



MINISTRY OF HEALTH MALAYSIA

MALAYSIA'S HEALTH

2007

FOREWORD

For many of us, the last decade of the 20th century were years of unimpeded progress. However, much of the social, economic and demographic transformation that we see today comes with a price. Climatic and other environmental changes have been shown to have direct and indirect consequences on our health. Rapid advances in science and technology have led to a better understanding of disease aetiology at the genetic level. At the same time, there are increased public expectations of more effective treatment of certain diseases that have hitherto remain elusive to complete cure. There is now an increasing global push for greater liberalisation of healthcare services which is seen as the catalyst to encourage foreign investments and medical tourism. Such a move has sparked off a worldwide debate on whether it actually promotes health benefits for the wider section of the population at large.

Nothing is more important to us than the well being of our population. To be successful, we need healthy economies. To have healthy economies, we need healthy communities. The consequences and impact of transformation and other health-related issues related to our population's health are reported, reflected and discussed in this 2007 report. It is my sincere hope this report will contribute towards the planning and evaluation of our health programmes and related activities, as we strive to provide the best possible care for the Malaysian population.



TAN SRI DATO' SERI DR. HJ. MOHD ISMAIL 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, technologically 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.

Contents

Foreword

Vision For Health

Mission Of The Ministry Of Health

PART 1

CHAPTER 1 - HEALTHCARE SERVICE

- 11 Addressing Early Childhood Caries in Young Children
- 23 Diagnosis and Management of Inborn Errors of Metabolism (IEM) in Malaysia
- 33 Towards Strengthening Paediatric Cardiothoracic Services
- 47 Implementation of Integrated Hospital in Malaysia
- 57 School Health Services-Past, Present and Future
- 79 The Development of Pathology Services in Primary Health Care
- 91 Integration of Primary Health Care Services Through the Reviewed Approach Strategy
- 104 Providing Safe Water Supply in Malaysia

CHAPTER 2 - POPULATION HEALTH

- 115 Climate Change in Malaysia
- 124 Plasmodium Knowlesi Infection In Malaysia
- 134 Typhoid in Malaysia with special focus on the state of Kelantan
- 148 National Strategic Plan For Emerging Diseases (MySED)
- 155 National Ear and Hearing Disorder Survey
- 167 The Third National Health & Morbidity Survey

CHAPTER 3 - HEALTH SYSTEM MANAGEMENT

- 181 Implementation of Meditag™ Hologram in Combating Counterfeit Medicinal Products in Malaysia
- 186 Initiatives for Drug Price Monitoring
- 194 ASEAN Pharmaceutical Harmonisation - Malaysia's Initiatives
- 201 Implementation of the Evidence Based National Clinical Practice Guidelines
- 211 Making the Malaysian Health Care System Safer: Addressing the problem of Preventable Adverse Events
- 219 Healthcare Spending: Putting Healthcare Financing into Perspective
- 234 National Registries

CHAPTER 4 - RESEARCH AND DEVELOPMENT

- 251 Use of ICT in the Dissemination of Health Information - MyHEALTH PORTAL
- 257 EVIPNet - Towards better Health Policy Decisions
- 263 Presence of Toxigenic Moulds in Paddy and Paddy Products
- 273 Determination Of Propionic Acid In Breads, Biscuits, Cakes And Muffins In Perlis, Kedah And Penang Using Gas Chromatography-Mass Spectrometry
- 281 Healthcare, The Way Forward - Towards Service Liberalisation

PART 2

- 293 EDITORIAL COMMITTEE
- 294 LIST OF CONTRIBUTORS
- 298 ACKNOWLEDGEMENT

PART 1

CHAPTER 1 **HEALTHCARE SERVICE**

CHAPTER 2 **POPULATION HEALTH**

CHAPTER 3 **HEALTH SYSTEM MANAGEMENT**

CHAPTER 4 **RESEARCH AND DEVELOPMENT**



CHAPTER 1

ADDRESSING EARLY CHILDHOOD CARIES IN YOUNG CHILDREN

SUMMARY

Early childhood caries (ECC) is still a common problem among preschool children in Malaysia. ECC, a virulent and rapidly progressing form of dental caries, is associated with many risk factors such as inappropriate feeding and dietary practices, inadequate attention to oral hygiene and lack of importance given to oral health care of young children. This condition is preventable. Addressing the related risk factors will lead to better oral health of these children towards attaining health for life. To achieve this, parents, childcare providers and health personnel directly involved in the care of children need to work together in synergy with the oral health team. Oral health is integral to general health and wellbeing. Prevention of dental caries in young children will thus ensure good oral health and contribute towards a better quality of life.

Introduction

Early childhood caries (ECC) is a virulent form of dental caries. It is a term used to describe dental caries in the preschool child where many teeth, including the upper maxillary incisors, are involved. This condition has previously been described as rampant caries, nursing caries and baby bottle caries because it was often found to be associated with prolonged bottle or breast feeding, especially where the child falls asleep with a bottle of milk in the mouth. The decay process may begin soon after dental eruption, developing on smooth surfaces of deciduous (milk) teeth. The condition often progresses rapidly and if left un-arrested or untreated, may have lasting detrimental effect on the child's dentition. Children who experience ECC are at greater risk for subsequent caries development in their permanent dentition.

*Early childhood
caries*

Studies have also shown that children with severe caries weighed less than controls and showed evidence of failure to thrive. After treatment of the decayed teeth, there was more rapid weight gain (catch-up growth) and improvements in their health and quality of life.

Situation Analysis

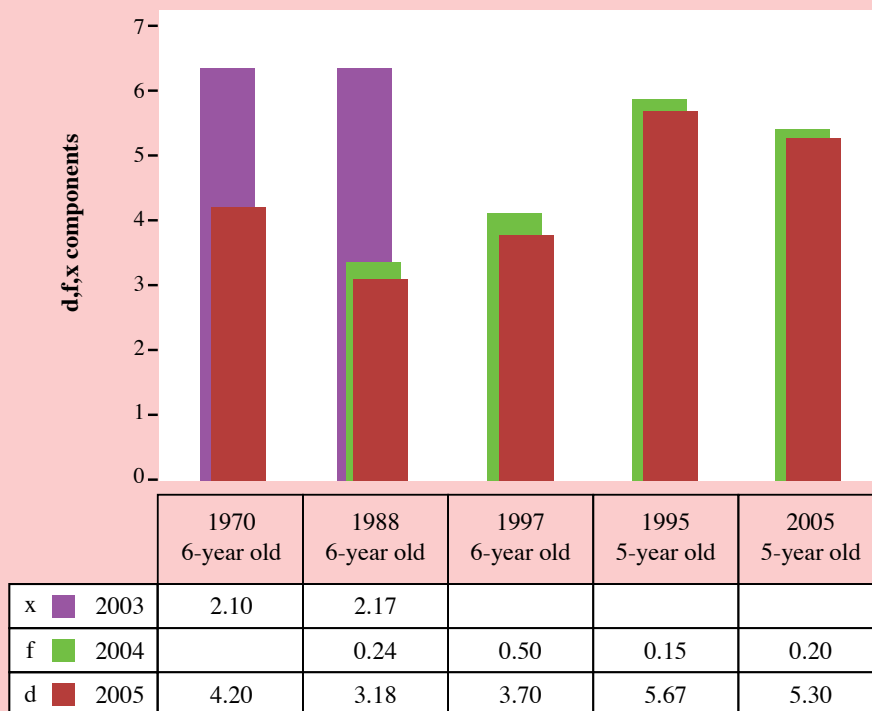
The first national epidemiological survey on preschool children in 1995 showed that almost nine out of ten children (87.1%) had tooth decay by the age of five. Findings from the more recent National Oral Health Survey of Preschool Children 2005 (NOHPS 2005) indicated only a slight improvement in caries status among this group of children. Dental caries continues to be a very common condition among 5-year-old children with caries prevalence of 76.2%. There were high caries levels in deciduous teeth with a mean of 5.6 teeth affected by dental caries. Most of the teeth affected were untreated, indicating a backlog of unmet treatment needs among this group of young children (Figure 1).

Oral health status of preschool children

There has been no large-scale study on the oral health status of toddlers (children aged 4 years and below) in this country. The NOHPS study in 2005 on 5-year-old children reported that more than half (55.8%) of the children had three or more deciduous teeth affected by caries and more than a quarter (25.3%) of them had more than ten deciduous teeth that were decayed, missing or filled due to dental caries (dmft>10). These findings may be indicative of the occurrence of ECC among children below 4 years.

In addition, service data from the Health Information Management System shows that the number of 6-year old school children who are caries-free is stagnating at about 33% from 2006 (Figure 2).

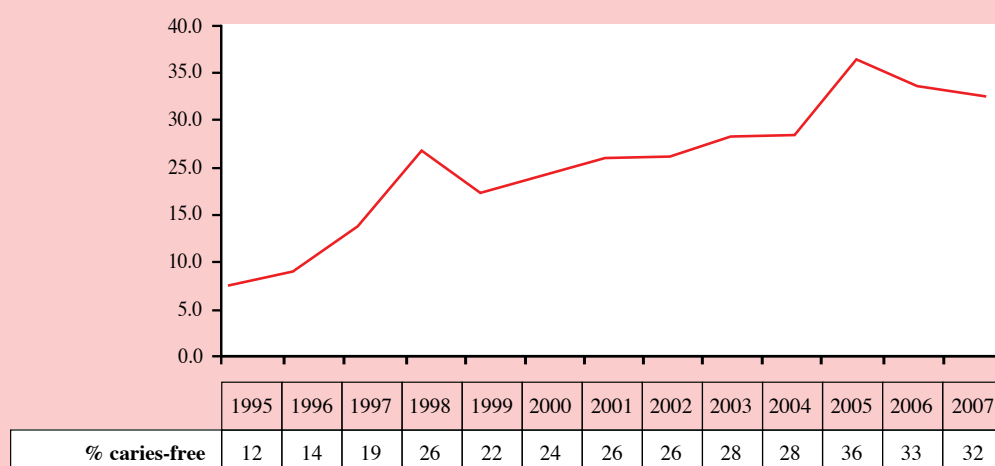
Figure 1: Comparison of d,f,x components in deciduous dentition, various surveys



d, f, x: Deciduous teeth that are decayed (d), filled (f) or indicated for extraction (x)

Source: Oral Health Division, MOH

Figure 2: Percentage of 6-year old children who are caries-free (1995-2007)



Source: Health Informatics Centre, MOH

Government oral health services in Malaysia began as a school dental service in the 1950s. It has since expanded to include other priority groups including antenatal mothers (1970s) and preschool children (1984). The antenatal programme targets mothers as agents of change towards better oral health for the family. The preschool oral health programme focuses mainly on oral health preventive and promotive activities among preschool children to create awareness and, inculcate good oral hygiene habits, besides familiarising the children with oral health services. In spite of these efforts, dental caries continues to be a major oral health problem among preschool children.

Current activities

Early childhood caries is a problem in both developing and developed nations. A study done in Brazilian nurseries reported that 46% of 3-4 year-old children had caries, with 17% of them having severe ECC. Occurrence of caries in this group of children was found to be significantly associated with social class, mother's educational level and the age at which breastfeeding was terminated. It was also reported that feeding bottles with added sugars were being given to 80% of children in the nurseries.

*Global picture of
ECC*

In the Philippines, 59% of 2-year old and 90% of 4-year old had caries. Almost half of the children were weaned at more than 2 years old. Tooth brushing was only started at about 2 years of age. Among 3-4-year old, a significant increase in caries levels was noted for those who started brushing at a later age, had frequent snacks, and only visited the dentist for emergency reasons. In Thailand, ECC is also a problem with 82.8% of children aged 15-19 months affected.

Dental caries has been reported as the most prevalent chronic infectious childhood disease in the United States. High rates of ECC are seen among children of low-income families and certain ethnic minorities, where parents have a lower educational level. The latest oral health data indicates that while oral health is improving for most Americans, tooth decay among preschool children is on the rise.

Over in the United Kingdom, the significant improvements observed in older children are not seen among 5-year old. In Sweden, time trends from 1967 found that caries prevalence among 4-year old fell from 83% (1967) to 42% (1987). However, from 1987 there was a shift in the trend of declining caries where since 1997, the caries prevalence has been on the rise - increasing to 46% in 2002. At the same time, between 1987 and 1997, an increase in the consumption of sweets and soft drinks was also noted.

Good nutrition and healthy eating is vital for the proper growth and development of a child. Inappropriate feeding practices or poor dietary habits, coupled with neglected oral hygiene, are associated with the development of dental caries in young children.

Risk factors for ECC

A review on risk factors in ECC reported that frequency and length of exposure are important. Infants with caries average 8.2 hours per day of bottle time, while caries-free infants average only 2.2 hours. The age of weaning was 22 months for infants with ECC and 14 months for those who were caries-free. Because young children are not able to control these factors, their oral health is greatly influenced by the attitude, knowledge and practices of their parents or carers towards oral health.

Prolonged bottle feeding

Many mothers reject the health professional's advice to discontinue bottle use by 12 months because of the fear that infants might stop drinking milk. Sugar was also added to ensure that more milk would be consumed or because of the perceived benefits of sugar. This finding is supported by a local study, which found that 29.1% of parents surveyed thought that sugar is essential for the growth of children.

Sweetened milk

Furthermore it has been noted that infants with nursing caries have a much higher level of mutans streptococci (MS) and lactobacilli than caries-free children. There is evidence of MS colonisation as early as 10 months of age and 25% of children aged 12 months and below had detectable levels of MS while 60% of those in 15-month age group were already infected. This study suggests that prevention of MS colonisation may need to be started before a child's first birthday.

Colonisation of Streptococcus mutans

Strategies In Addressing Early Childhood Caries

A review on current evidences in relation to the aetiology and prevention of dental caries in preschool children has suggested that potentially effective interventions should occur in the first two years of a child's life.

The oral health programme for antenatal mothers must be stepped up. Pregnant mothers at public health facilities are targeted for oral health education and screening followed by free dental treatment for those who need follow-up oral healthcare. However, the Modified Budgeting System Report for years 2000 to 2004 showed that coverage of antenatal mothers was less than 20%. There have been efforts to increase the coverage by improving and facilitating referrals for all new antenatal cases at maternal and child health clinics (MCHC) to dental clinics. In addition, providing immediate dental treatment, assigning special clinic days for antenatal mothers and setting up temporary dental clinics with portable dental equipment at the MCHC are some strategies that have also been implemented to reach out to more antenatal mothers. Good oral health status of mothers coupled with sound oral health knowledge and practices will benefit the child for a lifetime.

Enhancing oral health programme for antenatal mothers

The oral health programme for preschool children (1984) focused on oral health promotion activities. The main objectives of this programme are to create oral health awareness at an early age as well as to introduce the children to oral health personnel and oral healthcare in a familiar and friendly environment. This programme was reinforced in 2004 with the addition of a curative component using the atraumatic restorative treatment technique (ART) to address the high unmet treatment need of decayed teeth and thereby, encourage the children to brush more effectively. In addition, recognising the important role of preschool teachers as role models and the importance of their involvement in oral health promotion for the children, organising seminars to train preschool teachers was included as an essential activity to the programme.

Strengthening the preschool oral healthcare programme

Over the years with increasing numbers of women joining the workforce and the breakdown of the extended family system, more children under the age of five are being cared for in childcare centres. Childcare providers can also have positive influence on the nutrition and development of knowledge and attitudes of young children towards dietary and hygiene practices. Toddlers at childcare

Promoting early childhood oral healthcare

centres can therefore be a captive group for a structured programme in early oral health care.

Furthermore, in the earliest years of life, general health rather than oral health personnel are more likely to see these children on a more frequent basis. While dental attendance before the age of two is uncommon, contact at the child health clinics is high with regular appointments for immunisations and developmental assessment visits. The community nurses at the MCHC are therefore well placed to offer counselling and oral health advice to parents and help to reduce the incidence of ECC. With some simple training, they can also assist in identifying and referring high-risk children for further dental management.

Role of health personnel in preventing ECC

Parents and childcare providers should also be given adequate information in ensuring the child grows in an environment that promotes and maintains good oral health. Integrating oral health promotion and oral disease prevention into daily childcare practice would help to reduce caries prevalence in future generations, especially among high-risk children from lower income families.

Involving parents and childcare providers

Widespread use of fluoride has been an important factor in the decline in prevalence and severity of dental caries. There are a variety of modes in the delivery for fluorides among which are water fluoridation, fluoride toothpaste, fluoride mouth rinses and professionally-applied topical fluoride gels and varnishes. Water fluoridation has been accepted by the Government since 1972 and has contributed to the improvement in oral health status of school children and young adults in Malaysia. However, up to end 2007, only 73.3% of the Malaysian population benefited from fluoride in drinking water.

Topical fluorides in caries prevention

Professionally-applied topical fluoride is effective for caries prevention and offers an alternative means for harnessing the caries preventive effects of fluorides in children who are at high-risk for developing ECC. This modality of fluoride use may also be considered in situations where other forms of fluoride may not be available or deemed suitable. This is in accordance with the recommendations of the World Health Organisation that countries should ensure appropriate and affordable fluoride programmes for the prevention of tooth decay, especially to populations with inadequate exposure to fluoride.

Topical fluorides in high-risk approach

Professionally-applied fluoride varnish treats at-risk tooth surfaces in caries-susceptible individuals so that dental caries lesions are controlled and progression is retarded, arrested or even reversed. It has been recommended as appropriate for moderate and high prevalence child populations in community-based prevention programmes. Parents, childcare providers and child health nurses/general health personnel can be trained to recognise early signs of ECC and refer such children to dental clinics for fluoride varnish application.

Fluoride varnish for caries control

Challenges

Addressing the problem of ECC in young children cannot be the sole responsibility of the oral healthcare providers. It requires close collaboration and cooperation among parents, childcare providers and health personnel, in particular those involved in caring for children e.g. child health nurses in MCHCs, nurses working in maternity and paediatric wards, paediatricians and nutritionists. They need to be aware of the problems related to ECC, the risk factors contributing to its widespread prevalence and what they can do to overcome the problem. This will empower them to play the role required of them more effectively.

Working together with parents, childcare providers and health personnel

A clear and practical referral pathway needs to be put in place to ensure that all toddlers who are seen at child health clinics will also have access to oral health consultation and management.

Establishing clear referral mechanism

It is expected that dental nurses will play a major role in providing oral healthcare for toddlers in the future. This will be an added responsibility to their present core function in the school dental service. However, with the present number available and the limited output annually, it would take some time before this can be achieved. Currently, dental nurses are deployed at schools to provide outreach oral healthcare to primary and secondary school children, and are also the main players in our oral health programme for the preschools.

Human resource constraints

As an interim measure, it is suggested that dental surgery assistants (DSAs) be given additional training to provide oral health counselling to parents and carers of toddlers who are referred for dental consultation and to give follow-up appointments for the child who needs further dental management.

Extended and expanded role of DSAs

Consideration should also be given to the proposal for the setting up of dedicated oral health teams. There is a need to establish more preschool mobile dental teams whereby the scope of these teams can be expanded to include oral healthcare for toddlers.

Dedicated oral health teams

We foresee challenges in trying to change the perceptions and practices of parents, childcare providers and health personnel. A policy that incorporates oral health as a component of managing and promoting wellness in children should be adopted. A greater challenge lies in putting such a policy into action. This will require the commitment of the entire health team in accepting oral health as an integral part of general health and in working together with the oral health team towards achieving healthy growth and development of children. Thus, it is appropriate that we start from our young children with the message that it is “Never Too Early to Start” in promoting healthy lifestyle and health for life.

Oral health- gateway to general health

Conclusion

Working together in close partnership with parents, childcare providers, health personnel and other relevant agencies is important in ensuring oral health care starts from early childhood. Creating awareness on the importance of oral health in general health will contribute towards promoting and improving optimum growth and development of our young children towards health for life.

Oral health for optimum growth and development

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DIAGNOSIS AND MANAGEMENT OF INBORN ERRORS OF METABOLISM (IEM) IN MALAYSIA

SUMMARY

Inborn Errors of Metabolism (IEM) are a group of genetic disorders which can cause acute intoxication, mental retardation as well as significant morbidity and mortality if diagnosis and treatment are delayed. IEM was rarely reported in Malaysia, due to lack of awareness and inadequate diagnostic facilities. During the 7th and 8th Malaysia Plan, more than 20 biochemical genetic tests have been developed and established in Malaysia to diagnose IEM. From 1998 to 2008, a total of 191 patients with amino acid disorders and 255 patients with various organic acids disorders were diagnosed. The three commonest IEM in Malaysia were maple syrup urine disease (MSUD), urea cycle disorders (UCD) and methylmalonic acidemia. The establishment of laboratory diagnosis at the Institute for Medical Research (IMR) as well as the clinical service for treating affected patients at the Paediatric Institute, Kuala Lumpur Hospital (IPHKL) have allowed the early diagnosis and treatment of IEM patients. A rapid screening method to detect IEM was developed and a pilot project was successfully conducted to determine the incidence and the feasibility of introducing the Expanded Newborn Screening of IEM in Malaysia.

Introduction

Inborn Errors of Metabolism (IEM) comprise a group of genetic disorders that affect the metabolic pathways in the body. They may result from deficient activity of essential enzymes, deficiencies of cofactors or activators for the enzymes, or faulty transporters. When the normal body metabolism is disturbed, abnormal accumulation of toxic substances (substrate) may occur. On the other hand, the body may be unable to synthesize an essential compound that is needed for normal function. Both situations will result in adverse health consequences.

Definition of IEM

From a pathophysiologic perspective, IEM can be divided into three groups. The first group comprises disorders that cause acute or progressive intoxication from the accumulation of toxic compounds. In this group are the amino acid disorders (phenylketonuria, maple syrup urine disease (MSUD), urea cycle defects (UCD), homocystinuria, etc.), organic acid disorders (methylmalonic acidemia, propionic acidemia, isovaleric acidemia, etc.) and sugar

Types of IEM and their clinical features

intolerance (galactossemia, hereditary fructose intolerance). The common presenting features are poor feeding, lethargy, septicemia-like illness, seizure, metabolic acidosis and hyperammonemia. The second group comprises disorders due to defects in energy production. Included in this group are glycogen storage disease, gluconeogenesis disorders and fatty acid oxidation disorders. The affected individual commonly presents with growth failure, hypoglycemia and reduced fasting tolerance. The third group includes disorders with abnormal function of various organelles such as lysosomes, peroxisomes and mitochondrion. Patients usually present with progressive multisystemic disease.

The collective incidence of IEM worldwide is found to be around 1 in 3,000 live births in countries implementing population-based neonatal screening for all their newborn babies. The true incidence of IEM in most of the countries in Asia, including Malaysia, is still not known. IEM was thought to be rare in Malaysia 10 years ago, mainly due to under-reporting and the lack of awareness among clinicians as well as the lack of definitive laboratory diagnostic facilities. Cases were often misdiagnosed and mistreated as septicemia or cerebral palsy. This resulted in neonatal/infantile mortality as well as significant morbidity among survivors.

Incidence of IEM

Development Of Biochemical Genetic Testing For The Diagnosis Of IEM In Malaysia

The Institute for Medical Research (IMR) has played a central role in developing diagnostic tests and facilities for IEM in Malaysia. When it was first started some 20 years ago, the only diagnostic tests available were simple chemical tests such as the ferric chloride test to detect phenylketonuria, DNPH tests for screening of MSUD and screening tests for cystine/homocystine. Thin layer chromatography for screening of amino acids disorders was developed and became the only screening test available for the next 15 years. However, this is a qualitative method and can screen less than 10 amino acid disorders. Without definitive diagnostic facilities in the country, clinicians would usually send samples to Singapore and Australia, for confirmation.

IMR's roles in developing new diagnostic methods

In response to the urgent need for a definitive diagnostic service in the country, the IMR acquired a simple High Performance Liquid Chromatography (Reverse-phase HPLC) system during the 7th Malaysia Plan and successfully developed and established a quantitative method for the analysis of amino acids in plasma and urine. A Gas Chromatography-Mass Spectrometry (GC-MS) method which is more sensitive in detecting elevations of metabolites for the diagnosis of organic acid disorders was also developed. In 1998, the IMR diagnosed the first case of MSUD and propionic acidemia in the country.

MOH's commitment to develop laboratory diagnostic methods for IEM

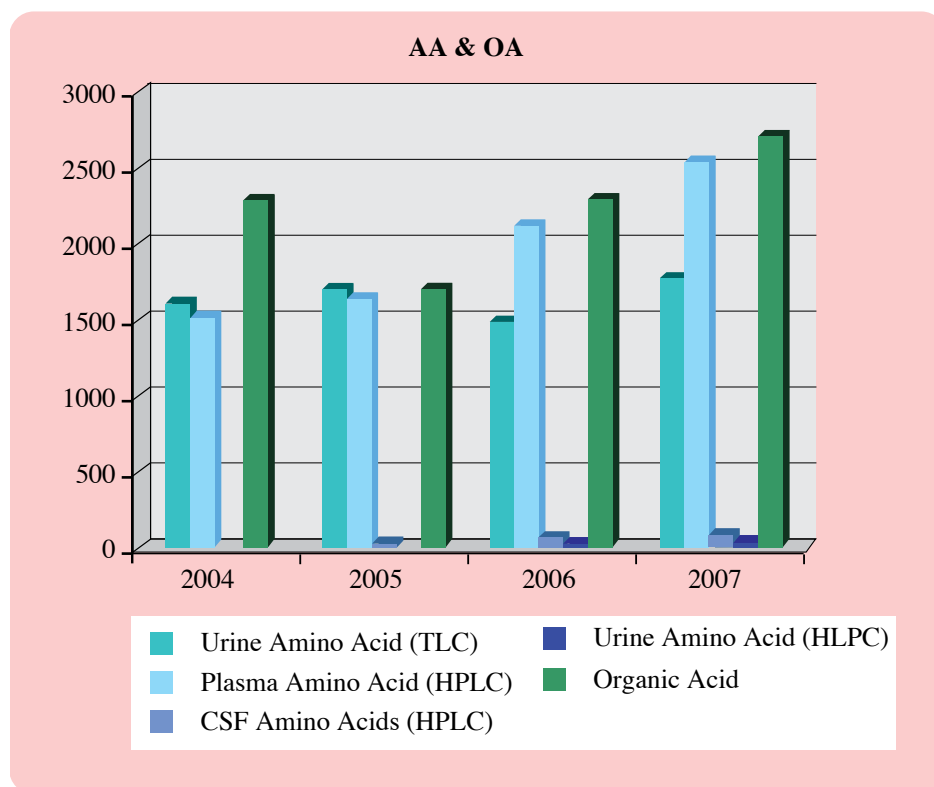
During the 8th Malaysian Plan (2001-2005), a fully automated ion-exchange amino acid analyser which detects more amino acids while minimizing manual intervention or supervision was acquired. This system allows automation of sample processing, injection and quantitation, hence improving the laboratory turn around time for amino acid related disorders.

Automation in amino acids analysis

Each year, about 2,000 to 2,500 samples are received for analysis of amino acids (plasma, urine, CSF) and organic acids (urine) (Figure 1).

Workload

Figure 1 : Number of samples for amino acids & organic acids analysis from 2004-2007



From 1998 to 2007, a total of 170 patients with amino acid disorders and 201 patients with various organic acids disorders were diagnosed. The three commonest IEM in Malaysia were maple syrup urine disease (MSUD), urea cycle disorders (UCD) and methylmalonic acidemia.

Common types of IEM in Malaysia

During the 8th Malaysian Plan, the IMR further expanded the range of diagnostic facilities to include more sophisticated IEM tests. In 2005, the Institute developed a method for rapid screening of IEM in dried blood spots using tandem mass spectrometry (TMS). More than 20 IEM diseases can be screened simultaneously using this method. Acquiring expertise in this diagnostic technology was important as it laid the foundation for the subsequent venture into newborn screening for IEM.

Rapid screening of IEM

In the current 9th Malaysian Plan, more specialized diagnostic methods for IEM diseases such as galactosemia, peroxisomal disorders, mucopolysaccharidoses, lysosomal storage diseases are being actively developed. To-date, 20 biochemical and 13 molecular genetic tests have been developed and are available at the IMR

Development of other more complicated biochemical genetic testing.

Treating Patients With IEM In Malaysia: A Smart Partnership Between Laboratory Experts And Clinicians

The clinical service for treating patients affected by IEM was established at the Paediatric Institute, Kuala Lumpur Hospital (IPHKL) in 1998. The team includes metabolic clinicians (paediatricians trained in metabolic medicine/clinical genetics), dietitians, neonatologists, nephrologists and nursing staffs. All positive cases diagnosed by IMR are communicated immediately to the metabolic clinician on duty. He would contact the primary care doctor to advise on the necessary emergency management. Patients would be transferred to IPHKL for management after the initial stabilization.

Clinicians' roles

For patients with disorders that present as acute intoxication such as MSUD, UCD and organic acidemia, acute detoxification measures would be carried out immediately to correct the metabolic derangement including hyperammonemia and metabolic acidosis. These include the use of pharmacological measures such as intravenous sodium benzoate and sodium phenylbutyrate for controlling blood ammonia and acute dialysis to rapidly remove all the toxic compounds (Figure 2). Long term treatment requires that these patients are put on special diet. Early treatment is crucial to prevent severe mental retardation.

Various forms of treatment for IEM

Figure 2 : A neonate in coma as a result of MSUD being treated with acute peritoneal dialysis



Treatment for patients with glycogen storage disease or fatty acid oxidation disorders would normally include frequent meals, use of slow releasing carbohydrates such as uncooked cornstarch and nocturnal continuous perfuse feeding in order to prevent hypoglycemia.

Management of patients with organelle diseases is mainly supportive. However, a few lysosomal disorders such as pompe disease and gaucher disease are potentially treatable with enzyme replacement therapy.

Supportive treatment

Genetic counseling is part of the routine care. Prevention strategies such as prenatal diagnosis and early high risk screening are also offered to families affected with IEM.

Genetic counselling

Early Detection Of IEM Through Newborn Screening –The Way Forward

Although significant progress has been made in diagnosing and treating IEM, the neurological outcome of many patients remains unsatisfactory due to the delay in diagnosis and treatment. Experiences in developed countries have shown that the outcome of patients with IEM could be greatly improved by pre-symptomatic diagnosis through newborn screening.

The importance of early diagnosis

Screening method using Tandem Mass Spectrophotometry (TMS) is a new state-of-the-art technology able to screen for more than 20 IEM diseases simultaneously including amino acid disorders, organic acidemia and fatty acids oxidation disorders. With this method, newborn screening programmes will allow all newborn babies to be screened for IEM during their first week of life, enabling treatment to be started even before symptoms develop, thus ensuring a better outcome.

Screening method of IEM

This screening technique uses a minimum amount of blood taken from a heel-prick and spotted onto a special filter paper followed by air drying for 4 hours. A 3-mm punch is made from the spot (equivalent to 3 ul of blood) followed by extraction of amino acids and acylcarnitines. It is then injected into the TMS. The running time is only 3 minutes for one sample.

Type of sample used

A 2-year pilot study by the IMR and the Paediatric Institute, HKL, to screen for IEM in neonates using dried blood spots and tandem mass spectrometry will be completed in 2008. This study involve eleven major hospitals. The results and experiences garnered from this pilot study will be useful for framing the national policy on screening newborns for IEM.

Pilot project on neonatal screening of IEM

This rapid screening method for IEM in high risk neonates and infants was offered to the hospitals in 2004 and requests for this test have increased over the years.

Towards Developing A Centre Of Excellence

The IMR is currently the national referral centre for IEM diagnosis for the Ministry of Health (MOH) hospitals as well as university and private hospitals. Samples are also received from patients abroad.

The IMR has organized several workshops and training sessions on the diagnostic techniques for analysis of amino acids and organic acids as part of the ongoing program on technology and knowledge transfer. Chemical pathologists, biochemists, other scientists and medical laboratory technologists from the MOH and university hospitals have benefited from this technical training. These training have enabled the Paediatric Laboratory at the Pathology Department, Hospital Kuala Lumpur to start their own service for the analysis of amino acids and organic acids in 2004 followed by the Central Diagnostic Laboratory of the University of Malaya Medical Centre in 2006.

Human resource development and technology transfer

The IMR is now recognized as a training centre for IEM research and biochemical genetic testing for two local Masters program namely the Master of Science program for Biochemistry and Biomedical Science as well as for the Part II Master of Pathology program. A one-month posting is usually required for those who are majoring in Chemical Pathology as their subspecialty.

Recognition of IMR as a training Centre

The IMR shall continue to develop more confirmatory diagnostic methods for the complicated and challenging diseases of hyperphenylalaninemia and pterins disorders, carbohydrate disorders, peroxisomal diseases, lysosomal storage diseases and mitochondrial disorders. Staff have been and are being sent for training overseas to acquire the relevant skills and expertise.

Future research and development

Conclusion

Major advances have been achieved in the diagnosis and treatment of IEM in Malaysia, significantly improving the outcome of affected patients. Early diagnosis is important and can be achieved through universal newborn screening and increasing the availability and range of advanced diagnostic tests especially for the more complicated IEM disorders.

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TOWARDS STRENGTHENING PAEDIATRIC CARDIOTHORACIC SERVICES

SUMMARY

Cardiology and cardiothoracic services in Malaysia has made tremendous progress since the setting up of the first service in the 1980s. The provision of paediatric cardiothoracic service is a natural progression of this service, where an estimated 4,000-5,000 children are born with congenital heart disorders each year. There are currently 58 hospitals providing cardiothoracic services in the country, including university hospitals and private hospitals and four in the Ministry of Health. However, paediatric cardiothoracic service in Ministry of Health has not developed in tandem with the adult cardiothoracic service. Currently, the National Heart Institute (IJN) is the main centre for paediatric cardiology and cardiothoracic service in the country. Waiting time for paediatric cardiac surgery remains high, mainly due to lack of paediatric cardiothoracic surgeons. In the Ministry of Health, surgery for congenital heart disease is largely undertaken by adult cardiothoracic surgeons who would have basic training in paediatric cardiac surgery. Children with simple congenital heart diseases have been successfully operated in Penang Hospital, Sultanah Aminah Hospital, and in Sarawak General Hospital. This has lessened the need for referrals to the National Heart Institute. The Ministry of Health is making efforts to strengthen paediatric cardiothoracic service by providing additional funding to improve facilities in existing centres, while further collaborations with local and foreign paediatric cardiothoracic surgical centres are being explored.

Introduction

Congenital heart disease (or a congenital heart defect) is an abnormality in the structure of the heart and primary blood vessels of a newborn infant. It takes a wide variety of forms but there are basically two categories of congenital heart defects: acyanotic heart defects (where the infants are known as ‘pink’ babies) and cyanotic heart defects (‘blue’ babies). Seventy-five per cent of infants with congenital heart defects have acyanotic defects which involves the structure of the heart. Cyanotic heart defects account for approximately 25% of all congenital heart diseases, mainly because the survival rate in infants is lower than those born with acyanotic defects.

Pink and blue babies

There is no local data on the incidence of congenital heart defects in Malaysia. However, internationally, it is about 8-10 per 1000 live births. With a birth rate of about 500,000 per annum in Malaysia, it is estimated that about 4,000 – 5,000 children will be born with congenital heart defects yearly. About one third of these children have simple lesions and will not require any intervention while another two thirds will require cardiac intervention or surgery - one third during early infancy and the other one third later in life.

*Incidence of
congenital heart
defects*

The history of cardiothoracic service in Malaysia dated back in the 60's where the first service was provided by the Lady Templer Hospital in Kuala Lumpur. The hospital carried out close-heart operations which do not require cardiopulmonary bypass (mainly ligation of PDA/Closed Mitral Valvotomy for Rheumatic Mitral Stenosis). Thoracic operations such as lung resection for tumour and TB were also performed. The first open heart surgery in Malaysia was carried out in the University Hospital, Kuala Lumpur in 1975, followed by Hospital Kuala Lumpur in 1982.

*First cardiothoracic
service in Malaysia*

As early as the 1970's, the Malaysian Government has been sending children with congenital heart defects to private cardiac centres both locally and overseas for surgery due to the lack of paediatric cardiothoracic surgeons and facilities within the country. This practice is continued until today in Sabah, with the help of Non-Government Organisations. Table 1 shows the distribution of cardiothoracic surgeons (adult and paediatric) in Malaysia in 2007.

Table 1 : Hospitals with Adult and Paediatric Cardiothoracic Surgery Services in 2007

Hospital	Number of Cardiothoracic Surgeons	
	Adult	Paediatric
A. MOH Hospitals		
1. <i>Hospital Pulau Pinang</i>	1* + 1 trainee	
2. <i>Hospital Sultan Aminah, Johor Bahru</i>	4*	
3. Sarawak General, Kuching	2* + 2 trainees	
4. <i>Hospital Serdang</i>	2	
<i>Total number of surgeons</i>	12	
B. University Hospitals		
1. Nasional Univ. of Malaysia Hospital (HUKM)	2	
2. Hospital Univ. Sains Malaysia (HUSM)	2	
3. Universiti Malaya Medical Centre (PPUM)	1*	
<i>Total number of surgeons</i>	5	
C. National Heart Institute (IJN)	19 (16 + 3*)	
D. Private Hospitals		
1. Kedah Medical Centre	1*	
2. Penang Adventist Hospital	1	1 (expatriate)
3. Gleneagles Medical Centre, Penang		1 (paed + adult)
4. Lam Wah Ee Hospital	1	
5. Island Hospital Penang	1	
6. Ipoh Specialist Hospital	1	
7. Hospital Pantai Ipoh	1	
8. Gleneagle Intan Kuala Lumpur	2	1
9. Selangor Medical Centre	1 (visiting)	
10. Ampang Puteri Specialist Hospital	2	
11. Subang Jaya Medical Centre	3	
12. Pantai Medical Centre Kuala Lumpur	3	
13. Damansara Specialist Centre	2	
14. Hospital Pantai Air Keroh	1	
15. Mahkota Medical Centre	1	
16. Johore Specialist Hospital	1	
<i>Total number of surgeons</i>	12	3
Total number of hospitals	25	3
Grand total of cardiothoracic surgeons	58 (47 + 11*)	3

*Adult cardiothoracic surgeons who are able to operate on paediatric patients with body weight <10 kg

Source: Medical Development Division, MOH (2007)

In the early 1980s, few diagnostic and cardiac surgery facilities were available for children suffering from congenital heart defects in Malaysia. Over the last decade or so, there has been rapid development of cardiothoracic services in the country, with increasing number of paediatric cardiologists and cardiothoracic surgeons to provide interventional procedures or cardiac surgery for patients with congenital heart defects. Several new cardiac centres had been set up, both in the public and private sectors. The National Heart Institute was established in 1992, followed by centres in Penang Hospital (1994), Hospital Sultanah Aminah, Johore Bahru (1996), Sarawak General Hospital (2001) and the latest, Serdang Hospital in 2006.

Development of cardiothoracic centres in MOH

However, paediatric cardiothoracic service is still hampered by limited number of paediatric cardiothoracic surgeons in the Ministry of Health (MOH) centres. Since September 2005, the Ministry has been relying on adult cardiothoracic surgeons to carry out surgical interventions for children with simple and average cardiovascular defects based on risk stratification of surgical procedures. More difficult and complex cases are being referred to the National Heart Institute.

Paediatric cardiothoracic service is still lacking

Current Status

The population in Malaysia is still relatively young with about 15% less than 15 years of age. Since congenital heart disease is the commonest organ anomaly in the newborn, there should be a large number of children who are suffering from potentially curable congenital heart disease. Over the years, the total number of cardiac surgeries performed has increased and many lesions such as Patent Ductus Arteriosus (PDA), Atrial Septal Defect (ASD) and some Ventricular Septal Defect (VSD) are now being occluded via transcatheter approach.

Young population

However, the waiting time for paediatric cardiac surgery remains long. This could be attributed to several factors. Despite the increase in the capacity for paediatric cardiac surgery in the country, capacity in the Ministry of Health (MOH) centres is still inadequate for the current birth rate and number of complex cases. With the introduction of prostaglandin and interventional cardiology, many babies with duct-dependent lesions or complex lesions survive beyond the neonatal period and require multiple-staged cardiac surgery or interventional procedures to palliate the cardiovascular defects.

Long waiting time for surgery

In a study in 2005, data from 10 hospitals showed that there were 493 paediatric cardiac patients waiting for cardiac surgery. The majority (475 patients, 96.3%) were for open-heart surgery, 16 for PDA ligation and 2 for repair of Coarctation of Aorta. The study also found that 42% of these children had been waiting for more than 12 months and only 20% waited for less than 3 months. For the state of Sabah, even though paediatric patients have access to the National Heart Institute and the Gleneagles Medical Centre, Kuala Lumpur through the help of NGOs, one patient waited for 3 years for an open-heart surgery. The situation is better in Sarawak where no patient waited for more than 6 months as an adult cardiac surgeon in the Sarawak General Hospital (SGH) is capable of doing paediatric cardiac surgery since 2005. The paediatric cardiologist in SGH is also capable of carrying out interventional procedures.

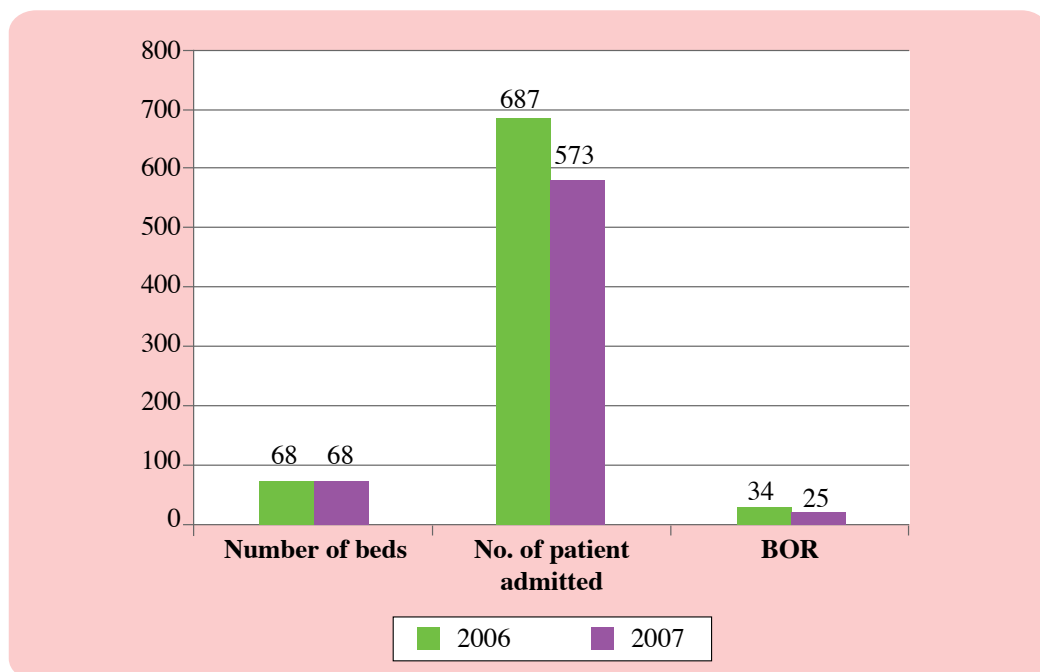
*Waiting Time Study
(2005)*

The number of beds for cardiothoracic services in 2006 and 2007 remained at 68 beds. However, the number of admissions has decreased significantly due to various mechanical and infection control problems that occurred at the Operating Theatre, Cardiac Intensive Care Unit and Cardiothoracic Wards for a prolonged period. Nevertheless, the number of invasive procedures carried out for paediatric cases has increased markedly as depicted in Figure 1, 2 and 3.

*Statistics for
Paediatric
Cardiothoracic
Service*

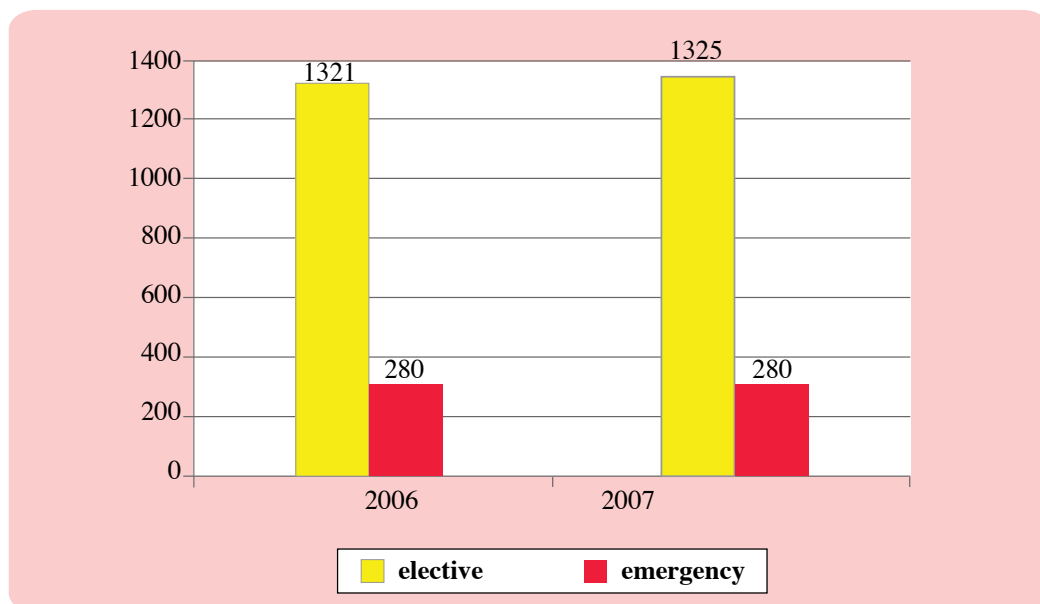
The majority of invasive paediatric cardiac procedures were undertaken by the Penang Hospital, while Sarawak General Hospital (SGH) did the most in terms of the range of case-mix. The number of surgeries carried out by SGH has increased tremendously from 2005 (Figure 4) and constituted about 20% of the total cardiothoracic surgeries performed, compared to other centres in MOH which still lagged at about 10% to 12% of the total cardiac surgeries carried out each year.

Figure 1 : Cardiothoracic Surgery Services in 2006 and 2007 - facilities and volume



Source: IDS, MOH (2007)

Figure 2 : No. of Cardiothoracic Surgery Performed in 2006 and 2007



Source : IDS, MOH (2007)

Presently, MOH has 4 paediatric cardiologists and their services are available in Penang Hospital, Kuala Lumpur Hospital (Paediatric Institute), Sultanah Aminah Hospital in Johor Bahru and from February, 2005 in Sarawak General Hospital. All these hospitals are equipped with cardiac laboratory facilities except in the Kuala Lumpur Hospital. Hence, no cardiac catheterisation procedures are undertaken by the resident paediatric cardiologist. Figure 3 shows the workload in terms of the number of invasive procedures carried out at the various centres in 2006 and 2007. Although Sultanah Aminah Hospital started earlier with the surgical component in 1996, paediatric cardiology service was only started in 2005, and invasive paediatric interventions in 2006.

Paediatric cardiologists in MOH

The MOH has provided additional funding of RM 10 million for the upgrading of facilities in its cardiac centres in 2006 and 2007. There are also plans to place a resident paediatric cardiologist at the Serdang centre, while other options to further develop services at this centre, including linking up with overseas centres are being explored. MOH will continue to send children with congenital heart disease to South Korea for Sabahan children in collaboration with the NGOs. MOH is also considering sending children from poor families who are stable and fit for air travel, to a cardiac centre in India as a cost-effective means of providing more accessible paediatric cardiothoracic service to these affected children.

Budget allocation

To ensure a high standard of cardiothoracic service in its centres, and in promoting professional accountability and responsibility, the MOH monitors clinical outcomes as Key Performance Indicators in these centres. In addition, the Peri-operative Mortality Review Program (POMR), a repository of outcome data, is being maintained akin to many professional bodies in the world. Data gathered so far indicated that the performances of our centres are of comparable international standard of competency and skills. The operative outcomes remain low in mortality (less than 3%) and morbidity till the present time.

