MINISTRY OF HEALTH MALAYSIA

MALAYSIA'S HEALTH 2005

foreword

The Ministry of Health, as the lead agency in healthcare provision, and authority on health in Malaysia, leads the way in directing the development of healthcare services in the country. We are proud to present Malaysia's Health 2005 which provides the latest developments in the Ministry of Health, population health, health system management as well as research and development in the health sector in Malaysia.

The 2005 report covers several current issues, among them the National Influenza Pandemic Preparedness Plan; Harm Reduction in the Prevention and Control of HIV/AIDs; and plans for the Development of Regulations on Medical Devices. Topics on Control of Unregistered Drugs; Malaysia's approach to Suicide Prevention and New Generation Hospitals provide interesting reading on health sector development in Malaysia.

We will continue to strive towards further improvements to this technical report series and make it an important source of information on health sector development in the country. We hope this report will enlighten our readers on the evolving health scenario in Malaysia, especially for those who are directly involved in the healthcare sector.

TAN SRI DATUK DR. MOHAMAD 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.

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Chapter 1

HEALTH CARE SERVICES

EMERGENCY MEDICAL AND TRAUMA CARE SERVICE IN MALAYSIA

SUMMARY

Emergency medical and trauma care service (EMTS) is a major and important component of hospital care service in the country. The development of the Emergency Medicine as a specialty and the commencement of local Masters Programme in the training of Emergency Physicians in 1998 have helped to improve and upgrade the provision of EMTS in the country. However, much more needs to be done to enhance the quality and level of EMTS in the country, among them, improvements to pre-hospital care service; adequate staffing; enhancing skills and competence of emergency department personnel. Improvements to structure, equipment and work processes as well as adoption of quality standards would further help to upgrade EMTS provided to the public.

Introduction

ED, critical first point of contact with patients

Emergency medical and trauma care service (EMTS) is a crucial component of any hospital service, providing 24 hour non-stop service throughout the year. It is a critical 'first point of contact' between healthcare providers and the acutely ill and trauma patients where early and appropriate intervention could greatly influence morbidity and mortality of cases coming to the hospital. Therefore, a high level of skill is required for emergency medical personnel to ensure prompt, effective and high quality service is delivered to improve patient outcome.

New ED leadership

EMTS has seen some new developments over the last 5-10 years, especially with the emergence of our locally trained emergency medicine specialists. The first batch of such specialists graduated in 2003 and since then, almost all state capital hospitals have emergency physicians heading the Emergency Departments. These emergency physicians have provided the leadership for the further development of emergency care service in the country.

ED attendance

A total of 4.409 million attendances at the emergency departments/ units were recorded in 2005 of which about 3.5 million were recorded in hospitals in Peninsular Malaysia, 0.5 million in Sabah and another 400,000 attendances in Sarawak. However, a large proportion of the patients seen were not real emergencies but rather, non-emergency acute illnesses.

Mission

To provide initial, comprehensive and holistic emergency medical and trauma care services in the hospital and pre-hospital settings which include resuscitation, stabilisation and definitive treatment to all patients in need so as to lessen morbidity and reduce mortality in such patients.

Objectives

The objectives of emergency medical and trauma care service are as follows :

i) Providing holistic emergency care with emphasis on technical aspects and corporate culture of professionalism, teamwork and caring service
ii) Providing emergency care through skilful emergency medical personnel who meet professional standards.
iii) Developing an organisation that emphasis on research and continual professional development

Scope and service system

ED before and now

The scope of service and the service system offered by the Emergency Department (ED) were unclear for many years. Emergency Departments, therefore, became a dumping ground for patients where diagnosis were unclear, as well as for medical officers who have no career plan. This was due to the lack of 'senior cover' or specialist overseeing the running of the department.

However over the years, this has changed. Emergency service is now recognised as the most important front line service in a hospital, and emergency medicine has gain more respect with its emergence as a specialty. The current scope of service in the Emergency Department are as follows :

i) Pre-hospital care service (Ambulance) service

Pre-hospital care

This is a first responder service provided by all Ministry of Health (MOH) hospitals except Hospital Kuala Lumpur where the service is provided by the St. John's Ambulance, the Red Crescent Society and the Civil Defence.

ii) Emergency medicine

Emergency care

This service is the back bone of the EMTS which comprise of holistic and comprehensive approach to diagnostic, therapeutic and definitive treatment provided to patients in the emergency department.

iii) Emergency medicine specialist service

Emergency specialist care

This is provided by emergency physicians who are stationed at the ED. ED specialist service was started at HKL in 1993 and is now provided at all state capital MOH hospitals. It will eventually be extended to all the district hospitals with specialist services.

iv) Medical observation

Observation

Providing temporary on-bed monitoring of patients pending decision on admission. These observation bays with beds are only available in the state capital and bigger district hospitals.

v) Medical standby

Medical cover

Medical cover for special events which are mainly government functions involving the Head of State or Government. From time to time, it covers international events hosted by the Government and attended by Heads of States from foreign countries. Some of the major events that had been covered are as follows :

- Commonwealth Games (SUKOM) in 1998
- South East Asia (SEA) Games, 2001
- Non-Aligned Nation Members (NAM) Meeting, 2003
- Organisation of Islamic Countries (OIC) Meeting, 2003
- Association of South East Asian Nations(ASEAN) Summit, 2005

vi) Disaster management

Disaster management

This is one of the 'core business' of EMTS. Emergency departments have been directly involved in the management of disasters in this country, acting as the main focal point for emergency response to disasters. This include major catastrophes like building collapse, the most famous of which was the Highland Towers incident in 1993; natural disaster like the Tsunami in 2004; and standby for other disasters, in particular airport disasters. The emergency departments must always be vigilant on other possible emerging disasters like bioterrorism and nuclear accidents.

vii) One Stop Crisis Centre (OSCC)

One-stop crisis management

This centre has been operational since 1993 at the Kuala Lumpur Hospital. It has since been extended to all hospitals in the country. OSCC aims to provide a one-stop service and care for cases of violence against women and children, sexual assault and rape victims. OSCC is one of the essential services in EMTS. It has become a model used by the WHO to provide similar service in other countries such as Bangladesh, India, Philippines, Indonesia and Thailand.

Human resource and training

The Ministry of Health is going towards the training of a skilled group of staff that would be working in the Emergency Department. The staff would be trained towards pre-hospital care, disaster management and will also now be looking towards being trained in the handling of Hyperbaric Chamber.

i) Short training courses

Short-training courses

Training is one of the most important aspects of human resource development and it has been greater emphasis in the 9th Malaysia Plan. Short in-service training courses are conducted locally by the respective hospitals or nationally from time to time, among them are as follows :

- Basic Life Support (BLS)
- Advance Life Support (ALS)
- Major incident management
- Patient triaging

- Managing patients in crisis (domestic violence, sexual assault, child abuse, and others)
- Wound management

A new course on handling of casualties of weapons of mass destruction (Hospital-based mass casualty) is being introduced in collaboration with the American Embassy.

ii) Post-basic Emergency Medicine

Post-basic training course

This is a 6 months post-basic training opened to medical assistants and staff nurses aimed at improving the level of competence of emergency department personnel. The first post-basic emergency course was started in May 1989 at the Medical Assistants Training College in Seremban. Currently, the programme is provided at two other training colleges in Ipoh and Kuching.

iii) Emergency medicine specialist training

Local Masters programme

This is a four year Masters programme which was started by Universiti Sains Malaysia (USM) in 1998. Since then, the programme is now available at two other universities, namely, the National University of Malaysia (Universiti Kebangsaan Malaysia, UKM) and the University of Malaya where the latter has just started in 2005. Upon graduation, these officers undergo a six-month pre-gazetment training in one of the accreditated hospitals before final gazetment as an emergency medicine specialist (emergency physician). Currently there are 21 gazetted emergency physicians working in the Ministry of Health hospitals and another 7 working in the university/Ministry of Defence hospitals **(Table 1).**

Table 1 : Distribution Of Emergency Medicine Specialist in Malaysia, 2005

Hospital	Number
Hospital Kuala Lumpur	6
Hospital Selayang	1
Hospital Serdang	1
All other state hospitals	13
USM Hospital, Kubang Krian	3
UKM Hospital, Cheras	2
Ministry of Defence	2
Total :	28

EMTS New Initiatives

i) Ambulance control and dispatch control centre

This was a pilot project that was carried out in mid 2004 to the end of 2004. Following the Tsunami disaster in December 2004, this pilot project was extended to 7 sites after it was noted to be successful in Penang. The sites include Hospital Pulau Pinang, Hospital Kangar, Hospital Ipoh, Hospital Melaka, HTAR Klang, Hospital Temerloh and Hospital Batu Pahat..

ii) Motorcycle squad

This squad moves on a motorcycle and acts as a First Responder to an emergency call. It is particularly useful in crowded urban areas like the Klang Valley where the traditional ambulance may not be able to respond to emergency calls speedily due to heavy traffic. The motorcycle squad manned by trained paramedic will be dispatched as a first responder to emergency calls, while awaiting the arrival of the ambulance. This project would be piloted in the Klang Valley in the late 2006.

iii) Pre-hospital care project

The pilot project involving the establishment of 'Pre-hospital Care Unit' at the Emergency Departments has been planned for the Klang Valley and Penang Island and is expected to take off in early 2007.

iv) Hyperbaric chamber service

The first hyperbaric chamber service providing mainly decompression therapy to deep sea compression sickness incidents, will be first established at the Emergency Department in Hospital Kuala Terengganu as several islands in the state are popular destinations for divers. Two other centres will also be established in Hospital Sungai Buloh and Hospital Kota Kinabalu.

Issues and challenges

i) Career development

The current policy of 'promote & transfer' is no longer suitable because it prevents skill expansion of emergency medical personnel. A clearer

Review "promote &

career path must be set up in emergency medicine to encourage more personnel to further their studies up to the tertiary levels. First degree courses for the support staff should be recognized and encouraged. Furthermore, extended roles for the paramedics should be considered.

transfer'' policy

Attractive career path in Emergency Medicine should be established for the medical officer waiting in the Emergency Department.

ii) Norms

Norms for the EMTS personnel at all levels must be revised and separate from outpatient department norms to reflect a totally different scope of service provided in the emergency department. Besides the usual workload norm in terms of number of patients managed per day, staffing norms for EMTS personnel must take into consideration special factors such as :

Staffing norm for ED

- Condition of patients – whether critical and semi critical
- Average time spent on critical patients
- Actual core services provided (first responder, EMS, medical standby, inter-facility transfer and others)

iii) Training

Opportunities for short courses and long term courses must be expanded and extended. Under the 9th Malaysia Plan, local and overseas training courses have been introduced to give more exposure to the staff on disaster management, pre-hospital care and also in hyperbaric medicine.

Further training opportunities

iv) Pre-hospital care

The Ambulance service in the country has to be upgraded and improved, including water ambulance service though air ambulance would be costly to be provided under the Ministry of Health. Inter-hospital networking among all the hospitals in the state must be further enhanced to provide a more efficient pre-hospital care service.

Upgrading of pre-hospital care service

vi) Service standards

Work processes development including clinical guidelines and critical pathways must be emphasized in order to sustain high standard of

Introduction of service

EMTS care. Service standards and professional standards need to be addressed. Proposals for the indicators of standards of care are as follows :

standards

- Preventable trauma death
- Triaging error
- Waiting time in non critical zone
- Door to needle time in thrombolytic therapy for acute myocardial infarction
- Rate of miss fractures in the Emergency Department

vi) Structure and layout

Modern emergency department designs incorporate features that cater for the many different categories of patients being managed at the ED while structural layout provides ease of patient flow and support new concepts in patient care. Structural layout since 1994 has been based on dedicated zones according to physical condition of the patient. Treatment zones are colour coded to ensure efficient execution of the emergency care from the time of arrival of the patient at the ED to exit for the ward, home or mortuary. Components of the ED by zone should include the followings :

Proper physical structure and design of ED

- Triage zone
- Critical Zone
- Semi-critical zone
- Non-critical zone
- Asthma zone
- One Stop Crisis centre (OSCC)
- Observation ward
- Procedural zone
- Decontamination zone
- Emergency operation zone

vii) Inappropriate use of ED

EDs are increasingly being used as a primary care centre for acute but non-emergency conditions. This is particularly so in urban areas where hospitals, in particular EDs, are readily accessible and where health clinics do not provide after office on-call service. The problem could be related to socio-economic factors. A large segment of the urban population are working during office hours and often sought treatment for themselves or family members after work. The

Inappropriate use of ED

large number of non-emergency patients create congestion and long waiting for patients, resulting in complaints at times. The problem is compounded by the fee structure which encourages use of ED facility as the payment of RM1 is a token, compared to the much higher fees charged by the private clinics.

To overcome the problem, out-of office hour primary care service under the "hospital-locum" service system was introduced in October 2002. Currently, it is being provided by the bigger hospitals. It is perhaps time to consider revising fee structure for ED to promote a more appropriate use of ED as a centre for emergency service.

Review fee structure in ED

Conclusion

Emergency medical and trauma care service in this country has evolved significantly over the last ten years. However, much more can be done in terms of human resource, facility, service and organisational developments to ensure this crucial first point of contact with the hospital under emergency conditions truly reflect the level and standard of service provided by the hospital. An efficient, effective and high quality EMT service can make a difference to the outcome of patients in reducing morbidity and mortality associated with medical emergencies and trauma.

In line with the theme of the 9th Malaysian Plan to "Achieve Greater Health through Consolidation" and the goals of Enhancing Healthcare Delivery and Reducing Disease Burdens, it is hoped that sufficient resources would be provided to develop EMTS further towards better health for all Malaysians.

REHABILITATIVE SERVICES IN MALAYSIA

SUMMARY

Rehabilitation medicine involves the prevention and reduction of disability and handicap arising from impairments, and the management of disabilities from a physical, psychosocial and vocational perspective. Rehabilitation medicine as a specialty only started in 1996 with the posting and establishment of the Rehabilitation Medicine department in Hospital Kuala Lumpur. The development of rehabilitation medicine is still slow with only seventeen rehab physicians in the country, of which half are in the Ministry of Health hospitals. The main bulk of rehabilitation service is still being delivered by the physiotherapists and occupational therapists where the focus is mainly on physical rehabilitation of mobility and Activities of Daily Living. Training programmes for various categories of rehabilitation professionals have been started in the local universities in recent years. However, the number is still limited and the acute shortage of rehabilitation professionals will hamper the development of rehabilitation service in the country.

Introduction

Defining rehabilitation medicine

Rehabilitation medicine refers to the care provided in returning an individual to his or her maximum possible functional capability following the loss of function and/or ability. In a broader sense, Rehabilitation medicine is the branch of medicine concerned with the prevention as well as reduction of disability and handicap arising from impairment and the management of disabilities from a physical, psychosocial and vocational perspective. It emphasizes maximal restoration of the physical, psychological, social and vocational function of the person, the maintenance of health and the prevention of secondary complications of disabilities.

The demand for rehabilitation services is growing world-wide. The World Health Organization (WHO) estimates the number of people who require rehabilitation services at any point in time to be 1.5% of the total population of any particular country.

Second National Health and Morbidity Survey

The Second National Health Morbidity Survey (1997), revealed that the proportion of our population with overt disabilities (including stroke, spinal cord injury, cerebral palsy etc.) is about 6.5%. Factors associated with the increase in this demand for rehabilitative services

in Malaysia include better perinatal care; change in the demographic structure of the population and changes in pattern of disease from acute infectious diseases to chronic life-style related diseases. These, respectively have resulted in increased survival rates for children with disabilities; a higher proportion of the elderly as a result in increase life expectancy and an increase in the number of persons with disabilities. The Malaysian Burden of Disease and Injury Study (2001) indicated that ischaemic heart disease, cerebro-vascular accidents and motor vehicle accidents are high among the top 10 disease burdens in the country.

Injuries due to industrial accidents

Industrial accidents have also resulted in premature deaths and disabilities. A study conducted by the Social Security Organization revealed that from 1998 to 2002, a total of 50,992 insured persons were permanently disabled while another 91,896 insured persons were found to be invalid. The number of insured persons suffering each year from permanent disability has stabilized to less than 12,000 per year recently. The number of insured person suffering from invalidity however, increased significantly from 13,316 persons in 1998 to 23,449 persons in 2002. Such a trend reflects increasing wastage of valuable human resources especially for a nation such as Malaysia which faces a labour shortage. Thus, this demonstrates the importance of Rehabilitation Medicine.

Scope of rehabilitation medicine service

Rehabilitation medicine requires a holistic or integrated approach and is best achieved through the combined and coordinated use of the skills of medical and allied health professionals. This addresses not only the physical but also vocational, social, home and psychological rehabilitation of persons with loss of ability.

In Malaysia, rehabilitation medicine encompasses the following services :

- Consultation services for assessment, therapeutic and rehabilitative care
- Nursing care
- Physiotherapy
- Occupational therapy
- Medical Social services
- Speech therapy
- Orthotic and Prosthetic services

The main clients of rehabilitation consultation are amputees; neuromedical and neurosurgical patients; patients with spinal cord injuries; persons requiring orthotic services; paediatric patients with physical handicap such as cerebral palsy and spina bifida as well as cardio-respiratory patients. Other clients require assessments for their driving licenses; assessments for wheelchair requirements or specialized wheelchair seating needs; home modification and vocational placement. Patients are normally referred from other departments of the hospital as well as from primary health centers for this service. Currently the services are provided in 19 primary health care facilities as well as all secondary and tertiary hospitals.

Main clients of rehabilitation medicine service

Current status of rehabilitation medicine services in Malaysia

Rehabilitation medicine specialist service was first started in Hospital Kuala Lumpur in June 1996. Currently, there are seventeen rehabilitation medicine specialists in the country. Out of the seventeen, only nine are with the Ministry of Health. However, this service is only available in three MOH hospitals namely, Hospital Kuala Lumpur, Hospital Putrajaya and Hospital Seremban. Non-specialist rehabilitation services provided by the allied health professionals are available in most large hospitals throughout the country, including some larger health clinics. These include physiotherapy, occupational therapy and speech therapy services.

Development of rehabilitation medicine specialist service

Hospital Putrajaya also serves the Bangi Vocational Rehabilitation center which is a training centre for the physically handicapped under the Ministry of Women and Family Development. The University of Malaya Medical Center has the most comprehensive Rehabilitation Medicine service. However, it is constantly challenged with the problem of brain drain of its trained personnel, increasing demand for its services as well as the lack of financial support to expand its services

Physiotherapists, occupational therapists, the main providers of rehabilitation service

Currently, most of the rehabilitation services are managed by individual clinical disciplines, supported by physiotherapists, occupational therapists, speech therapists and medical social workers. Rehabilitation services delivered by physiotherapists and occupational therapists are focused mainly on physical rehabilitation of mobility and "Activities of Daily Living" (ADL). These have been in existence in Malaysian hospitals for decades, and still form the backbone of rehabilitation services for the majority of government hospitals nationwide.

Rehabilitation physicians needed for more complex disabilities

However with increasing complexity of disabilities, Rehabilitation Physician forms the essential bridge to address the complex needs of these patients. With increasing acute care workload and increasing number of patients needing long term rehabilitative care, the future will see additional emphasis being given to developing Rehabilitation Medicine as a specialty and organized as a department, for close liaison and continuity of care of patients.

Rehabilitation services provided by health clinics and other agencies

Rehabilitation service in health clinics

From 1996, under the expanded scope of activities, rehabilitative services were introduced to selected health centres. Currently there are 115 health centres providing rehabilitative services for children with special needs, 229 for geriatric patients and 23 centres providing psychosocial rehabilitative services for the stable mental patient. These services are being provided by trained paramedics such as public health nurses and medical assistants. Case management plans of the clients receive input from the physiotherapist and occupational therapist in hospitals and clients are followed up at the health centres under the supervision of the therapist in nearby hospitals.

Rehabilitation service by other agencies and NGOs.

Rehabilitation services are also provided by other government agencies and non-government organizations (NGOs). The Department of Social Welfare provides rehabilitation services through its 313 Community-based Rehabilitation (CBR) centers that focus mainly on social, educational and vocational rehabilitation and which caters to all ages. The National Stroke Association of Malaysia (NASAM) conducts rehab sessions which include physiotherapy, occupational therapy and speech therapy for stroke survivors through its 6 centres in Petaling Jaya, Ampang, Penang, Perak, Malacca and Sabah.

Categories of rehabilitation medicine professionals

Rehabilitation medical services are provided by many different healthcare professionals who look after different aspects of rehabilitation. They include:

HC Professional	Role
Rehabilitation physician	Consultants / specialists in rehabilitation medicine supervise rehabilitation programs for complex cases and assess and manage the care of patients requiring multidisciplinary rehabilitation services

Nursing/ Medical assistants	Rehabilitation nurses and medical assistants in wards provide comprehensive care and assist patients to become more independent as their condition improves
Physiothera-pists	Physiotherapists design individual programs for patients and assist them in physical rehabilitation
Occupational therapists	Occupational therapists identifies individual treatment plans and assist patients to return to their former activities, which include personal care, domestic tasks, work, driving and home/work adaptations
Speech therapists	Speech Therapists assess and rehabilitate those with speech and swallowing problems
Medical social workers	Medical Social Workers offer supportive assistance which includes financial, prosthetic aids, vocational placement, networking with relevant agencies, and community placement in preparation for the patients to return to the community.
Clinical psychologists	Psychologists assess and assist in rehabilitating those with behavioural problems that interfere with a person capacity to be rehabilitated, especially head injury cases, cerebrovascular accidents
Counselors	Counselors provide moral support, guidance and counseling for those who need mental support while adjusting to their disabilities, including the carers
Rehabilitation technicians	Orthotic and prosthetic devices for disabled persons are manufactured and provided by rehabilitation technicians

Human resource

Distribution of rehabilitation physicians

Currently, there are 17 rehabilitation physicians in the country with only 9 working in the Ministry of Health, 5 in University Hospitals and 3 in the private sector. Malaysia has a need of between 150 rehabilitation physicians based on the planning norm of 1:150,000 (Medical Development Division, Ministry of Health) to 300 based on the Royal College of Physician, London (RCPSC)'s norm of 1: 85,500 population.

Physiotherapists and occupational therapists

As for the physiotherapists, there are currently 405 physiotherapists in the Ministry of Health and 218 in private practice while the number for occupational therapist is 364, most of them are in the public sector (270 in MOH hospitals, 10 in health clinics, 16 in university hospitals and 5 in Social Welfare Centers) while 16 are in the private sector and 8 are with non-government organisations.

Speech therapists

The number of speech therapists in the country is very limited, totaling 83 with most of them in the universities (38); 25 in MOH hospitals and another 20 are in private facilities. The distribution of the physiotherapist, occupational therapist and speech therapist in the Ministry of Health by state are as shown in the table below.

Table 1: The distribution of the physiotherapist, occupational therapist and speech therapist in the Ministry of Health by state, 2005

States	Physio-therapist	Occupational therapist	Speech therapist
Perlis	6	5	1
Kedah	19	12	2
Pulau Pinang	31	19	1
Perak	40	35	3
Selangor	38	32	3
Negeri Sembilan	13	15	1
Melaka	11	7	1
Johor	31	29	4
Pahang	19	13	0
Terengganu	16	7	1
Kelantan	22	11	1
Sabah	52	21	1
Sarawak	50	38	2
WP K. Lumpur	46	26	4
Total	**405**	**270**	**25**

Training in rehabilitation medicine

Training of rehab physicians

The training of rehabilitation physician is presently available only at the University of Malaya as a postgraduate Masters Programme. This is a four year post-graduate programme was started in 1997. It is a closed system program where trainees spend their full four years in the university. The programme attracts only a handful of candidates each year, except in 2002/2003 session which attracted 9 candidates. Previously, trainees spent a 6 month elective period at the Melbourne Extended Care and Rehabilitation Services, Australia. However, this was stopped in 2004 due to the cost involved.

Open masters programme preferred

It is envisaged that the Open Masters program will be adopted, with candidates spending at least one to two years in an accredited government hospital and rehabilitation consultant physicians of these hospitals will become honorary lectures of the academic institutions to facilitate the training, monitoring and enhancement of competency of the trainees in meeting service needs upon their graduation.

Training of speech therapists

Speech therapists are presently trained at the National University of Malaysia (UKM). This is the only training centre for speech therapists at the moment. This four years training programme was started in 1995.

Training of physiotherapists and occupational

Physiotherapist training programme started in 1976 at the College of Physiotherapy in Hospital Kuala Lumpur while the College of Occupational Therapist commenced its training programme in 1984. Both these are a three year diploma programme under the Ministry of Health. These training colleges moved to the Allied Health Sciences College in Sungai Buloh in 2004 but practical training is still based at the Kuala Lumpur Hospital.

Degree programme in physio and occupational therapy

Since the past five years, UKM has offered a degree program for physiotherapy students while the degree programme for occupational therapy started this year (2005). In the same year, MARA University of Technology (UiTM) also initiated a degree program for physiotherapy and occupational therapy.

Post-basic rehab training programme for paramedics needed

There is no special training in rehabilitation medicine for nurses and medical assistants. However, it is important to establish a post-basic programme for rehabilitation nursing in the future. The delivery of acute and long term rehabilitation care is inherently dependent on competent nursing support, and presently, this is lacking in

Malaysia. The post-basic program would facilitate the development of this needed trained manpower, and provide a career incentive for personnel to venture and commit to the development of this service.

Future development of rehabilitation medicine

Rehabilitation medicine identified for development since the 7th Malaysia Plan

Medical Rehabilitation was identified as one of the seven major activities of the Medical Program since the 7th Malaysia Plan (1996 – 2000) and again under the 'Extended Medical Care' activity of the 8th Malaysia Plan (2001-2005). The plan included the building of a special Rehabilitation Hospital to provide a comprehensive range of rehabilitation services. This centre would have provided the impetus for the development of rehabilitation service in the country. However, this plan had to be delayed and brought forward to the 9th Malaysia Plan (2006-2010). In addition, the rehabilitative services that were initially slated for all MOH hospitals and health clinics had to be deferred or reduced in scope and size due to human resource constraints.

Levels of rehabilitation medicine service

For planning and development of rehabilitation medicine services in the Ministry of Health hospitals and health clinics, six levels of services have been identified as follows:

Level	Description
1	Limited range of medical rehabilitation services provided by non-specialised staff (nurses/medical assistants) and by visiting physiotherapists
2	As in level 1 plus physical and vocational rehabilitation provided by professional staff for assessing and rehabilitating physical disabilities. Counseling services provided. Have access to specialized care. Day care services provided. Non in-patient rehabilitation wards. (+ physiotherapist, occupational therapist, counselors)
3	As in level 2 plus social rehabilitation services provided by professional staff. No formal rehabilitation wards. May have visiting medical rehabilitation specialist services. Quality assurance activities undertaken. (+ medical social worker)

4	As in level 3 plus full range of medical rehabilitation services (including speech and psychological rehabilitation) provided by professional teams appropriate to other services provided within the hospital. Inpatient rehabilitation wards provided for medical rehabilitation. Full time medical rehabilitation specialists available for consultation and participation in wards rounds. Consultation available from other specialists. Formal QA program. (+ speech therapist, psychologist, medical rehabilitation consultations)
5	As in level 4 plus professional staff may have subspecialty interest/skills relevant to the needs of the designated population such as stroke rehab, head injury rehab, cardiac rehab, pain rehab. Artificial aids and prosthesis fabricated. Rehabilitation technology services provided. Regular basic and undergraduate training undertaken. (+ trainers, subspecialists, therapist, with advanced skills)
6	As in level 5 plus regular postbasic and postgraduate training for a range of professional disciplines. Conducts formal research projects.

Specialties in rehabilitation medicine

Various specialties of rehabilitation services would be developed in phases. These include neuro rehabilitation, cardiac and pulmonary rehabilitation, spinal rehabilitation and paediatric rehabilitation with cardiac and neuro rehabilitation to be developed first. A Stroke Day Care centre was established in December 2003 in Hospital Kuala Lumpur. This centre is headed by a neurologist and the cases are jointly managed by multidisciplinary team comprises of rehabilitation physician, physiotherapist, occupational therapist, speech therapist and the rehabilitation nurse.

