expected to have been well trained in the clinical care management of patients especially in the medical and surgical related fields and thus be competent to manage patients at any hospital. He/She needs to acquire competence in basic clinical skills, be able to perform certain basic diagnostic and therapeutic procedures expected of them and manage the patient appropriately. He/she must be able to recognize and identify patient cases that cannot be appropriately managed at his/her level and hence take appropriate actions including consulting other officers or referring the patient onwards for further management.

***Basic clinical skills***

Therefore it is proposed that all medical officers designated as house officers be posted and be trained in the 5 basic disciplines of Internal Medicine, General Surgery, Paediatrics, Orthopaedics, and Obstetric & Gynaecology before they are posted out to work at any workplace.

- ***Well trained in emergency care***

It is expected that a medical officer is competent in acute critical care e.g. intubation , resuscitation and maintenance of care of ill patients.

***Knowledge and skills in emergency care***

A training in Basic Life Support, Advanced Life Support and Advanced Cardiac Life Support and simulation trainings, preferably during the housemanship year is recommended to meet this need.

- ***Competent in handling and managing trauma cases (MVA and other trauma)***

To ensure that a medical officer is competent in managing trauma patients, it is recommended that training in at least Basic Trauma Life Support (BTLS) is incorporated during the housemanship year. Training in Advanced Trauma Life Support (ATLS) is further recommended in order to ensure that the medical officer is capable of managing trauma patients.

***Managing trauma patients***

An organized training module for a posting in the Emergency Department would be beneficial for all outgoing housemen. A period of two weeks is considered sufficient.

- *Possess a full and thorough knowledge of fluid management and support, and capable of managing cases with such problem*

It is compulsory for all medical officers to have a full knowledge of fluid management (adult and paediatric) in order to ensure their competency in managing patients.

*Knowledge of  
fluid  
management*

## **Conclusion**

The pre-registration year is very important as it is essentially an educational period for the completion of basic medical education. The experience gained as an apprentice is highly crucial for development of appropriate skills and attitudes required of a professional.

Currently, there are deficiencies in the implementation of this phase of the educational programme. Issues range from administration of the programme to the facilities and the supervisors. The ultimate goal is however, to help the young graduate move from an academic environment to working environment through careful guidance and supervision.

List of Hospitals Approved for Houseman Training as of 31<sup>st</sup> December 2004

Hospitals	Maximum Number of Housemen Allocated
1. Hospital Kangar	20
2. Hospital Alor Setar	56
3. Hospital Sungai Petani	12
4. Hospital Pulau Pinang	72
5. Hospital Seberang Jaya	24
6. Hospital Taiping	41
7. Hospital Ipoh	70
8. Hospital Teluk Intan	35
9. Hospital Sri Manjung-Lumut	12
10. Hospital Kuala Lumpur	173
11. Hospital Tengku Ampuan Rahimah, Klang	71
12. Hospital Selayang	32
13. Hospital Kajang	20
14. Hospital Seremban	53
15. Hospital Kuala Pilah	26
16. Hospital Melaka	51
17. Hospital Muar	28
18. Hospital Sultanah Aminah, Johor Bahru	65
19. Hospital Tengku Ampuan Afzan, Kuantan	37
20. Hospital Kuala Terengganu	48
21. Hospital Kota Bharu	45
22. Hospital Umum Sarawak, Kuching	48
23. Hospital Sibiu	18
24. Hospital Queen Elizabeth, Sabah	45
25. Hospital Tawau	12
26. Hospital Universiti Kebangsaan Malaysia	30
27. Hospital Universiti Sains Malaysia	45
28. Pusat Perubatan Universiti Malaya	70
<b>Total</b>	<b>1,259</b>

## Appendix 2

### Number of Provisionally Registered Persons Extending Houseman Training According to Reasons, 2002-2004

Reason for extension	Year		
	2002	2003	2004
Poor Work performance	68	39	45
Sick leave and exceeded leave entitlement	53	40	41
Maternity leave	19	9	16
Unpaid leave	9	9	3
Others	13	5	13
<b>Total</b>	<b>162</b>	<b>102</b>	<b>118</b>

## Appendix 3

### Number of Provisionally Registered Persons Extending Houseman Training According to Disciplines and Reasons, 2002-2004

Disciplines	Medicine			Paediatric			Obs & Gyn			Surgery			Orthopaedic		
	02	03	04	02	03	04	02	03	04	02	03	04	02	03	04
Poor Work performance	22	15	13	11	9	5	22	15	19	5	4	8	1	2	6
Exceeded leave entitlement	2	3	5	1	2	1	-	4	5	1	2	4	-	-	1
Sick leave	12	8	7	11	8	2	24	8	15	19	3	8	6	1	3
Maternity leave	2	3	4	1	1	1	4	3	4	8	1	1	3	1	1
Unrecorded/ Unpaid leave	2	2	3	-	1	-	2	2	-	1	-	1	1	-	-
Fail to report for duty	-	1	-	-	-	-	-	1	1	1	1	-	-	1	-
<b>Total</b>	<b>40</b>	<b>32</b>	<b>32</b>	<b>24</b>	<b>21</b>	<b>9</b>	<b>52</b>	<b>33</b>	<b>44</b>	<b>35</b>	<b>11</b>	<b>22</b>	<b>11</b>	<b>5</b>	<b>11</b>

**Number of Provisionally Registered Persons Extending Houseman Training  
According to Training Centres, 2000-2004**

Training Centres	Number of House Officers		
	2002	2003	2004
1. Hospital Tengku Ampuan Afzan, Pahang	5	-	-
2. Hospital University	11	-	-
3. Hospital Alor Setar, Kedah	17	5	9
4. Hospital Universiti Sains Malaysia	7	-	1
5. Hospital Tengku Ampuan Rahimah Klang	5	11	12
6. Hospital Ipoh, Perak	3	-	1
7. Hospital Pulau Pinang, Penang	5	-	1
8. Hospital Sungai Petani, Kedah	2	-	2
9. Hospital Kuala Lumpur	29	17	21
10. Hospital Melaka	5	2	7
11. Hospital Muar	2	3	-
12. Hospital Sultanah Aminah	11	15	16
13. Hospital Seberang Jaya	2	-	2
14. Hospital Taiping	3	4	1
15. Hospital Queen Elizabeth	3	8	8
16. Hospital Kota Bharu	31	13	17
17. Hospital Umum Sarawak	3	1	2
18. Pusat Perubatan Universiti Malaya	13	8	9
19. Hospital Kuala Pilah	1	6	-
20. Hospital Teluk Intan	1	1	-
21. Hospital Pulau Pinang	3	-	-
22. Hospital Seremban	-	-	-
23. Hospital Kangar	-	2	1
24. Hospital Kuala Terengganu	-	4	5
25. Hospital Sungai Petani		2	-
26. Hospital Selayang		-	3
<b>Total</b>	<b>162</b>	<b>102</b>	<b>118</b>

# SAFETY AND HEALTH IN DENTAL LABORATORIES

## SUMMARY

Audits on compliance to Guidelines on Occupational Safety and Health in the Dental Laboratory were undertaken in 40 dental laboratories in nine districts of Perak over 2003 and 2004. Data obtained was analysed and reported in nine broad categories - basic availability of guidelines, personal protection and environmental cleanliness, adequacy of facilities, keeping safety signs, ensuring safety by reducing risk to hazards, methods and frequency of waste disposal, the state of the physical condition of laboratories, the need for equipment and finally how the nine districts fared in this audit. It was found that compliance to the Guidelines has improved considerably over the two years. However, there is further room for improvement for basic infrastructure and there is a dire need for funds to upgrade and purchase basic equipment to help facilitate compliance to the Guidelines. The audit serves as template for application in other states, and lessons learnt have led to further measures for continuous quality improvement.

## Introduction

Dental technologists are predisposed to injury and ill health due to physical, chemical, biological, ergonomic, and psychosocial hazards related to materials, equipment and work procedures in dental laboratories. Addressing these concerns for safety and health in dental laboratories, the Oral Health Division initiated a series of discussions to formulate guidelines. Subsequently, the Guidelines on Occupational Safety and Health in the Dental Laboratory was approved by the Malaysian Dental Council in November 2002<sup>1</sup>. The guidelines outline processes that need to be taken by those working in, or who are involved with, dental laboratories to ensure their safety and health.

*Emphasis on safety and health in dental laboratories*

This article reports on an audit on compliance to these Guidelines undertaken in 2003 and 2004 in nine districts of Perak. It is hoped that the experience in Perak will serve as template for conduct of audits in other states towards continuous improvement in compliance to the Guidelines.

To heighten awareness of dental technologists on the need to ensure safety and health in their laboratories, the Dental Unit Safety and Health Committee of the State Health Department of Perak prepared a checklist (PKKKP-2)<sup>2</sup> based upon the Guidelines with input from dental technologists themselves.

*Empowering dental technologists*

The checklist was used as the instrument to audit selected dental laboratories in 2003. Subsequently, a second audit was done in 2004. The main aim of the annual auditing is to make dental technologists conscious of safety and health in their own respective workplaces through “LEARNING BY DOING” instead of assuming that any change of behaviour can be brought about through merely attending courses. Hence, the auditors were selected from among the dental technologists themselves, as self-auditing would give them a certain degree of empowerment.

**Methodology**

Forty out of 50 dental laboratories in Perak state were involved. The selection was limited to laboratories with dental technologists (Table 1).

*Selection criteria*

**Table 1 : Number of Dental Laboratories by Districts**

Districts	No. of dental laboratories
1. Kinta	12
2. Larut, Matang, Selama (LMS)	6
3. Manjung	5
4. Hilir Perak	4
5. Batang Padang	3
6. Kerian	3
7. Hulu Perak	3
8. Kuala Kangsar	2
9. Perak Tengah	2
<b>Total</b>	<b>40</b>

A briefing on use of the checklist was given to nine auditors. Selection of auditors was based on seniority. Each was given laboratories for auditing outside of their own district. For the year 2003, auditing commenced for nine days, while for year 2004, the auditing exercise was better co-ordinated and reduced to two days. Each auditor, on average, utilised two days to complete the task.

*Establishing the audit team*

The checklist consists of 48 variables under 12 headings. There were both categorical and ordinal types of data. The categorical data were given a score of either 0 for "NONE" and 2 for "YES" and the ordinal data were given scores of 0 for "NONE", 1 for "PARTIAL COMPLIANCE" and 2 for "FULL COMPLIANCE".

*Formulating the checklist*

The scores were later entered and summed up for each laboratory and the mean calculated for the district. The data was analysed and reported in nine broad categories.

*Preparing for analysis*

- Basics - the availability of guidelines and accessibility to training
- The Practice of Personal Protection & Environmental Cleanliness
- Adequacy of Facilities
- Safety Signs
- Safety Precautions Undertaken
- Waste Disposal
- Physical Condition of Laboratory
- Need for Equipment
- Scoring - Overall performance by the nine districts expressed in percentages

## Findings

Over the two years, there were only slight improvements in dental laboratories that kept copies of the Guidelines, and the number of dental technologists who have attended training sessions (**Table 2**). It would seem that some dental technologists do not show urgency in obtaining copies of important guidelines, in spite of having attended training sessions on safety and health.

However, there was considerable improvement in the practice of personal protection, except for protection from Hepatitis B, and in the practice of infection control during the transport of dentures at different stages of construction from the laboratory to the clinic (**Table 3**).

**Table 2 : Basics - Availability of Guidelines and Accessibility to Training**

Basic Items	2003	2004
Have Guidelines on Infection Control	71% (28)	67% (26)
Have Guidelines on Safety & Health in the Dental Laboratory	77% (30)	85% (33)
Had training - briefing/demo/courses/seminars	85%	95%

**Table 3 : Personal Protection & Environmental Cleanliness**

Items on Personal Protection and Environmental Cleanliness	2003	2004
1. Hepatitis B Vaccination	85%	87%
2. The use of gloves	75% (30)	97.5% (39)
3. The use of masks	65% (26)	97.5% (39)
4. The use of aprons	72.5% (29)	97.5% (39)
5. The use of goggles	97.5% (39)	97.5% (39)
6. The practice of infection control	95% (38)	82.5% (33)
7. Cleanliness	70% (28)	77.5% (31)

There has been concerted effort at solving the problem of clogged drainage pipes by installing plaster traps. There has also been considerable improvement in putting up warning signs (**Table 4**).

*Adequacy of facilities*

There has been some improvement in the provision of safety precautions. The methods and frequency of waste disposal from dental laboratories have also improved considerably (**Table 5**).

*Waste disposal*

Over the two years, there was considerable improvement made to the physical state of facilities based on findings from the first year of auditing (**Table 6**).

*Physical facilities*

Scores were added for each district and inter-district scores compared (Table 7). There were dramatic improvements in scores for Perak Tengah, Hulu Perak, Larut, Matang, Selama (LMS), Kerian and Hilir Perak; and moderate improvements in Manjung, Batang Padang and Kuala Kangsar.