Ensuring high quality service

Figure 3 : Number of Invasive Procedures done in 2006 and 2007

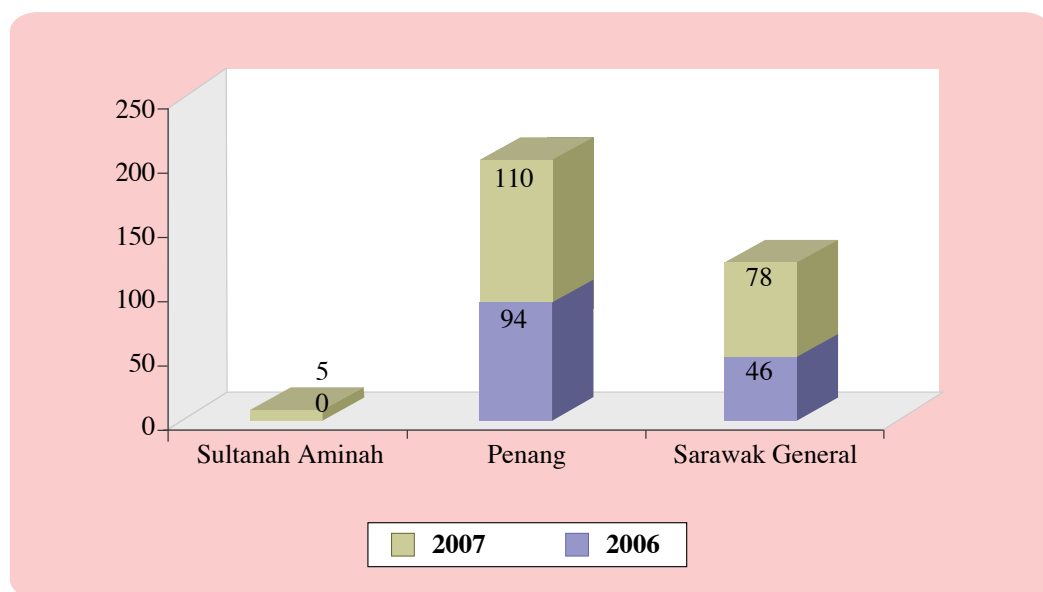
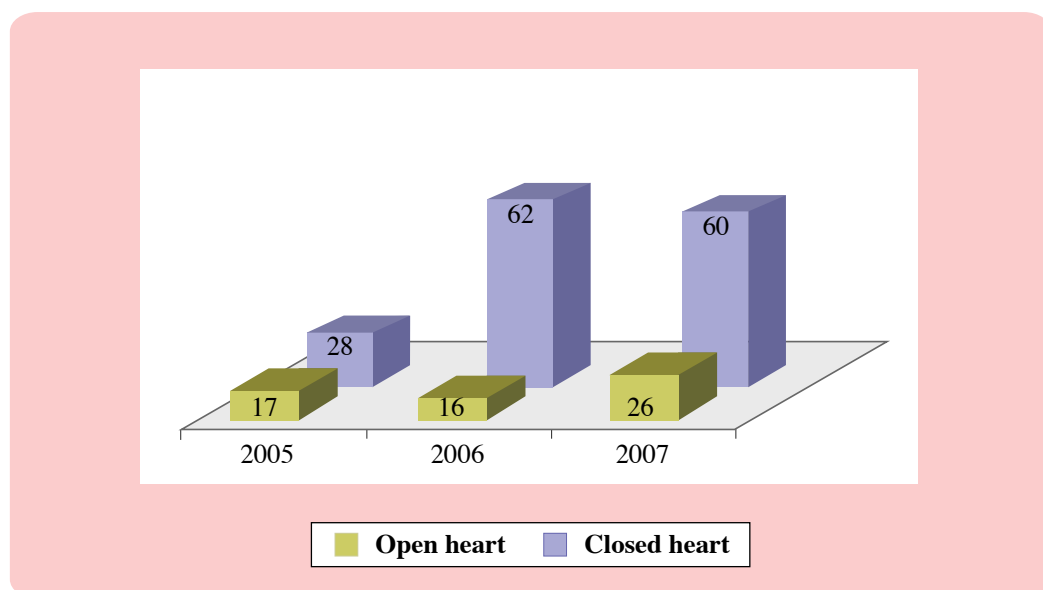


Figure 4 : Paediatric Cardiac Surgery done in Sarawak General Hospital from 2005 to 2007



Issues

There is increasing realisation that lack of facilities for sustainable paediatric cardiac service results in a significant number of preventable deaths and suffering. It is estimated that 15 million children die or are crippled annually by potentially treatable or preventable cardiac diseases in the developing world and Malaysia is no exception. A study on models in other countries with similar capacity will provide further insight into how paediatric cardiothoracic services in the MOH could be further improved.

Need for paediatric cardiothoracic service

As in most cases, the success of a paediatric cardiac service or program is built on its human resource and teamwork. Highly trained, dedicated and committed medical professionals and staff are vital for the success of paediatric cardiothoracic services.

Prerequisites for success

The Bristol Affair in UK has taught us a valuable lesson that in this day and age, there is no excuse for technical incompetency and half-hearted attempts at providing a service. The critical elements and organisational requirements of the paediatric cardiothoracic centres for high-quality outcomes have to be considered and provided. It is therefore mandatory to keep an accurate record of all surgeries and their outcome, as well as having a central database where data on patients who undergo surgery or intervention are recorded. The outcome and details of complications must be noted so that risk stratification can be established. In MOH, these activities are being carried out manually except for the Sultanah Aminah Hospital which has a home-grown hospital-based system. A registry such as for Congenital Heart Disease and Rheumatic Heart Disease has yet to be developed and formalised. A link to performance monitoring of the surgeons or paediatric cardiologists who undertake invasive procedures must be established.

Strategy for the way forward

For the successful development of paediatric cardiothoracic services in the Ministry of Health, the following approaches need to be considered:

1. National standards should be developed as a matter of priority for all aspects of care and treatment of children with congenital heart disease. The standards should address diagnosis, surgical and other treatments, and continuing care. They should also include standards for primary and social care, as well as for effective hospital care. The standards must extend to the needs of patients with congenital heart disease who grow into adulthood. *National standards*
2. A comprehensive and integrated approach towards development of cardiology and cardiothoracic service by MOH is required to achieve a continuum of care, from the time of diagnosis to the time of intervention or surgery, and continuing into adulthood. The approach is through establishing Congenital Heart Surgery as a sub-discipline of cardiac surgery where such surgeons treat not only children but also adults born with heart defect. This is the trend in most developed countries in the world especially in the European countries. *Comprehensive and integrated development*
3. Standards of service should be provided and made available. These include :
 - Number of surgeons: 3 paediatric cardiac surgeons per centre, excluding adult cardiac surgeons working in the same hospital. *Service standards*
 - Number of cardiologists: 1 paediatric cardiologist for half a million population.
 - Number of procedures per surgeon: a minimum of 50 paediatric open-heart surgeries per year or 125 operations a year as a congenital heart surgeon as in Europe.
 - Number of procedures carried out by a paediatric cardiologist: a minimum of 40 procedures per year.

4. Priority areas for implementation to strengthen paediatric cardiothoracic service include:

- Manpower training for a core team of paediatricians, intensivists, surgeons, paediatric cardiac anaesthetists and perfusionists, nursing and other paramedical staff. They should be sent to established and reputable centres overseas for at least a year, working as a team. *Manpower requirement*
- Infrastructure issue has to be addressed. The service can be started in an existing cardiac unit and does not require a separate paediatric cardiac intensive care unit initially. However for a new centre with an anticipated workload, a separate Paediatric CICU, OT and cardiac laboratory should be developed. Diagnostic elements should include a fully equipped paediatric echocardiography laboratory, paediatric catheterisation and electrophysiology laboratory, and appropriate additional facilities and capabilities for comprehensive laboratory and non-invasive diagnostic evaluations of critically ill children. Therapeutic components should include a paediatric cardiac catheterisation laboratory equipped for interventional cardiology and trans-catheter radiofrequency ablations, a cardiac operating suite suitable for surgical treatment of all paediatric cardiac patients and paediatric intensive care. *Infrastructure requirement*
- Equipment should include ECHO machine with trans-oesophageal probe and nitric oxide analyser for the management of pulmonary hypertension and left ventricular assist device. List of essential equipment for invasive and non-invasive procedures need to be prepared and provided for. *Equipment*
- Collaboration such as outsourcing of services either from local private hospitals or overseas centres should be given consideration as a short term measure. The present collaboration with the National Heart Institute has to be continued and strengthened in the future. *Collaboration with private and overseas centres*
- A special budget to be provided for the above purposes and on a continual and sustainable manner. *Adequate budget provision*

A panel convened by the WHO to advice on the optimal resources for paediatric cardiac services concluded that a centre with capacity to perform 300 to 500 paediatric operations annually is needed in developed countries for every 2 million populations. There is no accurate statistics available on the need for paediatric cardiac services in the developing countries but it is likely that the requirement should be higher, probably in the order of 1 centre per million population.

*Paediatric cardiac
centre requirement*

As such, the MOH has to strive hard to develop at least 1 paediatric cardiac centre, preferably in Hospital Serdang in the very near future through collaborative efforts and enabling projects with the National Heart Institute as well as renowned paediatric heart centres from overseas. Resources including personnel, infrastructure, equipment, training, quality assurance program as well as sufficient operating funds need to be provided to ensure its sustainability and high quality care.

*Paediatric
cardiothoracic centre
in Hospital Serdang*

A paediatric cardiothoracic centre should be able to provide all of the sophisticated diagnostic services and the full range of treatments, interventions, and surgeries needed. One can assume that some cardiac operations in congenital heart disease patients will be replaced by interventional procedures, such as percutaneous closure of ventricular septal defects, balloon dilatation, transcatheter radiofrequency ablations for pathologic tachycardia and stent implantation in patients with aortic coarctation, or deployment of covered stents to treat aortic aneurysms that occur after prior coarctectomy. The development of more interventional treatment options will reduce the number of surgical procedures, which is urgently needed and thus, MOH has to keep-up with the advances in medical technology for the benefit of the nation.

*Ideal paediatric
cardiothoracic centre*

The outlook for children born with congenital heart disease continues to improve as a result of advances in paediatric cardiac surgery, catheter interventions, medical and peri-operative management and imaging techniques. Most patients are now expected to live to adulthood. This would lead to an increase in adults with congenital heart disease in the future and they need to be supported. The need for follow-up of congenital heart disease in adult life is likely to grow linearly, with increasing complexity and increasing need for reinvestigation and re-intervention with time. Appropriate provision should be made for adequate manpower, resources, and facilities for care of these patients. However, these adults must also be

Bright future awaits

encouraged to take responsibility for their own health and make informed decisions regarding careers and lifestyle. This is yet another challenge and that will need to be addressed by MOH in the near future, specifically in terms of organisation of appropriate structures even though currently these patients are being managed by the adult cardiologists and adult cardiac surgeons.

Conclusion

Paediatric cardiothoracic service is still under-developed in Malaysia with long waiting time for surgery. Further improvements are needed in terms of human resource training and development; infrastructure; adequate funding; developing national standards for care and for service delivery. Collaboration with local private and overseas cardiac centres of excellence would hasten the development of paediatric cardiothoracic service in the MOH, in addition to improving access to and reducing time for surgeries.

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IMPLEMENTATION OF INTEGRATED HOSPITAL IN MALAYSIA

SUMMARY

Over the last few decades, traditional medicine has made significant contributions towards the health of our people. Traditional medicine continues to be patronised by the community to treat disease and maintain health. It is widely acknowledged that the use of Traditional and Complementary Medicine (T&CM) is widespread and increasing. Taking heed from WHO's Traditional Medicine Strategy 2002-2005, the Cabinet approved the implementation of 'Integrated Hospitals' project in 2006. This report describes the processes and issues involved in the setting up of "Integrated Hospitals".

Introduction

The National Health Delivery System in Malaysia is predominantly western, frequently referred to as modern scientific medicine. Western trained health personnel provide health and medical care. Over the last five decades, Malaysia has made considerable progress in the provision of healthcare to its population through an extensive network of facilities spread across the country propagating improved health maintenance. Together with a stable development of the country's economy, the resulting favorable health outcomes received commendable acknowledgement by the World Health Organization. The country's healthcare system is among the best in developing countries. A nationwide survey conducted in 2004 on the use of Traditional and Complementary Medicine (T&CM) by the Malaysian public showed that 69.4% (67.6% - 71.2%) of the population had ever used T&CM in their life time, while 55.6% (53.8% - 57.4%) reported having used T&CM in the last 12 months prior to the survey.

Malaysian healthcare system is western orientated

Use of T&CM in Malaysia

The Ministry of Health (MOH) has taken a positive and proactive approach towards T&CM to ensure its quality and safety for the consumers. It supports efforts to integrate T&CM into modern medicine and is committed to introduce it incrementally, where appropriate, into the mainstream of our national healthcare system.

MOH's positive approach towards T&CM

WHO Traditional Medicine Strategy 2002 – 2005

According to WHO, Traditional Medicine (TM) is widely used, growing rapidly and is of economic importance. In Africa, up to 80% of the population uses TM to help meet their healthcare needs. In Asia and Latin America, populations continue to use TM as a result of historical development and cultural beliefs. In China, TM accounts for around 40% of all healthcare delivered. Meanwhile, in many developed countries, Complementary & Alternative Medicine (CAM) is becoming more and more popular.

Rapid growth and use of T&CM globally

In France, 75% of the population had used CAM for at least once, while in Canada it is 70%; Australia, 48%; USA, 42% and Belgium, 38%. In many parts of the world, expenditure on TM/CAM is not only significant, but growing rapidly. In Malaysia, an estimated US\$ 500 million is spent annually on this type of healthcare, compared to about US\$ 300 million on allopathic medicine. In the US, total 1997 out-of-pocket CAM expenditure was estimated at US\$ 2700 million while in Canada, the United Kingdom and Australia, annual CAM expenditures were estimated at US\$ 2400 million, US\$ 2300 million and US\$ 80 million respectively.

Use of CAM in developed countries

WHO has identified four main issues and challenges in the development of T&CM to its full potential. They are issues related to policy; safety, efficacy and quality issues; access; and rational use. WHO has drawn up a framework for action with Traditional Medicine Strategy incorporating four objectives:

Objectives of WHO Traditional Medicine Strategy

- Policy — Integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies and programmes.
- Safety, efficacy and quality — Promote safety, efficacy and quality of TM/CAM by expanding the knowledge-base on TM/CAM, and by providing guidance on regulatory and quality assurance standards.
- Access — Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations.
- Rational use — Promote therapeutically sound use of appropriate TM/CAM by providers and consumers.

Initial focus on policy & achieving safety, efficacy and quality

Implementation of the strategy will initially focus on the first two objectives. Achieving safety, efficacy and quality objective will provide the necessary foundation for achieving access and rational use objectives. To echo WHO's strategy, Malaysia has put in concerted efforts towards tackling the first two objectives. The Malaysian National Policy on T&CM was published in 2001 and further reviewed in 2007. A Cabinet Paper was also presented for the establishment of integrated medicine at government hospitals.

Cabinet Directive

In January 2006, the Cabinet approved the integrated hospital concept and three hospitals were chosen for the pilot project, namely: Hospital Kepala Batas in Penang; Hospital Putrajaya and Hospital Sultan Ismail, Johor Bharu. Cabinet also directed that efforts be made to evaluate the training and education system of T&CM in other countries, and subsequently to accredit T&CM courses provided at competent training centres overseas. These initiatives are crucial to ensure sufficient supply of suitable human resources in this area of development in the future.

*Cabinet approval :
Integrated Hospital
and accreditation of
training centres*

Concept

It was agreed that the implementation of integrated hospitals will adopt the 'integrative concept' whereby T&CM practices selected must be applied in combination with allopathic treatment. Only selected T&CM services with proven scientific evidence and efficacy will be considered in this integrated hospital project.

Integrative concept

A few prerequisites were considered before its implementation to ensure the success of the project. These include establishing potential clinical benefits, safety, associated risks and credible scientific evidence as documented proof, and source of information. Issues related to medico-legal situations were to be considered like dealing with cases of malpractice, wrong labelling or misinformation.

Pre-requisites

Integration and harmonisation of traditional and modern medicine emphasizes the importance of respectful co-existence. Within this model of integration, the prerequisite of harmonisation is to develop and hold a good understanding of other approaches to healthcare. Modern medicine practitioners need to be more aware of the

*Importance of
respectful co-
existence*

nature of practice, principles and context of traditional medicine. Similarly, T&CM practitioners need to be more aware of the nature and practice and strengths of modern medical approaches. Therefore, the need for formalised training of T&CM practitioners must be emphasized strongly and vice versa while allopathic medical practitioners must also be made aware of the nature, principles and strengths of T&CM practices.

IMPLEMENTATION OF INTEGRATED HOSPITALS IN MALAYSIA.

The general objective of this project was to plan and establish a T&CM Unit in the three pilot hospitals selected for T&CM practices. Other specific objectives identified were as follows:

1. to identify the scope of T&CM services provision
2. to identify the infrastructure, logistics and financial requirements
3. to identify suitably trained practitioners
4. to develop guidelines, operating procedures and other regulations
5. to facilitate research and development activities.

Scope of service

The following services were considered as selected practices in this project :

1. Oncology
 - Pain management (acupuncture)
 - Palliative care
 - Adjunct herbal treatment by Traditional Chinese Medicine (TCM) Physician.

2. Rehabilitation

- Nutritional therapy
- Traditional Chinese massage (tuinalogy)
- Reflexology

3. Post Natal Care

- Traditional Malay massage
- Herbal bath

4. Wellness therapies

- Other traditional massage
- Qi-gong
- Aromatherapy

5. Chiropractic

6. Other supporting services such as Klinikal Test Laboratory and Pharmacy

Infrastructure, logistics and financial requirements

To facilitate cost estimation of infrastructure and logistics requirements, three services were focused on, namely acupuncture, traditional herbs as adjunct treatment and traditional massage. Estimated cost for upgrading the existing facilities in the three hospitals were as follows:

1. To prepare 3 consultation rooms with basic equipment (each hospital RM 120,000) x 3 hospitals = RM 360,000 *Cost estimation*
2. To prepare treatment rooms for acupuncture, traditional herbs as adjunct treatment and traditional massage with beds and other equipment (each hospital RM300,000) x 3 hospitals = RM900,000

3. To prepare registration counter and waiting area (each hospital RM20,000) x 3 hospitals = RM60,000
4. Set up of herbal storage room and space for keeping records (each hospital RM40,000) x 3 hospitals = RM120,000
5. Clinical research – RM360,000
TOTAL COST = RM1,800,000

Human Resource

Suitably trained practitioners were identified to ensure that appropriate services are provided to patients. A few well-known local midwives were selected and trained to provide traditional massage. The selection was done in collaboration with the hospitals' Board of Visitors. *Training of selected midwives in traditional massage*

For acupuncture services, members of the Integrated Hospitals Steering Committee visited a few private hospitals already offering such a service. Collaboration with acupuncturists from these private hospitals was adopted to facilitate the start of acupuncture service in these Integrated hospitals. Practitioners from the Chinese Practitioner Bodies were very cooperative about this project. *Collaborative efforts with private hospitals and practitioner bodies*

In the future, MOH plans to create permanent posts relevant to the advancement and further development of Integrated Hospital services.

Guidelines, Operating Procedures and Other Regulations

Implementation of 'Integrated Hospital' project in Malaysia is not an easy feat. Therefore, it is imperative that the T&CM Act, which is being drafted currently, be comprehensive to ensure the success of this project. Areas of paramount importance are: *Proposed T & CM Act*

- Policy
- Financial Management
- Facilities and equipment management
- Human Resource Management

Mechanism of Implementation

A Steering Committee with the Director General of Health as chairman and members from various departments of the MOH was formed. Together with the steering committee, committees at state level were also formed to ensure its smooth implementation.

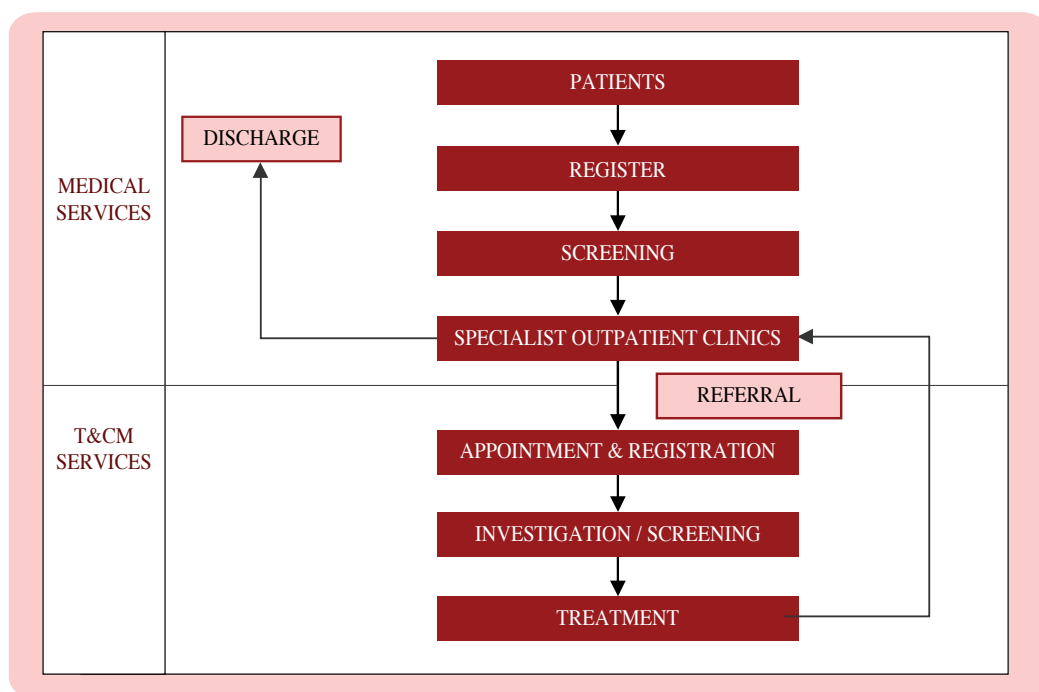
Organisation and Administration

Steering Committee

Director General of Health (chairman)

Members: Deputy Director General of Health (P&ST)
Director, T&CM Division, Ministry of Health
Secretary, Finance Department, Ministry of Health
Secretary, Human Resource Department, Ministry of Health
Legal Advisor, Ministry of Health
Selected members from relevant Practitioner Bodies
State Health Director
Hospitals Directors

Workflow chart of T&CM Unit in Integrated Hospital



Actual Implementation

Three traditional medicine practices were selected to be introduced into the integrated hospital program namely Malay traditional massage, acupuncture and adjunct herbal medicine for patients on chemotherapy. For the adjunct herbal medicine service, Traditional Chinese Medicine (TCM) Oncologists from People's Republic of China (PRC) were hired on contract basis, primarily, to facilitate technology transfer.

*Malay traditional
massage,
Acupuncture and
adjunct herbal
medicine for patients
on chemotherapy*

T&CM unit in Hospital Kepala Batas started on October 18th 2007 and was officially opened by Right Honourable Prime Minister of Malaysia, YAB Dato' Seri Abdullah Haji Ahmad Badawi on October 26th 2007, together with official opening of the hospital itself.

Initially, access to service was through referral by the hospital's medical doctors. However, to cater for the overwhelming response and requests by the public, the Malay Traditional Massage and Acupuncture were later opened to walk-in patients.

For the immediate future, final preparations are being carried out to open T&CM Units in Hospital Sultan Ismail, Johor Bahru and Hospital Putrajaya to facilitate start of services soon.

Future Plans

Depending on the success of the three pilot hospitals, the Integrated Hospital project would be extended to other hospitals in the country. Other suitable practices are currently being evaluated for inclusion into the project, namely: some form of Ayurveda therapy or 'panchakarma' and post natal care. As with other services already included in the project, starting these new services would require a lot of research for scientific evidence and potential clinical benefits.

*Panchakarma & post
natal care*

Conclusion

Integrated medicine is attractive because it focuses on health and healing rather than disease and treatment. Patients are being viewed holistically as physical, mental and spiritual beings. It also get doctors and patients to work together to maintain health by focusing on lifestyle factors such as diet, exercise, quality of rest, sleep and nature of relationships. In an era where modern medicine costs are escalating, the concept of integrated medicine could provide possible cost-savings and affordable healthcare. Furthermore, it also promotes individual responsibility & empowerment on the management of their illness.

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SCHOOL HEALTH: PAST, PRESENT AND FUTURE

SUMMARY

The current status of school health services in Malaysia has influences from previous global and local experiences. When the school health program was first established its main focus was on health education, health assessment, healthy living in school and community participation. With the introduction of new school health models, Malaysia adopted the Health Promoting School concept as the entry point in creating a healthy school setting. Today the school health program faces greater challenges than decades ago. The school has been identified as an important setting which will make differences in reducing future disease burden. To achieve such a noble goal, it must evolve from its traditional model into a dynamic, robust and innovative system which emphasizes on focusing on the health and education needs of the school children. The role of paramedics in the school health program needs to be re- aligned and the standard of health care for this population needs to be reviewed to ensure universal access to quality care.

Introduction

Schooling is part of a child's growing up process. Health and learning are factors which interdependently influence the child's achievement in school. A healthy child is less likely to be absent from school and can focus on his studies and is more likely to get better grades. Similarly, educated people are more likely to be healthy and to take necessary action to maintain good health compared to those who are less educated. Hence, the school remains as an important setting for investment in the health of the future generation.

Relationship between health and learning

School Health across timeline

Historically, learning was the privilege of the aristocrats and the rich. Their children were taught in their homes by paid governess. As education became part of the daily life of the ordinary man, schools were built to cater for collective learning. Schools in the 16th and 17th century were described as lacking in basic amenities, and were overcrowded, dark and dirty. There was no structured curricular and teachers were more interested in delivering their subject rather than the method of teaching or improving the learning environment in school. The unhygienic environment exposed children to various adverse health conditions and this was reflected by an increasing number of absentees from school.

*Evolution Of School
And School Health
Programme Across
Timeline*

Huge improvement in the health and education environment was accomplished through improvement in the design of school buildings resulting in reasonable classroom size and better seating arrangement. Inventions such as artificial lighting, heating system and construction of lavatories further improved the school physical environment in the 19th century.

The success of controlling small pox outbreak was achieved through school inoculation and subsequently laws on compulsory school vaccinations were introduced. Today schools continue to be an important setting in controlling vaccine preventable diseases.

After the Second World war, it was recognised that some disabilities may prevent children from achieving their optimal potential. Hence, hearing and vision screening became a part of the school health service.

In the beginning, the responsibility for providing care to the school population fell upon the health institutions and both the school physician and nurse played major roles in managing the health of the school children. Resource limitation and competing health priorities made the health sector re-think its strategies in investing in school health. This was followed by the taking over of the school health service by the education sector and this is practiced by many countries till today.

Models of Good Care in School.

In the mid 1970s, the school health programme advanced beyond personal and environmental health care. With the recognition of the child's health and education needs as ultimate goals in the provision of health care to this population, new approaches and models of health care for the school population emerged. Amongst the examples of models frequently adopted were Coordinated School, 8 components models, Focusing Resources on Effective School (FRESH), Health Promoting School and effective school.

*Models of School
Health Programmes*

Model of health care for school population in Malaysia

The Malaysian School Health Program, known as the *Rancangan Kesihatan Sekolah* (RKS) was founded in 1967 as a joint programme under the wings of the Ministry of Health and the Ministry of Education. A year after its inception, the model of care for RKS was developed in 1968. The four fundamental elements for the RKS were: School Health Services, School Health Education, Healthy living in school and community participation. The RKS became the lifeline of the School Health Program until it was further strengthened under the umbrella of the Health Promoting School in 1998.

*School Health
Model in Malaysia
– Rancangan
Kesihatan Sekolah
1968 – 1998*

The Health Promoting School (HPS) is a concept introduced by the World Health Organisation following the resolution in the Ottawa Charter. The HPS recognizes the school as an important setting to be nurtured to be a healthy environment for children to learn and grow.

*Health Promoting
School – 1998 till
present*

Malaysia implemented the HPS concept locally known as *Program Bersepadu Sekolah Sihat* (PBSS) in 1998. The PBSS encouraged schools to be developed into healthy setting through 6 pillars: School health Policy, healthy physical environment, healthy social environment, health skills, community participation and the school health services.

The RKS landscape in Malaysia

In the late 60s to the 80s, the success of the RKS was closely tied to its partnership with the Ministry of Education through the *Jawatankuasa Bersama Rancangan Kesihatan Sekolah* at National, State, district and school level. Formation of the National Joint RKS committee was followed by formation of state committees in Penang, Melaka, Pahang and Perlis in 1968, Negeri Sembilan, Johor and Pahang in 1969 and other states in Peninsular Malaysia in the following two years.

*Rancangan
Kesihatan Sekolah –
exploring the past*

The school Health Service

In its humble beginning, the school health service was delivered by the local authorities through their urban health clinics. Establishment of the RKS formalised the delivery of the School Health Service (SHS) in the rural areas. In the first 7 years of its initiation the SHS was carried out by the same staff providing the maternal and child health service.

*The School Health
Service*

The SHS focused on personal care, prevention of vaccine preventable diseases, health screening and assessment. Among the health services initiated were immunisation against tuberculosis, diphtheria and tetanus, inspection for head lice, and scabies and prevention and treatment of worm infestation. School Health service did not reach East Malaysia until the 1980s.

Delivering the service to school population

It was envisaged that the school teams would be the key player at district level in the planning and implementation of the school health service. The target was to establish at least one school team in every district. In 1975, only two health teams were established, in Kuala Lumpur and Kuala Terengganu. However temporary teams were developed in several other states. The difficulty in setting up teams with a medical officer as the head of the team was overcome through increasing the number of medical officers in rural health services in the 3rd and 4th Malaysian Plan.

*School Health
Service Delivery*

In the 1980s, school health services were implemented in Sabah and Sarawak. Due to the shortage of nurses, Sarawak employed Junior Health Assistants and Community Nurses to provide the service. While other states managed to provide service to the preschool

*School Health in
Sabah and Sarawak*

children as well, this could not be done in Sarawak because of shortage of manpower. Later the Assistant Medical Officers took over the main role in delivering health services to school children. Today about 95 Assistant Medical Officers provide the Sarawak School Health services as one of the services provided by their mobile teams.

At the end of 1998, a total of 159 school teams had been established in Peninsular Malaysia. However with the expansion of the scope of public health service delivery in 1996, the school health program had to compete for existing resources.

The school health teams

There are 3 types of school teams delivering health services in school, the School Health Team, the Dental Health team and the inspectorate team. Both the School and Dental health teams visit schools on a yearly basis to provide mobile health care. The inspectorate team plays a major role in building inspection, food safety and prevention of vector borne communicable diseases.

*Types of School
Health teams*

The School Health service Packages

The School Health Package refers to health and health related services delivered by the Ministry of Health (MOH), the Ministry of Education or collaborative effort between the two Ministries.

*School Health
Service Package*

Services by Ministry of Education

By the mid 1970's, the Ministry of Education had successfully introduced health curricular, campaigns and distributed health education materials in schools. Health curricular were designed and revised for primary and secondary education and teachers were trained in health related matters at national, state and district level. In the 1970s teachers were sent to study various aspect of health at certificate, diploma and master level. Changes in the Ministry of Education Policy in the early 1990s observed that health topics became part of the physical education and other subjects in the curriculum.

*Ministry of Education
Service Package*

In the mid 1970s the Ministry of Education initiated inquiry on students coming to school without breakfast. This led to the introduction of the School Food Supplementary Program and Milk Program for students from low income family in the primary schools.

Services by Ministry of Health

Beside the regular school health services provided by the School teams, various activities have been introduced to the school population. Activities such as construction of proper latrines, provision of safe water supply, dengue control in school, anti drug campaigns and school cleanliness campaign began in the 1970s as measures to reduce communicable and non communicable diseases in schools.

*Ministry of Health
Service Package*

In the 1990s when new programme were introduced by the Public Health Division, new activities were introduced in schools. These included health awareness against HIV/AIDS, Healthy Life Style Campaign, Adolescent Health Programs and the *Doktor Muda* programme.

School Health Monitoring System

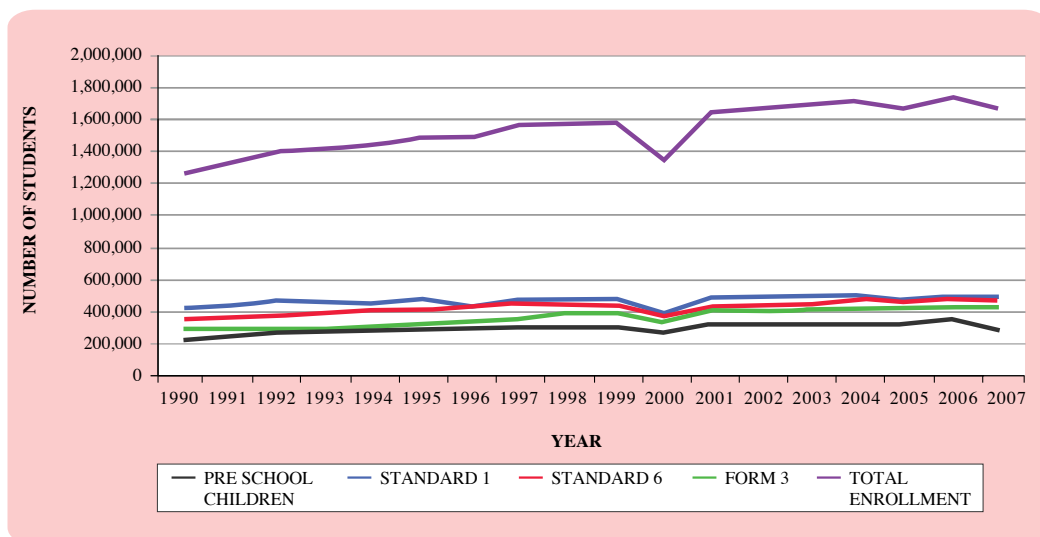
In 1989, the health management and information centre initiated structured organised compilation of maternal and child health returns including the school health data. This allowed school health performance to be monitored closely at district, state and national level. The system also provides warning signs of potential problems and thus allows for timely and appropriate action to be taken at district, state and national level.

*School Health
Monitoring System*

Achievement Over The Past 40 Years

Over the last 40 years, the SHS has provided health assessment and care to millions of school children with an annual average of 1.8 million pre-school, Standard 1, Standard 6 and Form 3 students. *Service coverage*

FIGURE 1 : PRE SCHOOL, STANDARD 1, STANDARD 6 AND FORM 3 STUDENTS' ENROLLMENT FROM 1990 TO 2007

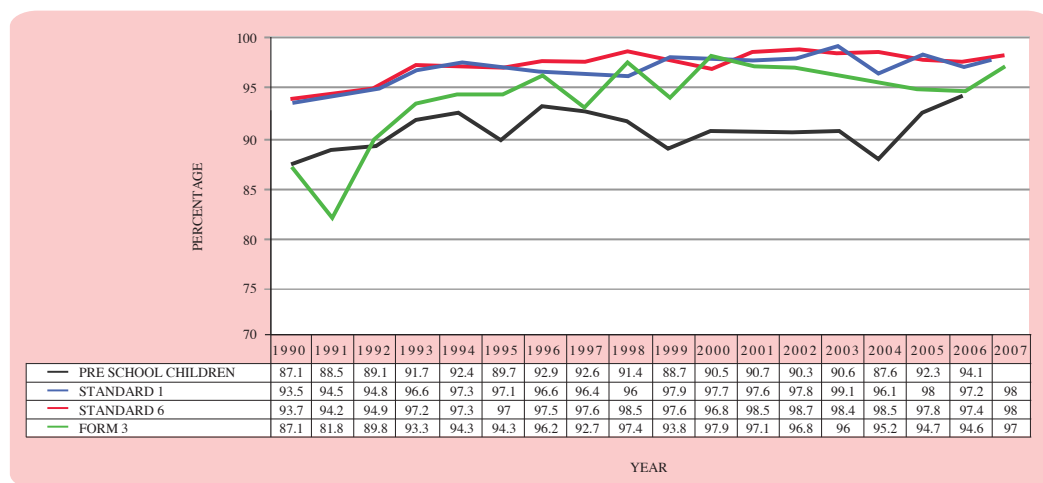


Source: Health Management and Informatic, MOH

While the number of students continues to increase yearly, the number of school health teams does not increase proportionately to the number of students. The shortage of doctors has great implication on their performance in the SHS. Today only 34 percent of SHT are headed by medical doctors. *School children examination by Nurses and Assistant Medical Officers*

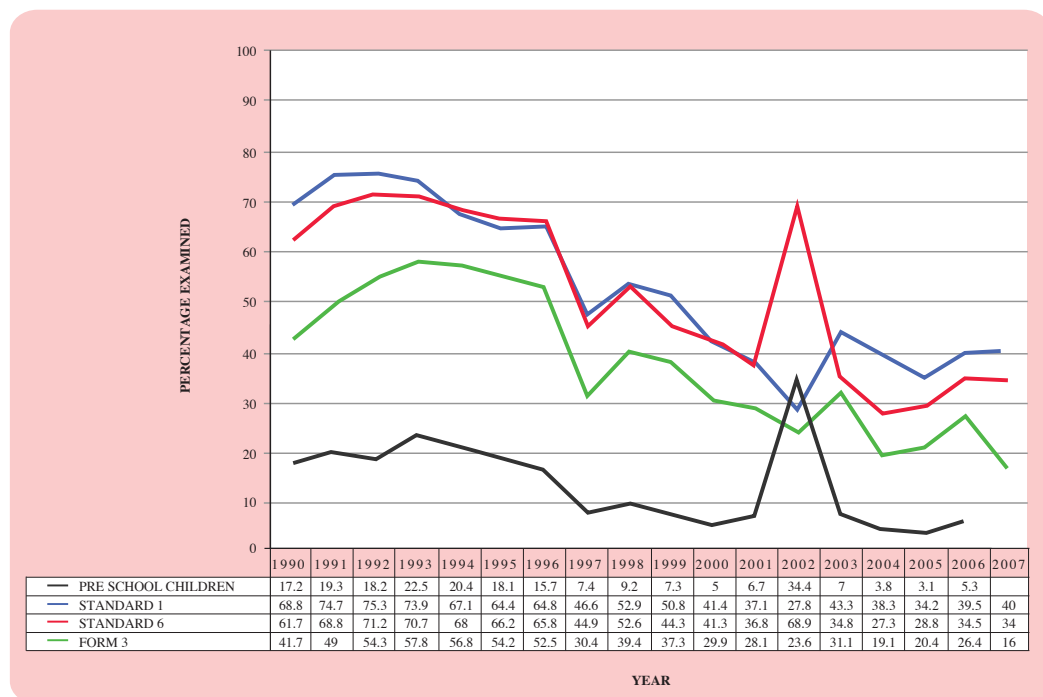
The school health nurses play a major role in ensuring that the school children have access to health service during their schooling years. The nurses' coverage since 1990 is shown in figure 2. The decline in the number of school health doctors in many states in Peninsular Malaysia is very apparent after 1995 as shown in figure 3.

Figure 2 : Percentage Of School Children Examined By Nurses From 1990 To 2007



Source: Health Management and Informatic, MOH

Figure 3 : Percentage Of School Children Enrolled In Government Schools Examined by Doctors



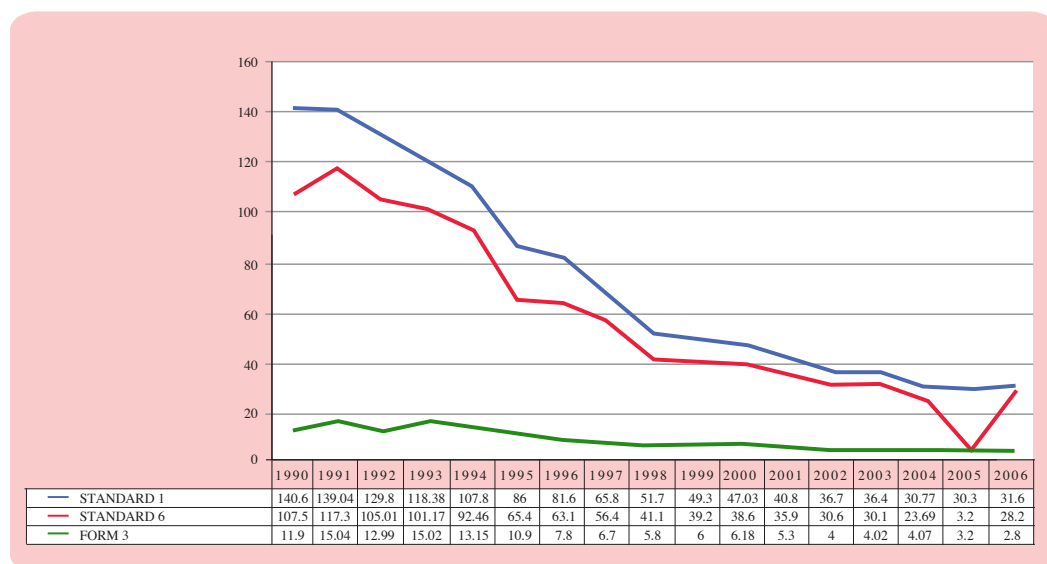
Source: Health Management and Informatic, MOH

The School Children Morbidity Patterns.

The reduction in health related morbidity was observed among all children examined over the last 40 years. The detection rate for head lice (figure 4) and scabies have declined tremendously among the Standard 1 students over the years and further reduction is observed among the older student population. Similarly the detection rates of anemia and worm infestation are on the decline. Refer to figures 4 and 5.

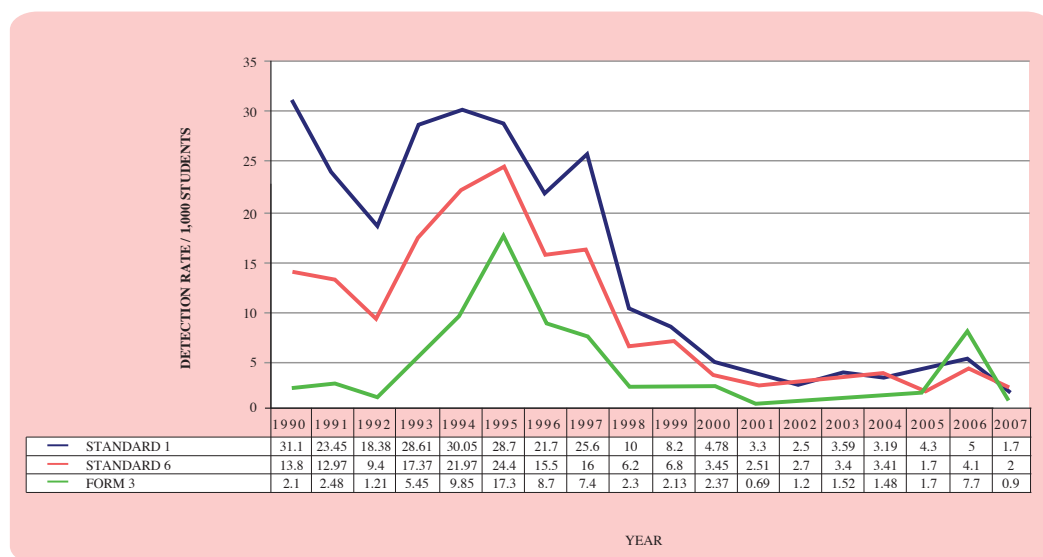
Head lice and scabies

Figure 4 : Rate Of Head Lice Detection Per 1,000 Standard 1, Standard 6 And Form 3 Students Examined Between 1990 To 2006



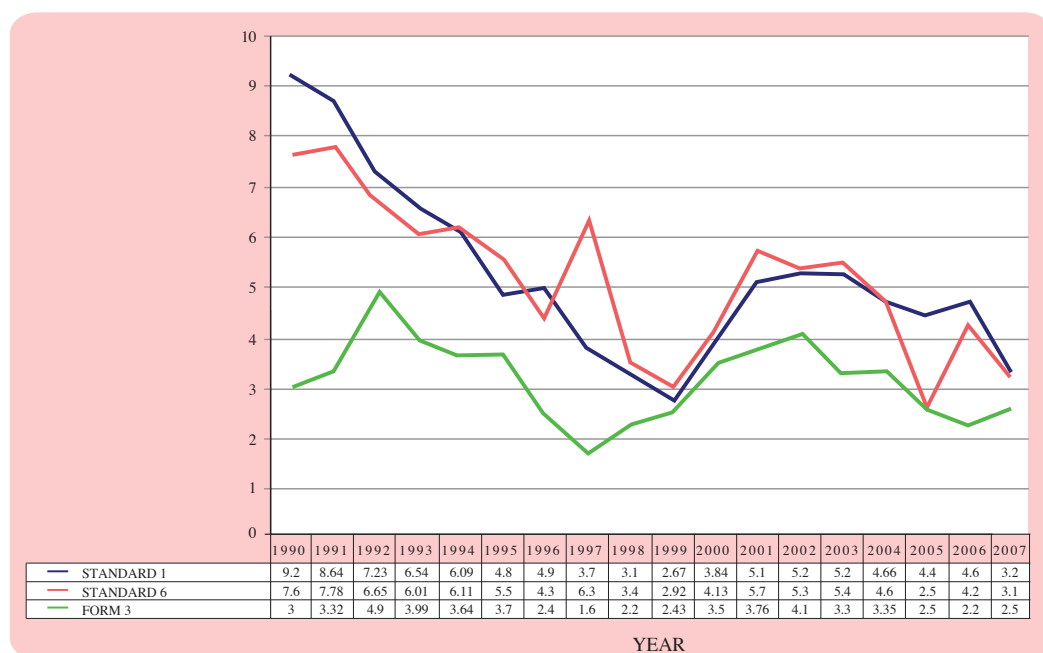
Source: Health Management and Informatic, MOH

Figure 5 : Worm Infestation Detection Rate For Every 1,000 Standard 1, Standard 6 and Form 3 Students Examined Between 1990 to 2007



Source: Health Management and Informatic, MOH

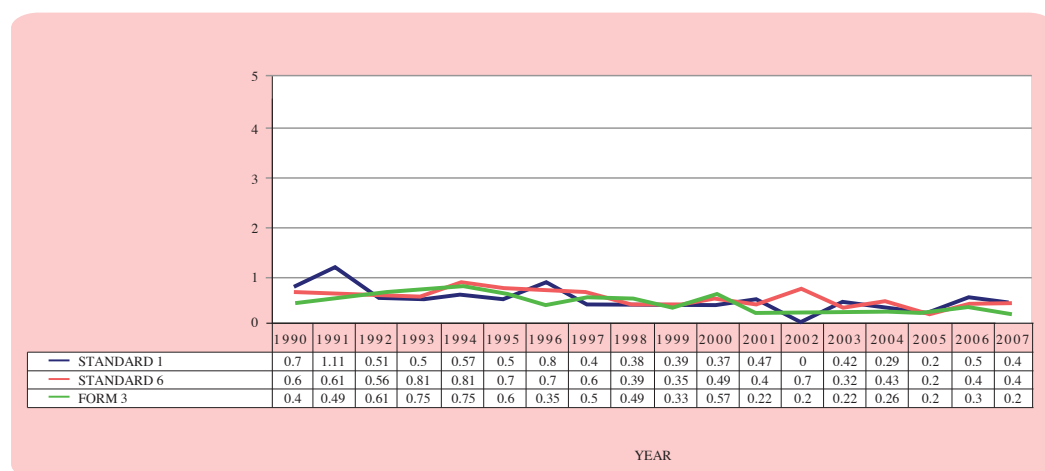
Figure 6 : Scabies Detection Rate For Every 1,000 Standard 1, Standard 6 and Form 3 Students Examined Between 1990 To 2007



Source: Health Management and Informatic, MOH

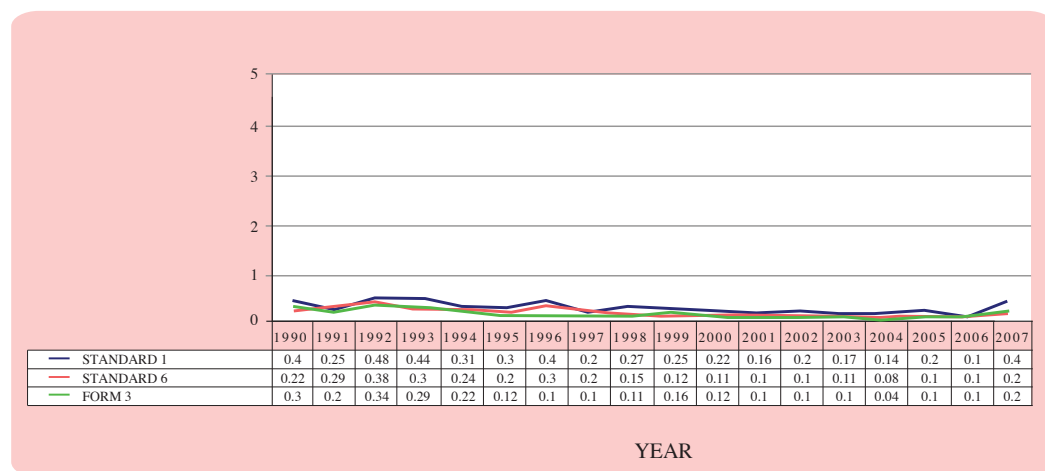
Over the 17 years period, it was observed that the detection rate of hearing and musculoskeletal deformity remained lower than the rate observed in the population in other countries. Inappropriate environment for testing, and the use of crude techniques have been identified to contribute to the inadequacy in the screening for these conditions. Better and appropriate techniques need to be employed to improve the yield.

Figure 7 : Hearing Problem Detection For Every 1,000 Standard 1, Standard 6 and Form 3 Students Examined Between 1990 To 2007



Source: Health Management and Informatic, MOH

Figure 8 : Musculoskeletal Problem Detection Rate Among Every 1,000 Standard 1, Standard 6 And Form 3 Students Examined 1990 To 2007



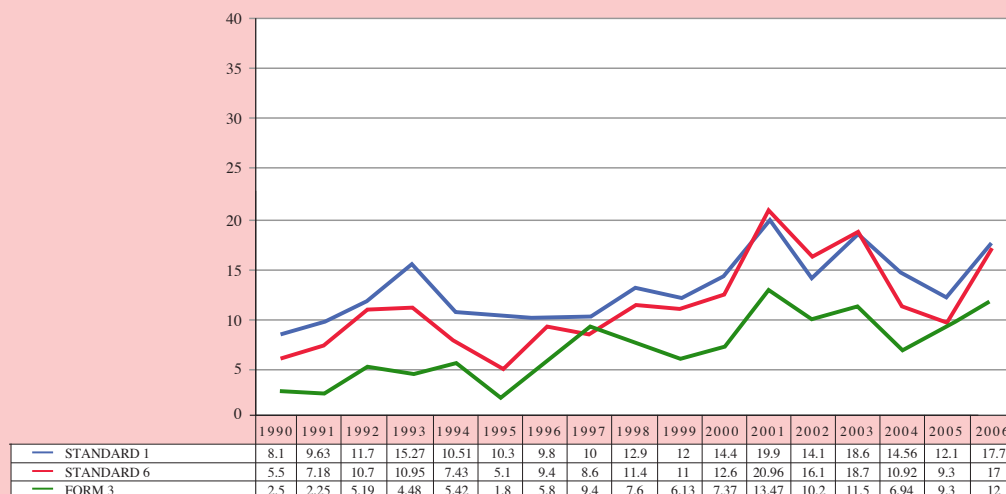
Source: Health Management and Informatic, MOH

The percentage of visual acuity problem detected among Standard One students was selected as a proxy measure of the quality of SHS delivery. States not achieving the set target of 2 percent, were required to run corrective measure for the shortfall in quality and take necessary remedial action. In 2006 the percentage of detection had increased to 5 percent in line with evidence showing a higher percentage of children detected with visual acuity problem in school population surveys.

Between the period of 1990 to 2007, the Ministry of Health data showed an increase in the incidence of visual defect detection rate among all age groups. In 1990 the rate of visual acuity problem detected was 7 per 1,000 Standard One children examined. This rose to 58.78 per 1,000 in 2007. Similar observations were seen among the Standard 6 and Form 3 students. This urged the MOH to revise the cut off point for visual defect detection among Standard One students from 2 to 5 percent in 2006. This higher level of detection is necessary to ensure that no child is missed and left untreated for visual defect during the early years in school.