Conclusion

Rehabilitation medicine is an important component of medical care service in the country as the burden of disease moves towards more chronic debilitating disorders. One of the biggest challenges in the development of rehabilitation medicine service is the acute shortage of all categories of rehabilitation healthcare professionals, in particular rehabilitation physicians. However, with the local universities starting training programmes for the rehabilitation therapists, the situation

will improve a little. Training for rehabilitation physicians need to be increased while post-basic rehabilitation nursing need to be considered to hasten the development of rehabilitation medicine service to meet future needs of the country. There is also a need to work with other agencies and NGOs involved in rehabilitation service to increase accessibility of rehabilitation service to those who need them

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SPECIALISATION AND SUBSPECIALISATION IN THE MINISTRY OF HEALTH

SUMMARY

As the practice of medicine has grown more complex, coupled with public expectations, there has been a need for doctors to specialise and subspecialise. Specialisation and subspecialisation have enabled the Ministry of Health in its medical care programme to provide specialist medical services in 61 (55 hospitals and 6 institution) of its 131 hospitals and medical institutions. Specialisation and subspecialisation training programmes can be pursued both locally and abroad. The MOH recognizes some 100 basic specialty degrees and 117 subspecialties in 16 broad clinical disciplines. For the year-end 2005, 2014 specialists. (inclusive of 220 contract specialists) served in the Ministry of Health hospitals representing 43.6% of the total specialist workforce in the country. This includes 419 formally gazetted subspecialist or specialists who have undergone training in subspecialty area of interest. With specialisation and subspecialisation programmes, the MOH is currently providing resident tertiary care specialist services on a regional basis (5 regions), secondary care specialist services in all state hospitals and varying scopes of secondary care specialist services in specific district hospitals. The training programmes for specialists and subspecialists are monitored objectively by formalised specialty and subspecialty training committees. Specialist attrition to the private sector is a perennial issue that needs to be addressed.

Introduction

Rapid advancements in science and technology have continually added new dimensions and knowledge to the practice of medicine and making it more complex. Thus, it has become increasingly difficult for physicians to keep pace with advancements in all areas of medicine and be an expert in all. The need to keep abreast with latest development becomes even more relevant as doctors grapple with an increasingly knowledgeable public, thanks to advancements in information technology where medical knowledge is no longer confined to those in the medical fraternity. This has lead to greater demand for specialist services in the country and all over.

Specialisation and subspecialisation

Knowledge and sound evidence-based clinical judgments are the competencies that justify the physician's status as a professional. Physicians have a duty to maintain and add to their knowledge new developments in medicine throughout their professional careers. Hence, specialization and subspecialisation have become more essential than ever, in order to develop expertise in specific areas, taking advantage on the vast knowledge available on each particular area.

Defining specialisation and subspecialisation

The term specialisation in medicine can be defined as medical practice limited to some special branch of medicine or surgery, especially by one (specialist) whom, by virtue of advanced training, is certified by a specialty board as being qualified to so limit his of her practice. A specialist is defined as one who possesses a postgraduate qualification in a basic clinical specialty. The term subspecialisation refers to the limited practice of a branch of medicine subordinate to a specialty. A subspecialist is one who has further specialisation in a particular area in that specialty.

Specialist service delivery

The provision of specialist and subspecialist healthcare services is delivered through two parallel healthcare systems that exist in this country, i.e. those provided by the public or government health sector and those by the private sector. In the public sector, the Ministry of Health (MOH) is meeting this demand of the majority of the population through its extensive network of healthcare facilities. Other government sectors providing specialist and subspecialist healthcare services though on a much smaller scale include the Ministry of Higher Education (3 University Hospitals), and the Ministry of Defense (2 Armed Forces Hospitals).

The private health sector has responded concomitantly to demand for specialist services, resulting in the growth of private healthcare sector, in particular specialist clinics and medical centres, as well as private hospitals which offer mainly specialist services.

Specialist services in the Ministry Of Health

Holistic service provision by the Ministry of Health

The Ministry of Health is the main healthcare provider in the public sector, from primary healthcare in the health clinics and outpatient departments in hospitals; to basic inpatient, specialist and subspecialist medical care services in the hospitals.

Development of specialist services and facilities have been well planned in terms of geographical distribution and service types offered. They are being continually upgraded through progressive development in priority areas to enhance the quality of care provided. These include basic specialist services in all state hospitals and identified district hospitals as well as tertiary subspecialty services on a regional basis and in centres of excellence for various disciplines at the national referral centres.

Levels of specialist service

Specialist services are sometimes defined by their levels, namely secondary and tertiary specialist services. Secondary level specialties are generally those that are acquired as a first level of specialization after the basic medical degree. Tertiary level specialist services are further subspecialty training in a particular area of the general specialty. The terms secondary and tertiary are however, relative and changes over time as the country develops. They were also defined for the purpose of planning and development as illustrated in the way secondary level specialist services were developed in consecutive 5-year Malaysia Plans as follows :

6th Malaysia Plan (1991-1995)	7 basic secondary level specialist services • General medicine • General surgery • Paediatrics • Obstetrics and Gynaecology • Anaesthesiology • Pathology • Radiology
7th Malaysia Plan (1996-2000)	15 secondary specialist services • 7 of the above • Orthopaedics • ENT • Ophthalmology • Psychiatry • Dermatology • Emergency Medicine • Rehabilitative Medicine • Geriatrics
8th Malaysia Plan (2001-2005)	Continuation of the above 15 specialty services

At the conclusion of the 8th Malaysia Plan (2001-2005), there are a total of 125 MOH government hospitals and 6 MOH special medical institutions in the whole country. Of these, a total of 61 hospitals and institutions, comprising of state level hospitals and the larger district hospitals, provide specialist services varying in scope of disciplines.

Specialist service provision by government hospitals

In general, all state hospitals are to provide full secondary level specialist services and designated tertiary care services by resident specialists. The district hospitals with specialists provide varying scopes of specialist services by resident specialists and also visiting specialists from the state hospitals while other district hospitals are covered by visiting specialists from the state hospitals and district hospitals with specialists. In addition specialist services are also provided in hospitals by specialists from medical colleges utilising government hospitals for their undergraduate training programmes, and also by private doctors contracted on a sessional or honourarium basis by some hospitals. The list of hospitals providing secondary and tertiary level specialist services are shown in **Appendix 1.**

Specialist and subspecialist human resource

Specialist norms

Traditionally the MOH uses the Canadian specialist-population norms in projecting its specialist complement needs. In the 80's the norms used were 1/6 of the Canadian norms. Subsequently, it was revised to 1/3 in the 90's and currently, the Ministry adopts the full Canadian norms for planning purposes. However there are no particular norms for projecting the needs for subspecialists. The MOH has been guided by both "service norms" of 1 department per 1 million population and also by regional centre needs. **(Appendix 2)**

Specialist and subspecialist complement

As of year-end 2005, the country has a total of 4,615 specialists (all sectors) compared to the need for 15,235 specialists in 32 major disciplines.

Of these, 2,013 (43.6%) serve in the Ministry of Health, including 231 contract specialists, constituting 27.2% of the total 7,393 doctors serving in the MOH in 2005. Of the 2,013 MOH specialists, 1,285 (88.5%) are specialists in various disciplines, including contract officers and those undergoing pre-gazettement training **(Table 1).**

Table 1: Specialist and subspecialist manpower in the Ministry of Health (including public health), Dec. 2005

Category	Permanent	Contract	Total
Specialist	1579	206	1785
Subspecialist	203	25	228
Total :	**1782 (88.5%)**	**231 (11.5%)**	**2013 (100.0%)**

On record in the Ministry of Health, 227 (11.3%) had been gazetted as subspecialists in various areas of specialties. Another 200 odd specialists are undergoing various stages of subspecialty training. This figure, however, does not portray the actual situation as many subspecialists do not proceed to be gazetted as subspecialist as it does not provide any difference to the scheme of service.

Specialist training

Specialisation in the early years

Before the 70's, doctors who wished to specialize had to do so abroad on their own, mainly in the United Kingdom or Australia. Beginning early 70's, the University of Malaya began coordinating local training programmes for foreign specialist degrees like the Membership of the Royal College of Gynaecologists (MRCOG) and Membership of the Royal College of Physicians (MRCP).

Local specialist (Masters) training programmes

Realising the urgent need for more specialists for the country's healthcare delivery system, the local universities introduced local master's specialisation training programmes. This was initiated by University of Malaya in 1973 in the disciplines of pathology, medical psychology and community health, followed by the University Kebangsaan in 1981 in the disciplines of general surgery and orthopaedics and University Sains Malaysia in 1988 in the discipline of internal medicine. Although specialisation certification can be pursued locally, those who wish to obtain foreign specialisation certification are free to do so.

Open Masters training programme

The Master's specialist training programme subsequently introduced the concept of "open" Master's degree specialisation programme in July 1996 where the training period is conducted in both accredited MOH hospitals and the university hospitals, as opposed to the earlier "closed system" where the full duration of training is conducted in the university hospitals. Presently 1419 doctors are pursuing the Master's training programme in the three universities in 19 specialty courses **(Table 2)** and 26 MOH hospitals are accredited as training centres for the Master's open

programme **(Table 3)**. Some of the newer masters training programmes offered include neurosurgery and plastic surgery in 2001 at Universiti Sains Malaysia and clinical oncology in 2003 at University of Malaya.

Table 2: Number of Remaining Trainees in Local Masters Training Programme (2002– 2005)

Clinical Discipline	2002/2003 (Year 4)	2003/2004 (Year 3)	2004/2005 (Year 2)	2005/2006 (Year 1)	Total
Obstetric & Gynae	29	38	33	33	133
Anaestesiology	35	45	40	21	141
Paediatric	19	8	10	18	55
Internal Medicine	20	29	23	36	108
Psychiatry	7	8	11	25	51
Radiology	28	25	23	22	98
Surgery	34	37	25	42	138
Ophthalmology	22	20	18	30	90
Orthopaedic	18	25	34	34	111
Otorinolaryngology	16	17	21	17	71
Pathology	13	15	30	33	91
Family Medicine	21	20	18	25	84
Public Health	39	41	42	41	163
Sports Medicine	1	3	2	0	6
Rehab. Medicine	3	2	9	3	17
Emergency Med.	8	8	8	12	36
Plastic Surgery	2	3	1	1	7
Neurosurgery	2	0	4	5	11
Oncology	0	1	2	5	8
Total :	**317**	**345**	**354**	**403**	**1419**

Source: Training and Human Resource Planning Division, Ministry of Health

MOH doctors who are selected for the Master's Programme are offered scholarships by the Public Service Department (Hadiah Latihan Perseketuan). An average of about 400 scholarships are offered each year for MOH doctors to pursue the programme. For foreign specialist certification, MOH doctors are either provided scholarships by the Public Service Department in selected specialty disciplines where there is no local programme. Many doctors pursue foreign specialist certification in basic specialties on own their own (self-study and self-financing) while undertaking the local master's training programme.

The expansion of the local Master's programme and overseas post-graduate training for specialists has increased specialist output in the basic specialties. Between 2000 and 2004, 1384 specialists had graduated from the Master's programme, with increasing numbers yearly. A postgraduate training committee oversees the Master's specialist training programmes.

Table 3: MOH hospitals as training centres for open system masters training programme (20 clinical disciplines)

State	Hospital	Total
Perlis	Hospital Kangar	1
Kedah	Hospital Alor Setar	1
Pulau Pinang	Hospital Pulau Pinang Hospital Seberang Jaya	2
Perak	Hospital Ipoh Hospital Taiping Hospital Ulu Kinta	3
Selangor	Hospital Tengku Ampuan Rahimah Hospital Selayang	2
W.P. Kuala Lumpur / Putrajaya	Hospital Kuala Lumpur Hospital Putrajaya	2
Negeri Sembilan	Hospital Seremban	1
Melaka	Hospital Melaka	1
Johor	Hospital Sultanah Aminah Hospital Muar Hospital Batu Pahat	3
Pahang	Hospital Tengku Ampuan Afzan	2
Terengganu	Hospital Kuala Terengganu	1
Kelantan	Hospital Kota Bharu	1
Sarawak	Hospital Umum Sarawak	1
Sabah	Hospital Queen Elizabeth Hospital Likas	2
Institusi	Hospital Permai, Johor Hospital Sentosa, Sarawak Hospital Bukit Padang, Sabah	3
Total		**26**

Source: Medical Development Division, Ministry Of Health

Subspecialist training

Enrolment

A gazetted specialist wishing to further subspecialise in a particular field of a clinical discipline may apply to do so, and if selected has to undergo a pre-determined training programme, which currently is a minimum of 3 years duration, and spend a major part of his/her practice in that subspecialty. There are also specialists with special interests who have undergone a period of training in a particular clinical field within their specialty, but not subspecialising. The education and training for subspecialisation programmes is more intensive and confined to a narrower area of medical practice.

Fellowship Training Committee

In 2001, the Ministry of Health formalised the Fellowship Training Committee and Individual Fellowship Training Committees at subspecialty level, responsible for the overall planning for fellowship training. Presently there are 117 subspecialties within 16 major secondary specialist disciplines, and a further 20 subspecialties have been proposed for the additional secondary specialist disciplines of emergency medicine and rehabilitative medicine.

Subspecialty training programmes are being conducted in various specialties at recognized training centres locally. Between 2001 and 2005, 329 trainees have were offered foreign subspecialty training programmes in 14 broad disciplines **(Table 4).**

Generally, all state level hospitals are accredited local training centres for subspecialty training programmes in specific areas of subspecialties depending on the availability of trainer or mentor subspecialists. The commoner subspecialties for example, nephrology and cardiology are provided in more than one hospital while some are provided exclusively in one particular hospital, for example, Hospital Selayang is the only centre that provides subspecialty training in hand and micro-surgery, hepatology and liver transplants while Hospital Kuala Lumpur provides training in oncology and radiotherapy.

The training is of residency type and currently being planned towards a formal exit examination certification. To facilitate the training, each specialty has established its own specialty committee responsible for the planning, organisation and supervision of the programme. A specialist wishing to sub-specialise undergoes supervised training under a consultant for a period of 2-3 years and often followed by additional exposure in overseas centres.

For Fellowship Training Programmes currently not available in the country, the specialist may pursue the training in accredited centres abroad under a credentialed trainer. As with the local Master Programme, the Public Service Department offers scholarships for subspecialisation training abroad.

Table 4: Number of Trainees Offered Foreign Subspecialty Training Programmes (2001 – 2005)

No.	Discipline	Year					Total
		2001	2002	2003	2004	2005	
1	Medical	9	11	11	7	20	58
2	Surgery	9	6	12	3	10	40
3	Paediatric	7	7	4	4	7	29
4	Obstetrics & Gynaecology	3	4	5	4	7	23
5	Anaestesiology	3	7	8	6	10	34
6	Orthopaedic	4	4	10	6	15	39
7	ENT	2	4	4	4	5	19
8	Ophthalmology	2	4	5	2	6	19
9	Psychiatry	5	2	5	0	2	14
10	Pathology	3	5	8	4	8	28
11	Radiology	4	5	6	1	2	16
12	Radiotherapy	2	2	0	0	1	5
13	Forensic Medicine	0	0	0	0	2	2
14	Palliative Medicine	0	0	0	0	1	1
Total		**53**	**61**	**78**	**41**	**96**	**329**

Source: Medical Development Division, Ministry of Health

System of recognition - specialist and subspecialist

Recognition of specialist status

A medical practitioner wishing to practice in Malaysia must register with the Malaysian Medical Council. However, this registration does not differentiate a specialist from a general practitioner. Within the MOH, there is a formal system of evaluation and gazettement for specialist doctors after a specified period of working under supervision.

Gazettement of specialist

In granting recognition to the various postgraduate qualifications reference is made to the entry qualification, duration of course, structure of course and examination. MOH specialist recognition is not obligatory for the private sector or in the universities. For MOH medical specialist degree recognition, the current MOH circular lists 20 specialty disciplines consisting of some 100 degrees both from recognized local and foreign institutions.

Pre-gazettement training

The granting of specialist status will identify practitioners who have completed a residency and have expertise in a specific field of medicine. On completing a postgraduate training programme, doctors in the MOH are required to undergo a period of assessment or validation of their knowledge, skills and experience in their respective fields of training. On satisfactory completion of the assessment period, the practitioner is gazetted as a specialist. This process is useful for assessing the clinical competence of a specialist. The gazettement period for a specialist of the local Master's programme is six months and for overseas specialist degrees is 18 months. Specialists who have been working overseas are also required to undergo a probationary period to assess their clinical competence.

Gazettement of subspecialist

A specialist in turn will be gazetted as a subspecialist if he or she has undergone a pre-determined training programme, which currently is a minimum of 3 years duration, and has spent a major part of his/her practice in that subspecialty.

Classification of specialists

Specialists in the Ministry of Health are designated in three hierarchical status - as clinical specialist, consultant and senior consultant based on the duration of specialist service after gazettement. A clinical specialist refers to one with five (5) years or less of post-gazettement working duration. A consultant is a specialist who has between five (5) to ten (10) years of post-gazettement working duration. A senior consultant is a specialist with ten (10) or more year's post-gazettement working duration and in the U54 service category or higher.

Credentialing and privileging

The Ministry of Health has also established and implemented a process of credentialing and privileging for specialists. It has begun initially for specialised procedures outside the approved scope of core procedural skills required of specialists in their respective clinical fields. It is intended to eventually be implemented for all doctors and allied health professionals.

Issues in specialization and subspecialisation

Unmet specialist human resource needs

Specialist shortages

Despite the fact that between 2000 and 2004, 1384 specialist had graduated from the Master's programme, there is still a shortage of specialists in the MOH. This shortage is due to rapid expansion of specialist and subspecialist services in MOH hospitals, consumer expectations and attrition to the private sector. Expansion of subspecialty training has, to a certain extent, contributed to the retention of specialists in state capital hospitals with subspecialty services.

Between the years 2000 to 2005, the total number of Ministry of Health specialists increased from 1371 to 2014, representing a 46.9% increase. When comparing specialist numbers year-end 2005 to that of 2000, there were 6% fewer plastic surgeons and 11% fewer urologists, the same number of hand and micro-surgeons (2), and hardly any significant increment in forensic medicine specialists (7.6%), cardiologists (8.6%), radiotherapist and oncologist (11.1%) and paediatric surgeons (15%). Most significant increases were rehabilitative specialists (160%), otorhinolaryngologists (80%), obstetricians and gynaecologists (73%), and ophthalmologists (64.6%). **(Table 5).**

Table 5: Number of specialists serving in the Ministry of Health by disciplines. 2000-2005

Discipline	2000	2001	2002	2003	2004	2005
Internal Medicine	154	154	169	181	221	235
General Surgery	133	136	154	161	183	190
Obstetrics & Gynaecology	133	136	154	161	183	190
Orthopaedic	108	132	135	138	160	171
Paediatric	143	158	168	180	219	216
Ophthalmology	79	82	96	108	128	130
ENT	45	45	54	56	70	81
Psychiatry	45	45	54	56	70	81
Rehabilitative Medicine	3	5	4	4	7	8
Emergency Medicine	-	-	6	10	18	22
Anaesthesiology	138	139	162	175	200	207
Radiology	89	80	82	94	106	113
Pathology:	99	119	123	107	107	123

Source: Medical Development Division, Ministry of Health

Attrition of specialist

Between the years 2000 and 2005 a total of 313 specialists resigned from government services. **(Table 6)** The attrition rate of specialists since 2000 showed an upward trend. The highest rate were from the disciplines of rehabilitative medicine, otorhinolaryngology, orthopaedics and radiology. The lowest attrition rate were the paediatricians.

Table 6 : Number of Ministry of Health specialists who resigned from services (2000-2005)

Year	Specialist Resignation				Specialist rate of resignation
	U41-U44	U48-U52	> U54	Total	
2000	27	13	1	41	2.9%
2001	14	12	2	28	1.9%
2002	4	12	3	19	1.9%
2003	33	27	4	64	3.7%
2004	26	45	0	71	3.7%
2005	38	16	9	90	4.5%
Total	**142**	**125**	**19**	**313**	**2.35%**

Source: Medical Development Division, Ministry of Health

Opportunities for specialisation

With recent introduction of specialist training programmes in the disciplines of emergency medicine, plastic surgery and neurosurgery, it is envisaged that the shortages of specialists in these disciplines will be addressed. It is recommended that the specialist manpower development plan be effectively implemented to ensure more doctors are given opportunities to pursue postgraduate training by considering flexible training programmes to meet the needs of those not able to train full-time and to anticipate the increasing proportion of women in the medical profession.

Human resource planning and development

The continuing formal training of health personnel by the Ministry of Health is a policy issue that needs to be addressed. Accurate human resource projections particularly with regards to doctors, dentists, pharmacists and other allied health personnel should be objectively undertaken and resourcefulness is a challenge. There is always a need to more effectively implement the long-term plan to develop the specialist manpower needs for the country.

Outsourcing specialist services

Apart from these measures the MOH should continue utilizing specialists from the private sector on a sessional or honorarium basis to provide specialist services in government hospitals where the need arises.

Inequitable distribution of specialists manpower

Specialist posting to district hospitals

There still remains the difficulty in expanding and sustaining specialists' services in district hospitals. Most specialists are concentrated in the state capital hospitals especially tertiary care centres, and also in the private sector in urban cities.

Strategies to address equity and access

Mandatory posting of specialists to district hospitals for a time-specific period undertaken in a transparent manner is a strategy to address this issue. Apart from expanding the scope of specialist services to more district hospitals, other strategies addressing equity and access to specialist services include the well-established referral system, specialist visitations to district hospitals without specialists, hospital-networking and telemedicine.

Reward system for specialist to serve in the periphery

To effectively reduce human resource maldistribution, between urban and peripheral / rural sectors, by using combined approaches such as providing financial incentives, accelerated promotions, time-limit on the assignment, granting of priority for further training and in-service training, adequate housing and means of communication and transport.

Credentialing specialists

Who is a specialist?

Though there is a formal system of credentialing specialists in the MOH, there is no formal system of certification in the private sector. The implication is that there is at present no control as to who can call themselves specialists and charge specialist rates.

Strengthening credentialing and privileging process

A system of specialists register is presently being worked out between the Academy of Medicine and the MOH. The MOH being the custodian of healthcare should ensure that a credentialing process for specialists be effectively implemented by strengthening the National Credentialing Committee and by having user-friendly credentialing guidelines with functioning Hospital Privileging Committees in place to enable all healthcare providers to be credentialed.

General specialist versus subspecialists

The trend towards more specialisation is an integral part of continued professional development of a specialist. With the increase interest in subspecialties, the number of specialists subspecialising in various disciplines has been increasing, from 85 in 2001 to 339 in 2005. However the medical discipline remains the most popular with the majority of trainees in the disciplines of nephrology, cardiology, and gastroenterology. Also the disciplines of infectious disease, nuclear medicine and endocrinology have seen increases in subspecialists facilitated by fast tract entry into the training programme. Applications for subspecialty training in geriatrics and plastic surgery have not been encouraging.

Regional centre shortages

Distribution of specialists to regional centres and centres of excellence has been affected by the small number of subspecialists available to provide the services and the high workload of subspecialty services. An effective subspecialty unit would require a minimum of 3 to 5 subspecialists, which the MOH finds difficulty in establishing such units.

Dwindling numbers of general specialists

While there is a definite need for a subspecialist to provide the best possible care to the community, there are concerns over the dwindling numbers of general specialists, especially for general medicine and general surgery. There is a formalized Fellowship Training Committee at the Ministry level and individual Fellowship Training Committees at the subspecialty levels. Subspecialty training has been somewhat affected due to shortages in specialists.

Specialty balance

There should be an equitable emphasis on general specialties and subspecialties to ensure an appropriate balance. The MOH will need to define clearly doctors to specialists ratio norms to effect objective human resource planning for general and specialist services.

Loss to private sector

Brain drain

The country has seen a rapid development of the private healthcare sector. For the year-end 2005, there were 222 private hospitals, private nursing homes and private maternity centres having a total of 10,794 hospital beds (24% of total hospital beds for the country). This has led

to a steady loss of government specialists, doctors and allied health personnel to the private sector. Between the years 2000 and 2005, 313 specialists resigned from the MOH while in 2005 alone, 90 specialists resigned from government service.

Retention of specialists

Poor retention of specialist within the public sector continues to be a major drawback and must be addressed through objectively planned strategies to minimize this exodus. Consideration should be given to improvements in working conditions, better career development / pathways, attractive remunerations and better opportunities for continuing professional development.

Career development bureaucracy

There is evident dissatisfaction among the newly graduated specialists, with regard to PTK (competency) examinations which they have to pass as a pre-requisite for promotion. Infrequent exams, delayed examination results, bureaucratic delays and the addition of intervening hierarchical grade levels have prompted many junior specialists to leave government service for the private sector, with the potential of affecting future provision of specialist services in the MOH.

Retaining specialists in the MOH

The Government recently has provided incentives in various measure to retain specialists in the public sector among which are:

- Increasing normal after office hours working allowances from between 59% to 340% effective 1st June 2005.
- Tax exemption for after office hours working allowances and specialists incentive allowance.
- Expediting the process for specialist promotions to Grade U48 pay scale after post-gazettement.
- Proposal to appoint specialists without experience directly to Grade U43 pay scale and specialists with experience directly to Grade U47 pay scale
- Creating 298 extra promotional (Special Grade A, B, C) for specialist years period 2005-2010
- Extending specialists services on contract basis up to the age of 65 after compulsory retirement.
- Improving facilities and working environment and providing needed medical equipments for clinical practice.

Strengthening specialists and subspecialists training

Separate specialty and subspecialty training committees

Currently at the MOH, there exist two separate committees to oversee the Master's specialist training programme and the subspecialty training programme. For future plans to be effective, the Conjoint Board and these committees need to be linked.

Strengthening Fellowship training programmes

Other issues and strategies related to specialists and subspecialists training included the effective implementation of the subspecialties development plan by strengthening the Fellowship training programmes by having more available training posts, formal assessment of training programmes with exit certification for all trainees.

Utilizing the private sector for specialist and subspecialty training

The possibility of optimizing the expertise and resources available in the private sector and private universities in training programmes for specialists and subspecialists, in view of the lack of available trainers and resources in the country could be further explored.

Strengthening basic training programme for medical officers

There is also the need to strengthen the basic training program for medical officers for a more comprehensive exposure before they embark on specialty programmes.

Conclusion

Specialisation and subspecialisation are natural progressions in hospital medicine with continual advancements in medical science and technologies, coupled with increasing patient expectations. The MOH has to also define in clearer terms the direction in which specialist and subspecialty services are to be developed. This development must be in consonant with medical technology advances, growth of the medical profession and the perceived needs and demands of the population.

Doctors who wish to do specialisation and subspecialisation should be guided and facilitated with options of career development plans and pathways in an objective manner. This is a combined challenge for the Medical Development Division, the Training Division and the Human Resource Division of the MOH. Activities to develop specialist services in the MOH have continued despite the many

constraints. Objective steps are being taken to further improve the situation within the resources available to ensure equity in access and quality of health care provided for all. Specialty balance across clinical disciplines is a challenge and while we encourage specialisation and subspecialisation to improve the quality of health care, one needs also to take cognizance of the negative effects of extensive or over specialisation.