*Inter-district scores*

The projected total estimate to ensure compliance to the Guidelines in terms of adequately equipping the 40 dental laboratories was RM 724,150 (Table 8).

*Need for funds*

**Table 4 : Adequacy of Facilities and Signage**

	2003	2004
<b>Items on Adequacy of Facilities</b>		
1. Plaster-traps to prevent clogging of drainage pipes	25% (10)	65% (26)
2. The segregation of labs to wet & dry areas	60% (24)	60% (24)
3. Availability of equipment repair rooms	12.5% (5)	12.5% (5)
<b>Items on 'Warning Signs'</b>		
1. "No food & drink"	32.5% (13)	97.5% (39)
2. "Inflammable"	22.5% (9)	77.5% (31)

**Table 5 : Physical State of Facility**

Items on Physical State of Facility	2003	2004
1. Ceiling	67.5% (27)	87.5% (35)
2. Windows	67.5% (27)	90% (36)
3. Blinds	37.5% (15)	45% (18)
4. Floor	72.5% (29)	82.5% (33)
5. Walls	65% (26)	87.5% (35)
6. Lighting	70% (28)	92.5% (37)
7. Ventilation	62.5% (25)	92.5% (37)

**Table 6 : Safety Precautions and Waste Disposal**

	2003	2004
<b>Items on Safety Precautions</b>		
1. Adequate number of plug points	82.5% (33)	85% (34)
2. Gas links that are in good condition	67.5% (27)	97.5% (39)
3. Inflammable items kept at safe distance to reduce risk to fire	77.5% (31)	97.5% (39)
4. No loading on single electricity source	75% (30)	35
5. Gas tanks placed outside the lab to reduce fire hazard	32.5% (13)	32.5% (13)
6. Provision of fire extinguishers/fire blankets	90% (36)	90% (36)
7. Provision of First Aid boxes	17.5% (7)	75% (30)
<b>Items on Waste Disposal</b>		
1. Method	37.5% (15)	97.5% (39)
2. Frequency	57.5% (23)	95% (38)

**Table 7 : Scoring District Performance**

District	2003 Score	2004 Score
1. Kinta	87	85
2. LMS	47	74
3. Manjung	74	79
4. Hilir Perak	68	89
5. Kerian	65	89
6. Kuala Kangsar	85	88
7. Batang Padang	78	82
8. Hulu Perak	64	86
9. Perak Tengah	35	70

**Table 8 : The Need for Equipment**

Equipment	Units needed x Unit cost	Cost (RM)
Dust extractor	2,000 X 2	4,000
Polishing lathe	6,000 X 11	66,000
Fume extractor	12,000 X 24	288,000
Exhaust fans	150 X 12	1,800
Ergonomic chairs	750 X 7	5,250
Lighting at 1200 lux	100 X 11	1,100
Air conditioners	1,500 X 26	39,000
Plaster Dispenser	2,000 X 34	68,000
Stone Dispenser	2,000 X 36	72,000
Surveyor	1,000 X 13	13,000
Ultrasonic cleaner	1,000 X 32	32,000
Water heater	3,000 X 34	102,000
Vibrator	300 X 12	4,800
Electronic wax-up	800 X 34	27,200
<b>Total</b>		<b>724,150</b>

## Discussion

Dental technologists are trained in a range of skills involved in the fabrication of prostheses used in the mouth and facial region. Items entering the dental laboratory are essentially inert materials that have been in contact with the patient’s mouth, saliva, and possibly, blood. Appliances leaving the laboratory are then returned to the clinician to be tried or inserted in the patient’s mouth.

*Increasing awareness*

Data show the need to step up access to important Guidelines on Infection Control and on Safety and Health in the Dental Laboratory for reference. Although dental technologists may have attended training sessions on safety and health, access to these documents is very important for purpose of constant reference.

*Need for reference material*

According to a study by Verran et al.<sup>3</sup>, perceived and/or actual remoteness from patients, lack of appropriate training, and lack of relevant research may lead to relatively little attention being paid to infection control policy within dental laboratories. A study by Kugel et al.<sup>4</sup> indicates that these concerns may be further compounded by lack of communication between dentists, staff members and dental laboratory personnel and that poor training of laboratory personnel in disinfection techniques may have a direct effect on the prosthetic results achieved in dental practices. Agostinho et al.<sup>5</sup> concluded that the polishing of dental prostheses can cause a dangerous cycle of cross-contamination involving dentists, laboratory technicians, patients and auxiliary personnel and is a possible source of transmission of communicable diseases in the laboratory and requires improved techniques for infection control.

*Potential occupational hazards*

However, concern for personal safety may have been taken too far in that there may be inappropriate use of gloves while operating micro-motors. This is unnecessary and may result in glove tears and clogging by sharp burs leading to minor injuries. Using surgical gowns is also inappropriate. It was observed that disinfection of impressions from the laboratory to the surgery was not usually carried out at some clinics. Evidence seems to indicate that disinfection may not be necessary after all. An in-vitro study by Sofou et al.<sup>6</sup> revealed that even after severe contamination, the risks to dental laboratory personnel are minimal and the study recommended “normal” hygienic procedures instead of disinfection.

*Addressing inappropriate processes*

The issue of cleanliness in laboratories may be compromised by lack of manpower. For Perak, however, this problem was rectified by the filling up of attendants’ posts at the time of preparation of this report.

There was not much improvement in the number of facilities with segregated dry and wet areas due to lack of space. The congestion is so bad that in some cases, the laboratory doubled up as a store for the clinic, and in another housed the janitor’s tools like brooms, mops, and dustpans. Some new clinics were also designed without sufficient windows to allow natural light. The audit also highlighted the crucial need for strategically placed exhaust fans to remove not only the dust in the air but also steam vapours. Hence, it is recommended that such input be considered in future designs of dental laboratories.

*Improving facilities*

Overall, the audit showcased many problems for which corrective actions were taken. These included rectifying potentially dangerous power supply connections, re-checking contents of First Aid kits, removing potential fire hazards such as keeping flammable materials such as books and acrylic monomer away from open flames, avoiding curtains in laboratories, appropriately storing gas tanks, and choosing appropriate fire extinguishers.

*Rectifying potential dangers*

Knowledge on appropriate use of disposal bags was heightened. Previously, there was overzealous use of clinical waste (yellow) bags, as many did not understand the differences between clinical or scheduled and domestic waste.

The dramatic improvements in some districts show that the awareness and conformance in these districts have improved because of this audit. Overall, the audit has shown that both management and the staff concerned need to work together as a team to bring about change for the better. It has helped in the assessment of needs for equipment and for upgrading of existing equipment.

*Immediate benefits of the audit*

More controlled studies are desirable, in order to identify any potentially hazardous procedures, and to assess risks for these procedures. The move for the quality system under MS ISO 9000 in the Ministry of Health Malaysia addresses these concerns in the public sector.

Dental technologists are also subject to metals, waxes, resins and silica that can cause irritation or allergic reactions, affecting either the skin or the respiratory tract. Post-market monitoring of adverse reactions caused by dental materials has been carried out in some countries. Van Noort et al.<sup>7</sup> reported that Norwegian, Swedish and UK projects have received 1,268 reports over 11 years, 848 reports over 5.5 years and 1,117 reports over 3 years, respectively, relating to adverse reactions seen or experienced by dental personnel and patients.

*Identifying other occupational hazards*

They observed that presently, there are no harmonized criteria for what can be classified as an adverse reaction related to dental materials. Under-reporting is a recognised problem, and lack of awareness and clarity as to what constitutes an adverse reaction may be contributory factors. A pro-active reporting system takes a considerable time to become established, but can generate a lot of potentially useful information. There is a need to raise awareness among dental professionals of the potential for adverse reactions due to dental materials, and to develop an internationally-accepted system of data

*Need for harmonized criteria*

gathering that can produce the evidence to reflect the extent, severity and incidence of adverse reactions to dental materials.

Literature on potential occupational hazards in the dental laboratory has highlighted diseases such as pneumoconiosis and silicosis induced by exposures to dental materials. Although no study has yet demonstrated a link between these diseases and occupational exposure of dental technologists, the Malaysian dental profession needs to be vigilant on all counts of potential occupational hazards as well as recommendations made for exposure-control methods in dental laboratories<sup>8-12</sup>.

## Conclusion

The audit on compliance to Guidelines on Safety and Health in the Dental Laboratory in Perak serves as a template for other states to follow suit with similar audits. The formulated checklist with input from dental technologists has put into perspective aspects of safety and health in the dental laboratory that has to be given focus by both management and operating personnel, and the audit underlines the need for training to raise awareness on these aspects. The use of the checklist has also identified need for improvement of basic infrastructure to help facilitate compliance as well unmet equipment needs.

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# SAFETY AND HEALTH OF DENTAL PERSONNEL IN THE USE OF DENTAL AMALGAM

## SUMMARY

Dental amalgam is a restorative material in use for more than 150 years but its use has generated much debate due to its mercury component. In 2002, the Oral Health Division of the Ministry of Health (MOH) published the sentinel document 'Position Statement on Use of Dental Amalgam' which incorporated an updated *Code of Practice for Dental Mercury Hygiene*. Several initiatives have been taken to monitor safety and health of MOH dental personnel with regards to handling of dental amalgam and also as recipients of dental amalgam restorations. Monitoring of dental amalgam use in MOH dental facilities covers several areas: adherence to the Code of Practice at the workplace, assessment of urine mercury levels among dental personnel, and assessment of ambient mercury vapour levels in dental surgeries. The Division continues to play the lead role in exercising vigilance on continuing use of dental amalgam.

## Introduction

Dental amalgam continues to be the material of choice in restoring teeth in load-bearing areas of the mouth, in spite of the increasing array of alternative materials. The use of dental amalgam has been extensively scrutinised and analysed over more than 150 years of its use. The World Health Organisation (WHO) and the *Federation Dentaire Internationale* (FDI) continue to support its use.

## *Dental amalgam in dentistry*

When combined with other metals, such as silver, tin and copper, it forms a biologically inactive amalgam<sup>1</sup>. Mercury helps the amalgam to set without shrinking, forming a strong and serviceable restoration that stands up to the pressures of chewing and grinding. Studies indicate that amalgam restorations are preferred by over 75% of dental practitioners in the UK<sup>2</sup> and by 54% of dental practitioners in the USA<sup>3</sup>. However, use of mercury in dental amalgam continues to be a contentious issue, generating many differing professional and lay opinions.

In 2002, the Malaysian Dental Council endorsed a 'Position Statement on Use of Dental Amalgam'. The document encompasses an updated *Code of Practice on Dental Mercury Hygiene*. The Position Statement considers a scientific perspective to continuing use of dental amalgam worldwide, and clarifies the stand of the dental profession of Malaysia on its continued use in the country.

*Continuing use of dental amalgam in Malaysia*

In producing this document, the dental profession commits itself to vigilance on all on-going research and updates on its use. Prior to the publication of this sentinel document, a previous older version of the *Code of Practice for Dental Mercury Hygiene* had already been in use in the MOH since 1980.

This paper elaborates on the various initiatives of the oral health services of the Ministry of Health Malaysia (MOH) to safeguard health and safety of its dental personnel and hence its patients. In laying stress on the dental personnel, it is to be noted that dental personnel handle dental amalgam on a regular basis and yet are 'patients' themselves, being recipients of dental amalgam restorations. These make them doubly exposed to any risks pertaining to use of mercury in the dental environment.

### **Putting dental amalgam into perspective**

Mercury is a naturally occurring substance. About 50% released to the environment is from human activity. Of that amount, 50% is emitted from combustion of fuels for energy production and about 34% from waste combustion. Sources associate manufacturers and consumers with 13% emission, with dentistry contributing less than 1%<sup>4</sup>.

*Differentiating amalgam from mercury*

Dental amalgam is not mercury, in spite of having mercury as a component. Hence, accurate differentiation of dental amalgam from its mercury content deserves emphasis. This is due to the fact that dental amalgam is often characterised as mercury, in spite of amalgam being an inert matter.

More recent literature emphasises issues of amalgam waste management with regard to the potential of mercury release to the environment. High heat incineration of amalgam waste results in release of mercury to the air. Therefore, it is not the existence of amalgam scraps that is of issue but rather the handling and ultimate treatment of such scraps. However, amalgam scraps subjected to two

differing Environment Protection Agency (EPA) extraction procedures in the USA indicate minimal concentrations of mercury released into the environment<sup>5</sup>.

### Monitoring dental amalgam use

#### *Knowledge and practice of dental surgery assistants (DSA) on use of dental amalgam*

In Malaysia, there is a dearth of studies on mercury hygiene knowledge and practice among dental personnel. In 2002, the same year of publication of the Position Statement on Use of Dental Amalgam, a study was undertaken on dental surgery assistants (DSAs) in five states of Peninsular Malaysia – Kedah, Terengganu, Selangor, Federal Territory Kuala Lumpur (FTKL) and Johor<sup>6</sup>. The aim was to assess knowledge and practice on dental mercury hygiene among DSAs in public sector dental clinics. The responses from 552 DSAs reflected a 90.5% response rate from these states.