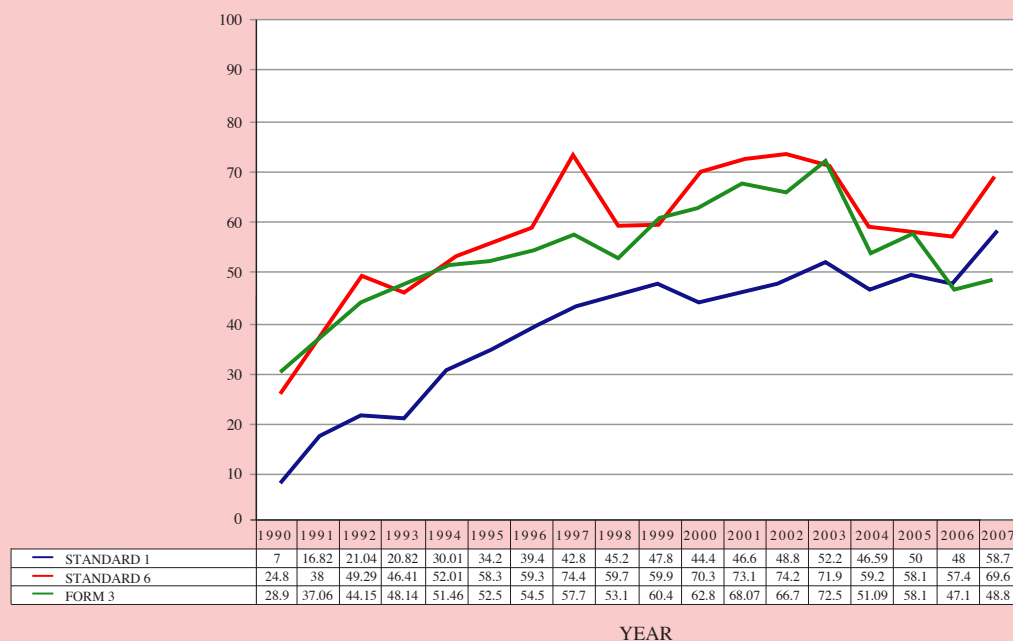
Prior to 2007, malnutrition, defined as inappropriate nutrition i.e under and over nutrition) was used as a proxy indicator in the monitoring of the children's nutritional status. Since 1990 the incidence of malnutrition was on the rise for preschool, Standard 1, Standard 6 and Form 3 students.

Figure 9 : Malnutrition Detection Rate For Every 1,000 Standard 1, Standard 6 And Form 3 Examined From 1990 To 2006



Source: Health Management and Informatic, MOH

Figure 10 : Visual Defect Detection Rate For Every 1,000 Standard 1, Standard 6 And Form 3 Examined Between 1990 To 2007



Source: Health Management and Informatic, MOH

Gaps And Barriers In Providing Health Care To School Children

Over the last 40 years, the Ministry of Health has strived to ensure that school children have access to health care during their schooling years. Within this period, the School Health Program has successfully covered 98 percent of school children in the government funded schools, reduced the burden of diseases resulting from poor hygiene practices and imparted health education to millions of school children.

Though the service coverage appears satisfactory, it has to be reminded that the school enrollment was gathered from only government funded schools. There are still pockets of school children population in the private sector that do not have access to school health service. The mechanism and mode of service delivery for these children need to be looked into.

Universal access to health care

Today more adults have risk of cardiovascular diseases than before, and more school children are reported to be overweight, to have mental problems and to be involved in risk taking health behaviors. A proportion of school children have made unhealthy choices in life making them vulnerable to unhealthy behaviors which may affect their future life. These lifestyle risk behaviors require intensive efforts to identify those at risk and those who are already engaged in these unhealthy behaviors and offer help in the form of behavior modification.

Changing disease pattern

The School Health Teams are not equipped to deal with these new diseases in the school community. Given the number of students they have to serve and the time allocation for each student, it is difficult for them to take on the task of managing these new diseases. Therefore, new strategies have to be formalised to ensure these school children receive the much needed health care.

School Health – Future Direction

To move forward, the current school health service needs to move beyond traditional care to a more robust and dynamic health care. It needs to address the issue of universal access to basic health care for all school children in the public and private sectors, and in urban and rural areas including the remote areas. Care should also be provided to the child with disability and the child with chronic illness in school.

Universal access to all school children

The service package delivered should be appropriate to the child's needs as he grows. Health education and screening have to be packaged in an attractive and systematic manner. Standard of care need to be introduced to ensure the best method in delivering the service. The future package of health service should include new services and screening technologies and specific interventions which may benefit the future health of the children.

School health service package

The nutritional status of the school children in this country is worrying and needs urgent attention. Traditional programs which focus only on the school child have to be replaced with more comprehensive and holistic approaches. The family members, school authorities, school canteen operators, various government and food industries have to work together to ensure these children are given the opportunity to make healthy food choices from an early age. We can learn from the success of the Scandinavian countries in reducing the population cardiovascular risk factors. Community based programs such as walking to school, weight management in school, healthy food choices in school and at home will enhance the child's skills in making healthy choices.

Learning for success initiatives

It is crucial that health care be integrated with the school curricular and extracurricular activities. Existing activities such as *Doktor Muda* should be continued and further improved. The training given to these children should enable them to practice healthy lifestyle, deliver health messages to their peers and support the school in running health services to children.

Linking health and school curriculum

The key to success of the future school health programme is the ability to integrate the child's educational needs and health requirements. The programme should be integrated into the child's

Future school health service

daily activities both in school, at home and in the community. The future school health program should provide holistic and comprehensive care which takes into account the physical, social and psychosocial development of the child. This can be achieved through promotive, preventive, curative and rehabilitative care.

Conclusion

The School Health Programme is relevant and will continue to stay. It is important that this programme diverts its investment into health services which have proven to show positive impact on the health of the child rather than to continue with its traditional service delivery.

With an increasing number of children with special needs enrolled in school, it is inevitable that services for the disabled child and the chronically ill child need to be established. The stake holders for school health need to utilise new public health strategies in the delivery of effective school health services.

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THE DEVELOPMENT OF PATHOLOGY SERVICES IN PRIMARY HEALTH CARE

SUMMARY

Pathology services in primary health care clinics have started since 1956, and have since grown. Currently, 70% of all primary health care clinics in the country are equipped with pathology services. These laboratories consist of basic level laboratories and level 1a laboratories providing more complex services. The roles of pathologists have also expanded into planning, human resource and asset management apart from its traditional role of running pathological services. Various activities were conducted to ensure quality consistency of pathological tests performed in these laboratories. In order to attain better services in the future, the unit plans to improve pathological services at primary health care clinics by utilising several measures, including strengthening of human resource and technical expertise, credentialing measures, infrastructure development and work organisation. It is envisaged that planned efforts will meet future needs in the delivery of accessible and equitable primary health care with no compromise in quality and safety.

Introduction

Primary care services in the health clinics in Malaysia, started with a basic package of essential care to deliver the eight elements of primary health care (PHC). Since then, the scope and content of PHC have undergone expansion to include newer areas of concern, such as women's health, community mental health, health of older persons, to name a few. New activities such as low risk birthing centres, rehabilitation services for the elderly and disabled, and counselling rooms for the adolescents, are becoming common features. In some clinics, space is provided for psycho-social rehabilitation activities of mental patients. Several community-based facilities have been developed, some in partnership with related agencies and the community itself, such as the Community-based Rehabilitation (CBR) Centres for children with special needs.

*Primary care services
in the health clinic*

In line with the expansion of services in the primary health care clinics, progress in supporting services in these clinics, including radiology, pharmacy and pathology services, has developed in parallel.

Development of pathology services in primary health care clinics

When the rural health service in Malaysia was established in 1956, clinical laboratories, manned by assistant medical laboratory technologists, performed basic investigation such as, haemoglobin level analysis, urine analysis, stool analysis, blood smear for malaria parasite and sputum for acid fast bacilli.

Expanded function of pathology services in primary health care

The range of services has since been upgraded in keeping with the current development in clinical investigation and management of diseases including, haematology, biochemistry, microbiology and serology. The laboratory personnel have also been upgraded to medical laboratory technologists in line with the expanded functions of pathology services in primary health care including:

- a) Planning, preparation, implementation, monitoring and evaluation of the related operational policies in primary health care
- b) Evaluation of the performance of the laboratories and the appropriateness of technology to health care in the community setting
- c) Ensuring implementation of standards for laboratory procedures at the primary health care clinics
- d) Development and maintenance of laboratory database
- e) Planning and evaluating Quality Assurance programmes for laboratory services
- f) Planning for future needs and upgrading of laboratories

Laboratory Services in Primary health care

There are 2 types of laboratories in primary health care; the one which is headed by assistant lab technician - the clinical laboratory, which only covers minimal tests such as basic blood investigations (Haemoglobin levels), urinalysis, stool analysis, blood smear for malaria parasite and sputum for AFB. The other type of laboratory is headed by the lab technician - Pathology Lab type Ia. The services provided ranges from haematology, biochemistry, microbiology and serology.

*Workload and
distributions of
human resources*

In 2007, 70% (635 out of the total 903) of the health clinics and maternal and child health clinics in the country are equipped with laboratories, with a total of workload of 31,407,210 tests. The states of Pahang, Perak and Johor were the three states with the highest workload. Table 1 shows the distribution of workload by states. Of these, 83% are manned by laboratory technologists, numbering a total of 959. Perak, Johor and Sarawak have the highest number of technologists as shown in table 2 below.

Table 1: Workload of the pathology services by states.

No.	States	Biochem	Hemato	Microb	Others	Total
1.	Perlis	496,933	93,972	13,524	0	604,429
2.	Kedah	1,502,295	357,138	113,864	42,988	2,016,285
3.	P. Pinang	1,372,852	209,872	192,716	0	1,775,440
4.	Perak	2,991,073	630,821	377,506	5,693	4,005,093
5.	W.P KL	757,335	128,996	26,716	10,421	923,468
6.	Selangor	1,033,446	273,769	91,988	0	1,399,203
7.	N.Sembilan	2,069,966	553,358	147,265	14,222	2,784,811
8.	Melaka	1,363,388	242,147	232,130	11,032	1,848,697
9.	Johor	2,829,478	789,512	361,968	14,410	3,995,368
10.	Pahang	2,054,066	660,617	712,451	320	3,427,454
11.	Kelantan	1,047,052	299,152	660,608	0	2,006,812
12.	Terengganu	960,612	284,202	161,570	575,995	1,982,379
13.	Sarawak	1,521,185	428,494	127,521	599	2,077,799
14.	Sabah	1,502,073	438,237	203,403	416,259	2,559,972
	Total	21,501,754	5,390,287	3,423,230	1,091,939	3,140,7210
	Percentage (%)	68.5	17.2	10.9	3.4	100.0

Table 2 : Distributions of laboratory technician (grade U36, U32, U29) and lab assistants by states.

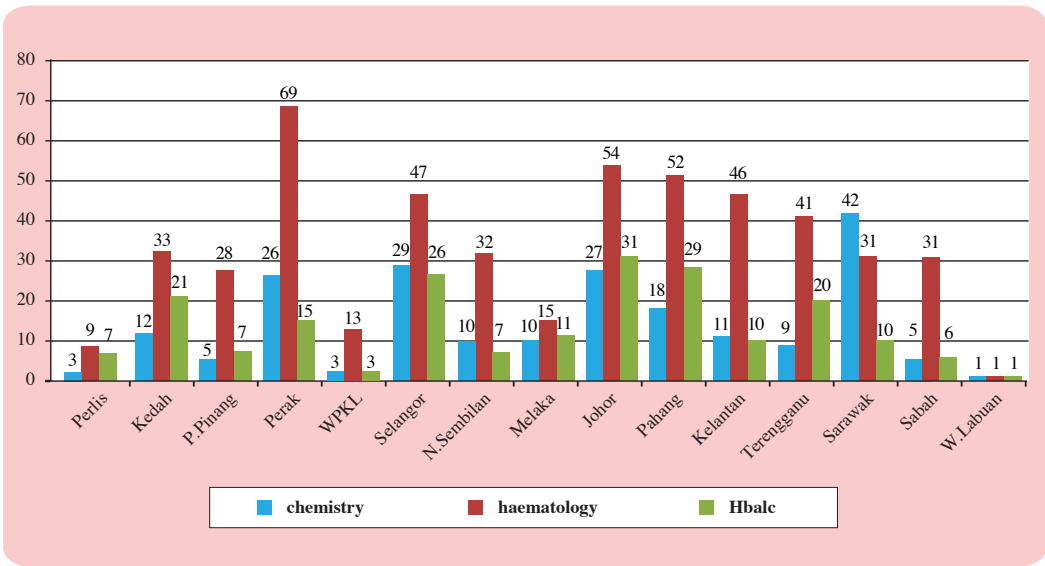
No.	States	U36	U32	U29	Total JTMP*	Total PTMP**
1.	BPKK	0	1	0	1	0
2.	Perlis	0	2	13	15	3
3.	Kedah	0	3	63	66	13
4.	P. Pinang	0	2	48	50	9
5.	Perak	0	8	97	105	26
6.	W.P KL	0	3	14	17	0
7.	Selangor	0	2	81	83	14
8.	N.Sembilan	0	3	54	57	13
9.	Melaka	0	4	36	40	3
10.	Johor	0	6	83	89	20
11.	Pahang	0	3	69	72	15
12.	Kelantan	0	3	86	89	15
13.	Terengganu	0	4	51	55	8
14.	Sarawak	0	10	103	113	21
15.	Sabah	0	6	101	107	3
	Total	0	60	899	959	163

*JTMP : Juruteknologi Makmal Perubatan (Medical Lab Technologist)

**PTMP : Pembantu Teknologi Makmal Perubatan (Assistant Medical Lab Technologist)

The equipment that is available in primary health care laboratories includes haematology analysers (519), chemistry analysers (207) and HbA1c analyser (201) as shown in figure 1 below. The equipment is still insufficient to meet the present needs.

Figure 1 : Distributions of equipments in the laboratories by states



The Laboratory referral system

As the range of laboratory services in the different primary health care clinics varies, based on the scope of services available, a referral system was established within the network of primary health care clinics to ensure access to the full range of available laboratory tests regardless of the type of clinic where the patient was seen. A lower level laboratory sends specimens to the nearest higher level laboratory where the test is available, even to the nearest hospital laboratory if necessary. This system ensures that laboratory investigation is made available to the patient, even when the test is unavailable at his or her local clinic, without having to travel to the nearest facility where the test is available.

The referral system

Ensuring Quality of Laboratory Services in Primary Health Care Clinic

Primary health care laboratories, which serve as a medical supporting service, need to provide accurate, precise and timely results to the physician and patient. In 2000, clinic-specific quality standards were introduced as part of the National Quality Assurance Programme, including for laboratory services in primary health care clinics. The QAP indicators then measured turn-around times for specific tests, namely full blood count and urine analysis.

*Quality Assurance
Programme for
pathology*

In 2005, a pilot project expanded this to participation in the External Quality Assurance Services (EQAS). The proficiency testing program, concerned not only with specimen examination but also with specimen collection, transport and handling and with methods for the reporting of the results. It is aimed at monitoring and improving the external quality control performance of primary health care clinics in Malaysia.

Proficiency testing started with clinical chemistry, involving 33 clinics from 10 states in cycle 4. However, the number of participants increased to 74 clinics from 13 states in cycle 5 (July 2006-June 2007). Parameters that were evaluated were albumin, total bilirubin, direct bilirubin, calcium, chloride, cholesterol, HDL-cholesterol, creatinine, glucose, phosphate, potassium, total protein, sodium, triglycerides, urea, uric acid, alanine transaminase, aspartate transaminase, alkaline phosphatase etc. The program is designed to provide laboratories with the accurate comparison of performance with other laboratories using same methodology and/or instrument/reagents. Used in conjunction with daily Internal Quality Control, the program gives laboratories added confidence in patient test results and provides valuable information for monitoring performance and trouble-shooting.

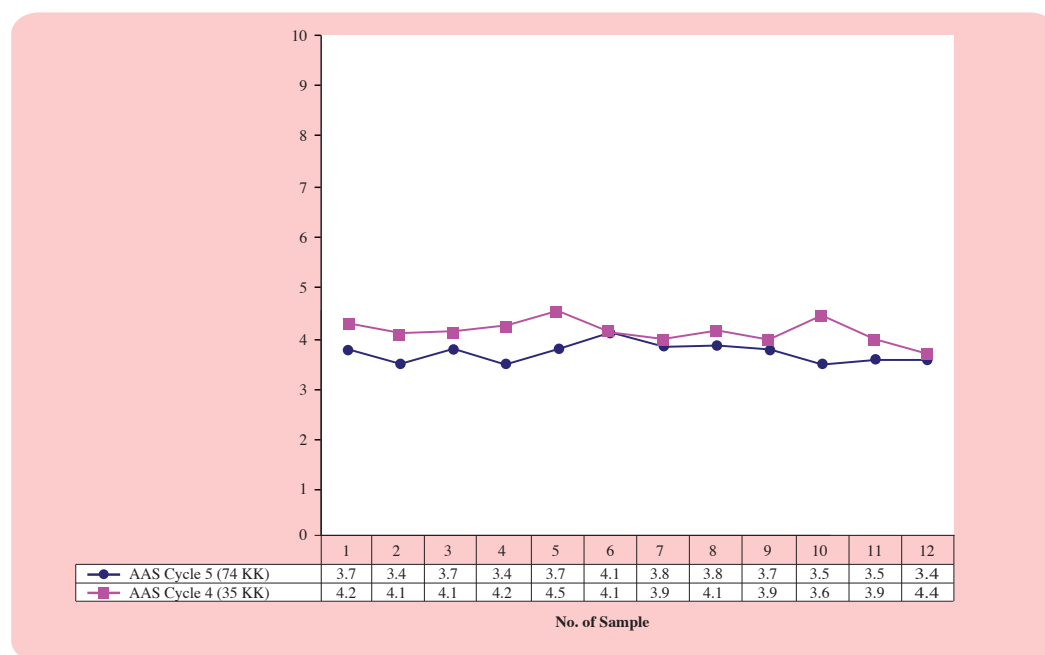
The objectives of the program are the following:

- a) To initiate and to give an awareness of delivering a quality laboratory services in all health clinics
- b) To increase and improve the quality of laboratory services and reliability of the tests in all health clinics
- c) To monitor and evaluate the achievements of quality control activities via peer comparison

d) To identify common errors and develop corrective plans

This programme has completed 2 cycles- - Cycle 4 and Cycle 5, starting from July 2005 till June 2006 and June 2006 till July 2007 respectively. These 2 cycles' performance was assessed and comparison made among the 33 participants (cycle 4) and 74 participants (cycle 5). Figure 2 below shows overall comparisons of Performance of Cycle 4 and 5 based on a performance scale. As shown in figures, subsequent cycles have shown an improvement in the performance of the clinics in achieving the set standard.

Figure 2: Comparisons of Performance of Cycle 4 and 5 Based on Performance Scale



Challenges and the future

The future development of the primary health care clinics poses opportunities as well as challenges in the delivery of pathology services. Pathology services need to develop in tandem with the services delivered in the clinics as it is an integral part of patient care, whether in the screening process, during intervention and follow up care. As the primary health care clinics undergo stratification by the level of service delivered, the complementing pathology services will also undergo development from basic to advanced services.

Challenges and ensuing measures

The challenges and opportunities facing the future delivery of laboratory services in primary health care include the following:

- a) Implementation of integrated services
- b) Maintenance of existing equipments
- c) Rapidly developing technology, including ICT
- d) Human resource development
- e) Threat of Emerging and re-emerging infectious diseases
- f) The role of the Public Health Laboratory

The ensuing measures are proposed to utilise the opportunities presented:

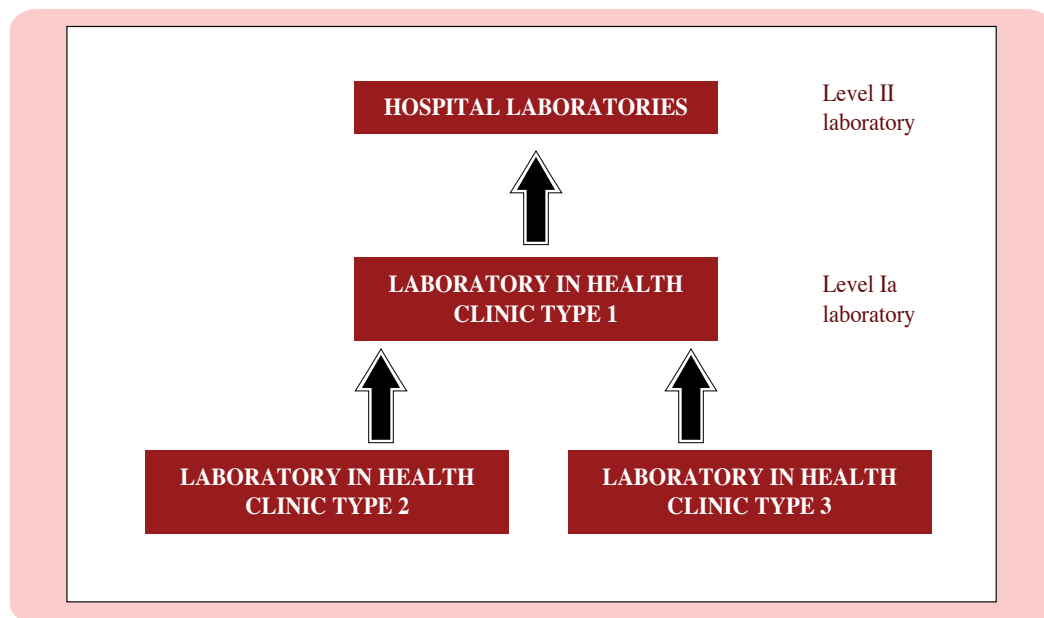
- i) Strengthening of the State Technical Coordinating Committee for Pathology Services to ensure resources in hospital and primary health care facilities are complementary especially in maintaining quality and proficiency through joint audits as well as the continuing professional development of laboratory personnel.
- ii) Partnership with private sector laboratories in identified areas, especially in maintenance and operations of equipment and quality assurance activities.
- iii) Professional development through structured post-basic courses, to promote specialisation and increase competencies, as well as through formalising the continuing professional

development system. Competencies are needed in all laboratory processes, including pre-analytical, analytical and post analytical. The following areas need to be supported to increase proficiency, namely, management of medical laboratories; human resource; inventory, purchase & storage; record keeping; and laboratory information system.

- iv) Credentialing of laboratory facilities aiming for ISO: IEC 15189
- v) Strengthening quality initiatives, for example, universal implementation of internal quality control, expansion of implementation of external quality assurance, enhancing audits and improving the monitoring of present QAP indicators
- vi) Continuing enhancement of infrastructure and resources to meet future service needs. A two-tier system is proposed where all health clinics equipped with laboratory services are manned by laboratory technologists. This level also serves as collection centers for referral to the second tier laboratories. The second tier is the level 1a laboratories in clinics which deliver a more comprehensive range of services.

Aside from establishing laboratories at all primary health care clinics, existing clinics needed to be upgraded. This can be in the form of increasing the services and capabilities, optimising the utilisation of facilities and increasing the quality of tests performed at the laboratories. Other measures include enhancing lab information systems to reduce turn-around time (TAT), avoid repetition of record taking, and increase the accuracy of records, and to facilitate retrieval of test results.

The following flow chart shows the proposed referral system for laboratory services at the primary health care clinics.



(Clinical laboratory (collection centres) with medical laboratory technologist)

With improvement of facilities and services, there are concurrent implications on cost and human resources.

vii) **Laboratory Safety**

Safety in the lab should be not be a separate entity but integrated into the setting up and improving of the laboratory services. A laboratory safety guideline is being developed for implementation. The requirement for the safety and health of laboratory personnel is mandated and includes looking into laboratory design and appropriate biohazards/biosafety cabinets.

viii) Organization and management of primary health care laboratory services at all levels of the organisation needs to be enhanced. The Primary Health Care Division plans for establishment of new units and posts at the national, state, district and clinic levels.

Conclusion

The pathology laboratory services at the primary health care clinics have evolved over the decades, as the services delivered in the primary health care clinics have expanded to cater for the changing clientele brought about by the epidemiologic and demographic transition experienced by Malaysia.

With the expansion of laboratory services, continuous efforts have been taken to ensure the quality of the services delivered. In anticipation of future development of laboratory services at the primary health care level, proposals to reorganize, strengthen existing and develop new services will meet future needs in the delivery of accessible and equitable primary health care, with no compromise in quality and safety.

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INTEGRATION OF PRIMARY HEALTHCARE SERVICES THROUGH THE REVIEWED APPROACH STRATEGY

SUMMARY

The double burden of communicable and non-communicable diseases in Malaysia necessitates the expansion of scope of services at Primary Healthcare (PHC) clinics in the Ministry of Health (MOH). Integration of services is thus critical for effective care delivery. The Reviewed Approach in PHC (REAP) is presented - an investment to re-engineer delivery of healthcare at the PHC level based on the approach successfully utilised by the Maternal and Child Health (MCH) programme. REAP looks into integrating the various services into an efficient network converging on management of individuals rather than conditions in isolation. The new framework is represented by the acronym WISE for Wellness, Illness, Support, Emergency & Information. This new approach requires trained multi-disciplinary and multi-skilled PHC teams, and changes to work processes aimed at centralised registration and “breaking walls” of dedicated clinics. The initiative will provide a more holistic approach to effective care for individuals at the PHC level, ultimately towards reducing the burden of diseases presently impacting the population.

Introduction

As experienced by other countries, Malaysia is dealing with the double burden of communicable as well as non-communicable diseases, brought upon by demographic and epidemiological transition. In the Burden of Disease study done in Malaysia in 2003, the leading causes of Disability-Adjusted Life Years (DALYs) were non-communicable diseases (Table 1).

Double Burden of Diseases

Therefore, in Malaysia’s current 5-year planning cycle, the Ninth Malaysia Plan, the thrust is to achieve better health through consolidation of health services with the primary goals being to prevent and reduce disease burden, and to enhance healthcare delivery. Hence, a review of the approaches to achieve these goals is necessary.

Consolidation of Health Services - Thrust of 9MP

Table 1: Leading Causes of DALYs, Malaysia, 2003

Rank	Diseases	Males		Diseases	Females	
		DALYs	%		DALYs	%
1.	Ischaemic Heart Disease	164,846	10.0	Ischaemic Heart Disease	113,887	9.2
2.	Road Traffic Accidents	133,789	8.2	Road Traffic Accidents	86,372	7.0
3.	Cerebrovascular Diseases	94,059	5.7	Cerebrovascular Diseases	67,211	5.4
4.	Septicaemia	70,232	4.3	Septicaemia	57,483	4.6
5.	ALRI	49,649	3.0	ALRI	56,390	4.6
6.	Diabetes Mellitus	47,060	2.9	Diabetes Mellitus	38,994	3.1
7.	COAD	45,459	2.8	COAD	37,890	3.1
8.	Hearing Loss	44,566	2.7	Hearing Loss	32,815	2.6
9.	Unipolar Major Depression	42,259	2.6	Unipolar Major Depression	28,946	2.3
10.	Cirrhosis	37,902	2.3	Cirrhosis	26,925	2.2
Total (111 diseases)		1,646,896		Total (111 diseases)	1,240,997	

Source: Malaysian Burden of Diseases and Injury Study 2003

The situation has necessitated the expansion of the health services rendered at the primary healthcare (PHC) clinics in the country. If in the 1970s and 1980s, the focus was mainly on maternal and child health (MCH) services and episodic care for acute illnesses in the outpatient clinics; in the 1990s, wellness and prevention activities for all age groups and continuous care of chronic diseases became increasingly important. Prevention and control of locally endemic diseases have expanded to encompass non-infectious and chronic diseases such as heart diseases, hypertension, diabetes, cancer and non-intentional injuries.

In many urban PHC clinics, services have been implemented for 'Workers' health'. 'Mental health' is also now being incorporated into PHC. In the MCH clinics, the scope of services has been broadened to include care of children with special needs, screening for hypothyroidism and thalassaemia, and expansion of child immunisation to include newer antigens to protect children against diseases that were previously not included, such as haemophilus influenza, mumps, rubella and hepatitis B.

*Expanding PHC –
Focus on Wellness
and Prevention*

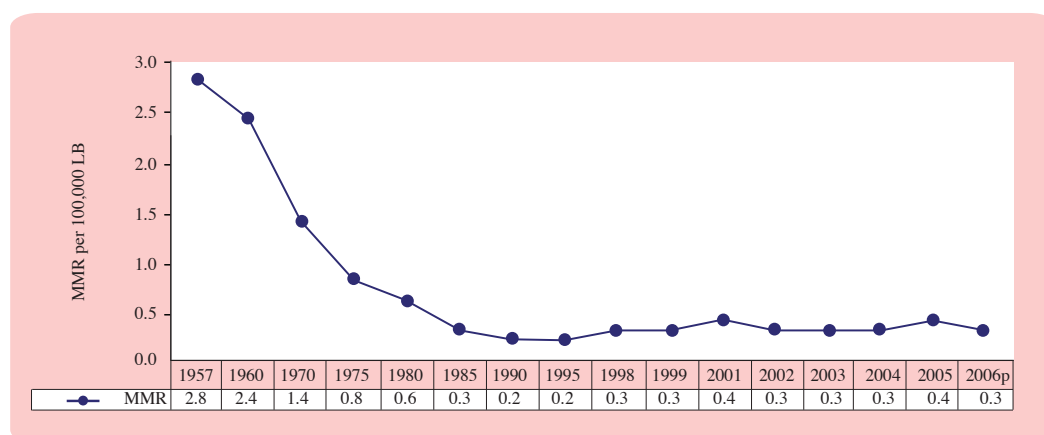
The comprehensiveness of the scope of such services at PHC level has necessitated integration of the various services at PHC clinics. The need for integration was deemed critical as resources had to be managed efficiently for effective service delivery at first point of contact and for working with the various stakeholders.

THE REVIEWED APPROACH IN PRIMARY HEALTH CARE (REAP)

There have been many lessons learnt from the MCH programme, including components of screening, examination and immunisation, health education, follow-up and home visits, as well as treatment services. Thirty years of investment in the MCH programme through dedicated clinics with dedicated staff (which included trained midwives, public health nurses, trained doctors and obstetricians), effective MCH and Family Planning protocols and an effective referral system, has seen a dramatic reduction in the Maternal Mortality Ratio (MMR), from 282 per 100,000 livebirths in 1957 to 30 in 2006; and the Infant Mortality Rate, from 41 per 1000 livebirths in 1970 to 5 (Figures 1 & 2).

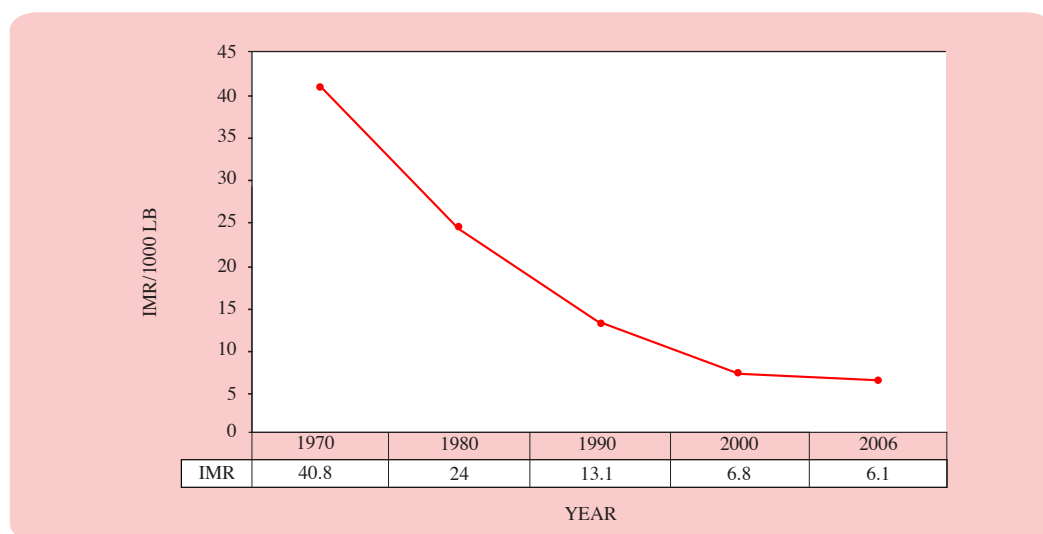
*Lessons Learnt from
MCH Services*

Figure 1 : Maternal Mortality Ratio (per 100,000 live births), Malaysia, 1957 - 2006



Source: Department of Statistics, Malaysia

Figure 2 : Infant Mortality Rate (per 1,000 Live births), Malaysia, 1970 - 2006



Source: Department of Statistics, Malaysia

The diseases influenced by the delivery of the MCH Programme showed a lower burden of disease in terms of DALYs (Table 2).

Table 2 : DALYs of Selected Diseases, Malaysia, 2003

Disease	DALYs
Measles	126
Polio	102
Hypertenion in pregnancy	1,268
Maternal sepsis	171
Obstructed labour	14

Source: Malaysian Burden of Disease and Injury Study 2003

The increasing demands on PHC services posed by the rise in non-communicable diseases have necessitated a review of the framework and processes in PHC, based on the approach used in the successful delivery of MCH services.

OBJECTIVES

The objectives of the reviewed approach of the delivery of PHC services in health clinics are to:

Objectives of the Reviewed Approach

- 1) Prevent and reduce disease burden by treating the ill, managing those with risks and preventing the onset of preventable risks
- 2) Enhance healthcare delivery for fast access to safe and high quality services with greater comfort in a hassle-free environment.

Supporting objectives are to:

- Optimise resources through sharing of resources, including multi-skilled human resource that can be managed through remote means
- Enhance research towards evidence-based planning and interventions
- Manage crisis and disasters through increased capacity and capability of the human resource, adequate and appropriate facilities as well as implement current protocols for management
- Strengthen the health information management system through reducing repetitive requests, increasing safety by reducing errors and facilitating continuity of care by enhancing sharing of data and information.

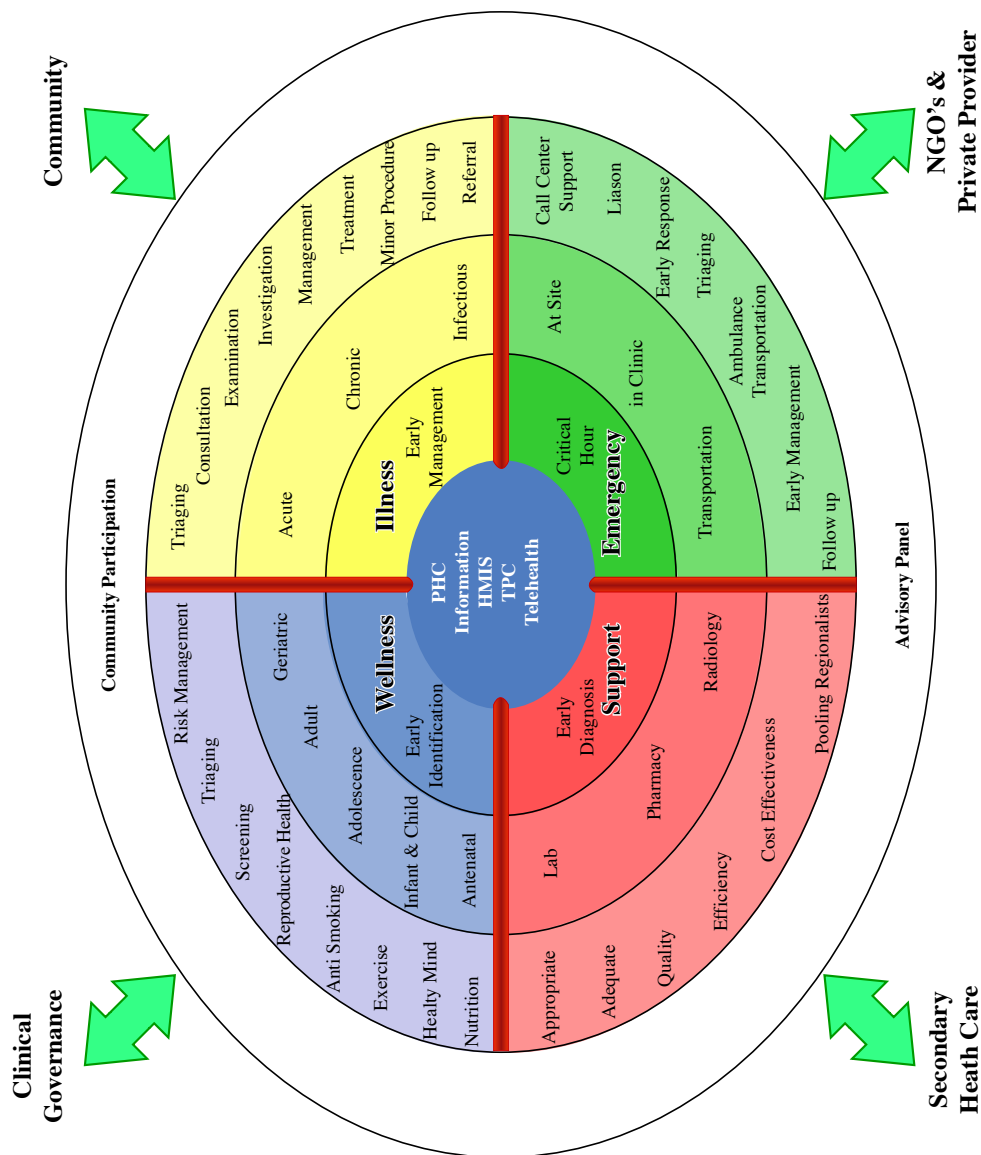
THE FRAMEWORK

The reviewed framework in integrated services at the PHC clinic can be described by the acronym WISE, representing Wellness, Illness, Support (clinical), Emergency and Information (Figure 3).

WISE Framework

Figure 3 : Framework of Reviewed Approach of Primary Healthcare Delivery

Reviewed Approach of Primary Health Care Clinics (REAP)



The services in the PHC facilities in Malaysia include promotive, preventive, curative and rehabilitative services. Curative services include referral of cases, follow-up of patients with chronic medical conditions, admission to rest beds, passive case detection for malaria, symptomatic case detection for tuberculosis, minor surgery, circumcision, and dental interventions. Family health services include the established MCH services like antenatal care, postnatal care, clinic and home delivery, family planning, health education, nutrition, school health services, as well as the expanded scope of services. These expanded services include those for non-communicable diseases (for example, diabetes programme, early detection of cancers), communicable disease (for example, modified syndromic approach for sexually transmitted diseases, HIV screening, counseling and treatment), wellness programme (screening of women, screening of those above 40 years for cardiovascular risk factors), tobacco cessation programme, blindness prevention, mental health, elderly and adolescent health programs. Promotive services include environmental sanitation and health education, while rehabilitative services include community-based rehabilitation for children with special needs.

*Comprehensive range
of services*

All these services are available at the rural clinic although on a different scale compared to the bigger facilities in urban health clinics, depending on the composition of the primary healthcare team members and the available support services. Various levels of the PHC clinics have different supporting services, for example, laboratory and radiology services.

REVIEW OF PROCESSES

Wellness Focus

The MCH program has already targeted the mother, woman, child, adolescent, and geriatric population in its expanded services. The target group for the wellness approach is the healthy population aged from 10 to 70 years. Integrated comprehensive screening is done according to age group and the clinical pathways developed in the management of risks. The focus will also be on health education and behaviour modification or rehabilitation

*Wellness Approach
for Healthy
Population*

Illness Management

Management of ill patients who suffer from acute, chronic, non-infectious or infectious diseases follow the same clinical processes, thus the consolidation of “islands of clinics” with the Reviewed Approach in Primary Healthcare (REAP). This is more cost-effective than to have dedicated clinics and dedicated staff to run disease-specific clinics, for example, diabetes, hypertension, asthma, HIV, TB, and Quit Smoking.

*Consolidation of
“Islands of Clinics”*

Emergency Support

Pre-hospital care in the PHC clinics have been integrated with the call-centre services stationed at the hospitals. This has necessitated the upgrading of the emergency services at the clinics with not only the provision of adequate space, communication facilities, ambulances and equipment, but also the training of human resource in emergency care and crisis/disaster management.

*Pre-hospital Care at
PHC*

Clinical Support

Pathology, pharmacy and radiology services had to be developed and upgraded at the PHC clinics to meet the increased scope of services. The sharing of services with the better equipped hospital clinical support services was facilitated to improve these services at the PHC level.

*Clinical Support
Services*

Information Support

This was necessary to achieve seamless care and the resource implications were not only in providing space and getting IT technicians, but also the change management needed to bring the existing staff to an IT work environment. A re-organisation of the work process was also needed at the clinics which implemented the Teleprimary Care (TPC), Malaysia's first home-grown Information Communication Technology (ICT) for government primary healthcare clinics. Clinical and population information can be accessed through this system. The Lifetime Health Record is presently piloted in one state in Malaysia.

*Change Management
to IT Working
Culture*

Malaysia has taken very ambitious steps in ICT. The Telehealth project has much to promise for overall healthcare including PHC. Specifically for PHC, the Ministry of Health (MOH) is now putting in place the inputs for the TPC project. These benefits will come through the various applications of ICT – Teleconsultation, continuing medical education (CME), mass customized and personalized health information and education (MCPHIE), and the Lifetime Health Plan (LHP). This is in line with MOH policy to use ICT not for its own sake, but as an 'enabler' for making healthcare more accessible, equitable and efficient.

Human Resource Development

PHC service providers must therefore, be multidisciplinary, with a range of competencies to manage clients at first point of contact. Due to the perpetual insufficient numbers, the ever-expanding scope of PHC services, and the increasing demands and expectations of consumers, staffs are being further trained in multiple skills.

*Multidisciplinary and
Competent Teams*

However, the rising need for specialised healthcare providers is undeniable. Over the years, more categories of staff were established in the PHC clinics that include the Family Medicine Specialists (FMS), physiotherapists and occupational therapists. The FMS was first introduced in 1997 and there are currently 160 distributed in the PHC clinics throughout the country.

In-service and post-basic training is much needed in PHC in the areas of risk identification and management, wellness management, emergency management and chronic disease management.

Review of Physical Infrastructure

Not only does the reviewed framework call for the integration of the various PHC services, the design of the PHC clinics has also physically encompassed all these integrated services under one roof, thus facilitating the sharing of resources. Rooms in the clinics are function-specific and not disease-specific. For example, the health education room can be used to give talks to diabetics, patrons of the Quit Smoking clinics, or adolescents who have been grouped for life-coping skills. Newer designs accommodate the bigger space needed for the expanded scope of services, and these bigger PHC clinics can cater to more than 800 patients daily. Existing clinics will be modified, extended and upgraded to cater to the needs of the new integrated services. It is planned that by 2010, a sum of RM1.8 billion would have been spent on development of physical infrastructure.

*Newer Clinic Designs
for Integrated
Services*

Figure 4 : Types of Health Clinics



Source: Primary Health Care Section, Ministry of Health

Improving Quality

The MOH has emphasized Quality in healthcare since the 1980s. Although the Quality Assurance Programme (QAP) was introduced in hospitals in 1985, the PHC clinics began slightly later in 1989. Since then, the number of PHC activities implementing this programme has increased considerably. In addition to the QAP, other quality initiatives are also now established in all PHC outlets, such as the Client Charter, Quality Control Circles, MS ISO 9000 Certification, Work Culture Improvement. Such initiatives include internalising the culture of innovation, and many award-winning innovative projects have been the products of PHC staff.

QAP in PHC Services

Harnessing Other Health Providers

The MOH is by far the major provider of healthcare in the formal sector, providing access for almost every individual. The private sector is a fast growing industry in the urban areas and comprises clinics, managed care organizations (MCOs) and hospitals. However, these provide largely curative primary care rather than the comprehensive PHC of the MOH. In the informal sector, traditional and complementary medicine (T/CM), mainly ethnic-based, are used by a large section of the population. There are also health services by Non-government organisations (NGOs) that meet specific needs, such as halfway homes for battered women, cancer respite and hospice care. The government has made it a clear policy that T/CM is to be streamlined so that it is better regulated and can offer a viable and safe alternative for the community.

*Collaboration
with other service
providers*

RESULTS

Although it is still too early to see the impact of REAP on the burden of diseases, the processes to improve healthcare delivery have shown progress by the development and utilisation of Standards for Clinical Pathways and Standard Operating Procedures as well as an integrated Screening Protocol. An effort to improve public-private partnership has been started through an initiative to offload patients from the overcrowded government PHC clinics to private sector general practitioners (GPs). There is also an effort to attract the private GPs to provide services in the government clinics by offering attractive remuneration. The infrastructure of the newly-built clinics and the upgrading of the existing clinics reflect the integrated services delivered in these clinics. Health informatics has progressed further with expanding use of TPC to urban sites as well as remote clinics. Initiatives to improve client satisfaction have been implemented, for example, by real-time monitoring of the waiting time for clients to access services.

Standard Operating Procedures and Standards for Clinical Pathways

Conclusion

In recognition of its success in achieving and maintaining a health status enjoyed by her population, the PHC system in Malaysia is further supported by planned investments in human resource, infrastructure, and new technology. One of these is the re-engineering of the delivery of healthcare at the PHC clinic to better meet challenges brought about by demographic and epidemiologic transitions with its double burden of communicable and non-communicable diseases.

REAP-WISE Initiatives Provide More Holistic Approach

Although the REAP-WISE initiatives have barely reached a year of implementation, the concept and principles are shared here, to illustrate the potential of such an initiative. Given the various parallel programmes initially introduced, it would have required double or more the space and manpower in the health clinics. This approach is believed to be able to reduce that possibility. In addition, it is expected to provide a more holistic approach to care of individuals, delivered effectively at the PHC level towards ultimately reducing the burden of disease impacting the population.

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PROVIDING SAFE WATER SUPPLY IN MALAYSIA

SUMMARY

Access to safe water supply and sanitation are basic human rights and important for the protection of public health. The lack of proper water supply and sanitation results in water borne diseases which some may lead to deaths, higher health maintenance costs, lower worker productivity, lower school enrolment and the denial of the rights of all people to live in dignity.

Due to the importance of water to the well being of the population, the Malaysian Government has given high priority to the development of the public water supplies infrastructures in its 5 year development plan. In remote areas where public water supplies are not within reach, the Ministry of Health has initiated the Rural Environmental Sanitation Programme (RESP) later known as BAKAS since the early 70s. The programme concentrated on implementing a total environmental health programme within the rural community including the construction of temporary low cost water supply systems.

Apart from providing water of adequate quantity to the population, drinking water of acceptable quality is an important element to the healthy well being of the population. The Ministry of Health has been monitoring the quality of drinking water since Independence. A major revamp of this programme was carried out in the early Eighties leading to the launching of the National Drinking Water Quality Surveillance Programme (NDWQSP) in 1983. The NDWQSP is an inter-agency collaborative programme based on the latest available knowledge and designed for continuous improvement of drinking water quality towards achieving zero defects.

Introduction

Safe water supply and adequate sanitation are important to protect health and are among the basic human rights. Ensuring their availability to all communities would contribute greatly to improve the health status and quality of life, leading to productivity for development.

According to the Global Water Supply and Sanitation Assessment 2000 Report by UNICEF, there is evidence that provision of adequate sanitation services, safe water supply, and hygiene education represents an effective health intervention that reduces the mortality caused by diarrhoeal diseases by an average of 65% and the related morbidity by 26%. Inadequate sanitation, hygiene and water result not only in higher mortality and morbidity but also in higher health costs, lower worker productivity, lower school enrolment and, perhaps most importantly, the denial of the rights of all people to live in dignity.

Diseases related to contaminated drinking-water, unsanitary food preparation, inadequate excreta disposal and unclean household environments constitute a major burden on the health of people in the developing world and are among the leading causes of ill-health. Sustainable health is not possible without effective and adequate water supply and environmental sanitation.

Five - year Malaysia Plan

The first formal water supply system in the country began in Penang in 1804, before the Second World war. All major towns had treated water supply; however there was no expansion during the Japanese occupation in 1941-1945. Water supply systems then further developed after independence. Nevertheless, the rural water supply was somewhat neglected until the Third Malaysia Plan (1976-1980).

Since the Third Malaysia Plan, emphasis had been given to providing safe water to all the Malaysia by the construction of dams, rehabilitations and upgrading of existing plants, improvement of water supply systems such as replacement of old pipelines, building new storage reservoirs and pipe replacements. Up to the end of 2007, the Malaysian Government had allocated Ringgit Malaysia 5,023 million towards improving the supply of water (Table 1).

In remote areas where public water supplies are not within reach, the Ministry of Health (MOH) initiated the Rural Environmental Sanitation Programme (RESP) later known as BAKAS since the early 70s. The focus was on implementing a total environmental health programme within the rural community including the construction of temporary low cost water supply systems (Table 2).

Table 1 : Water supply expenditure under the 5 – Malaysia Plans

5 - Year Plan	Period	Water Supply Expenditure
Third Malaysia Plan	1976 - 1980	538
Fourth Malaysia Plan	1980 - 1985	2,085
Fifth Malaysia Plan	1986 - 1990	2,348
Sixth Malaysia Plan	1991 - 1996	2,089
Seventh Malaysia Plan	1996 - 2000	2,772
Eight Malaysia Plan	2001 - 2006	4,809
Ninth Malaysia Plan	2007 - 2011	8,010 (estimated)

Source: Malaysia Water Industry Report

Table 2 : Five –year Malaysia Plan Allocations for Water Supply under RESP

5 - Year Plan	Period	Water Supply Expenditure RM (million)
Fourth Malaysia Plan	1980 - 1985	14.8
Fifth Malaysia Plan	1986 - 1990	31.6
Sixth Malaysia Plan	1991 - 1996	55.2
Seventh Malaysia Plan	1996 - 2000	55.7
Eight Malaysia Plan	2001 - 2006	44.6
Ninth Malaysia Plan	2007 - 2011	32.2 (estimated)

Source: RESP, Engineering Service Division , Ministry of Health Malaysia

Rural Environmental Sanitation Programme In Malaysia

Under this National Rural Environmental Sanitation Programme (RESP) which latter came to be known as the BAKAS (*Bekalan Air dan Kebersihan Alam Sekeliling*) programme, community participation was an essential component for its success. The MOH provided materials needed and technical expertise while the villagers provide the manpower. Water supply projects by the MOH is only initiated in localities where public water supply was projected to be unavailable within 5 years. This programme proved to be successful and resulted in the dramatic reduction of water borne diseases in rural areas of Malaysia.