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Appendix 1

Distribution of Resident Secondary Care Specialist Services in MOH Hospitals (As of December 2005)

STATE.	HOSPITAL	General Medicine	General Surgery	Paediatric	O&G	Orthopaedic	Anaesthesiology	Ophthalmology	Otorhilaryngology	Psychiatry	Pathology	Radiology	Rehab. Medicine	Emergency Med.	Dermatology	Geriatric	Total
Perlis	Hospital Kangar	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		□□
Kedah	Hospital Alor Setar	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		□□
	Hospital Sungai Petani	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓					□□
	Hospital Kulim	✓	✓	✓	✓	✓	✓				✓						□
	Hospital Lang□a□i		✓		✓	✓	✓										□
P.Pinang	Hospital Pulau Pinang	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		□□
	Hospital Seberang □aya	✓	✓	✓	✓	✓	✓				✓	✓					□
	Hospital □u□it																
	Merta□am							✓	✓	✓							□
Pera□	Hospital Ipoh	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		□□
	Hospital Taiping	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓					□□
	Hospital Telu□ Intan	✓	✓	✓	✓	✓	✓		✓	✓							□
	Hospital Seri Man□ung	✓	✓	✓	✓	✓	✓	✓									□
	Hospital Slim Ri□er			✓	✓												□
Selangor	Hospital Klang	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	□□
	Hospital Selayang	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		□□

STATE.	HOSPITAL	General Medicine	General Surgery	Paediatric	O□G	Orthopaedic	Anaesthesiology	Ophthalmology	Otorhilaryngology	Psychiatry	Pathology	Radiology	Rehab. Medicine	Emergency Med.	Dermatology	Geriatric	Total
	Hospital Serdang			✓	✓	✓	✓	✓	✓		✓	✓	✓	✓			□□
	Hospital □a□ang	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓					□□
	Hospital □anting			✓												✓	□
□P□L.	Hospital □uala Lumpur	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	□□
	Hospital Putra□aya	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓					□□
	Hospital Labuan	✓	✓														□
□ Sembilan	Hospital Seremban	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	□□
	Hospital □uala Pilah	✓		✓	✓	✓	✓	✓		✓							□
	Hospital Port Dic□son	✓															□
Mela□a	Hospital Mela□a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		□□
□ohor	Hospital Sult. Aminah	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		□□
	Hospital Muar	✓	✓	✓	✓		✓	✓	✓			✓					□
	Hospital □atu Pahat	✓	✓	✓	✓	✓	✓	✓	✓								□
	Hospital □luang	✓	✓	✓	✓	✓											□
	Hospital Segamat	✓	✓	✓	✓	✓	✓										□
Pahang	Hospital □uantan	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		□□
	Hospital Temerloh	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓					□□
	□uala Lipis				✓												□
Terengganu	Hospital □uala Trengganu	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		□□

STATE.	HOSPITAL	General Medicine	General Surgery	Paediatric	O&G	Orthopaedic	Anaesthesiology	Ophthalmology	Otorhilaryngology	Psychiatry	Pathology	Radiology	Rehab. Medicine	Emergency Med.	Dermatology	Geriatric	Total
Terengganu	Hospital Kemaman	✓	✓	✓	✓	✓	✓										□
Kelantan	Hospital Kota □ahru	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		□□
	Hospital Kuala Krai	✓	✓	✓	✓	✓	✓	✓			✓						□
Sara□a□	Hospital □mm Kuching	□	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		□□
	Hospital Sibu	✓	✓	✓	✓	✓	✓	✓				✓					□
	Hospital Miri	✓	✓	✓	✓	✓	✓	✓				✓					□
	Hospital Sri Aman				✓												□
	Hospital □intulu		✓	✓	✓	✓											□
	Hospital Kapit		✓														
	Hospital Sari□ei				✓												□
Sabah	Hospital □E	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓		✓			□□
	Hospital Li□as			✓	✓		✓										□
	Hospital Sanda□an	✓	✓	✓	✓	✓	✓	✓	✓								□
	Hospital Ta□au	✓	✓	✓	✓	✓	✓	✓				✓					□
	Hospital Keningau	✓	✓	✓	✓	✓	✓	✓	✓			✓					□
	Hospital Lahad Datu	✓	✓	✓	✓	✓	✓	✓	✓								□

Source□ Medical De□elopment Di□ision□ Ministry o□ Health

No.	Specialty	Norms (based on Canadian norm)	Expected Number	Present Stock	Shortfall
			2005	Dis. 05	2005
1	Physician	1:16,000	1,646	457	-1189
2	Surgeon	1:23,000	1123	613	-510
3	Paediatrician	1:25,000	1045	608	-437
4	O&G Specialist	1:26,000	992	565	-427
5	Orthopaedic Spec.	1:46,000	575	230	-345
6	Anaesthesiologist	1:25,000	1045	464	-581
7	Ophthalmologist	1:50,000	523	375	-148
8	ENT Surgeon	1:76,000	340	202	-138
9	Radiologist	1:27,000	967	321	-646
10	Pathologist	1:43,000	601	217	-384
11	Rehab. Specialist	1:200,000	131	13	-118
12	Psychiatrist	1:15,000	1751	171	-1580
13	Emer. Med. Spec.	1:167,000	156	34	-122
14	Forensic Path.	1:200,000	131	20	-111
15	Family Med. Spec.	1:25,000	1045	215	-830

Source: Medical Development Division, Ministry of Health

HOSPITAL INFECTION CONTROL

SUMMARY

Hospital acquired infections (HAIs) result in longer hospital stay and cost to the patient and hospital. The national Hospital Infection Control Programme utilizing point prevalence surveillance involving 17 major public hospitals in the country, including 3 university hospitals, was started in 2002. This has brought about greater awareness on the seriousness of nosocomial infection (NI) and a decline in the prevalence of nosocomial infections in most participating hospitals. To strengthen infection control in hospitals, a formal infection control training course is being conducted by the Infection Control Association of Malaysia (ICAM) and the Ministry of Health for various categories of healthcare professionals. The establishment of dedicated hospital infection control nurse in hospitals has further strengthened the programme in hospitals. The programme would be expanded to all hospitals in the Ministry of Health and it is hoped private hospitals in the country would initiate similar programme in their hospitals.

Introduction

Hospital acquired infections (HAIs) or nosocomial infections (NI) are on the increase, more so with greater use of invasive procedures and more aggressive modalities of medical therapies to treat disease. The infections are acquired as a result of hospital treatment from which the patient was not suffering from at the time of admission to the hospital. HAIs increase the length of hospital stay, and incur costs in treating the infection acquired and the complications that ensued.

HAIs remain a significant problem for the MOH hospitals. Evidence based counter measures of known effectiveness are not being implemented consistently or vigorously in many hospitals. Infection control must be everyone's responsibility from clinicians, cleaners and ancillary workers to patients and relatives, but evidence that this message has been adopted is scarce. Thus, efforts put into strengthening the Hospital Infection Control Program will certainly reap substantial benefits for the hospital.

MOH's commitment to Hospital Infection Control

The Ministry of Health (MOH) is committed to ensuring that infection control programme are actively and effectively implemented. Hospital acquired infections have a much higher profile now then before. At the central strategic level, it has been accorded a higher priority with the launch of a number of key requirements. Infection control is one of the major criteria required to complement the clinical governance initiatives and hospitals are required to self assess their performance against hospital accreditation standards.

Organisation

Hospital Infection and Antibiotic Control

In the 1980s, individual hospitals initiated their own infection control activities. Since 2001, the programme has been reorganized to fulfill a more effective and goal oriented role with the added function of antibiotic control. Thus, the committee became known as Infection and Antibiotic Control Committee operating at two levels. At the national level, the National infection and Antibiotic Control Committee (NIACC) is chaired by the Director General of Health and the secretariat is at the Quality in Healthcare section of Medical Development Division.

At the hospital level, the Hospital Infection and Antibiotic Committee (HIACC) chaired by the Hospital Director, is responsible for the implementation of hospital infection control programme in the hospital. Members of the committee include heads of clinical departments, senior clinicians, microbiologist, pharmacist, infection control nurses and other co-opted members.

The State Infection Control Committee chaired by the State Director of Health coordinates the functions and activities of all HIACCs in the state.

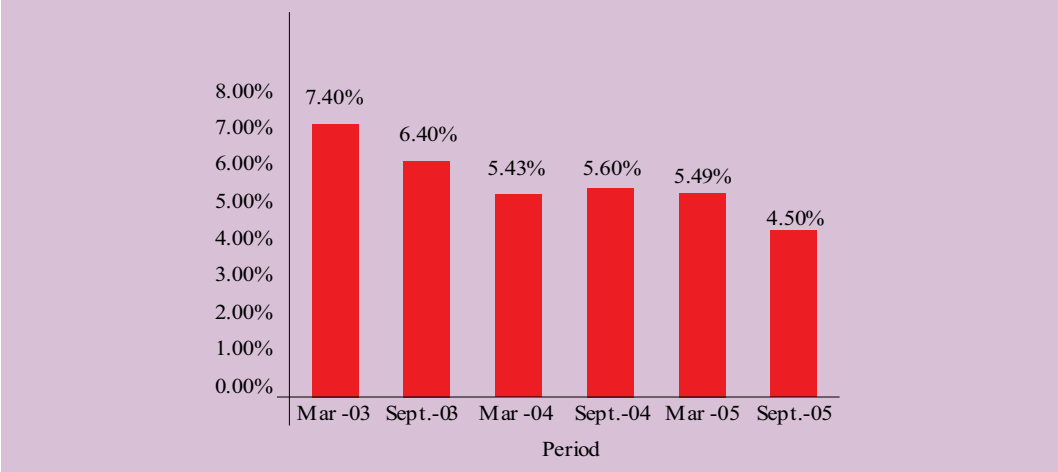
Nosocomial infection surveillance

Surveillance which involves data collection, analysis and feedback of results to clinicians, is central to detecting infection, dealing with them and ultimately reducing infection rates. Lack of comparable data on rates and trends of infections limited the MOH understanding of the infection problem. Nevertheless, since the initiation of the Point Surveillance Programme by the MOH in 2002, surveillance has been collected. This provides very useful data on the state of NI in Malaysian hospitals. However, this is limited to public sector hospitals only.

Point prevalence surveillance

Point prevalence surveillance involves a one day survey to determine the prevalence of hospital acquired infections in participating hospitals. It is conducted twice a year in the months of March and September in Hospital Kuala Lumpur, 13 state hospitals and three university hospitals throughout the country. **Figure 1** shows the NI rate for these 17 participating hospitals for the period 2003-2005. It is noted that there is a declining rate from 7.4% at the beginning of the programme to 4.5% in September 2005.

Figure 1 : Nosocomial infection rates from 17 participating hospitals, March 2003 – September 2005)



Source: Medical Development Division, Ministry of Health Malaysia, 2005

Further analysis of these 17 hospitals indicate that 13 of the 17 hospitals had a decreasing trend between their initial and the last cycle in September 2005 while 4 showed an increase **(Table 1).**

One tertiary care hospital (A4) and one regional hospital (B4) showed NI rates that were higher than hospitals in their respective categories. Generally, state hospitals had a lower NI rate except for two hospitals (C5 and C6).

Table 1 : Nosocomial infection rates in 17 hospitals, March 2004 – September 2005

Hospital	Mac 04	Sept. 04	Mac 05	Sept.05
A1	6.10%	6.40%	6.40%	2.90%
A2	9.83%	3.92%	3.85%	5.20%
A3	-	-	7.10%	4.70%
A4	9.66%	12.23%	6.41%	11.10%
B1	2.22%	4.60%	3.74%	2.90%
B2	3.53%	3.00%	3.30%	2.80%
B3	4.72%	4.21%	5.25%	3.20%
B4	12.27%	11.62%	6.97%	8.40%
C1	6.53%	1.80%	3.93%	3.10%
C2	3.54%	4.10%	3.80%	2.90%
C3	4.94%	3.60%	3.90%	3.10%
C4	3.24%	1.61%	3.04%	2.20%
C5	6.39%	5.51%	4.30%	5.30%
C6	4.43%	2.90%	5.00%	7.40%
C7	1.82%	4.32%	4.40%	2.20%
C8	6.57%	5.02%	2.50%	4.00%
C9	3.62%	6.51%	1.75%	1.60%

Note : A1-A4 = HKL and 3 university hospitals, ; B1-B4 = 4 busy regional hospital (HSAJohor Baru, Hospital P. Pinang, Hospital QE, Hosp. Umum Sarawak), C1-C9 = other state hospitals

Types of nosocomial infection

Pneumonia, blood stream infections (BSI) and surgical site infections (SSI) are consistently the commonest types of nosocomial infections encountered. **Table 2** shows the types of NI reported between March 2004 and September 2005

Table 2 : Common types of nosocomial infection from point prevalence studies in 17 hospitals, March 2004 – September 2005

Type of Infection	Mar 2004	Sept. 2004	Mar 2005	Sept. 2005
SSI	21.8%	20.1%	26.5%	24.0%
BSI	17.8%	17.8%	18.1%	17.2%
UTI	10.0%	9.9%	6.2%	8.2%
Pneumonia	26.7%	24.5%	24.4%	24.6%
Clinical sepsis	14.7%	13.1%	12.6%	17.2%
Others	9.0%	14.6%	12.2%	8.8%
Total :	**100.0%**	**100.0%**	**100.0%**	**100.0%**

SSI-Surgical site infection, BSI – blood stream infection; UTI-urinary tract infection

Ventilation associated pneumonia (VAP)

VAP a serious problem in critically ill patients

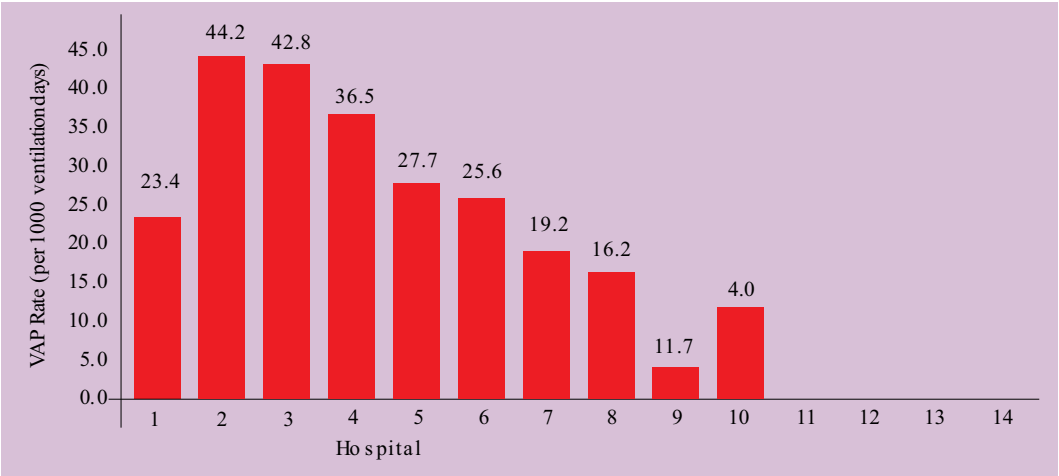
Ventilated associated pneumonia is a serious problem in critically ill patients with a high fatality rate. Point Prevalence Surveillance carried out consistently showed that pneumonia is among the highest form of NI in the hospitals.

The National Audit on Adult Intensive Care Units (NIACCU) 2003 reported that the incidence rate for ventilated associated pneumonia was 26.9% per 1000 ventilator days where 79.0% of the VAP were associated with gram-negative organisms notably *Acinetobacter* and *Pseudomonas.*

Prevalence of VAPs - a one day point prevalence study

A more in-depth study involving 14 MOH hospitals (Hospital Kuala Lumpur and 13 state hospitals) was carried out between June to August 2004 showed the prevalence of VAPs which ranges from 0 to 44.2 per 1000 ventilated days **(Figure 2).** Being a one-day point prevalence study, 4 hospitals had zero episodes of VAP during the study period.

Fig 2: Ventilation associated Pneumonia (VAP) in 14 MOH hospitals



Source : Report of Task Force for the study of VAP, Jan 2005, Ministry of Health Malaysia

Antibiotic resistance

Surveillance on common antibiotic resistance

Tracking resistance patterns of Methicillin Resistance Staphylococcus infections (MRSA) and Extended Spectrum Beta-Lactamases producing organisms (ESBL) provide a rough estimate of growing magnitude of troublesome pathogens in the hospitals. Therefore continuous surveillance of antimicrobial prevalence of MRSA, ESBL and Vancomysin Resistant Enterococci (VRE) to assess trend and appropriate use of antimicrobial agent is imperative.

In order to minimize the morbidity and mortality due to antimicrobial resistant infection have lead the policy makers to formulate guideline to reduce unnecessary and inappropriate use of antimicrobial agents. The Pharmaceutical Division, Ministry of Health issued the second edition of Guidelines on the use of Antibiotics in 1994.

MRSA and ESBL on the decreasing trend

Figure 3 and 4 show the annual average percentage of MRSA and ESBL in 17 hospitals under the national NI surveillance programme. The rates for MRSA and ESBL is on the decreasing trend between 2003 and 2005 for almost all hospitals except hospital C6 for MRSA and hospital C4 for ESBL. This is a favourable sign that continual surveillance and greater awareness of MRSA and ESBL has perhaps produced positive changes in practices, resulting in the reduction of these rates.

Fig 3: Annual MRSA reported in 17 hospitals, 2003-2005

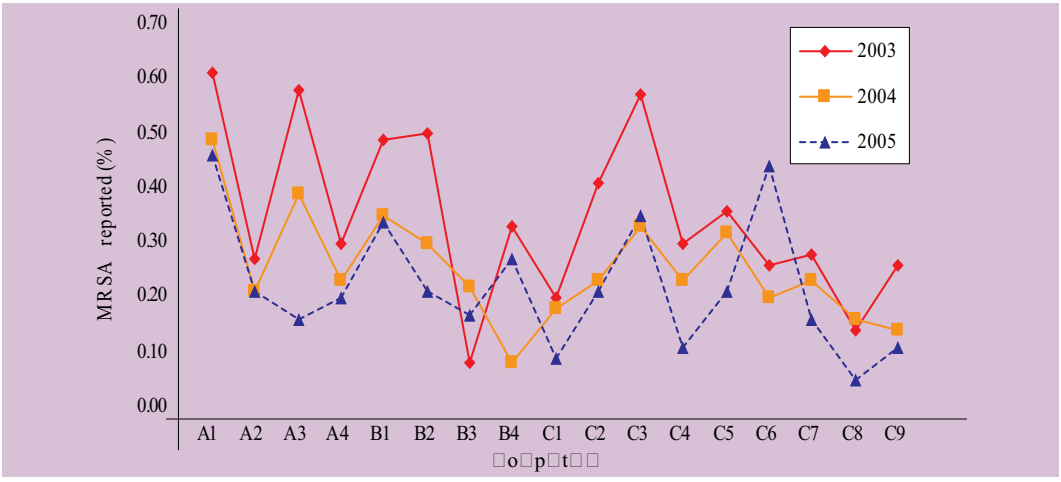
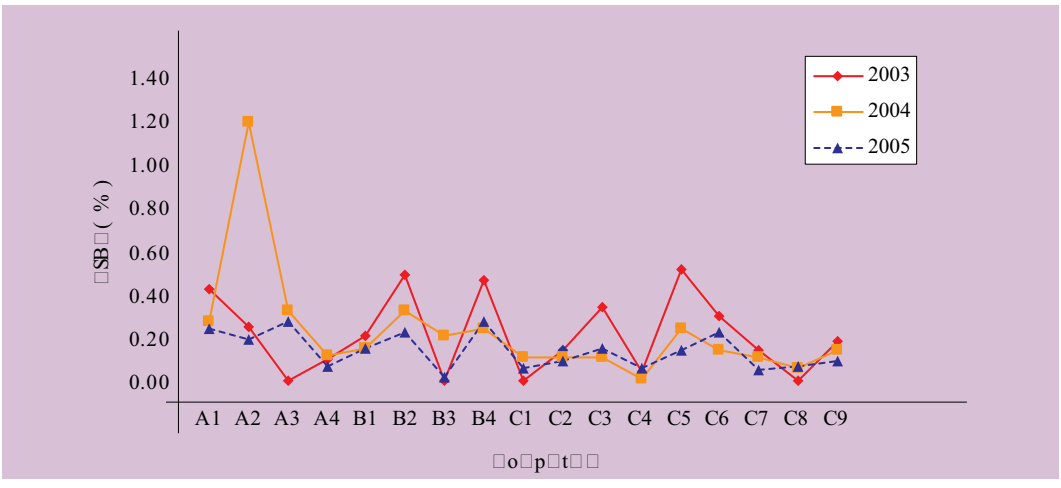


Fig 4: Annual ESBL reported in 17 hospitals, 2003-2005



Human resource development

Training of infection control personnel

Trained infection control nursing personnel forms the backbone of the hospital infection control programme. Currently formal infection control training courses are conducted by the Asia Pacific Society of Infection Control (APSIC) which is recognized by the University of New South Wales, Australia. Since 2003, the Infection Control

Association of Malaysia (ICAM) and Ministry of Health has been conducting APSIC training once a year. A total of 440 personnel had been trained under this programme between 2003 to 2005 **(Table 3).**

Table 3 : IPSIC Training Programme, 2003-2005

Year	Number Trained				
	Doctors	Scientific Officers	Nursing Personnel	Others	Total
2003	7	13	99	3	122
2004	2	4	115	2	123
2005	8	12	145	30	195
Total	**17**	**29**	**359**	**35**	**440**

Source : Medical Development Division, Ministry of Health Malaysia, 2005

Posts of infection control nurse

Realising the importance of infection control nurses in achieving success in the program, the MOH had created several posts for infection control sisters and nurses (ICN) in hospitals. Although not all these posts are filled, nevertheless, it is a move in the right direction. The MOH has also adopted a planning staffing ratio of 1 ICN : 250 beds as an optimal target. However, this is still below the US Joint Commission standards of 1.5:200 beds for the accreditation of healthcare organizations. Currently, there are 153 infection control nurses in the MOH hospitals. All except two MOH hospitals have infection control nurse.

The MOH is also aware of the shortage of clinical microbiologists and is looking into training of more such personnel in this area. At the present, there are only 12 clinical microbiologists and 12 infectious diseases specialists actively involved in infection control.

Conferences and seminars

Besides formal training, substantial allocations have also been given for training of all categories of healthcare workers in recent years. This includes participation in infection control conferences and seminars. In addition, regular updates are also conducted by various State level Infection Control Committees.

Hospital design and facilities

Many of the MOH hospitals are operating at very high levels of bed occupancy which can compromise good infection control practice. The MOH has taken infection control as an integral part of bed management policies. Thus, newly constructed hospitals should not encounter problems of over crowding.

Better hospital design in new hospitals for infection control

New hospitals are now designed to have appropriate ventilation systems in wards and proper isolation rooms. In the wake of recent new emerging infectious diseases like SARS and Nipah encephalitis, isolation rooms in designated hospitals are equipped with negative pressure and hepar filters to enhance safety of the hospital environment. Allocations have also been provided to upgrade isolation wards in more hospitals to include the above features.

Conclusion

Hospital infection control is a major concern

Hospital infection control is a major concern for the MOH. The national hospital infection control programme utilizing point prevalence surveillance involving 17 major public hospitals in the country, including university hospitals, has brought about greater awareness on the seriousness of nosocomial infection in hospitals. The programme has yielded some data concerning the status of nosocomial infection in the country. Targeted surveillance surveys and observational behavior studies will identify problem areas and remedial measures needed. Continual surveillance, education and close attention to remedial measures are needed to ensure HAIs are effectively controlled.

Need for expansion of programme to other hospitals

The programme needs to be expanded further to involve all hospitals in the country, while it is hoped that private hospitals would also initiate such a programme as a continual effort towards quality improvements in patient care. More trained infection control personnel are needed to strengthen hospital infection control programme in the country.

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OPTIMISING INTENSIVE CARE SERVICE IN MALAYSIA

SUMMARY

Intensive Care Unit (ICU) in Malaysia was first started in University Hospital in 1965. Currently (2005), there are 547 ICU beds in Malaysia representing 1.5% of hospital beds in the country and a ratio of 2.4 beds to 100,000 population. This is low as compared with developed countries. To achieve a ratio of 5 ICU beds per 100,000 population for an estimated population of 26 million, Malaysia will require a total of 1,300 ICU beds. Strategies to overcome the current shortage of ICU beds include expanding ICU beds in current hospitals; opening up non-functioning ICU beds; networking and optimizing use of current available beds through proper triaging and selection of patients. Further development of intensive care service include development of integrated multi-disciplinary ICUs; step-up in training of intensivists; improving on nursing support and development of paediatric ICUs where case load is sufficiently large.

Introduction

Definition of ICU

Intensive care units (ICUs) are specialized areas where critically ill patients requiring advanced life support are managed by a team of specially trained doctors and nurses. The ICU is an integral component of an acute care hospital, providing care for the critically ill patients from medical diseases or following trauma or surgery. Intensive care beds are defined as one with the capability for intensive monitoring and mechanical ventilation.

Development of ICU in Malaysia

ICUs were established in the 1960's during the poliomyelitis epidemic where patients were ventilated and managed in specialized units with increased nurse to patient ratio. The impetus for the specialty of intensive care came from advances in anaesthesia, coronary care and resuscitation. Early intensive care units were generally the extensions of the recovery rooms used for post-surgical patients.

First ICU in 1965

The first ICU in Malaysia was established in University Hospital of the University of Malaya in 1965. Since then, such units have been set up in other government hospitals, mainly state hospitals. From the 1970s

to 1980s, many Ministry of Health hospitals converted the general wards or the recovery rooms in the operation theatre to become the general ICUs. These 'makeshift' ICUs were generally small with space constraints. Purpose-built ICUs became available in new hospitals built from the 6th Malaysia Plan (1991-1995) onwards. New generation hospitals built in the 7th and 8th Malaysia Plans (1996-2000, 2001-2005) such as Selayang, Serdang, Ampang and Sungai Buloh hospitals have well designed ICUs with a higher ratio of intensive care beds.

ICU comes under Department of Anaesthesia

Intensive care service in the Ministry of Health (MOH) hospitals comes under the Department of Anaesthesia and Intensive Care. Care for these patients care is coordinated by the anaesthetists with input from the primary unit consultants. However, in the last few years, ICUs are increasingly being managed by dedicated intensive care teams directed by certified intensivists. Currently, these intensivists are anaesthetists who have undergone a two year specialized training in intensive care.

Distribution of intensive care beds

Current Situation

According to a national survey carried out in Jun 20051, there are a total of 104 intensive care units providing 547 intensive care beds in Malaysia. Of these, the Ministry of Health (MOH) has a total of 48 ICUs (46.2%) and 268 beds (49%) in 39 hospitals **(Table 1).**

Table 1: Number of intensive care units and beds in Malaysia, 2005

Type of hospital	No. of ICUs (%)	No. of ICU beds (%)
MOH, state hospitals	26 (25.0)	173 (31.6)
MOH, district hospitals	22 (21.2)	95 (17.4)
Military hospitals	1 (1.0)	2 (0.4)
University hospitals	4 (3.8)	41 (7.5)
Private hospitals	51 (49.0)	236 (43.1)
Total	**104 (100.0)**	**547 (100.0)**

Source : National Audit of Adult Intensive Care Unit (NAICU) report 2005

Table 2: ICU beds in some selected countries

Country	No. of ICU beds	% of hospital beds	ICU beds /100,000 pop.
Australia	1,595	3.0	7.5
France	22,000	3.2	38.4
Germany	23,000	2.7	28.5
Italy	5,480	1.2	9.4
Japan	14,670	2.7	11.8
Spain	5,800	3.0	14.8
UK	5,000	2.7	8.5
United States	77,600	6.3	30.5
Singapore	180	2.7	7.0
Malaysia	547	1.5	2.4

Source : NAICU report 2005

Unequal geographical distribution

The 547 beds in Malaysia represent 1.5 % of total acute hospital beds in the country, and gives the ratio of 2.4 ICU beds per 100,000 population. This is relatively low ratio when compared to some developed countries like France and United States with more than 30 beds per 100,000 population while UK, Australia and Singapore have between 7.0-8.5 beds per 100,000 population **(Table 2).**

As can be seen from **Table 3**, there is an unequal geographical distribution of ICU beds in the country. States with the lowest bed : population ratios are Terengganu, Pahang, Sabah and Negeri Sembilan while Melaka, Penang and the Federal Territory (FT) of Kuala Lumpur have the highest ratios. Almost half of the ICU beds, both public and private combined, are concentrated in 3 states, namely FT Kuala Lumpur, Penang and Selangor (272 beds or 49.7%). A significant number of intensive care beds (43.1%) are in the private sector, especially in Melaka, Penang and Selangor, which may not be as readily accessible to the public due to financial constraints.

Table 3 : Distribution of ICU beds by state (Malaysia), 2005

State	Government hospitals	Private hospitals	Total
Johor	28	15	43
Kedah	19	6	25
Kelantan	19	3	22
Melaka	8	26	34
N.Sembilan	8	2	10
Pahang	11	3	14
Penang	34	50	84
Perak	25	18	43
Perlis	4	0	4
Sabah	23	9	32
Sarawak	28	9	37
Selangor	22	43	65
Terengganu	7	0	7
WPK.Lumpur	71	52	123
W P.Labuan	4	0	4
Total	**311 (56.9%)**	**236(43.1%)**	**547(100%)**

Source : NAICU report 2005

It can also be seen from **Table 4** that intensive beds constitute between 1.1% -1.2% of the total acute beds in the MOH hospitals compared to 3% in private hospitals.

Table 4: ICU beds as percentage of hospital beds, 2005

Type of hospital	ICU beds /hospital beds
State hospitals, Govt.	1.1%
District hospitals, Govt.	1.2%
University hospitals	(not available)
Private hospitals	3.0%
Total	**1.5%**

Source : NAICU report 2005

A study in Germany estimated that 6.1 % of total number of hospital beds are required for intensive care bed2. In Malaysia, the recommended minimum percentage of ICU beds are 3% for hospitals without subspecialty services and 5% for hospitals with subspecialty services.

Norm for intensive care beds

The Malaysian ICUs are typically small with an average of 4 beds. The average size of ICU in state hospitals is 6 beds as compared to 10 beds in universities. It is recommended that the minimum size for ICU for cost-effectiveness is 8 to 12 beds3.