A questionnaire was utilised to assess knowledge and practice on storage, use, handling and disposal of dental amalgam. Results are shown in **Table 1**. For some dimensions, items pertain only to practices that best reflected application of knowledge.

The self-reported results showed DSAs have overall good understanding of procedures for storage, use, handling and disposal of dental amalgam/mercury due to their training. Almost three-quarters of the DSAs had been trained at the Dental Training College in Penang while the remainder had been trained on-the-job. However, results also indicate that about one-quarter were unsure on procedures for management of mercury spills as well as for storage of scrap amalgam.

As the above study had the inherent bias of being self-reported and only involved five states, findings were interpreted with caution. Of note is that the results indicated that the majority (97%) understood the health risks they face and the need for precautionary measures and vigilance.

However, there were discrepancies in knowledge and practice. For example, while 94.2% agreed that it is important to remove amalgam excess from instruments before autoclaving, smaller proportions (83.8% in dental clinics and 88.9% in school clinics) professed to actually

*DSAs' mercury hygiene knowledge and practice*

*Good knowledge and understanding*

*Discrepancies in knowledge and practice*

**Table 1 : Routine Practices on Mercury Hygiene in General Dental Clinics (GDC) and School Dental Clinics (SDC)**

Items	Practices		Knowledge (%)
	GDC (%)	SDC (%)	
<b>1. Storage</b>			
a. mercury kept in unbreakable and tightly sealed container prior to treatment	80.6	95.0	98.5
b. amalgam scrap stored under the water	97.6	96.8	NA
<b>2. Usage</b>			
a. use precapsulated alloy	17.3	50.4	NA
b. do not use precapsulated alloy with broken seal	18.9	NA	NA
c. only use amalgamator	NA	93.9	NA
d. still using mortar and pestle to mix amalgam	NA	0.8	NA
<b>3. Handling</b>			
a. always wear gloves and face mask when assisting in amalgam filling	90.2	90.2	NA
b. remove excess amalgam on used instrument before sterilisation	83.8	88.9	94.2
c. keep sterilised instrument away from mercury container	96.5	96.1	NA
d. squeeze out excess mercury with dental napkin	NA	12.8	NA
<b>4. Disposal</b>			
a. make sure that amalgam waste, used capsules, extracted teeth with amalgam filling, used napkins, gloves, cotton roll contaminated with amalgam are disposed as clinical waste	87.3	68.4	86.8
b. throw all excess amalgam into the sink	NA	0.9	NA

NA – Not applicable

doing it all the time. The study corroborated the move by the Oral Health Division for additional training and phasing out use of bulk alloy/mercury to use of precapsulated alloy/mercury.

### *Monitoring adherence to the code of practice for dental mercury hygiene*

Subsequent to the publication of the Position Statement, the Oral Health Division tested checklists on practices for dental mercury hygiene and subsequently published a *User Manual on Recommended Practices for Dental Mercury Hygiene 2005*. The manual elucidates use of a checklist and questionnaire on work processes for dental amalgam. Sections of the checklist pertain to monitoring topics encompassed in the *Code of Practice for Dental Mercury Hygiene* :

- Working environment (ventilation / flooring/ worktops)
- Equipment and materials (storage of materials, storage of waste/ scrap amalgam)
- Handling
- Disposal of waste/scrap amalgam

A questionnaire was also formulated on :

- Training
- Handling
- Disposal

It was recommended that monitoring be observational and where necessary, interactive, to elicit information on aspects that cannot be directly observed, for example, on training received. Interaction would also give two differing perspectives of objective observation versus personal responses.

Initial visits in 2003 to 15 dental facilities in seven states showed good ventilation and good working infrastructure such as floors that are not potential mercury traps. It was found at that point in time that 75% of the dental facilities used bulk alloy/mercury. There were several negative points – it was found that amalgamators (40%), mercury containers (13%) and waste amalgam containers (27%) were placed close to the autoclave, a heat source. The visits revealed 40% using glass containers for waste amalgam (potential breakage) and 33% storing waste amalgam dry and not under water as recommended.

*Formulating a User Manual to monitor adherence to Code of Practice*

*Monitoring 2003*

With dissemination of the Position Statement and increased focus on proper use and handling of dental amalgam, subsequent random visits to 9 dental facilities in five states in 2005 revealed conformance to the points of issue raised from the initial visits. All waste amalgam was found stored in plastic containers under water with a layer of oil, all amalgamators, mercury/alloy and waste amalgam were stored in cool places, away from autoclaves and sunlight. Amalgamators were also found removed from proximity to air-conditioners to avoid dissipation of any potential mercury vapour in the surgery. Instruments for dental handling were also now stored separate from other instruments. As expected, bulk alloy/amalgam were still found in use due to staggered phasing out in favour of precapsulated alloy/mercury.

### *Follow-up 2005*

#### *Mooting a collaborative study on mercury exposure of dental personnel*

Concurrent to the above monitoring, the Oral Health Division submitted research need in year 2002 for a study on mercury exposure among dental personnel. This need was met through a collaborative research project headed by the Environmental Health Research Centre (EHRC) of the Institute for Medical Research (IMR) of the MOH, with participation from the oral health services, the Public Health Department, MOH and the Department of Occupational Safety and Health (DOSH) of the Ministry of Human Resource. The study aimed to determine the prevalence of high urine mercury level among MOH personnel and to determine risk factors for their mercury exposure.

### *Mercury exposure in dental personnel*

In this study, health personnel served as controls as they function in almost similar clinical environment as the dental personnel. Recruitment of subjects was in the ratio of 3 dental personnel to 1 health personnel. There was matching of personnel, for example for every 3 dental officers, 1 medical officer was recruited. Similarly dental nurses were matched against medical assistants / staff nurses / health inspectors. Dental surgery assistants were matched against the community or assistant nurses, while the attendants in dental clinics were matched against those in health clinics. Only operating dental personnel who handled restorative materials were included in the study. The total number of respondents recruited was 1,409 (75.3%) dental personnel and 462 (24.7%) health personnel.

### *Approaches*

The questionnaire utilised was designed to provide information on demographic and personal details, characteristics of job and facilities, precautionary methods adopted at work as well as other possible factors to mercury such as hobbies and use of cosmetics. Items were based on literature review of possible risk factors. Respondents were also required to provide at least 20 ml of urine sample for mercury analysis and to undergo oral health examination for the number of amalgam fillings in their mouth.

*Use of questionnaire and assessing urine mercury levels*

The Threshold Limit Value (TLV) for urine mercury level for dental personnel was set at 50 microgram/litre and 20 microgram/litre for the controls. Mean urinary levels among dental personnel (3.19 microgram /litre) and health personnel (2.94 microgram /litre) were not significantly different and very much below the TLV values.

*Low urine mercury levels*

Preliminary results presented at a professional forum<sup>7,8</sup> concluded that occupational exposure is not the main factor for mercury exposure among MOH personnel. Other factors such as environmental exposure, seafood consumption and use of mercury-containing cosmetics could affect the urinary mercury level.

*Occupational exposure not a factor found*

### *Monitoring ambient mercury vapour levels in dental clinics*

Monitoring also encompass efforts at assessing mercury vapour levels. An assessment of the working environment of trainee dental nurses in the Dental Training College in Penang showed levels of mercury in the air correlated with the number of amalgam restorations done<sup>9</sup>. However, the highest level was found during the simultaneous handling of dental amalgam by 63 students – a situation that does not equate with working conditions in the field. In spite of the large number of students concurrently handling amalgam at one time, the highest level of 23 microgram/m<sup>3</sup> was still well below the recommended threshold limit of 50 microgram/m<sup>3</sup>.

*Assessing mercury vapour levels in various dental facilities*

Specific dental procedures, such as opening of amalgam capsules and opening of the amalgam container indicate high but transient levels of vapour ranging from 83–350 microgram/m<sup>3</sup>.

However, a study to assess mercury vapour levels in 9 dental facilities in Malacca and Negeri Sembilan using a similar mercury vapour analyser found very low levels of mercury vapour levels, with the highest transient level of only 7.3 microgram/m<sup>3</sup> at an amalgamator dispenser<sup>10</sup>. Thus, the ambient air levels in field dental facilities were found to be well below the threshold limit of 50 microgram/m<sup>3</sup>.

*Sustained low mercury vapour levels*

## *Discussion*

In spite of the 'comfort' of results showing low ambient mercury vapour levels in MOH dental facilities and adherence to the *Code of Practice for Dental Mercury Hygiene*, the dental profession cannot afford to relax its vigilance to safeguard safety and health of patients and staff. While epidemiological and public health studies have not shown conclusive evidence of adverse health effects of dental amalgam use on the population, contention continues to centre around difficulties of harnessing evidence and of designing studies to demonstrate cause-and-effect.

*Continuing vigilance*

The oral health service is mindful that environmental readings fluctuate throughout the day in the dental surgery. Therefore, the collaborative study headed by EHRC with involvement of DOSH is looking into time-weighted assessment of mercury levels over an 8-hour day with a mercury vapour analyser capable of such an undertaking.

*Further mercury vapour assessment*

Research has also expanded from 'biological' monitoring of mercury levels in individuals to direct environmental exposure measurements<sup>4,5,11</sup>. The present occupational exposure standard accepted in the USA is 50 microgram/m<sup>3</sup> while many European countries have a standard of 25 microgram/m<sup>3</sup>. In the Malaysian context, further monitoring of the true environmental exposure in the dental surgery during a normal working day and the effect of ventilation and heating on the levels of mercury vapour are indicated.

Regular and systematic training and monitoring will also ensure non-complacency of dental personnel in their everyday handling of dental amalgam. It would seem that the training and monitoring system put in place has reaped positive results in proper understanding and adherence to the Code of Practice, while objectively putting into perspective the health risks. The main objective is not to unnecessarily 'sensationalise' risks that can be addressed through proper procedures and prudence.

*Continuing training*

Additionally, the Oral Health Division sees a downward trend in use of dental amalgam in the MOH. Over five years, amalgam restorations as a proportion of total restorations done in schools dropped from 48.5% (2000) to 25.2% (2004) for deciduous teeth and from 65.4% (2004) to 49.5% (2004) in permanent teeth (**Table 2**). These data from the

*Increasing preference for alternative materials*

Health Management Information System (HMIS) of the MOH best illustrate the trend in declining use of dental amalgam in preference for alternative tooth-coloured materials as these become increasingly tested and accepted. Certainly, there has been increasing use of alternative tooth-coloured materials for restorations in deciduous teeth as these materials become tested over time.

**Table 2 : Proportion of Amalgam Restorations to Total Restorations in School Dental Programme of the MOH (2000-2004)**

Year	Deciduous Restorations			Permanent Restorations		
	Amalgam	Total	%	Amalgam	Total	%
2000	292,154	602,380	48.5	699,914	1,070,848	65.4
2001	248,709	592,050	42.0	609,614	1,015,202	60.0
2002	214,994	593,164	36.2	572,942	1,031,273	55.6
2003	166,144	564,965	29.4	518,140	1,008,519	51.4
2004	141,514	561,529	25.2	538,754	1,088,224	49.5

## Conclusion

The Oral Health Division has played the lead role for the dental profession in Malaysia in clarifying the stand of the dental profession for continued use of dental amalgam. At the same time, it has initiated and sustained efforts to ensure adherence to the *Code of Practice for Dental Mercury Hygiene* in MOH dental facilities through the formulation and implementation of a user manual.

*Continuing vigilance*

Although international data show minimal contribution of mercury to the environment from dentistry, the dental profession continues to scan the horizon for continuing research on dental amalgam use. The MOH will continue to give emphasis to appropriate occupational hygiene practices and health surveillance of dental personnel. At the same time, there is on-going assessment of infrastructure of dental clinics to ensure safety and health of all who use them. Longitudinal monitoring is warranted to assess variations in exposure of members of the dental team.

*Sustaining monitoring*

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# HEALTH MANAGEMENT INFORMATION SYSTEM (HMIS)

## SUMMARY

The Health Management Information System in the Ministry of Health which was established in 1985 has served the Ministry well in producing health statistics and various reports that provide information for planning and development of health services as well as an important tool for decision making in Ministry of Health. To facilitate the provision of timely, reliable and valid data from an enterprise-wide system perspective, an Integrated, Comprehensive Health and Health Related Information System for the country is necessary. The participation of the health care stakeholders through the development and operation of a National Health Information Action Plan will ensure timely data for health information. A well structured organization supported by highly skilled and competent personnel is envisioned in the future through the establishment of a Center for Health Information in the country.

## Introduction

A Health Management Information System (HMIS) is essential for the effective planning, development, monitoring and evaluation of health programmes and activities in a country. It is a decision support system for health managers at different levels of management, in particular, decisions on resource allocation.

### Definition

To be effective, health information has to be actively managed to provide timely, accurate and useful information to facilitate decision-making for multiple purposes across diverse organizations, settings, and disciplines. Health information management involves continual data collection and processing, analysis, generation of meaningful information in the form of health statistics and reports, and their dissemination to people who need them.