*Rural Environmental
Sanitation
Programme (BAKAS)*

Types Of Water Supply Systems Under BAKAS

In providing safe water supply to the rural communities, the following objectives were kept in mind:

Water supply systems under BAKAS

- Access to all individuals in a village
- Water to be provided in adequate quantities
- Water to be provided as close as possible to the house
- Water that is safe for consumption

Only some physical treatment was able to be administered. The main source of disinfection was to encourage the rural folk to boil the water before consumption. The different types of low cost water systems introduced are described in the following paragraphs.

Gravity-feed Piped-water System

A dam is usually constructed at the hill source to impound the water and this water is then piped down to the village using galvanized pipes or plastic pipes. The water sources are usually clear sources with little contamination and therefore not much treatment is provided. The height of the impoundments are determined so as to achieve sufficient pressure at the last household connection

Gravity-feed Piped-water System

Basic requirements for a gravity-feed system include:

- availability of sufficient water;
- availability of sufficient head; and
- free from contamination (particularly from agricultural activities, where fertilizers, weedicides and pesticides may be used).

Well Water Systems

More than 97% of the fresh water is found as ground water. Generally, groundwater is of much better bacteriological quality than surface water. The cost to develop a water supply system using ground water source is less costly than using surface water source.

Well Water System

Wells can be classified in three ways, namely, by their depth, method of construction and by the aquifer tapped.

Well Water Systems With House Connections

Well water is pumped to an elevated tank normally by electrical pumps and is then supplied to several houses by gravity through a network of piping system.

*Well Water Systems
With House
Connections*

Rain Water Storage System

Rainwater harvesting systems (RWHS) was introduced in 1968 mainly for domestic used. This system is an ideal solution for providing water supply to individual families or groups of families in areas where safe and adequate alternative sources are lacking, such as in the coastal areas where the surface water sources are normally polluted (grossly) and the ground water sources are difficult to extract.

*Rain Water Storage
System*

Rain water is collected from the roof surface (also known as roof catchment area) and stored in storage tanks (either above ground or underground). The storage capacity is calculated such that the basic needs of at least drinking and cooking are satisfied for most parts of the dry season, while other alternative sources are used for other domestic requirements. Rain water collection system and storage facilities are expensive; therefore the system is constructed only in areas whereby the villagers are able to bear the additional costs involved.

By the end of 2007, the numbers of RWH increased to 31,664 serving a population of 67,651.

Public Water Supply / MOH Connection

Public Water Supply / MOH Connection is a project offered to those below poverty household income in areas where the public water supply is available. This connection is funded by Ministry of Health based on the available fund under the RESP.

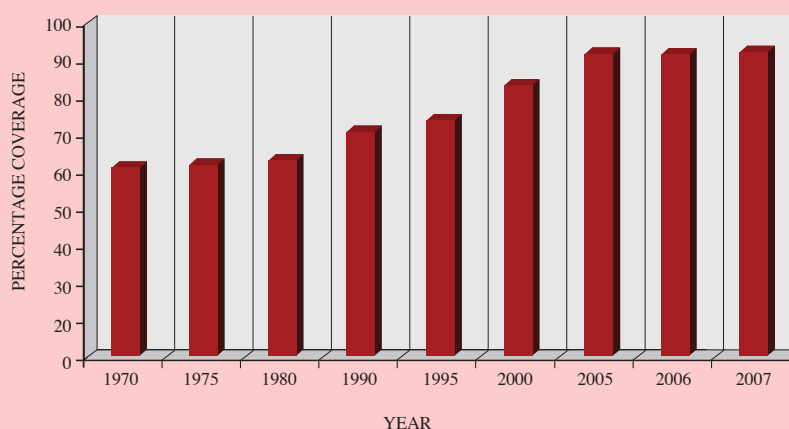
*Public Water Supply /
MOH Connection*

Water Supply Coverage

Presently the urban population in Malaysia enjoys 100% coverage of water supply provided by the public water supply systems. In the rural areas, until December 2007, about 95.41% of houses received proper water supplies (Figure 1). The water supply came from various agencies such as Water Supply Departments (64.04%), Ministry of Health (24.71%), and others (6.65%).

Water supply coverage

Figure 1 : Percentage of water supply coverage in rural area



Source: RESP, Engineering Service Division , Ministry of Health Malaysia

Millennium Development Goals (MDGs)

Water Quality

The year 1990 has been set as the MDG baseline year to initiate implementation of Goal 7, which is ensuring half of the world population getting access to improved source of drinking water.. Realising the importance of water quality, surveillance of drinking water quality has been one of the important preventive health programmes instituted by the (MOH). Although this has been monitored since Independence, a major revamp of this programme was carried out in the early Eighties leading to the launching of the National Drinking Water Quality Surveillance Programme (NDWQSP) in 1983.

Water Quality

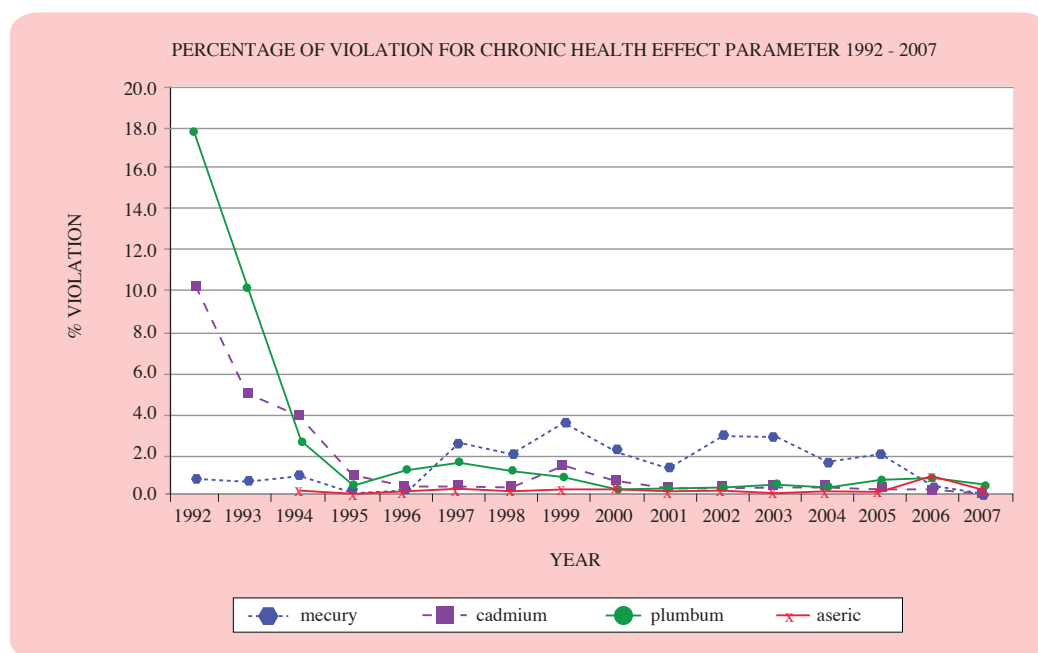
Today the NDWQSP is used as a tool to benchmark not only the status of water quality but as a yardstick for the efficiencies of the

water purveyors in providing safe drinking water. Twenty – eight parameters are being analysed - their physical characteristic, bacteria, organic and inorganic content.

In 2007 more than 150,000 samples had been analysed. The percentage of E-Coli conformance for 2007 was 99.6%, and overall conformance for all parameters was 97.96%.

The percentage of violation for chronic health effect parameters in Malaysia from 1992 to 2007 is given in Figure 2.

Figure 2 : Violation for Chronic Health Effect Parameter (1992-2007)



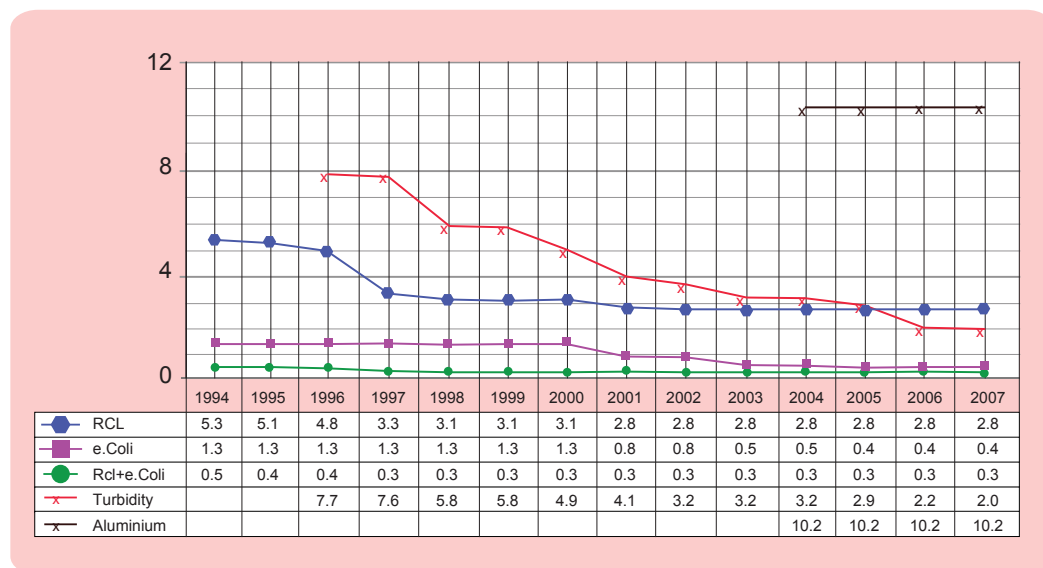
Source: NDWQSP, Engineering Service Division , Ministry of Health Malaysia

Quality Assurance (QA)

Quality improvement, an important element in the NDWQSP was introduced 1993.

Five indicators has been chosen under the QA programme for NDWQSP (Residual Chlorine, E-Coli, Combine Rcl and E-Coli, Turbidity and Aluminium). Since its initiation, improvements to the water quality has been reported (Figure 3).

Figure 3 : NDWQSP Indicators Performance (1993-2007)



Source: NWQSP, Engineering Service Division, Ministry of Health Malaysia

Conclusion

Adequate and safe water supplies are crucial for the health and well being of any community. The Malaysian Government has given high priority in the development of safe water supply infrastructures in the country. Since Independence, providing sufficient quantity and quality of water has been one of its important preventive health programmes.

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CHAPTER 2

CLIMATE CHANGE IN MALAYSIA

SUMMARY

By the year 2050, the ambient temperature in Malaysia is projected to increase by 2°C, and with substantial variability in rainfall. Generally, there would be more extreme weather events and natural hazards. Certain areas will have increase precipitation while others would have more severe droughts.

Temperature and rainfall rise would allow vectors of malaria, dengue and other arboviral diseases to survive in a wider area. Food and water borne diseases will also be affected by climate change. Climate and seasonality are also important determinants of airborne diseases with the health impact of haze being one example. In addition, extreme weather events would directly lead to injury and death, and temperature rise would lead to more heat related illnesses, especially among the vulnerable population.

Several measures have been outlined to help us adapt to the health impact of climate change. Foremost would be the continued strengthening of our health care system and disease surveillance.

Introduction

The science of climate change started way back in 1800. However, it is only from 1990 that the community in general accepted the fact that global warming is occurring at an accelerated rate with human activity as the main contributor. In 1992, the United Nations Framework Convention on Climate Change (UNFCCC), informally known as the Earth Summit was held in Rio de Janeiro. The treaty was aimed at stabilizing greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system.

UNFCCC was produced at Rio de Janeiro in 1992

The principal update of the UNFCCC is the Kyoto Protocol, an international and legally binding agreement to reduce worldwide emissions of greenhouse gases. It was enforced on 16 February 2005.

The Kyoto Protocol enforced on 16 February 2005

The Regional Framework for Action to Protect Human Health from Effects of Climate Change in the Asia-Pacific Region was developed in Bali in December 2007, to build capacity and strengthen health systems in the region. Malaysia is committed in addressing this global issue. The National Climate Change Committee was established in January 1995 after ratifying the UNFCCC in 1994. In the same year, Malaysia ratified the Kyoto Protocol in 2002 and established the National Committee on Clean Development Mechanism (CDM), one of the three mechanisms established to reduce greenhouse gas emission under the protocol.

Local scenario

Malaysia is a coastal nation covering an area of 329,733 sq.km. Coastal areas are home to more than 60% of the total population. Most coastal regions are low-lying areas that are less than 0.5m above the highest tide, or are within 100m inland of the high-water mark, and would be especially vulnerable to sea level rise.

Ambient temperature in Malaysia is projected to increase by 2°C by 2050

It is predicted that the ambient temperature in Malaysia is projected to increase by 2°C and with substantial variability in rainfall by 2050. In general, there would also be more extreme weather events and natural hazards. Certain areas will have increase precipitation while others would have to face more severe droughts. These changes will have a major impact on the health of the people.

Health impacts

The main impact on health includes increase in vector borne, waterborne and airborne diseases. These diseases are recognized as the climate sensitive diseases of significance for our local scenario. There will also be illness from extreme weather events such as flood and droughts and higher temperature would also lead to heat related illness.

1) Health impact related to vector borne diseases

Vectors require specific ecosystems for survival and reproduction. Therefore, climate change would have a direct effect on vector distribution and transmission dynamics and consequently in diseases, such as, dengue, malaria, filariasis and Japanese encephalitis.

Climate change would have direct effect on vector distribution and transmission dynamics

Malaria remains and is still a problem in some rural areas in Malaysia. However, with effective control measures, the number of malaria cases detected in the country has dropped significantly from over 200,000 in 1961 to about 5,000 cases in 2006. The incidence of malaria has decreased to the level of pre-elimination based on the WHO classification (Figure 1).

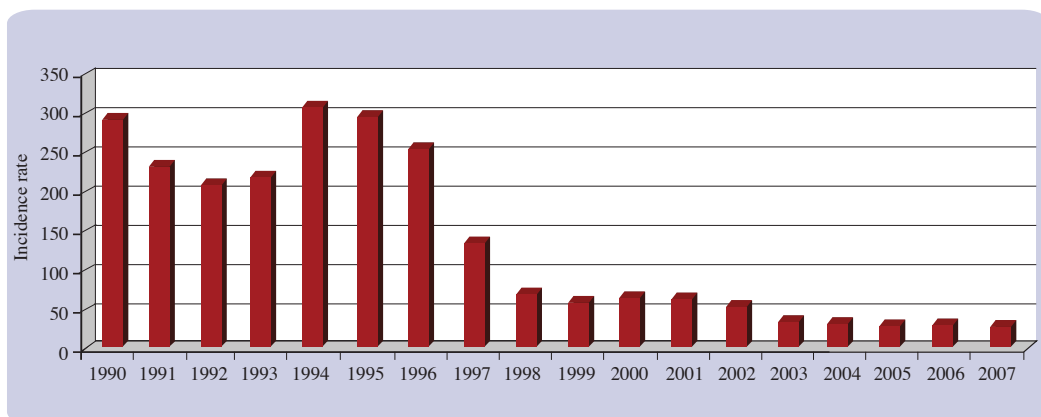
However climate change can trigger a resurgence of the disease. Malaria vectors have been shown to have seasonal prevalence. Increases in temperature and rainfall would most probably allow them to survive wider than their current distribution limits. The extended area would depend on the magnitude of the change in climate. There is also a possibility that an increase in sea level may lead to a corresponding rise in coastal vectors due to an increase in breeding ground, as there will be more areas covered with brackish water.

Climate change can trigger a resurgence of malaria

Increased incidences of dengue and dengue haemorrhagic fever are observed especially in urban areas after heavy rainfall. The rainfall provides suitable breeding conditions for *Aedes albopictus* and *Aedes aegypti* mosquitoes. A model studied by the Institute for Medical Research (IMR) shows that high rainfall is required for high transmission of dengue. Studies have also shown that these mosquitoes thrive better at higher temperatures. This is why with climate change there is potential increase in latitudinal and altitudinal range of dengue, and potential extension of transmission season throughout the year. It has also been suggested that increase in drought may also lead to increase of cases due to increase household water storage. Dengue continues to be a problem to control (Figure 2).

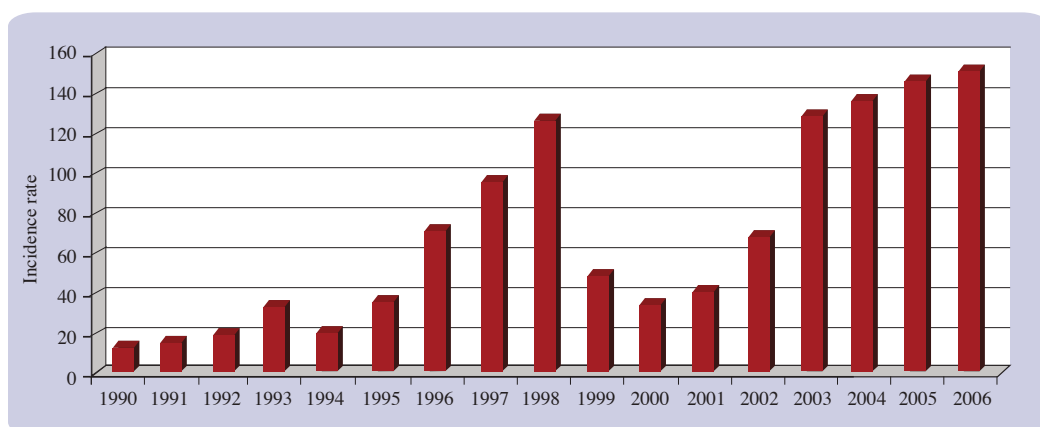
*Rainfall provides suitable breeding conditions for *Aedes albopictus* and *Aedes aegypti*. These mosquitoes also thrive better at higher temperatures*

Figure 1 : Incidence of malaria per 100 000 population in Malaysia (1990-2007)



Other arboviral diseases are also known to breed over a wide range of climatic zones and may invade areas that are not infested at present, if temperature and humidity rise. Under favourable environmental conditions, these diseases can change from endemic to epidemic forms. An increase in temperature shortens the reproductive cycle and extrinsic development period of the pathogens, allowing transmission of diseases, such as Japanese encephalitis (JE), which is transmitted by the *Culex* mosquito and is of particular interest as it has been known to occur in Malaysia since 1951.

Figure 2 : Incidence of dengue per 100 000 population (1990-2006)

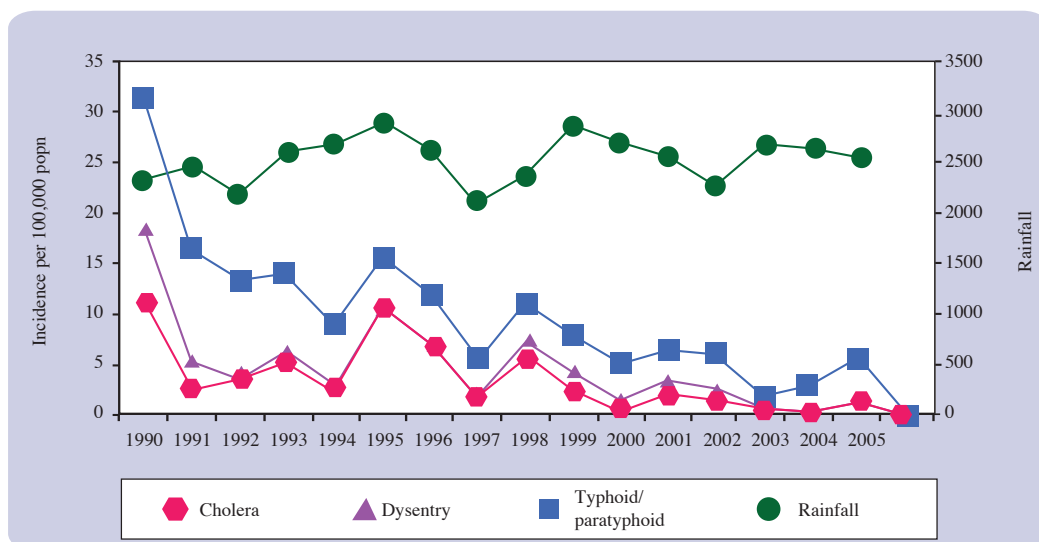


2) Health impact related to food and waterborne diseases

Spread of food and water-borne diseases are due to both direct and indirect health effects of climate change (when there is lack of access to safe drinking water). These include diarrhoeal diseases caused by various organisms (e.g. *Escherichia coli*, *Vibrio cholera*, and viruses), other viral diseases (e.g. hepatitis A and poliomyelitis), and protozoan diseases (e.g. giardiasis and amoebic dysentery). Studies have shown that the agents which transmit cholera naturally live in very small marine organisms (identified as plankton) in both ocean and river water. Changes in monsoon patterns can trigger a bloom of these organisms resulting in a cholera outbreak. Some studies also suggest that climate change can increase the spread of cholera by creating patterns of rainfall that support disease transmission. The general trend of water borne diseases in the country are showing declining trend (Figure 3).

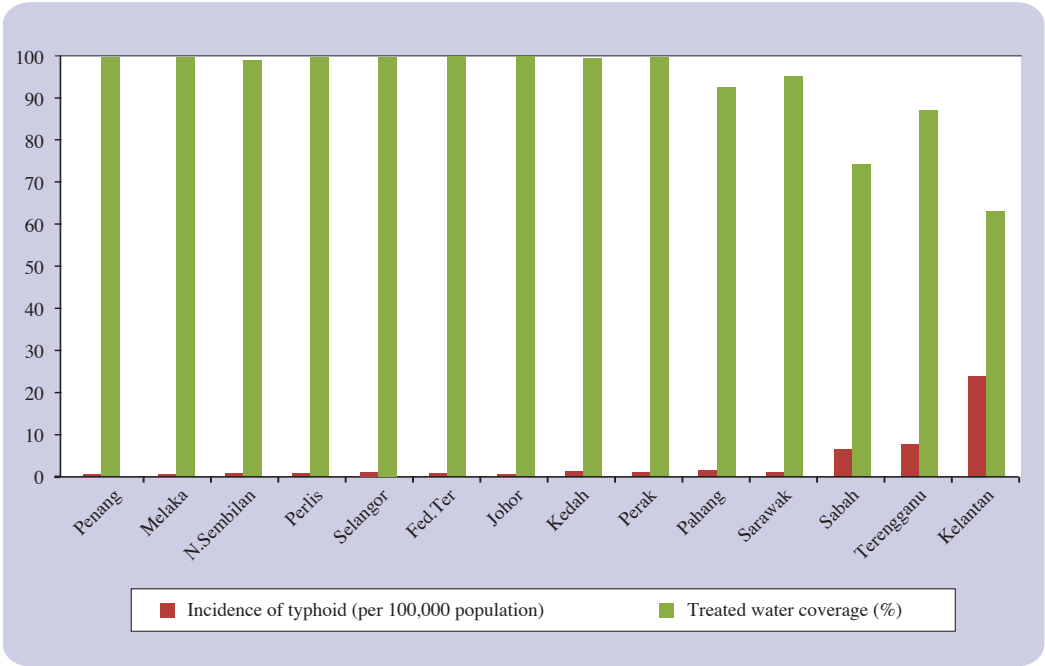
Changes in monsoon patterns can trigger a cholera outbreak

Figure 3 : Incidence of waterborne diseases per 100 000 population in Malaysia (1990-2005)



Improvement in environmental sanitation and access to clean and safe drinking water supply contributed to the decline of these diseases. For example, it could be generally noted that the incidence of typhoid is high in states with less safe drinking water coverage (Figure 4).

Figure 4 : Incidence of typhoid in relation to treated drinking coverage



3) Health impact related to air pollution

Climate and seasonality are important determinants in the incidence of air-borne diseases, such as asthma, and other respiratory infections. The net effects of global climate change on such diseases are, however, difficult to forecast. An increase in temperature increases the formation of ground-level ozone, a pollutant with well-established adverse effects on respiratory health. In Southeast Asia, the El Nino effect was strongly felt in 1997. The prolonged drought contributed to the development of forest fires and this, coupled with the existing wind pattern, caused widespread haze over the Southeast Asia region. Ministry of Health records showed that there was an increase of complaints related to conjunctivitis, bronchitis and asthma among the local population during the haze episodes of 1990, 1991, 1994 and 1997 in Malaysia.

There was an increase of complaints related to conjunctivitis, bronchitis and asthma during the 1990s haze episodes

4) Health impact related to temperature rise

Heat and heat waves are very likely to increase in severity and frequency with increasing global average temperatures. The effect of temperature was also seen in the El Nino. The increase in temperature was felt in the Southeast Asia region with reports of heat waves that caused loss of lives. These conditions can be expected to influence human health and well-being in proportion to the degree of heat stress. Heat stress can cause mild cardiovascular problems to severe tissue damage and, in extreme cases, death. These effects are concentrated among vulnerable groups of people, such as, the elderly, the very young, the malnourished and those with pre-existing respiratory and cardiovascular conditions. With the expected increase in the proportion of the elderly population in 2050, the impact of extreme heat on this vulnerable group will need to be addressed.

Heat stress can cause mild cardiovascular problems to severe tissue damage and, in extreme cases, death.

5) Health impact related to extreme weather events

Injury and death are the direct health impacts most often associated with natural disasters such as floods and hurricanes. Secondary health effects are spread of infectious diseases related to changes in ecological systems (such as bacterial and fungal proliferation) and in public health infrastructures (such as the availability of safe drinking water).

The emergence of fatal Nipah encephalitis in 1999-2000 has been attributed to extreme draught and forest fires brought about by the El Nino phenomena.

Adapting to health impact of climate change

One of the main strategies outlined internationally in adapting to the health impact of climate change is establishing an effective health service system. This is already one of our strengths. There is a need for continued investment in improving health infrastructure and in building human resource capital.

Malaysia also has a very strong vector control program. We have been very successful in managing and controlling vector borne diseases. However there is a need for continued vigilance on infectious diseases, aided by the strengthening of disease surveillance system.

The improving network of public health laboratories is also an important step in getting prepared for the future in disease management. Many diseases require laboratory diagnosis, which means that a good surveillance and control program would depend on the availability of good quality laboratories and trained laboratory technicians.

There is a need for disaster preparedness and response as we anticipate an increase in extreme weather events. A Rapid Response Command Centre is planned to be put in place. This involves various sectors and stake holders.

Adaptation strategies:

- *Improve health service*
- *Strengthen disease surveillance*
- *Improve public health laboratories*
- *Disaster preparedness and response*

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PLASMODIUM KNOWLESI INFECTION IN MALAYSIA

SUMMARY

***P. knowlesi*, a simian malaria, was first described in India in 1931. This malaria infection came to the attention of the Ministry of Health after a large focus of cases was reported in the interior part of Sarawak in 2004. Subsequently, more cases were reported in Peninsular Malaysia as well as in Sabah, and the neighbouring countries of Thailand, Myanmar and the Philippines. The ability of *P. knowlesi* to replicate and cause hyperparasitaemia within 24 hours of infection, and severe hepatorenal dysfunction suggest that *P. knowlesi* is potentially life threatening.**

This report examines various aspects of epidemiology of the disease and vector, clinical manifestations, diagnosis and treatment, control measures, as well as challenges faced in the control of *P. knowlesi* transmission.

Introduction

P*lasmodium knowlesi* (*P. knowlesi*) was first described in India in 1931 and recognized as a simian malaria in the long-tailed and pig-tailed monkey. Naturally acquired *P. knowlesi* infection in human was first reported in the state of Pahang, Malaysia in 1965 and later in Johor in 1971. However, very little attention was given to *P. knowlesi* as a public health problem until a large focus of this malaria infection was reported among the local population in the interior part of Sarawak in 2004. Subsequently, more cases were reported in Peninsular Malaysia, as well as in Sabah and from the neighbouring countries of Thailand, Myanmar and the Philippines.

Plasmodium knowlesi
first described in
India

The discovery of this *plasmodium* infection was made possible with the use of molecular detection method (Polymerase Chain Reaction - PCR). Prior to this, *P. knowlesi* had been microscopically misdiagnosed as *P. malariae* due to their morphological similarity. This suggests that *P. knowlesi* infections could have existed much earlier, but was not diagnosed and reported.

P. knowlesi and
P. malariae

In recent years, numerous studies had been conducted in Malaysia to look into various aspects of *P. knowlesi* transmission like determining its prevalence and vector incrimination. However, the possibility of human-to-human transmission of *P. knowlesi* has not been established as yet.

This report highlights various issues pertaining to *P. knowlesi* infection in Malaysia, such as epidemiology, case definition, diagnosis, treatment and control. The status of *P. knowlesi* as a zoonotic disease needs to be addressed as well.

Report highlights

Clinical Manifestation

More than 50% of the cases presented with fever, chills, rigor and abdominal pain. There is thrombocytopaenia, anaemia and jaundice in fatal cases.

Severe fatal infections are associated with manifestation of end organ failure including liver, kidney, lungs and brain as well as DIVC (disseminated intravascular coagulation). Most of the cases had been associated with history of having gone into a forested area.

*Complications of
P. knowlesi*

Laboratory Criteria

- i) Detection of parasite in peripheral blood film stained using Giemsa stain, which resembles that of *P. malariae* in morphology.
- ii) Confirmation of presence of parasite is by polymerase chain reaction (PCR) based tests.

*Laboratory criteria
for diagnosis for
P. knowlesi*

Case Classification

i) Suspected

A person presented with clinical features of malaria with a recent history of having visited a forested/malarious areas known for high prevalence of *P. knowlesi* species.

*P. knowlesi classified
as suspected,
probable and
confirmed cases*

ii) Probable

A person presented with clinical features of malaria with a recent history of having visited a forested/malarious areas known for high prevalence of *P. knowlesi* species, coupled with microscopic

findings featuring a combination of *P. malariae* morphology and/or with end organ failure manifestations and (parasite density > 10,000 per microscopic field).

iii) Confirmed

A person presented with clinical features of malaria with any or all of the above, and positive PCR for *P. knowlesi*.

***P. knowlesi* is potentially life threatening**

Fatal cases of *P. knowlesi* had been reported in Sarawak. Studies by Janet et al 2008 indicated that there were 4 deaths out of 266 *P. knowlesi* cases confirmed by nested PCR method for the period 2001–2006(1.94%). All of them presented with hyperparasitemia and developed marked hepatorenal dysfunction.

P. knowlesi fatality
rate

The ability of this parasite (asexual) to replicate and cause large parasites in the blood (hyperparasitaemia) within 24 hours of infection, and cause severe hepatorenal dysfunction suggests that *P. knowlesi* is potentially life threatening.

Ministry of Health (MOH) has been monitoring data on *P. knowlesi* since 2007. The fatality rate for 2007 was 0.96% (3 deaths). The fatality rate of *P. knowlesi* is relatively high compared to overall malaria fatality rate of 0.33 % in 2007. It is also higher than *P. falciparum* fatality rate of 0.73 % in 2007.

Case fatality
compared to other
malarias

P. knowlesi vectors

Anopheles species belonging to the *Anopheles leucosphyrus* complex are believed to be the vectors responsible for the transmission of *P. knowlesi* from monkey to human in countries where *P. knowlesi* malaria had been reported in the human population.

In Peninsular Malaysia, studies carried out in the 1960's showed that *An. hackeri*, *An. latens*, *An. introlatus* and *An. cracens* which belong to the *Anopheles leucosphyrus* complex, were involved in simian malaria transmission.

Vectors for P. knowlesi

A study conducted in Kapit, Sarawak, in 2004 indicated that *An. latens* was the vector for both simian (*P. knowlesi*) and human malaria.

*An. Latens,
a vector in Sarawak*

An. latens breeds in clear spring water in tiny seepages at the source of streams, or along foot hills in the dense jungle. They are most commonly found in water containing dead/decomposed leaves which is slightly acidic in nature (pH 6.0 – 6.4). This species do not prefer to breed in polluted and dirty water.

Habitat for An. latens

Adult *An. latens* prefer to rest outdoor (exophilic) and could commonly be found high above the ground level (acrodendrophilic) in search of blood meal. This vector is known to be simio-anthropophagic in nature, with monkey to human biting ratio of 1:1.3.

In the forest, *An. latens* prefer to bite between 7 – 8 pm in the evening. However, its peak biting time is around mid-night in the farms and longhouses. This mosquito species is generally abundant in the period between April-June and October-December.

Biting times

In another study in Kuala Lipis, Pahang, in 2007, *An. cracens* was established as the vector of *P. knowlesi*. The peak biting time for this mosquito species is between 7-9 pm. In the forest, less number were found biting after 10 pm but they continued to bite throughout the night in the fruit orchard. *An. cracens* is known to be anthropophagic with a biting ratio of monkey to human of 1:5.6. Earlier studies found that *An. cracens* prefer to breed in various types of water pools in shaded hilly areas.

*An. Cracens, a vector
in Pahang*

In Sabah, *An. balabacensis* is the primary vector for human malaria. It is very likely that this species is also involved in the transmission of *P. knowlesi* in Sabah. Investigations carried out in Lawas District in the northern region of Sarawak bordering Sabah, revealed that *P. knowlesi* sporozoites were found in wild-caught *An. balabacensis* (unpublished report). However, study is now being undertaken to establish the role of this vector and other related anopheline species as potential vector of *P. knowlesi* in Sabah.

An. balabacensis, a vector in Sabah

Larvae of *An. balabacensis* are found in various kind of pools with at least a little shade, but more so in muddy wallow, hoof prints, wheel ruts and other rather temporary water collections.

Habitat for An. balabacensis

This species is most common in hilly areas. It does not rest in houses by day but readily enters to bite at night, especially after 10 pm, with peak numbers after midnight.

Current Status of *P. knowlesi* in Malaysia

In 2007, there were 313 cases (5.54%) of *P. knowlesi* out of 5,456 total malaria cases reported in Malaysia. The majority of *P. knowlesi* cases were from Sarawak with 231 cases (73.8%), followed by Sabah 40 cases (12.8%) and Pahang 11 cases (3.5%).

Majority of P. knowlesi cases are in Sarawak

Current Vector Control For *P. knowlesi*

Indoor residual spraying (IRS) and *insecticide treated nets* (ITN) are the main vector control methods currently being used for the control of malaria vectors in Malaysia.

Control measures

Since the transmission of *P. knowlesi* occurs in the jungle or outside the house, IRS and ITN are not effective in preventing the transmission of this parasite.

A more practical approach is through educating people to take personal protective measures if they intend to enter jungle areas known for *P. knowlesi* transmission, such as wearing appropriate protective clothing; using mosquito repellents and taking malaria chemoprophylaxis. They should also be advised to sleep under ITN if they are staying overnight in the jungle.

Protection for host

Confirmatory Test For *P. knowlesi*

Diagnosis of Plasmodium infection is based on microscopic examination of peripheral blood films stained with Giemsa stain. However, it is not possible to differentiate *P. malariae* and *P. knowlesi* microscopically. PCR technique is the only confirmatory test available but there are still some limitations using this technique as follows :

PCR technique is a confirmatory test for P. knowlesi

- i) The PCR result for *P. knowlesi* is only available after 2 weeks.
- ii) There are only three PCR centres to confirm *P. knowlesi* in the country, namely the National Public Health Laboratory in Sungai Buloh; the Public Health Laboratory in Kota Kinabalu and the Parasitology Laboratory in University Malaysia Sarawak.

Amplification of DNA by the polymerase chain reaction (PCR) has provided the opportunity to devise highly sensitive methods of *P. knowlesi* detection. Nested PCR assay is based on the Plasmodium DNA sequence of the small subunit ribosomal RNA (SSUrRNA).

In this strategy, two rounds of amplification are carried out, with the product of the first reaction serving as the template for a second reaction. In this manner, a single parasite genome can be detected routinely and reproducibly, and the sensitivity then depends solely on the quantity and nature of the initial DNA template. A single parasite can be reproducibly detected in the DNA template directly purified from 10 µL of blood (0.000002% parasitemia).

Treatment For *P. knowlesi*

Current treatment for uncomplicated of *P. knowlesi* is the same as treatment for uncomplicated of *P. malariae*, that is, chloroquine and primaquine for three days. This treatment is effective to cure *P. knowlesi* infection. So far, there has been no report of drug resistance.

Treatment using chloroquine and primaquine for 3 days

For complicated *P. knowlesi* cases, treatment follows the regime for management of severe malaria cases.

Detail treatment schedule is in **annex 1**.

Currently, there are no guideline or recommendation from the World Health Organisation (WHO) in handling *P. knowlesi* infection.

Issues and Challenges in Controlling *P. knowlesi* and the Recommendation

The challenges faced by the MOH in addressing the *P. knowlesi* infection are as follows:

- i) Lack of proper guideline on management of *P. knowlesi* cases leading to improper management of severe *P. knowlesi* infection. The last review by the MOH on guidelines for the management of malaria was in 1993. The issue of proper management for *P. knowlesi* cases was not addressed in this guideline. Thus, it is timely now for the Ministry to review and update the guideline on management of malaria cases including the management of *P. knowlesi*. *Need to review guideline for management of malaria*
- ii) *P. knowlesi* is a new zoonotic disease in Malaysia. Little is known about this new zoonotic disease. More studies and a proper action plan is needed to ensure the transmission of, and infection by *P. knowlesi* are handled effectively. It will need the involvement of other agencies such as the Veterinary Services Department, Forestry Department, Wildlife Department, Drainage and Irrigation Department, Universities, FELDA and FELCRA, and other planned development scheme. *More studies on P. knowlesi and Plan of Action for Control needed*
- iii) Due to the limited number of PCR centres for confirmatory tests on *P. knowlesi*, the MOH should consider increasing the number of centres with such capabilities in the country. *Need to increase laboratory confirmatory centres*

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SUMMARY OF CURRENT MALARIA TREATMENT POLICY – MALAYSIA

SPECIES	UNCOMPLICATED LAB-CONFIRMED	TREATMENT FAILURE	SEVERE MALARIA	PREGNANCY*
<i>falciparum</i>	i) CQ+PQ 3 days (in CQ sensitive areas) ii) CQ+SP+PQ - 3 days and SP only on first day in suspected CQ resistant areas iii) SP+PQ - single dose regime in CQ resistant areas in the State of Sabah	i) QN - 7 days ii) QN+T - 7 days iii) MQ - use for multi-drug resistance	i) QN - 7 days ii) QN+T - 7 days	QN - 7 days * Chemoprophylaxis for pregnant women is not usually practiced *All cases of malaria in pregnancy are treated in hospital and closely monitored
<i>vivax</i>	CQ+PQ - CQ for 3 days and PQ for 14 days			
<i>malariae</i> / <i>knowlesi</i>	i) CQ+PQ 3 days ii) SP+PQ (in Sabah) 3 days iii) CQ (in Sarawak) 3 days			
Mixed infection <i>a) falciparum</i> + <i>vivax</i>	i) CQ+PQ - CQ for 3 days and PQ for 14 days ii) SP+CQ+PQ - SP for 1 day, CQ 4 days, PQ 14 days (in Sabah)			
<i>b) falciparum</i> + <i>malariae</i>	CQ+PQ 3 days SP+PQ (in Sabah) 3 days			

CQ = Chloroquine; PQ = Primaquine; QN = Quinine; T = Tetracycline;
SP = Sulphadoxine-Pyrimethamine, please refer to
“Guidelines for the Management of Malaria 2000” for details on dosage.

TYPHOID SITUATION IN MALAYSIA WITH SPECIAL FOCUS ON THE STATE OF KELANTAN

SUMMARY

The incidence of typhoid fever in Malaysia has markedly declined from more than 10 per 100,000 population in 1978 to less than 2 per 100,000 population in 2007. In the state of Kelantan the annual incidence from 1999 to 2007 is more than 5 per 100,000 population which exceeded the national average annual incidence of 5 per 100,000 population for the same period. A 5-year plan (2004 to 2008) to reduce the incidence of typhoid in Kelantan has been implemented and focussed on 5 priority areas namely enhancing health promotion, strengthening case surveillance, improving case management and follow up, providing safe water and sanitation through the Water Supply and Environmental Sanitation Programme (BAKAS) as well as promoting food safety practices. The 5-year plan has successfully produced significant result as the targeted incidence of less than 10 per 100,000 population was achieved 2 years ahead of schedule.

Introduction

Typhoid fever is caused by *Salmonella enterica* Serovar Typhi (*S. typhi*), a Gram negative bacterium. A similar but often less severe disease is caused by *S. paratyphi* A and, less commonly, by *S. paratyphi* B (Schotmulleri) and *S. paratyphi* C (Hirschfeldii). Human is the only known natural host and reservoir for *S. typhi*. The common mode of infection is by ingestion of an infecting dose of the organism, usually through contaminated water or food. Although the source of infection may vary, person to person transmission through poor hygiene and sewage contamination of water supply are also very important. Infection with *S. typhi* usually, occurs via ingestion of food or water contaminated with excreta from typhoid fever cases or carriers.

Nomenclature and mode of transmission of typhoid

Typhoid fever is a global health problem. Its real impact difficult to estimate because the clinical picture may be confused with those of many other febrile infections. The disease burden is also underestimated because of the lack of bacteriology laboratory facilities in most developing countries. In 2004, WHO estimated

the global typhoid fever burden at 21 million cases annually resulting in an estimated 216,000 to 600,000 (1-4%) deaths per year, predominantly in children of school age or younger. It is estimated that 90% of these deaths occur in Asia. On the other hand, it was reported that the global mortality estimates from typhoid have been revised downwards from 600 000 to 200 000.

This report provides the current situation of typhoid fever in Malaysia focusing on the state of Kelantan. Kelantan was highlighted since the annual incidence of typhoid in this state has always been higher compared to other states.

Objective of the report.

Typhoid surveillance in Malaysia

In Malaysia, typhoid case surveillance definition are as follows:

1. Suspected: a case that meet the clinical case definition.
2. Probable: a suspected case with positive serodiagnosis or antigen detection test but without isolation of *S. typhi/ paratyphi*
3. Confirmed: isolation of *S. typhi/paratyphi* from blood, stool or other clinical specimens.

As with other communicable diseases, notification of typhoid is compulsory under the Prevention and Control of Infectious Diseases Act 1988 (Act 342). All suspected typhoid cases are required to be notified, even before it is confirmed by laboratory test. This is to ensure that all suspected typhoid cases are properly investigated and any potential outbreak could be detected as earlier as possible.

Typhoid notification is mandatory.

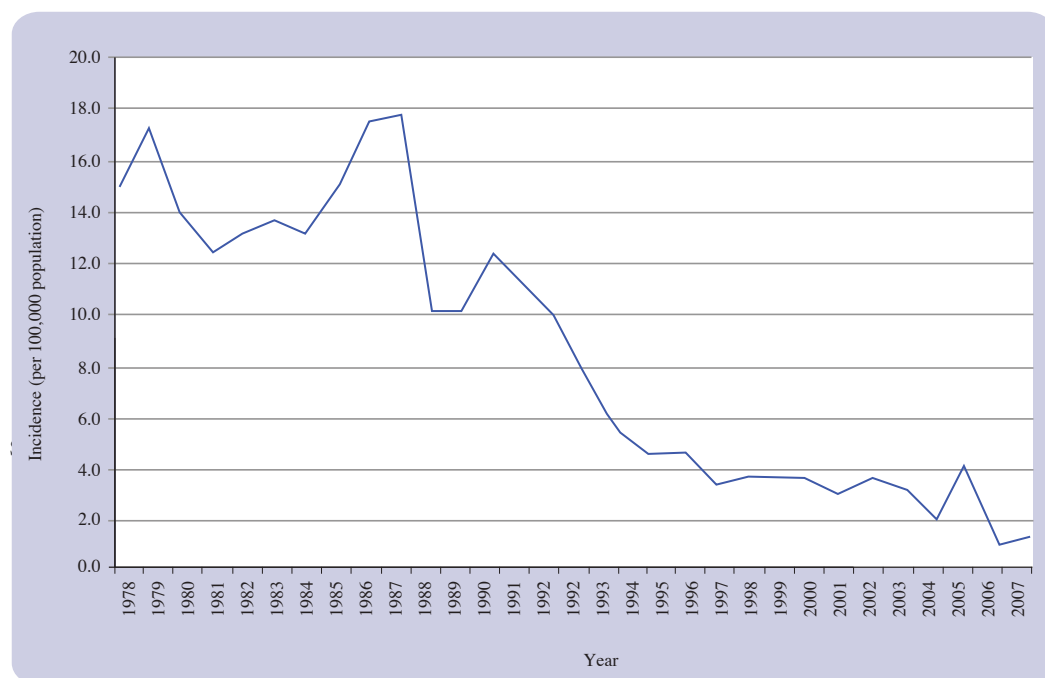
The Communicable Diseases Control Information System (CDCIS) is an electronic database notification system on communicable diseases introduced in 2002. Prior to that, data was collected and registered on a manual basis. Since 2004, the CDCIS has been fully implemented and all data collected by this electronic system. Through this system, electronic notification is received from government health facilities consisting of health centers, outpatient departments and hospitals. However, notification from private hospitals and general medical practitioners is still being done manually i.e. by fax and phone. Nevertheless, to ensure that all data have been captured in the CDCIS, such manual notification will later being registered and entered into the CDCIS system by the District Health Office.

Typhoid Situation in Malaysia

During the past 20 years, the incidence of typhoid in Malaysia has markedly declined from more than 10 per 100,000 population in 1978 to less than 2 per 100,000 population in 2007 (Figure 1). Annual incidences of typhoid in Malaysia for the past 10 years (1998 to 2007) have been consistently below 5 cases per 100,000 population. Based on the classification used by Crump et al (2004) in which overall regional typhoid fever incidence are classified into high (>100 cases/100,000 population/year), medium (10 – 100 cases/100,000 population/year), and low (<10 cases/100,000 population/year), then Malaysia may be described as being in a low endemic region since 1992.

Generally typhoid trends are declining.

Figure 1 : Trend of Typhoid Fever in Malaysia, 1978 to 2007



Source: CDCIS

In Malaysia the annual incidence of typhoid fever in Kelantan has been comparatively higher compared to other states (Table 1). The occurrence of typhoid fever was found to be sporadic with occasional outbreaks that were confined to a few areas only. Infection usually occurred in areas where safe water supply and sanitation, food handling and personal hygiene practices are lacking.

Table 1: Incidence of Typhoid/Paratyphoid (per 100,000 population) in Malaysia by States, 2003 – 2007

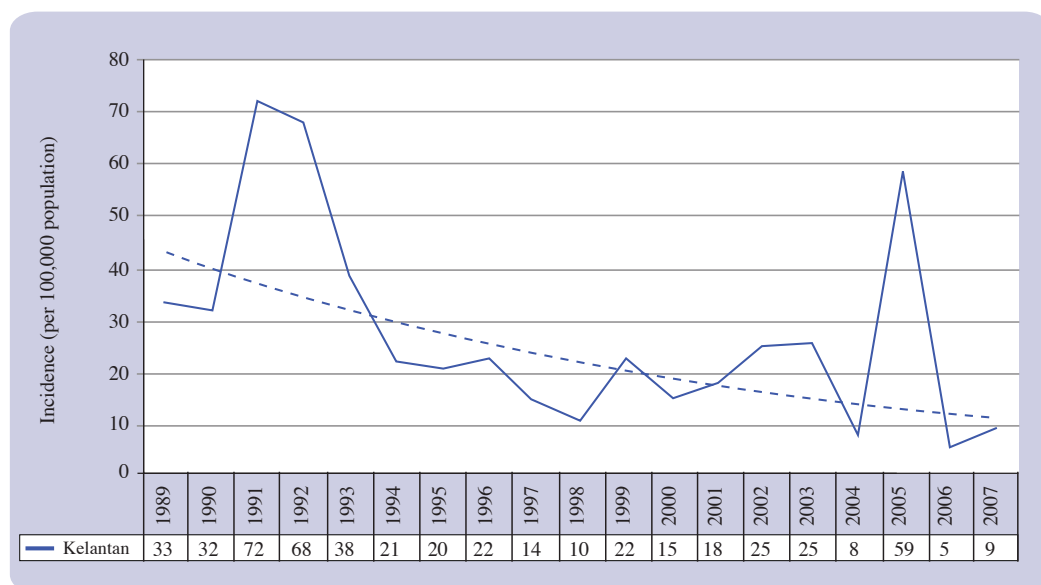
States	Year				
	2003	2004	2005	2006	2007
Kelantan	24.8	7.5	58.9	4.9	8.7
Sabah	6.3	5.5	2.1	1.3	2.2
Johor	0.7	0.5	0.4	0.3	1.4
Pahang	1.5	0.6	0.8	0.1	1.2
P.Pinang	0.2	0.4	0.6	0.2	1.1
Melaka	0.3	0.3	0.1	0.3	1.0
Perak	1.3	1.1	0.8	0.6	0.9
Kedah	1.8	1.2	1.0	1.0	0.5
Selangor	0.6	1.1	1.0	1.0	0.4
W.P	0.7	0.8	0.1	0.1	0.3
Terengganu	7.3	3.2	0.8	0.9	0.3
Sarawak	1.1	1.5	0.7	0.5	0.2
N.Sembilan	0.4	0.4	0.7	0.0	0.1
Perlis	0.5	1.4	0.0	0.4	0.0
Malaysia	3.1	1.9	4.1	0.8	1.2

Source: CDCIS

Typhoid Situation in Kelantan

Annually the number of cases and incidence of typhoid fever in Kelantan has always been higher. However, the overall trend has generally been on the decline, especially the past 10 years (figure 2). It was only in 2005 that there was a 3-fold increase in incidence attributed to a major outbreak that occurred between April to June, with 735 reported cases and 2 deaths (Table 2).