Utilisation of intensive care beds

In 2005, approximately 30,000 patients in Malaysia were treated in ICU, of which about 13,000 patients were treated in MOH hospitals (43%). This constituted 1.9% of total MOH hospital admissions for the year. The mean bed occupancy rates (BOR) in the government state and university hospital ICUs are high (82.8% and 84.8% respectively) while that for private hospitals are below 50%.

Admissions to ICU

Table 5: Number of Trainees Offered Foreign Subspecialty Training Programmes (2001 – 2005)

No.	Hospital	No. Of Admission	Patients Days	BOR
1	Sultanah Aminah, JB	1012	1133	113.0%
2	Kuala Lumpur	1,053	5,165	111.1%
3	Queen Elizabeth	563	3,079	105.4%
4	Umum Sarawak	570	1,938	101.1%
5	HTAR Klang	418	2,128	94.4%
6	Pulau Pinang	514	2,755	93.1%
7	Seremban	309	1,452	90.0%
8	Melaka	661	2,009	87.5%
9	Ipoh	466	2,303	87.0%
10	Kota Bharu	429	2,210	86.5%
11	HTAA Kuantan	463	2,375	85.5%
12	Selayang	672	6,586	82.3%
13	Kuala Terengganu	460	1,656	78.6%
14	Alor Setar	447	2,022	70.0%
15	Kangar	280	644	65.0%
16	Private Hospitals	14,870	NA	48.9%

Source : NAICU report 2005

BOR in ICUs

The Scottish Intensive Care Society audit recommends a mean occupancy rate of 70 to 75 % as a reasonable benchmark. **Table 5** shows the BOR of state level and tertiary level hospitals in the Ministry of Health where all but the last three hospitals had BOR of more than 80%. It is to be noted that the BOR is calculated based on midnight census and the actual BOR is higher as the data does not capture same day discharges or deaths before 12 midnight.

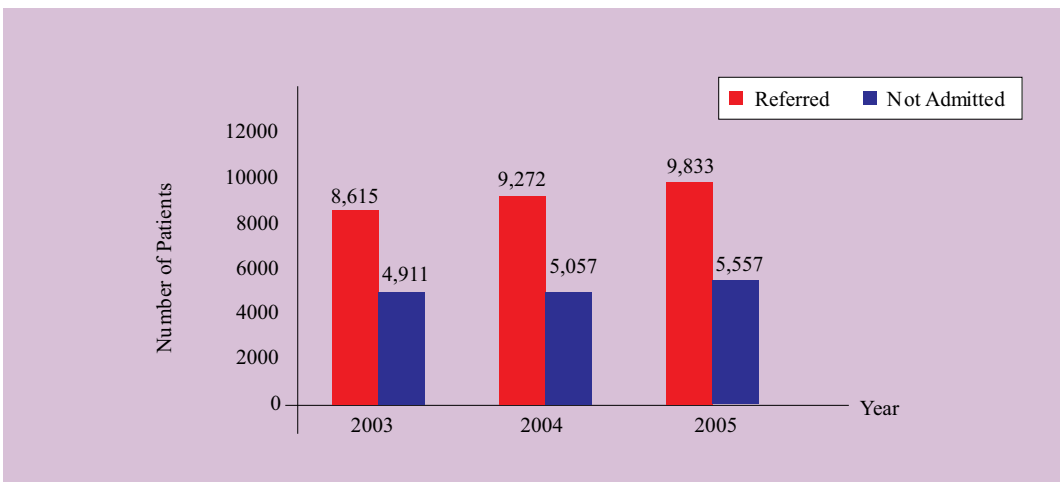
Issues in intensive care service

1. Shortage of ICU beds

Shortage resulted in lack of post-operative care

The shortage of ICU beds in Ministry of Health hospitals was first highlighted in the reports of the Peri-operative Mortality Review in the 1990s. The lack of post-operative intensive care was identified as a major contributing factor in post-surgical deaths. The National Audit of Intensive Care Units reported that close to 5,000 patients could not be admitted to fourteen ICUs in MOH hospitals in 2003 due to the lack of beds. Subsequent reports in 2004 and 20054,5 showed a worsening situation **(Figure 1).**

Fig. 1 : Number of patients referred and number not admitted in 14 MOH ICUs, 2003-2005



Additional ICU beds needed

Currently Malaysia has 2.4 ICU beds per 100,000 population. This low ratio is compounded by the fact that in Malaysia, government hospital ICUs only contributed to 57% of total beds whereas in developed

countries like Australia, government hospitals contributed to 75% of the nation's ICU beds6. In order to achieve a ratio of 5 ICU beds per 100,000 population for an estimated population of 26 million, Malaysia will require a total of 1300 ICU beds.

Additional ICU beds in new hospitals

Assuming 65% of these beds are based in Ministry of Health, our hospitals would require a total of 845 beds, that is, an additional of 577 beds to the current 268 beds. This will partly be overcome with additional ICU beds that will be made available in 5 new and replacement hospitals which will be operational in the next 2 years (2005/2006), namely Hospital Temerloh, Hospital Serdang, Hospital Ampang, Hospital Sg. Buloh., Hospital Alor Star and Hospital Sg. Petani. In addition, there are also plans to upgrade and expand existing ICUs in hospitals that are already operating in full capacity, for example, Hospital Kuala Lumpur, HTAR Klang and HSA Johor Baru.

2. Non-functioning ICU beds

Not all available ICU beds in MOH hospitals are functioning due to shortage of staff or essential equipment. **Table 6** indicates the position of 7 hospitals with non-functioning ICU beds.

Table 6 : Available but non-functioning ICU beds in MOH hospitals, 2005

Hospital	Maximum bed capacity	No. of functional beds	Remaining available beds (but non-functioning)
Selayang	24	12	12
Kajang	6	4	2
Putrajaya	11	7	4
Port Dickson	4	0	4
Kota Bharu	12	7	5
Ipoh	22	16	6
Kangar	5	4	1
Total :	**84**	**50**	**34**

3. Integrated intensive care service

Comprehensive development plan needed

A comprehensive development plan is necessary to ensure that intensive care is developed in tandem with advances made in other disciplines and their needs, the national health plan and the expectation of the community. In the last decade, intensive care has undergone rapid development and a shift in the organization of the service.

In UK, the Health department stated that existing division between ICU and High dependency Unit (HDU) should be replaced by a classification that focuses on the level of care that individual patients need. Physical separation into ICU and HDU are not recommended7. In the US, the Leapfrog group mandates that all ICUs should be directed by intensivists and care must be delivered by a dedicated team of trained doctors and nurses. Fragmentation of intensive care and the establishment of organ specific ICUs are not encouraged.

4. Training of intensivists

Number of intensivisits in Malaysia

The number of intensivists in Malaysia has increased steadily in the last five years and currently there are eight serving the various states **(Table 7)**. Each year under the MOH subspecialty training programme, one to two specialists are awarded scholarship or paid leave to pursue intensive care training overseas.

There is an increasing interest and commitment among trainees to seek certification by examination, for example, European Diploma in Intensive Care (EDIC).

Table 7 : Distribution of Intensivists in Ministry of Health Hospitals, 2005

Hospital	No. of Intensivist
Alor Setar	1
P. Pinang	1
Selayang	1
Kuala Lumpur	2
Klang	1
Melaka	1
Johor Baru	1
Kuantan	1 (seconded to IIU)
Total	**9**

To encourage local specialists to pursue EDIC programme, MOH and the Intensive Care Section of the Malaysian Society of Anesthesiologists have collaborated with the European Society of Intensive Care Medicine (ESICM) to hold the part two examination in Malaysia. The first of such examination was held last year (2004) at Hospital Selayang and the coming examination for 2006 will be held in Hospital Kuala Lumpur in August.

EDIC programme

Five specialists are currently undergoing training and they have been earmarked for hospitals in Kuala Terengganu, Kota Bharu, Putrajaya, Selayang and Ipoh. Thus it is hoped that by 2010, there will be at least one intensivist in every state. To ensure that the standards of training in intensive care are maintained, a document on the requirements for credentialing of an Intensivist was jointly prepared by the Intensive Care Section of Malaysian Society of Anaesthesiologists and the Anaesthetic Service of Ministry of Health in 2005.

Intensivist in every state by 2010

5. Nursing support

The role of the nurses in the ICU setting cannot be over-emphasized. Good nursing care forms the cornerstone of intensive care. It is observed that in general, the quality of intensive care nursing in MOH ICUs has not been on par with the developed countries. This could be due to the low percentage of trained nurses in the ICU. The NAICU 2003 report showed that only 37.5% of ICU nurses in the fourteen state hospitals had post-basic intensive care nursing training. The preliminary report of NAICU in 2005 showed that only 16% of ICUs have more than 50% of the nurses trained in intensive care nursing. This low percentage of trained nurses could be due to the low intake of nurses for post-basic intensive care nursing and the high transfer rate among nurses especially in hospitals in the West coast.

Shortages of ICU trained nurses

Recommendations

1. Strategies to overcome the shortage of beds

1.1. Expanding intensive care physical facilities

In hospitals where the ICU is functioning at its maximum capacity, for example, Hospital Pulau Pinang, Hospital Umum Sarawak, Hospital QE Kota Kinabalu, Hospital Teluk Intan and Hospital Sri Manjong, the plan is to build new ICUs or expand existing units. In hospitals with multi-disciplinary high dependency units, it is recommended that

Expansion in existing hospitals

these units be upgraded to intensive care level, for example, Hospital Kota Bharu and Seberang Jaya.

1.2. Utilise all designated but non-functioning ICU beds

Resolving issue of non-functioning ICU beds

More staff (nurses and medical officers) shouId be posted to hospitals where ICUs are not functioning at maximum capacity, for example, Hospital Selayang, Kajang, Ipoh, Serdang, Kota Bharu and Taiping. In hospitals where ICU beds cannot function due to the lack of certain critical equipment e.g. ventilator, these equipment should be provided for. This is to ensure all designated ICU beds are functional.

1.3 Networking of ICUs

Networking of ICUs in the Klang Valey and by zone

In geographical regions within a reasonable traveling distance (less than 2 hrs by land), networking can be carried out to share ICU beds in order to reduce the effects of peak and low demands. This will ensure that all deserving patients will receive intensive care at the time of contact and improve outcomes. Networking has been established in hospitals in the Klang Valley since 2004. This should be extended to other regions:

- Northern network involving Hospital Penang, Seberang Jaya, Sungai Petani and Alor Setar
- Southern network involving Hospital Johor Baru, Pandan, Muar, Batu Pahat and Melaka
- Perak : Hospital Ipoh, Taiping, Teluk Intan and Sri Manjong

Tracking ICU beds - ICU Bed-watcher

To ensure successful networking and the ability to track the number of beds available in a continuous manner and in real time, a software called "ICU Bed-watcher' has been developed. This was introduced to the Klang Valley network March 2005 and is now fully operational. Authorized personnel from the 6 hospitals in Klang Valley (Hospital Kuala Lumpur, Selayang, Klang, Kajang, Putrajaya and Serdang) are able to view the ICU bed situation by accessing the website http://www.icu.org.my and refer deserving cases appropriately.

1.4. Optimise utilization of beds

Triaging and selection of patients

This includes training of doctors in triaging and selection of patients, use of management care plans and protocols and withdrawal and withholding of life support in non-survivors. In line with this, the MOH in collaboration with the Intensive Care Section of the Malaysian

Society of Anesthesiologists will conduct a series of road shows to increase awareness on withholding and withdrawal of therapy. A national forum will also be planned where foreign experts and senior clinicians from the various disciplines are invited to share their views and come up with a consensus statement.

Extending ICU Audit to all ICUs in MOH

The National Audit on Intensive Care Units (NAICU) which was established in 2002 should be extended to all ICUs in the Ministry of Health. The audit allows continuous monitoring of performance and patient outcome and ensures accountability and better patient care. It is proposed that eventually all ICUs in the country (public and private) shall be mandated to participate in the audit as is the case in the UK. NAICU should be made the pre-requisite for all ICUs seeking accreditation or recognition as training centres.

2. Establish an integrated Intensive Care Service

Integrated ICU

It is recommended that intensive care services should be integrated and provided by a dedicated team of trained doctors and nurses. The ICU should function as a closed unit and directed by a qualified intensivist.

All ICUs (including organ specific ICUs, for example, neuro ICU, nephro ICU, cardiothoracic ICU) and high dependency care units in the hospitals should be integrated under one service. Historically high dependency units (HDU) were introduced to provide a step between intensive care and ward care in order to overcome the shortage of intensive care beds. They provide monitoring and support to patient at risk of developing organ system failure but not for managing patients with multi-organ failure. The HDU is an area where patients are managed post discharge from ICU before returning to the wards. This involves multiple transfers and does not allow flexibility in bed utilization and sharing of equipment and staff. It operates as an independent unit physically separated from the ICU and may be headed by separate medical and nursing team. Numerous papers have shown that an integrated and dedicated intensive care team improves patient outcome, reduces hospitalization cost and ensures optimal utilization of resources.

Step-down care within ICU to minimize patient

Integrated intensive care/high dependency units are common in Australia and the trend is for increased integration and flexibility in the way that beds are used. Under this concept, patients who are weaned off from mechanical ventilation remain in same the bed in the ICU

but with a 'step-down' in nursing ratio and other interventions. This reduces the cost of hospital care without having to move the patient from one unit to another thus minimising the risk of transportation. More importantly, the patient remains under the care of the same intensive care team. It also reduces the stress of patients and relatives from another transfer and thus results in better patient outcome.

movement

The current trend is towards establishing big multi disciplinary ICUs catering for all disciplines including specialised surgical disciplines. For example, The Alfred Hospital in Australia in its upgrading exercise in year 2000 amalgamated its three specialist ICUs that is cardiothoracic, trauma and general intensive care units into a 35 bedded ICU which incorporate both intensive care and high dependency patients.

Multi-disciplinary ICUs

3. Increase the critical mass of intensivists

This can be achieved by:

- increasing scholarship per year from 1-2 to 4 per year
- encouraging participation of non-anaesthetic specialists, for example, physician, surgeons, emergency physicians to take up intensive care as a subspecialty
- consolidating the link with European Society of Intensive Care Medicine and to recognize the European Diploma in Intensive Care (EDIC) as the 'national examination' for the purpose of certification. Intensive care subspecialty training programme should be standardized and based on the curriculum as outlined in the Anaesthetic Subspecialty Training Programme for Intensive Care.
- recognizing and gazetting intensivist as a sub-specialist based on set criteria proposed by the Intensive Care Section, Malaysia Society of Anaesthesiologists. **(Appendix 1).**

4. Improve nursing care by :

- ensuring that ICUs are appropriately staffed and that the nurse to patient ratio remains constant during the three shifts
- increasing the intake for post-basic intensive care nursing.
- intensifying in-house training as part of the credentialing process
- ensuring that nurses in ICU remain in the unit for a minimum period of three years

Similarly, the University College London Hospital will soon be moving into a new hospital complex which has an ICU with provision for up to 35 critical care beds, making it the largest unit of its kind in London. It is proposed that future ICUs should have bigger number of beds to provide for 'stepped down care' thus allowing sharing of staff and equipment and resulting in better patient and relatives' satisfaction.

Intensive care services should be categorised according to the level of acuity e.g. Level 1 to Level 3. This will help determine the appropriate level of resources needed to provide care and help establish parameters for the level of care that each hospital is reasonably expected to provide.

Level 1 ICU

- Level 1 ICU is equivalent to the HDU or acute care ward and should be made available in all district hospitals without an anaesthetist. The unit should have 4 to 6 beds and be capable of providing intensive monitoring and basic intensive care such as oxygen therapy and inotropic support but not invasive mechanical ventilation. The nurse to patient ratio is 1 is to 2-3 patients.

Level 2 ICU

- Level 2 ICU refers to one that is located in a district hospital with anaesthetist capable of providing intensive care. The number of beds should be 6 to 10 beds and capable of providing mechanical ventilation. Nurse to patient ratio is 1 to 2 for non ventilated patients and 1 to 1 for ventilated patients.

Level 3 ICU

- Level 3 ICU refers to those that should be available at all state hospitals with facilities for multiple organ support such as mechanical ventilation and renal replacement. Nurse to patient ratio is 1 to 1 or more and the unit shall operate as a closed unit directed by an intensivist or an anaesthetist with special interest in intensive care.

The number of beds required will range from 16 to 35 or approximately 3 to 5 % of hospital beds depending on services provided by the hospitals.

5. Paediatric Intensive Care Units

Intensive care for paediatric patients

Currently in MOH hospitals, pediatric patients are managed in the general ICUs except in hospitals where there are dedicated Pediatric ICUs, for example, HKL and Hospital Ipoh. Pediatric patients comprised about 10% of the cases admitted to the general ICUs. In

addition, a number of critically ill children were also managed in the neonatal ICU or the acute bays in pediatric wards.

The Joint Faculty of Intensive Care Medicine, Australia and New Zealand in its *Policy Document Review 2003 on Minimum Standards for Intensive Care* recommended that a pediatric ICU should have a minimum of 300 admissions per year to ensure sufficient clinical workload to maintain clinical expertise.

Based on the Australian model, we recommend that Pediatric ICUs be established in KKM state hospitals where the case load exceeds 300 admissions per year. Pediatric ICUs in the state hospitals shall be managed by the Pediatric Departments.

Conclusion

Optimal intensive care for Malaysian will be hopefully achieved once issues highlighted in this paper are addressed. Ministry of Healthcare addressing the issues mentioned in stages and it is hoped that Ministry of Health Hospitals will have enough ICU beds for all the critically ill admitted in our hospitals and at the same time delivering high standard of care for these patients. Greater emphasis should be placed on training for all categories of staff managing the ICU at all times.

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Requirements for the credentialing of an Intensivist

An intensivist must fulfill all the following:

1. Have a recognised degree in Anesthesiology, Internal Medicine, Surgery or other related disciplines.

2. Have completed 24 months training in intensive care. These 24 months must be spent full-time in intensive care in recognised centres, which could be :

   a.) Unrestricted recognised training
   Refers to Level 3 ICUs in major tertiary/ referral hospitals with at least 2 consultant intensivists, who have at minimum a 50% involvement in the unit. Total admissions of at least 750 per year with a diverse case mix, normally including five of the following six specialties: trauma, general medicine, general surgery, acute cardiology, burns and neurosurgery.

   b) 6 months recognised training
   Refers to Level 3 ICUs in major tertiary/ referral hospitals with at least one consultant intensivist, who has at minimum a 50% involvement in the unit. Total admissions of at least 500 per year with a diverse case mix, normally including general medicine, general surgery and trauma.

   The unit should also meet the following criteria:

   - *Perform research, regular medical audits and quality improvement programmes.*
   - *Has continuous medical educational programmes including bedside teachings, journal clubs and grand rounds.*
   - *Has adequate educational facilities, which include medical library facilities and computerised search system.*

3. Have obtained certification after completion of training from one of the following: (from year 2006 onwards)

   a) EDIC (European Diploma in Intensive Care)
   b) FFICANZCA (Fellow of Faculty of Intensive Care, Australian New Zealand College of Anaesthetists)
   c) FRACP (Int Care) Fellow of the Royal Australian College of
   d) Physicians, endorsed in Intensive Care
   e) ABCCM (American Boards, Critical Care Medicine)

CHRONIC PAIN MANAGEMENT SERVICE

SUMMARY

Pain management service encompasses the management of acute pain, cancer pain and chronic pain. While Acute Pain Services were set up in the Ministry of Health (MOH) in the early 1990s, chronic pain services only started in 2000 with the setting up of the Pain Clinic at Hospital Selayang. Currently there are only 4 trained pain specialists and 7 pain clinics in the MOH. Selayang Hospital is the main center, and clinics have also been started in Penang, Kota Bharu, Ipoh, Batu Pahat, Johore Bahru and Melaka. The Hospital Ipoh pain clinic also offers acupuncture as a modality of treatment as the pain specialist there has been trained in this. Pain medicine is a relatively new field and needs to be developed much more, especially chronic cancer and non-cancer pain. Although anaesthesiologists are the main specialists involved in pain medicine, all doctors need to have a better knowledge and understanding of acute, chronic and cancer pain to ensure more effective management of the different types of pain in patients.

Introduction

Holistic multidisciplinary approach in pain management

The core business of the chronic pain management services in the Ministry of Health is to ensure that all patients with chronic cancer and non-cancer pain have access to good pain management. This is done using a holistic multidisciplinary approach, which recognizes that pain is not just uni-dimensional but is better approached using a bio-psycho-social perspective. Effective pain management includes the use of appropriate analgesic medications and techniques delivered by an appropriate method, appropriate exercise and mobilization, and the incorporation of a psychological approach into the overall management of the patient.

Pain medicine, a very young specialty in Malaysia

Pain medicine is still a very young specialty in Malaysia, and in the MOH specialized pain management services were only started in 1993 with the establishment of Anaesthesiology-based Acute Pain Services (APS). The next development was in 2000 with the setting up of chronic pain clinics in Hospital Selayang, followed by clinics in 6 other hospitals over the next few years. These pain clinics currently form the core of the pain management services in the MOH and are not only involved in the management of patients with pain but also

in teaching and training of other doctors and health care providers in order to improve the overall management of acute, chronic and cancer pain.

Chronic pain

Chronic pain is different from acute pain

Chronic pain is different from acute pain and has to be approached differently. In acute pain, short-term analgesic techniques using strong opioids and regional nerve blocks are very effective, as the pain goes away after the tissues heal and there is no need for long-term analgesia. In patients with chronic pain, however, the pain persists for more than 3 months, and continues after tissues have healed.

Chronic pain as a disease

Chronic pain is now recognised as a disease in its own right, a disease of the nervous system which has to be treated aggressively, separately from the underlying condition which may have contributed to or brought about the chronic pain in the first place. Although pain relief is usually what patients seek, worldwide experience has shown that this is not possible in most chronic pain conditions. More importantly though, studies have shown that pain relief alone is not enough to bring about improvements in mood and function of patients with chronic pain, and, conversely, that patients with chronic pain can increase their function and improve their mood despite continuing pain.

Cancer pain

Pain in patients with advanced cancer

Pain is a symptom in over 70% of patients with advanced cancer. According to WHO, the majority (over 90%) of cancer pain can be controlled by easy means, the main one being the appropriate use of oral morphine. The role of pain specialists and pain clinics in the management of cancer pain is to apply more advanced and invasive techniques for the control of pain in the 5-10% of patients where oral analgesics and simple parenteral analgesics is not enough.

Pain clinics

Pain clinics aim at providing accurate diagnosis, and formulating a rational plan of management for patients with chronic pain, in order to relieve suffering, to improve patients' ability to cope with pain, and to return patients to productive living.

Pain management

The first chronic pain clinic in MOH was established at the Hospital Selayang in 2000. This was a multidisciplinary pain clinic, run by a

consultant anesthesiologist trained in pain medicine, with support from a physiotherapist, consultant psychiatrist and clinical psychologist. As there are no specific posts for clinical psychologists in this setting, a clincial psychologist was recruited on a "voluntary" basis from one of the local universities. A lecturer from the College of Physiotherapy in HKL was also recruited to be the pioneering physiotherapists as she had had some training in pain management. Later other local physiotherapists were also trained and have subsequently joined the multidisciplinary team. The workload has increased since, especially over the last 2 years **(Table 1).**

team and training

Table 1 : No. of patients in Hospital Selayang Pain Clinic 2000 – 2005

Year	New Cases	Follow-up	Total
2000	19	32	51
2001	36	121	157
2002	57	203	260
2003	115	245	360
2004	119	441	560
2005	136	545	681
Total	**482**	**1587**	**2069**

Subsequently 3 other specialists have been trained in pain medicine and have started pain clinics in their respective hospitals, one each in Hospital Kota Bharu, Hospital Batu Pahat and HSI Johore Bahru, and Hospital Ipoh. In order to increase the number of pain clinics available in the Ministry of Health, pain clinics were also started in Hospital Pulau Pinang and Hospital Melaka, with the pain specialist from Selayang hospital providing the consultant service to run these clinics. To date, therefore, there are 7 Pain clinics in MOH hospitals. All Pain clinics are administratively under the Department of Anaesthesia; most clinics are run once a week, except for that in Hospital Selayang which is run two days a week. Due to logistic reasons, the clinic in Hospital Pulau Pinang is currently not active.

Other pain clinics

All the pain clinics in the MOH take a multidisciplinary approach to pain, and function in cooperation with the departments of Physiotherapy and Psychiatry. In patients with chronic pain, psychosocial factors usually play a much bigger role and these factors have to be addressed in order to achieve good outcomes. In

Pain and psychosocial factors

addition, many patients with chronic pain have developed secondary deconditioning and are physically inactive, thus active physiotherapy plays a critical role in their management.

There is an increasing trend in the number of patients referred to and seen in the Pain clinics, especially Hospital Ipoh **(Table 2)**, the limiting factor being the staffing The clinic in Melaka Hospital is very new and is only run once a month with a visiting consultant from Selayang hospital

Table 2: No. of patients in Hospital Ipoh Pain Clinic 2003 – 2005

Year	New Cases	Follow-up	Total
2003	40	44	84
2004	36	157	193
2005	31	234	265
Total	**107**	**435**	**542**

Characteristics of patients seen pain clinics

Pain clinics see both non-cancer and cancer patients but the majority of patients treated are those with non-malignant pain. Patients with cancer pain are mostly managed by Palliative Care Units in the MOH hospitals. The majority of patients were aged between 40-49, but patients of all age groups were seen **(Figure 1)**. Patients were also about evenly distributed between all the three ethnic groups **(Figure 2)**.

Fig. 1: Age of patients, Hospital Selayang Pain Clinic, 2000-2004

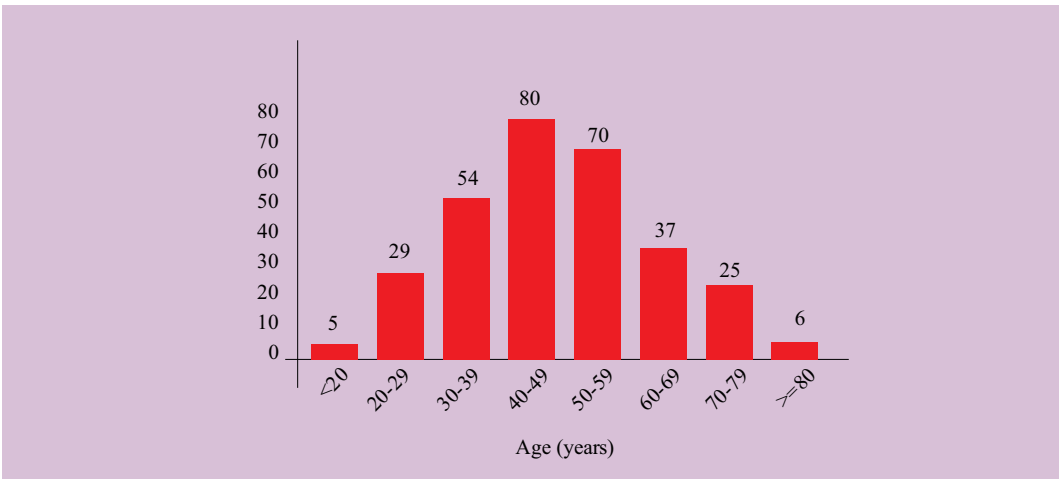
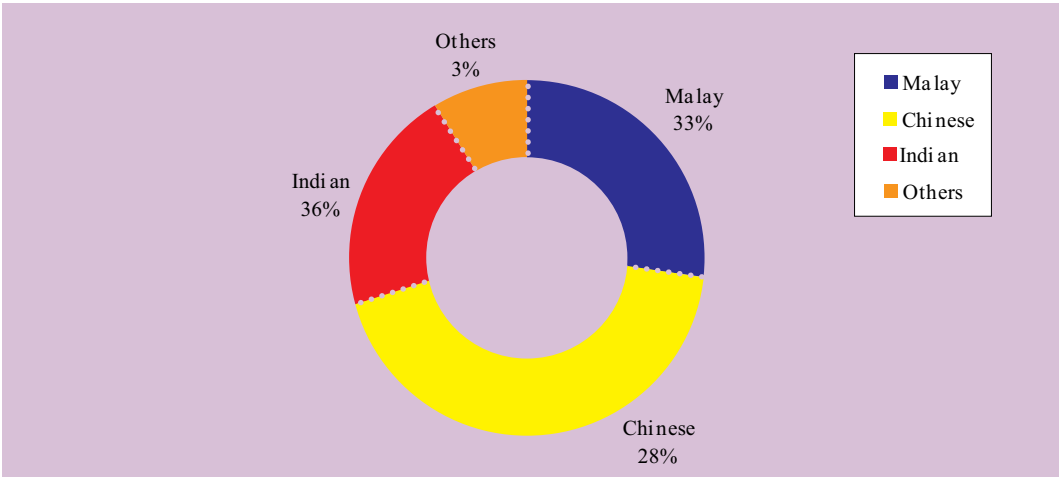


Fig 2: Ethnic group of patients, Hospital Selayang Pain Clinic, 2000-2004.