Closely related to HMIS are two terms *Medical Informatics*, and *Health Informatics*. *Informatics* is the branch of science concerned with the use of computers and communication technology to acquire, process, store, analyze data and transforming them into useful information that can be displayed in various forms for more effective communication. Hence, '*Medical Informatics*' is concerned with the collection and processing of data to generate information concerning diseases and patients.

### Decision support system

The terms '*Health informatics*' is now more commonly used, reflecting a wider meaning, recognizing the scope of health which goes beyond diseases and patients. Health informatics is thus an essential and pervasive element in all healthcare activity. It is also the name of an academic discipline developed and pursued over the past decades by a world-wide scientific community engaged in advancing and teaching knowledge about health.

## **Evolution of health information management in Malaysia**

### *Pre-independence period*

Information support is essential in the development and provision of healthcare services. Such information is required for each of the three phases of health system management - namely planning, implementation and evaluation, providing information on resources used as input, services produced as output, and health outcomes for the eventual impact. Over the years, the management of health data has evolved into a system that captures information at each of the three phases of health system management.

During the British Civil Administration days (1874-1941), health information and events were recorded and documented as a by-product of services provided by the Medical Department. Data were generated at the service outlets, namely at hospitals, static (outdoor) and traveling dispensaries, maternal and child welfare centers, municipal clinics, leper settlements and mental institutions. Some form of procedure existed for recording these data into registers. Data from these registers were then reported on some predetermined formats according to types of services or activities.

Sanitary inspectors and public health nurses carried out collection of data for the public health activities in the course of their work. In the hospitals, static dispensaries and institutions for special diseases, data collection was carried out by hospital assistants and nurses. The data collection process was coordinated by the Medical Branch of the Medical Departments in each State.

*Collection of data for public health activities*

The annual *State Health Situation Assessment Report* was given to the Medical Department Headquarters (one for Straits Settlement States and the other for the Federated Malay States) to prepare an annual report on the health situation of the country as a whole.

Between 1948 to 1962, the gathering of health information rested with the Medical Services under the Ministry of Social Welfare. There appeared to be minimal effort at coordination of health information during this period, although the quantity and variety of data collected had increased as a result of more diversified health activities.

### *Post-independence*

In 1963, with the formation of Malaysia, the Ministry of Health and Social Welfare were merged to become the Ministry of Health. The responsibility for health information collection, in particular workload statistics, continued to be undertaken by the Medical Services Division for report writing purposes.

By the second half of the 1960's, this function was taken over by the Medical Records and Health Statistics Unit set up in the Planning and Development Division. The Unit functioned as a data coordination unit for the Ministry of Health.

In 1972, a Operation Research Unit (ORU) was set up. The primary function of this unit was to monitor the development of the National Health Information System (NMMIS). To strengthen the national health information system, the Ministry sought assistance from the World Health Organisation (WHO) in 1975 to study and recommend improvements to the existing system. After the study, MOH accepted WHO's recommendation to establish a comprehensive information system through a Health Management Information System Development Project (NHMISDP).

Following this in November 1978, the Chief Secretary to the Government directed all Ministries and Government Departments to set up Documentation Units to ensure proper documentation of data which are comprehensive and up-to-date, to assist the Government Agencies to take timely and effective actions in planning and decision-making. In compliance to this directive, the Information and Documentation System Unit (IDS) was established in the Ministry of Health in 1981, replacing the Medical Records and Health Statistics Unit and the Operations Research Unit, which functions till this day.

### *Establishment of IDS Unit*

## Achievements

### *Use of statistical health information*

Within the Ministry of Health, the HMIS system is being utilized by health planners and managers at all levels – from National Programme Directors/Managers to state, district and institutional levels. At the national level, they are used for health policy formulation, planning and development of programmes, activities and services, as well as resource allocations. At all levels, they are used for monitoring and evaluation of programmes, activities and services, as well as for research purposes. Secondary users include external agencies such as the Economic Planning Unit (EPU) in the Prime Minister's Department for health sector planning; research scholars conducting studies in specific areas and students from institutions of higher learning.

### *Achievements*

### *Statistical Reports and Publications*

The IDS produce several regular reports and annual publications. Among them are

- MOH Annual reports
- Indicators for Monitoring and Evaluation for Strategy for Health For All
- Health status reports
- Health performance reports
- Health utilization reports
- Health Facts
- HMIS reports by sub systems

Besides the above publications, several other ad hoc reports and health related information are available on request.

### *ICD-10 and medical records*

In line with WHO recommendation to introduce ICD-10 coding for classification of medical diagnosis, all hospitals in the country, both public and private hospitals, are required to code diagnosis using the ICD-10. Since ICD-10 was implemented in 1999, the MOH had conducted several training sessions to Assistant Medical Record officers (AMRO) and various categories of staff throughout the country.

### *ICD coding*

### *Interagency Collaboration Locally and Internationally*

HMIS data are shared and used by various government agencies locally as well as by international agencies such as WHO, SEAMIC and UNICEF. Information generated by this system will not only benefit the Ministry of Health, but also external agencies like the Statistics Department, Economic Planning Unit, and others.

### *Development of Health Informatics Standards*

Standardisation of health data and health information is vital in ensuring sharing of information across health care settings, both locally and internationally. In the 8<sup>th</sup> Malaysia Plan (8MP), initiatives were instituted to develop Health Informatics Standards. The Planning and Development Division was entrusted with the task of developing, maintaining and updating Health Informatics Standards. This was done in collaboration with the Telehealth Division and the end users of the Ministry.

*Standardization  
of data and  
information*

Several technical working groups were set up to develop the standards for the various specialty disciplines and activities. Among the standards and datasets developed so far, are the Facility codes, National Health Data Dictionary and Lifetime Health Record datasets. This will be an ongoing exercise, with the collaboration of universities and other industry partners.

*Networking  
infrastructure*

### *Health Management Information System Phase II infrastructure*

The networking infrastructure for HMIS (HMIS II) was further improved in the 8MP. The project covered all hospitals, district health offices, as well as selected health clinics. The availability of HMIS II infrastructure has enabled on-line data transfer among the users at all levels. Hence, various health reports, management and statistical reports as well as notification of infectious diseases can be generated in a timely manner as well as when needed. This had minimised the need for storage space for hard copies of documents. The issues related to networking and broadband connectivity is being addressed in the Information Technology Strategic Plan.

### *Reviewing HMIS sub-systems*

The National HMIS consists of several subsystems and formats for data collection has been revised and updated, among them, the Medical

Care Information System, Family Health Information System and Dental Information System to capture data for the expanded and upgraded services. A new reporting format for Blood Transfusion Services has also been developed.

Software applications for inpatient and outpatient workload have been enhanced to incorporate information on discharge diagnosis according to ICD-10. The database on detailed patient demographics, diagnosis and clinical discipline has been developed and implemented in the MOH hospitals. This data base has been the source of information for various research studies and creation of disease registries.

*Software  
application*

Communicable Disease Control Information System (CDCIS) was developed jointly by the Disease Control Division, and the Information Technology Centre (PTM). With this achievement, notification of diseases by the doctors can be conducted on-line to the respective health offices.

### *Challenges*

The 8<sup>th</sup> Malaysia Plan had envisaged a national HMIS to be a nationwide integrated HMIS covering both the public and private sectors. For this to happen, a National Health Informatics Centre (NHIC) is being proposed. The establishment of this centre and implementation of an integrated health information system for the country pose many challenges which are discussed below.

There is a need now to address data and information required on Population Health especially in areas of Health promotion and disease prevention, disease and conditions registries, disease surveillance and others. The required protocols and formats to accommodate the above need to be developed. The establishment of an integrated Health information System requires the setting up of a comprehensive data base/data warehouse supported by a robust and resilient infrastructure.

*Population  
health data*

### *Increasing use of ICT in healthcare delivery*

Continued investment in computing resources has resulted in diversity in the deployment of technology. Technology has become more complex, pervasive and interlinked, enabling more sophisticated exploitation of information. This, in turn, highlights the need for better

and enhanced information management policies, practices, and procedures and more uniform information content and messaging standards.

There has been an accelerated and heightened awareness of changing public health imperatives such as the need for reemerging communicable diseases and disaster preparedness, including disease surveillance initiatives. There are growing challenges to identify and solve community and global health problems. The movement toward a national health information infrastructure promises a significant change in the landscape.

In the fast changing environment, especially with rapid advancing technologies, the health planning approach must be more integrated, sensitive, receptive and responsive to change and needs. Therefore there is a need for outcomes monitoring and quality insurance indicators.

*Evidence-based  
health planning*

### **Health information management in Malaysia – the future**

Health Information Management System is essential to support evidence-based planning, management and decision making. With advancements in computing and information communication technology, there is an opportunity to change the manner in which the health information is managed. The requirement of an integrated and comprehensive health and health related information system for the country demands a well structured organisation supported by highly skilled and competent personnel.

#### ***National Health Informatics Centre***

The National Health Informatics Centre will be responsible for compilation and coordination of all health and health related information in the country. The Centre will focus on Strategic policies and activities in the Health Informatics. Establishment and deployment of Health Informatics Standards, operations and documentation of all health and health related documents.

#### ***National health information action plan***

A strategic plan for health information system will be developed to coordinate information from all stakeholders. There will be increasing role played by the universities, private sector and industry partners.

*National  
Collaborative  
effort*

These national collaborative efforts will ensure an Integrated Health Information for the health sector. The objectives of the National Health Information Action Plan are as follows :

- To improve governance and establish national collaboration through the establishment of National Institute of Health Information.
- To facilitate operations at the institutional level through deployment of electronic patient management systems in all hospitals and clinics.
- To improve access to timely and quality information through the implementation of electronic reporting system for all HIMS data.
- To review and develop legal and security framework for compliance to the provision of health and health related information.
- To develop and maintain national standards for health information management to allow for interoperability.
- To develop and maintain human capital for health informatics in the country.
- To liaise with national and international agencies on all aspects related to the health information management.

### *HIMS-e*

HIMS-e is an electronic reporting system for the collection, collation and analysis of Health information in MOH facilities. A web-based reporting system has been proposed whereby all health and health related data from MOH and non-MOH facilities, as well as the private sector can be transacted for timely and quality health information.

The scope of works for the above system will be :

- To create a data base to collect data needed for statistical reporting.
- To allow for data entry by the patient number (raw data) instead of cumulated data.
- To conduct data quality checks.

### *National health data ware house*

The National Health data ware housed in MOH will manage all health and health related information for population health projections, predictions and analysis. This will include information from both

public and private sector. This would be facilitated with the implementation of HIMS-e and the electronic patient summary system in the hospitals and clinics.

### *Training and manpower development*

Medical health informatics is a specialized area and requires properly trained personnel. The health informatician will be an expert group trained in the manner of medical research as in analysis and documentation of reports.

In-service, basic and post basic courses in health informatics shall be conducted to increase the pool of appropriately trained personnel for the challenges ahead.

### **Conclusion**

The healthcare industry, being an information intensive industry with many stakeholders, requires strong governance in the planning and management of health information. In line with the 9<sup>th</sup> Malaysia Plan goals and IT Strategic Plan, there is a urgent need to upgrade current capability of the IDS unit and establish the Health informatics Center to provide support for evidence based planning in the country. The Health informatics standards will provide a basis for standards nomenclature and practices, in line with Clinical Practice Guidelines for outcome measurements and monitoring of the health status of the population.

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# HEALTH PLANNING AND DEVELOPMENT IN THE MINISTRY OF HEALTH

## SUMMARY

Malaysia's national health plan is one component of the bigger picture in nation building. It addresses the health needs of the population towards achieving national goals, as outlined in the national strategic plans. The health planning process requires reliable and comprehensive health data and information from all sectors. To be effective, health planning must complete the full planning cycle, from health situational analysis through implementation plans, to the evaluation process, and back to the starting point for the next planning cycle. Priority setting and decision making process to identify areas of concern must be evidence-based and supported by a strong Health Management Information System. In this respect the Malaysian National Health Account and the Disease Burden Study are valuable planning tools. Implementation has to be monitored while evaluation methodology needs to be further improved to identify weaknesses and strengths of the health plan and the planning process.

## Introduction

The Malaysian health planning and development process forms part of the national development plan, which consists of short-term (annual) strategic plan, medium-term (5-year) and long-term plan made by the Government through the National Development Council.

*History of  
health planning  
in MOH*

Health Planning in the Ministry of Health (MOH) began in 1956 with the inception of the *first* Five-Year Malaya Plan (1956-1960). Subsequently, health planning has been carried out on a five-yearly cycle in the context of the national long-term and medium-term plans. Each 5-year Health Plan provides the direction for health and health-related agencies to address health needs of the population.

The 5-yearly plan came to be called the 5-year Malaysia Plan when Sabah and Sarawak joined the Malaysian Peninsular to form Malaysia, a new nation, in 1963. Thus, the first Malaysia Plan was born in 1966, covering the period 1966-1970.