Figure 2 : Incidence of Typhoid (per 100,000 population) in Kelantan, 2000 – 2007



Source: CDCIS

Table 2 : Incidence of Typhoid (per 100,000 population) in Kelantan By District, 2003 – 2007

District	2003		2004		2005		2006		2007	
	C	I	C	I	C	I	C	I	C	I
K.Bharu	162	35.8	30	6.6	599	126.0	31	6.4	88	18.5
Jeli	19	45.2	18	42.9	5	11.3	2	4.4	8	17.9
P.Puteh	14	11.8	4	3.4	19	15.3	6	4.7	9	7.2
P.Mas	22	11.8	15	8.0	26	13.2	12	6.0	12	6.1
K.Krai	4	3.7	2	1.9	10	8.9	2	1.7	4	3.6
Machang	3	3.4	5	5.6	7	7.4	1	1.0	3	3.2
Tumpat	22	14.5	15	9.9	76	47.6	15	9.2	5	3.1
T.Merah	8	6.8	8	6.8	6	4.8	3	2.4	2	1.6
G.Musang	3	3.4	5	5.6	1	1.1	0	0.0	1	1.1
Bachok	104	83.4	8	6.4	139	106.0	2	1.5	1	0.8
Kelantan	361	24.8	110	7.5	888	58.9	74	4.9	133	8.7

C = Number of cases, I = incidence (per 100,000 population)

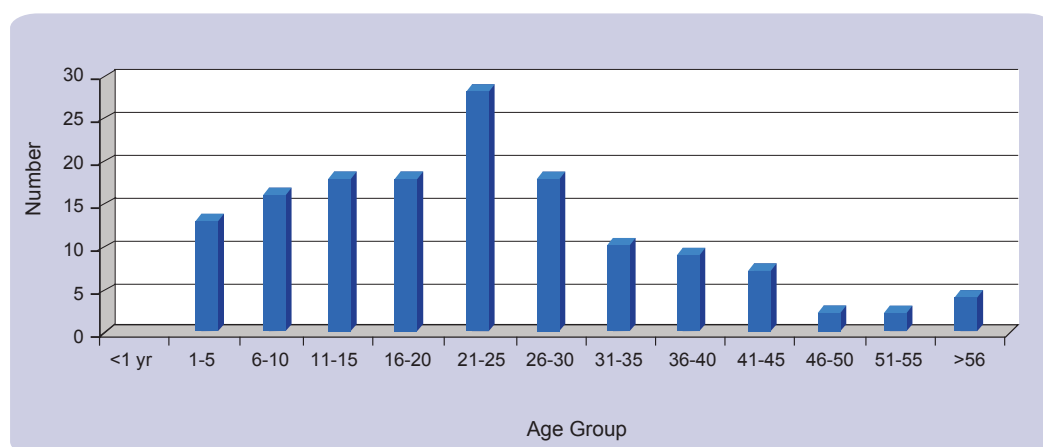
Source: CDCIS

The majority of districts in Kelantan have an annual incidence of more than 5 per 100,000 populations (Table 2). These districts include Kota Bharu, Jeli, Pasir Puteh, Pasir Mas and Tumpat. In 2007, the highest incidence was recorded in Kota Bharu (18.5 cases per 100,000 population) followed by Jeli (17.9 cases per 100,000 population). The incidences in other districts were comparatively lower.

Typhoid incidences were comparatively high in Kelantan.

Three outbreaks were reported in Kelantan in 2007; two were from Kota Bharu district and 1 from Jeli. All outbreaks were point source and confined to localized areas. One of the outbreaks occurred among staff and student of a higher learning institution in Kubang Kerian. Investigations revealed the source of infection as originated from a food handler who was also found to be a chronic carrier. Two other reported outbreaks were attributed to poor water supply and sanitation.

Figure 3: The distribution of Typhoid cases by age group in Kelantan, 2007



Source: CDCIS

As shown in figure 3, most of typhoid cases reported in 2007 were among the adult groups- mainly students of a higher learning institution and the working adult. School children only contributed about 41% of typhoid cases in Kelantan

All typhoid cases in Kelantan in 2007 were Malaysians, of which 94% were Malays. This was expected as 85% of population in Kelantan were predominantly Malays.

Contributing Factors for Typhoid in Kelantan

Inadequate safe water supply was a major contributing factor for the occurrence of typhoid outbreak in Kelantan. In March 2003, 128 typhoid cases were reported in Bachok district and investigations found it to be associated with the use of contaminated water for the preparation of food and drinks for a wedding ceremony. In addition, poor hygiene and food safety practices also contributed to the high number of typhoid cases in Kelantan as exemplified in an outbreak in 2005 in which contaminated ice and ready-to-eat (RTE) food distributed to street hawkers and night markets were implicated. Transmission of infection from typhoid carrier particularly through food handlers was also another important factor for typhoid outbreaks in Kelantan. In 2007 an outbreak occurred in a higher learning institution in Kubang Kerian in which 33 individuals were infected. Investigations revealed that the source came from a food handler who was a chronic carrier.

Three important contributing factors

Typhoid Prevention and Control

Prevention and Control of typhoid Fever in General

Surveillance and Response

Typhoid is a notifiable disease under the Prevention and Control of Infectious Diseases Act 1988 (Act 342 of Malaysian Laws). All suspected typhoid cases are required to be notified, even before confirmation by laboratory test. This is to ensure that typhoid cases are caught early and permit early public health intervention. Acting on suspected cases also acts as early warning mechanism alerting for possible outbreak scenario.

Public health measures in Malaysia in General.

An electronic system known as The Communicable Diseases Control Information System (CDCIS) have been fully implemented within all government health facilities since the year 2004 to facilitate notification and data management. Through this system, all notified cases can be monitored promptly at all health levels including district, state and national level, so that control measures can be supervised closely at each level. In 2006, the 2nd edition of the guideline for the Management of Typhoid Outbreak in Malaysia, was published. In addition, a series of outbreak management courses for field health personnel were carried out regularly, as a collaborative activity with the Institute of Public Health.

Effective Treatment and case Follow Up.

Early diagnosis of typhoid fever and prompt institution of appropriate antibiotic treatment are essential for optimal clinical management. Appropriate antibiotic treatment (the right drug, dose, and duration) is critical to cure typhoid with minimal complications. Standard treatment with chloramphenicol or amoxicillin is associated with a relapse rate of 5-15% or 4-8% respectively, whereas the newer quinolones and third generation cephalosporins are associated with higher cure rates.

*Recommended
antibiotic regime for
typhoid treatment in
Malaysia.*

The emergence of multidrug resistant typhoid (MDR) in the 1990s led to widespread use of fluoroquinolones as the treatment of choice for suspected typhoid, especially in South Asia and South East Asia where the disease was endemic. The majority of *S. typhi* strains in Malaysia are still sensitive to chloramphenicol or ampicillin. As recommended in the National Antibiotic Guideline 2008, MOH, the 1st line treatment for typhoid case is Chloramphenicol 50-100mg/kg/24h PO in 4 divided doses for a minimum of 14 days whereas the alternative treatment are either 3rd generation Cephalosporins, e.g. Ceftriaxone 60-80mg/kg IV q24h for 7-14 days or Ciprofloxacin PO/IV or Pefloxacin 20-30mg/kg/24h IV in 2 divided doses for 7-14 days.

It is estimated that between 1 to 5% of patients infected by *S. typhi* become chronic carriers. Although the percentage is relatively low, it can be potentially dangerous if these carriers are also food handlers. In addition, infection by *S. typhi* usually occurs via ingestion of food or water contaminated with excreta from typhoid cases or carriers. Preventing a typhoid case from becoming a typhoid carrier requires effective treatment and proper follow up. In Malaysia, all cases need to be admitted and complete antibiotic treatment. Following that, all typhoid cases in this country are required to be followed up for at least 12 months. During the follow up, regular stool samples are taken and tested for *S. typhi*. In 2007, from 325 typhoid cases that were reported 80% were followed up and none of them became a chronic carrier. All typhoid carriers need to be treated according to the recommended guidelines.

Provision of Safe Water and Sanitation.

Typhoid fever is a food and waterborne disease and the main preventive measure is to ensure access to safe water. In Malaysia, the coverage of safe water supply in most part of this country is more than 95%.

Promoting Food Safety Practice Among Food Premise Operators and Food Handlers

Another common mode of typhoid infection is by ingestion of an infecting dose of the organism through contaminated food. In order to ensure that food safety practices are not being compromised by food premises operators and food handlers, food premises inspection has been regularly conducted by the Ministry of Health. In 2007, 88,968 food premise inspections have been carried out. In addition, all food handlers are required to be vaccinated against typhoid to minimize the risk of infection to the food handlers as well as to the consumers.

Typhoid Prevention and Control - Focus in Kelantan

Since 2004, Kelantan Health State Department has implemented a 5-year plan to reduce typhoid incidence from 24.8 per 100,000 populations in 2003 to less than 10 per 100,000 populations in 2008. The plan focused on 5 priority areas namely health promotion, strengthening surveillance and monitoring, case management and follow-up, provision of safe water and sanitation through the BAKAS programme, and promotion of food safety practices.

Specific public health measures in Kelantan.

Health Promotion

To reach communities at all levels, all possible means of communication have been applied by Kelantan State Health Department. This included conducting health promotion at least 1 session a month in markets, and at least 1 session a week in a hospital, through congregational Muslim Friday Prayer Sermon for at least 4 sessions in a year and promotion through local radio station for at least 4 sessions a year. Community involvement is the cornerstone of behaviour change with regards to hygiene and for setting up and maintenance of the needed infrastructure. To sustain community participation, collaboration with the local councils, community leaders and other agencies have been established through regular

Strengthen Surveillance and Monitoring

Surveillance of typhoid cases as well as monitoring preventive and control measures has been carried out closely both at district and state level through daily and weekly monitoring. The CDCIS data are monitored daily by the district health office personnel particularly for clustering of notified cases which may portend an early warning for outbreak occurrence. Preventive and control measures have also been overseen regularly through weekly meetings in district and state level. In addition, 3 monthly technical meetings were conducted regularly at the state level to oversee public health measures carried out at district level.

Case Management and Follow Up

A good case management includes case isolation, prompt antibiotic therapy and proper follow up. All typhoid cases need to be admitted. All typhoid cases should have at least 3 stool clearances before they are discharged and undergo follow up after 3, 6 and 12 months. From 133 typhoid cases that were reported in 2007, 95% were able to be followed up for 12 months and none developed into a chronic carrier.

Provision of Safe Water and Sanitation Through the BAKAS Program.

Since 1973, Rural Environment and Sanitation Program (BAKAS) has been a main player in providing safe water supply and sanitation in rural area. In order to reduce typhoid cases in Kelantan, it was targeted that 95% of houses in rural area will have safe water supply and 100% have proper sanitation. In 2007, there were 252,822 houses in Kelantan which were classified as in rural area. Of this, 95.4% have safe water supply, and 97.9% have proper toilets.

Promotion of Good Food Safety Practice

Good food safety practice among food handlers has been promoted mainly through food handlers training. Food premise grading has also been carried out as a collaborative activity with the local councils. It was estimated that there were 25,918 registered food handlers in Kelantan in 2007. Among them 60% had underwent food handler training conducted by the district health office.

Food safety practices among food handlers are monitored through regular food premise inspections. In 2007, 8,615 food premises were inspected in Kelantan and 420 premises (4.9%) were closed because of their substandard food safety practices.

Discussion

Prior to the early 1990's, the annual incidence of typhoid fever in Malaysia had been consistently more than 10 per 100,000 population. Based on classification made by Crump et al (2004), it was comparable with regions with moderate endemicity of typhoid fever. However, the annual incidence has persistently been lowered to less than 10 per 100,000 population since 1992; and further reduced to less than 5 per 100,000 population since 2002. It can be concluded that Malaysia had rapidly transformed from a country with moderately to low endemicity for typhoid fever since 1992.

Malaysia had rapidly transformed from moderately endemic to low endemic country of typhoid fever

Significant improvement was also seen in the Kelantan state, which was known as a typhoid endemic state in Malaysia. The incidence before 1996 was consistently more than 30 per 100,000 population but subsequently this was lowered to less than 10 per 100,000 population in 2004. It was only in 2005 that a fluctuation occurred when there was a 3-fold increase in the incidence because of a major outbreak occurring between April to June 2005 involving 735 cases and 2 deaths. In response to that outbreak, a special budget of RM6.5 million was allocated and was utilized for implementation of public health measures in 2006. The focus was on improving water supply and environment sanitation through the BAKAS project, promoting good food safety practice among food handler, and health promotion. The measures carried out produced marked reduction in the incidence of typhoid for the subsequent years.

The 5-year plan in Kelantan beginning from 2004 produced significant results. The targeted incidence of less than 10 per 100,000 populations in 2008 had been achieved in 2006, 2 years ahead before the end of the prescribe 5-year plan. However, the consistency and continuity of all public health measures should not be compromised. The 5-year plan should be revitalized, and be followed by another long term plan to ensure the incidence continue to decline to more acceptable levels.

Public health measures in Kelantan showed significant result.

WHO had reported that the global magnitude of typhoid fever may

have been underestimated as a result of insufficient bacteriology laboratory facilities in most developing countries. However in Malaysia, sufficient number of laboratories are available to facilitate diagnosis of all suspected cases.

The magnitude of typhoid chronic carrier in Malaysia especially among food handlers has never been evaluated. Identifying a typhoid carrier among food handlers is a big challenge in this country as there is no effective laboratory test able to detect typhoid carriers. Stool culture may show specificity to asymptomatic carrier. It however lacks sensitivity and speed. The isolation of *S. typhi* from stool may also be very difficult since excretion of the organism in these asymptomatic carriers is often intermittent. In the past, the serum Vi-antibody was used to screen the typhoid carrier in some country but this practice has been abandoned since most people with raised Vi antibody were also to be found not a *S. typhi* carrier.

Any effort by researchers to develop an effective test for the detection of typhoid carrier should be encouraged. However, any test developed should be highly sensitive and specific, affordable and safe. As recommended by WHO, typhoid carriers should be excluded from any activity involving food preparation and serving. They should not resume their duties as food handlers until they have had three negative stool cultures at least one month apart.

Identifying typhoid carrier among food handlers is a big challenge.

Although it was reported that the majority of *S. typhi* strains in Malaysia are still sensitive to chloramphenicol or ampicillin, the trend of Multi Drugs Resistance (MDR) typhoid is alarming. Comparisons of 2 published documents (I Merican, 1997 and VKE Lim, 2002) revealed that *S. typhi* resistance to Chloramphenicol was increasing from 3.4% (1991) to 5.7% (1995) and 8.6% (2000). Unpublished data from laboratory based surveillance (Bacteriology Unit IMR) reported that in 2007, 17.5% of 183 *S. typhi* isolate in government hospitals are resistant to Chloramphenicol.

MDR typhoid may not have been a major threat in Kelantan since most cases were local. Unpublished data from laboratory based surveillance data in the Institute for Medical Research (IMR) revealed that from 545 *S. typhi* that was isolated from Kelantan in 2005 (where major outbreak occurred), none were resistance to chloramphenicol. However, in other states where there is influx of foreign worker especially from known MDR typhoid endemic countries such as from the Indian continent, the MDR typhoid poses

MDR typhoid.

a threat. It was reported in 2006 that the incidence of typhoid among non Malaysians was 2.2 per 100,000 population; of and of these 37.7% were Nepalese and 13.1% were Bangladeshi, where both countries were within the MDR typhoid endemic regions.

In Kelantan, 41% of typhoid cases reported in 2007 were among school children.

WHO recommended immunization program among school-age and/or preschool-age children in areas where typhoid fever in school age groups gave a significant public health problem, particularly where antibiotic resistant is prevalent. However, since school age children as well as MDR typhoid were both not a major problem in this country, introduction of immunization among school children might be less a priority than other public health measures such as health promotion, strengthening surveillance and monitoring, case management and follow up, provision of safe water and sanitation, promotion of food safety practice as well as training for health professionals.

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NATIONAL STRATEGIC PLAN FOR EMERGING DISEASES (MySED)

SUMMARY

Outbreaks of infectious diseases such as the Nipah virus infection, severe acute respiratory syndrome (SARS) and Avian influenza (H5N1) have impacted Malaysia in terms of human and animal health and economic growth. Such outbreaks underline the importance of preparedness and constant vigilance for early detection and rapid response in the prevention and control of diseases. With effect from June 2007, each country is obligated to comply with minimum requirements under the revised International Health Regulation 2005 (IHR 2005). The WHO Western Pacific Region Office (WPRO) together with the South East Asia Office (SEARO) has developed an Asia Pacific Strategy for Emerging Diseases (APSED) - a strategic framework for countries to build the capacity required under the IHR 2005. The Ministry of Health Malaysia (MOH) embraces the vision of APSED and has drafted Malaysia's own strategic document and action plan (MySED). MySED will be the framework for a national safety net for emerging diseases, which requires MOH to build partnerships for preparedness, planning, prevention, prompt detection, characterization, rapid containment and control of any infectious diseases.

Introduction

Emerging infectious diseases outbreaks such as the Nipah virus infection, severe acute respiratory syndrome (SARS) and currently Avian influenza (H5N1) have had impacts in Malaysia in terms of human and animal health and economic growth. Occurrences of such epidemic-prone infectious diseases underline the importance of early detection and rapid response in the prevention and control of diseases. Such threats call for continuous preparedness and constant vigilance in the Ministry of Health Malaysia (MOH).

*The Threat of
Emerging Infectious
Diseases*

The purpose of the revised International Health Regulation 2005 (IHR 2005) of the World Health Organization (WHO) is to ensure maximum security against the international spread of diseases with minimum interference with world traffic. Under IHR 2005,

*IHR 2005 and
APSED*

member states are required to assess existing Public Health systems; and to develop and implement plans of actions to ensure that the core capacities for surveillance and response are present and functioning.

The WHO Western Pacific Regional Office (WPRO), together with the South East Asia Regional Office (SEARO), has developed a strategic framework for member countries to assess and build capacity to prepare for, identify and respond to emerging diseases as required under the IHR 2005. This *Asia Pacific Strategy for Emerging Diseases* (APSED) supports member countries in such capacity-building in compliance with IHR requirement, with the promise of specific and immediate support for influenza pandemic preparedness.

This article describes the *National Strategic Plan on Emerging Diseases* (MySED) developed by Malaysia in compliance with the IHR 2005.

The National Strategic Plan on Emerging Diseases (MySED)

Malaysia's National Strategic Plan on Emerging Diseases (MySED) *MySED* is based on the APSED. The MOH vision of MySED is to minimize health, economic and social impacts of emerging infectious diseases. This calls for improvement of health protection through beneficial partnerships for preparedness, planning, prevention, prompt detection, characterization, rapid containment and control of any infectious diseases. There are five objectives:

1. Reduce the risk of emerging diseases
2. Strengthen early detection of outbreaks of emerging diseases
3. Strengthen early response to emerging diseases
4. Strengthen preparedness for emerging diseases
5. Develop sustainable technical collaboration within the Asia Pacific Region

The MOH has conducted the baseline capacity assessment using the standard questionnaire of the WPRO. Gaps have been identified between current capacity in Malaysia and the required core capacity of the IHR 2005. The MySED work plan adopts a stepwise approach to achieve the minimum core capacity by 2010 and has identified five key programme areas

Key Programme Areas

- Surveillance and Response,
- Laboratory,
- Zoonoses,
- Infection Control and
- Risk Communication.

The MySED Work Plan Implementation has further identified key activities in each of the programme areas:

Surveillance and Response

- Review existing national law(s) and/or regulation(s) and/or policy and identify areas that need to be revised to ensure they support the country surveillance and response system and fulfills the requirement of IHR 2005
- Evaluate the weaknesses of existing Event-based Surveillance at national, state and district level
- Produce Standard Operating Procedures (SOP) on data management for Indicator-based Surveillance
- Strengthen current capacity on surveillance and response via training and simulation exercises
- Establish SOP for communications between National IHR Focal Points with WHO and other ministries / departments
- Manage stockpiles

Laboratory

- Establish a national Laboratory Technical Advisory Committee (LTAC) for Infectious Diseases
- Create and maintain National Inventory/database on laboratory services (MOH and all relevant laboratories)
- Assess laboratory capacity at national, state and local level for support during health crisis
- Establish National Internal and External Quality Assessment Programme
- Develop national biosafety and biosecurity programme
- Strengthen existing national laboratory-based surveillance system and develop mechanism for networking and sharing information between laboratory (public and private), animal and human health authorities
- Train laboratory staff on outbreak response-related activities and conduct simulation exercise

Zoonoses

- Strengthen intersectoral zoonotic diseases committee for early detection and alert, including mechanism for information system between animal and human health authorities especially at state and district level
- Establish intersectoral working committee for risk reduction management of zoonotic diseases at animal production and transportation systems, and market place
- Strengthen national cross-sector and joint programmes for rapid response to priority zoonotic diseases, including the development of SOPs and training

Infection Control

- Review and regularly update the policy and SOPs of infection control including mechanism for rapid notification of unusual occurrence of infectious disease
- Develop action plan to handle surge capacity for infection control at all levels
- Conduct regular refresher courses on infection control
- Expand surveillance on antimicrobial resistance in relation to hospital acquired infection (HAI) prevalence

Risk Communication

- Develop a national Risk Communication Strategic Plan
- Strengthen current capacity on risk communication via training and exercise management
- Conduct risk assessment research particularly pertaining to risk communication in a specific group

Monitoring and Evaluation

A monitoring and evaluation work plan has also been developed to monitor the outcomes and goals of the Plan. Evaluation of implementation has been planned twice yearly. Core capacity assessment could be conducted yearly. Evaluation will be conducted through formal assessment using standardized format and working visits for each programme area.

Assessment Plan

The first two years, 2006-2007, was focused on influenza preparedness when the National Influenza Pandemic Preparedness Plan was developed and officially launched. Year 2009 will see the conduct of mid-year and joint assessments to appraise the network between central and local levels targeted for the end of 2009.

Resources

Effective implementation of the MySED Work Plan requires investment in human, financial and other resources at all levels. Initial funds will be made available from operational budgets of the MOH. However, the development and/or conduct of specific projects to fulfill the MySED work plan will require specific budgets according to each key programme area.

*Need for Resource
Investments*

Conclusion

The MOH plays the lead role to ensure maximum health protection against emerging diseases in the country and hence, will continue to guide and collaborate with all relevant agencies. MySED and APSED will be the strategic documents to be used, and in the Malaysian context will contain the action plans needed by all relevant agencies to ensure compliance with IHR 2005 requirements. The time line set by IHR 2005 is June 2012. Malaysia has complied with most of the MySED and APSED requirements based on the evaluation and assessment of entry point conducted in 2007.

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NATIONAL EAR AND HEARING DISORDER SURVEY

SUMMARY

The National Ear and Hearing Disorders Survey is the first nationwide survey that looked into the magnitude of hearing impairment and ear diseases. The prevalence of hearing impairment in the general population was 17.1%, with a significantly lower prevalence among Malays compared to Chinese, and higher among males compared to females. The prevalence of ear disorders in Malaysia was 16.1%, the majority due to preventable causes; impacted wax was 9.0%, chronic suppurative otitis media was 5.1%, and otitis media with effusion was 2.9%. Only one third of the respondents who were perceived or informed as having ear or hearing problems sought treatment. Based on the findings, a National Plan of Action for Otorhinolaryngological and Audiological services was developed and implemented in 2007. The plan focuses on preventive strategies at primary, secondary and tertiary levels to provide comprehensive services and reduce morbidity.

Introduction

The need for a National Ear and Hearing Disorders Survey was raised at the Ministry of Health (MOH) Annual Research Dialogue as evidence-based data was needed for policies and programmes for Otorhinolaryngological and Audiological services in the country.

A need of evidence-based data

According to the 2005 estimates of the World Health Organization (WHO), 278 million people worldwide have moderate to profound hearing impairment whereby at least half of all hearing impairment is preventable. Eighty percent of deaf and hearing-impaired people live in low and middle income countries, and one quarter of cases begin in childhood. Worldwide, the number of people with all levels of hearing impairment is rising, mainly due to a growing global population and longer life expectancies. It is also reported that in developing countries, fewer than one in 40 people who would benefit from a hearing aid has one, and 50% of deafness and hearing impairment is avoidable through prevention, early diagnosis and management.

The objectives of this survey were to determine the national prevalence and causes of ear disorders and hearing impairment, and to identify the actions needed and the resources required for intervention. *Survey Objectives*

The study design was based on the World Health Organization (WHO) Ear and Hearing Disorder Survey protocol WHO/PBD/PDH/99.8 (1), with some modification to suit the local situation. A two-stage stratified sampling design with probability proportional to size (PPS) was used. *Methodology*

The sample size calculated was 7,908, based on 1.0% estimated prevalence of profound hearing impairment. Data collection was by individual face-to-face interview using a structured questionnaire, followed by hearing assessment by Audiologists and ear examination by Otorhinolaryngologists. The analysis accounted for the complexity of the study design, and weights were used to estimate the affected population. The confidence interval was set at 95%.

A total of 7,041 respondents participated in the 2005 National Ear and Hearing Disorders Survey, giving a response rate of 97.9%.

Findings on Hearing Problems

Hearing Impairment

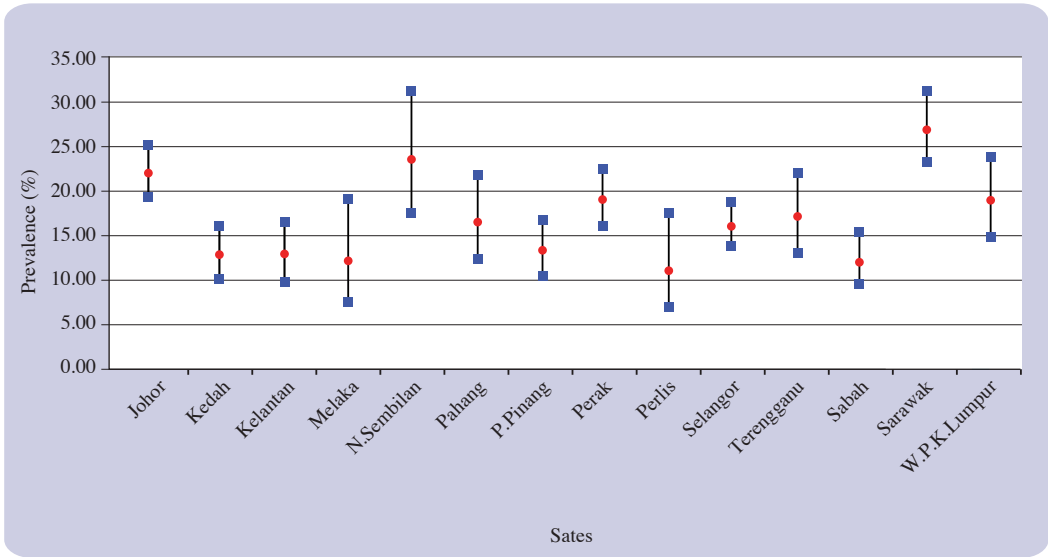
Hearing impairment was defined as the average hearing threshold of more than 25dB by a definitive test (Play Audiometry or Pure Tone Audiometry). Hearing assessment for Play Audiometry (for respondents 3 to 7 years) was done at 1, 2 and 4 kHz while Pure Tone Audiometry (for respondents above 7 years) was done at 1, 2, 3 and 4 kHz. The grade of hearing impairment is based on WHO Classification as:

- Mild (26-40dB)
- Moderate (41 – 60dB)
- Severe (61 – 80dB)
- Profound (81dB or more)

The prevalence of hearing impairment in the general population was 17.1% (16.14, 18.19). Prevalence of unilateral and bilateral hearing impairment was 5.4% (4.78, 6.00) and 11.4% (10.54, 12.24) respectively. By grade, ‘mild’ hearing impairment was 12.1% (11.25, 13.02), and ‘moderate’ to ‘profound’ hearing impairment was 5.0% (4.51, 5.62). Prevalence of hearing impairment by state is shown in Figure 1.

*Prevalence of
Hearing Impairment*

Figure 1 : Prevalence of Hearing Impairment by States



There was no significant difference in the prevalence of hearing impairment between respondents from urban [17.3% (16.03, 18.71)] and rural areas [16.8% (15.31, 18.44)]. There was a lower prevalence of hearing impairment among Malays [15.7% (14.49, 17.04)] than Chinese [21.0% (18.65, 23.66)]; and prevalence was higher among males and among the elderly aged 60 and above, compared to those aged 20-59. Hearing impairment was lowest among adolescents. (Figures 2 and 3).

*Prevalence of
Hearing Impairment
by Socio
demographic Profile*

Figure 2 : Prevalence of Hearing Impairment by Age Group

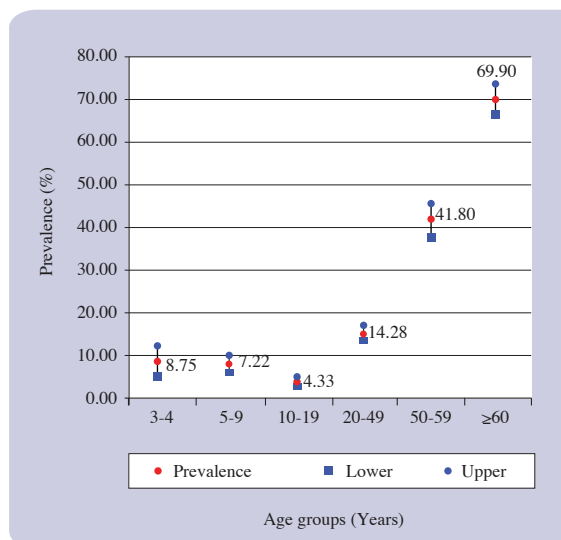
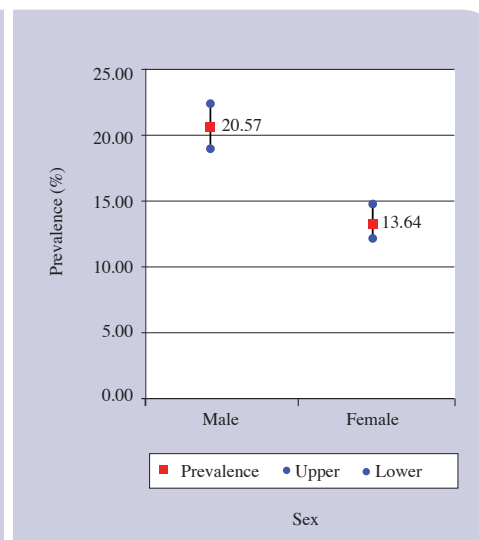


Figure 3 : Prevalence of Hearing Impairment by Sex



The prevalence of hearing impairment was inversely proportional to household income; 18.6% (17.15, 20.11) among respondents with low household income, 16.1% (14.41, 17.94) among middle household income, and 15.0% (12.63, 17.66) among high household income respectively. Among respondents aged 25 years and above, the prevalence of hearing impairment was higher among those with no formal education compared to other levels of education.

Causes of Hearing Problems

This survey also looked into common causes and symptoms of hearing problems such as presbycusis and tinnitus.

Presbycusis

Presbycusis is defined as bilateral symmetrical hearing loss without any other concomitant causes for those aged above 50 years. The prevalence was 32.6% (29.57, 35.87), but was higher for those above 60 years [43.5% (38.81, 48.39)]. Presbycusis was found significantly higher among males.

Prevalence of Presbycusis

Those who were informed, or perceived, as having hearing problems increased with age. It was also noted that the prevalence of presbycusis with tinnitus was 10.7% (8.80, 13.05).

Tinnitus

Tinnitus is an auditory phantom sensation (ringing in the ears) experienced when no external sound is present. It can be continuous or episodic. The prevalence of tinnitus among respondents aged 18 years and above was 26.4% (24.80, 28.00). *Prevalence of Tinnitus*

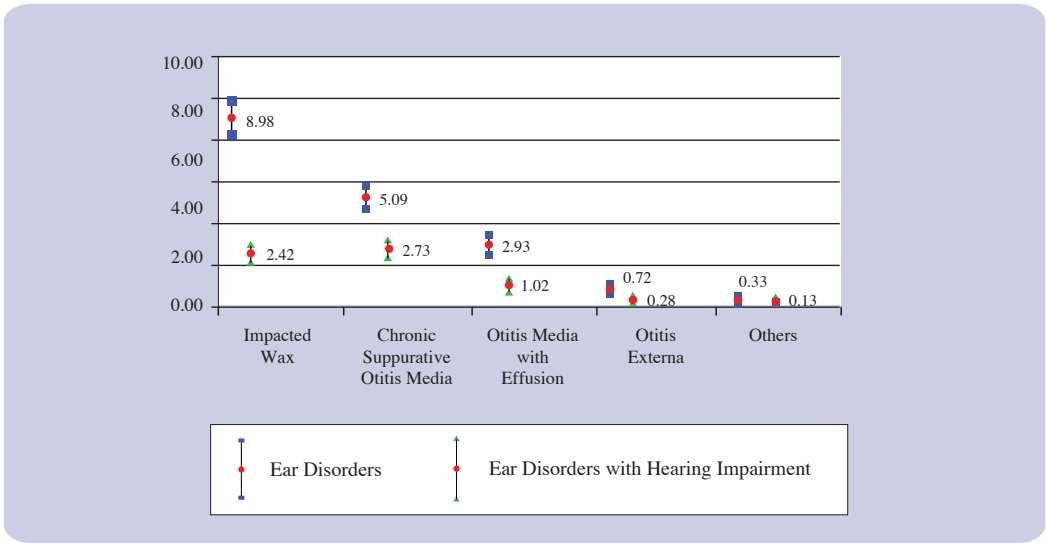
Tinnitus was noted as significantly higher among Malays compared to Chinese and Indians. There was no significant difference by sex. About 50% of the respondents had unilateral tinnitus and 35.0% bilateral.

Among the predisposing risk factors reported for tinnitus, the commonest was barotrauma, followed by recreational noise, head injury and drugs secondary to tuberculosis treatment. The prevalence of tinnitus increased with the severity of hearing impairment, both unilaterally and bilaterally. Tinnitus with continuous ringing caused more difficulty in sleeping and disturbed daily activities as compared to episodic tinnitus.

Findings on Ear Disorders

The prevalence of ear disorders was 16.1% (15.14, 17.20). Impacted wax and chronic suppurative otitis media were the most important causes of ear disorders. Prevalence of ear disorders and ear disorders with hearing impairment is shown in Figure 4.

Figure 4 : Prevalence of Ear Disorders and Ear Disorders with Hearing Impairment



Impacted Wax

The prevalence of impacted wax in Malaysia was 9.0% (8.19, 9.84). Children aged less than 10 years had significantly higher prevalence compared to other age groups. It seems to be a condition of socio-economic disadvantage being about 3 times higher among those with no formal/incomplete primary education (15.7%) compared to secondary (4.8%) and tertiary (4.8%) education levels, and higher in households with lower income.

Prevalence of Impacted Wax

Chronic Suppurative Otitis Media (CSOM)

CSOM is a very common ear disease especially among the developing countries. It is a condition characterized by perforated tympanic membrane with or without ear discharge or decrease hearing. Due to limitations of this survey, CSOM was diagnosed among respondents with perforated tympanic membrane, with or without ear discharge.

Prevalence of CSOM

The prevalence of CSOM was 5.1% (4.55, 5.69). However, among this group, 78.3% were not aware of having ear disease. The proportion of CSOM with hearing impairment was 57.8%. Only 14.4% with CSOM had ear discharge and only 1.1% of such cases had cholesteatoma. Prevalence of CSOM was higher among respondents above 30 years compared to younger age groups.

Otitis Media with Effusion (OME)

Otitis media with effusion (OME) is defined as effusion in the middle ear with conductive hearing loss without symptoms of acute inflammation. However, due to limitations in this survey, OME was defined as respondents with clinical features of OME (dull, brown or retracted tympanic membrane, or with bubble or air-fluid level) with type B tympanogram.

Prevalence of OME was 2.9% (2.51, 3.40). Among those with OME, 46.5% were found to have hearing impairment. It was found that prevalence of OME was lower among those with tertiary education (2.4%) compared to those with primary (4.1%), secondary (2.5%) or without formal education (2.9%).

Prevalence of OME

Health Seeking Behaviour

Among respondents who were informed or perceived to have hearing problems, less than one-quarter (22.8%) had sought treatment while about one-third (36.0%) with ear disease sought treatment. All respondents who sought treatment did so at medical facilities (Hospital/Clinics) and none had resorted to traditional treatment or self medication.

Health Seeking Behaviour

Discussion

Hearing impairment and deafness are serious disabilities that can impose a heavy socioeconomic burden on individuals, families, communities and countries. Children with hearing impairment often experience delayed development of speech, language and cognitive skills, which may result in slow learning and difficulty progressing in school. In adults, hearing impairment and deafness often make it difficult to obtain, perform, and keep employment. Both children and adults may suffer from social stigmatization and isolation as a result of hearing impairment.

This survey had noted that the overall prevalence of hearing impairment among those aged three years and older was 17.1%. This finding is comparable to a survey done in Egypt (16.0%) and Australia (17.4%). However, the prevalence from this study is much higher than that of the United States (8.6%).

The prevalence of disabling hearing impairment (moderate to profound) was 5.0% in this survey. This is comparable to the prevalence in other surveys done in South East Asia Region; India (6.3%), Indonesia (4.6%), Myanmar (8.4%) and Sri Lanka (8.8%).

*Disabling Hearing
Impairment*

There was a significant difference in the prevalence of hearing impairment by sex with it being higher among males (20.6%) compared to females (13.6%). A similar finding was also noted in the US (10.5% males as compared to 6.8% females) and Australia (21.0% males as compared to 13.9% females). However, the survey in Egypt had noted no sex difference.

*Hearing Impairment
Higher among Males*

The burden of hearing impairment and deafness falls disproportionately on the poor, because they may lack awareness on healthcare and are unable to afford the preventive and routine care necessary to avoid hearing loss, or to afford hearing aids to make the condition manageable. Hearing impairment can also make it more difficult to escape poverty by slowing progress in school and the workplace, and placing people in social isolation.

*Higher Hearing
Impairment among
Lower Socio
economic Status*

This survey had found that the prevalence was higher among those with lower socio-economic background (low household income and low level of education). Similar findings were seen in US where the prevalence of hearing impairment decreases as family income increases; those with family income of less than \$10,000 are twice as likely to have hearing impairment as those with a family income of \$50,000 and over. Additionally, among the adult population in the US, the prevalence of hearing impairment is greater for those who are not high school graduates (less than 12 years' education) as compared to high school graduates.

The elderly were more likely to have hearing problems, where persons 60 years and older are 5 times more likely to have hearing impairment compared to persons aged 20-49 (69.9% and 14.6% respectively). These findings were comparable to a study in the US, where it was estimated that persons 65 years and older are 8 times more likely to have hearing impairment compared to persons aged 18-34 (29.1% and 3.4% respectively). The Egypt survey also noted higher prevalence among the elderly compared to younger age-groups.

*Higher Hearing
Impairment among
Elderly*

This study found bilateral hearing impairment (11.4%) to be higher compared to unilateral hearing impairment (5.4%). This finding is comparable to that of the Egypt survey (12.2% bilateral and 3.8% unilateral). This indirectly increases the burden of the problem due to hearing impairment.

*Higher Bilateral
Hearing Impairment*

The prevalence of presbycusis among 60 years and above was 43.5%. Comparison with other studies was difficult due to different definitions. A study in Thailand had noted that the percentage of elderly above 60 years with presbycusis was 52.4% while in Egypt it was 22.7%. By age group, the prevalence of presbycusis increased with age; 39.9% among 60-70 years to 49.5% among 70 years and above. A similar trend was also seen in Australia - 58.4% among 60-70 years to 74.0% among those aged 70 years and above.

*Presbycusis
Increased with Age*

The prevalence of tinnitus among respondents aged 18 years and above was 26.4%. However, this prevalence was much higher compared to that in Sweden (13.2%) and Scotland (17.1%). It was also noted that among 50 years and above, the prevalence of presbycusis with tinnitus was 10.7% which was comparable to the study in Taiwan (prevalence was 13.9%).

*Higher Prevalence of
Tinnitus*

The prevalence of impacted wax was 9.0% which was lower compared to the prevalence in other countries; Oman (11.7%), India (15.9%) and Indonesia (13.2%). However, the prevalence of OME (2.9%) was comparable to India (3.0%), Myanmar (2.1%) and Sri Lanka (2.1%).

*Preventable Ear
Disorders*

WHO had noted that chronic middle ear infection is the main cause of mild to moderate hearing impairment in children, while wax or foreign bodies blocking the ear canal can cause hearing loss at any age. This survey noted that the ear disorders with highest hearing impairment were chronic suppurative otitis media, impacted wax and otitis media with effusion. This is comparable to a national household survey in Egypt, which also noted that the commonest causes of hearing impairment were otitis media with effusion, followed by chronic suppurative otitis media.

This survey had found that the prevalence of hearing impairment due to ear disorders was only 6.58%, while 4.4% was due to presbycusis. Prevalence of hearing impairment due to unknown causes was about 5%.

Unknown causes

National Plan of Action

The research findings were successfully translated into a National Plan of Action for Otorhinolaryngological and Audiological services. Based on this advocacy strategy, various health education materials were produced and distributed. A health promotion campaign known as *Jom Dengar* was also launched.

*Utilization of
research findings -
Now and the Future*

At the Primary Care level, programs for the Prevention of Deafness and Intervention Program for Disabled Persons were implemented. For children of school-going age, a screening checklist will be prepared to identify children with hearing problem.

A High Risk Newborn Hearing Screening program has also been implemented at 30 government hospitals, while the Guidelines for High Risk Neonatal Hearing Screening will also be distributed to government hospitals.

Audiologists have implemented the Auditory Training Program in 13 hospitals since 2007, with the Standard Operating Procedure for Hearing Aid Prescription and Fitting to be distributed in January 2008.

A Cochlea Implant Program is to be implemented in MOH hospitals in 2008. The Operational Policy on Cochlear Implants is currently awaiting approval from the Director of Medical Development Division, Ministry of Health.

Conclusion

The World Health Organization through its Member States aims to reduce and eventually eliminate avoidable hearing impairment and disability through appropriate preventive and rehabilitative measures. Its strategic target is to eliminate 50% of the burden of avoidable hearing loss by the year 2010.

The utilization of evidence-based data from this survey demonstrates how research can improve healthcare at primary, secondary and tertiary levels by contributing to the development and modification of policies and practices, including successful implementation of intervention strategies.

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THE THIRD NATIONAL HEALTH AND MORBIDITY SURVEY

SUMMARY

The Third National Health and Morbidity Survey (NHMS III) was conducted in 2006 with the objective of providing health related community-based data and information for the Ministry of Health to review health priorities, program strategies and activities and planning for allocation of resources. Six scopes and 18 research topics were included in the survey. The survey was divided into 4 phases; survey preparation (identifying the scope of survey, pilot study, training of data collection teams), field data collection, data analysis and report writing. A two stage stratified random sampling design with proportionate allocation to the population size was adopted in the survey. The data collection was done from April 2006 to August 2006 in selected Living Quarters (LQs) throughout the country by 74 data collection teams. The overall response rate for the survey was 90.3%. The prevalence of selected health topics were calculated. Health related information and several plan of actions were expected from this survey.

Introduction

The First National Health and Morbidity Survey (NHMS I) was conducted by Institute for Public Health, Ministry of Health, Malaysia in 1986 with the aim of providing supplementary data that could be used for the development and evaluation of health programs in Peninsular Malaysia. The survey focused mainly on providing information on the load of illness and disability among the various sub-populations. The survey explored the extent and type of utilization of health services by the population, as well as reasons for not utilizing health services by those who actually needed to.

As a follow-up to the NHMS I, the Second Health and Morbidity Survey (NHMS II) was conducted 10 years later in 1996 with the main objective of providing community-based data and information for the MOH to review health priorities, programme strategies and activities, and planning for the allocation of resources. It adopted the scope and approach of the NHMS I so as to enable comparison between the findings of NHMS I and NHMS II. In addition, the NHMS II was extended to Sabah and Sarawak to provide information on health and morbidity status of the whole country.

Ten years on, the Third National Health and Morbidity Survey (NHMS III) was conducted in 2006. This survey retained as much as possible the important aspects of the NHMS II and also focused on other currently important health issues faced by the community. In this survey, 18 research topics had been included to give a comprehensive situation of the health status in Malaysia.

Objectives

The general objective of the NHMS III was to provide health related community-based data and information for the MOH to review health priorities, programme strategies and activities and planning for allocation of resources.

General objective

The specific objectives were :

- i) To determine the load of illness in the population as well as the impact of these illnesses on the community. *Specific objectives*
- ii) To determine the pattern of utilization of health care services (government, private, traditional & self-medication).
- iii) To determine the household consumption cost of health & medical care and the proportion of the population covered by different sources of payment for medical and health care.
- iv) To determine the prevalence of specific health behaviours (infant feeding practice, physical activity, papsmear test, breast examination, sexual practice, smoking and alcohol consumption)
- v) To determine for selected health problems namely hypertension, IHD, diabetes, asthma, acute diarrhoeal disease, ARI, accidents, and disability, the:
 - state and national prevalence rates
 - socio-demographic pattern and distribution
 - community health seeking behaviour
- (vi) To compare the morbidity and health services utilization pattern in 2006 with that in 1996.

Scope of the Survey

To facilitate in identifying the scope of the NHMS III, suggestions and feedback were obtained from the health programme managers, state health directors, representatives from universities and health related organizations on the priority issues and problems to be included in the survey. The NHMS III Main Research Group (MRG) reviewed and studied closely the feasibility and practicality of the suggested research topics. Extensive literature reviews was done. Technical and research experts in the identified research areas were consulted for further advice and comments.

*Main Research
Group*

The research topics short-listed were then presented to the NHMS III Advisory Committee for discussions on merit of it's inclusion in the survey. These topics were refined further by the MRG, based on the decision made during the Advisory Committee meeting.

Advisory Committee

The study scope was tabled to the NHMS III Steering Committee for approval. The approved scope of the survey were :

Steering Committee

- i) The load of illness in the community
- ii) Health seeking behaviour in relation to the illness
- iii) Health expenditure
- iv) The prevalence of selected health-related behaviours (physical activity, nutritional status, infant feeding practices, pap smear examination, breast examination, smoking, alcohol consumption, sexual behaviour)
- v) The prevalence and health seeking behaviour of selected health problems (hypertension, diabetes mellitus, hypercholesterol, asthma, injury, physical disability, psychiatric morbidity)
- vi) Population perceptions and practices for selected health related topics (dengue prevention practices, oral health, health information)

Sampling

The NHMS III utilized the sampling frame maintained by the Department of Statistics, Malaysia. Malaysia is divided into artificially created contiguous geographical areas called Enumeration Blocks (EB). Each EB has about 80 to 120 Living Quarters (LQ). The EBs formed the sampling frame for NHMS III. A two stage stratified random sampling design with proportionate allocation to the population size was adopted in the survey (stratification was based on state and strata). The first stage sampling involved sampling of the EBs. The second stage sampling involved random sampling of the LQs in the sample EBs (8 LQs for each selected EB).

Stratified random sampling

In the course of sample size calculation, the following factors were taken in consideration, ie: estimated prevalence rate, response rate of the NHMS II, margin of error and design effect. The survey findings addressing the specific objectives of the survey were expected to be used for state level health programme planning. Thus, the calculation of the sample size has taken into consideration that the data is valid at the state level. In addition to the major factors mention earlier, the availability of resources, namely financial and human resources and the duration of the survey also became part of the process in determining the sample size.

Preparation of Field Areas and Logistic Support

A number of state liaison officers were recruited in preparation for the survey. Strong networking with state liaison officers and District Health Officers (MOH and local authorities) from the areas sampled for the survey was established.

Liaison Officers

Field scouts were mobilized from these areas to identify and tag the LQ's selected for the survey, as well as informing the community and related government agencies of the planned survey. State liaison officers were also assisting Field Supervisors in the arrangement of transportation, accommodation and other logistics for the survey teams.

Scouts

Pilot Study

A pilot study was conducted on a sample of EB's (not included in the NHMS III) about two months prior to the actual nationwide survey. It was conducted in three different areas in the Klang Valley, namely Sepang, Klang and Bangsar. The population in these locations comprise of three distinct socio-demographic strata that are rural, semi-urban and urban. The objective of the pilot study was to test the following aspects:

Pilot Study

- i) The questionnaire
- ii) The scouting activities
- iii) The field logistic arrangement
- iv) The central monitoring and logistic support

Organization of Data Collection Teams

Two main survey implementation groups were formed which are the Central Coordinating Team and the Field Data Collection Teams. The Central Coordinating Team's main roles were to monitor and coordinate the progress of implementation and provided administrative support in terms of financial and logistic arrangement for the field survey.

Central Coordinating Team

The Field Data Collection Teams were responsible to oversee and manage the field data collection process as well as undertake quality control. The field data collection had been conducted throughout Malaysia simultaneously, spanning within a period of 4 months starting from April 2006 until July 2006. Teams were organized to move into 5 regions in Peninsular Malaysia (north, south, east, central1 and central2), 2 regions in Sabah and 4 regions in Sarawak for data collection.

Data Collection Teams

Members in each of the field data collection team were:

- a) 1 team leader,
- b) 3 interviewers,

- c) 3 nurses,
- d) 1 Public Health Assistant to function as the survey scout
- e) 1 Driver

For the NHMS III, 74 data collection teams were formed. They were managed by their respective Field Supervisors throughout the duration of the survey. Teams visited the selected LQ's which were identified and tagged by the field scouts at least 1 week prior to the survey. The relevant team members conducted an interview, clinical examination and blood investigations.

Training of Data Collection Teams

A training period of 2 weeks for interviewers, team leaders and nurses were held to familiarize them with the questionnaire, develop their interpersonal communication skills and appreciate the need for teamwork. Mock interviews in the class room and individual interviewing practice under supervision were conducted. Team leaders had in addition, input on methods of supervision, teamwork and quality control. In addition, the nurses were trained on the techniques of using all related equipments used in clinical examination. They were also taught on the method of referring respondents. Training were organized by the training working group committee and coordinated by The Central Coordinating Core team at central level for Peninsular Malaysia teams, Sabah and Sarawak. A fieldwork manual was produced for the survey and was used as practical guide and reference.

Training

Methods of Data Collections

Methods of data collection included the used of survey questionnaire (face to face interview and self-administered), anthropometric measurement, blood pressure measurement and blood investigation.