The main source of referral was from government hospitals, with a large number from the orthopaedic surgeons; however, patients were also referred by oral surgeons, general surgeons, neurologists and a number of other specialists **(Figure3)**. Types of pain include both nociceptive (musculoskeletal and visceral) pain and neuropathic pain, again in almost equal distribution, and site of pain included all parts, from the face to the back and legs **(Tables 3 and 4).**

Fig 3: Source of Referral of patients, Hospital Selayang Pain Clinic, 2000-2004

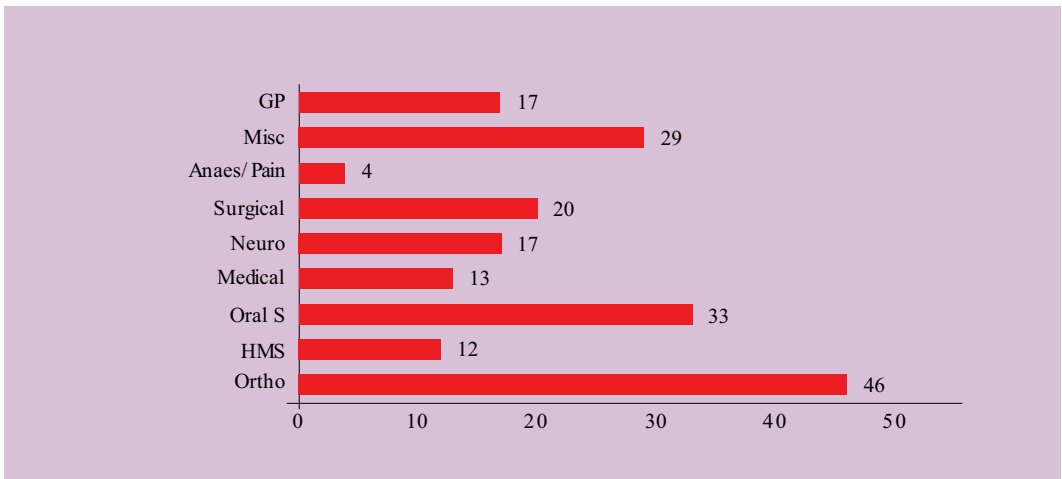


Table 3 : Type of pain of patients, Hospital Selayang Pain Clinic, 2000-2004

Type of pain	No. of patients	%
Cancer	28	12.7
Musculoskeletal	70	31.8
Neuropathic	85	38.6
Visceral	24	10.9
Mixed	13	5.9
Total	**220**	**100**

Table 4 : Site of pain of patients, Hospital Selayang Pain Clinic, 2000-2004

Site of pain	No. of patients	%
Cancer	28	12.7
Musculoskeletal	70	31.8
Head / face	38	19.8
Upper Limb	36	18.8
Neck and Upper Limb	13	6.8
Back	26	13.5
Lower limbs	25	13.0
Back and lower limbs	14	7.3
Abdomen	24	12.5
Chest / abdominal wall	10	5.2
Multiple sites	6	3.1
Total	**192**	**100**

Management modalities in chronic pain

Pain assessement before commencement of treatment

A multidisciplinary approach to management of chronic pain is taken for all patients. The management begins with a thorough assessment where patients are seen separately by a pain specialist, a physiotherapist and a clinical psychologist or psychiatrist. All patients are also assessed using self-administered questionnaires which assess the level of disability, self confidence, anxiety, depression and stress, and "catastrophising" (a term used by psychologists to refer to thoughts like "The pain is killing me") as well as active coping. After the assessment, the team meets to discuss the best management plan for the patient and then each of the members of the team carries out his/her part of the management plan.

Multi-treatment approaches

Management includes the use of analgesic drugs, including "traditional" analgesics like NSAIDs and opioids and antineuropathic drugs, nerve blocks, physiotherapy and psychological modalities. In the Ipoh hospital clinic, acupuncture is also offered as the specialist there was trained in this modality of treatment. Psychological approaches include a clear explanation of the pain and what it means, so that the patient has a good understanding of his/her pain, and teaching the patient self-management skills like relaxation and pacing. Treatment with drugs alone are less suitable in patients with chronic non-cancer pain as they will either develop long term side effects or their dose requirements will escalate over time. Therefore, a multimodal approach that includes self-management techniques is very important in patients with non-cancer pain. Patients are treated on an individual basis initially, but those who do not do well or those who have high levels of distress and disability are treated in a group program using a cognitive behavioural approach, described in the next section.

Patients with difficult cancer pain are managed mainly with the use of invasive techniques like the insertion of intrathecal catheters for spinal administration of morphine and local anaesthetics, neurolytic blocks like celiac plexus blocks for pain from pancreatic carcinoma, and combinations of drugs like lignocaine, ketamine and morphine. However these patients constitute only a small proportion of the patients seen in a pain clinic.

The MENANG Pain Management Programme (Program MENANGani Kesakitan)

The MENANG pain management programme

Systematic reviews and meta-analyses have provided evidence of the effectiveness of pain self-management based on cognitive-behavioural principles. These interventions aim to equip patients with the necessary skills to improve their social, occupational and psychological functioning and decrease reliance on passive modalities, such as taking unnecessary medication and undergoing repeated procedures.

Training in Sydney Hospital

In November 2001, a team of 4 people comprising a pain specialist, physiotherapist, psychiatrist and nurse were sent by the Ministry of Health to observe a 3-week program Pain Management & Research Centre (PMRC) at the Royal North Shore Hospital in Sydney, and returned to start the Menang Programme in June 2002. The structure and approach of the Menang Programme is essentially the same as the Sydney program, but while the Sydney program runs for 3 weeks and is an outpatient program, the Menang Programme runs for two weeks

and patients are admitted when necessary, for example outstation patients.

Approach in Menang Programme

As with the Sydney program, the Menang Programme emphasised re-formulation of the pain (as chronic but not sinister), goal setting, education about pain, applied relaxation training, training in identifying and challenging unhelpful thoughts and beliefs, practising effective problem-solving and pain management strategies like activity pacing, daily planning; programmed exercise and systematic encouragement of activities to limit avoidance behaviours and to regain confidence in functioning despite pain. Pain medications are also gradually reduced and eventually stopped over the two week period. Two programs are run per year, and 7 groups have been completed by the end of 2005 **(Table 5).**

Encouraging results

Results have been very encouraging, with significant improvements achieved by most participants on measures of daily function, mood, confidence, distressing beliefs, medication use, and physical performance. Although not an intended outcome, there was also a median reduction in usual pain scores despite substantially reduced use of analgesic medication and increased activity levels. These outcomes are consistent with those reported from similar programs assessed in randomised controlled trials with different chronic pain patient populations in the UK and Australia.

Table 5: *Menang* Programme, Hospital Selayang, 2002-2005

Year	Group No.	No. of participants (patients)
2002	1	10
2003	2	9
	3	10
2004	4	10
	5	**8**
2005	6	11
	7	9
Total		**67**

Challenges in pain management

A number of challenges exist for the future of the *Menang* Programme. The concept that complete relief of pain is not always necessary for improvements in function, mood, and lifestyle is not easily accepted and is especially important for all to grasp, including health care professionals, employers and relatives of sufferers of chronic pain, and the community as a whole. There are implications for resource allocation: this treatment can reduce the need for ongoing attendance at hospital and multiple drug use, but it does require skilled staff and time, especially in the more disabled and distressed patients. At the moment there is no specific recognition of this type of self-management approach to chronic pain as a treatment modality, and no specific staff allocated to run such programs. We need to address this in the Ministry of Health so that we can continue to offer pain management programs as a treatment option to patients with chronic pain, so that they can improve their function and their mood, despite continuing pain.

Conclusion

Pain medicine is a relatively young in Malaysia but has great potential to make a big difference to the management of patients with chronic pain. Furthermore, and perhaps more importantly, the application of self-management techniques and encouragement to reduce reliance on medication and doctors, has the potential to relieve the increasing burden on health services posed by the growing population of patients with chronic diseases, including chronic pain. The Ministry of Health should definitely invest more resources into developing the field of pain medicine.

ADVANCES IN ORAL HEALTHCARE IN MALAYSIA

SUMMARY

There has been remarkable progress in oral healthcare in Malaysia since its inception as a school dental service. Expansion in scope to encompass all segments of the population and evolution of care to include complex specialty care has brought progress in care delivery and improvements in oral health status. Dental education has seen a greater focus on higher standards while research includes forays into more basic sciences and greater collaborative ventures. The contributory role of oral health to general health is increasingly recognised. The electronic/digital revolution has brought an explosion of information on disease causation, diagnostics, treatment philosophies, treatment plans, and the increasing shift to evidence-based care with technological and mechanistic advances charted in all dental disciplines. There is also an increase in interdisciplinary approach to the management of complex medical and dental conditions. Much, however, remains to be done for oral healthcare in Malaysia, including quicker uptake of developments and trends to develop a competitive edge.

Introduction

The past

The oral health services of the Ministry of Health (MOH) started off as a school dental service in 1946, and the Dental Division was part of the Medical Department then1. In 1947, the dental needs of the then Federation of Malaya were met by 50 private practitioners and 400 registered dentists alongside only 20 government dental officers serving in 26 dental clinics. Dentists then were trained mainly in Singapore and care rendered was mostly basic outpatient care confined to emergency dental treatment.

The present

Oral healthcare in the country has since made great strides. By 31 December 2004, the MOH oral health service is 8,015 strong; with 1,060 dental officers and 1,199 dental nurses, among other oral health personnel in its fold[2]. The number of facilities has also burgeoned to 1,926, with 3,326 dental operating units/chairs[3]. There are now three dental faculties, 1,439 private practitioners and 74 registered dentists to a population estimated at 25.6 million4 in 2005. This gives a dentist to population ratio of 1:10,032 population.

Service delivery

Care has also evolved to include specialty oral healthcare. The number of recognised specialties in the country has increased from two in the 1950s to seven currently, namely oral surgery, orthodontics, paediatric dental surgery, periodontology, oral pathology/oral medicine, restorative dentistry and forensic dentistry. There are now 242 dental specialists providing specialty clinical oral healthcare in the country, with 96 of them serving in the MOH.

Diagnosis forms the basis of all treatments and there is a move towards more sophisticated diagnostics. Detection and treatment of oral and systemic diseases affecting the maxillofacial complex contribute a major area for research and innovative treatment. Globally, there is increasing recognition of dental pain and dental radiology as fields of specialty.

MOH performance indicators

It is the aim of the MOH to provide access to oral healthcare to at least 25% of the nation's population, visit at least 90% of primary schools and treat 90% of primary schoolchildren, visit at least 70% of secondary schools and treat at least 70% of secondary schoolchildren5.

The target for coverage of 25% of the population seems to be within grasp, with more than 5.9 million patients (23.1% of the population) rendered care in 2004. The target for primary schools has been surpassed since 1998. Visits to primary schools have increased gradually from 91.4% (1998) to 96.1% (2004) with coverage of 93.9% and 96.9% of primary schoolchildren respectively. For secondary schools, 76.2% of schools were visited with coverage of 63.9% of secondary schoolchildren (targeted 70%).

Outcome indicators

The MOH oral health service has moving outcome targets of 30%, 60% and 50% caries-free dentition for 6-, 12-, and 16-year-olds respectively. It has certainly made progress, albeit not as effectively as it had hoped. Figures for caries-free dentitions in these age groups increased from 12.7%, 41.9% and 28.0% respectively in 1995 to 28.8%, 57.1% and 48.2% in 2004.

There have been improvements in oral health status for all age categories in many parameters of oral health. More teeth are retained for longer periods and in better condition now than before **(Table 1)**. In the year 2000 epidemiological survey of adults aged 15 years and above, the mean number of teeth present was 22.5 with more than 80.0% of the population having 20 teeth or more[6].

Table 1 : Oral Health Status of Malaysians 15 Years and Above from Epidemiological Surveys of 1974/757 and 2000[6]

Age group	Mean *DMFX Per Su		Mean number of teeth present		Having Pocket
	1975	2000	1975	2000	1975
15-19	6.2	2.9	26.7	28.3	10.5
20-24	8.8	4.4	26.9	29.4	17.4
25-29	11.5	6.0	25.0	29.0	22.5
30-34	12.1	8.4	24.0	27.3	36.3
35-44	14.5	12.1	21.2	23.4	39.2
45-54	17.8	15.6	16.8	18.5	45.2
55-64	20.7	20.1	13.0	12.8	42.4
65+	25.2	23.5	7.5	8.2	32.6
Overall	13.2	11.3	21.6	22.5	29.0

**DMFX – Teeth Decayed, Missing, Filled or indicated for extraction*
Source: Oral Health Division, MOH

Current trends and developments

Oral health and general health

There is growing realisation of the inter-relationship between oral and general health. General health affects oral health and poor oral health has detrimental impacts on general health - jeopardizing food choices, intakes and nutrition status. The mouth has been termed the 'mirror of the body' as many general conditions manifest with oral signs and symptoms.

Common risk approaches

Numerous factors, especially lifestyle, affect both general and oral health leading to adoption of common risk approaches in managing these diseases. The medically-compromised and the infirmed may present for dental treatment, necessitating sound medical knowledge on the part of the dental professionals.

Socio-demographic changes

There is increasing number of older persons in the population. In 1990, the elderly aged 65+ years made up 3.7% of the country's population[8], increasing to 5.8% of the population in year 20006. This affects healthcare provision, as special dental programmes need to be developed in gerondontology to manage increasing edentulism, root caries, malignancy, and medical conditions, as well as fiscal challenges. Gerondontology is presently not a specialty. However,

an oral healthcare programme for the institutionalised elderly was started in 1993 aimed at enhancing the quality of life of the elderly through improving their oral health[4]. This programme was extended to include those attending dental clinics of the MOH and community day care centres.

Developments in dental education

Dental professional programmes

There have been tremendous advances in dental education in the country[1]. The Faculty of Dentistry, University of Malaya (UM) was the pioneer to offer a four-year local dental undergraduate degree programme with its first intake of 32 students in May 1972. Before that, dentists were mainly trained in Singapore or abroad. There are now three local dental degree programmes. The National University of Malaysia (UKM) started in 1997 and the Science University of Malaysia (USM) followed suit in 1999. Currently, all three programmes have a total output of about 150 graduates annually. Presently, the Asian Institute for Medical Sciences (AIMS) and a few others in the pipeline are private entities providing dental degree programmes.

Dental auxiliaries training

Dental education now covers a broader base to encompass critical thinking, research, science (and the scientific method), medicine, behaviour, communication, patient and practice management. The dental curriculum of UM became a five-year programme in 19951. Post-graduate studies were initiated in 1994 with the Master in Community Dentistry (MCD) programme and this was further expanded in 2000 to include the Master in Clinical Dentistry (MClinDent) in Oral Surgery, Periodontology, Paediatric Dentistry, and Oral Medicine/ Oral Pathology[1]. All undergraduate programmes are now five-year programmes and post-graduate studies are now a common feature.

Parallel advances have been charted in dental auxiliary training. The Dental Training School (now College) in Penang was established in 1949 to train 'Dental Nurses' based on a New Zealand curriculum. Training for dental technologists, then known as dental mechanics, was initiated prior to World War 2 in the King Edward VII College of Medicine, Singapore. Formal training in the Penang Dental Training School began in 1951.

In 1996, these certificate courses for dental nurses and technologists were upgraded to diploma level. For the first time in 1998, post-basic courses were introduced for both groups. To date 104 (63 dental nurses and 41 dental technologists) have completed post basic training[9].

On-the-job training for dental surgery assistants (DSAs) began in 1951. Formal training started in the Penang Dental Training School in 1982. In 1993, the mode of training was changed to incorporate distance learning.

Clearly, for all three categories of dental auxiliaries, as well as the dental professionals, there has been a convergence towards higher standards.

Information Technology (IT) and dentistry

Electronic records

Advances in information technology (IT) are have impact on direct provision of oral healthcare and in other related fields such as patient management, research, and dental education.

The MOH started a computerisation programme for patient dental care data in 1998. An electronic clinical dental record system was introduced to support the following functions :

- core business of patient care
- services that facilitate this function
- clinical preventive activities, and
- generation of management decision reports.

Scope of IT in dentistry of the MOH

The system comprises patient registration, appointment bookings, comprehensive and complete patient clinical records that include case notes, charting and treatment planning, diagnosis, treatment procedures, prescription, referrals, billing, and follow-ups. Expanded modules such as the oral maxillo-facial, orthodontic, periodontic assessment and oral cancer screening are also part of this clinical information system.

Pilot studies on electronic dental records

Pilot studies in selected dental clinics in Selangor were carried out in 1999 and 2003. Future phased implementation in the country will be undertaken under the Ninth Malaysia Plan (2006-2010).

The need for the dental researcher to be knowledgeable in biomedical informatics is just beginning to be recognised. Advances in IT will influence techniques of dental research and consequently the methods and materials used to deliver oral healthcare.

Use of Digital Imaging

Intra–oral cameras and digital radiography enable practitioners to store and retrieve, manipulate and analyse visual patient information.

These are decision support tools in planning treatment that requires the integration of many disciplines and many types of clinical information. Radiovisionography (RVG) facilities have been provided to selected dental clinics in state hospitals, and specialist dental clinics in the capital of Kuala Lumpur.

IT in dental education

The use of IT in dental education is continually increasing. There is application of IT to curriculum development, computer assisted learning (CAL), educational administration, dental practice administration and clinical research. In some local universities, multimedia teaching, electronic mail and conferencing are useful tools applied in undergraduate teaching. The development of new software and systems also allows many undergraduates in this country to undertake their own electronic searches.

Dental libraries that have used computers for database searching have made much contribution to the design and development of an integrated system for dental education. Such facilities are available in most universities. The MOH library can now be accessed online, thus enabling personnel to have continuing education and professional development. The newest development in the MOH is to encourage continuous professional education among staff.

for Malaysian Dental Council IT

To strengthen and improve the smooth functioning of the Malaysian Dental Council, the following functions can be processed electronically:

- processing and issue of Annual Practicing Certificates (APC)
- online registrations of dental practitioners.

The electronic processing and issue of APCs began a few years ago. However, to improve the efficiency and effectiveness of the system, there is a need to upgrade the existing system.

Registration of private dental clinics

Registration of private dental clinics is compulsory under the Private Healthcare Facilities and Services Act 1998. Computerisation of the various activities involved will improve the efficiency of the services provided. The proposed plan for implementation is to develop an online registration system to establish the network linkages, thus creating a database system for approval of applications.

Regulating dental devices

A national committee was set up in 2004 to implement the forthcoming national registration of dental devices for regulatory control to improve safety on use of instruments /equipment/ materials/apparatus/

appliances. A National Medical/ Dental Device Registration and Surveillance/Vigilance System will be developed soon.

Dental research

Increasing research conduct

Closely intertwined with advances in dental education is dental research. Evolution of the evidenced-based approach10 has increasingly propelled dentistry as a medical science with additional demand for technical expertise[11] and dentists as learned professionals. There is increasing need to cultivate an enquiring, curious, problem-analysing, problem-solving dentists. This gave impetus to inclusion of research in the profession resulting in growing interest and involvement with increased output of dental scientific presentations and papers. The research culture is certainly growing; the country has only recently hosted the 27th Asian Pacific Dental Congress, which saw participation of an international mix of speakers and delegates with presentations of 41 free papers and 43 posters from local participants[12.]

Types of research

The Oral Health Division has, since its inception, conducted 16 dental epidemiological surveys and various health systems research (HSR) projects. The Stomatology Unit of the Institute for Medical Research (IMR) focuses on clinico-pathological research for oral cancer and precancers[13]. Various state dental departments are involved in self-identified and sometimes centrally identified HSR projects to provide solutions to various problems related to oral healthcare delivery.

Recently, the scope of research has expanded to include collaborative projects. These include a cost analysis study of various dental procedures with University of Malaya, and an occupational health study with the Environmental Health Research Centre(EHRC) of the IMR to evaluate urinary mercury levels among dental personnel. The fluoride content of toothpastes available locally has also been investigated in a collaborative project between the Sarawak State Dental and Chemistry Departments.

The future in oral health research

Globally, advances are seen in genomics, proteomics, stem cell, molecular biology, nanotechnology, and bioinformatics. Genomics and proteomic advances resulted in improved clinical (including salivary) diagnostics methods; and the increasing understanding of bodily processes at molecular levels have led to better understanding of disease causation, pathophysiology, natural history, and the application of such knowledge for better disease diagnostics, treatment planning, therapeutics and intervention.

Genetic testing will allow for pre-symptomatic identification of at-risk individuals to permit the implementation of preventive intervention strategies. Genes are reportedly etiologically important in chronic periodontitis, childhood dental caries, cleft lip/cleft palate and oral squamous cell carcinoma[14]. These and many other oral diseases, however, are complex genetic diseases in which multiple different genes increase an individuals' susceptibility. Further, environmental, nutritional and behavioural factors interacting with the gene and gene products play a part in the risk of these dental diseases in an individual. Genetic testing for oral diseases is currently limited but will continue to evolve.

Local dental researchers are not yet in the forefront of research in these fields. However, isolated works15 and many recent local post-graduate research works have witnessed modest forays into more basic science, molecular, oral biology and dental material researches. The premier dental faculty of the nation has also recently won awards at the 33rd International Exhibition of Inventions, New Techniques and Products in Geneva. **(Table 2).**

Table 2: Awards Won in Geneva by the Dental Faculty of The University Of Malaya

1.	OMX Probiotic Dentifrice for Oral Health
2.	Skinplast for Ulcers and Wounds
3.	ORTHOPROS - UM Novel Orthodontic Prosthesis
4.	Computer Software for Repositioning the Jaw and the Face and for giving Qualitative 3D Impression of the Patient's Face after a Cranio-maxillofacial Operation
5.	TriAquora Rinse – Alcohol Free Plant-based Oral Healthcare Product
6.	Computer Software for 3D Production of Models for Cranio-facial Reconstruction from CT and MRI Images
7.	Polyhydroxyalkanoates (PHA) as a Scaffolding Material for RigidFracture the Maxillofacial Skeleton

UM has also recently spearheaded an ambitious Intensification of research Priorities Areas (IRPA) funded project on oral cancer[16] in collaboration with Oral Surgeons/Pathologists of the Ministry of Health, and the Cancer Research Initiative Foundation (CARIF) involving highly advanced research technology including DNA micro-array technology.

The local dental fraternity is nevertheless, privy to information from cutting-edge research works on the world-wide-web. The impact of

these advances on dental care in Malaysia is the increasing onus on the profession to keep abreast with innovations in products and services. Competency requirements will indirectly impose a need for continuing professional education, which is already underway for those in the civil service. The increasingly knowledgeable clientele with equally easy access to information are indirectly the impetus to ongoing self-improvement, critical to ensuring a continued high standard of dental care especially in the private sector.

Towards more evidence-based practices

The practice of dentistry should be evidence-based. The cornerstones of evidence-based practice are clinical practice guidelines (CPG) and systematic reviews. The Oral Health Division has to date produced five CPGs with three more in the pipeline. Additionally, 11 guidelines have been produced on issues of infection control, occupational safety and implementation of the various programmes for differing age groups and categories of patients.

Advances in primary dental care

Dental caries aetiology

Dental caries is now increasingly managed as a preventable infectious disease caused by specific micro-organisms (MS) of which Strep. mutans and Strep. sobriius are the main aetiological agents17. Prevention of caries is by interfering with the transmission of MS, eliminating established MS populations from the oral cavity, increasing the acid resistance of the teeth and control of the consumption of carbohydrate composition of the diet.

Chemotherapeutics

Although anti-mutans vaccines can be produced, the cost is prohibitive. Use of antibiotics can cause resistance and opportunistic infections that are of far worse consequences than dental caries. Chemo prophylactic agents for MS elimination include chlorhexidine and cetylpyridinium chloride; plant derived compounds such as sanquinaria extract; metal ions such as Zn and Cu , sodium dodecyl sulphate and triclosan. These are normally delivered as mouth wash/rinses or toothpastes.

Fluorides

Efforts to increase the acid resistance of the teeth are achieved through application of fluorides (through toothpaste or mouthwash) or addition of phosphates, both of which promotes remineralisation.

Pit and fissure sealants

Elimination of MS from pits and fissures of primary and permanent molars are difficult. Treating teeth with pit and fissure sealants has been shown to prevent colonisation. The Oral Health Division started a fissure sealant programme in 19994. This is a school-based clinical

preventive programme targeted at children at risk to occlusal caries. In the years 2000-2003, a total of 431,758 teeth in 265,558 subjects were fissure sealed, representing approximately 77% of subjects and teeth considered at risk[2].

Sugar substitutes

Control of the carbohydrate composition of the diet can reduce the level of MS. Xylitol, sorbitol, saccharin and aspartame are a few of the common sugar substitutes used which are locally available. However, current evidence still shows that fluoride is still the best anti-caries chemical agent and owing to persistent efforts of the MOH, 62.4% of the public water supply in Malaysia is fluoridated[2].

Towards minimal cavity preparation

Caries management was traditionally aimed at its removal and the restoration of the tooth. The current paradigm in the treatment of caries is that of an ongoing dynamic process of demineralisation and remineralisation. Research has shown that the caries fronts are relatively sterile and appropriate proprietary linings/cements with antibacterial characteristics can render any remaining bacteria quiescent. This has led to a shift in treatment philosophies, from one of extension for prevention to minimal cavity preparation.

Evolution of adhesive dentistry

Restorations previously were dependent on physical design features such as dovetails and undercuts for retention. Current nanotechnology has improved bonding systems of restorative materials to tooth, the so-called adhesive dentistry. The use of amalgam as a restorative is on the decline. Today, composites resins are frequently applied to posterior teeth and are not limited to small restorations. Special posterior composites for easier handling are available[18].

Aesthetic dentistry

Teeth are increasingly valued for their contribution to appearance and social acceptability. Crown, bridges, veneers, and implants are now available to restore loss of tooth or to improve aesthetics. Advances in dental ceramic technology have made available restorative materials with enhanced appearance that also meet functional and longevity criteria. Bonded crowns have had exceptional clinical success but have the disadvantage of poor harmonisation with adjacent natural teeth. All-ceramic restorations are now available. In addition, use of computer-aided design (CAD) and computer-aided manufacturing (CAM) systems can provide dentists with ceramic and polymer options for inlays, onlays, veneers and crowns.

CAD/CAM technology

With the current globalisation/liberalisation policy, there is eagerness to promote health tourism. For dental care, there is already an

entrepreneurial offer to set up a laboratory using CAD/CAM technology to serve as a hub for the prosthetic needs of the ASEAN region (Mode 3 delivery – Commercial Presence, for trade in services under the General Agreement on Trade and Services or GATS).

Tooth whitening

Globally, tooth whitening, the process that makes teeth appear whiter with removal of extrinsic or intrinsic stains, is becoming popular as a cosmetic procedure. Several bleaching systems for professional in-clinic or dentist-supervised self/home application are now available. These products are often available over-the-counter, but patients are best advised to use products only after consultation/advice by a dentist.

Advances in dental specialties

Advances in Orthodontics

Use of digital cephalometry is available locally for better imaging, patient education, diagnostics, treatment planning and documentation. The orthodontists are involved in multi-disciplinary management of cleft lip/cleft palate repair as well as treatment of obstructive sleep apnoea (OSA), a potentially life-threatening breathing disorder due to collapse of the airway during sleep. OSA is treated effectively with mandibular advancement surgery and devices (functional type appliance) in co-operation with maxillofacial surgeons, ENT surgeons and chest physicians[19].

Digital technology is now available for simulation of treatment results. Lingual orthodontics with braces applied on the lingual rather than the facial aspects, aesthetic brackets and coloured bands offer better aesthetics during treatment20 for those willing to pay.

Advances in Periodontology

Use of inflammatory markers has not yet found its place in local clinical practice for identification of the individual at risk. Many of the periodontists in the country have digital imaging technology, which contribute to improved diagnostics and treatment planning.