While the 5-year plan is meant to be a national health plan, in reality, the implementation plan is principally a Ministry of Health affair for its facility and service development. This is not surprising as the Ministry of Health is still the major healthcare provider in the country while development in the private sector is mainly driven by market forces. However, since the Seventh Malaysia Plan (7MP), efforts have been made to greater integrate health plans with involvement of other health related agencies including non-MOH public sector, private sector and Non-Government Organizations.

In the early days, the 'health planning' process was a simple exercise of approving and implementing health facility projects with a given budget approved for the 5-year plan. Later, it progressed to a more systematic approach where proposals were to include clear objectives and show linkages for improvement in healthcare.

As the country progressed, more sophisticated planning processes were being adopted to ensure a more rational planning of healthcare services. Health planning has since evolved from being facility development focused, to cover a wider perspective of health and healthcare development in the country.

In the 8MP (2001-2005), a "Policy to Practice" approach was adopted, where the planning process starts with a common set of policies. These get translated into plans with objectives, strategies and implementation targets at the Ministry of Health level. During the 7MP, a more structured evaluation of the 5-year health plans was introduced. In the 8MP, the evaluation was further improved by incorporating Key Performance Indicators (KPI) which allows for continuous monitoring and evaluation of the plan. This requires reviewing and improving the Health Management Information System (HMIS) in the MOH to ensure that evidence is readily available for effective use in all health planning processes.

This 'policy to practice approach' will continue to be adopted under the 9MP (2006-2010) where the whole health sector works together to improve not only health but also the wealth of the nation.

## National strategic plan

As mentioned earlier, health planning in Malaysia is carried out in the context of the national planning process which consists of long-term and medium-term strategic planning.

The long-term strategic plans are known as the Outline Perspective Plans (OPP) which are for a 10-20 year period. In the OPP1 (1971-1990), also known as the New Economic Policy, emphasized on national unity, social restructuring and eradication of poverty. Under this policy, the health sector's contribution included control of communicable diseases and strengthening of rural health services and training facilities.

With the OPP2 (1991-2000), also known as the National Development Policy, focused on growth with equity, balance and equitable development. This period saw the expansion of MOH healthcare facilities and a rapid growth of the private health sector. The National Vision Policy was introduced in OPP3 (2001-2010), with the thrust on sustainable growth, creation of a united nation, promotion of an equal society and the creation of a knowledge-rich population using information and communication technology (ICT) as the enabler.

The medium term plans, also known as the *5-year Malaysia Plans*, are consistent with the long-term strategic plans.

The MOH as the lead agency in matters related to health plays a major role in the formulation of the national 5-year health plans. This document contains the direction for the health sector for each 5-year period and delineates *goals, strategies* and *plan of action* on how to achieve the set targets with an in-built mechanism to monitor its implementation.

The 5-year national health plan is the basis for planning activities under each MOH Programme. For example, the Health Education Division draws up plans to enhance promotion of healthy lifestyle practices (plan of action) to reduce the disease burden of the country (strategy) to ultimately enhance the health status of the population (goal).

The states and districts, meanwhile, carry out their respective plans based on these 'generic' health plans formulated by the Programmes and Activities at federal level. This allows some level of uniformity in the implementation of the national health plan yet has enough flexibility to enable local implementation to suit local needs.

*Outline  
Perspective  
Plans - long  
term strategic  
planning*

*The 5-year  
Malaysia Plans*

## Malaysian health planning and development process

### *Guiding principles*

In formulating the 5-year Health Plans, as for all federal level planning, the MOH is guided by national policies and plans that include Vision 2020, the National Vision Policy, the National Integrity Plan and National Economic Recovery Plan.

*National policies & Vision for Health*

In line with the nation's Vision 2020, the Ministry of Health also adopted a Vision for Health which envisaged "a nation of healthy individuals, families and communities through a health system that is equitable, affordable, efficient, technologically appropriate, environmentally adaptable and consumer-friendly, with emphasis on quality, innovation, healthy promotion and respect for human dignity, which promotes individual responsibility and community participation towards an enhanced quality of life" policies.

### *Methodology of 5-year health planning process*

The formulation of the 5-year Malaysia Health Plans involves detailed technical planning. To be effective, this planning process must be supported by relevant, current and valid data or information to ensure goals, objectives, and strategies are evidence-based. Goals and objectives are those of national importance or of great significance, and strategies must be implementable. As an example, during the 9MP (2006-2010), the MOH plans to develop and improve the quality of health services through consolidation strategies. Strategies delineated to realize this goal include emphasis on upgrading of existing facilities rather than building of new facilities, investing more on human capital and training facilities. In this respect, relevant Programmes and Activities must be supported to ensure continuity and sustainability of healthcare delivery.

*Evidence-based decision-making process & feasibility of implementation*

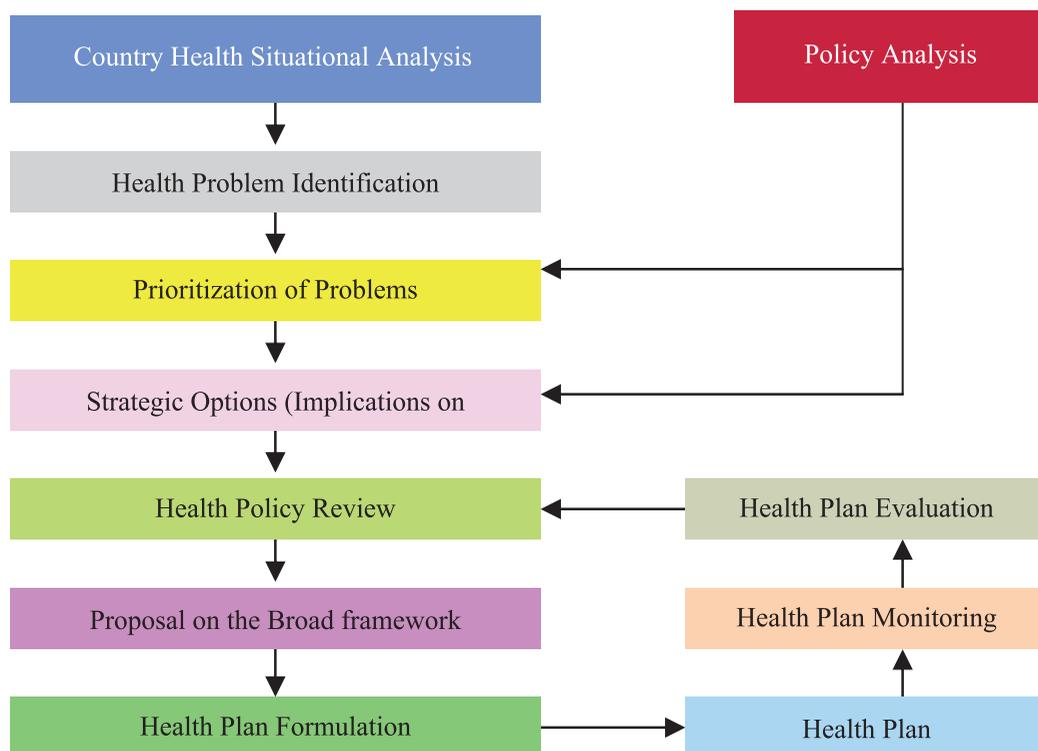
The 5-year Health Plan and Development Planning Cycle is shown in **Figure 1**.

*Planning cycle*

The 5-year planning process begins with a country health situational analysis. This looks at the health status of the population, their health needs and concerns. The analysis reviews policy, programme and project implementation at all levels. It measures the achievements, identify bottlenecks in implementation and suggest measures to improve the country health situation. The analysis provides the current scenario and the way forward.

*Situational analysis*

**Figure 1 : The 5-Year Health Planning and Development Process**



Source: Planning and Development Division, MOH

Areas to be given priority during the next 5-year period are identified commensurate with resource availability.

*Prioritisation of areas*

Involvement of various stakeholders in health both from the public sector and private sectors including the NGO's in the formulation of health plan is achieved through various avenues such as through the MOH Annual Health Dialogues, various workshops and discussion for the preparation of the 5-year plans including the 5-year health plan conference, and discussion in the Inter-Agency Planning Group (IAPG) meetings that is coordinated by the EPU and where issues of health and non-health matters and others are discussed.

*Intersectoral & intra-sectoral involvement in health planning*

Technical Working Groups (TWGs) formed in preparation for the 5-year plan is headed by representatives from the MOH and are developed to study various topics, titles or prioritised issues pertaining to health. Members of these TWG groups are usually among representatives or experts from various stakeholders in that particular

field of health issue that is being studied. Recommendations of the TWGs are made after considering the implications and resources available for implementation. Usually all TWG papers will be presented at the IAPG meetings and there will be further discussions and deliberations on areas of concern.

Based on various inputs such as health situational analysis, evaluation of 5-year plans and its recommendations, TWGs and its recommendations, and other inputs, the existing health policies are reviewed and where necessary, new policies formulated. These health policies, the prioritised areas of concerns and suggested strategies are then translated into the 5-year Health Plans.

The proposed health plan is then submitted to the MOH Policy and Planning Committee (JDPKK), which is the highest policy decision-making body in the MOH. Once approved and endorsed, the national health plan is presented to the Health Minister for final approval before submitting to EPU in the Prime Minister's Department. Subsequently, within the MOH, the proposed facility and infrastructure development will be identified either centrally or locally at the State and District level. Health system plans will be implemented at all levels of health care through out the 5 years and all these will be in tandem with the 5-year plan.

*Approval and endorsement of health plan*

### **Monitoring and evaluation**

The process continues with monitoring of the health plan implementation. Achievement and progress of the plan is monitored annually through analysis of key performance indicators (KPI). The central Government monitors each sector's achievement through a "policy achievement" evaluation system (*pencapaian dasar*). Similarly, the achievement and progress of the various programmes and activities are monitored at both federal and state levels. Financial performance is monitored through progress reports on development budget spending. In the middle of the 5-year period, a mid-term review is jointly conducted by the MOH and the EPU. This review allows for adjustments to the 5-year health plan and commensurately, budgetary re-alignment.

*Mid-term review*

Structured evaluation of the health plan conducted at the federal level provides feedback for the next planning cycle. During the evaluation process, an array of questions will provide clues to identify

*Evaluation of health plan*

significant or critical areas of concerns. The evaluation exercise must be able to signal areas of concern for the next 5-year plan to work on. This evaluation of the 5-year health plan is done prior to the completion of the respective 5-year period.

### *Healthcare facility and infrastructure planning*

Within the Ministry of Health, facility and infrastructure development can be identified centrally or locally at the state and district or even hospital levels. However, they must be in tandem with the 5-year national health plan. Thus, under the 9MP, priority will be given to proposals for upgrading of hospital facilities rather than building of new hospitals.

All healthcare facilities including private healthcare facility planning and development must comply with all relevant laws regulating such facilities.

### **Issues, challenges and the way forward**

#### *Adequacy and reliability of health and health-related information*

Effective health planning depends on the availability of health data and information, and the reliability of such data. A true national health situation data must be able to reflect the health situation for the whole country using data from all or most stakeholders from the public and private health sectors as well as from all health-related sectors. Data from MOH are readily available but information from other sources such as the private sector, NGOs, universities and local councils need to be improved and harmonized within the existing health data.

Access to non-MOH databases and other Government of Malaysia (GOM) studies needs to be improved. The collection of primary evidence from surveys such as the National Health and Morbidity Surveys (NHMS) and the National Disease Burden Study needs to be supported. The HMIS under the MOH must be strengthened and made the one-stop centre for all health and health-related information data source in this country.

*Healthcare  
facility planning*

*Strengthening  
data source*

### *Priority setting and decision-making*

Health sector decision-making is complex where decision-makers must balance needs and demands in an environment of scarce resources to advice, and to maintain and sustain a desired health goal. Priority setting itself requires skill in balancing variables that have very different quantitative relationships and lie in different dimensional scales. These decision-making and priority setting skills need to be enhanced within the MOH itself, especially among the health planners.

*Increasing capacity and capability of health planners*

### *Monitoring health sector-wide implementation*

The Health Plan is a strategic plan for the whole health sector. An effective monitoring mechanism is needed to gauge its implementation and a methodology to identify bottlenecks early must be devised to allow successful implementation of the health plan.

*Inter and cross-sector monitoring mechanism*

### *Establishing a National Health Accounting System*

A National Health Accounts (NHA) to describe who pays (sources of healthcare funding), for what (types of providers and functions of health services) and at what cost (health expenditure) is needed to monitor the trend, level and distribution of health expenditures in Malaysia. This planning tool needs to be institutionalised in MOH for health planners to use.

*Institutionalising a Malaysian National Health Accounts*

### *Healthcare facility planning to be congruent with need*

Under-utilisation or over-utilisation of healthcare facilities can be avoided if quantifications of the projected patient care needs (both primary and derived) are evidence-based. An integration of the physical facility planning (both new and existing), and human resource planning is required to improve operational problems. Regular reviews of relevant standards, norms and guidelines are needed to plan and develop safe and functional, value-for-money facilities that will pave the way towards benchmarking against other health facilities at local and international level. Adoption of new technology also requires careful evaluation and economic analysis before they can be adopted in a project.