The Questionnaire

A bilingual (*Bahasa Malaysia* and English) pre-coded questionnaire were designed, pre-tested and piloted prior to the survey. Self-administered questionnaires also had been developed for a sub-sample of household members for questions pertaining to culturally sensitive issues or areas such as sexual behaviour and practices. The self-administered questionnaires were left with the selected household members and were collected by the team members at a later time of the day.

*Self-administered
questionnaire*

The interview

All adult members who qualify from the selected LQ's were invited to be interviewed face-to-face by the relevant team members. Parents or guardians provided information for their children aged 12 years and below (primary school). Interviews were conducted in the morning till late evening 5 days a week. Where an interview had been unsuccessful due to the absence of the respondent at the selected LQ, repeated visits were conducted after leaving messages with neighbours or by other means for an appointment at a later date. A household member can only be classified as a non-responded if at least 3 visits were unsuccessful.

*Face to face
interview*

For the first part of the interview which covers sections on general household, socio-demographic and economic profile, load of illness, health utilization and consumption cost, a trained non-medical or paramedical interviewer were conduct the interviews. Sections pertaining to specific health problems and involving blood or other physical or medical examination were conducted by trained nurses.

Anthropometrics measurement

All household members were measured for their height, weight and waist circumference after obtaining verbal permission.

Blood pressure measurement

All household members 18 years old and above were examined for their blood pressure after obtaining verbal permission. Digital electronic blood pressure meters were used. Two readings of systolic and diastolic pressure taken within 15 minutes apart were recorded and the average reading used for analysis. Respondents were informed of the findings, and if any abnormality was found or suspected, they were given a referral letter and advised to seek further treatment at the nearest health facility.

Blood investigations

All household members 18 years old and above who had verbally consented to the test were examined for the cholesterol level. If the household claimed that they were not diabetic, they were also examined for their blood glucose level. Blood glucose was determined using finger prick methods after an overnight fasting 8 to 10 hour. The results of the tests were immediately made known to the respondents.

*Cholesterol and
glucose tests*

Findings

A total of 17,251 LQs were identified during the field survey. A total of 15,519 LQs were successfully visited during the survey period while another 1,732 visits were unsuccessful resulting in an overall LQ response rate of 90.3%. Some of the reasons for non-response were 'Locked LQs' (1.8%), 'Empty LQs' (3.4%), 'Demolished LQs' (1.3%), 'Unable to Locate LQs' (0.6%), 'Not a LQ' (0.8%), 'Dangerous LQs' (<0.1%), 'Language Problem' (<0.1%) and other reasons (0.5%).

Response Rate

A total of 56,710 respondents were interviewed from 59,938 eligible individuals identified. A total of 1,828 (3.1%) individuals were not available after 3 visits and 1,400 (2.3%) eligible respondents were excluded from analysis because of refusal to participate to the modules but only response to socio-demographic module.

Some of the findings of the survey were summarized in Table 1.

Table 1 : Summary of estimated national prevalence of health problems/diseases included in NHMS III

DISEASE		PREVALENCE (%)	95% CONFIDENCE INTERVAL
Diabetes	i) Overall Diabetes Mellitus (≥ 18 years old)	11.6	11.2 - 12.0
	ii) Known Diabetes Mellitus (≥ 18 years old)	7.0	6.7 - 7.3
	iii) Newly Diagnosed Diabetes Mellitus (≥ 18 years old)	4.5	4.3 - 4.8
	iv) Impaired Glucose Tolerance (>18 years old)	4.2	4.0 - 4.5
Hypertension	Overall Hypertension (≥ 18 years old)	32.2	31.6 - 32.8
Hypercholesterolemia	Overall Hypercholesterolemia (≥ 18 years old)	20.6	20.1 - 21.3
Nutritional Status	Nutritional Status in Adult (≥ 18 years old)		
	i) Underweight	8.5	8.2 - 8.9
	ii) Normal Weight	48.4	47.7 - 49.0
	iii) Overweight	29.1	28.6 - 29.7
	iv) Obese	14.0	13.6 - 14.5
	v) Abdominal Obesity	41.2	40.5 - 41.9
	Nutritional Status in Children (< 18 years old)		
	i) Underweight	13.2	12.6 - 13.9
	ii) Normal Weight	81.4	80.8 - 82.0
	iii) Overweight	5.4	5.0 - 5.7
Asthma	i) Asthma in adult (≥ 18 years old)	4.5	4.3 - 4.8
	ii) Asthma in children (< 18 years old)	7.1	6.7 - 7.6
Smoking	i) Adult smoker (≥ 18 years old)	21.5	21.0 - 22.0
	ii) Adolescent smoker (≥ 13 years old - less than 18 years old)	8.7	7.7 - 9.8

DISEASE		PREVALENCE (%)	95% CONFIDENCE INTERVAL
Alcohol consumption	Overall alcohol consumption (≥ 13 years old)	7.4	6.9 - 8.0
Psychiatric morbidity	i) Psychiatric morbidity in adult (≥ 16 years old)	11.2	
	ii) Psychiatric morbidity in children (≥ 5 years old - less than 16 years old)	20.3	
Load of Illness	i) Acute Respiratory Illness	18.2	17.5 - 18.5
	ii) Acute diarrhoeal diseases	5.0	4.8 - 5.2
	iii) Recent illness/injury	23.6	22.9 - 24.3
	iv) Chronic pain	7.1	6.7 - 7.4
Injury	i) Home injury	6.5	6.2 - 6.8
	ii) Road injury	4.4	4.2 - 4.6
	iii) Recreational area injury	1.7	1.6 - 1.9
	iv) Workplace injury	4.8	4.5 - 5.1
	v) School injury	7.0	6.5 - 7.6
Physical disability	Overall physical disability	0.63	0.6 - 0.7
Physical activity	Overall physical inactivity	43.7	42.9 - 44.5
Women's health	i) Breat examination (≥ 18 years old)	70.4	69.5 - 71.1
	ii) Pap smear examination (≥ 18 years old)	43.7	42.9 - 44.6
Infant feeding	Exclusive breast feeding	19.3	15.5 - 23.7

Expected output

Some of the expected output from the NHMS III were :

- i) Information on identified health related community – based data will be made available for the Ministry of Health to review health priorities, programme strategies and activities and planning for allocation of resources *NHMS III report*
- ii) A report on the general findings of NHMS III and 18 research reports encompassing each research topics covered under the NHMS III will be written *Plan of action*
- iii) Several plans of actions to be formulated by relevant national and state members, based on the recommendations of the NHMS III *Presentation & publication*
- iv) Presentations at national and international conferences *Burden of Disease*
- v) Publications in local and international journals
- vi) Important prevalence findings will be used to strengthen the National Burden of Disease estimates for the midterm review of the RMK9

1. Institute for Public Health, The Third National Health and Morbidity Survey 2006: General Findings. Institute for Public Health, Kuala Lumpur
2. Institute for Public Health, The Third National Health and Morbidity Survey 2006: Study Protocol. Institute for Public Health, Kuala Lumpur

The image features a central horizontal band of light grey color. Above and below this band are solid gold-colored borders. The grey band contains abstract, flowing lines in both gold and white. On the left side, there are several concentric, overlapping arcs that sweep from the bottom left towards the center. On the right side, there are numerous thin, parallel lines that curve upwards and outwards, creating a sense of motion and depth. The text 'CHAPTER 3' is centered within the grey band in a white, serif typeface.

CHAPTER 3

IMPLEMENTATION OF MEDITAG™ HOLOGRAM IN COMBATING COUNTERFEIT MEDICINAL PRODUCTS IN MALAYSIA

SUMMARY

The use of the hologram security label (Meditag™) is being implemented in Malaysia as the Government is concerned with the problem of counterfeiting, manufacturing and selling of imitation and unregistered medicinal products. The Ministry of Health Malaysia has issued a directive to all product registration holders on the use of a hologram security device to authenticate; and to verify that products sold have been duly registered with the Drug Control Authority (DCA) and the related regulations. The hologram security label (Meditag™) is only one of the many innovative technologies that are employed by the Ministry to complement its enforcement activities in ensuring public safety and in combating counterfeit medicinal products in Malaysia.

Introduction

In 1985 Malaysia started mandatory registration of medicinal product with the Drug Control Authority (DCA) of the Ministry of Health Malaysia (MOH). This is to ensure products in the local market are safe and are of quality. Since then incidences have occurred whereby the registration numbers of other products have been illegally copied resulting in the sale of counterfeit products to the public. The hologram security labels which incorporated innovative technology was introduced in 2005. The hologram security labels complemented the use of registration numbers on the products in overcoming the problem of fraudulent registration and counterfeits. Only licensed importers and manufacturers with Good Manufacturing Practice (GMP) license are allowed to purchase the security labels to be affixed on to their products.

*Ensuring product
safety - Hologram
security labels*

Implementation

The affixation of Meditag™ hologram security label to products is only applicable to pharmaceuticals, which include traditional products and health supplements. Cosmetics are currently not included. Implementation on the use of the hologram labels have been carried out in 2 phases.

*Implementation
phases*

Phase 1 began in May 2005 for all medicinal products which are non-parenterals, and phase 2 covering parenterals/injectables implemented in July the same year. Products like vaccines and biologicals which are temperature sensitive and require cold chain maintenance are exempted from the requirement of security labelling. Local manufacturers with GMP license including product re-packers for products imported in bulk and packed locally or licensed importers shall be responsible for affixing the security device onto the individual unit packs. The hologram shall be affixed onto the outer packaging of the products on the product label. Where there is no outer packaging, the label shall be applied to the immediate packaging, that is, the bottle label. The hologram label may not be applied onto the outer shrink wrap. The customer purchasing a product should be able to locate the presence of the hologram without having to open the packaging.

All products that are meant to be supplied to hospitals including large volume parenterals should also have hologram label affixed to each individual unit of Intravenous Drip (IV Drip). None of the labelled product particulars shall be covered over by the hologram security device.

There is no specific funding from the government for the project but the pharmaceutical industries and licensed importers will have to pay for the hologram labels. Each label costs RM 0.056 and the price is not inclusive of delivery charges, insurance charges, taxes and sales duties. The minimum order is 1 roll or 2 sheets, with each roll consisting of 15,000 labels.

The Effectiveness of the Hologram Meditag™ Labels

Hologram Meditag™ labels are of high quality and the probability of this hologram labels being counterfeited is low due to the security features.

Labels are of high qualities and security features

Pharmacy enforcement officers are provided with special decoding devices and microscopes to identify and verify label authenticity. Legal action can be taken on cases involving fake products.

The Meditag™ labels are being supplied only to registered importers and manufacturers with GMP license, and it carries unique serialised numbers enabling product to be traced to its owners.

With the introduction of Meditag™ labels, manufacturers and importers can be assured that their product is safe and protected and subsequently the consumers will be protected from counterfeit products. This hologram Meditag™ labels is unique because it serves as one security label for all medicinal products in Malaysia.

Consumer Awareness

Training and awareness program in the form of road show, and seminars, for consumers, enforcement officers and community pharmacists have been conducted. A total of 1,700 pieces of decoders were distributed to pharmacies throughout the country. The next phase will be to distribute the decoders to traditional medicine wholesalers throughout the country to be used as a screening tool before the products is distributed to the consumers.

Awareness program

A public awareness programme in collaboration with the National Committee on Quality Use of Medicines has been coordinated in stages to disseminate information on the implementation and purpose of the security device. Although consumer education and awareness program will take time to succeed, nevertheless it is a giant step forward in strengthening consumers right, safety and health and in reducing the counterfeit medicinal products in Malaysia.

Proactive Measure

As a safety measure to prevent counterfeiting of the hologram Meditag™ labels, the supplier of the security label has taken proactive effort to review the security features and to enhance the hologram labels to a new version in September 2006. *Safety measure*

Penalty

The penalty for the registration holder who fails to implement the hologram label on their product under the Sale of Drugs Act 1952 is a fine not exceeding RM 50,000 for the first offence and a fine not exceeding RM100,000 for the second and subsequent offences. *Offence*

Conclusion

Combating counterfeit medicinal products must be addressed with a multi-pronged approach together with strong political will, sound legal provision, efficient regulatory system, vigilant enforcement, effective collaboration and networking with the industries. The use of technologies with the implementation of Meditag™ hologram has assisted the consumers to acquire genuine products and the enforcement in combating counterfeit medicinal products. *Multi-pronged approach*

1. The Control of Drugs and Cosmetics Regulation 1984
2. Drug Control Authority (DCA) Directives.

INITIATIVES FOR DRUG PRICE MONITORING

SUMMARY

Guided by the Malaysian National Medicines Policy (MNMP) to contain the cost of medicines and improve affordability and accessibility to quality medicines, the Pharmaceutical Service Division of the Ministry of Health initiated measures to monitor the prices of medicines. Price information collected will build a database necessary for planning and implementing strategies towards achieving the objectives of the MNMP in containing cost and improving affordability and accessibility of medicines. *My.MedPrice*, a bulletin of medicines price information for the general public was published. The initial baseline price survey showed that medicines procured by the Ministry of Health were 60% cheaper than in the private sector and the private sector medicines prices in East Malaysia were 8% higher than those in Peninsular Malaysia. The price survey launched in 2006 showed there was no price increase in 2006 in Malaysia. It also showed that medicines procured by the public sector were at acceptable prices as the prices were only 1.02 times higher than the International Reference Price (IRP). However, in the private sector, medicines were 4.87 times higher than that of the IRP. This indicates that bulk procurement of medicines by the Ministry of Health has been effective in cost containment.

Introduction

Escalating health care expenditure is a major public concern world wide. Malaysia is no exception. Medicine, being an essential component of health care, accounts substantially in the total health care cost. In fact, rising medicine cost has often been quoted as one of the major factors contributing to escalating health care expenditure.

Rising medicine prices cause increase in health care expenditure

Rising Medicines Expenditure

The Ministry of Health (MOH) is the lead government agency responsible for health matters and it provides health care services through its extensive network of hospitals and health clinics located strategically country wide. The health care services provided can be considered as practically free as the fee that a patient pays for per clinic visit is just nominal. Patients pay RM5 per visit to specialist clinics and RM1 per visit to primary health care clinics. Medicines are also provided free of charge. In the year 2000, the Ministry of Health spent RM346 million on medicines. By 2007, the medicines expenditure went up to RM1.355 billion. Medicines expenditure of the Ministry of Health expanded rapidly in recent years (Table 1) and increased by almost 4 folds in the span of 7 years.

*Ministry of
Health medicines
expenditure expanded
by 4 folds in the last
7 years*

Table 1 : Ministry of Health Medicines Expenditure (Year 2000 to Year 2007)

Year	Expenditure (Million Ringgit)
2000	346
2001	485
2002	527
2003	781
2004	808
2005	937
2006	1,252
2007	1,355

Rise in health care expenditure could be caused by increase in usage or price, or both. Many factors contribute to increase in usage or demand for health care. Population growth, aging population, increase in disease burden, rising level of affluence and changing life style are commonly cited factors. There are also factors that can result in medicine price increase. Newly introduced medicines for diseases for which no prior or less effective pharmacotherapy existed normally cost more. In the absence of price control regulations, medicines tend to increase at a rate considerably greater than that of inflation.

*Many factors
leading to increase
in medicines
expenditure*

Medicine price increase is one single factor which receives considerable public attention or may even cause public outcry if the increase is too much and unreasonable. The implication of medicine price increase on health care is often far-reaching. Uncontrolled rise in medicine price leads to escalation in medicine expenditure. It affects affordability of the public to acquire the necessary medicines. Accessibility of the public to essential medicines may also be curtailed. At present, there is a pressing need to contain rising medicine expenditure while not compromising on the quality of care as well as the access to health care for the population at large.

Medicines price increase affects affordability

Establishment of Medicines Price Unit

In 2005, the Pharmaceutical Services Division, Ministry of Health, set up the Medicine Price Unit to oversee medicine prices in Malaysia. It is envisaged that the unit will spearhead the effort to gather pertinent information and implement measures to meet the objectives as outlined in the Malaysian National Medicines Policy (MNMP). The MNMP was approved by the Government of Malaysia in 2006. Basically, the policy defines and states priority on the medium and long-term goals set by the pharmaceutical sector. It provides a basic framework for organising and improving the pharmaceutical system. The policy is essential to continually ensure equitable and timely access to good quality essential medicines that Malaysians need, and at a price individuals and community can afford. It is also essential that medicines meet appropriate quality standards, that there is a rational and sustainable financing system and a viable local pharmaceutical industry.

Malaysian National Medicines Policy

The Medicines Price Unit of the Pharmaceutical Services Division has undertaken a number of initiatives in ensuring that the Malaysian pharmaceutical system is capable of providing continuous equitable and timely access to affordable and good quality medicines especially where medicine pricing is concerned.

Medicines Price Unit undertakes a number of initiatives in medicine price monitoring

Medicines price surveys

The Malaysian pharmaceutical industry is a multibillion ringgit industry. While there are legislations governing the safety, quality and efficacy of medicines, there is still no specific legislative control over the pricing of medicines in Malaysia. Nevertheless, in order for the MOH to ensure that the MNMP is implemented especially on policy of medicine cost containment, affordability and accessibility,

nation wide monitoring of prices of medicines becomes obviously important. The Medicines Price Unit is set up to develop and build a national database on medicine prices information.

Baseline medicines price survey

Price monitoring activities started with the objective of getting an overview of medicines price trend in Malaysia. This is a prerequisite for setting up a national database of medicine prices. Initially, prices for a total of 238 brands for 30 commonly used medicines were collected from 33 public premises and 35 private premises.

*Baseline medicines
price survey*

The main findings of this baseline survey for the selected 30 commonly used medicines were:

- (i) In the private sector, medicine prices in East Malaysia were 8% higher than in Peninsular Malaysia.
- (ii) Medicines of original brands were 47% cheaper in the public sector as compared to the private sector.
- (iii) Generic medicines were 60% cheaper in the public sector as compared to the private sector.
- (iv) Medicines bought from concession company, Pharmaniaga Logistics and by tender were 60% cheaper than that in the private sector.
- (v) Medicines bought by local purchases in the public sector were 48% cheaper than that in the private sector.
- (vi) In the public sector, original brands were 33% more expensive than generics and in the private sector original brands were 114% more expensive than generics.
- (vii) Wholesale medicine prices in the public sector were 1.3 times higher than the International Reference Price (IRP).
- (viii) Gross retail prices in the private sector were 4 times higher than the IRP.

The price monitoring surveys launched by the Medicine Price Unit collected 4 data sets in 2006 and 2 sets in 2007. The survey covered 100 types of medicines and involved 93 premises comprising 44 Ministry of Health and 46 private premises in both Peninsular and East Malaysia, and 3 university hospitals. The types of medicines surveyed consisted of four groups as shown in Table 2.

Medicines price survey 2006

Table 2 : Groups of medicines surveyed

GROUPS	NUMBER OF MEDICINES	NUMBER OF BRANDS
1. Common prescription medicines and non-prescription medicines for diseases with highest morbidity	30	394
2. Newly registered patented medicines	29	29
3. Medicines with special indications such as transplant and oncology medicines	10	45
4. Top 40 most highly used medicines as reported by the National Medicines Use Survey other than those in Group 1	31	243
Total	100	711

Footnote: Private sector medicines price refers to prices obtained from the retail market and private hospitals. Medicines price from general practitioners were not included.

Summary findings of the 2006 medicines price survey involving 100 types of medicines consisting of 711 brands are as follows:

- (i) The overall prices of medicines in the public sector and private sector were found to be 1% and 9% higher respectively in East Malaysia compared to Peninsular Malaysia.
- (ii) The original brands were 3.68% more expensive than the generic brands in the public sector.
- (iii) The original brands cost about two times more (100% more expensive) than the generic brands within the private sector.
- (iv) Within the public sector, medicines price differences were fairly acceptable as the median price ratio was found to be 1.02 times higher than the International Reference Pricing (IRP).

- (v) The overall median price ratio for the private sector was found to be 4.87, meaning that prices of medicines in the private sector were 4.87 times higher compared to the IRP.
- (vi) There were no specific patterns of either an increase or a decrease of the medicines prices in Malaysia in 2006.

Publication of medicines price information

Currently, the Pharmaceutical Services Division, Ministry of Health publishes *My.MedPrice*, a bulletin on medicine prices. It is to fulfill one of the requirements stated in the MNMP, that is to provide ‘independent and objective information on price of medicines to health care professionals and consumers’. Two issues of the bulletin on the highlights of the medicine price monitoring surveys have been published so far. The bulletin can be accessed at the Pharmaceutical Services Division website www.pharmacy.gov.my.

My.MedPrice bulletin

Monitoring of newly listed medicines in the Ministry of Health Malaysia Medicines Formulary (FUKKM)

Listing in the FUKKM enables medicines to be made available in the MOH’s health care facilities. To gain listing in the FUKKM, pharmaceutical companies have to provide evidence of medical benefits and of low price. To avoid profiteering by raising prices immediately after gaining entry into the FUKKM, close monitoring of prices on these listed items are carried out. Upon submission of application to list a drug in the FUKKM, the pharmaceutical company must also submit a proposal with an agreement that there will be no price increase exceeding the quoted price for 1 year. Even after one year, the increase in price must also be duly justified. This monitoring effort has been credited to prevent newly listed medicines from causing sudden exorbitant increase in medicines expenditure in the Ministry of Health.

Measures to curtail price increase of newly listed medicines

Development of a national database for medicine price

The development of a national database for medicine prices collected from various sources and all over Malaysia will provide useful information about the true pricing picture of the local pharmaceutical industry. By providing pertinent facts and figures about medicines usage, expenditure and prices, the database can contribute tremendously towards medicines price transparency. The data can also generate output of price trending, price mark-ups and price variation among states, zones or regions.

A national database for medicine prices

Malaysian Medicines Price Index

To monitor the fluctuation of medicine prices in the country, the Medicine Price Unit is proposing the establishment of the Malaysian Medicine Price Index. The Index will be a reality when the National Database of Medicine Prices is fully developed. With reliable, valid and up-to-date medicine price data gathered through appropriate information and communication technology, the Medicines Price Index could become an official indicator on the current trend of medicine price fluctuation.

*A proposed
Malaysian Medicines
Price Index to
monitor price of
medicines*

Price control

Malaysia imposes no price control over the sale of medicines to consumers. However, the MOH as the largest provider of health care services manages to secure medicine supplies at much lower prices than the private health care sector. This is shown in the findings of the price monitoring surveys. The procurement of medicines is done through open tender and in some instances, direct negotiation. For medicines supplied under the concession agreement, the concession company, Pharmaniaga Logistics conducts similar open tender system and direct price negotiation. Through bulk purchase and open tender system, the MOH indirectly brings down the prices of medicines. Its medicines expenditure accounts for about 50% of the prescription medicines expenditure of the nation.

*Ministry of Health
procures cheaper
medicine supplies
through bulk
purchase and open
tender system*

Conclusion

Medicines price is an important issue to everyone; the individuals, the community and the government. The problem of high price affects ultimately the health and wellbeing of individuals and community. The medicine price monitoring initiatives of the Pharmaceutical Services Division are concerted efforts aimed at containing medicines expenditure as well as to ensure affordability and access to quality medicines by individuals and the population at large.

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ASEAN PHARMACEUTICAL HARMONISATION – MALAYSIA’S INITIATIVES

SUMMARY

Malaysia proposed the concept of pharmaceutical harmonisation in ASEAN Member Countries and this was agreed upon at the Senior Economic Officials Meeting (SEOM) in early 1999. The 13th meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) held in March 1999 in Manila, saw Malaysia being appointed as the leading country in the Pharmaceutical Product Working Group (PPWG). Hereof, the ACCSQ-PPWG was subsequently formed in September 1999 in Kuala Lumpur. Malaysia has since hosted three ACCSQ-PPWG meetings. To ensure consistency of product application amongst all ASEAN Drug Regulatory Authorities, the ASEAN Common Technical Requirements (ACTR) and ASEAN Common Technical Dossier (ACTD) was established and subsequently adopted for implementation. In July 2003, Malaysia initiated the implementation of the harmonised ACTR/ACTD for generic products. It was assigned to lead a task force on the ASEAN labeling requirements and was also responsible for the preparation of the ASEAN Guideline on Bioavailability and Bioequivalence (BA/BE). A BA/BE Task Force working towards Mutual Recognition Agreement was formed in the year 2005 with the appointment of Indonesia as the lead country. In 2005, a Task Force on Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP) Inspection was also formed with Singapore as the Chair and Malaysia as the Co-Chair. Under this leadership, the ASEAN Sectoral MRA on GMP Inspection of Manufacturers of Medicinal Products was drafted. To establish an efficient and effective alert system, coordinate post-marketing issues affecting the safety and quality of healthcare products within ASEAN, and to enhance pharmacovigilance capabilities among Member Countries, a Post-Marketing Alert (PMA) System has been established with Malaysia and Singapore as the first two ASEAN countries to initiate the Pilot implementation of the System. The initiatives taken by Malaysia in every aspect of the recommendations by the PPWG clearly indicated Malaysia’s full commitment towards achieving the harmonisation of pharmaceutical requirement among ASEAN member countries.

Introduction

The ASEAN Economic Community aims to establish ASEAN as a single market and production base, to turn the diversity that characterizes the region into opportunities for business complementation and to make the ASEAN *ASEAN Economic Community*

a more dynamic and stronger segment of the global supply chain by the year 2015.

In moving towards the ASEAN Economic Community, ASEAN has agreed to institute new mechanisms and measures to strengthen the implementation of its existing economic initiatives. These include the launching of the ASEAN Free Trade Area (AFTA) in 1992. AFTA aims to promote the region's competitive advantage as a single production unit. The elimination of tariff and non-tariff barriers among Member Countries is expected to promote greater economic efficiency, productivity and competitiveness. *AFTA*

Pharmaceutical Product Working Group (PPWG)

A Conformity Assessment of products or services generates results that determine their marketability. Apart from the need to ensure compliance to standards themselves, it is often that the duplicative testing procedures arising from different systems of conformity assessment in various countries have become serious barriers to trade. Recognizing the contribution of these standards and testing procedures to facilitate and liberalise trade and investment in the region, the ASEAN Consultative Committee for Standards and Quality (ACCSQ) endeavored to harmonise national standards with international standards and implement mutual recognition arrangements on conformity assessment. Priority for harmonization are given to those standards used in technical regulations amongst its Member Countries. *ACCSQ*

In 1997, the ACCSQ received a mandate to work towards eliminating technical barriers to trade posed by regulators, without compromising product quality, efficacy and safety. *Technical barriers to trade*

The concept of pharmaceutical harmonisation among ASEAN Member Countries was proposed by Malaysia and was agreed upon at the Senior Economic Officials Meeting (SEOM) in early 1999. The 13th Meeting of the ACCSQ held in March 1999 in Manila, agreed that a Pharmaceutical Product Working Group (PPWG) be set up, with Malaysia leading. This led to the formation of the ACCSQ-PPWG in September 1999 in Kuala Lumpur. *Formation of PPWG*

The term of reference for ACCSQ-PPWG is to develop harmonization schemes of pharmaceutical regulations amongst the ASEAN Member Countries to complement and facilitate the objectives of AFTA. The *Objective of PPWG*

PPWG also serves as a platform to bring together expertise and experience from both the pharmaceutical industry and the regulatory authorities of the ASEAN Member Countries. Since its inception, the PPWG has met thirteen times.

Malaysia's Initiatives Towards ASEAN Pharmaceutical Harmonisation

Being the lead country for the PPWG, Malaysia hosted three meetings as of the year 2007. The first ACCSQ-PPWG Meeting was held in Kuala Lumpur in September 1999. In its second hosting, the seventh ACCSQ-PPWG Meeting was held in Penang in July 2003, and the third again in Kuala Lumpur in July 2007.

Lead country of PPWG

The scope of the PPWG included exchanging information on existing requirements and regulations, reviewing requirements and regulations and conducting comparative studies, studying other harmonized procedures and regulatory systems and developing technical documents toward achieving a mutual recognition agreement. The multi-pronged strategies laid down in the initial work plan included comparing existing product registration requirements for pharmaceuticals, developing ASEAN common technical requirements for pharmaceutical product registration, adopting a common technical dossier and implementing the harmonised ASEAN Common Technical Dossier (ACTD).

Scope of PPWG

The harmonization project initially involved preliminary assessment of current international guidelines such as those of the International Conference on Harmonisation (ICH) and the World Health Organisation (WHO), coupled with feasibility studies, and developing common technical requirements on quality, safety, efficacy, administrative data and product information. The ASEAN Common Technical Requirements (ACTR) is a set of written materials intended to guide applicants to prepare application dossiers in a way that is consistent with the expectations of all ASEAN Drug Regulatory Authorities. By consolidating the common technical requirements, a common technical dossier - the ASEAN Common Technical Dossier (ACTD) was established and subsequently adopted for implementation. The ACTD is composed of four parts, namely Part I - Administrative Data and Product Information, Part II - Quality (Overall Summary and Reports), Part III - Non-Clinical / Safety (Summary and Study Reports) and Part IV - Clinical/Efficacy (Overview, Summary, Assessment Reports and Study Reports).

Strategies of PPWG

Commitments from ASEAN member countries are reflected by the key roles they undertook in coordinating the relevant sections. Malaysia was assigned to handle the administrative data, product information and the glossary sections. The drafting of the ACTR and ACTD started in the PPWG's Third Meeting in the year 2001 and adopted by the PPWG at its Sixth Meeting in Siem Riep, Cambodia in the year 2002.

Malaysia initiated the trial implementation of the harmonized ACTR/ACTD in July 2003 for generic products. The implementation of the ACTR/ACTD for generic products in Malaysia was implemented through an online submission of applications for registration as of 1st July 2003.

*Implementation of
ACTR/ACTD in
Malaysia*

Malaysia was also very much involved in the capacity building initiatives for the ASEAN Drug Regulatory Authorities especially in the implementation of the ACTR/ACTD. Since we initiated the ACTR/ACTD implementation earlier as compared to other ASEAN Member Countries, Malaysia was invited to provide views and knowledge in the implementation of the ACTR/ACTD to other Member Countries. Training courses and consultations were organised and conducted in collaboration with the European Committee (EC) and the World Health Organisation (WHO). Two officers from the National Pharmaceutical Control Bureau (NPCB), were appointed as facilitators to the Drug Regulatory Authorities of Vietnam and Myanmar in June 2004 and February 2005 respectively. Officers from the NPCB also participated in the 'WHO-ASEAN Harmonisation of Regulatory Requirements Country Review Visit' to Cambodia (November 2003) and Thailand (April 2004). Malaysia hosted a regional training workshop on the ACTR/ACTD in 2004 for ASEAN regulators under the EC-ASEAN Regional Economic Cooperation Programme on Standards and Conformity Assessment.

*Capacity building
initiatives*

The eighth PPWG Meeting has noted concerns regarding differences in labeling requirements in Member Countries. As there was a need for labeling harmonisation in order to reduce ASEAN trade barriers, Malaysia was assigned to lead a task force on labeling to resolve the relevant issues. It was reported that out of 16 labeling requirements, 15 items have been harmonised amongst Member Countries, except for the country-specific requirements. In this regard, the meeting agreed with Malaysia's proposal not to pursue further the harmonisation of country-specific requirements as it involved individual country laws. Consequently, the twelfth PPWG

*Labeling
harmonisation*

Meeting agreed that the list of country specific requirements should be posted on the ASEAN website as well as websites of Drug Regulatory Authorities for the reference of stakeholders.

In addition to the ACTR/ACTD, specific technical documents addressing requirements for bioequivalence/bioavailability studies, process validation, analytical validation and stability studies have also been established within the ASEAN initiative. Malaysia was responsible for the preparation of the ASEAN Guideline for the Conduct of Bioavailability/Bioequivalence (BA/BE) Studies and this was adopted at the eighth ACCSQ-PPWG Meeting in Bangkok, July 2004. Malaysia had also conducted surveys in 2004 and 2005 on BA/BE Studies and its implementation in ASEAN Member Countries. As the lead country for the ASEAN BA/BE Guideline, Malaysia successfully implemented the requirement on the conduct of BA/BE studies for generic immediate release product. The list of products requiring BA/BE before a product can be considered for registration in Malaysia has since increased to sixty nine active ingredients and this requirement will be extended to all active ingredients in future. With the implementation of requirements for BA/BE in Malaysia, expenditure on expensive innovator and imported products can be reduced and the increased usage of cheaper generic products will translate into an overall cost saving in healthcare. The need for BA/BE studies also serves as a catalyst for existing local BE centres to upgrade their facilities in meeting internationally recognized standards. This will propel Malaysia in its bid to become a Regional Centre of Excellence in the conduct of BA/BE studies. *BA/BE requirements*

The eighth ACCSQ-PPWG meeting also agreed on the possible development of sectoral Mutual Recognition Arrangements (MRA) for the ASEAN pharmaceutical sector. In view of this, the tenth ACCSQ-PPWG Meeting in 2005 appointed a BA/BE Task Force consisting of representatives from all Member Countries to be led by Indonesia, with the assistance of Malaysia. The PPWG endorsed recommendations made by the Task Force including the harmonization of the comparator product. Being the lead country for the BA/BE guideline, Malaysia has been abiding to ASEAN requirement. The next action plan will be to explore the possibility of developing a framework for mutual acceptance of the BA/BE Study Report. *MRA on BA/BE*

In 2005, the PPWG meeting also agreed to form a Mutual Recognition Agreement (MRA) Task Force on Good Manufacturing Practice (GMP) Inspection. Singapore and Malaysia co-chaired the Task Force. The ASEAN Sectoral MRA on GMP Inspection of Manufacturers of Medicinal Products was subsequently drafted. Member Countries were requested to submit final comments by 31 December 2007.

MRA on GMP

Malaysia has also been actively involved in developing the Post-Marketing Alert (PMA) System for defective and unsafe pharmaceutical/medicinal products in the ASEAN region. With the objective of establishing an efficient and effective system of alert on post-marketing issues affecting the safety and quality, the system further aims to enhance the pharmacovigilance capabilities among ASEAN Member Countries. The PPWG meeting agreed to adopt the establishment of a PMA System in the region with Malaysia and Singapore being the first two countries in adopting it.

Post-Marketing Alert System

With significant initiatives towards ASEAN pharmaceutical harmonization continuing to be developed, Malaysia will carry on its effort to be actively involved.

Effort towards harmonisation

Conclusion

The ASEAN initiatives toward pharmaceutical regulatory harmonisation is truly a unique blend of diverse practices molded into a common requirement conducive to the ASEAN pharmaceutical environment. With clearly defined agenda, efforts to harmonise pharmaceutical regulatory issues within ASEAN Member Countries will subsequently facilitate trade and market access. An important prerequisite to any harmonised approach is a firm legal foundation and well-structured drug regulatory system in each participating country. Malaysia, with its well-structured drug regulatory system in place will continue to play a leading role towards ASEAN pharmaceutical harmonisation. Nevertheless, close cooperation among ASEAN Member Countries is a catalyst towards harmonisation.

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IMPLEMENTATION OF THE EVIDENCE BASED NATIONAL CLINICAL PRACTICE GUIDELINES

SUMMARY

The development of evidence-based clinical practice guidelines (CPG) is resource and labour intensive. In spite of extensive research, there is still no strategy to effectively monitor the implementation of CPGs. It appears that the simultaneous implementation of multiple strategies may not only be the most effective method, it also fits with the comprehensive character of today's quality systems.

The CPG development group will need to decide on the combination of strategies and plans, and tailor them to the needs and feasibility of each of the CPGs. During the decision making process, the group must also consider the scheduling of strategies so that each intervention can be optimally executed to ensure sustainability of the implementation strategy.

At the national level, the strategies that should be planned by development groups are awareness campaigns, onward dissemination and practitioners' educational campaigns.

MaHTAS needs to expand its scope, strengthen its capability and increase manpower to improve the utilization of the CPGs and assess its impact on the quality of care.

Introduction

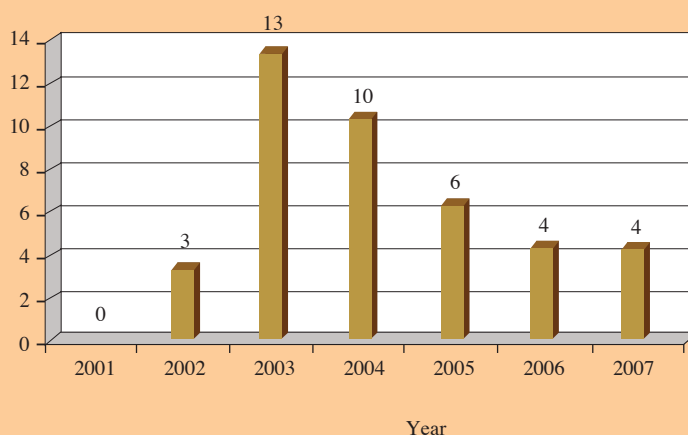
Quality of health care is of a major concern of the Ministry of Health Malaysia (MOH). There are reports demonstrating disparities in the health care system at a number of levels. One disparity is the "clinical care gap"- a discrepancy between evidence-based knowledge and day to day practice. To minimize such gaps, the MOH has mandated that all clinical practice guidelines (CPG) being developed should be based on the evidence based approach. Hence in April 2001, the Health Technology Assessment Section or now known as Malaysian Health Technology Assessment Section (MaHTAS) was identified to be the developer and coordinator for CPGs in the MOH. A handbook

*MOH's commitment
to CPG Development*

entitled “Guidelines for the development of CPGs” was produced to inform guideline developers of the processes involved in formulating evidence-based CPGs. *MOH's commitment to CPG Development*

The emphasis then, was the production of evidence-based CPGs. To date there are 48 CPGs developed as shown in Figure 1. The section is also responsible for the printing and dissemination of these CPGs. They are made available in the MOH and the Malaysian Academy of Medicine websites.

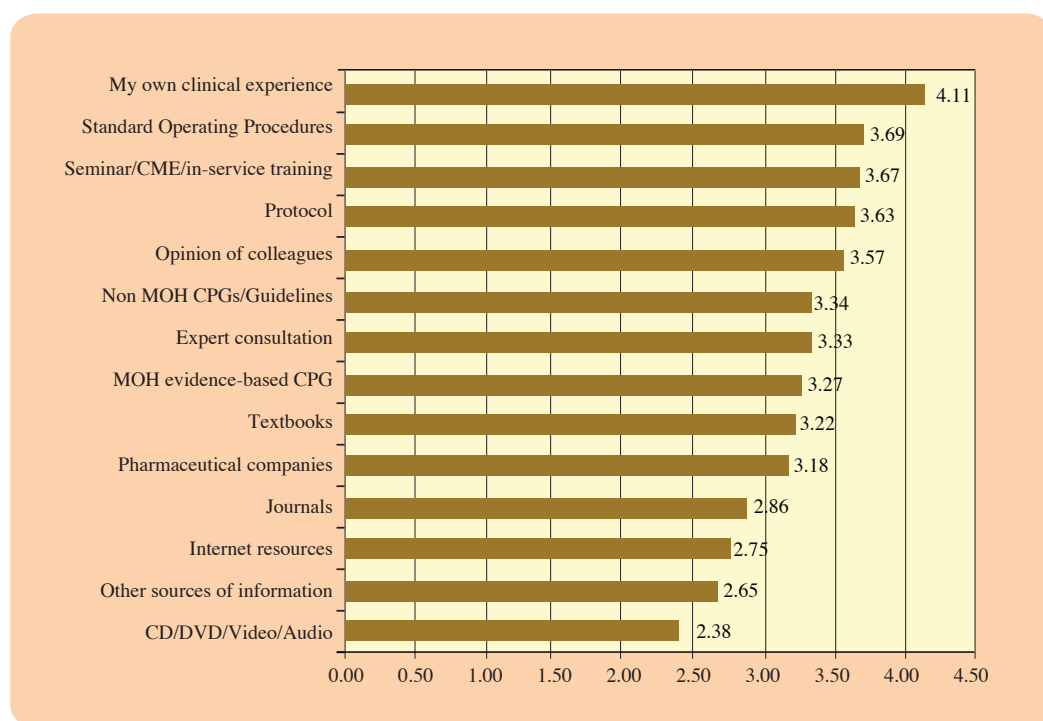
Figure 1 : Number of CPGs produced from 2001-2007



The MOH is currently concerned with the utilization of CPGs as much effort, time and resources have been invested in their development. The MOH has sought the assistance of the World Health Organisation (WHO) and in 2007 was awarded a contractual partnership for planning and implementation of the evidence-based CPGs.

Preliminary findings of a recent survey 2 on the effectiveness of CPGs in managing certain diseases in Malaysia reported nurses (44.1%) made decisions based on clinical experience (mean 4.11) instead of CPG's (mean 3.27) (Figure 2)

Figure 2 : Overall sources of information in clinical decision making



2.0 Factors influencing implementation

2.1 Levels of implementation

Three levels of implementation have been identified namely at the policy, practitioner and consumer levels. Successful implementation of CPGs, require policy changes (for example funding requirements and access to care), system changes (for example streamlining services and care pathways) and most importantly practitioner changes (changing attitudes, knowledge and decision support).

Policy, practitioner & consumer

2.2 Barriers to implementation by the practitioner

Physician adherence is critical in translating recommendations into practice. Cabana et al identified 7 barriers to physician adherence to using CPGs- lack of awareness, familiarity, agreement on what has been stipulated in the CPGs, lack of self efficacy especially

in their relevance in preventive health programs and counseling, lack of faith in the outcome, inertia of previous practices and external barriers such as guideline related barriers (CPGs are not user friendly), patient related barriers (patients resistance) and environmental barriers (difficult acquisition of resources).

In a recent meta-review, it was noted that the actual use of the CPGs depended on - ease of understanding, easiness of implementation and if they required specific resources. These factors influenced the probability of their implementation. In addition, awareness of the existence of the guidelines and familiarity with its content affects implementation. Guidelines are less likely to be followed when the patient has co-morbidities as this will not be addressed in the guideline. Finally, environmental characteristics e.g. a lack of support from peers or superiors, as well as insufficient staff and time, appear to be the main impediments to implementation.

*Role of the physician
in implementing CPG*

In addition, three systematic reviews mentioned that age of the healthcare professional and or their experience were determinants to the implementation of CPGs. Young professionals or less experienced ones are more inclined to use CPGs compared to the older and more senior specialists.

2.3 Implementation strategies

Grimshaw et al in a HTA report, found that, among the many strategies, patient mediated intervention (20%) and clinical reminders at time of consultation (14%) had moderate to large effects in affecting the practice change of the practitioners and the consumers in relation to the use of CPGs. Strategies with moderate effects were found to be educational outreach programs (11%), whilst interactive educational meetings, educational materials and formal meetings had a smaller effect. Using local opinion leaders and mass media had mixed effects.

3.0 Implementation plan for MOH

Effective 2008, MaHTAS will introduce further terms of reference for the CPG development groups. As CPGs are being formulated, implementation strategies focusing on practitioners and consumers need to be considered in order to increase the utilization of the CPGs (Figure 3).

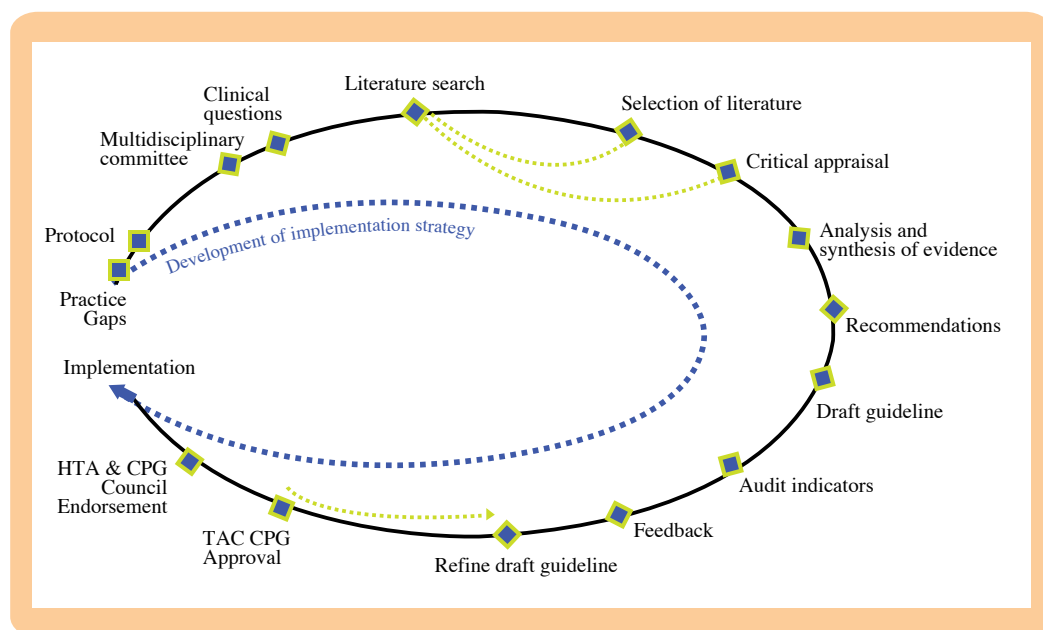
Increase terms of reference to CPG development group

Several strategies have been identified. These include mass media campaigns, practitioner's education material such as clinical reminders and training modules, audit and performance feedback, patient mediated interventions, appointment of opinion leaders and/or combined interventions.

The activities under each strategy will be planned, and tailored to the needs and feasibility of each developed CPGs. These implementation strategies would depend on the burden of disease and the variation of practice.

It is imperative that strategies at two different levels are drawn up, one at the national level and another at the institutional level. At the national level, the following strategies should be planned: awareness campaigns, onward dissemination and practitioner's educational campaigns.

Figure 3 : Guideline development and implementation plan



3.1 Awareness campaigns

(i) Creating awareness about the evidence-based CPG work processes

The development of evidence-based CPGs has been gaining popularity amongst societies and healthcare professionals in Malaysia. However, there are those who are still unaware of the advances in evidence-based CPG development. The MOH evidence-based CPGs are in line with the Appraisal of Guidelines and Evaluation of Research (AGREE) instrument which is an internationally validated guidelines appraisal tool.

Road shows

The HTA section will continue to conduct road shows in the states, universities and to the societies informing them of the evidence-based work processes. The use of booths to display the development process and existing CPGs are another platform to create awareness within the community of healthcare providers.

(ii) Creating awareness about newly approved CPGs

The expanding body of research makes it difficult for any physician to be aware of every applicable guideline and critically apply it to practice. The HTA section has already launched the CPG on Management of Dengue Infection in Adults (2nd edition) at the national level together with media coverage. This has created awareness both in the public and private sectors and has resulted in an increased demand for the CPG. Similarly, other CPGs will be launched at the national level to create awareness amongst practitioners and consumers.

Launching

(iii) User friendly features in the new CPGs

For busy primary care practitioners, it has been recommended that provisions be made to provide information on the key messages/ recommendations of the CPG. The CPG on the Management of Major Depressive Disorders (2007) and the CPG on Management of Dengue Infection in Adults (2nd edition) have all utilized this strategy.

Key messages & recommendations

(iv) Information about new CPGs using mass media

Professional journals like *Malaysia Medical Journal* and the *Medical Tribune* may be a forum that can feature the newly approved CPGs. A member of the development group will be assigned to furnish a write-up on the reasons for developing the CPG as well as highlighting the key recommendations drawn from the CPG.

3.2 Dissemination strategies

(i) Increase volume in printed CPGs

All evidence-based CPGs are made available electronically both on the MOH and the Academy of Medicine web pages. However, a large proportion of health care professionals and even medical students have been requesting for their own copy of the CPG. Therefore the MOH has decided to increase the number of copies being printed, to ensure adequate coverage for the public and private sector.

(ii) Different formats of CPG

Printed and electronic materials are widely used as passive dissemination strategies and need to be sufficiently persuasive, informative and relevant to the health care professional. Locally, professionals have been requesting guidelines be more user friendly and recommendations made more unambiguous and clear.

The MOH has considered the requests of the practitioners and are developing three different versions of educational materials namely:

- Full guidance- original guide/ source document
- Quick reference – summary of CPG recommendations with key messages and algorithms
- Patient version guidelines and patient leaflet information - these patient guidelines and leaflets are based on the full guidance that has been developed by the MaHTAS. These materials will provide education for the community at

Full guidance, quick reference and patient version guideline

large including the consumers and care giver organizations on the recommendations of best practice.

3.3 Practitioners Education Programmes

The development group together with MaHTAS will develop educational resources based on the CPGs. These training modules focus on interactive learning methods and are designed to improve the knowledge gaps among health care professionals. *Training module*

A core group of multidisciplinary trainers from each state will be identified and trained at the national. In the states, these trainers will be encouraged to organize small group training programmes targeting different categories of healthcare professionals.

To date two training modules have been developed namely for CPGs on the Management of Major Depressive Disorder and on the Management of Dengue Infection in Adults (2nd edition). Due to the lack of resources, the MOH is targeting its efforts towards healthcare professionals in the government facilities. It is fervently hoped that in the near future these training modules will be used by the relevant societies to train the general practitioners and those in the private sector.

3.4 Audit Indicators

Evidence-based (process or outcome) indicators have been introduced since 2007 for many of the CPGs that have been approved. A new performance indicator has been developed for the CPG on the Management of Major Depressive Disorder and the CPG on the Management of Hypertension (3rd edition). *Audit indicators*

It is imperative that a baseline assessment performed comparing the current practice with the recommendations. However at the current moment MaHTAS does not have enough staff to monitor these audit indicators. *Multiple strategies considered to be effective*

Conclusion

The implementation of CPG has always been a challenge for the MOH. In spite of extensive research carried out, there is still no effective strategy to monitor the utilization of CPGs. It appears that the simultaneous implementation of multiple strategies may not only be the most effective method, it also fits with the comprehensive character of today's quality systems.

The CPG development group will need to decide on the combination of strategies, plan and tailor them to the needs and feasibility. During the decision making process, the group should also consider the scheduling of strategies so that each intervention can be optimally executed and the sustainability of the implementation strategy ensured.