Regenerative techniques have been available in the treatment of loss of supporting structures surrounding teeth such as alveolar bone, cementum and periodontal ligament. These techniques include root conditioning, bone grafts, bone substitutes and guided tissue regeneration. Autogenous bone is the most effective graft material that promotes new bone formation. Decalcified and freeze-dried bone allograft are commercially available but carries the risk of disease transmission and as such are increasingly replaced with alloplasts

or synthetic substitutes such as synthetic hydroxy apatite, tricalcium phosphate, and bioactive glass[21].

The increasing interest and demand for aesthetics of the gums have favoured the advances of periodontal plastic surgery to correct or eliminate anatomic, developmental or traumatic deformities of the gingival or alveolar mucosa. Recent advances include sub-epithelial connective tissue grafting[22].

Advances in Paediatric Dental Surgery

Advances in paediatric dentistry have been charted especially in caries management, pain control and behaviour management, restoration of teeth, and management of oro-dental trauma[23]. Fluoride remains the best method of caries prevention and it is now known that the topical effects of fluoride on teeth are most effective. Water fluoridation is still the most important method of delivery in this country. Several alternative methods are topical use of fluoridated toothpastes and applications of fluoride varnishes or gels. Novel techniques such as fluoride slow-releasing glass devices are still not available locally at this juncture.

Aesthetic tooth repair

Modern bonding materials now enable bonding of fractured permanent incisor crowns onto the tooth if the fractured portion is available. Moderate fluorosis can be managed with micro-abrasion technique or tooth whitening. Aesthetics of discoloured teeth with intrinsic stains can be much improved with direct composite veneers without any prior tooth preparation.

Greater emphasis is now placed on preservation of the pulp. Formocresol used in pulpotomies is being replaced with ferric sulphate. Resin-based bonding materials have also been advocated as pulp capping material in place of calcium hydroxide (CaOH). The literature reports apexogenesis (process of maturation of the root) as opposed to apexification (apical closure) to enable traumatised anterior young incisors to have continued growth development[23]. Apical closure through normal physiologic mechanisms with Mineral Trioxide Aggregate (MTA) is increasingly preferred, although at high costs.

Local analgesia remains the main method of pain control in paediatric dentistry but there is increased practice of in-office sedation in the dental treatment of the apprehensive child or the special child by our paediatric dental specialists.

Advances in

In-situ-hybridisation and immuno-histochemistry has long been

Oral Pathology/ Oral Medicine

applied in clinicopathological studies in the Stomatology Unit of the IMR. Other tools emerging in diagnostic pathology include the polymerase chain reaction (PCR), complementary DNA (cDNA), microarray, flowcytometry, laser microdissection and other state-of-the-art technology are all available within the various units of the IMR, local universities, as well as NGOs such as CARIF, for application in oral diseases as well.

Advances in Prosthetic Dentistry

Traditional restorative philosophy was based on the concept of maintaining a complete dentition of 28 functional teeth24. There has, however, been a change in treatment philosophy based on the 'shortened dental arch (SDA)' concept. Based on need for oral function in its widest sense, many patients can function with ten (instead of 14) occluding pairs of teeth. Every reasonable attempt should be made to maintain a complete dentition but the SDA concept provides a rational problem-oriented approach to ensure that the burden of attempting to maintain a full dentition is not excessive.

There have been improvements in almost all materials used for prostheses, their fabrication, as well as refinements in prosthodontic techniques, the most profound being that of dental implants. These provide a potentially permanent method of stabilising a fixed or removable prosthesis. Implants are also gaining popularity in orthodontics as anchorage supports. Sub-periosteal implants have been developed which may be placed in the hard palate to provide intra-oral anchorage, eliminating the need for patient compliance with headgear.

Advances in Oral and Maxillofacial Surgery

Oral and Maxillofacial Surgery is the specialty of dentistry which deals with the diagnosis and surgical management of anomalies and pathological processes of the teeth and their supporting structures[25]. These specialists are involved in the surgical management of pathologies, detractions, injuries of the oro-facial regions as well as other procedures such as surgical removal of impacted third molar, surgical endodontics, and orthognathic surgery. They are often also the specialists to whom medically compromised patients are referred for management.

Guidelines for antibiotic use

Recent guidelines from the National Institute for Clinical Excellence (NICE)[26] recommended that routine prophylactic removal of pathology-free impacted third molars should be discontinued. Indications for third molar removal were pericoronitis, cyst formation, non-restorable carious lesions, destruction of adjacent teeth or bone and tumours.

The role of prophylactic antibiotics in third molar surgery remains controversial. Current literature shows little evidence for the use of prophylactic antibiotics for the removal of impacted third molars and that indiscriminate use of antibiotics can lead to development of resistant strains, secondary infection, toxicity of antibiotics and allergic reactions. Use is considered justified in the presence of an active infection at the time of surgery where there is risk of sub-acute bacterial endocarditis or when patient is immunocompromised.

Changing techniques of root treatment

Failed endodontics is most commonly due to inadequate removal of bacteria and their toxins within the root canal system. Re-root treatment is thus considered the first line of treatment before considering surgical intervention. Surgical endodontics is the recourse when the skilled practitioner is certain that no better results can be achieved by non-surgical treatment or if a biopsy is required. There have been changes in the way surgical endodontics is carried out. The traditional bevel cut at the root apex increase the cut dentinal tubules in a bucco-lingual direction making the sealing of the canal system more difficult. Perpendicular root resections, a more demanding technique especially in inaccessible sites such as lower incisor and molar roots, are currently recommended. The use of methylene blue greatly aids visibility in inaccessible sites.

Newer root filling substances

A number of substances have been used as root end filling material including traditionally amalgam, or zinc oxide eugenol. Amalgam has the disadvantage of staining mucosa, prone to scatter, mercury contamination, corrosion, electrochemical reactions, need for undercut preparation and moisture contamination. Recent materials to provide a hermetic seal include immediate restorative materials (IRM), super ethioxybenzoic acid and mineral trioxide aggregate (MTA). MTA has shown better seals, and excellent tissue response with reduced peri-radicular inflammation. DIAKAT is a new material similar to MTA whose use is under investigation[25].

orthognathic surgery

For severe facial skeletal discrepancies, orthognathic surgery may be indicated[26]. The most common procedures are sagittal split mandibular osteotomy and Le Fort I maxillary osteotomy either individually or combined. Other operations include intra-oral vertical subsignoid osteotomy, high Le Fort II and III osteotomies. Orthognathic surgery has not changed greatly but fixation is now nearly always achieved internally using mini or microplates used with small self-tapping monocortical screws.

The greatest innovation for treatment of facial deformity is distraction osteogenesis. First used for leg lengthening this technique has been adapted for treatment of maxillary and mandibular hypoplasia. The jaw is fractured, the distractor applied and then after 3-4 days, distraction of 1 mm per day is done until the desired length is achieved. External distractors have given way to internal distractors. The close consultation between the orthodontist and oral surgeon is critical for the success of orthognathic operations[27].

The rapidity of scientific and technological advances made in the various medical and dental fields have made it increasingly difficult to keep up to date in all associated fields, so that an interdisciplinary approach has become essential to increase patient benefits especially in the treatment of complex medical and dental conditions.

Upholding standards

The number of dental specialists is increasing and it is timely that a Dental Specialist Accreditation board be set up to determine qualification and training programmes, and a great need for a Dental Specialists' Register to uphold the standard of dental care in Malaysia.

Conclusion

There has been much progress in dental care in Malaysia in tandem with global advances. However, much remains to be done to ensure equitable access to care for the population. There is need for the dental workforce to not only be aware of current developments and trends but also to embrace these more quickly for a competitive edge.

While country developments have ensured that Malaysian dental professionals are always at the forefront of knowledge, of more importance is that these knowledge be translated into appropriate and timely interventions for the client who should be the focus of all concerns.

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CHALLENGES FOR GENERIC DRUGS

SUMMARY

The increasing use of generic therapeutics has led generics to capture 14% of the global healthcare market in 2004, with overall revenues of USD 58 billion. The imminent patent expirations of many major drugs in major markets will provide a major growth stimulus for the generic companies as they compete to capture market share from multi-billion dollar drugs whose patents expire in this period. Cost containment pressures on healthcare and issues on access and affordability of essential medicines, will lead to increased adoption of generic substitution and prescribing practices by governments of many countries. To maximize the generic industry's capacity to meet the challenges of rising demand, Malaysia needs to improve the current market conditions for generic medicines and generate a stronger public awareness of their benefits.

Introduction

Medicine, a major component in healthcare

Health is a basic need and governments have a duty to their citizens to protect and promote public health. Medicines constitute a major and important component in the provision of healthcare service for the population, to reduce morbidity and mortality associated with the illness. According to the World Health Organization (WHO) in its *Regional Strategy For Improving Access to Essential Medicines* in the Western Pacific Region for 2005-2010, expenditure on medicines usually accounts for 25 to 50% of total public and private health expenditures in developing countries.

Health is a basic need and governments have a duty to their citizens to protect and promote public health. Medicines constitute a major and important component in the provision of healthcare service for the population, to reduce morbidity and mortality associated with the illness.
According to the World Health Organization (WHO) in its Regional Strategy For Improving Access to Essential Medicines in the Western Pacific Region for 2005-2010, expenditure on medicines usually accounts for 25 to 50% of total public and private health expenditures in developing countries.

Ageing populations, increasing incidence of chronic diseases, dramatic rise in prices for originator pharmaceuticals and the rapidly rising treatment costs, are causing governments throughout the world to review the sustainability of their health care provisions.

For the developing world, the challenge is in providing its populations with an acceptable level of healthcare and ensuring patient access to quality, safe and effective medicines while reducing the cost of pharmaceutical care. In the developed countries the focus is on containment of cost of medicines rather than on access to medicines.

Generic, a cost saving alternative

Generic medicines provide the opportunity for major savings in the healthcare expenditure since they may be substantially lower in price than the innovator brand. Hence the relative affordability of generic pharmaceuticals in comparison to their branded counterparts, further enhanced by the increasing costs of healthcare, is seen as a cost effective means of controlling the fastest growing budget item in healthcare: pharmaceuticals.

Today, the use of generic drugs has been increasing steadily, internationally.

This report will describe the role and significance of the generic drugs in relation to healthcare and the issues and concerns pertaining to its place in the industry.

The generics invasion

The World Health Organization (WHO) defined generics as pharmaceutical products that contain the same active ingredient in the same amounts as the original products on which they are based. Marketed after the expiry of patent or other exclusivity rights, generics are legally available from multiple sources and are intended to be interchangeable with the original product.

Generics are approved for marketing by national authorities after they are found to have the same quality, safety and efficacy as the original product and are either under a non-propriety name (INN or other approved name) or under brand names ('branded generics').

Generic name versus Brand name

Depending on national legislation, the above elements may be different in some countries. The term 'multisource' products has been introduced to encompass both branded and unbranded generics.

A generic name is that of the active drug substance while a brand name is the registered trademark under which the drug is sold. Generics and brand names may contain different non active ingredients (such as colouring, bulking agents) and hence may differ in terms of characteristics like colour, flavour size and shape.

Malaysian healthcare sector overview

Malaysian Healthcare system

The Malaysian healthcare system which has traditionally been essentially government driven has grown rapidly since the 1980s particularly in the private sector.

The healthcare sector encompasses a broad spectrum of goods and services. Services include hospital based care and primary care while goods include western medicines, traditional medicines, health/ dietary supplements and medical devices. The provision of adequate and affordable healthcare is essential for the wellbeing of any citizen. About 80 percent of the healthcare services is provided by the public sector.

The Malaysian government considers the country's healthcare industry as one of the its top priorities and continuously strive to implement new schemes to help boost the country's healthcare sector.

Healthcare expenditure

The Malaysian healthcare sector has grown rapidly since the 1980s and the industry is growing at a rate of 6-8 % annually. It is currently valued at around USD 1 billion. In 1990, healthcare expenditures were close to RM1.8 billion (USD 426 million) and in 1997 almost doubled to RM 3.4 billion (USD 805 million).

The Malaysian healthcare industry is heavily subsidized and spends an enormous amount of money on medicinal drugs annually. In 2004, the Malaysian government spent about RM 800 million subsidizing 97% of the drug costs in government hospitals and clinics as compared to RM 288 million in 1996. The amount subsidized is increasing every year by 10 to 15 %.

The costs of healthcare in Malaysia is on the rise. There is an increasing concern over whether the government can continue to sustain this level of subsidy in the years to come.

Malaysian pharmaceutical industry overview

Product category

The Malaysian pharmaceutical industry can be broadly categorized as prescription, over-the-counter (OTC), traditional and health/food supplements. The prescription medicines comprise of patented and generic drugs, the sale and transaction of which are confined to doctors and pharmacists. The OTC, traditional medicines and health/food supplements may be sold by non professional outlets and to the public.

Domestic capability

The domestic industry which comprises of local, foreign and joint venture companies with factories in Malaysia, has evolved into a modern, sophisticated sector of the Malaysian economy and capable of producing a wide range of pharmaceuticals which include mostly generic drugs such as antibiotics and painkillers. It has the capability to produce almost all dosage forms including sterile preparations (eye preparations, injections) soft gelatin capsules and powders.

The 36 members of the Malaysian Organization of Pharmaceutical Industries (MOPI), collectively produces about 35% of Malaysian medicine requirements. In terms of product range, MOPI members have the capabilities to manufacture more than 80% of product categories in the National Essential Drug List (NEDL).

Malaysian Pharmaceutical Market Value

The Malaysian pharmaceutical market in year 2004 was estimated at USD 665 million (RM 2527 million) exhibiting growth of around 10%. However, strong growth is anticipated in the market which propels a Compound Annual Growth Rate from year 2001 to 2007 at an estimated 12.5%.

Currently, approximately 70% of the local market is monopolized by the multinational companies, while Malaysian companies comprise about 20-30% of the market. With healthcare high on the list of government priorities, the prospect of the pharmaceutical industry appears favorable.

Global Generic Market

In year 2003, the global generic drug market was estimated to be between USD 19 and USD 22 billion, with compound growth of 11-12% annually. Currently, it is estimated at approximately 11% or USD 53.9 billion of the global pharmaceutical sales.

EU market

The European Union's (EU-25) generic market today is worth around seven billion euros, compared to around 70 billion euros for the total European pharmaceutical market value.

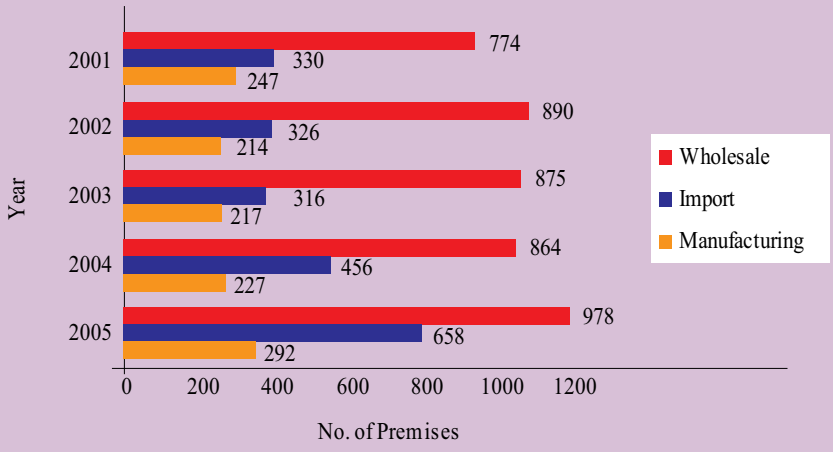
The size of the generic market differs widely in the various EU member states, mainly as a consequence of the different policies followed. Generics make up a relatively large part of the pharmaceutical market in Germany (41%), Sweden (39%) and the United Kingdom, UK (22%).

Licensed manufacturers/premises

Growth status

In year 2005, a total of 1928 licenses were issued by the Drug Control Authority (DCA). Of these, 292 were for licensed manufacturers, 658 licensed importers and 978 licensed wholesalers **(Figure 1).**

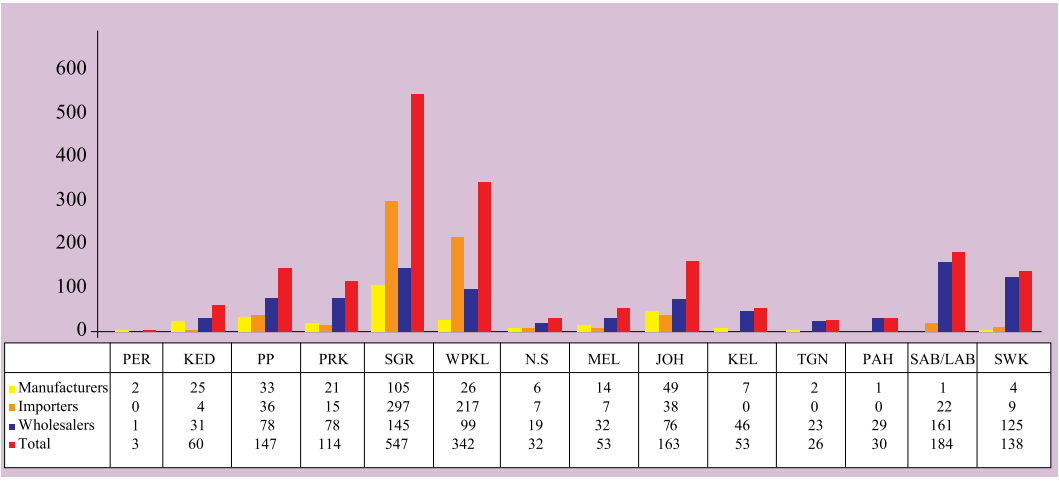
Figure 1 : Number of Licenses (Year 2001-2005)



Geographical distribution of licensed premises

Geographical distribution of licensed premises for the year 2005 is illustrated in **Figure 2.** Selangor remained as the state with the highest number of licensed premises, followed by Wilayah Persekutuan (Kuala Lumpur) and Johor.

Figure 2 : Geographical Distribution of Licensed Premises (Year 2005)

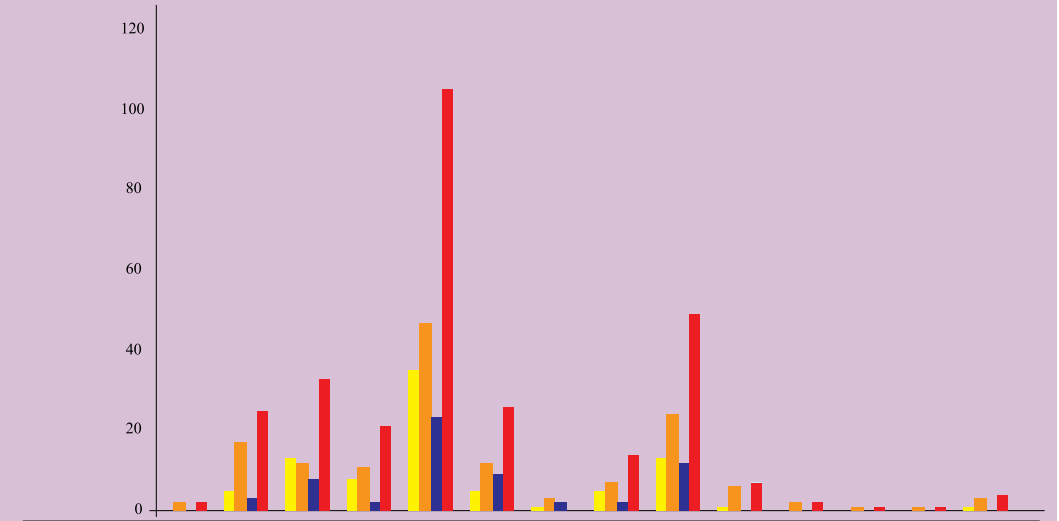


	PER	KED	PP	PRK	SGR	WPKL	N.S	MEL	JOH	KEL	TGN	PAH	SAB/LAB	SWK
Manufacturers	2	25	33	21	105	26	6	14	49	7	2	1	1	4
Importers	0	4	36	15	297	217	7	7	38	0	0	0	22	9
Wholesalers	1	31	78	78	145	99	19	32	76	46	23	29	161	125
Total	3	60	147	114	547	342	32	53	163	53	26	30	184	138

Categories of licensed manufacturers

Categories of licensed manufacturers for the year 2005 are as illustrated in **Figure 3**. A total of 87 manufacturers were licensed to produce pharmaceuticals, 48 traditional medicines and 61 produce cosmetics.

Figure 3 : Categories of Licensed Manufacturers (Year 2005)



	PERLIS	KED	PP	PRK	SGR	WPKL	N.S	MEL	JOH	KEL	TGN	PAH	SAB/ LAB	SWK
Pharmaceutical	0	5	13	8	35	5	1	5	13	1	0	0	0	1
Traditional	2	17	12	11	47	12	3	7	24	6	2	1	1	3
Cosmetic	0	3	8	2	23	9	2	2	12	0	0	0	0	0
Total	2	25	33	21	105	26	6	14	49	7	2	1	1	4

Products registered

As of 2005, a total of 117,466 products were registered by the DCA. A total of 37,947 products were registered in year 2005 of which 327 (0.86%) were prescription products; 300 (0.79%) OTC products; 1,308 (3.45%) traditional medicines and 36,012 (94.9%) cosmetics. Breakdown of products registered between 2001 and 2005 is shown in **Table 1.**

Table 1 : Total Number of Products Registered (Year 2001-2005)

Year	Prescription Drugs	OTC Products	Traditional Medicines	Cosmetics	Total
2001	180	624	1,344	309	2,457
2002	342	235	864	159	1,600
2003	324	275	1,349	4,721	6,669
2004	353	226	970	40,762	42,311
2005	327	300	1,308	36,012	37,947

New Drugs

From the year 2001 to 2005, the total number of applications received for New Drugs (previously known as New Chemical Entity) was 408 **(Figure 4)**. Of these, 330 (80.9%) were approved, 26 (6.4%), rejected and 18 (4.4%) deferred for additional information. In year 2005, 43 products (58%) were registered and 1 (1.4%) deferred.

Figure 4 : Registration Status of New Drugs (Year 2001 - 2005)

	2001	2002	2003	2004	2005
Received	111	81	53	89	74
Approved	61	52	89	85	43
Rejected	15	3	4	4	0
Deferred	4	11	1	1	1

Biotechnology products

A total of 24 applications were received and 11 products were registered. Examples of biological products are vaccines, serum for therapeutic use, antitoxin, blood components and its derivatives as well as other products derived by biotechnology method such as interferon and erythropoietin.

Local and imported products

The number of locally manufactured products constitutes 26.2% (9,933) and the imported products 73.8% (28,014) of the total number of products registered in the year 2005. The ratio between locally manufactured and imported products for prescription drugs is in the order of 29:71; 50:50 for OTC products; 71:29 for traditional medicines; and 24:76 for cosmetics as shown in **(Table 2).**

Table 2 : Number of Local and Imported Products Registered (Year 2005)

Month	Prescription Drugs		OTC Products		Traditional Medicines		Cosmetics		Total	
	Local	Import	Local	Import	Local	Import	Local	Import	Local	Import
Jan	2	21	6	16	41	11	838	2,271	887	2,319
Feb	1	11	3	11	53	28	1,249	2,827	1,306	2,877
Mar	13	29	11	16	83	43	1,043	2,920	1,150	3,008
Apr	13	13	10	12	102	37	750	2,303	875	2,365
May	6	23	12	11	91	36	315	1,666	424	1,736
June	5	17	14	12	85	39	481	2,419	585	2,487
July	18	21	21	17	62	15	759	2,551	860	2,604
Aug	7	19	12	7	76	22	1,093	2,985	1,188	3,033
Sept	12	36	11	22	154	60	771	3,016	948	3,134
Oct	7	14	18	14	111	52	672	1,907	808	1,987
Nov *	-	-	-	-	-	-	-	-	-	-
Dec	12	27	33	11	68	39	789	2,387	902	2,464
Total	**96**	**231**	**151**	**149**	**926**	**382**	**8,760**	**27,252**	**9,933**	**28,014**

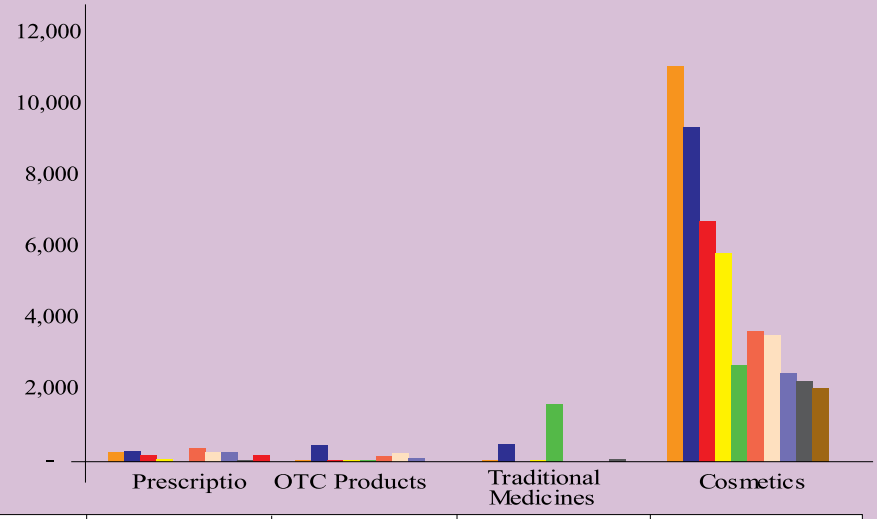
*No DCA meeting in November 2005**

Based on the total number of locally manufactured products registered (n = 9,933), 0.96% were prescription drugs, 1.5% OTC products, 9.3% traditional medicines and 88.2% cosmetics. For imported products (n = 28,014), 0.8% were prescription drugs, 1.5% OTC products, 1.4% traditional medicines and 97.3% cosmetics.

Sources of imported products

The leading foreign sources of imported products include France, United States of America, Italy, Japan, Germany, Thailand, China, U.K, Australia, and Canada. Together they account for approximately 22.2% (55,137) of our total imports (n = 71,457). Products imported from ASEAN countries such as Indonesia, Thailand, Singapore and Philippines constitute nearly 10.7% (7,621) **(Figure 5).**

Figure 5: Major Sources of Imported Products (Year 2005)



	Prescriptio	OTC Products	Traditional Medicines	Cosmetics
France	251	39	32	11,083
US	304	446	473	9,390
Italy	184	28	1	6,763
Japan	63	41	21	5,843
China	4	26	1,612	2, 724
Germany	380	142	14	3,668
Thailand	270	215	14	3,542
UK	247	105	10	2,474
Taiw an	55	12	86	2,267
Canada	170	42	20	2,076

Generics: Relation to healthcare

Global perspectives WHO advocacy

WHO has long advocated the use of generics of known quality as a cost effective means to ensure access to and availability of essential medicines.

European countries

In some EU member states (UK, Germany), generics are promoted and are seen as a tool to contain rising pharmaceutical costs. Generic medicines play an increasingly equitable access to medicinal care in the EU. The generic medicine is fast becoming the major supplier of pharmaceuticals in the EU, providing more than 60% of medicines to countries of Central and Eastern Europe, and up to 50% in Western European countries such as the UK, Denmark and Germany. The growing role of equivalent generic products is due in large part to their reduced price. This works effectively to make medicinal treatment affordable to a large number of patients throughout Europe.

Recognizing the budgetary importance of generic drugs coupled with the increasing demands of healthcare provision and costs, the Ministry of Health Malaysia, (MOH), as part of a cost containment measure, has been promoting the use of quality, safe and efficacious generics to substitute the equivalent originator drugs.

Potential benefits of generic drugs

Equivalent versions of originals

Generics are products containing well established drugs whose safety and efficacy are well known and provided they are well made, generics are to all intents and purposes identical to the original products and can thus be used interchangeably.

Assurance of quality, safety and efficacy

As with all pharmaceuticals, generic drugs must meet the established standards of quality, safety and efficacy as stipulated by the Drug Control Authority (DCA), Ministry of Health Malaysia, before they are registered and given market approval in the country.

Regulatory control

The promulgation of the Control of Drugs and Cosmetics Regulations in June 1984 laid the groundwork necessary towards moulding a systematic pharmaceutical regulatory system in Malaysia

As the national drug regulatory agency, the National Pharmaceutical Control Bureau (NPCB) and its executive arm, the DCA (established in January 1985), employ global best drug regulatory practices. The objective of drug regulation is to ensure that therapeutic substances

approved for the local market are safe, efficacious and of quality and also to ensure that cosmetic products approved are safe and of quality.