*Evidence-based projections of needs*

## Conclusion

In planning a national health plan, the planning process must involve all relevant stakeholders in health to ensure better acceptance and improved implementation. Health planning must use every available tool to ensure plans reflect the true healthcare needs of the population. Better monitoring and an effective evaluation system must be built into the process to improve implementation of the health plan and to gauge its impact. A good Health Management Information System is vital for successful health planning.

*Good planning requires data, information, and support of stakeholders*

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# CONTINUING PROFESSIONAL DEVELOPMENT (CPD) FOR HEALTHCARE PROFESSIONALS

## SUMMARY

Healthcare professionals must maintain a high level of competency in the midst of rapid development in medical science and technology to ensure the delivery of quality healthcare service. The Ministry of Health Malaysia initiated discussions on the development of a CPD implementation plan for the country, outlining the organization structure, process of monitoring and evaluation, award of CPD points as well as self evaluation. Effort is being made to integrate CPD programme for healthcare professionals in the Ministry of Health, and the government's Competency-based Evaluation system for the civil service introduced in 2002.

## Introduction

In an era of rapid advancements in medical science and technology, it is essential for healthcare professionals to continually upgrade their skills and knowledge to be effective and competent as healthcare professionals. Competence is vital and forms the core of the work ethics of professionalism in the medical profession. To ensure that standards of competency are being maintained at all times, healthcare professionals at various levels must be continually evaluated. The trend towards regular revalidation of competencies for all medical practitioners will require doctors to prove that they are competent and that their skills are up to date.

*Competency,  
vital for  
professionals*

Realizing the importance of continuing professional development (CPD) in ensuring a highly competent workforce, a national workshop was held in January 2004 to discuss issues pertaining to the implementation of a CPD programme in the country. A second workshop will be held in early 2005 to discuss the issue of integration of CPD and the new government competency-based evaluation system for the civil service. This report highlights issues discussed at both workshops and the conceptual framework for CPD programme in Malaysia.

*National  
workshop on  
CPD*

## Continuing professional development (CPD)

CPD has been defined as “the systematic maintenance, improvement and broadening of knowledge, understanding and skills, and the development of personal qualities necessary for the execution of professional duties throughout the individual’s working life”.

*Definition of CPD*

In simple words, it means continual learning to maintain a sufficiently high standard of professional competence to fulfill one’s present or future roles effectively, and to remain employable in an ever competitive job market.

CPD is more than the traditional continual medical education (CME). CPD programme deals with issues that are linked with professional competency, provision of quality health care and improved health outcomes, all of which lead to measurable improvements in the process and outcomes for patient care. It also deals with issues related to the changing roles of healthcare professionals, the need for better team work, the importance of effective communication, and continuing education.

*CPD versus CME*

The CPD is required to maintain professional competence in an environment of rapid changes in technology and clinical practice, where there is increasing public expectations and demand for better quality of care, as well as need for greater accountability. Hence, healthcare professionals must keep abreast with new developments and advances in their respective areas of work to practice up-to-date medicine. Thus, CPD will ultimately improve patient care, in addition to providing intellectual challenge and fulfillment to the healthcare professionals.

*CPD is essential to maintain competence in changing environment*

CME refers to the continuing transmission of medical knowledge, values and norms to members of the medical and allied health professionals in order to keep them abreast of development in their field so that they may continue to perform optimally in their roles as health care providers. The programme usually involved a top-down approach with formal lectures and short courses, where the focus is mainly on clinical performance and not on patient outcomes. Such passive dissemination of information is the least effective method in influencing changes in physician practice and will not therefore affect patient outcomes.

*CME - continuing transmission of knowledge and values*

Thus, while CME contributes to and is a component of CPD, CPD is essentially a broader and more holistic process than CME. CPD goes beyond the traditional CME which largely caters for updating of technical knowledge. CPD encompasses the transmission and acquisition of other knowledge, skills and personal qualities relevant to and necessary for the present job, as well as for the future roles and responsibilities, such as managerial, conceptual and human relation skills. However, during the past decade, the distinction between the two is becoming less clear, as modern CME programmes have come to include topics beyond the traditional clinical medical subjects.

*CPD is broader than CME*

### **Ensuring professional competency**

The ultimate goal of CPD is to improve health outcomes and patient satisfaction through enhancing professional competence. Key issues in ensuring competency include evaluation of professional competence, the necessity for revalidation or recertification and dealing with “problematic” and incompetent health care providers.

*CPD will improve health outcome*

At present, there is no way of knowing exactly how competent a health care provider is, apart from the usual feedback from patients or other healthcare associates. Often, the number of certificates of attendance at scientific meetings that are strategically displayed, and perhaps, the number of credit CME points being accumulated may be perceived as an indication of one’s competency. Such certification and points may not accurately reflect the actual competence of the healthcare professional concerned, as certificates and points can be collected during registration at scientific meetings without much indication as to whether one has benefited from such meetings.

*CME points may not reflect competency*

Some of the tools used for evaluating professional competence include benchmarking performance against professional standards, medical audit, Peer review, patient outcomes studies and patient satisfaction studies.

*Tools in evaluating competency*

### **Revalidation**

Revalidation and recertification may be necessary to assess real performance in practice and ensure competence to continue to learn. The USA is a firm believer of recertification as they are of the view that the disparity of skills amongst healthcare providers makes it imperative to maintain common core standards. The Americans issue time-limited certificates and conduct formal examinations. The UK,

*Revalidation systems in various countries*

Australian and Canadian Colleges do not have formal examinations. Instead their assessment is linked to performance. Some use credit system or set number of hours of attendance at CME programmes per year. In Canada, weighted credit systems are used, where greater emphasis is given to selected CME programmes and different programmes are given different credits or hour. Only the Netherlands has a legislated recertification system although UK and several other countries are considering introducing compulsory revalidation.

Malaysia is probably not ready for any form of recertification exercise for our healthcare professionals at this stage. However, looking at the trend in developed countries, it is imperative that this would be the way to go in the future. There is also a need for some kind of mechanism to identify under performing doctors, and provide avenues for them to improve.

*Malaysia may not be ready for revalidation system*

### **Organizational structure**

To ensure a successful CPD programme in the country, some form of organization is needed. This organization should be an independent body, with representation from various professional groups. It will play a stewardship role and be responsible for the development of CPD programmes for the various professional groups. In the interim period, however, it is proposed that a National CPD Committee under the Ministry of Health be established, until such time its function can be taken over by an appropriate body. The main role of the National CPD Committee is to identify, develop and promote standards for quality continuing medical education utilized by professional groups in their maintenance of competence and incorporation of new knowledge.

*National CPD Committee*

### *Terms of Reference :*

- Formulate policies on CPD and recertification.
- Accredite CPD providers based on agreed criteria.
- Endorse guidelines on criteria of CPD contents and award of CPD points.
- Monitor and oversees the quality of CPD activities.
- Monitor the implementation of CPD activities.
- Make recommendation on the reports receive from various subcommittees.
- Provide avenue for appeals.

## *CPD Subcommittees*

To facilitate the above functions, the various professional groups should establish subcommittees to define their respective CPD needs and advise the National CPD Committee. The members should consist of senior members of that profession and may include representatives from the MOH, professional bodies, universities and others, where relevant.

*Subcommittees  
for various  
professional  
groups*

### *Terms of Reference :*

- Identify relevant CPD activities.
- Assist/ensure availability of CPD activities.
- Establish criteria for awarding of CPD points.
- Evaluate CPD activities conducted by providers.
- Award credit points based on established criteria.
- Establish minimum CPD credit points required for every member per year (Calendar year: 1 Jan – 31 Dec).
- Establish database to monitor members' progress (on-line).
- Establish discipline specific website with links to members and CPD Board.

### **The CPD process**

- **Registration :** a health professional will register on line with the CPD National Database/Registry, managed by the CPD secretariat.
- **Providers Application :** the organizations/agencies/departments who carry out CPD activities (CPD Providers) will apply to the CPD secretariat for credit points for their activities and submit the attendance lists.
- **Submission of CPD Activities :** individuals submit their CPD activities (with verification at local level by their immediate supervisors), on line or paper-based to the CPD secretariat.
- **Record-keeping/ Documentation :**
  - a) Personal Development Plan – the individual is responsible for maintaining its records on professional development activity. To assist in this process, every individual is encouraged to have, at the beginning of the year; their own

Personal Development Plan (PDP) to identify, plan and chart their CPD needs annually. This can form the basis for future appraisal and serve as evidence to support revalidation.

- b) CPD Logbook – the individual is required to maintain a logbook to record CPD activities for each year. The log can be maintained either in paper or electronic format once there is better access to the Internet.

*Monitoring :*

- a) Evidences collected from the logbook.
- b) Documented evidence of involvement or Attendance record of specific course/sessions.
- c) Certification from skills courses

Individual, supervisor and professional group CPD Sub-committee can monitor CPD performance on line and in real time.

### **CPD activities - CPD credit points award system**

The MOH's CPD Programme has extended its programme to all healthcare professionals in the MOH, including the allied healthcare professionals. The CPD utilizes a credit point award system in which a generic format of activities is designed that can be translated for use and is applicable to all healthcare professionals. There is no limit to the range of subjects to be undertaken, which include the areas of technical, managerial, professional and personal development. In general the CPD Credit Point Award System has two major sections, namely :

- Functional/clinical/core activities which are directly related to technical competence of the individual (Category A 1 – A 10).
- Generic/non-core activities which are related to overall personal development of the individual (Category B 1 – B 3).

Individuals will earn credit points after successfully undergoing CPD activities with verification. In the public sector, such CPD credit points could be used as a career pathway for doctors. This means that to be eligible to a higher level, an individual must provide evidence that he/she has participated in some form of CPD activities for which the CME points attained meets the eligibility criterion required for promotion.

*CPD credit point system*

*CPD points to support career development*

## CPD requirements

Each profession would determine the minimum credit points desirable per year to maintain and improve competency. A healthcare professional must obtain at least 75% of category A and 25% of category B points each year. However, there is no limit to the acquisition of points for CPD.

CPD carries with it the implicit understanding that the healthcare professional would take personal responsibility for/her his own professional development. This includes analyzing his/her learning needs, putting into place and executing a development action plan for an appropriate career pathway. The individual should monitor his/her progress and maintain a professional development record or a portfolio on training activities undertaken and practical experience gained, with sufficient details as documentary support to facilitate validation.

*Individual responsibility for CPD*

## Personal development plan / electronic diary

To facilitate CPD, all healthcare providers shall be provided with a record card or electronic diary. The setting up of Online CPD monitoring as part of Tele-CME will serve the functions of Electronic Diary and shall provide the directory of accredited CPD providers and serves as a linkage between CPD providers and users. It will facilitate the awarding of CPD credit points by channeling the points accumulated by the end-user to various relevant professional bodies awarding such points and also be a tool for health care personnel to plan their CPD activities. The user can of course undertake in self-directed learning or self-regulation by choosing appropriate packages in the privacy of his/her clinic or whatever facility that is available for CPD transmission.

*Electronic diary to record and track progress and CPD points*

The use of multimedia, the internet and more importantly, the Tele-health initiative will make CME and CPD more accessible to all doctors, both in the public and the private sector as well as in rural or urban areas. This form of Tele-CME would allow the practitioner to have instant information to support patient care. An added advantage is that all such activities can be captured and be automatically awarded the relevant credit points. The availability of such “just-in-time” information support system is likely to be attractive and considered relevant to practitioners and, therefore be easily accepted and patronized by them, leading to better patient care and health outcomes.

*Tele-CME to support CPD*

## **CPD and Competency-based Evaluation (*Penilaian Tahap Kecekapan- PTK*)**

In line with the government's initiative to improve efficiency of the public service, as well as to develop a knowledgeable and competent work-force, the government introduced a competency-based evaluation system ( PTK) for its civil service in November 2002. This consists of incremental levels of assessment by way of in-service training courses, oral and written projects, and examinations for different categories of work-force. Results of the evaluation are used for pay increments as well as used as basis for promotion..

*New competency based evaluation (PTK) for civil service*

While in principle, the PTK system is accepted as necessary to develop a more knowledgeable and competent civil service, there are also concerns that the system does not truly measure technical competency in the various professional realms. Moreover, the requirements of two systems for the same purpose will lead to frustrations for the professionals and waste of resources, including time spent away from work. CPD shares the same objectives as the PTK but is specific to the areas of technical/professional development.

*CPD and PTK serve the same purpose*

As such, it is desirable that the CPD be integrated into the PTK system. A national workshop was held in January 2005 to discuss ways to integrate CPD into PTK<sup>2</sup>. The basis for integration is as follows :

*Proposal for integration of CPD and PTK for healthcare professionals*

- CPD covers all elements and objectives of PTK.
- Duplication of work (CPD and PTK).
- Reduce time away for officers to sit for exams and attend courses.
- Motivation of staff and recognition of self-development.
- CPD allows for customization of assessment for different specialties and subspecialties.
- Standardization in the performance assessment system, particularly in the functional competencies.