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MAKING THE MALAYSIAN HEALTH CARE SYSTEM SAFER: ADDRESSING THE PROBLEM OF PREVENTABLE ADVERSE EVENTS

SUMMARY

The occurrence of adverse events such as complications from medical treatment remains a perennial problem in all health care systems. Ensuring patient safety, often defined as freedom from “iatrogenic” problems, is a difficult task, with no simple solutions. It requires concerted action at all levels to address it. Making the Malaysian health care system safer has always been one of the goals of the Ministry of Health, which has made concerted efforts to implement many Quality Improvement activities that ensure the safety of its clients. Much ground work on patient safety has been undertaken by the Patient Safety Council, supported by the Ministry of Health. This has resulted in the identification of a number of key areas to be addressed and critical programmes to be implemented. Developing a safe health care system necessitates the institutionalisation of a culture of quality and safety, “non-blaming” learning culture as well as a “systems-approach”. Various key initiatives including support for the World Alliance for Patient safety activities, encouraging and supporting patient safety projects at local, regional as well as national levels, adhering to Hospital Accreditation standards and implementing Patient safety Solutions, have been instituted. In addition, research on patient safety topics as well as networking with regional and international bodies will also go a long way to ensure that a safety culture permeates the Malaysian health care system.

Introduction

Professor Charles Vincent, a world-renowned patient safety expert has been quoted as saying that *“Medicine has always been an inherently risky enterprise, with the hopes of benefits and cure ALWAYS linked to the possibility of harm”*. According to Dr. Richard Lewis, Special Advisor of the National Patient Safety Agency, United Kingdom, *“All health care systems around the world occasionally unintentionally harm patients whom they are seeking to help”*, with estimated adverse events rates ranging between 3.7% to 16%. Approximately half of these being preventable.

Even though the advent of modern, evidence-based scientific medicine in the 20th century had continually made medicine a safer enterprise, the occurrence of adverse events such as complications from medical treatment remain a perennial problem due to the increasing complexity of health care that is being provided to our patients.

Thus, while health care is usually provided safely, sometimes, things can go wrong and this is the very premise of the systems approach being advocated by patient safety experts throughout the world such as Lucian Leape, Mark Chassin and Donald Berwick of the United States. The systems approach states that a certain number of errors are inevitable in human-designed systems and this is the reality that we have to come to terms with. Our duty is to minimize such adverse events, as total elimination is not humanly possible.

Awareness of the nature and scale of adverse events in Medicine: a major public health problem

International concerns for patient safety have led to the establishment of the World Alliance for Patient Safety, a movement championed and spearheaded by the World Health Organisation (WHO), which has galvanised world-wide action for the attainment and enhancement of patient safety. It was officially launched in October 2004; Malaysia became a signatory to this noble effort in May 2006. In addition, the Patient Safety Council of Malaysia was formed in 2003 to lead national efforts to enhance the safety of our health care system, with the Director-General of Health Malaysia advising the Hon. Minister of Health on important patient safety issues.

There is now widespread awareness of the nature and scale of medical harm at international level.

Making the Malaysian health care system safer has always been one of the goals of the Ministry of Health (MOH). Numerous efforts but within the limits of its own resources have been initiated to implement many Quality Improvement (QI) activities to ensure the safety of its clients. Improving patient safety has thus become a core issue for our own health care system. However, knowledge of the best ways for government initiated efforts to improve patient safety is still evolving with actions to improve patient safety needing to operate at multiple levels of the health care system simultaneously.

Making the Malaysian health care system safer has always been one of the goals of the Ministry of Health

World-wide, safety experts are in agreement that the issue of patient safety is an enormous one. The World Alliance for Patient Safety's Global Safety Challenge targets a specific area every two years;

the first challenge being “Clean Care is Safer Care” and the present challenge being “Safe Surgery Saves Lives” for 2007-2008. Efforts to improve safety cannot be realised overnight. The massive amount of ground work undertaken by the Patient Safety Council, supported by the MOH, has resulted in the identification of a number of key areas to be addressed and critical programmes being implemented. It should be noted that the pursuit of quality and safety is not a one-person crusade but one that requires the concerted efforts of all the major stakeholders.

The issue of patient safety is an enormous and difficult one.

Developing a safe Malaysian health care system necessitates the institutionalisation of a culture of quality and safety within the Malaysian health care system. The first step to a safer health care system is for everyone to acknowledge that the provision of health care is a risky enterprise – which health care organisations are to be considered as “high-risk organisations”. The problem of preventable adverse events is a perennial one. The next step is to develop a “non-blaming” or “non-punitive”, learning culture.

Developing a safe Malaysian health care system necessitates the institutionalisation of a culture of quality and safety within the Malaysian health care system.

Having set the general tone in its “non-punitive and non-blaming” policy towards medical mishaps, many other initiatives have been implemented by the Patient Safety Council and the MOH. These include the following:

Patient Safety Council activities

- (i) Commissioning three WHO experts on patient safety from Australia and the United Kingdom to assist in the development of *Patient Safety Strategies* for Malaysia, including *National Patient Safety Goals and Targets*. These strategies are being fine-tuned by the Medical Care Safety Technical Advisory Committee of the Patient Safety Council. Policies and Standards on Risk Management based on the Australian/New Zealand Risk Management Standard 4360 have also been formulated by the WHO Consultant. In the pipeline will be the formulation of policies relating to managing of adverse incidents and open disclosure.
- (ii) An important product of a non-blaming culture is a mandatory Incident Reporting and Learning System where national data can be obtained regarding “clinical incidents”. In addition, a voluntary reporting system of “near misses” or “other non-mandatory incidents” is also essential to delineate the incidents that lessons can be learnt from. To this end, the MOH has already been monitoring 31 incidents in MOH hospitals. An electronic Malaysian Incident Reporting Information System

An Incident Reporting and Learning System is vital for sharing of information on patient safety so that adverse events can be prevented or minimised in future

(MIRIS) has been developed and tested, assisted by our WHO consultant for patient safety. It has been piloted in Hospital Kuala Lumpur.

- (iii) A National Report Card on patient safety is also on the cards. The MOH will be monitoring 33 key patient safety indicators from 2008. An electronic Patient Safety Indicators programme is expected to be developed in the near future to further enhance the indicator feedback system by providing near real-time data on patient safety performance.
- (iv) A study conducted in 2005 by the Institute for Health Management on the prevalence of adverse events in an MOH hospital reported a rate of 3% of adverse events occurring among hospitalised patients. A larger scale effort is being undertaken by the MOH under the auspices of the National Patient safety Council to study 13 core areas of patient safety. These studies will be conducted by the Institute for Health Systems Research in 2008
- (v) International Networking: WHO's World Alliance For Patient Safety and First Global Patient Safety Challenge 2005 - 2006

International networking is vital for the dissemination of lessons in safety as well as collaborative efforts to promote patient safety

On 15th May 2006, the Honourable Minister of Health Malaysia signed Malaysia's country pledge to support the WHO's Global Challenge for Patient Safety in the presence of key WHO officials from Geneva. The Global Patient Safety Challenge 2005-2006: "CLEAN CARE IS SAFER CARE" focused on improving hand hygiene standards in healthcare and on helping to implement successful interventions. The 1st Global Patient Safety Challenge targeted an increase in hand hygiene compliance among health care providers. Strategies on Hand Hygiene activities were as follows:

Malaysia is a signatory to the World Alliance for Patient Safety

- National guidelines produced (adopted WHO document) in 2006.
- Hand Hygiene Campaigns conducted at national level (2006) and State level (2007) had contributed to the increasing awareness on the importance of hand hygiene compliance and practice.

- Continuous training on hand hygiene in all hospitals as regular or routine activities of the infection control units.
- Budgetary allocation for alcohol-based hand rub (ABHR)
 - o Critical care areas in hospitals -targeted in 2006.
 - o Hospital-wide implementation in 2007 with a request for extra budget being made.
- Distribution of educational materials on the techniques of hand hygiene and 5 moments in hand hygiene.
- Observation of hand hygiene practice with a component from WHO Multi-modal Hand Hygiene Strategies and Tools (was adopted in 2007).

The MOH is also strengthening its Infection Control programme through increased budgetary allocations as well as strengthening its monitoring capacity through the monthly monitoring of MRSA and ESBL Klebsiella organisms. Twice yearly Nosocomial Infection Surveillance is also carried out in collaboration with the University hospitals.

(vi) Hospital Accreditation Programme

Sixty Government hospitals and 17 private hospitals had successfully attained the accreditation status awarded by the Malaysian Society for Quality in Health (MSQH) by December 2007.

The Hospital Accreditation Programme conducted by the MSQH is a key enabler of a culture of safety in health care organisations

(vii) Clinical Audit of Peri-operative Deaths – the MOH

Perioperative Morbidity And Mortality Review (POMR)

The 6th POMR Report was printed and distributed in late 2007. The 7th Report (2004 – 2006) is expected to be published in 2008. A total of 30 bulletins concerning POMR deaths that can be used as continuing professional education and "lessons learnt" have been published to date. In addition to the ongoing audits, targeted morbidity and mortality reviews have been implemented.

Clinical Audits have a very important role to enhance patient safety

(viii) Clinical Audit of Adult Intensive Care Units (NAICU)

This programme began on 1 February 2002 with the aim of improving the quality of care of intensive care services by identifying remediable deficiencies within the service. Fourteen State hospitals (except Kangar Hospital) with 4 or more ICU beds (including Hospital Selayang) are involved in this study. One of the spin-offs from this study was the introduction of the VAP Care Bundle programme, initiated in 2006 to improve the safety of ICU patients.

(ix) Blood Transfusion Safety

The Blood Transfusion Safety Technical Advisory Committee of the Patient Safety Council has formulated a number of action plans to ensure the safe administration of blood including the development and implementation of Guidelines for the Transfusion of Blood Products

(x) Undergraduate Programme on Patient Safety

Discussions are under way, led by the Continuing Professional Development and Consumer Education TAC to incorporate patient safety topics into the Medical student under-graduate curriculum. Patient safety topics will also be incorporated into the “post-basic” curriculum for nurses.

Making safety a universal agenda should extend to all health care under-graduates and entrants to the health care professions

Future PLANS

Malaysia will continue to support the WHO in its Global Patient Safety Challenge. The “Clean Care Is Safer Care” Campaign will continue to be undertaken in all MOH hospitals while a new programme for “Safe Surgery Saves Lives” will be developed by a panel of technical experts. Issues to address will include; Surgical Site Infections, Safe Chest Tube insertion, Patient Identification and Correct Surgery, National “Time Out Day” for safe surgery. Malaysia will ratify this initiative officially in 2008.

Training in Root Cause Analysis (RCAs) Training for MOH staff will be conducted in 2008 for a select group of “Quality Champions” who will then conduct “Echo training” for other MOH members.

A Registry of Trained staff will be developed and they will constitute the pool to conduct RCAs and external enquiries when needed.

Implementation of Evidence-based Patient Safety Practices: Care Bundles and other individual Patient Safety Practices

Other care bundles such as Catheter-related Blood Stream Infection prevention are planned to be implemented in 2008. The Acute Pain Services will continue to be expanded while the VAP protocols are planned to be expanded to all specialist hospitals in the MOH.

Conclusion

The achievement of patient safety is a never-ending journey and poses a major challenge for everyone. Much more needs to be done to improve safety in our health care system.

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2. Walshe E, Boaden R. Reporting and preventing medical mishaps; lessons from non-medical near-miss reporting systems. *British Medical Journal*. 320:759-763
3. World Health Organisation: World Alliance for Patient Safety <http://www.who.int/patientsafety/worldalliance/alliance/en/>
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HEALTHCARE SPENDING: PUTTING HEALTHCARE FINANCING INTO PERSPECTIVE

SUMMARY

National Health Accounts (NHA) is a tool which describes public and private expenditure flows within the health sector of a country. NHA describes, in an integrated way, who pays, how much and for what. The Malaysian NHA puts into perspective healthcare financing information that provides a profile of current public and private health expenditures, and provides inputs for development of health financing strategies. The 2006 NHA Report indicates a rising trend in health expenditure, with private expenditure surpassing public since 2004, and curative care being the largest in both sectors. Another interesting trend is that private household out-of-pocket expenditure is the highest, with the bulk being spent on ambulatory healthcare. In terms of healthcare financing, it indicates a willingness to pay, and a source of finance to tap. This trend is occurring despite the comprehensive public service being provided free at point of care. There is a need to look at the responsiveness and the level of acceptance of public facilities.

Introduction

National Health Accounts (NHA) describes expenditure flows within the health system of a country, in both the public and private sectors. The Malaysian National Health Accounts project was initiated by the government in 2001. Total Health Expenditure (THE) is the standard definition of areas of health spending measured and reported in national totals. The first report published in 2006 for the period 1997 - 2002, was the first attempt to organise and document THE. Before this, figures on private health expenditure were scanty, while the most available health expenditure figures were from the public sector – hence an underestimated figure of health expenditure as a percentage of Gross Domestic Product (GDP). The second report made public covered the period 1997 - 2006 and is a refined and improved version of the first.

*National Health
Accounts (NHA)*

This paper looks at the NHA from the healthcare financing (HCF) perspective, in particular issues with implications on HCF arising from NHA findings, namely:

- funders and payers of care:
- sources and quantum of financing of curative care and relevant preventive care/activities, and
- providers of care.

These will be discussed with reference to care provision in terms of hospital (in-patient) and ambulatory (out-patient) care

The Value of NHA

NHA is a tool that describes public and private expenditure flows within the health sector of any country. It describes the sources, uses, and channels for all funds utilised in the whole health system, in short - who pays, how much and for what. Hence, NHA provides a broad view of the sources and uses of health expenditures in Malaysia. These include private-public mix in terms of financing and provision, but within the constraints of assumptions used in data mining and collection and their subsequent analyses.

*NHA Describes
Sources,
Uses and Channels of
Health Funds*

There are limitations to NHA, among others, a financial rather than an economic approach to costs, and the inability to look at allocative efficiency. NHA does not make the distinction of whether the expenditure is justified (appropriate). Be that as it may, the public sector has good grounds to attest to better health outcomes from public goods and preventive care provided (accepted indicators of justified financing).

NHA adds value when there is government and civil society concerns about whole system financing and financing reforms, and when there is a need to look critically at resource allocation. NHA thus, raises the standard of planning health system strategies, from the management of programs to government appraisal.

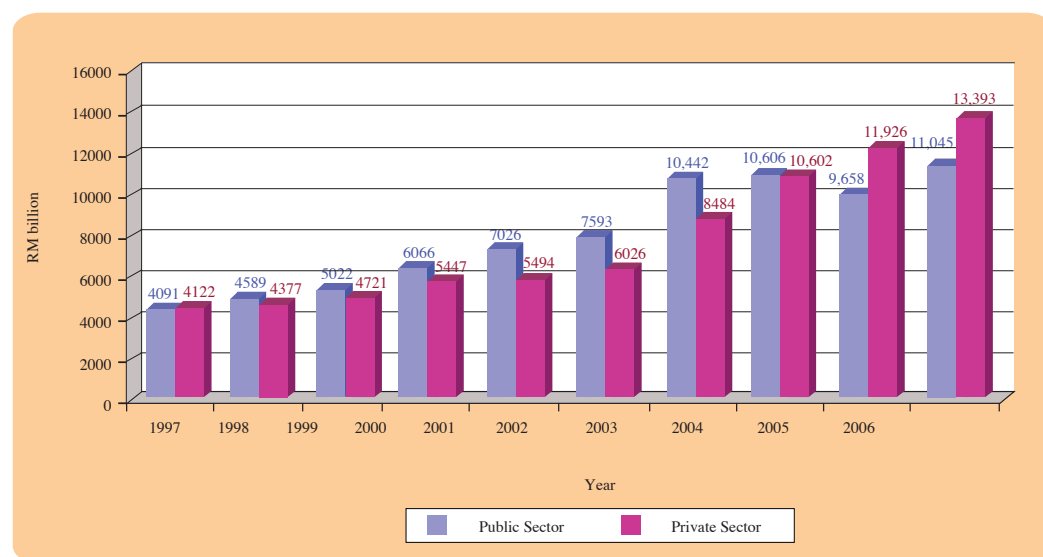
NHA Findings: The Global Picture - Quantity of Financial Resources Used for Health and Usage Trends

The following findings are reported.

- There is a rising trend in health spending in public and private healthcare sectors (Figure 1). Malaysia's THE has a Compound Annual Growth Rate (CAGR) of 11% from 1998 to 2006, driven by rapid adoption of advanced medical technologies, an ageing population and a more demanding public.

Rising Trend In Health Expenditure

Figure 1 : Total Expenditure on Health by Source of Financing (Public versus Private), 1997 - 2006



- In 2006, the THE was RM24.788b, with public and private healthcare expenditures at RM11.045b and RM13.743b respectively. Current literature indicates that medical cost pressures are highest in Malaysia relative to Hong Kong and Thailand. Private healthcare expenditure has overtaken public expenditure beginning year 2004. This trend continued into 2005 and 2006. The list of payers in the private sector is shown in Table 1.

Private Health Expenditure has Overtaken Public

Table 1 : Total Expenditure on Health in the Private Sector by Sources of Financing, 2006¹

SOURCES OF FINANCING IN THE PRIVATE SECTOR	RM b	%
Private household out-of-pocket	10,050	73.13
Private insurance enterprise (other than social insurance)	1,899	13.82
All Corporations (other than health insurance)	1,634	11.89
Private MCOs and other similar entities	82	0.60
Non-profit Institutions serving household NGOs	69	0.50
Rest of the World	9	0
Total	13,743	100.00

MCO – Managed Care Organisation

NGO – Non-government Organisation

- MOH expenditure, in real and nominal terms, has increased despite the fact that due to inflation, the ringgit in 2005 (reference year 100) is worth only 26.8 cents its value in 1970 (Appendix A). The 2004 MOH expenditure remains on record as the year with the: *Increasing MOH Expenditure*
- highest percentage of national budget (8%) compared with other years,
- highest percentage of Gross National Product (GNP) at 3.63% (4.5% GDP), and per capita expenditure (RM362)²
- per capita expenditure increasing three fold in 20 years.
- Total curative care expenditure increased from 60% in 2002 to 63% of THE in 2006. In numerical terms, THE figures were estimated at RM14b and RM24.8b for 2002 and 2006 respectively. In 2006, private expenditure for curative care exceeded public expenditure (Table 2). *Increasing Expenditure for Curative Care*

¹ Table 5.6 MNHA Health Expenditure Report (1997-2006)

² Since then % GDP has plateaued

Table 2 : Breakdown of Curative Care Expenditure, 2006

SECTOR	THE (2006) RM (million)	%	Curative RM (million)	%
Public	RM 11,045	45	7,417	48
Private	RM 13,743	55	8,150	52
		100		100

- Curative care³ consumed the largest amount - RM15.56b or 63% for total public and private sector expenditure (Table 3). The “other expenditure” component totalled RM9.2b of which private expenditure is large at RM5.59b. It constitutes 41% of private expenditure⁴ with the major components being:

- Ancillary services RM 2.432b
- Medical goods to out-patients RM 1.723b

Ancillary services include clinical laboratory, diagnostic imaging, patient transport and emergency rescue among others. Medical goods dispensed to out-patients include pharmaceuticals (inclusive of traditional and alternative medicines), therapeutic appliances and other medical durables and non-durables.

Table 3⁵ : Breakdown of Care by Sector

SECTOR	TOTAL EXPENDITURE (RM b)	%	CURATIVE CARE EXPENDITURE (RM b)	%	OTHER EXPENDITURE ⁶ (RM b)	%
Public	11.05	44.6	7.417	47.6	3.633	39.4
Private	13.74	55.4	8.150	52.4	5.590	60.6
Total	24.79	100	15.567	100	9.223	100

³ This classification is by function and includes in-patient, day care, out-patients services of curative home care

⁴ see Table 5 for the OOP component

⁵ Taken from Tables 5.5 and 5.8 of MNHA Health Expenditure Report 1997-20

⁶ This excludes those in footnote 3 and encompasses rehabilitative care, long term nursing care, ancillary services, medical goods dispensed to out-patients, public health services (including prevention and health promotion) and health programme administration and insurance.

- In terms of care setting (hospital/non-hospital) for curative care, hospital care (73%) takes the bulk of the expenditure for both sectors (Table 4). Expenditure for non-hospital setting in the private sector is more than double that of the public sector. *Higher Workload in Government Hospitals*

Figures from the National Health and Morbidity Survey III (NHMS III) in 2006 indicate that government hospitals have four-fold higher admissions than private hospitals, yet have an expenditure of only 1.25 times larger than private hospitals. This brings into question the efficiency factor and the charges levied on patients in the private sector.

Table 4: Breakdown of Curative Care Expenditure by Sector and Level of Care⁷

SECTOR	HOSPITAL CARE (RM b)	NON-HOSPITAL SETTING CARE ⁸ (RM b)
Public	RM 6.2b ⁹	RM 1.2b
Private	RM 5.1b ¹⁰	RM 3.1b
Total	RM 11.3b	RM 4.3b

- Spending on research is low (<0.03%) and spending by local authorities on health is also low. Funding for training of health personnel made up 3.4% of THE in 2006. Private sector expenditure on training is less than that of the public.
- Present administrative costs for public sector seem low at 8.7%. However, for private health insurance it is 37% - a forewarning of the need to design a social health insurance system that is efficient.

⁷ Modified from Figure 7.1 of MNHA Health Expenditure Report (1997-2006)

⁸ Non-Hospital setting care (ambulatory) is classified under Function of Health Care (expenditure by function) This should not be confused with Ambulatory Care under the classification of Providers of Health Care as reported in paragraph 3.3.1

⁹ MOH portion RM 5.242b. Note: These include out-patient curative care (RM 2.8b) and day cases at hospital setting (RM 202m). (Table 6.3 of MNHA Health Expenditure Report 1997-2006)

¹⁰ In terms of efficiency and cost per patient, government hospitals (excluding MOH special institutions) admit 8 2.6% of cases compared with 16.9% in private hospitals (NHMS III). The Health Informatics Centre, Ministry of Health reported that the total admission into MOH hospitals in 2006 was 1,895,787 patients.

Healthcare Financing: Sources of Financing

All finances ultimately come from people or activities of people. Hence, it is important for any financing study to not only look at the funding agent (government, insurance, corporations etc.) but also at sources of funds. The major sources of THE in 2006 were:

Major Sources of Health Funds

- Household out-of-pocket (OOP) expenditure, the main source, at RM10.05b
- General revenue (central government) at RM9.234b
- Private insurance (other than social insurance) at RM1.899b and
- Payment from All Corporations (other than health insurance) at RM1.634b.

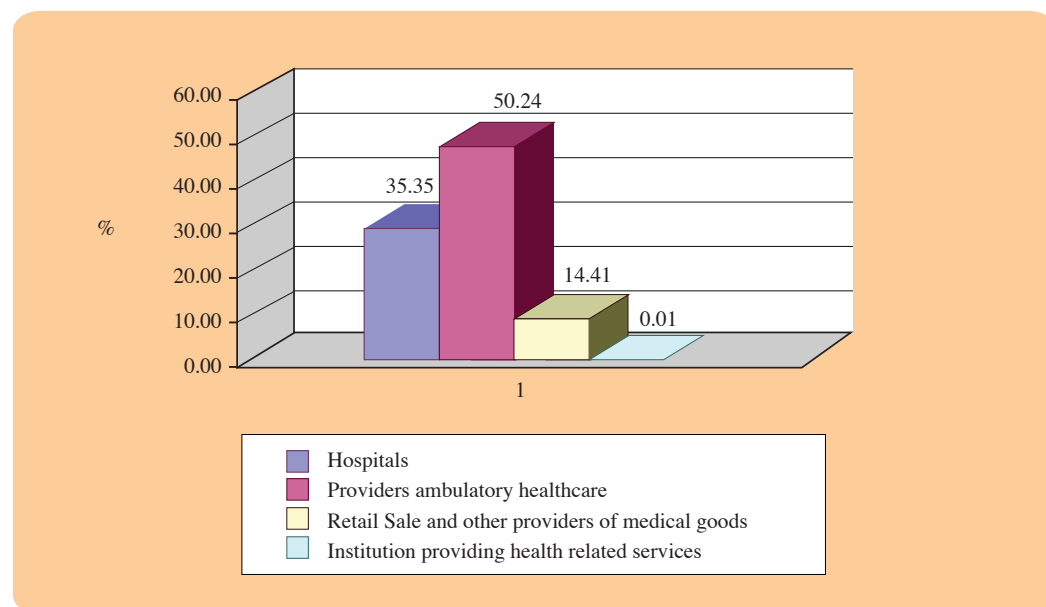
The review below focuses on the principal payers for curative and preventive care other than the Government.

Out-of-pocket (OOP) Expenditure

From the perspective of financial sources, OOP expenditure in 2006 (RM10.05b) was the largest source, followed by central government (RM9.234b). In 2001, OOP expenditure (RM4.045b) was less than central government expenditure (RM7.026b). The bulk of OOP expenditure was on ambulatory¹¹ healthcare (RM4.925b) followed by hospital expenditure (RM3.466b) (Figure 2).

¹¹ Providers of ambulatory care includes medical practitioner clinics, dental clinics, traditional and alternative care, among others

Figure 2 : Cross Classification of Private Household Out-of-Pocket Expenditure by Provider of Health Services, 2006



Other OOP expenditures were on ancillary services and purchase of medical goods (Table 5).

Table 5 : Cross-Classification of Private Household OOP Expenditure by Providers of Health Services, 2006¹²

PROVIDERS OF HEALTH SERVICES	RM (million)	%
Providers of Ambulatory Care	4,925	49.0
Hospitals	3,466	34.49
Retail Sale and other providers of medical goods	1,413	14.06
Institution providing health related services	246	2.45
Total	10,050	100.0

¹² Source: MNHA Health Expenditure Report (1997-2006)

In summary

- OOP expenditure accounts for the highest proportion of private source of funding *Salient Points on OOP Expenditure*
- OOP expenditure for ambulatory care was more than hospital care (and surpassed that spent by government for out-patient services)¹³
- OOP has risen from 32% (2001) to 40% (2006), a demotion in terms of national economic development status. OOP is more in less developed countries while developed countries have a low percentage of OOP payment.
- The poorest 10% of the population suffers from a high financial burden of OOP, even though public service is delivered almost free of charge. This phenomena needs to be investigated in the context of access and preference¹⁴.

The likely reasons for the high OOP expenditure may be consumers' preference/choice or non-responsiveness of the public sector, one of which is the long waiting time for treatment of some conditions.

The findings indicate that the public, in particular the middle income groups, is willing to pay when goods are affordable (without reference to quality). This has been facilitated by economic forces operating in a saturated out-patient market that has kept prices down.

This makes OOP an important source of funds. There is a need to harness this fund for greater efficiency in relation to healthcare financing and the strategy to make primary care doctors gatekeepers.

In contrast, expensive hospital care is less affordable, and private hospital care is expensive. In general, OOP is regressive and there is a need to address catastrophic expenditure incurred by those in the lowest decile¹⁵. *OOP is Regressive*

¹³ see 3.3.1

¹⁴ sources: Health Expenditure Surveys (HES) 1998/1999 and 2004/2005

¹⁵ World Health Survey 2002, Country Report for Malaysia (Volume IV), reported that 4% of households were exposed to catastrophic spending and 2% impoverished.

Insurance

Worldwide, from 1998 to 2004, expenditures on private pre-paid plans grew 9.5% CAGR. This growth was highest in three countries (Malaysia, Hong Kong and Thailand), with private hospitals receiving 70% of the revenue. Insurance sources report an association between the recent regulation on fees and an increase in hospital bills, and the insurance industry has expressed concerns on the rising claims in the last three years. However, the NHA reports the reverse, with claims being only slightly more than half of premiums collected.

Check and Balance

The existence of pricing standards provides Malaysia's healthcare system with greater price transparency than Hong Kong or Thailand. The MMA fee schedule¹⁶ has improved insurers' ability to manage physician fees, but they lament the absence of regulations to standardise hospital charges. A 1996 study indicated that doctors' fees constitute 40% of the total hospital bill¹⁷. The study needs to be repeated to determine trends.

Healthcare Financing: Types of Care and Goods Purchased

A study of healthcare financing is incomplete without it being complemented by the “*sources and uses*” matrix. These matrices have been developed to assist policy making.:

Ambulatory Care

- The total expenditure on ambulatory care was RM7.743b. Expenditure by public facilities showed 20% of total expenditure (RM1.491b) on ambulatory care¹⁸. The private sector expenditure constituted the remainder 80% (RM5.952b), of which the principal source was OOP (RM4.925b).

Hospital Care

- Cross classification of providers and sources of healthcare showed that 55% of hospital expenditure was incurred in the public sector (RM6.2b), while that in private hospitals was 45% (RM5.1b). In the public sector the largest expenditure was in MOH hospitals (RM5.2b).

¹⁶ Regulation on fees under the Private Healthcare Facilities and Services Act 1998 was published; this has become the reference

¹⁷ Healthcare Cost in Malaysia: Dr. Lim Kuan Joo 1996

¹⁸ Source: Table 13. Zailan A (2008). Laporan Bengkel Akaun Kesihatan Nasional Malaysia

Inferences from the Healthcare Financing Perspective

- Expenditure has been rising steeply in the last few years. Hospital care in particular, is on the increase in the public and private sectors – hence a need to look at trends in cost containment initiative such as day care, day surgery and ambulatory care. Retail expenditure for supplementary health goods has declined. Public sector is still the main player in providing public goods such as preventive and promotive services.
Expenditure for private and public hospital care is on the increase
- Based on workload, the public sector sees and treats more cases than the private sector, and at lower cost. This brings efficiency in the private sector into question. The prices charged by hospitals, excluding consultant fees, need to be standardised. This has been voiced by the private health insurance industry
- Payment to providers in the private sector is an issue. Expensive private hospital care can be attributed in part to the fee-for-service payment mechanism and its inherent moral hazards. Hence, it is imperative that payment system based on capitation for primary care and case-mix Disease-related groupings (DRG) for in-patient care be implemented rather than outright fee-for-service¹⁹.
Fee-For-Service Payment Mechanism and Moral Hazards in the Private Sector
- The RM13,743 million spent in the private sector needs to be taken into account in the planning of the healthcare financing mechanism, in particular the non-OOP, amounting to RM3.693b. This amount is paid by insurance, corporations, private Managed Care Organisations (MCOs) and similar entities, non-profit institutions serving household NGOs and Rest of World. Issues arising includes:
 - o Role of private insurance: in some countries, private insurance are not allowed to offer what is being offered by the National Healthcare Financing Mechanism (NHFM). Its role is supplementary and offers are limited to what is not provided or eligible for under the NHFM,
 - o The position of contributions by corporations through insurance or via MCOs (third party) or direct payment to providers is another issue, when contribution to the National Health Insurance (NHI) is mandatory.

¹⁹ A living example is South Korea today. The majority of hospitals are for-profit and despite a closed hospital system and high co-payment, the fee-for-service provider payment system has put the Nation Health Insurance Corporation (NHIC) in the red. The Korean government came to the rescue by earmarking sin tax (tobacco) for health.

- o The high OOP expenditure by the population indicates a willingness to pay, more for primary care than hospital care. A large sum is also spent OOP for ancillary services and medical goods to out-patients. OOP should be incorporated into a strategy to reduce moral hazard in terms of co-payment and extraneous payment for ancillary services and medical goods. *High OOP Expenditure Indicates Willingness to Pay for Ambulatory Care*
- o High OOP in some developing countries is associated with relative under-spending and under-provision by the authorities. The World Health Organisation (WHO) has indicated that developed countries, the majority of which have social health insurance, have a low percentage of OOP payments at 18%, while OOP for upper middle income countries stand at 30%. Malaysia's figure of 40% is high despite the fact that healthcare provided by government is highly subsidised and comprehensive. This may reflect public preferences and the responsiveness (or lack of) of the public service.
- At present, public healthcare administrative cost is low at 8.7%²⁰. Any rise will lead to increase in overall cost of healthcare. The National Health Security Fund Study in 1985 estimated administrative cost at 18%. The challenge is to develop a mechanism that is efficient.
- NHFM needs to package attractive services:
 - o Package it in such a way to entice population, for example in terms of subsidized primary care, affordable hospital care and financial protection safety net in event of catastrophic payment
 - o Develop public facilities that are at par with private facilities in terms of aesthetics, courtesy and other public relations aspects

²⁰ Cost of Administration in US and Canada is 31% and 16.7% of healthcare expenditure respectively (1999), NEMJ 2003; 349:768-75.

Conclusion

NHA has provided useful insights into health spending and the main players in the provision of healthcare. The public, in particular, the middle income group, is willing to spend out-of-pocket for healthcare. The Health Expenditure Surveys (1998/99 and 2004/2005) has indicated that OOP expenditure in Malaysia is mildly progressive for this group. There is opportunity for the healthcare financing mechanism to tap into this source of financing. However, there is a need for further study into the lowest decile where OOP is still regressive.

NHA data provides useful input into the design of healthcare financing mechanism for Malaysia in terms of preferences of the public, the responsiveness of the public delivery system and the need to look closely on the appropriateness of care and pricing in the private sector.

*NHA Provides Useful
Inputs for and Future
NHFM*

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Health Budget

All values in Ringgit Malaysia (RM)

YEAR	TOTAL MOH ²¹ BUDGET NOMINAL	TOTAL MOH BUDGET REAL	Per capita (real)	Inflation
2005 ²²	7,860,430,500 ²³	7,860,430,500	301	100.0
2004	8,997,011,200	9,265,716,992	362	97.1
2003	7,556,006,410	7,895,513,490	315	95.7
2002	6,299,073,770	6,658,640,348	271	94.6
2001	5,765,553,410	6,206,193,121	240	92.9
2000	4,931,315,300	5,377,661,177	231	91.7
1999	4,512,258,219	4,996,963,697	220	90.3
1998	4,237,960,000	4,826,833,715	218	87.8
1997 ²⁴	3,446,938,00	4,128,069,461	191	83.5
1996	3,424,700,000	N/A	N/A	N/A
1995	2,593,231,000	3,299,276,081	159	78.6
1992	2,352,578,600	3,327,692,503	126	70.7
1990	1,840,300,000	N/A	N/A	N/A
1988	1,239,399,700	2,031,802,786	120	61
1983	1,034,468,227	1,830,917,215	123	56.5
1982	1,184,172,130	2,176,787,003	150	54.4
1981	1,011,686,365	1,964,439,543	139	51.5
1980	895,579,857	1,909,551,933	139	46.9
1975	405,011,250	1,071,458,333	88	37.8
1970	183,033,101	682,959,332	65	26.8

*Source: Health Informatics Centre, Planning and Development*²¹ Source: Health Informatics Centre, Planning and Development Division²² Reference year 100 – Department of Statistics, Malaysia²³ Source: Malaysia National Health Accounts²⁴ recession

NATIONAL REGISTRIES

SUMMARY

The patient registry is a valuable tool which provides timely and robust data on the real world view of clinical practices, patient outcomes, safety and treatment comparative clinical and cost effectiveness. The Ministry of Health, through the Clinical Research Centre, supports a growing number of registries covering a variety of therapeutic area such as nephrology, transplantation, ophthalmology, neonatal, endoscopy, trauma, diabetes, cardiology, oncology and orthopaedics. Registries provide clearly needed hard data and evidence to support our policies and clinical decision-making in improving access to treatment and in improving the provision and delivery of clinical services (cancer care, dialysis, coronary care etc) in Malaysia. A patient registry is also useful for pharmaceutical and medical device companies to evaluate safety signals and determine factors leading to adverse outcomes in a patient population.

Introduction

A patient registry is a carefully organized system that uses observational study methods to collect uniform data (clinical and others) to evaluate specified outcomes for a population defined by a particular disease or therapy (target disease or therapy) and that serves one or more predetermined scientific, clinical, or policy purposes. The resulting clinical database describes a file (or files) derived from the registry.

*Patient registries
vital to evaluate
population outcomes
for a particular
disease*

Patient registries have four common objectives. These are to:

1. Describe the natural history of the target disease
2. Determine the clinical and cost effectiveness of treatments for the target disease
3. Monitor the safety and harm of therapeutic products and services for target disease
4. Evaluate access to, and quality healthcare for the target disease

Natural history of the target disease

Patient registry data derived from real-world clinical settings is ideally suited to describe the characteristics of patients, the healthcare they received, and the resulting long term patient survival and quality of life outcomes. The data is also useful for describing the variations in patient care and outcomes across different patient groups, clinical practices, healthcare sectors or geographic regions, and the secular trend over time of such variations in Malaysia.

Data from registry may be used to identify differences in patient care

Clinical and cost effectiveness of treatments for the target disease

Patient registry data from real-world clinical practices in Malaysia is also useful for determining the clinical and cost effectiveness of treatments provided. Multiple studies have demonstrated disparities between the results of clinical trials and results in actual clinical practice. Furthermore, efficacy in a clinical trial for a well-defined population may not be generalizable to the Malaysian population. The registry is also particularly useful for tracking effectiveness outcomes for a longer time period than is typically feasible with clinical trials.

Efficacy in a clinical trial may not be generalizable to the Malaysian population

Beyond clinical effectiveness, the registry may also be designed to collect resource use and cost data for the same patients to be used in modelling cost effectiveness. Cost effectiveness refers to a means to describe the comparative value of a health care product or service in terms of its ability to achieve a desired outcome for a given unit of resources.

Registry can be used to collect information on the cost effectiveness of a particular treatment

Monitoring the safety and harm of therapeutic products and services for the target disease.

The patient registry can serve as an active surveillance system for the occurrence of unexpected or harmful events for products and services. Patient registries offer several advantages for active surveillance. First, the current practice of spontaneous reporting of adverse events relies on a non-systematic recognition of an adverse event by a clinician and the active effort by the clinician to make a report to manufacturers and health authorities. Second, these events are generally reported without a denominator (i.e., the exposed population), and therefore an incidence level is difficult to determine. Because patient registries can provide systematic data

Registry as an active surveillance system

on adverse events and the incidence of these events, they are being used with increasing frequency in the areas of health care products and services.

Evaluating access to and quality of healthcare for the target disease.

Patient registry data can be used to assess differences between providers or patient populations based on performance measures that compare treatments provided or outcomes achieved with “gold standards” (e.g., evidence-based guidelines) or comparative benchmarks for specific health outcomes (e.g risk-adjusted survival rates). Such programs may be used to identify disparities in access to care, demonstrate opportunities for improvement, establish differentials for payment by third parties, and provide transparency through public reporting.

Patient registry to observe course of disease

The patient registry is clearly a powerful tool to observe the course of disease; to understand variations in treatment and outcomes; to examine factors that influence prognosis and quality of life; to describe care patterns, including appropriateness of care, access to treatments and disparities in delivery of care; to assess effectiveness; to monitor safety; and to change behaviour through feedback of data.

More resources for better treatment

Its benefits are evident from several perspectives:

- For clinicians, registries can collect data about disease presentation and outcomes on large numbers of patients rapidly, thereby producing a real-world picture of disease. This establishes the evidence base to underpin clinicians’ demand for more resources to better treat their patients
- For academic organization or medical association, a registry might assess the degree to which clinicians are managing a disease in accordance with evidence-based guidelines, focus attention on specific aspects of a particular disease that might otherwise be overlooked, or provide data for clinicians to compare themselves with their peers.
- From the perspective of policy-makers and payers, registries can provide detailed information from large numbers of patients on how procedures, devices, or pharmaceuticals are actually used

Assessment according to evidence-based guidelines

Effectiveness of procedures, devices, or pharmaceuticals

and on their effectiveness in different populations. This information may be useful to drive resource allocation for under served herapeutic groups and for determining coverage or reimbursement policies.

- For a drug or device manufacturer, a registry might demonstrate the performance of a product in the real world, meet a post-marketing study commitment, develop hypotheses, or identify patient populations that will be useful for product development, clinical trials design, and patient recruitment. The U.S. Food and Drug Administration (FDA) has noted that “through the creation of registries, a sponsor can evaluate safety signals identified from spontaneous case reports, literature reports, or other sources, and evaluate the factors that affect the risk of adverse outcomes such as dose, timing of exposure, or patient characteristics.” *Evaluate safety signals*

MOH’s Commitments

As part of MOH, the Clinical Research Centre has a broad Public Health Mission

To improve patient health outcome through ethical and quality research.

- This is also related to RMK 9 KPI which states enhancing use of research evidence at all levels and also in improving collection and dissemination of research information
- The patient registry has contributed to 97 publications since 2002 and has indirectly contributed in improving the quality of health services in the country. *Patient registry has contributed to 97 publications since 2002*
- It is also used as a tool to assess the competency and skill of the doctor especially using CUSUM as performance indicator tool and for training purposes.
- Establishing a pool of investigators and doctors in various fields for the purpose of research.
- It can also prove the commitment, dedication and the seriousness we have in the health industry to attract contract research which is one of our national missions to achieve developed nation status by 2020.

Organization

Setting up a patient registry in Malaysia

It takes much to set up and operate a patient registry. Key success factors are:

1. An able leadership, typically the well respected key-opinion leaders in the relevant clinical discipline, to galvanize the commitment of all stakeholders *Competent, skilled and organised patient registry set-up and operation*
2. Source Data Providers (SDP) buy-in is obviously crucial. SDPs are the individual clinicians or clinical departments who report the required data to the registry. Patient registries however also receive data from other sources such as other clinical databases and, particularly important, data from the National Registration Department (*Jabatan Pendaftaran Negara*) to ascertain or verify mortality outcomes of registered patients.
3. Skilled organization, which will typically include the sponsors to provide funding, a Governance Board with broad oversight responsibility, a Steering Committee to direct the registry operations, and a Registry Coordinating centre for day-to-day operations.
4. Skilled human resource in a multi-disciplinary team, including the all important dedicated and obsessive administrative personnel and other supporting staff to operate the registry day-to-day
5. Competent clinical epidemiological, biostatistician and data processing capability, and a sophisticated IT infrastructure to underpin that.

And of course the financial resources to pay for much of the above

Registry Design

This is a multi-centre, observational cohort study designed to evaluate the health outcomes of patients with a specific *Broad patient inclusion criteria*

disease undergoing treatment at participating clinical centres.

- Selection of study sites and subjects

Patient inclusion criterion is deliberately broad and shall include any patient with a confirmed diagnosis of that specific disease.

There are no prescribed study visits. Patient will attend the clinical site as and when required per the standard of care at the site. Required data shall be collected as they become available.

Similarly these patients are to be recruited from various practice settings from all over Malaysia to ensure the results are generalized to the Malaysian population to which its results will be applied.

- Selection of treatments

Any modalities (various drugs, surgeries and other therapies) of treatment for the specified disease are included, as the patient registry is intended to observe patient care as it is actually provided in real-world clinical practice, rather than treatment that is deliberately assigned, as in clinical trials or treatment determined or recommended by guidelines.

*No deliberately
designed treatment
approaches*

- Selection of outcome measures

The primary outcome of interest is morbidity and mortality of the disease.

*To determine
morbidity and
mortality*

- Duration of registry

The patient registry is designed to observe secular changes in clinical practice as well as to observe long term morbidity outcome. Hence, the registry ought to operate a few years to meet many of its objectives that require long term patient follow-up.

*Involves several
years to observe
long-term outcomes*

Registry data

The data elements to be collected by the registry shall be relevant and reliable with modest burden to sites, shall comply with existing data standard where this exists, shall be compatible with established data set used by other existing registries, and shall employ standard terminology where available.

Relevant and reliable data

Two datasets are defined:

- Core dataset: These are data elements that are needed to address the key questions for which the registry was created.
- Non-core dataset: these are speculative data elements included to provide an opportunity to generate hypotheses or to explore other subsidiary questions not of primary interest to the registry.

DATA MANAGEMENT and QUALITY ASSURANCE

Data collection

- **Electronic CRF**

Case Report Forms (CRFs) are implemented electronically (eCRF), through software application that are fully validated and conforming to regulatory requirements for electronic data capture, where applicable

Data collection is through CRFs

- **Paper CRF**

Where eCRF could not be implemented for technical or resource reason or as a backup measure, the registry will also supply paper CRFs

Ethical and legal considerations

Several ethical and legal issues require critical considerations in the design and operations of any patient registry. Participation in patient registry in Malaysia is entirely voluntary; there is no legal provision to compel any individual or institution to report data to

Patient involvement is voluntary

a registry. Hence, to secure and maintain SDP buy-in, any registry must conduct itself in accordance with the highest ethical standards and applicable regulations in the country. In particular, we expect registries in Malaysia to comply with the ethical principles as stated in the Declaration of Helsinki, CIOMS's International Guidelines for Ethical Review of Epidemiological Studies, Good Pharmacoepidemiological Practice as well as applicable local research guideline such as those of our National Institute of Health (NIH).

Patient registry resembles observational research that involves the participation of human subjects. In compliance with current NIH research guideline, the registry protocol must be reviewed and approved by a properly constituted Independent Ethics Committee (IEC). Moreover, patient registry typically also operates under a waiver from the requirement to obtain individual informed consent from the patients whose data are reported to the registry by participating clinical sites. This requires explicit justifications and approval by IEC. Usual justifications of such waiver, in accordance with current ethical guidelines are:

1. Registry is an observational research and involves no physical risk to the subjects.
2. The waiver will not adversely affect the rights and welfare of the subjects
3. The requirement of individual informed consent would make the conduct of the registry impracticable and unscientific. In particular, observational research (unlike randomized trial) needs to avoid selection bias that the requirement for informed consent would inevitably introduce. A waiver permits the registry to include all patients who are eligible, rather than those who consent.
4. The registry cannot be practically be conducted without access to patients' health information
5. An adequate policies and procedures will be implemented by the registry to protect patients' data and prevent improper use or disclosure. No individual information will ever be disclosed; only aggregate statistical results will be published by the registry.
6. Patients will not actually be enrolled since the registry is based entirely on review of medical records. The registry does not collect data that is not already routinely available.

Registry protocol reviewed and approved by Independent Ethics Committee

As individual informed consent is waived for registries, detailed justifications is needed

No individual information will be disclosed

The registry does not collect data that is not already routinely

7. The registry is carried out under the public health authority residing with the Ministry of Health, the primary sponsor of most registries in Malaysia.

available as it is based on review of medical records

In addition, in view of the confidential medical information, often identifiable, that are collected and stored. A registry must institute stringent information security policies and procedures, supported by state of the art data protection technology. These must be in accordance with the requirements regarding personal data protection in applicable local guidelines, and for us in Malaysia, often with applicable US and European standards too, until such time the much anticipated Malaysian Data Protection regulations are enforced.

Registry require strict information security policies and procedures as it has access to confidential information

Since most registries in Malaysia are funded largely by public funds disbursed through the CRC MOH, it is desirable that the operations of patient registries be transparent. This means making information about the registry operations public and readily accessible to anyone who is interested. Transparency in registry operations is desirable because it helps to realize the potential benefits of the registry; educates the public and other stakeholders about the scientific process; contributes to public and professional confidence in the scientific integrity and validity of the registry processes, and thus its findings; and finally, transparency increases the scientific utility of the registry data by promoting inquiries from interested scientists.

Majority of Malaysian registries are supported largely by public funds

Transparency essential to improve scientific utility

To this end, a registry is expected to achieve transparency by publishing a regular report on its findings at least annually and disseminating the report free of charge to anyone who is interested through its official website; and by providing information on the registry's objectives; governance, policy & organization; methods, operations & data sources available to anyone who is interested through its official website

Finally, concerning registry data ownership, in theory, it is likely that the health information compiled by the registry will satisfy the statutory definition of a compilation, and thus copyright law may provide a legal basis for claims of ownership and legal restrictions on access to and use of the registry data by other parties. In practice, however, given the large number of parties involved in the creation of a registry, from funders, participating clinical sites and individual specialists involved in its design, it is uncertain how any claims of property rights in the registry data may be distributed and legally

constituted. Further, the health information in the registry are information concerning individual patients, it is also uncertain how patients would respond, favourably or adversely, to any such claims of data ownership.

As a practical matter, since “ownership” implies operational control of the registry data and publication rights, a funding agency such as the CRC, should agree to cede control of the registry operations and publication rights to the Steering Committee, the membership of which shall be appointed after due consultation with participating SDPs and individual subject matter experts involved in the creation of the registry.

Ownership may be given to Steering Committee

Patient data protection

To ensure that requirements regarding personal data protection are met, data will be collected and stored in accordance with applicable local regulation where the patients are recruited [14,15], and with applicable US and European specifications [16, 17, 18] or until such time Malaysian Data Protection regulation are enforced.

Compliance to local regulations on data protection

If a third party is processing data on behalf of the registry and sponsor, a contractual procedure will be signed between the registry/ sponsor and the third party to ensure compliance with above mentioned requirements

Registries currently supported by CRC in Malaysia

In working towards accomplishing our stated mission, which is “To improve patients’ outcomes through quality clinical research”, the CRC has an important role in promoting and supporting the establishment and operations of patient registries in Malaysia (Appendix).

CRC has an active role in promoting and supporting registries

Conclusion

Any serious effort to advance healthcare in Malaysia requires hard information on its availability and distribution, and its effect on our population health outcomes. The availability of such information is currently very limited for most diseases in our country. There is a cogent need to establish more high quality patient registers in Malaysia to bridge the information gap. We urge all stakeholders in healthcare, whether as policy-makers, funders or providers to support this mission critical national endeavour.

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18. US Health Insurance Portability and Accountability Act 1996 (HIPAA).