Drug regulation which was initiated in Malaysia in 1985 was implemented in phases. Activities associated with drug regulation include processing of applications prior to registration with emphasis on evaluation of documents submitted, quality control assessment of products, inspection , licensing and auditing of manufacturers, packers and wholesalers of medicines to ensure their premises and practices meet an acceptable international standard. Adverse drug reactions monitoring and market surveillance are conducted both locally and internationally, through collaboration and networking with other national regulatory agencies and the WHO.

Price competition

Generics are considerably less expensive than the innovator medicine because their manufacturers do not incur the risks and costs associated with the research and development of the latter which is costly, time consuming and one that is not without risks or failures. The availability of relatively lower priced generic drugs can bring down the price of innovator drugs through market competition, producing savings to both the consumer and the government. Some reports estimated generic drugs reduce prescription costs by well over 50% without loss of quality or safety.

Consumer choice

With commercially available generic drugs, consumers will have the opportunity to choose cheaper brands with savings to themselves as individuals and taxpayers. Generics stimulate innovation through competition and increased consumer choice, creating new sources of enterprise and generating new employment and investment opportunities

Documentation requirements

Bioequivalence (BE) requirements

In the manufacture of generic drugs, the three concepts of quality, safety and efficacy apply in the same way as they do to the innovator product. Since generic drugs contain established active ingredients, clinical studies are unnecessary although bioequivalence (BE) data will be required. A BE study demonstrates therapeutic equivalence between the test product and the originator product used as a reference

With the increasing availability of generic products in the domestic market, the Ministry of Health Malaysia through the DCA, introduced

BE requirement as a mechanism to further ensure that generic products available are therapeutically equivalent to the innovator product. The move for BE requirement on oral immediate release products was initiated in December 1999 for 3 selected active substances. As of March 2004, the number of active substance listed for bioequivalence study is 43.

Quality control

For generic medicines, as with all pharmaceutical products, scientifically controlled quality is of paramount importance. Quality assurance of medicines is a feature of all procedures and processes employed throughout the production chain. Quality has to be built in at each critical stage of the production process, the end result of which is the production of a medicinal product fit for its purpose and use. In essence, the quality must be assured at the time of manufacture and throughout the shelf life of the product.

Stability study

Stability study is one of the most important parameters to be considered because drugs with poor stability may not produce the desired therapeutic effects. There is also a possible toxicity of the degradation products which can be detrimental to peoples health. The objective of a stability study is to determine the period of time during which a pharmaceutical product is able to maintain its chemical, physical, microbiological and biopharmaceutical properties when stored under defined conditions.

PIC/S membership

As a member of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) since January 2002, Malaysia's standards for inspection and licensing are at par with other members who are in this scheme, including Europe, Australia and Canada.

The PIC/S, conceived by the European Free Trade Association which upholds good manufacturing practices, are two international instruments between countries and pharmaceutical inspection authorities which provide together an active and constructive cooperation in the field of Good Manufacturing Practice.The move is expected to raise the standards of the local pharmaceutical industry. The recognition has enabled Malaysian pharmaceutical companies to export their products more easily to PIC/S members, mainly in the European Union.

Generics: Potential/estimated savings

Innovator and generic drugs play separate, equally important roles in healthcare. While innovator drugs are responsible for bringing newer and better treatment to patients, generic drugs offer affordable medicines and reduce the cost of healthcare to patients and the government.

Generics in US

Generic drugs in the US account for about 40% of all prescribed medicines. A study based on data from a year 2000 National Medical Expenditure Survey in the US concluded that switching to generic drugs could save US adults up to USD 8.8 billion a year.

Generics in EU

European governments are increasingly relying on generics to save on healthcare costs. The prescribing of generic medicines in Britain is increasing and is higher than in many other EU countries. About 76% of all prescriptions are written generically.There is a potential increased annual savings at nearly USD 9 billion, an 11% cost reduction, if generic equivalents replaced brand name pharmaceuticals.

Industry perspectives

Market drivers

In recent years the issues driving the international generic industry include patent expirations of many major drugs, an estimated 42, in the period between 2005 to 2009 in major markets. Also, the market drivers include governmental curbs on healthcare spending in developing countries and cost containment efforts in the US and other international markets.

All these will provide a major growth stimulus for the generic companies as they compete to capture market share from multi-billion dollar drugs whose patents expire in this period. Furthermore, the development of advanced manufacturing in developing markets has created fresh opportunities for both the research based and generic manufacturers.

Getting the right environment for generics

Recognizing the potential contribution of generics to healthcare, there is thus an urgency to create the proper competitive and legal environment for the industry to continue meeting the challenges of providing high volumes of cost effective equivalents to the Malaysian healthcare system.

WHO perspective

According to the WHO, generics should have a prominent place in national medicines policy. The five principal areas for action that can contribute to ensuring this are supportive legislation, effective regulation, systematic processes of generic selection, price and financing incentives and professional and public acceptance.

Supportive legislations Laws and regulations

Without laws and regulations to protect the local industry, the companies have to compete with the more established multinational brands in its own country. National Policy on access to medicines, patent law and patent law amendment are safeguard measures for generic production.

National Drug Policy

Currently, Malaysia is in the process of formalizing its National Drug Policy which will provide clear direction and guidance for the nation to embark on future medicines related programmes to support the healthcare needs of the country.

WHO Collaborating Centre

As a WHO collaborating Centre for Regulatory Control of Pharmaceuticals since 1996, the NPCB has and will continue to play important roles to fulfill the commitments and expectations as stated in its terms of reference.

ISO Certification

The quality management system of NPCB based on MS ISO 9001 version 2000 is current and certified by the Standards and Industrial Research Institute of Malaysia (SIRIM). The scope of certification is on Regulatory control of pharmaceuticals, traditional products and cosmetics through registration, licensing and surveillance activities.

The ISO certification achieved by NPCB is testimony of its having a good quality management system in place and reflects the total commitment of the staff towards implementing its philosophy and requirements. This has benefited the pharmaceutical industry in many ways including transparency of the system, reduced bureaucracy and creating a more clientele responsive approach.

Encourage generic selection: Buy local Policy

Strong government promotions to consumers to encourage 'Buy Malaysian' which was mooted by the 1997 Asian economic crises and fuelled by the adverse impact of the currency depreciation brought positive changes towards sustaining the viability of the local pharmaceutical industry.

National Essential Drug

The National Essential Drug List (NEDL) launched in 1999, was a step towards the formulation of a National Drugs Policy. Based on the WHO

model List of Essential Drugs, the NEDL is intended to be used as a standard guideline for prescribing and is primarily aimed as a cost containment measure for both the public and private healthcare sectors. The adoption of the NEDL serves as an effort towards promotion of rational drug use and improving accessibility to drugs.

List (NEDL)

The trend in most countries is to increase generic prescribing and dispensing whenever possible as a suggested means of lowering the costs of healthcare. Recently, the government requested to review the system of prescribing and dispensing medicines as the government could not go on subsidizing the increasing costs. It was suggested that government hospitals dispense more generic drugs as they were cheaper, safe and of the same quality as patented drugs.

Generic prescribing

Health professionals and consumers have to be assured that the DCA approved generic drugs have met the same stringent standards as the innovator drug. Health professionals, while ultimately responsible for implementing best therapeutic options, have a vital role to play in promoting quality use of medicine through good treatment choices and good communication with consumers.

Professional and public acceptance

Medicine pricing issues have always been of great concern for developed and developing countries due to high cost incurred in pharmaceutical care. The high cost of medicine is recognized as one of the major barriers to access to essential treatments for many in developing countries. Research shows that huge differences exist for the same medicine within a country and between countries.

Price controls

Malaysia does not have laws to control drug prices. Instead, market forces were allowed to stabilize prices and foster competition. Since medicines are essential items there is a need for the government to monitor prices.

A medicine price survey conducted in West Malaysia from October 2004 to January 2005, concluded that in general, prices of medicines were high in the private sector. In private pharmacies, price of innovator brands were 16 times higher than reference prices and generics were 6.6 times higher. In dispensing doctor's clinics, the figures were 15 times higher for innovator brands and 7.5 for generics. Mark-ups were high, especially those applied by dispensing doctors (innovator brands 50-70%, generics were up to 316%) . Retail pharmacy mark-ups were also high (innovator brands 25-38%, generics 100-140%).

Medicine price survey

Medicine price monitoring system

The Pharmaceutical Services Division, Ministry of Health Malaysia, has established a Medicines Price Monitoring Unit to collect information on price of medicines in Malaysia as part of a requirement in the proposed National Medicines Policy. The policy shall be developed to ensure fair, reasonable, affordable and stable prices of drugs, especially essential drugs.

Issues and concerns with generics

Pharmaceutical industry, a strategy sector for national growth

The potential of the domestic pharmaceutical industry has been recognized by the Malaysian government who has identified it as a strategic industry which should be promoted. A strong and viable generic drug industry will not only reduce Malaysia's dependence on imports and reduce health care costs, but also ensure availability of affordable medicines that are safe, efficacious and of quality to the public and enhance export earnings.

Preferential government treatment for domestically manufactured products will further foster local companies to enter this profitable market, and expedite the growth of the Malaysian pharmaceutical industry.

Though the generics market is largely risk free, the pharmaceutical producers are urged to organize themselves better nationally, as well as regionally and be able to meet not only intellectual property related challenges but market challenges too.

Globalization and liberalization

The increasing globalization of commerce and trade and the merging of pharmaceutical companies are internationalizing the pharmaceutical production. International norms and standards become more important than before.

ASEAN Free Trade Area

Globalization process has had an impact on healthcare with threats and opportunities in the generic pharmaceutical market. The implementation of the ASEAN Free Trade Area (AFTA) which is a collective effort by ASEAN member countries to reduce/eliminate tariffs on intra-ASEAN trade in the goods sector will provide enormous potential for market expansion of Malaysian companies.

The flow of pharmaceutical products from neighbouring countries is expected to increase, tightening competition and pushing local manufacturers to create competitive advantages. Malaysia's businesses must strategize to tap the ASEAN market by establishing linkages

and strategic alliances, not only in other ASEAN countries but also globally.

Data exclusivity

One of the major concerns raised by generic medicine manufacturers worldwide is over provisions that grant companies generating test data (which is submitted to the government authorities) exclusive rights over that data, commonly known as 'data exclusivity' provisions.

Data exclusivity (DE) would prevent the Drug Control Authority (DCA) from relying on the originator's clinical test data in order to register the generic version until the data exclusivity period (between 5 to 11 years) has expired.

The Ministry of Health, Malaysia understands the concerns of multinational companies regarding the need to set provisions for DE in an effort to safeguard intellectual property rights. The final decision by the Ministry of Health Malaysia for DE in pharmaceuticals will take into account the views from all parties, whereby it must not jeopardize the interests of both the domestic and multinational pharmaceutical industry.

Import of raw materials

Malaysia is dependent on imports of raw materials(bulk actives, excipients, packaging materials).High cost of raw materials can lead to intense domestic and price driven competition in the market place. Despite the pharmaceutical industry's insistence that drug prices in Malaysia are relatively low, there is no denying that drug costs escalate from time to time. Drug prices are especially affected in the events of economic crises or currency crises.

Recognition of local BE studies: Strategies to strengthen and accreditate BE centres

Currently, there are 5 BE centres in the country with 4 based in the local universities (in Selangor, Kelantan, Penang and Kuala Lumpur) and one owned by a private hospital in Penang. ASEAN member countries have adopted the harmonized ASEAN BE guideline for the conduct of BE studies. Malaysia needs to strengthen, upgrade and increase existing capacity of its BE centres in terms of infrastructure, laboratory, clinical facilities and together with a qualified and trained workforce.

The accreditation of the BE centres will further enhance it's credibility and competence, which will result in the recognition and acceptance of its BE studies internationally. In the advent of globalization and trade liberalization, it is imperative that our local manufactured products can be accepted with confidence globally.

Incentives for BE centres

To facilitate, encourage and expedite the full implementation of BE requirement on generic drugs will require the governments' participation and commitment. Proposals on incentives for the BE centres include financial allocation for capacity building through a National Capacity Building Fund, tax exemptions and reimbursements.

Biopharmaceuticals

Patent expirations of biopharmaceuticals are beckoning generic drug companies but numerous hurdles remain to be a profitable business. Biotechnology products are expensive and the availability of generics would spur competition and hopefully reduce prices.

The issue of the manufacture, approval and marketing has become a major source of debate within the industry due to reasons of cost containment and patent expiry. Generic biological products are harder to characterize than small molecules drugs and thus harder to prove equivalent entities.

Safety and other contentious scientific issues surrounding the prescription biosimilars pharmaceutical market are staggering and in some cases seemingly insurmountable compared with traditional generic drug market.

Malaysia needs to address regulatory hurdles (technical issues like bioequivalence), the political environment which affects development (Malaysia's Biotechnology Policy), and the commercial and competitive costs of biosimilars.

Internet peddlers

The search for cheaper pharmaceutical products leads consumers directly to the doorsteps of internet peddlers and suppliers in other countries advertising cheap and quality products.

These products may not have undergone the evaluation and testing process that a registered product would have been subjected to. Consumers are exposed to unnecessary risks because an unregistered product is an unknown entity whose quality, safety and efficacy are highly questionable

The existing legislation in Malaysia serves not only to control dietary supplements, cosmetics, traditional medicines and pharmaceuticals but also to protect the health of the public in general.

Research and Development

It is important for the industry to maintain and increase their capacity and develop long term strategies for sustainable future growth which will help boost profitability, drive market share and enhance Research and Development (R&D) productivity. In this context the local pharmaceutical industries need to put more emphasis on R&D.

The government has taken steps to maintain an attractive environment to support pharmaceutical R&D. The 8th Malaysia Plan (years 2001-2005) has identified pharmaceuticals and nutraceutical biotechnology to be explored and exploited by local manufacturers tapping on the rich flora and fauna available in the country.

Enhancing access and availability

Information technology

The NPCB has ongoing initiatives to improve timely registration of safe, efficacious and quality pharmaceutical products. Initiatives include upgrading Information Technology facilities, which is in line with global trends, reviewing evaluation processes, procedures and strengthening the workforce.

Online registration

The current QUEST 2 Online system is a paperless web based application accessible via internet connectivity. It was launched in February 2002 for cosmetics and July 2003 for generic and OTC drug applications. The format for generic drug application is based on the ASEAN Common Technical Document/Requirement and aimed at increasing efficiency, accessibility and convenience of applicants.

ASEAN Harmonization

Efforts towards ASEAN Harmonization were initiated through the ASEAN Consultative Committee for Standards and Quality (ACCSQ) which was formed by the ASEAN Economic Ministers to facilitate and complement the objectives of the ASEAN Free Trade Area (AFTA).

Hence the ACCSQ Pharmaceutical Product Working Group was formed with the objective of developing harmonization schemes of pharmaceutical regulations of the ASEAN member countries in order to complement and facilitate the objective of AFTA, particularly, the elimination of technical barriers to trade posed by regulations, without compromising the quality, efficacy and safety of drugs.

The NPCB has ongoing activities with the pharmaceutical industry to encourage and facilitate the harmonization process which will be fully implemented in January 2009.

Conclusion

In recent years, the number of highly lucrative medicines coming off patent has seen the role of the generic industry change, taking an even more important role in the pharmaceutical sector. Generic drugs provide the opportunity for major savings in healthcare expenditure since they may be substantially lower in price than the innovator brand.

The availability of relatively lower priced generic drugs can bring down the price of the originator drugs through market competition, producing savings to both the consumer and the government.

With healthcare high on the list of government priorities, coupled with cost cutting initiatives of national healthcare systems, the prospect of the pharmaceutical industry appears favorable. Creating the proper legal and competitive environment through faster registration procedures, less restrictive regulatory processes, increased promotion of generics by doctors and pharmacists and better awareness of generics by the consumers, are nevertheless essential for the industry to continue meeting the challenges of providing high volumes of cost effective generic equivalents to the Malaysian healthcare system.

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Chapter 2

POPULATION HEALTH

DENGUE CONTROL IN MALAYSIA

SUMMARY

Dengue is a major public health problem in Malaysia and the incidence of dengue in the country has been on an increasing trend. The incidence has been the highest over the last two years with DEN 1 as the main circulating serotype. Selangor and the Federal Territory of Kuala Lumpur are two States with the highest number of dengue cases in the country, contributing to between 45- 48% of the total number of cases in the country. Prevention and control of dengue is a multi-prong approach focusing on the vector and the community at risk. Control of dengue is not dependent on the health authority alone. Community involvement is crucial in combating the disease. COMBI (Communication for Behavioural Impact) is increasingly being used to effect positive behavioural changes in the community towards control of Aedes breeding. Further strengthening of laboratory capabilities and research on dengue are needed to curb the transmission and outbreaks of dengue in the country.

Introduction - global overview

Global disease burden

Dengue is one of the most important mosquito borne diseases in the world. Some 2.5 billion people, two fifths of the world's population, are at risk from Dengue[1,2]. The disease occurs in two main forms, the commoner dengue fever (DF) and the more serious dengue haemorrhagic fever (DHF). DF and DHF are primarily diseases of tropical and sub tropical countries, with predominance in the urban and sub-urban areas.

The World Health Organization (WHO) estimates that currently, there are about 50 million cases of dengue infections worldwide every year. The disease is now endemic in more than 100 countries in Africa, the Americas, the Eastern Mediterranean, South-East Asia and the Western Pacific regions. Countries in South-east Asia and the Western Pacific are most seriously affected[1,2].

Increasing global trend

The spread of dengue is attributed to expanding geographic distribution of the four dengue viruses and of their mosquito vector, the most important of which is the predominantly urban species Aedes aegypti. A rapid rise in urban populations is bringing ever greater numbers of people into contact with this vector, especially in

areas that favour mosquito breeding, for example, where household water storage is common and where solid waste disposal services are inadequate.

Dengue situation in Malaysia

Incidence of dengue in Malaysia

Dengue is endemic in Malaysia. With urbanization and increasing pace of development, the disease has been on the rising trend. **Figure 1** indicates the incidence trend of dengue fever from 1973 in Malaysia. The incidence was less than 10 per 100,000 population in the 1970s and 1980s, except for 1974 and 1982 where the incidence was 22.0 and 20.7 per 100,000 respectively. It was stable at about 30 per 100,000 population in the earlier part of 1990s until 1996 when it started rising and reached a peak of 123.4 per 100,000 during the pandemic outbreak in 1998[3].

Dengue trend in Malaysia

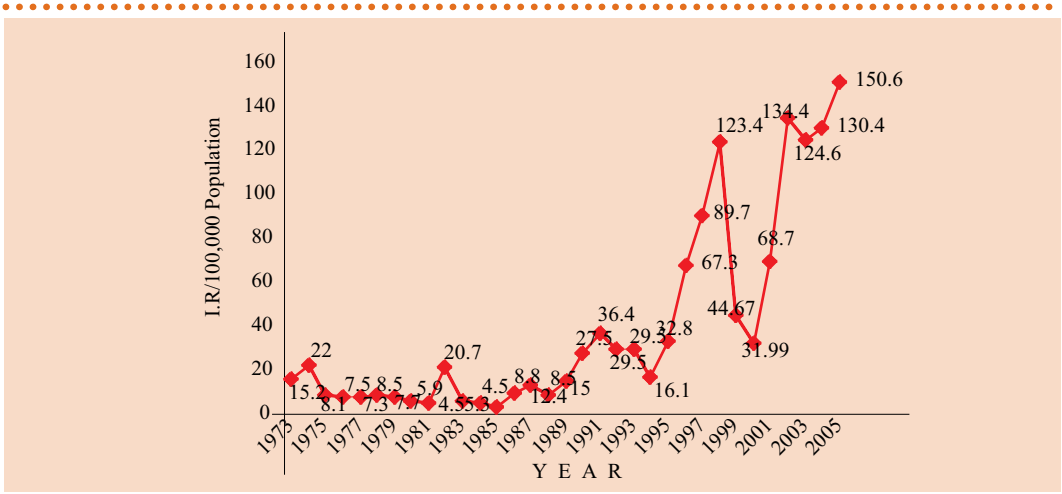
After a decrease for two consecutive years, the incidence has been on the increasing trend again. The year 2005 recorded the highest incidence in the country, with an incidence of 150.6 per 100,000 population.

Selangor and FT Kuala Lumpur the most affected states

A total of 38,996 dengue cases were reported in 2005, compared to 33,895 cases in 2004. Ninety-five percent of the cases in 2005 were dengue fever with 108 deaths compared to 102 deaths in 2004.

The incidence of dengue is highest in Selangor and the Federal Territory

Fig. 1 : Incidence of Dengue in Malaysia, 1973- 2005



of Kuala Lumpur, two of the most urbanized and densely populated states in the country. These two states constitute 45% to 48% of the total dengue cases in the country. In 2005, 12,729 of dengue were reported in Selangor compared to 9,189 cases in 2004 (an increase of 38.5%) while the corresponding figure for FT Kuala Lumpur were 5,515 and 6,288 cases respectively (an increase of 14%). Outbreak was also reported on the Penang island in October 2005 where a total of 3,460 cases were reported in 2005 compared to 1,761 cases in 2004 (an increase of 49.1%).

Aetiology

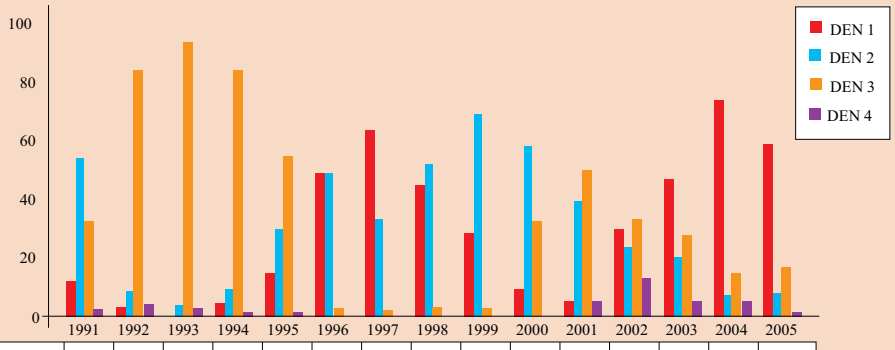
Dengue serotypes

Dengue Fever (DF) and Dengue Haemorrhagic Fever (DHF) are caused by the dengue virus of the Arbovirus family. There are four viral serotypes, namely DEN 1, DEN 2, DEN 3 and DEN 4. Infection with one serotype provides lifelong immunity to that particular serotype but confers only transient and partial protection against infections by the other serotypes. Hence, the exposed population can have more than one dengue infection during their lifetime. There is evidence that sequential infection with dengue increases the risk of more serious disease resulting in dengue haemorrhagic fever[4].

Dengue serotype trend

Sero-surveillance of the dengue serotypes indicates that DEN 1 as the predominant serotype in the last two years (2004, 2005) with 73.4% and 58.6% respectively of the total.The last predominant DEN 1 infection was in 1997 where it made up 63.5% of the infections monitored **(Fig.2).**

Fig. 2 : Dengue Serotype Surveillance in Malaysia, 1991-2005



	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
DEN 1	11.9	3.7	0	4.8	14.7	48.7	63.5	44.4	28.2	9.3	5.4	29.8	46.9	73.4	58.6
DEN 2	54.2	8.6	4.1	9.5	29.5	48.7	33.4	51.9	69.2	58.1	39.2	23.8	20.6	7.4	8.4
DEN 3	32.5	83.7	93.1	84.1	54.6	2.6	2.1	3.7	2.7	32.6	50	33.3	27.8	14.6	17.1
DEN 4	1.4	4	2.8	1.6	1.2	0	0	0	0	0	5.4	13.1	4.7	4.6	1.2

Transmission of dengue fever

Mosquito vector

Human reservoir

The disease is transmitted by a vector; the Aedes mosquito of which two species, *Aedes aegypti* is the principal vector while *Aedes albopictus* has also become increasingly involved in the transmission of the disease. Humans are the main amplifying host of the dengue virus, although studies have shown that in some parts of the world monkeys may become infected and perhaps serve as possible reservoirs. There is no environmental reservoir for this organism.

Breeding places

In Malaysia, *Aedes aegypti* breeds primarily in man-made containers like earthenware jars, metal drums and concrete cisterns used for domestic water storage, as well as discarded plastic food containers, used automobile tyres and other items that collect rainwater. It also breeds extensively in natural habitats such as tree holes and leaf axils.

Infected mosquitoes

The dengue virus is transmitted to humans through the bites of infective female *Aedes* mosquitoes, a day biting mosquito. The *Aedes* mosquito acquire the virus from feeding on the blood of an infected person. The virus eventually enters the salivary gland and multiples there. Thereafter, the mosquito becomes infective and continues to harbour the virus for the rest of its life.

Transovarial transmission

Infected female mosquitoes may also transmit the virus to their offspring by trans-ovarial (via the eggs) transmission, but the role of this in sustaining transmission of virus to humans has not yet been clearly established[5].

Clinical features

Spectrum of clinical illness

The incubation period of dengue ranges from 2 to 10 days, but generally, it is between 5 to 7 days. Dengue has a wide spectrum of clinical illness ranging from asymptomatic, to mild sub-clinical infection, to dengue fever with classical symptoms and the more serious potentially fatal dengue haemorrhagic fever. Undifferentiated fever may be the most common manifestation of dengue.

Dengue Haemorrhagic Disease

Dengue Fever (DF) generally is a self-limiting disease and seldom cause death. The clinical features of dengue fever vary depending on various factors. Infants and young children may have a non-specific febrile illness with rash. Older children and adults may have either a mild febrile syndrome or the classical dengue fever with abrupt onset and high fever, severe headache, pain behind the eyes, muscle and joint pains, gastrointestinal symptoms, and rash.

Dengue Shock Syndrome

Dengue Haemorrhagic Fever (DHF) is a potentially fatal entity that is characterized by high fever, haemorrhagic phenomena ranging from just bleeding under the skin (petechial rash) to bleeding into vital organs and in severe cases, circulatory failure. The illness commonly begins with a sudden rise in temperature accompanied by facial flush and other non-specific constitutional symptoms of dengue fever. The fever usually continues for two to seven days and can be as high as 40-41°C, possibly with febrile convulsions and haemorrhagic phenomena.

In severe cases, the patient's condition may suddenly deteriorate after a few days of fever. The temperature drops, followed by signs of circulatory collapse. The patient may rapidly go into a critical state of shock and die within 12-24 hours, or quickly recover following appropriate volume replacement therapy.

Diagnosis

Diagnosis by various methods

For the purpose of instituting immediate prevention and control measures, notification of dengue infection is made based on clinical presentation supported by presence of thrombocytopenia and evidence of haemoconcentration.[5] Confirmatory diagnosis requires further laboratory investigations which include :

- Dengue serology – IgG or IgM antibody titres to one or more serotype virus
- Detection of dengue virus genomic sequences in serum, autopsy tissue or cerebrospinal fluid samples by polymerase chain reaction (PCR).
- Isolation of the dengue virus from serum or autopsy samples;
- Demonstration of dengue virus antigen in autopsy tissue, serum or cerebrospinal fluids samples by immuno-histochemistry, immunofluorescence or ELISA.

Factors influencing dengue outbreaks

Climatic factor

Climatic factors play an important role in the seasonal upsurge of dengue disease. Dengue cases increase during the rainy season, especially if the rainy days are interspersed with hot sunny days, which is the ideal climate for *Aedes* breeding.

Urbanization

Malaysia has undergone rapid socioeconomic development over the last 2 decades. This has resulted in major rural-urban migration and rapid population growth in the urban areas. Rapid physical development, created many man-made environment which facilitate the breeding of *Aedes* mosquitoes. High population density in an area with high index of *Aedes* breeding increase the chance of contact between mosquito and man, and hence the risk of dengue outbreaks in such areas.

Population movement

Population movement

Population movements play a major role in the spread of dengue infections. Persons with sub-clinical infections may carry the virus from one place to another, and cause an outbreak in another locality if the vector is present.

With a high number of people seeking employment in the urban areas, holiday and festive seasons see massive movements of these people back to their home towns and villages. The much improved road network system in the country also facilitate movements of people on all occasions throughout the country. Recent outbreaks of dengue cases in FELDA (Federal Land Development Authority) land schemes in Pahang was attributed to the return of workers and students from the urban areas to their homes in the FELDA schemes during the holiday season.

Vector movement

The vector too, may be transported from one locality to the next through the transport system and poses a threat to new virgin localities, especially if they are infected mosquitoes.

Changing Serotype

Changing serotype

Dengue outbreaks generally tend in a cyclic fashion depending on the type of circulating virus. Infection with one serotype provides lifelong immunity to that particular serotype but confers only transient and partial protection against infections by the other serotypes[4].

When a new serotype appears in a community, outbreaks occur due to absence of low herd community. Infection by this serotype would abate after sometime as the herd immunity increase, until the appearance of another circulating serotype[7,8].