Recommendations of the workshop have been forwarded to the Public Services Department for consideration and it is hoped that this would be accepted to the government.

## Conclusion

CPD for healthcare professionals is an important strategic instrument for improving the quality of healthcare service. It is a way of maintaining standards of healthcare for the population. Through CPD, all healthcare professionals can achieve professional and personal growth and development, as well as acquire and refine the skills needed for their current and future new roles and responsibilities. Investing in CPD is expected to improve health outcomes and provide greater satisfaction for the consumers or patients.

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*Chapter*

# 4

## RESEARCH AND DEVELOPMENT



# SETTING NATIONAL HEALTH RESEARCH PRIORITIES FOR NINTH MALAYSIA PLAN

## SUMMARY

The Combined Approach Matrix (CAM) developed by the Global Forum for Health Research was used to identify national health research priorities for the Ninth Malaysia Plan. Matrices and research priorities are prepared for the eight most important Burden of Disease (BOD) conditions, namely, (1) ischaemic heart disease, (2) mental illnesses; (3) cerebrovascular disease / stroke; (4) road traffic accidents; (5) cancers; (6) diabetes; (7) infectious diseases; and (8) respiratory illnesses. The process started in September 2005 with the appointment of a Steering Committee and Expert Groups for each of the BOD conditions. The process will culminate in a Forum to be held tentatively in January 2006 where recommendations of the Expert Groups shall be presented, discussed and endorsed.

## Introduction

Since the inception of the national Intensification of Research in Priority Areas (IRPA) research funding scheme during the Fifth Malaysia Plan, the Ministry of Health (MOH) has been entrusted with the setting of national health research priorities for each 5-year Malaysia Plan.

*Setting national health research priorities*

With foresight, the MOH has always ensured that the scope of national health research priorities extend beyond the context of IRPA such that they truly reflect the essential national health research needs of the country. In 2005, the MOH embarked on setting the national health research priorities for the Ninth Malaysia Plan (2006-2010).

In the past, health research priorities were largely based on consensus at national forums attended by representatives of researchers, health service providers and other relevant stakeholders. There were limitations to this methodology.

*Consensus at national forum*

The major limitation was that there was little background review of existing information on current and potential future health problems to identify gaps of knowledge that need to be addressed by research. Another limitation was that not all health or medical disciplines were

represented at such forums and thus some critical areas were not included. There was some opinion that the priorities set were very broad and were research interests of individuals rather than national priorities.

### Format for setting health research priorities

The problem of developing an ideal format for setting health research priorities is one faced by many nations at all levels of socio-economic development. To address this issue, the Global Forum for Health Research in 1996, developed a 'Combined Approach Matrix (CAM)' for setting of research priorities.

### *Combined Approach Matrix (CAM)*

CAM incorporates the best features of existing priority setting mechanisms and is endorsed by the World Health Organization (WHO). Briefly, CAM is a tool that aims to :

- classify, organize and present information that enters into priority-setting process;
- identify gaps in health research; and
- identify health research priorities based on a process that includes main stakeholders in health and health research. It incorporates both economic and institutional dimensions into a single tool.

The advantages of CAM compared to other tools are that :

- it organizes, summarizes and presents all available information on one disease, risk factor, group or conditions; and
- it facilitates comparisons between the likely cost-effectiveness of different types of interventions at different levels.

A proposal from the Secretariat Standing Committee for Medical Research, MOH, to use CAM for the setting of national health research priorities was approved by the Director General of Health. Based on findings of the national 'Burden of Disease (BOD) Study' by the Institute for Public Health, the top eight BOD conditions were identified for development of matrices and identification of research priorities. Those 8 conditions are :

### *Application of CAM for setting national health research priorities*

- ischaemic heart disease;
- mental illnesses;
- cerebrovascular disease/stroke;

- road traffic accidents;
- cancers;
- diabetes;
- infectious diseases; and
- respiratory illnesses

A steering committee chaired by the Deputy Director-General of Health (Research & Technical Support) was appointed. Members included a Deputy Chairman, a Secretary, and eight members who are Chairpersons of expert groups for each of the eight BOD conditions. Five of the Chairpersons are MOH officers and three from the Universities. The first meeting was held on 20 September 2005 where members were briefed on CAM and its application. Each Group Chairperson then identified their members and all were briefed on CAM at the first meeting of Expert Groups on 13 October 2005. All matrices and list of research priorities were to be submitted to the Secretary of the Steering Committee before 15 December 2005. At this juncture, only three groups have submitted their matrices and recommendations on research priorities.

*Status of activities*

Tentatively, a Forum was scheduled for early 2006 where matrices and recommended research priorities shall be presented, discussed and endorsed. The Forum will be chaired by the Director-General of Health and will be attended by members of the Steering Committee, members of Expert Groups, MOH and non-MOH health researchers, health service providers and other relevant stakeholders.

*Forum on setting national health research priorities*

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# GLOBAL INFORMATION HUB ON INTEGRATED MEDICINE: MALAYSIA STRATEGIC INITIATIVES

## SUMMARY

The increasing global interest on traditional and complementary medicine (T/CM) and the idea for a global information hub on T/CM has given Malaysia the opportunity to establish *InfoHub*, a global information hub on integrated medicine, a unique Malaysia initiative project. With strong support and commitment from the government, and the strength of ICT infrastructure already established in the multimedia super corridor, Malaysia was given the endorsement to implement this project by not only local but also international governance. Launched in October 2003, the prototype webpage *www.Globinmed.com*, contained information on T/CM from local partners as well as from the first international partner, NHionDemand, from USA. In order to ensure that InfoHub's vision is met, a strategic win-win partnership with local and international, government as well as non-government organizations (NGOs) is adopted, with phased implementation to ensure the success of the project. Currently it has been outsourced to a local IT company for management in the next 2 years before it will be taken over by the government.

## Introduction

The role of traditional and complementary medicine (T/CM) in contributing to the maintenance of human health has increased significantly over the years. The World Health Organization (WHO) reported that almost half of the population of industrialised countries and two-thirds or more of the population of most developing countries regularly use T/CM. In United States alone in year 1997, consumer sales in herbal medicine marked USD40 billion and in year 2000, the sales had doubled into USD80 billion. During the WHO's Alma Atta Declaration, all member countries were encouraged to integrate proven safe and efficacious T/CM into their health care delivery system, especially in primary health. However, in contrast to the present mainstream health care delivery system where to a large extent, healthcare providers direct demand, the growth of T/CM has been strongly influenced by the consumers. Parallel to this is the unprecedented demand for information on products, health care systems and traditions, and on services in T/CM.

*T/CM, a global trend*

Globalization, e-commerce and rapid innovations in telecommunication have created a paradigm shift in the way we exchange and share information. The new economy, as a result of the continuing advances in technology is aptly called 'K Economy' or knowledge-based economy. The internet has impacted on every aspect of our economy. To gain an edge in this demanding, constantly changing and increasingly competitive market, the world requires an information source that is reliable, accurate and comprehensive and one that is continuously updated and validated.

*Need for reliable info on T/CM*

Currently, there are more than 6,000 web pages and databases in the internet presenting information related to T/CM and herbal medicine. These information are available in many different styles, format and quality. Hence, it is really important that the public who view and access such information for various purposes, especially for those involved with decision making, are able to access information that is accurate and of quality.

*Web pages and internet databases on T/CM*

In this respect, Malaysia with her strong, stable and committed government has proposed the project, 'Global Information Hub on Integrated Medicine' (InfoHub) as part of Malaysia's strategic initiative in ensuring the integration of proven safe and effective T/CM into the country's respective national healthcare system. It is also our country's commitment to the world in delivering up-to-date, quality and accurate information pertaining to T/CM and integrated medicine.

*Government's commitment to Info Hub project*

The implementation of the project by the Malaysian Ministry of Health was endorsed by not only the Malaysian government but also relevant international organisations who see the benefits of such an infoHub.

### **Historical development**

At the 12<sup>th</sup> Commonwealth Ministers of Health's meeting in Barbados in November 1998 which was attended by 54 countries including Malaysia, the Ministers suggested that the scattered information regarding T/CM from the respective Commonwealth countries be gathered, evaluated and later centralised for easy access as part of their decision making for positioning T/CM appropriately. The meeting highlighted the importance of building partnerships on this area, within a broader process of health sector reform. This led to the formation and establishment of the Commonwealth Working Group (CWG) on Traditional and Complementary Health Systems.

*Starting point - the 12th Commonwealth Health Ministers' meeting, 1998*

Among the tasks of the group was the development of a framework for evidence-based policy and generation of a mechanism to share related information between member countries. The Global Initiative for Traditional Systems (GIFTS) of Health at Oxford University was requested to establish and co-ordinate the Working Group. Malaysia who was amongst the initial members of 15 countries, made a commitment to actively participate in these CWG activities.

A year later in November 1999, the Ministry of Health Malaysia hosted a meeting which was attended by representatives of CWG on T/CM, to discuss strategies for implementation of T/CM in Malaysia's health care system based on the drafted Malaysia's T/CM policy. Issues on the importance of developing an information repository in various fields in T/CM, and the hosting of a Commonwealth Resource Centre on T/CM were discussed. A proposal was made for the Institute of Medical Research (IMR) to take up the task. In 2001, as part of IMR reorganisation, Herbal Medicine Research Centre was established and part of her responsibility was to establish the above-mentioned information hub.

*Proposal for establishment of Commonwealth Information Resource on T/CM in Malaysia*

In October 2000, at the Health Research for Development Conference sponsored by WHO in Bangkok, Tan Sri Dato' Dr. Abu Bakar Suleiman, the then Director-General of Health Malaysia and Dato' Dr. Mohd Ismail Merican, the then Deputy-Director General of Health (Research and Technical Support) agreed to look into the possibility of housing the Commonwealth Information Resource on T/CM in Malaysia since the Multimedia Super Corridor (MSC) project is already entrenched in Malaysia.

Subsequent meetings in November 2000 to January 2001 between CWG on T/CM, the Malaysian Herbal Corporation (MHC) and the Ministry of Health Malaysia represented by IMR, chaired by Dato' Dr. Mohd Ismail Merican, led to the proposal write-up and the formulation of strategies required to launch the project. The proposal on forming a centralised information hub, underlying its objectives and benefits obtained from the establishment, outlining the strategies of the implementation, was prepared and finalised. The proposal also emphasised on the need of smart partnership among the Commonwealth member countries, government and non-government organisations in order to realise the vision of the project.

*Strategies for implementation*

In November 2001, after the concept paper was approved by the then Prime Minister of Malaysia, Tun Dr. Mahathir Mohamed, Malaysia presented a proposal to host the “Commonwealth Information Hub for Traditional and Complementary Medicine” at the 13<sup>th</sup> Commonwealth Health Ministers Meeting in Christchurch. The elements of Malaysia’s strengths; the Multimedia Super Corridor (MSC) set up, a melting pot of rich biodiversity, various ethnic groups practicing many forms of traditional knowledge, beliefs and practices, and the support of a strong and stable government; assisted our bid to host the information hub. The paper was discussed at length and members suggested that the paper be presented for further discussion at the pre-WHA meeting.

*Government’s blessing*

In May 2002, at the Pre-World Health Assembly (Pre-WHA) meeting in Geneva, Malaysia was given the endorsement to implement the project. The project was then renamed “The Global Information Hub on Integrated Medicine” to reflect the growing demand for T/CM alongside established methods of treatment. The word “Global” replaced “Commonwealth” to emphasize the potential geographical coverage of the InfoHub, and also taking into account the Internet’s global reach.

*Endorsement of the project: Pre-World Health Assembly (Pre-WHA) meeting in Geneva*

The Cabinet of the Government of Malaysia gave the approval for the implementation of the project in August 2002 with an allocation of initial budget to run its activities for the next five years. A Beta Group chaired by the Deputy Director-General (Research and Technical Support) and members from representatives of IMR, Malaysia Herbal Corporation (MHC), University Science Malaysia (USM), Multimedia Development Corporation (MDC) was formed to guide the IMR in the implementation of the InfoHub project. Two other committees that look into the technical as well as the information content of the project were also formed.

*Government allocation*

At the 5<sup>th</sup> International Traditional and Complementary Medicine Conference & Exhibition (INTRACOM) October 2003, held in Kuala Lumpur, a prototype of the InfoHub was subsequently launched with an address of [www.globinmed.com](http://www.globinmed.com) by Dato’ Seri Abdullah Ahmad Badawi. *Globinmed.com* has its content from Malaysia on Policy, Trade, Intellectual Property Rights, Safety and Herbal Database of Traditional Complementary Medicine. This was a result of local partnership contribution. Further contributions are from the first International partner, NHIonDemand (formerly known as IntraMedicine Inc.) that allowed the use of their webportal principal and also contents that

*Launching the project and its prototype*

covers the Traditional Chinese Medicine (Herbs, Formulas and Health Condition), Dietary Supplement Monograph, Research Track that covers Professional Monograph, Interaction and Depletions, and Health Condition & Disease States.