Appendix: Patient registers currently supported by CRC

#	PATIENT REGISTRIES	YEAR EST.	OWNER
ESTABLISHED REGISTRIES			
1.	National Renal Registry (NRR): <ul style="list-style-type: none"> • Malaysian Dialysis and Transplant Registry (MDTR) • Malaysian Registry of Renal Biopsy (MRRB) 	1993-2005	- MOH Nephrology - Malaysia Society of Nephrology
2.	National Transplant Registry (NTR)	2004	- MOH Transplant - Malaysia Society of Transplantation
3.	National Eye Database (NED): <ul style="list-style-type: none"> • Cataract Surgery Registry • Contact Lens Related Corneal Ulcer Surveillance • Tele-Diabetic Retinopathy Screening • Diabetic Eye Registry • Glaucoma Registry • Retinoblastoma Registry • Age Related Macular Degeneration (AMD) Registry 	2002	MOH Ophthalmology
4.	Malaysian National Neonatal Registry (MNNR)	2003	- MOH Paediatric - Perinatal Society of Malaysia
5.	Malaysian Liver Registry	2004	MOH Hepatology
6.	National Endoscopy Registry (NER)	2007	MOH Gastroenterology
7.	National Trauma Database (NTrD): Major Trauma & Traumatic Brain Injury Database	2005	- MOH Trauma - MOH Neurology
8.	Diabetes Registry of Malaysia (DRM) <ul style="list-style-type: none"> • Diabetes in Children & Adolescents Registry (DiCARE) 	2006	- MOH Family Medicine - MOH Paediatric & Medicine - HUKM & UMMC
9.	National Mental Health Registry (NMHR) : Schizophrenia	2003	- MOH Psychiatry Services - MOH Family Health Development - MOH Medical Development

#	PATIENT REGISTRIES	YEAR EST.	OWNER
10.	National Suicide Registry Malaysia (NSRM)	2007	- MOH Psychiatry Services - MOH Forensic Medicine Services
11.	National Cardiovascular Disease Database (NCVD): 1. Acute Coronary Syndrome (ACS) Registry 2. Percutaneous Coronary Intervention (PCI) Registry	2005	- MOH Cardiology - National Health Association of Malaysia
12.	National Dermatology Registry 1. Malaysian Psoriasis Registry (MPR) 2. Skin Biopsy Registry	2007	- MOH Dermatology - Malaysian Society of Dermatology
13.	NCPR: Colorectal Cancer	2007	- MOH Gastroenterology - MOH Oncology
14.	NCPR: Naso-Pharyngeal cancer	2007	- MOH ENT - MOH Pathology - Institute Medical Research
15.	National Surgical Patient Registry (NSPR) (Formerly known as Computerized OT Documentation System (COTDS) incorporating Post-Operative Mortality Review (POMR)	1996	- MOH Surgery - MOH Anaesthesia
16.	Malaysian Intensive Care Registry (MICR) (Formerly known as National Adult ICU Audit)	2001	MOH Anaesthesia

Source: 2007 CRC Annual Report



CHAPTER 4

USE OF ICT IN THE DISSEMINATION OF HEALTH INFORMATION – MyHEALTH PORTAL

SUMMARY

With increasing use of ICT in the country, the Ministry of Health has developed an online health education service through the MyHEALTH Portal. This health portal is developed to provide health information for the community through internet. It is a component of the Telehealth project under MSC Malaysia Flagship. MyHEALTH Portal provides quality health information consisting of a wide variety of health topics tailored for Malaysians. The portal was launched in 2006, in conjunction with the World Health Day celebration. A number of services are being provided in this portal. This include health education information by topics catering to different age groups; health services directory, ask the expert, health alert, health events, health news and articles, discussion forum, online poll, quiz and frequently asked questions. The portal will be expanded from time to time, to cater for the needs of users. It is hoped that this portal will become a leading source of health information for the public in future.

Introduction

Internet usage has grown at a tremendous pace over a short span of time, since its advent in the seventies. The worldwide internet usage now stands at 20 percent and 59 percent in Malaysia. Healthcare providers are increasingly looking into health promotion through the internet.

Increasing use of internet in promoting health



Main Page of Portal MyHEALTH

The MyHEALTH Portal (www.myhealth.gov.my) was launched by the Ministry of Health Malaysia on 25 April 2006. The portal is a component of the Telehealth project developed by Ministry of Health Malaysia under the MSC Malaysia Flagship.

*MyHEALTH Portal
- MSC Flagship
project*

It aims to provide health information and education to the Malaysian public through the Internet. The uniqueness of the portal is in providing a credible local source on a wide range of health information. It is hoped that this would help to improve individual's knowledge thereby increasing the individual's participation in managing his/her own and their family's health.

*Credible local
information source*

The objectives of MyHEALTH Portal are to empower and encourage individuals to be responsible for their health by providing reliable, timely and quality health related information which are easily accessible. It is also to create awareness on health risks for individuals by performing health risk assessment and bringing about desired behavioural change.

*MyHEALTH Portal
Objectives*



Yg. Bhg. Tan Sri Dato' Seri Dr. Hj. Ismail Merican with Y.A.Bhg. Datin Seri Rosmah Mansor during the launch.

This portal has a strong editorial board consisting of senior personnel from various health disciplines to ensure the quality of contents of the portal.

*Strong Editorial
Board*

At the launch of the portal in the year 2006, there were 479 topics written by qualified and experienced health personnel. In 2007, another 151 topics in English and 155 topics in *Bahasa Malaysia* were added, bringing the cumulative total of health topics to 630 in English and 634 health topics in *Bahasa Malaysia*.

Contents of Portal

Hits

*MyHEALTH Portal
Services*

*MyHEALTH Portal
Services*



MyHEALTH Portal Services

*MyHEALTH Portal
Services*

Health Events

The MyHEALTH portal provides a platform to inform the public about health events and health campaigns that are organised by Ministry of Health or health related non-government organisations, thereby providing publicity which can enhance public participation in health activities.

*MyHEALTH Portal
Promotion*



Highlight of Health Events



Some pictures taken during MyHEALTH Portal's promotion event.



Discussion Forums

This service provides opportunities for individuals or groups with common interests to interact and share their experiences in handling specific health issues.

*MyHEALTH Portal
Promotion*

FAQs

On this page, most frequently asked questions with answers are posted to provide additional information to the public.

Quiz

Some health quizzes are posted so as to enable interested users to test their knowledge on diseases.

Ask The Expert

This is a very special service that enables the public to pose questions via email on some health conditions which they are having difficulty to comprehend or handle. The questions posed are answered by a panel of health experts consisting of 241 specialists appointed by the Director General of Health Malaysia.

The ‘ask the expert’ service has drawn about 2,000 questions from the public and all questions have been duly answered by the panel of experts.

A screenshot of a web form titled 'Ask The Expert' on the MyHEALTH Portal. The form is yellow and orange. It includes a sidebar with a list of health topics like 'AIDS', 'Alcohol', 'Allergies', etc. The main content area has a heading 'Ask The Expert' and a paragraph explaining the service. Below this is a form with fields for 'Name', 'Email', 'Subject', and 'Message'. There is a 'Submit' button at the bottom. The footer contains a disclaimer about the service.

Ask The Expert service

The Way Forward

The response to the MyHEALTH portal as an alternative form of education has been very encouraging. However, several challenges are being encountered, and these include: the need to establish a 'Health Risk Assessment' tool; the provision of more contents and having these contents in other local languages; increasing publicity and providing multimedia support for the contents. The portal also requires dynamism to provide more interactive forms of learning. This will encourage the public to continually return to this portal for more information.

Future Challenge

EVIPNet – TOWARDS BETTER HEALTH POLICY DECISIONS

SUMMARY

Low and middle income countries lack resources to address their health system challenges and need high-quality evidence to use those resources efficiently. EVIPNet was launched in 2005 to provide support to these countries on developing evidence-based health policy by establishing mechanisms to transfer knowledge in support of evidence-based public health-care delivery systems, and evidence-based health related policies, and in doing so, foster dialogue and partnership between policy makers, researchers and civil society.

Introduction

In November 2004, a Ministerial Summit on Health Research was held in Mexico with a focus to improve the use of knowledge to improve health. Following the summit, a World Health Assembly resolution in May 2005 called upon the World Health Organization (WHO) to “*establish mechanisms to transfer knowledge in support of evidence-based public health and health-care delivery systems, and evidence-based health-related policies*”. In 2005, EVIPNet was launched.

Evidence-Informed Policy Network (EVIPNet) is an initiative by WHO to promote the systematic use of the best scientific research evidence available in policy-making. Focusing on low- and middle-income countries, EVIPNet aims to promote partnerships at the country level between policymakers, researchers and civil society. This network brings together country-level teams which are coordinated both at regional and global levels.

EVIPNet promotes use of research evidence for policy-making

WHO recognizes that low- and middle-income countries lack resources and are therefore in dire need to ensure that the best evidences are used to support the development of policies so that resources invested into the country are fully utilized.

EVIPNet's focus on low- and middle-income countries.

EVIPNet Global

Current EVIPNet regional teams are:

*Several regional
EVIPNet teams
launched*

1. EVIPNet Asia – launched March 2005

Country members: China (Beijing municipality, Shandong and Sichuan provinces), Lao PDR, Malaysia, Philippines, Vietnam

2. EVIPNet Africa – launched March 2006

Country members: Burkina Faso, Cameroon, Central African Republic, Ethiopia, Mali, Mozambique, Research East Africa Cooperation (Tanzania and Uganda), Zambia

3. EVIPNet Americas – launched July 2007

Country members: Bolivia, Brazil, Chile, Colombia, Costa Rica, Mexico, Mexico-USA Border PAHO Field Office, Paraguay, Trinidad and Tobago.



EVIPNet activities at the country level include:

*EVIPNet country
level activities*

- Establishment of priority setting mechanisms for policy relevant research syntheses and primary research.
- Production of research syntheses.
- Production of policy briefs and other user-friendly formats for research syntheses and discussions of policy options.
- Organisation of deliberative forums involving policymakers, and researchers and citizen groups.
- Investigation of the potential of clearing houses, observatories and rapid response mechanisms that might provide timely, highly qualified research syntheses and research relevant to policy.

EVIPNet Malaysia

Evidence-based decision making in Malaysia started in 1985 with the formation of the Health Systems Research (HSR) Programme to promote informed decision-making based on scientific evidence. Subsequently, many other units/initiatives have been introduced, including the Health Technology Assessment Unit (HTA), Evidence-Based Practice Unit (EBU) and the National Institutes of Health (NIH).

*EVIPNet Malaysia
to enhance evidence-
based decision-
making*

Malaysia is one of the countries under EVIPNet Asia which was launched in March 2005. EVIPNet Malaysia is currently led by the Institute for Health Systems Research (IHSR) under the Ministry of Health (MOH) and is supported by stakeholders, policy makers, information/ knowledge dissemination experts and researchers from MOH, universities and professional organisations. The first and former team leader of EVIPNet Malaysia was Dato' Dr. Maimunah A. Hamid, Deputy Director-General of Health (Research and Technical Support). This position has since been filled by Dr. Azman Abu Bakar, Director of IHSR.

The objectives of EVIPNet Malaysia are as follows:

1. Enhance evidence- based decision making by health managers and policy makers
 2. Support evidence needs for policy makers using the scope identified as the platform
 3. Augment and improve training to promote and advocate evidence-based decision-making
 4. Enhance existing and develop new linkages to support policy makers' needs
 5. Recognize and address the need for new research and systematic reviews
 6. Ensure the continuous growth, development and relevance of the network itself
- EVIPNET Malaysia's Objectives*

EVIPNet Malaysia's Vision is to be "*Partners in evidence-based decision making for health*". Its Mission:

- Core business: Promote knowledge translation
- Market: All levels of policy/decision makers and advocates
- Image to portray: Partnerships, transparency and integrity commitment to EVIPNet members: Enriching capacity and capability
- Social responsibility: Public's health at heart

As a pilot focal area, the initiative in Malaysia will serve the needs of national-level policy makers in Patient Safety issues, health system managers and practitioners in both public and private sectors. The aim is to develop a system, through the experiences of the pilot area, to enable the network to respond to matters beyond patient safety.

Patient safety as a pilot focal area

EVIPNet Malaysia Activities and Achievements

EVIPNet Malaysia activities include:

- training in Systematic Review
- production of research highlight documents – to inform relevant policy makers about evidence/ results from researches conducted.
- training on Policy Brief Development
- training in Policy Communication.

In 2007, EVIPNet Malaysia hosted a Systematic Review Training for other EVIPNet Asia sponsored by WHO under the guidance of a consultant from Canada. *EVIPNet Malaysia activities*

Conclusion

The development of EVIPNet is seen as a timely initiative to build on and strengthen efforts already initiated in the country. The network will act as a nucleus for coordinating and promoting the need for, and use of, high quality evidence for decision-making.

EVIPNet Malaysia Future Plans

In line with the increasing need for the use of best scientific evidence for policy making, EVIPNet Malaysia has lined up several activities to address the paucity of skills in the relevant fields:

- Capacity building in systematic review.
- Capacity building in development of policy brief.
- Capacity building for policy makers in managing policy prioritization

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PRESENCE OF TOXIGENIC MOULDS IN PADDY AND PADDY PRODUCTS

SUMMARY

Aspergillus and *Penicillium* are among two common moulds that can contaminate food and animal feed. Some of these moulds can produce mycotoxins that are hazardous to human health. The mycotoxins that are of concern include aflatoxin, ochratoxin A (OTA), deoxynivalenol (DON), zearalenone and citrinin. Due to the fact that toxigenic moulds can grow well in a tropical climate it is very important to determine the type of moulds present in rice, a staple food in Malaysia. The main objective of this study was to identify the toxigenic moulds found in paddy and paddy products including rice. One hundred and eighty samples were taken from three (3) different millers operating in Selangor and 35 food premises in Melaka. Nine types of samples comprising silo paddy, exposed stored paddy, brown rice, freshly polished rice, stored rice, broken rice, brewer's rice (*temukut*) and rice bran were involved. The direct and dilution plating techniques using Czapek-Dox agar (CDA) and cornmeal agar (CMA) were employed to isolate and cultivate the toxigenic moulds. Identification of the isolates was determined according to their morphological characteristics. Results showed that the five (5) most frequent toxigenic moulds were morphologically identified as *A. flavus* (65.0%), *P. chrysogenum* (63.3%), *A. niger* (42.7%), *Rhizopus microsporus* (38.9%) and *A. candidus* (19.4%). This study showed that the risk of samples being contaminated with mycotoxins would be on the high if paddy and paddy products were not properly handled.

Introduction

Mycotoxins are toxic and structurally diverse low-molecular-weight metabolites produced by moulds. Levels of mycotoxins that can cause risks, are avoided by consumers and many countries have regulated acceptable levels of mycotoxins in various agricultural foods. For example in Malaysia, the level of any mycotoxin in food must not exceed 5 parts per billion (ppb). Aflatoxins in groundnuts for further processing must not exceed 15 ppb and in milk the level of aflatoxin must not exceed 0.5 ppb. Mycotoxins can be produced during culture and storage. They contaminate a variety of feed and food consumed by animals or humans including cereals such as rice as well as fruits, grains, forages and manufactured products.

Most mycotoxins in feed and food are produced mainly by three genera of mould namely *Aspergillus*, *Penicillium* and *Fusarium*. Due to their toxic properties and their high stability to heat treatment, the presence of mycotoxins in the food chain is potentially hazardous to the health of humans and animals. More than 200 kinds of mycotoxins have been found, which can be categorized into 3 main groups. These include mycotoxins from *Aspergillus*, which produce aflatoxin, ochratoxin and sterigmatocystin, *Penicillium* which produce citrinin and verruculogen and *Fusarium* which produce deoxynivalenol (DON), zearalenone and T-2 toxins.

*Important moulds
that produce
mycotoxin*

The mycotoxins of major concern include aflatoxins, ochratoxin A (OTA), zearalenone and fumonins (Hussein & Brasel 2001). Aflatoxins are toxic and carcinogenic both in animals and humans, producing acute liver damage, liver cirrhosis, tumour induction and teratogenesis. *Aspergillus flavus*, *A. parasiticus* and *A. nomius* are among the main producers of aflatoxin. OTA may have nephrotoxic, neurotoxic and immunotoxic effects. The main producers of OTA are *A. ochraceus*, *A. carbonarius*, *A. niger* and *Penicillium verrucosum*. DON is produced by *F. culmorum* and *F. graminearum*. *Penicillium* spp. grows well over a wide range of temperatures (4 – 31°C), *Fusarium* spp. also grow over a wide range of temperatures (5 - 35°C) whereas *Aspergillus* spp. requires higher temperatures (12 – 39°C). Therefore, *Penicillium* and *Fusarium* are common in temperate climatic regions while *Aspergillus* species tend to predominate in warmer climates.

Main mycotoxin

Aspergillus and *Penicillium* are classified as storage fungi that can grow at a lower moisture content (<20%) as opposed to *Fusarium* which is classified as field fungi and requires higher moisture content (> 22%). Areas with high average yearly temperatures and high relative air moisture are favorable for mould growth. Malaysia with such a climate is susceptible to mould contamination and food spoilage. For these reasons, prevention of any mycotoxin from entering the food chain is of market importance and many countries have set maximum residue levels (MRL) for the toxins in certain foods and feed. Due to the fact that toxigenic moulds can grow well in tropical climates like Malaysia, it is very important to determine the types of moulds present in rice, the Malaysian staple food. Thus, the main objective of this study was to identify the toxigenic moulds present in the paddy and paddy products including rice. The findings will be used to predict the various types of mycotoxins that might be present in the samples.

Storage moulds

Materials And Methods

One hundred and eighty samples were taken randomly which consist of silo paddy, opened storage paddy, brown rice, polished rice, storage rice, broken rice, *temukut* and rice bran. These samples were taken from three (3) rice millers, five (5) replicates for each sample. Rice was also taken from 35 food premises operated in Banda Hilir, Melaka, in two (2) replicates from each food premise. All samples (1 kg) were ground, sieved and kept at -20°C until analysed.

Samples

The direct and dilution plating techniques using Czapek-Dox agar (CDA) and cornmeal agar (CMA) were employed to isolate and cultivate the toxigenic moulds. These two methods were carried out on two types of media to allow for variations of fungal species. Czapek-Dox agar (CDA) and cornmeal agar (CMA) was used to enumerate the maximum number of fungi especially of the *Aspergillus* and *Penicillium* species. For the direct plating method, for each sample, 5 grams of rice grains were plated directly onto two types of agar plates. Two replicate plates per media were prepared for each sample. For the dilution plating method, 2 g of grain samples were added to 10 ml of sterile distilled water in a McCartney bottle separately. This was shaken thoroughly and 100 µl of the contaminated water was pipetted onto two types of agar plates. Two replicate plates per media were prepared for each sample. All inoculated plates were incubated at 25 °C in stacks of not more than five. Each plate was examined for growth of fungi every 24 hrs until 10 days. The colonies of slow growing fungi were transferred to a different plate for identification. The identification of the isolates was determined according to their morphological characteristics. Species of *Aspergillus* were identified according to Raper and Fennel (1965) while species of *Penicillium* were identified according to Ramirez (1982). Difficult species were identified only to the genus level.

Identification of toxigenic moulds

Results And Discussion

Table 1 shows the 5 most frequent toxigenic moulds morphologically identified as *A. flavus* (65.0%), *P. chrysogenum* (63.3%), *A. niger* (42.7%), *Rhizopus microsporus* (38.9%) and *A. candidus* (19.4%). Others species of toxigenic moulds detected were *P. oxalicum* (15.5%), *A. fumigatus* (12.2%), *P. islandicum* (11.7%), *A. aculeatus* (10%) and *A. terreus* (6.7%). *Aspergillus* and *Penicillium* are common storage fungi. *A. flavus* was the dominant toxigenic mould in silo paddy, opened storage paddy, brown rice, stored

rice, broken rice, brewer's rice and rice bran. While the dominant toxigenic moulds found in rice taken from food premises was *P. chrysogenum* (Summary in Table 2).

Table 1 : Frequency of toxigenic moulds isolated in samples

MOULDS	NUMBER DETECTED (n = 180)	PERCENTAGE (%)
<i>A. flavus</i>	117	65
<i>P. chrysogenum</i>	114	63.3
<i>A. niger</i>	77	42.7
<i>R. microsporus</i>	70	38.9
<i>A. candidus</i>	35	19.4
<i>P. oxalicum</i>	28	15.5
<i>A. fumigatus</i>	22	12.2
<i>P. islandicum</i>	21	11.7
<i>A. aculeatus</i>	18	10.0
<i>A. terreus</i>	12	6.7

Table 2 : Dominant Toxigenic Moulds Detected According to Type of Samples

SAMPLES	Dominant* Toxigenic Moulds
Silo Paddy (n=15)	<i>A. flavus</i> (93.3%), <i>R. microsporus</i> (80%)
Opened Storage Paddy (n=5)	<i>R. microsporus</i> (100%), <i>A. flavus</i> (80%), <i>A. fumigatus</i> (60%)
Brown rice (n=15)	<i>A. flavus</i> (80%), <i>R. microsporus</i> (73.3%)
Fresh rice (n=15)	<i>R. microsporus</i> (60%), <i>A. flavus</i> (53.3%), <i>P. chrysogenum</i> (53.3%)
Stored rice (n=15)	<i>P. chrysogenum</i> (66.7%), <i>A. flavus</i> (60.0%)
Broken rice (n=15)	<i>P. chrysogenum</i> (60.0%), <i>A. flavus</i> (53.3%),
Brewer's rice (n=15)	<i>A. flavus</i> (86.7%)
Rice bran (n=5)	<i>A. flavus</i> (100%), <i>A. candidus</i> (66.7%), <i>A. terreus</i> (53.3%), <i>P. chrysogenum</i> (53.3%), <i>R. microsporus</i> (53.3%)
Rice taken from food premises (n=35)	<i>P. chrysogenum</i> (88.6%), <i>A. niger</i> (74.3%)

* More than 50% found in samples.

Fusarium was not detected in any sample due to the fact that it needs more moisture and samples studied were low in moisture content. These results were quite similar with the results obtained by Pitt and Hocking (1999) where they reported the toxigenic moulds found in the rice samples taken from Indonesia and Phillipines were *A. candidus*, *A. flavus*, *A. fumigatus* and *A. niger*. Allowing the toxigenic moulds to grow due to the improper handling, the risk of mycotoxin contamination should be taken into account. This study showed that the toxigenic moulds can be detected right from before the rice being milled, at the processing line and after it had been processed and stored. Moulds can grow and produce mycotoxins in plant material during the whole food chain from the field to the table. If good farming management is practiced and adequate storage facilities are available in the area, this can minimize the toxin contamination problem especially to the hazardous mycotoxins like aflatoxin and OTA.

*Toxigenic moulds
detected*

The non toxigenic moulds detected included *Rhizopus arrhizus* (67.8%), followed by *Mucor circinelloide* (27.2%), *A. sydowi* (18.3%), *Syncephalstrum polymorpha* (13.3%), *Absidia corymbifera* (10.5%) and *Cunninghamella polymorpha* (4.4%). Even though these moulds do not produce any mycotoxin, nevertheless their presence will affect the growth of other toxigenic moulds. *Absidia*, *Cunninghamella*, *Mucor*, *Rhizopus* and *Syncephalastrum* found in the samples for example are storage moulds that easily grow if the environment favours them.

*Non toxigenic moulds
detected*

The appearance of spots with high moisture can favour mould growth and the formation of mycotoxin. According to Shapira (2004), when a_w at a given spot starts to rise, the xerophilic species will be the first to grow. As a result of their metabolic activity, the moisture increases first at that spot and subsequently in other parts of the bulk. This will create favourable conditions for the growth of toxigenic moulds and can be hazardous to the health of those who consume the food if the level of mycotoxins exceeds the permitted level. If the toxigenic moulds were not detected in the samples, the mycotoxins produced by particular moulds can still be present. This is because the characteristics of the mycotoxin itself is very stable and can remain in the infected commodity even if there is no further mould seen or detected.

Growth of mould

Table 3 shows the reported mycotoxins produced by the toxigenic *Mycotoxin produced* moulds found in the samples. Various toxigenic moulds found in one sample can result in various mycotoxins that may be present simultaneously. Considering this coincident production, it is very likely, that humans and animals are exposed to mixtures rather than to individual compounds. According to Martins et. al (2003), only certain strains of moulds and conditions can produce mycotoxins. Thus, the presence of *A. flavus* in the study samples did not mean this species can produce aflatoxin because it depends the type of strain of *A. flavus* and also the condition where it can optimally grow. Nevertheless these collected data can be used to determine the level of contamination of toxigenic moulds in the samples. Further studies need to be carried out to check whether the toxigenic moulds isolated can produce mycotoxins.

Table 3 : Toxigenic moulds and reported mycotoxin produced

TOXIGENIC MOULDS	REPORTED MYCOTOXIN PRODUCED	REFERENCE
<i>A. flavus</i>	aflatoxin, OTA, sterigmatocystin	Czerwiecki et al. (2002), Cole & Cox (1981)
<i>P. chrysogenum</i>	OTA, roquefortine C	Cole & Cox (1981), Frisvad (1984)
<i>A. niger</i>	malformin A, OTA	Cole & Cox (1981), Magnoli et al. (2004)
<i>R. microsporus</i>	rhizonin A	Pitt & Hocking (1999)
<i>A. candidus</i>	kojik acid, citrinin, OTA	Cole & Cox (1981), Logrieco et al. (2003)
<i>P. oxalicum</i>	secalonic acid	Cole & Cox (1981)
<i>A. fumigatus</i>	fumitremorgin, gliotoxin, OTA	Cole & Cox (1981), Butchelli & Taniwaki (2002)
<i>P. islandicum</i>	emodin, islanditoxin, cyclochlorotine	Cole & Cox (1981), Pitt & Hocking (1999)
<i>A. aculeatus</i>	Secalonic acid, OTA	Cole & Cox (1981), Schmidt et al. (2004)
<i>A. terreus</i>	gliotoxin, patulin, terrein	Cole & Cox (1981)

Conclusion

This study showed that the risk of samples being contaminated with mycotoxins was high particularly if the paddy and paddy products were not properly handled at any point. Results of this study indicate that the risk of contamination from mycotoxins cannot be ignored. Thus, further studies need to be carried out to identify the types of moulds that can produce aflatoxin, OTA and other mycotoxins in paddy and paddy products.

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DETERMINATION OF PROPIONIC ACID IN BREADS, BISCUITS, CAKES AND MUFFINS IN PERLIS, KEDAH AND PENANG USING GAS CHROMATOGRAPHY-MASS SPECTROMETRY

SUMMARY

A study was conducted to determine the level of propionic acid in 237 samples of breads, biscuits, cakes and muffins from minimarkets, supermarkets and other local markets in Perlis, Kedah and Penang. A gas chromatography mass spectrometer was used to determine the levels of propionic acid. The procedure involved an extraction of propionic acid with ethyl acetate and acetic acid using isobutyric acid as an internal standard followed by GC-MS analysis with Helium as a carrier gas where the flow rate was 1.5 ml/min through a DBWAX 30 m x 0.25 mm x 0.25 μ m column. Propionic acid was detected in 43 samples with the average mean concentration of 1032.9 mg/kg. However, only 5 samples were found to contain more than 2000 mg/kg of propionic acid.

Introduction

Propionic acid inhibits the growth of mould and some bacteria. Most of the propionic acid that is produced is used as a preservative for both animal feed and food for human consumption. For animal feed, it is used either directly or as its ammonium salt. In human foods, especially bread and other baked goods, it is used as its sodium or calcium salt. Similar usage occurs in some of the older anti-fungal foot powders.

Propionic acid as preservative in foods

Spoilage of bakery products is mainly due to fungal growth; the major species involved are *Aspergillus*, *Fusarium*, and *Penicillium*. In addition to the substantial economic losses derived from the presence of mould, another concern is the potential mycotoxin production that may cause public health problems. Contamination by moulds can be prevented by irradiating the goods with infrared rays or microwaves, by using a modified atmosphere during packaging, or by adding chemical preservatives such as propionic acid (Gould, 1996). The maximum concentration of propionate that is allowed for packaged sliced bread by the Argentine Alimentary Code (AAC) is 0.4% (wt/wt). Most bakeries in Argentina use this upper limit concentration for the preservation of bread.

Propionic acid and its calcium, potassium and sodium salts are used widely as antimicrobial food additives, especially in bread. In the absence of reports of adverse effects on health (Joint FAO/WHO Expert Committee on Food Additives (JECFA) 1974), these preservatives have been used freely, but Griem (1985) has recently reported pre-neoplastic/precancerous changes in rats. It was found that 4% propionic acid in their diet induced hyperplasia, hyperplastic ulcers, papillomas and proliferation of basal cells in the mucosa of the forestomach.

Propionic acid is also useful as a chemical intermediate. It can be used to modify synthetic cellulose fibers. It is also used in pesticide and pharmaceutical products. The esters of propionic acid are sometimes used as solvents or artificial flavorings. Propionic acid, and its sodium, potassium or calcium salts, are currently permitted as a preservative in breads at levels up to 2000 mg/kg, as provided for under the Food Regulations 1985.

Propionic acid is used for extending the shelf life of bakery products. It is not harmful in small amounts, although a few individuals may be affected by even two slices of bread containing this preservative. Reactions that have been reported include headaches, stomach aches, diarrhea and eczema. In December 1990, the Department of Health's Committee on Toxicity (COT) in the United Kingdom set an Acceptable Daily Intake (ADI) of 0.6mg/kg body weight /day for propionic acid.

Materials and Methods

Test Materials

237 samples of flour confection which include breads, biscuits, cakes and muffins were used in this study. This research was conducted in two (2) parts. The first batch of 37 samples were analyzed by Food Safety and Quality Laboratory (FSQL) in Perlis in collaboration with Universiti Sains Malaysia (USM) in 2006/2007, and the other 200 samples were analyzed by FSQL the former in 2007/2008. All test samples were purchased at local retail outlets in Perlis, Kedah and Penang. All test samples were ground using a food processor for 5 minutes to obtain homogenised samples. For internal quality control (IQC), sandwich bread (Garden Bakery) was used in the method validation study, as well as a quality control material.

Test samples

Chemicals, Reagents and Standards

Analytical reagent grade ethyl acetate was obtained from Fisher Scientific (UK). While acetic acid was obtained from BDH (England). All chemicals were analytical grade or had higher purity levels unless otherwise stated. Both standards of propionic acid and the internal standard (ISTD), isobutyric acid were obtained from Acros Organics (USA). The stock solutions for propionic acid and isobutyric acid were prepared separately by dissolving appropriate amounts of these compounds in extractant solution (ethyl acetate : acetic acid; 1000:1). The working solutions were prepared by serial dilution of the stock solutions with extractant solution.

Isobutyric acid as internal standard in propionic acid analysis

Preparation of Calibration Solutions

For quantification during the study, a stock standard solution in extractant solution was prepared. The individual concentration of propionic acid and isobutyric acid was 10000 mg/L. A series of six (6) calibration solutions were prepared by diluting the stock standard solution with extractant solution resulting in a calibration range of 20-120 mg/L propionic acid and 50 mg/L isobutyric acid as internal standard, respectively.

Stock Standard

Sample Extraction

The test samples were ground using a food processor or electrical blender for sample homogenisation. Five milligram of homogenised samples were transferred into 100 ml Schott bottles followed by the addition of 50 mg/L isobutyric acid as an internal standard. 100 ml of extractant solution was added and the samples were shaken for 3 minutes. The samples were then allowed to settle down for 1 hour. The final solutions of all samples were filtered through 0.45 μ m nylon filters into the vials and the analytes were determined by gas chromatography with a mass spectrometer detector (GC-MS).

Samples should be homogenised as well before extraction

Fortification of Quality Control Materials

Test material for the internal quality control was fortified with 1200 mg/L of propionic acid and 50 mg/L of isobutyric acid to determine the stability of the analyte within the matrix and the ratio between standards was calculated. The recovery rate was replicated three (3) times and the data is presented in Table 1.

Internal quality check

Table 1 : Analytical recoveries (%)±SD of propionic acid in sandwich bread (Garden Bakery) (n=3)

Analyte	Fortification level, mg/L	Recoveries, %
Propionic Acid	1200	100.7 ± 0.1

Gas Chromatographic Determination

A Shimadzu gas chromatograph (Japan) equipped with a gradient pump was employed together with a Real Time Analysis (GCMS solution) Version chromatography manager workstation for instrument control as well as data acquisition and processing. The DBWAX analytical column (30 m x 0.25 mm x 0.25 µm) with Helium as a carrier gas was used for the separation of the target analytes at 1.5 ml/min. The selected ions, m/z were set at 74 for propionic acid and 73 for isobutyric acid and the column temperature was maintained at 70°C by using a Shimadzu temperature control module and the injection volume of standard and sample solutions at 1 µl by Auto Injector Shimadzu AOC-20I. The peak area measurements were adopted for all calculations of the analysis results using the equation as follows:

Using GC-MS to determine propionic acid and DBWAX column.

Concentration (mg/L) =

$$\frac{\text{Area of sample}}{\text{Area of ISTD}} \times \text{ISTD Concentration} \times \frac{\text{Final volume, ml}}{\text{Sample weight, g}}$$

Results and Discussions

Chromatographic separation of propionic acid and isobutyric acid was achieved by GC-MS analysis using Helium as a carrier gas. As observed in Graph 1, propionic acid was eluted at 74 m/z with a retention time 4.65 min while isobutyric acid was eluted at 4.8 min.

Propionic acid were found in 77 over 237 samples.

Graph 1: Propionic acid and Isobutyric acid

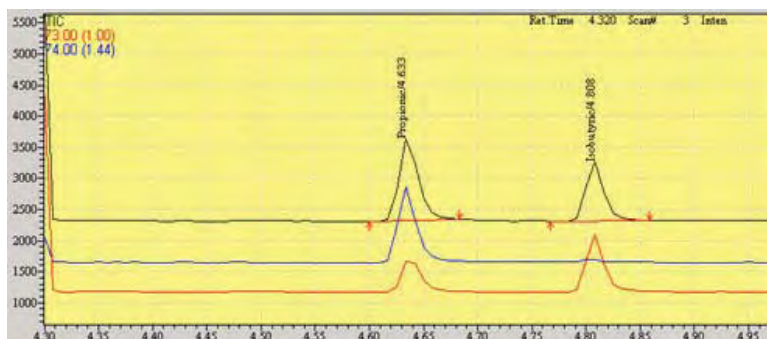


Table 2 : Type of test samples used in the study

Types of flour confection	No. of samples analysed	No. of samples detected with propionic acid
Bread	50	30
Biscuit	50	1
Cake	50	6
Muffin	50	6
Total samples	200	43

Tables 2, 3 and 4 show the results of the research undertaken by FSQL Perlis where 200 samples were analysed and Table 5 shows the results of 37 samples analysed in collaboration with USM.

Table 2 show a total of 200 samples of different types of flour confection that were analysed for propionic acid. Propionic acid was detected in 21.5% of the total samples (43 from 200 samples). However, only five (5) samples were found to contain propionic acid more than 2000 mg/kg as indicated in Table 4. The propionic acid was detected in bread (60%), biscuits (2%), cakes (12%) and muffins (14%).

The mean levels of propionic acid detected in 43 samples is summarised in Table 3. The results show that the average mean value of propionic acid found in the samples was 1032.9 mg/kg, where 1584.2 mg/kg was detected in breads, 390.0 mg/kg in biscuits, 727.7 mg/kg in cakes, and 1429.5 mg/kg in muffins.

- Total samples was 37.
- Propionic acid was not detected in three (3) samples.

Table 3 : Mean level of propionic acid detected in samples

Types of flour confection	Mean value, mg/kg	No. of samples detected with propionic acid
Bread	1584.2	30
Biscuit	390.0	1
Cake	727.7	6
Muffin	1429.5	6
Average mean	1032.9	

Table 4 : Mean level of propionic acid detected in samples that contravened the Food Regulations 1985

Types of flour confection	Mean value, mg/kg	Place
Sandwich Bread	3398	Sg Petani
English Bread	3369	Sg Petani
Roti Frankfurter	4057	Sg Petani
Sandwich Bread	3469	Alor Setar
Sandwich Bread	2292	Sg Petani
Average mean	3317.0	

Table 5 : Mean level of propionic acid detected in samples

Types of flour confection	Mean value, mg/kg	No. of samples detected with propionic acid
Bread	239.7	34
Average mean	296.7	

Conclusion

For the first batch of samples that were analyzed, propionic acid was detected in 34 out of the 37 samples, and all samples were within the permitted level of propionic acid as provided for under the Food Regulations (1985).

More propionic acid were added into bread product compare to biscuits product due to water contain in the product.

In the second batch, the results showed that propionic acid was detected in 43 out of 200 samples analysed but only five (5) samples were shown to contain more than 2000 mg/kg of propionic acid. Another 195 samples were found to be in compliance with the set. The most probable use of propionic acid in bread is to control mould infestation due to the fact that the water activity in bread is higher compared to that in biscuits. Data showed that only one (1) sample of biscuit analysed contained propionic acid. This is probably because biscuits are naturally dry, thus the water activity being too low to allow the growth of microorganisms. Propionic acid was also detected in muffins and cakes, but the number of samples was much lower compared to the number detected in breads. Cakes and muffins have a shorter shelf life compared to breads and are usually prepared fresh. Propionic acid and its related preservatives belong to the “Generally Recognised as Safe” (GRAS) list of chemicals. However, it could affect adults as well as children resulting in a wide range of health, behavioural and learning disabilities. With no evidence to suggest that propionic acid is carcinogenic to humans, the use of propionic acid in food is regarded as safe for consumers’ health.

The MOH will continue to monitor and enforce regulations on all food additives used by the food industry, including propionic acid. Action will be taken for any contravention. The objective of the Food Safety and Quality Programme is to ensure that all food sold in the market is safe to eat and complies with the current regulatory standards.

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HEALTHCARE, THE WAY FORWARD – TOWARDS SERVICE LIBERALISATION

SUMMARY

The introduction of liberalisation in trade and services has initiated a worldwide debate on the benefits of liberalisation in improving the economies of host countries. Liberalisation in healthcare services in particular, will witness the movement of people as well as technology, encourage foreign investments, promote services like telemedicine, medical tourism and encourage worldwide unity. Despite this, the world has to acknowledge the fact that liberalisation will bring about problems of access and equality especially for the poorer populations in developing countries. Therefore, the process of liberalisation should be ventured into with well thought-out strategies to strike a balance between economic/technology growth and the issues of access/equality to the local population.

Introduction

The world has witnessed a progressive trade liberalisation and economic growth, yet healthcare remains conspicuously un-globalised. This is due to the fact that healthcare services have been regarded as a non-tradable sector, whereby each country strives to ensure quality and access to healthcare for their population at large. Provision and consumption of services, however have become an increasingly important agenda. The incorporation of services in the General Agreement on Trade in Services (GATS) is one of the most important developments in healthcare service liberalisation.

Liberalisation of trade in services should lead to an optimal balance between preventive and curative services involving participation of both private industry and civil society.

Under GATS, Malaysia has made commitments in two major healthcare services sector namely hospital services and specialised medical services. Other than this, Malaysia has also made commitments under the ASEAN Framework Agreement in Services (AFAS) in the healthcare services sector including dental and specialised nursing services.

*Malaysia's
commitment GATS
and AFAS*

Mode of Delivery

Services delivered have been classified into several “Modes”. Services supplied from one country to another is known as cross-border supply or Mode 1. An example of cross-border supply for healthcare services is telemedicine which is the provision of services from a practitioner in one country to another practitioner or a patient in another country, predominantly via internet or satellite transmission of medical images. Telemedicine links between two sites include interactive video conferencing, teleradiology, telepathology, teleprimary care and many others. It is expected that virtual consultation will be one of the more important medium in the delivery of healthcare services.

Mode 1 – Cross-border supply

Consumers or firms making use of a service in another country are known as consumption abroad or Mode 2. Patients consuming medical services abroad represent a more significant source of international trade in healthcare services. In 2007, Malaysia had a total of 341,288 foreign patients, generating an income of RM 25.8 million. This has been identified as an area for potential growth by the country.

Mode 2 – Consumption abroad

Mode 3 or commercial presence is where a foreign company sets up a subsidiary or branch within another country in order to deliver the service locally e.g. private hospitals. In the World Trade Organisation (WTO), Malaysia is offering foreign equity of up to 40%. However this foreign equity among ASEAN Member States can be increased up to 70% by the year 2010.

Mode 3 – Commercial presence

Mode 4 or presence of natural persons is where individuals travel to another country to provide services in the host country on a temporary basis. Potential exchange of medical personnel between countries is attested across the world. Developing countries, particularly from Asia, supply over half of all migrating physicians, with around 100,000 doctors of Indian origin settling in the USA and UK alone. A 2007 estimate, for instance, also suggested that there were about 60,000 doctors of Indian origin working in the United Kingdom, contributing USD 8.9 billion to the UK economy. Active international recruitment has seen a particularly high level of mobility among nurses. The Middle East, for example, recruits nurses from Australia, Canada, India, Kenya, Malaysia, New Zealand, the Philippines, Trinidad and Tobago, and several other European countries.

Mode 4 – presence of natural person

Issues and Challenges

A crucial element and an important strategy that needs to be considered in the implementation of trade in healthcare services is to seek optimal use of forward and backward inter-linkages between domestic production and external markets for healthcare services, in order to foster the development of a competitive supply of healthcare services and a sustainable healthcare sector.

Interagency cooperation

Strategies developed to attract the overseas market for the healthcare sector need to have support from other government agencies namely the Ministry of Tourism, and the Department of Immigration. Healthcare services liberalisation will involve mobilisation of consumers and to the host country in seeking healthcare services. Thailand for example, has become one of the successful countries in the region in health tourism through interagency cooperation such as waiving of airport tax, and facilitating patients and their relatives with necessary visas. The latter include going to the hospital where a foreign patient is hospitalised if they need to renew their visa. Thailand, works very closely with its Tourism Ministry. In Malaysia, this inter-linkage between agencies has yet to be introduced.

Support from other agencies

Participation of Private Institutions

Currently, involvement of healthcare providers especially the private sector in healthcare liberalisation is very limited. Services provided by private hospitals to promote health tourism especially in Mode 2, are still individual hospital-based. There is still room to strengthen the efforts made to promote Mode 2 in bringing the foreign patients.

Role of private institutions

Database

Currently, there is very limited data on liberalisation in trade on services. Most of the data provided are based on estimates. There is also no definitive study or survey that has been carried out in the country to analyse the status of the four modes in liberalisation of trade on services.

Database requirement

Perception

The local healthcare industry and service providers perceive service liberalisation as a threat especially pertaining to Mode 3 and Mode 4. Examples of perceived threats are: incoming foreign practitioners to provide healthcare will deprive the locals from job opportunities, eventually escalate the healthcare cost, and induce the migration of government doctors to the private sector.

Perception of local healthcare industry and service providers

Domestic Regulations

The available domestic regulations have yet to address the needs for the liberalisation of healthcare services. Acts and regulations pertaining to professional and healthcare services as well as other health related laws need to be reviewed and amended to address pertinent issues. An appropriate regulatory framework supporting universal service provision and national health policies of equity and sustainability is required to strike a balance in the delivery of healthcare services.

Need of domestic regulations

Current Scenario

Today, Malaysia's involvement in healthcare liberalisation is recently more significant with several Free Trade Agreements (FTAs) being negotiated.

Involvement in healthcare liberalisation

Other than GATS and AFAS, FTAs between ASEAN-South Korea and ASEAN-China were finalised in 2007. The Malaysia-Japan Economic Partnership Agreement was signed in 2005 followed by the Malaysia-Pakistan Closer Economic Partnership Agreement in November 2007. Bilateral trade agreements between Malaysia and New Zealand, Australia, United States of America (USA), Chile and India are still at the stage of negotiation. In ASEAN, Malaysia has also been involved in negotiations between ASEAN-Australia/New Zealand and ASEAN-European Union (EU). Negotiation between Malaysia and Syria is still under study.

Free Trade Agreements

Malaysia has been elected as a permanent chairperson for the Healthcare Services Sectoral Working Group (HSSWG) in the ASEAN Coordinating Committee on Services (CCS). This working group discusses the Mutual Recognition Arrangement (MRA) for Medical and Dental Practitioners. To date, only the MRA on Nursing Services has been signed in December 2006.

ASEAN Coordinating Committee on Services

Malaysia's strategy to develop Economic Corridors in certain regions of the country will also bring about the expansion of the healthcare liberalisation. The Iskandar Development Region in Johore, for example, has offered foreign equity ownership of up to 100% for investment in healthcare sector.

*Economic Corridor
Development*

The Way Forward

The liberalisation of trade in services will be a good opportunity for the nation to boost economic growth. Although liberalisation of this sector is relatively new, Malaysia should attempt to capitalise and learn from the successes of other model countries.

Understanding Market Opportunities

- Investment Opportunity

In addition to local brands/hospitals, familiar settings/brands may encourage or instil confidence in foreign patients. Therefore, the presence of foreign renowned brands/hospitals such as Mayo Clinic, and Parkway Group Hospitals will help to further develop the industry.

Branding

The current 40% cap on foreign ownership is reported to be an obstacle for foreign investors as this does not give them control of the hospitals. However, there will be consideration to further improve foreign equity in future.

Foreign equity

Malaysia may also identify or develop local group healthcare investors which will look into investment opportunities in other countries besides creating its own brand name in healthcare industry.

- Customer Friendly Environment

Malaysia has the advantage of having a strong political will and stability which favours health tourism. Besides this, Malaysia's favourable foreign currency exchange, relatively cheap labour market and good quality healthcare are strengths that must be optimised. This will further enable the country to offer high quality healthcare services at a very competitive price. All these factors will be an attraction to foreign patients.

Malaysian Advantage

- Niche Market

The strategy should be focused on mechanisms and policy devices to support the supply of health services in all or any of the four modes of supply. Market opportunities rest upon product and services differentiation, which will vary depending on the market targeted. Malaysia should develop a niche market of its own and aim to be the hub for certain medical specialties such as cardiology, hepatology, endocrine surgery and other popular medical disciplines. Identification of Malaysia as the centre of excellence in specific medical disciplines will also be another advantage.

Niche market opportunities

- Dedicated Tourism Hospital

As support for the above, the Ministry of Health, Malaysia may consider establishing a dedicated Health Tourism Hospital – providing identified medical disciplines, including traditional and complimentary medicine, sufficient human resources and supportive professionals, highly sophisticated medical equipment and quality healthcare services. This hospital might initially be managed by the government, and later rolled out as a government linked corporate hospital.

Dedicated Tourism Hospital

- Marketing Strategies

New export capacities can be enhanced by preferential access to neighboring developing countries that can be augmented by religious, cultural and linguistic factors. Being a Muslim country, Malaysia should tap markets from the Middle East countries such as Saudi Arabia, Bahrain, Oman, Qatar and others. Within the region, Indonesia is the immediate potential market to be tapped, with the advantage of similar culture and language

Marketing strategies

Supply and demand driven mechanisms to stimulate the implementation of institutional arrangement facilities in and out of the country need to be enhanced as another marketing strategy in foreign markets.

Different market and healthcare services may require different strategies depending on factors such as market demand and size, presence of other competitors, and competitiveness of the service. In order to attain a competitive advantage in the healthcare industry,

these factors need to be considered in developing marketing approaches.

Linking healthcare and tourism, offering new services to healthy travelers and senior tourists (as have been captured in the Malaysia, My Second Home Programme) may be capitalised as new concepts of business ventures with other industries (e.g. hotels, travelling agencies and airlines) as part of the health tourism strategy.

Linking healthcare and tourism

The building of medical resorts and villages whereby a great diversity of healthcare services may be offered such as beauty treatments, anti-stress programmes and post-surgical convalescence, can be considered as another marketing strategy.

- Demand and Supply

The demand for cost-effective healthcare services is growing as delivery costs spiral upwards, consumer expectations of specialist care rise, and population ages (increase in elderly and chronic lifestyle illnesses). An intensive study to meet demands and supply will lead to the development of trading opportunities in this industry. This will include the movement of healthcare professionals providing services, introduction of new technologies, and types of medical disciplines to be provided.

Demand and supply

Development of resources and infrastructure

- Financial Support

With the recent global recession, financial support will be required. Healthcare services with good promising economic returns need to be identified and developed.

Finance

- Human Capital Development

Human capital development must be weighed against the potential negative effects such as brain drain and over-training of professionals in specific medical disciplines. The actual market demand and type of healthcare services to be provided need to justify the numbers of professionals and paramedics to be trained. At the moment, Malaysia is still having a shortage of certain specialties, therefore time-based and discipline based human capital development should be planned and trained.

Human capital development

- Infrastructure Development

Building a healthcare facility with the right size for the right market, and target covering identified disciplines are very important points to be considered in infrastructure development. This needs to be fully equipped with adequate medical equipment supported by appropriate technologies for support services such as medical records, laboratory support services, imaging, waste disposal management.

Infrastructure development

- Policy Development

Policies need to be introduced to promote and support development of health tourism in this country. They include development policies to support healthcare industry, health insurance schemes and all types of market incentives such as tax incentives and duty waivers.

Policy development

- Insurance Portability

Hospital fees in Malaysia are relatively inexpensive and competitively priced. Fees may be covered by an insurance scheme. However, there is a need to ensure that the insurance sector cooperates with private hospitals so that foreigners treated in Malaysia could utilise whatever insurance coverage from their home country.

Insurance portability

- Database and Research

Future development for healthcare services liberalisation needs to be supported by a reliable database and good research programme. This will enable policy makers and industry players to plan and develop the healthcare services industry.

Database and research

Strengthening Domestic Regulations

The available domestic regulations have yet to address the needs for the liberalisation of healthcare services. Acts and regulations pertaining to professional services and healthcare services and other health related laws need to be reviewed and amendments made to address pertinent issues in relation to this.

Domestic regulations

Interagency Cooperation

Strategies developed to attract the overseas market for the healthcare sector need to have support from other agencies namely the government such as the Ministry of Tourism, Department of Immigration and others. Healthcare services liberalisation will involve mobilisation of foreign consumers to the host country in seeking healthcare services. Thailand for example, has become one of the successful countries in the region for health tourism.

*Interagency
cooperation*

A closer network with related agencies such as the Ministry of Tourism, the hotel industry and the Department of Immigration need to be strengthened, thus developing a client-centred and client focused environment.

Networking

At present, health tourists enjoy fast track clearance and visa extension facilities. Similar facilities need to be extended to accompanying family members to attract patients seeking long term treatment in Malaysia.

Visa facilities

Conclusion

The maturity of the healthcare market is an important determinant of how successful a country will be in venturing into the liberalisation of healthcare services. Healthcare business is still steered by medical professionals, i.e. doctors. Malaysia undoubtedly has medical professionals of high caliber and is up to date with the current world class medical technology. Despite encouraging an influx of foreign professionals, liberalisation will also stem brain drain with thriving market opportunities. Liberalisation will only materialise with a more proactive role taken by the government. Domestic reforms in the healthcare sector and an enabling environment will be needed in promoting liberalisation with the promise of a good economic impact.

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