### **Mission, vision, objective and ownership**

The vision of the project is to promote and enhance the practice of traditional and complementary medicine (T/CM) towards the establishment of an integrated healthcare system with traditional, complementary and allopathic medicine in contemporary health care, through global communication and education with the availability of valid, up-to-date and comprehensive information.

#### *Vision of the InfoHub*

The mission of the project is to establish an Information Hub on Integrated Medicine, utilising strategic partnerships with other nations, international organisations and not-for-profit organisations (NGOs).

#### *Mission of InfoHub*

The general objective of InfoHub is to establish an Information Hub on Traditional & Complementary Medicine (T/CM) for Commonwealth countries and the world through Malaysia, utilising strategic partnerships with other Commonwealth nations, international organisations and NGOs.

#### *Objectives of InfoHub*

Several specific objectives were identified as follows :

- To develop a state-of-the art information resource on T/CM and integrated medicine that is commercially viable and sustainable;
- To establish a global electronic information resource that covers policy, practice, research, trade, education, safety, conservation and IPR of T/CM;
- To promote the generation and dissemination of T/CM information that is validated, up-to-date, widely available and evidence-based to the global consumers;
- To provide a specialised information service of T/CM information to consumers and professionals;
- To generate expertise in the development of a *portal* and the establishment of a resource information for integrated medicine; and
- To drive Malaysia in developing the local information resource on T/CM research, practice and training.

The InfoHub would be owned by Malaysia in partnership with other major stakeholders that are willing to contribute content, technology, expertise and resources.

## *Ownership of InfoHub*

### **Malaysia's collaborating partners**

To ensure immediate establishment of the InfoHub, the project team assisted by the Beta group, seek to reach out to the world, inviting other countries and nations to contribute further contents, technology improvement and advancement, as well as experts of various fields to form International Advisory Panel.

Criteria in choosing the partners were developed. The criteria include institutional stability, reputation and trust, as well as proven technical capacity, integrated medicine expertise and a track record in generating financially viable projects.

In the initial stage based on many meetings and visits by government officials, a list of possible partners as follows has been identified.

## *InfoHub Potential partners*

### ***Possible partners as content contributors***

- British Library – AMED (Allied and Complementary Medicine Database);
- Royal Botanic Gardens at Kew
  - database of plants
  - Kew's Chinese Medicinal Plants Authentication Centre (CMPAC)
  - indices all published plant names
  - herbarium sample collection;
- The New York Botanic Garden (NYBG)
  - 'Virtual Herbarium'
  - ethnobotanical research
  - molecular biodiversity projects
  - phytochemical discovery program;
- National Library of Medicine - MEDLINE
  - MEDLINE has a Complementary Medicine subset which is accessible via PubMed and was developed in conjunction with NCCAM at NIH;

- Columbia University : Columbia’s Rosenthal Center for Complementary & Alternative Medicine
  - information on botanical medicine; traditional medicine, especially Asian medical traditions; nutritional therapies; mind-body medicine; minority women’s use of TCAM
  - continuing education courses;
- Commonwealth Agriculture Bureau International
  - Aromatic and medicinal plants database
  - China Information Project with China collaboration;
- The Australian National Institute for Environmental Toxicology;
- The National Law School of India University, Bangalore.

Malaysia has also identified possible partners from ASEAN as well as China, Japan and Korea through discussions and deliberations at related meetings, especially during the 7<sup>th</sup> ASEAN and 1<sup>st</sup> ASEAN+3 Health Ministers’ meeting, in Penang in April 2004. The members collectively agreed to form a framework on integration of traditional and complementary medicine into the nation’s health care delivery and information sharing including contribution toward further development of InfoHub was agreed.

*Partners from  
ASEAN  
community*

### Implementation of the project

The implementation of the project was planned according to 3-phase strategy to achieve its objectives. These 3 phases (InfoHub growth, membership drive and commercialisation of InfoHub) will ensure InfoHub achieves self-sustainability and self-sufficiency.

At the first stage, the InfoHub Prototype will be migrated to Malaysia and its content will be enriched accordingly. Many related policies especially on its partnership will be established for continuity. The business structure of its management would also be established.

After the realisation of the first two phases, it is expected that InfoHub will become a globalised “one-stop” centre for information related to T/CM and integrated medicine as well as a major selling point that will attract potential customers globally to use the services provided through InfoHub. In this case, InfoHub will create a marketplace for alternative and herbal medicine. It is also expected that the infoHub

*InfoHub growth  
and membership  
drive phases*

will be generating a significant amount of traffic globally. This would present an opportunity to commercialise the market itself and it would be a right time to market InfoHub globally.

The commercialisation phase will look into all potential revenues for InfoHub activities that aim towards self-sustenance of the project. This exercise will include marketing InfoHub to potential advertisers who are interested in taking advantage of the huge traffic in the InfoHub and any potential commerce that can be transacted via the InfoHub. In this sense, InfoHub will facilitate an exchange of information for purpose of commercial activities. As the marketplace matures, it will guarantee InfoHub's gain in credibility and generate sufficient traffic for the InfoHub. This phenomenon can provide tremendous benefits to Malaysia, both directly and indirectly, such as :

- recognition of Malaysia as the world's premier T/CM and integrated medicine driver;
- the establishment of a common platform for integrated medicine on a global scale;
- income generation via activities from InfoHub.

However certain information will remain as free access and this will form a morale obligation from Malaysia to the community in this endeavour.

The experience gained at the prototype development so far, has shown that, partnership negotiations and business dealings remain the main crucial activities, especially when most partners are from outside the country. Thus, it was decided that in subsequent development of the prototype, the Ministry will out-source the service with a local IT company for a 2 year period ( August 2005 – September 2007 ). However, IMR will continue to play an active role and a few staff will continue to be part of the project team. The company will be advised by various relevant committees to ensure the government's interest is protected, especially its ownership and the intellectual property rights.

At the end of the term, it is expected that the project will be handed over to the government and managed by an entity to be identified later. The entity managing the project will be determined based on the business approach and its sustainability.

### *Commercialisation phase*

### *Current status*

### *Future management*

## Conclusion

With the establishment of the Global Information Hub on Integrated Medicine, Malaysia is confident that InfoHub will enable the practice of traditional and complementary medicine to be incorporated into the conventional healthcare system and thus, giving birth to a new holistic approach to an integrated healthcare system in the country. The InfoHub will be an ultimate one-stop resource on Integrated Medicine – a reality for the future, through smart partnerships, both locally and internationally.

# PROMOTING RESEARCH & DEVELOPMENT IN HERBAL MEDICINE

## SUMMARY

Natural products offer a vast and virtually unlimited source of new agents for pharmaceutical industries. In line with this, the Government has allocated vast amounts of funding through various mechanisms in the last two decades to promote research and development of Malaysia's own homegrown herbal medicinal products. This is especially important as with the growing use of T/CM, demand has also grown for evidence on the safety, efficacy and quality of T/CM products and practice. To promote R&D on herbal medicinal products, the National Committee for Herbal Medicine R & D (NRDHM) was set up in April 2002 and subsequently launched by the Minister of Health on 22 March 2003. The NRDHM has provided guidance to researchers on the importance and requirements for evidence on the safety, efficacy and quality of T/CM products and practices through the production of a set of 4 guidelines aimed at ensuring rigorous research and subsequently the production of Malaysian herbal medicinal products that is not only both safe and effective but also accepted globally.

## Introduction

It has been reported that an estimated USD 500 million is spent annually on Traditional and Complementary Medicine (T/CM) compared to USD 300 million on allopathic medicine. This broad use of T/CM is often attributable to its accessibility and affordability as well as the concerns about adverse effects of chemical drugs used in allopathic medicine. Together with the growing use of T/CM, demand has grown for evidence on the safety, efficacy and quality of T/CM products and practices.

*T/CM - a major health sector*

Natural products offer a vast and virtually unlimited source of new agents for pharmaceutical industries. The Government has allocated vast amounts of funding through various mechanisms in the last two decades to promote research and development of Malaysia's own homegrown herbal medicinal products but unfortunately, to date there has been no commercial Malaysian herbal medicinal product available. The reasons for this include the lack of a research and development blueprint in herbal medicinal products, fragmented and duplicated research. The lack of an attractive and conducive environment that

*Local R & D in herbal medicinal products*

can foster biotechnology development and investment in infrastructure as well as commercialization are also factors contributed to the situation. In addition to this, there is no one single facility that could cater for all aspects of research in natural products from discovery to marketing the final product.

### **The National Committee for Herbal Medicine R&D (NRDHM)**

To address the above issues, the National Committee for Herbal Medicine R & D (NRDHM), was approved by the Cabinet in April 2002 and subsequently launched by the Minister of Health on 22 March 2003. This committee, spearheaded by the Ministry of Health, has been charged to strategize the development and coordination of the master plan for R&D in herbal medicine research.

#### *Establishment of NRDHM*

The functions of NRDHM include :

#### *Functions of NRDHM*

- producing relevant guidelines to ensure quality, safety and integrity of data in line with local regulations;
- create harmonization, understanding and collaboration between researchers;
- identify training and infrastructure needs in herbal medicine R & D.
- assist in setting targets and facilitate new product discovery and development address issues pertaining to Intellectual Property Rights.

The committee is chaired by the Deputy-Director General of Health (Research and Support) and the members comprise of representatives from the various ministries, universities and appropriate stakeholder agencies such as Science University of Malaysia, Agriculture and Research Development Institute (MARDI), Drug Control Authority, Ministry of Science ,Technology and Environment, Ministry of International Trade and Industry , Ministry of Education, Malaysian Industry –Government Group for High Technology, Malaysian Herbal Cooperation and the Institute for Medical Research.

#### *Composition of NRDHM*

### **National Herbal Medicine R&D Guidelines**

In order to provide guidance to researchers on the importance and requirements for evidence on the safety, efficacy and quality of T/CM products and practices, NRDHM has produced a set of four guidelines as follows :

- *Guidelines for levels and kinds of evidence to support claims for therapeutic products*

*Evidence to support claims on therapeutic products*

These guidelines cover the various forms of evidence that can be used to support claims for therapeutic products. Claims fall into two broad categories - those based on evidence of traditional use of a particular product, and those based on scientific evidence. The guidelines also address the strength of evidence required to support a particular claim.

As traditional medicine is generally based on a different philosophy from Western medicine and has a different cultural background, assessing the strength of a claim must be handled differently from claims made on more easily ranked scientific evidence. These guidelines help to clarify how claims relating to products and substances used in traditional medicine should be addressed and also give guidance on methods of assessing scientific evidence.

- *Guidelines for the clinical evaluation of T/CM interventions*

*Procedures on clinical evaluation of T/CM interventions*

Intended to promote rigorous quality in herbal medicine research and to ensure the safety of herbal products in Malaysia, this guideline covers the correct procedure for carrying out the clinical evaluation of traditional/ complementary medicine (T/CM) interventions. While the requirements for the clinical evaluation of T/CM interventions are necessarily different from those required for pharmaceuticals, the quality of the studies should maintain the same high standards.

- *Guide to Intellectual Property Rights Management*

*Intellectual Property Rights*

It is important that those involved in the research and development of T/CM are aware of the issues related to Intellectual Property Rights (IPR) for the protection of their research discoveries. This guide emphasises the range of protective measures available to a T/CM or herbal medicine business, and provides advice on the layers of protection needed to fully protect a new formulation or discovery.

The document deals with all types of Intellectual Property, including the use and importance of trademarks, patents, copyright and industrial design.

- *Guidelines for standardisation, safety and clinical evaluation of herbal medicinal products*

*Standardisation of evaluation procedures*

This document takes into account that herbal or botanical drug products differ in unique ways from conventional drugs. For example, it may not be feasible to identify the active constituents of a particular herbal drug during its pre-clinical development stage. Thus, the documentation for herbal drugs will necessarily differ from documentation for synthetic or purified drugs with regards to ensuring the identity, purity, quality, strength, potency and consistency of a particular herbal medicine.

The guideline gives specific guidance on the information that must be reported and the documentation required with regard to the quality standards and technical requirements of a particular product.

The above guidelines pertaining to clinical research, standardization, toxicology studies and claims to serve as guidance documents to ensure rigorous quality in herbal medicine research and safety of our herbal products. It must be stated the evidential requirements will be different from those required for pharmaceuticals. However, the quality of the studies must be of the highest standards in order to ensure that these products are accepted not only in Malaysia, but also globally. These guidelines have been prepared in consultation with various existing guidance documents from the Federal Drug Control Authority (FDA), USA and the World Health Organisation (WHO).

*Guidelines based on international references*

## **Conclusion**

R & D in local herbal medicinal products is an exiting new area to be explored in Malaysia. It is hoped that good and high quality research will ultimately bear fruition in the form of various Malaysian herbal medicinal products that is not only both safe and effective but also accepted globally.

# part 2

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part two

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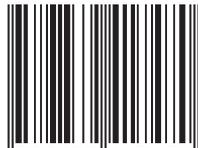
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