Current circulating serotype

The greatly increased number of dengue cases in 2004 and 2005 was attributed to the changing circulating serotype where the DEN1 serotype virus became the dominant type after the last appearance in 1997[3]. Rapid movement of population and population growth resulted in a new population composition with low herd immunity and hence its vulnerability.

Prevention and control of dengue fever

The National Dengue Control Programme encompass a broad approach with a combination of various strategies as follows :

- Disease surveillance through notification of all suspected cases of dengue from hospitals and outpatient clinics. In urban areas, this is channelled through the local authorities to the District and State Health Departments.
- Vector surveillance from Aedes survey conducted regularly and during case investigations. This is also a weekly report submitted by the district health departments and local health authorities.
- Laboratory surveillance of circulating dengue serotypes to the Institute for Medical Research, National Public Health Laboratory in Sungai Buloh and University Malaya Medical Centre.
- Vector control through source reduction of adult mosquitoes and mosquito larva by chemical and biological means, as well as environment management of rubbish disposal and public education.
- Management of dengue cases in hospitals and clinics to prevent deaths
- Law enforcement, which is provided under the Prevention and Control of Infectious Diseases Act 1988 and Destruction of Dangerous Disease Bearing Insect Act 1975 (Amendment 2000).
- Public Education in general and on targeted populations on preventive measures and early identification of illness. This is carried out through the mass media, exhibitions, health talks and distribution of health information materials.
- Community involvement through community participation on public education and environment cleaning campaigns.
- Research to better understand the bionomics of Aedes mosquitoes and dengue transmission pattern for better management of dengue outbreaks

In recent years, the Ministry of Health has come up with new approaches and strategies to combat Dengue. These include the following activities:

Newer approaches

a) COMBI (Communication for Behavioural Impact approach to inculcate positive behaviour change, centred mainly on reduction of Aedes mosquito breeding. The activity was first started in Johor Bahru in 2001 and since then, it has been extended to all States in the country. COMBI utilizes a combination of behavioural science approach and community participation from volunteers who are mainly the youths, though not necessarily limited to them, to inculcate positive behaviour changes such as regular inspection of premises to get rid of Aedes mosquito breeding places.

COMBI approach

b) COMFOG (Community Fogging) – empowering the community to control Aedes breeding through community fogging activity, with supervision from the Health Personnel.

COMFOG approach

c) Using Ovitrap as surveillance tool to monitor the adult mosquito density in a particular area to predict outbreaks. The results of monitoring can also be used to determine whether a preventive fogging is needed in the area.

Ovitrap

d) Establishing Dengue Management Team in the districts to come up with more effective ways in doing prevention and control activities, and dengue management teams in hospitals to better manage dengue patients during major outbreaks.

Dengue Management Team

e) Using biological control *(Bacillus thuringiensis israelensis)* as larvicidal agent to control Aedes breeding in less accessible places.

Biological control

f) Strengthening the enforcement activities especially in places such as construction sites, vacant lands / lots, abandoned projects and factories.

Law Enforcement

g) Using IEC Concept (Information, Education and Communication) to educate the community and updating their knowledge on Dengue and its prevention.

IEC approach

Conclusion

Control of dengue is a shared responsibility

Dengue infection is set to increase further with increasing urbanisation and population growth in such urban areas. Dengue is preventable but requires concerted efforts from all relevant parties – the health departments, local authorities, and most important of all, the community themselves. The community must take responsibility of their environment - get rid of Aedes mosquito breeding places in their premises and the surroundings.

Continual improvements needed

The health department and local authrorities, on the other hand, have to continue to strengthen all preventive and control strategies to ensure they are being carried out effectively. Research and continual search for better and more effective strategies would ensure this major public

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PREVENTION AND CONTROL OF ZOONOTIC DISEASES

SUMMARY

Many microbial pathogens and infectious diseases occurring primarily in wild and domesticated animals may be transmitted to humans and is known as zoonoses. Even though these occurrences are known to date back for centuries, it has increasingly become important as 75% of newly emerging diseases are zoonoses. These diseases cause negative impact on animal and human health and may affect commerce, travel, socio-economy and even pose as a security threat to a country. They must thus be prevented and controlled. The prevention and control of zoonotic diseases require cooperation and collaboration between multi-disciplinary experts and multi-agencies. The Nipah virus outbreak in Malaysia in September 1998 to May 1999 has proven that cooperation and collaboration are key factors in ensuring successful prevention and control of a zoonotic disease outbreak.

Introduction

Definition of zoonotic diseases

Animals are a vital source of food, provide a means of transport, generate income through animal farming and also contribute as a means of physical labour. In addition, domesticated animals are also kept as pets. However animals also harbour microbial pathogens including parasites. These pathological agents may be transmitted from animals to cause disease in man. Infectious diseases occurring primarily in animals can be transmitted to man and is known as zoonoses.

Transmission

The World Health Organisation defines zoonoses as "…those diseases and infections that are naturally transmitted between vertebrate animals and man, with or without an arthropod intermediate." Infectious diseases can be transmitted from animal to man directly; or indirectly through contact with faeces, urine, saliva blood or milk of infected animals.

First zoonotic agents described

Zoonotic diseases are known to date back for many centuries. In early times, it was recognised that ringworm in human was associated with close contacts with cats and dogs. Other examples include the

observation that glanders in horses and encephalitis in dogs may be associated with similar disease in human. Among disease agents that have been recognised early to cause zoonosis are as follows; cestodes (1800), nematodes (1800s), ringworm, (1840s), trematodes (1870s), tick-borne relapsing fever (1873) and *bacillus anthracis* (1877). Since its first description, many other agents have been identified, some of which were responsible for epidemics in human history.

Impact of zoonotic diseases

The significance of zoonotic diseases is growing continuously, with increasing commercialisation of animal trade and industry. The impact of these diseases on animal and human health and socio-economy are increasingly being felt by many countries especially developing countries. Apart from causing human morbidity and mortality, zoonotic diseases hamper agricultural production, decrease availability of food and create barriers to international trade.

Emerging zoonotic diseases

Currently, it is estimated that there are 1,415 microbes which can infect human. Of these, 868 (61%) are considered to be zoonotic. Zoonotic pathogens are twice as likely to be associated with emerging diseases. Emerging infections are defined as infection newly appeared in a population or have existed but rapidly increasing in incidence.

Occurrence of emerging zoonoses

Zoonotic diseases are on the increase and since 1973, more than 70% of newly recognized pathogens are zoonoses. Recent examples of emerging zoonotic diseases are as follows; Lyme disease, Ebola viral hemorrhagic fever, Hantaan viral diseases, E. coli 0157:H7, Monkey pox, West Nile virus, Cyclosporiasis, Australian bat Lyssa fever, Hendra virus, Nipah virus and Highly Pathogenic Avian Influenza H5N1 (HPAI H5N1). Most of these emergent zoonotic diseases involved the transmission of the etiologic agent to human from an ongoing reservoir life cycle in animals, without the permanent establishment of new life cycle in humans.

Factors influencing emergence of zoonoses

The factors influencing emergence of zoonotic diseases can be categorised as follows;

a) Ecological changes – deforestation, flood/drought, famine, climate changes;
b) Human demographic behaviour – migration, war / civil conflict, sexual behaviour and changing animal husbandry practices.

c) International travel and commerce – increasing worldwide movement of goods and air travel.
d) Technology and industry – changing techniques in food processing, organ transplantation, inappropriate use of drugs causing immuno-suppression and indiscriminate use of antibiotics.
e) Microbial adaptation and changes – mutation, natural selection and evolution.
f) Breakdown in public health measures – reduction of prevention programmes, inadequate sanitation, and inadequate vector control measures.

Recent zoonotic outbreaks in Asia and Malaysia

Two well known recent zoonotic outbreaks that occurred in Asia and Malaysia are the Highly Pathogenic Avian Influenza (HPAI) and Nipah encephalitis, due to influenza virus H5N1 infection and Nipah virus respectively.

Avian Influenza (AI)

Avian influenza H5N1 outbreaks in human

Avian influenza is a viral disease of wild and domestic bird that occasionally affects other animal species especially pigs. Human infection due to avian influenza is rare. The first documented human outbreak of avian influenza H5N1, occurred in Hong Kong in 1997. The source of infection in all cases was traced to contact with diseased birds in farms and in live poultry markets.

Avian influenza H5N1 outbreaks among birds in Asia

Currently, avian influenza H5N1 outbreaks occur in Asia. These outbreaks began in late 2003. Since December 2003, nine countries in Asia (Republic of Korea, Japan, and People's Republic of China, Vietnam, Thailand, Lao PDR, Cambodia, Indonesia and Malaysia) have confirmed outbreaks of avian influenza among birds / poultry caused by the influenza virus H5N1 strain. More than 100 millions birds have either died from the disease or have been culled in order to prevent its further spread.

Avian influenza H5N1 in humans in Asia

During these current outbreaks, humans also have been infected with avian influenza H5N1. Since January 2004 till November 2005, a total of 132 confirmed human avian influenza H5N1 cases with 68 deaths have been reported to the World Health Organisation (WHO). These cases occurred in Vietnam, Thailand, Cambodia, Indonesia and China. Most cases have direct contact with diseased birds. Human-to-human transmission, is rare .

Nipah virus encephalitis

Emergence of Nipah virus

Nipah virus was first discovered in Malaysia by a local researcher in 1999 and confirmed by CDC, Atlanta. Nipah virus caused disease in pigs and encephalitis in humans. Scientific evidence showed that certain species of fruit bats are the natural animal reservoir for Nipah virus.

Nipah encephalitis outbreak

From September 1998-December 1999, Nipah virus was identified as the cause of an encephalitis outbreak in states of Perak, Negeri Sembilan and Selangor. A total of 232 persons were laboratory confirmed to be infected with this virus with 91 deaths. Most of the victims were pig farmers or their family members or farms workers that were in direct contact with infected pigs.

Impact due to zoonotic diseases

Zoonotic diseases cause negative impact on human and animal health and may disrupt commerce, travel, socio-economic stability and even pose as a security threat.

Economic loss

In the Nipah virus encephalitis outbreak in Malaysia in 1999, case fatality rate was high at 39.2%. The cases were highest among the productive aged group who were bread winners in the family. During the outbreak, 1.1 million pigs were culled and the calculated monetary value of these pigs was estimated to be RM 221.5 million. The government paid out RM 133 million compensations to the affected pigs farmers while the farmers' total financial loss was estimated to be RM 471.2 million.

Zoonotic diseases have a negative impact on the socio-economy of animal farmers and their families. As an example, the current avian influenza outbreak leads to a stand-still in poultry production and income loss. Poultry in farms around infected areas had to be culled. Hard hit were small poultry farmers. Farmers are not the only people that will lose financially, but other economic sectors and industries are similarly affected. The Asian Development Bank estimated that the impact of Severe Acute Respiratory Syndrome (SARS) epidemic that occurred in 2003 which involved 26 countries in all continents cost losses of about USD 18 billion in terms of GDP or USD 59 billion in terms of business losses.

Potential threat as bioterrorism agents

Zoonotic disease pathogens are often mentioned in context of bioterrorism and biological warfare. Among pathogens implicated are anthrax, brucellosis, viral equine encephalitis, ebola/marburg, meliodosis, glanders, plague, psittacosis and tularemia. In this context, zoonotic diseases can pose as a security threat to any country.

Major health problem

Zoonotic disease outbreaks may lead to other major health problems. Avian influenza outbreaks currently occurring in Asia may lead to pandemic influenza if the influenza virus mutated with characteristics that facilitate transmissibility from human-to-human. If this happens, millions of people worldwide will be threatened.

The prevention and control of zoonotic diseases

Discovery-to-control continuum concept

Strategies for the prevention and control of zoonotic diseases are base on the principle of discovery-to-control continuum concept. Elements of a discovery-to-control continuum of zoonotic diseases especially emerging zoonoses are as follows,

a) Discovery (recognition of zoonotic disease);
b) Epidemiologic field investigation;
c) Etiologic investigation;
d) Diagnostic development;
e) Focused research
f) Technology transfer;
g) Training of staff for control, elimination and eradication.

Recognition of the disease

The disease must be recognised early in the initial phase of the discovery-to-control continuum. Local clinicians, pathologist (including medical examiners and forensic pathologist), veterinarians and animal scientists, ecologist, wildlife scientists, as well as public health officials should be trained to recognize zoonotic diseases early. Currently, many of the zoonotic diseases are under-diagnosed, as the diseases are not recognised. Initial investigation of zoonotic diseases (especially newly emerging diseases) must focus on morbidity rate, death rate, severity of disease, transmissibility, all of which are important factors or predictors of epidemic potential and societal risk.

Diagnostic laboratory support

Primary diagnostic laboratories and the reference laboratory networks play an important role in identifying and diagnosing agents of zoonotic diseases. In this era, high technology molecular microbiology and virology are used to characterise the pathogens to complement epidemiologic field investigation in identifying source of outbreak

and risk factors associated with the outbreak with precision so that appropriate public health intervention could be undertaken.

Discovery-to-control continuum – intermediate phase elements

In the intermediate phase in the discovery-to-control continuum, the continuum progresses to risk management. This phase may include elements as follow;

a) Technology transfer – involving diagnostic development;
b) Drug and vaccine development;
c) Sanitation and vector control;
d) Medical and veterinary care activities;
e) Training and continuing education;
f) Public education

Elements of final phases in discovery-to-control continuum

In the final phases of discovery-to-control continuum, public health delivery systems play an important role. The elements of this phase will lead to control, elimination and eradication of zoonotic diseases. However, the elements of this final phase are more expensive and require specialized expertise and resources. The elements of final phase are as follows;

a) Rapid case reporting system;
b) Surveillance system;
c) Disease register and vital records;
d) Staffing and staff support;
e) Logistic support;
f) Legislation and regulation;
g) Special clinical systems – including isolation of cases, quarantine, patient care;
h) Public infrastructure systems – including sanitation, sewerage, safe food and water supplies; and
i) Reservoir host and vector control

Multi-disciplinary expertise cooperation

Based on the discovery-to-control continuum concept, the control of zoonotic diseases need cooperation and collaboration between multi-disciplinary expertise comprising of clinicians, public health physicians, public health officials, pathologists, veterinarians, animal scientists, ecologist, wildlife scientist, ecologists, researchers, public educators, communication experts, sanitation technicians, administrators, politicians and the members of the community.

Multi-agencies cooperation and

Other than cooperation and collaboration between multi-disciplinary expertises, the prevention and control of zoonotic diseases need

cooperation and collaboration between multi agencies either government or non-government agencies at local, national, regional and international level. These include agencies involved with services in public health, veterinary, laboratory, education and law and enforcement.

collaboration

Managing zoonotic disease outbreaks – Malaysia's experience

Over a period from September 1998 to May 1999, clusters of viral encephalitis cases occurred in four localities in three states. A total of 265 cases of viral encephalitis with 105 deaths due to this outbreak were reported to Ministry of Health, Malaysia. Most of the cases were adult pig farmers.

Viral encephalitis outbreak – September 1998 to May 1999.

In the outbreak, culling of pigs was proven to be effective in controlling the spread of the disease. Culling was carried in two phases and a total of one million pigs were culled. Veterinary Services Department, army, local authorities and non-government organizations were involved in the culling operation. Farmers were compensated for the pigs culled. Law enforcement agencies such as Malaysian Royal Police Force were involved to ensure that no pigs were transported out from affected areas.

Pig culling operation

Special protocols and guidelines were issued. These include: managements of suspected cases of viral encephalitis; autopsy examination for Nipah infection; transport and disposal of dead bodies due to Nipah infection; safety equipment for occupational exposure to Nipah virus; and barrier prophylaxis for people exposed to Nipah virus. All patients suspected of having Nipah virus were placed in special isolation wards with close monitoring by special teams consisting of medical specialists, medical officers, physiotherapist, occupational therapist, counsellors and others.

Nipah virus encephalitis case management

Intensive health education for targeted groups (farm employers, farm employees) was carried out through mass media and schools. Posters, pamphlets and other health education materials in various languages were produced and distributed. Health education materials for special groups such as farm workers, abattoir workers and those involved in the trading and transport of pigs were also produced and distributed. Advice was given on the need to wear personal protective equipments (gloves, masks, goggles, boots and long sleeved shirts, apron). Personal hygiene, especially hand washing with hand washing was emphasised. .

Health education

Surveillance system

Rapid case reporting system, enhanced surveillance of viral encephalitis cases and disease register were established and continued to this day.

Organisational response

Organisational responses are an important component in the management of disease outbreak. During the Nipah encephalitis outbreak, several committees were established to coordinate control measures. These include: an Inter-Ministerial Committee for Control of Zoonotic Diseases chaired by the Deputy Prime Minister himself; a Technical Committee on the Control of Zoonotic Diseases; State Outbreak Committee and District Outbreak Committee. Members of these committees were from government and non-government agencies.

Experts assistance

As the Nipah virus was a newly recognised virus, Malaysia sought assistance from WHO for experts to assist in the control and investigations of the outbreak. Twelve experts from CDC Atlanta, two from Commonwealth Scientific, Geelong and Industrial Research Organisation (CSIRO), and one from Animal Research Institute, Queensland arrived to provide expert assistance.

Key factors for successful prevention and control

Based on experiences mentioned above, most of the elements of discovery-to-control continuum were implemented. There has been no repeat Nipah virus outbreak till now. . The cooperation and collaboration of multi-disciplinary experts and between multi agencies at local, national and international are key success factors in the control and prevention of Nipah virus outbreak in the country.

Avian influenza outbreaks in Kelantan

Based on the experiences of the from the Nipah virus outbreak, similar strategies and activities were also adopted in the control of the last Avian Influenza outbreak in Kelantan in August 2004 which were limited to poultry. No human case was detected.

Conclusion

Zoonotic diseases or zoonoses are on the increase globally and locally. The successful prevention and control of zoonotic disease requires close cooperation and collaboration from multi-disciplinary experts and between multi agencies, both government and non-government sectors.

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NATIONAL INFLUENZA PANDEMIC PREPAREDNESS PLAN (NIPPP)

SUMMARY

The National Influenza Pandemic Preparedness Plan (NIPPP) provides guidance for the preparedness and response needed in facing the threat of an influenza pandemic. It contains specific advices and actions to be taken by the Ministry of Health at different levels; spells out roles of various governmental departments and agencies as well as non-governmental organisations to ensure resources are mobilised efficiently before, during and after an influenza pandemic episode to reduce morbidity and mortality in human. The document is also an advocacy tool,providing policy and strategic framework for a multi-sectoral response, encouraging greater political commitment and promotes public reassurance that the Ministry of Health is fully dedicated and committed to protecting the Malaysian population from the threat of avian influenza in the country.

Introduction

Influenza pandemic threat

Over the last two years (2004-2005), outbreaks of the highly pathogenic H5N1 avian influenza in poultry were reported in some countries in Asia while isolated cases were also reported in several countries in Europe. Occurrence of human cases and the extremely high fatality rate among those infected gave rise to concern on an impending avian influenza pandemic that would have devastating consequences, both socially and economically.

Three pandemics had been recorded in the 20th century – the Spanish Flu (1918 –1919), Asian Flu (1957–1958) and Hong Kong Flu (1968–1969) which were caused by influenza virus originated from the avian influenza virus. The pandemics resulted in millions of lives lost. There is fear that the next global pandemic of a very virulent novel influenza virus may reach our shores faster than we anticipate with globalization, rapid human and animal traffic in the age of modern transport system. Hence, there is a need for extra vigilance, less we are caught unprepared if it happens.

Influenza virus

Influenza virus

There are three main types of influenza viruses; viz. A, B and C. Influenza C causes only mild disease and has not been associated with widespread outbreaks. Influenza A viruses carry 15 antigenic subtypes of haemaglutinin (HA) and nine antigenic subtypes of neuraminidase (NA). They have been found in wild aquatic birds and poultry with the current strains of H5, H7 and H9. Influenza viruses of the H1N1, H2N2 and H3N2 subtypes have been associated with widespread epidemics in human. Influenza B viruses are not divided into subtypes.

Antigenic drift

Influenza viruses have an ability to slightly change their structure from time to time. The process known as "antigenic drift" occurs frequently over time. It results in the appearance of different strains of circulating virus each year. The severity of the seasonal epidemic in any locality may be related to a drift in the previously circulating virus.

Antigenic shift

The viruses could also change dramatically and unexpectedly through a process known as "antigenic shift" by acquiring a new H or H+N surface proteins. This shift results in the appearance of a new or "novel" influenza virus that has never previously infected human or has not infected humans for a long time, for which the general population is unlikely to have any immunity or antibodies to protect themselves against the novel virus. The appearance of a novel virus is the first step towards a pandemic.

Signs and symptoms

Typical primary influenza illness lasts about a week and is characterized by abrupt onset of fever, muscle aches, sore throat, and nonproductive cough. In some persons, severe malaise and cough can persist for several days or weeks. Influenza infection not only causes primary illness but can also lead to severe secondary medical complications such as influenza viral pneumonia and secondary bacterial pneumonia or worsening of underlying medical conditions such as congestive heart failure, asthma, or result in other complications such as otitis media in children, and death from the illness itself.

The pandemic threat

A pandemic is a global disease outbreak. A pandemic influenza occurs when a new influenza virus emerges. It will cause serious illness and spread easily as there is little or no immunity in the human population. The recent outbreaks of avian influenza among poultry due to influenza virus H5N1 in Asia since the end of December 2003

has caused a lot of uneasiness among countries in the world. WHO postulated that prolonged outbreaks of avian influenza in poultry and human could trigger an influenza pandemic as influenza virus can mutate easily.

National Influenza Pandemic Preparedness Plan (NIPPP)

The Ministry of Health has taken the lead in developing a workable preparedness plan for influenza pandemic called the *National Influenza Pandemic Preparedness Plan (NIPPP)*. It is to facilitate an organised, coordinated and effective national preparedness and response in the event of an influenza pandemic.

Roles and responsibilities of different agencies

The plan provides a framework for preparedness and response, with specific advice and actions to be undertaken by the Ministry of Health at different levels. It also spells out roles of various governmental departments and agencies, as well as non-governmental organizations. All these are to effect rapid, timely and coordinated inter-sectoral and inter-agency actions to minimise morbidity and mortality of the illness, as well as social and economic disruption.

Organisational response in NIPPP

In dealing with the influenza pandemic, an organizational response is very critical - to provide policy direction, coordination and implementation of an action plan. Under the NIPPP, 3 committees have been established. They are :

1. *National Inter-ministerial Influenza Pandemic Committee (NIIPC)*

This committee will provide policy, direction and coordination of ministries, government departments and the relevant non-governmental agencies for controlling pandemic in the country. The Chairman of this committee is Minister of Health. The members are Secretary General and Director General from multi ministries and departments.

2. *National Influenza Pandemic Planning Committee (NIPPC)*

This is the technical and advisory committee for the Ministry of Health and Inter-ministerial Influenza Pandemic Committee. It will oversee the development and implementation of the outlined plan. The Chairman of this committee is the Director General of Health and the members are multi-disciplinary experts from Ministry of Health and other agencies.

3. *Influenza Pandemic Committee (NIPC)*

This committee is established at the national, state and district levels to ensure that the influenza pandemic plan is put into action. The committee will be activated when an influenza pandemic is declared by Ministry of Health.

The strategies and activities to be implemented in the preparedness plan encompass 4 areas of response, namely - public health response; medical response; laboratory response; and risk communication response. The extent or degree of response are based on the level of influenza pandemic alert. The **alert levels** are as follows :

Phase 1	**Interpandemic Period** No new Influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection may be present in animals. If present in animals, the risk of human infection or disease is considered to be low
Phase 2	No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease
Phase 3	**Pandemic Alert period** Human infection(s) with a new subtype, but no human to human spread, or at most rare instances of spread to a close contact
Phase 4	Small cluster(s) with limited human to human transmission but spread is highly localised, suggesting that the virus is not well adapted to humans.
Phase 5	Larger cluster(s) but human to human spread still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).
Phase 6	**Pandemic period** Pandemic phase: increased and sustained transmission in general population.

Preparing for pandemic influenza

Pre-pandemic period

Preparations made during the inter-pandemic period are very important in reducing morbidity and mortality associated with an influenza pandemic if it comes. Several steps have been taken by the Ministry of Health as preparation for the pandemic as follows :

Surveillance of influenza-like illness (ILI)

1. surveillance of influenza-like illness (ILI), a proxy of influenza infection. It is carried out by weekly reports from sentinel clinics throughout the country, chosen based on certain criteria set. The influenza virus surveillance is carried out by selected government and universities virology laboratories. Rumours surveillance for any unusual events related to respiratory systems including atypical pneumonia and acute respiratory syndrome are also implemented to increase the sensitivity of the surveillance system. The systems established are as an early warning for any influenza epidemic and pandemic.

Stockpiling of Oseltamivir

2. stockpiling of antiviral drugs *Oseltamivir* (Tamiflu). The World Health Organisation advised a stockpile of 25 % of the population. Malaysia has decided on a 10 % stockpile, with incremental increase each year. It is to be noted that the shelf life of *Oseltamivir* is only 4 years, and any overstocking would result in wastage as the expired drugs will have to be disposed of.

Vaccination of front-line health-care workers

3. vaccination for selected front-line healthcare workers (HCWs) and staff of the essential services such as the police, fire service, transportation service and others. Even though the normal two-seasons influenza vaccines does not have a protective effect to pandemic influenza, the vaccination policy will provide a logistic mechanism in our country and also to the vaccine supplier if pandemic were to occur.

Stockpiling of PPE

4. stockpiling of the personal protective equipments (PPE) for HCWs. When a pandemic occurs, there will be increased PPE usage and there will be shortage of supply in the market, coupled with a price increase.

Upgrading of isolation facilities in hospitals

5. upgrading of isolation facilities in hospitals. Even though the role of treating cases in hospitals during a massive pandemic is debatable, isolating influenza cases in the early phase of the pandemic is important to curb the spread of the virus.

6. risk communication to the public via the various channels available in the countries. The multilingual and multicultural factors are taken into consideration.

Risk communication

7. training of health staff in all disciplines, to reduce panic, to get their commitment and to ensure continuity of services in all departments.

Training

8. research on influenza.

To implement all these preparedness need a support and commitment from all agencies. A Cabinet Memorandum was presented in November 2005 and approved upon.

Activities during pandemic

Enhanced response

When a pandemic influenza occurs, disease and viral surveillance will be enhanced and the medical response will be activated. Public health response will be initiated at places including ports of entry to prevent the spread of disease. This might include closure of public functions and gatherings, and closure of schools. Risk communication will be intensified through media and hotlines.

NIPC alerted

The National Security Council will be alerted by the National Inter-ministerial Influenza Pandemic Committee (NIIPC) through the Cabinet when the pandemic reaches a proportion outside the capability and capacity of existing mechanism to handle pandemic.

Pandemic plan activated

This is expected to occur in phase 3 onward when the situation is considered a threat to the country's security. The Council will then be responsible for coordinating the overall incident management, as well as non-medical support and response actions across all federal departments and agencies at all levels. The Ministry of Health will continue to play the lead agency role for public health and medical emergency responses of the influenza pandemic.

Simulation exercise

Testing the plan

Even though all strategies and activities for the prevention and control of the influenza pandemic are well laid out in the NIPPP, it may not work as planned. A simulation exercise will be carried out to ensure the action plan works, and all weaknesses identified and rectified accordingly.

Regional and international cooperation

Inter-agency collaboration

Co-operation and collaboration between agencies at various levels are very important to ensure effective measures are taken for preventing and controlling the influenza pandemic. Regional cooperation has been strengthened among the ASEAN countries through the ASEAN + 3 Emerging Infectious Disease (EID) Programme. There is also a cooperation in this area in other regional forum such as APEC and ASEM.

International partnerships in preparing for influenza pandemic consist of capacity building i.e. training of human resources, anti-viral stockpiling, upgrading of facilities and sharing laboratory facilities; sharing information on important events and the progress and educating the public. The partnership will ensure that all countries are able to prevent and control the influenza pandemic effectively if it were to occur.

Conclusion

The NIPPP document serves as a resource for influenza pandemic preparedness; and stake-holders engagement and intensification of the pre-existing core capacities to enable a quick response to pre-empt the pandemic. It is aimed at minimising human morbidity and mortality, social disruption and the economic consequences caused by the pandemic. The plan is dynamic and would be continually updated to reflect new knowledge and experiences gained; and advances made by experts in the world. States and districts are required to have their own detail plan of action using this document as guidance; and the plan should be tested on the ground.

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HARM REDUCTION IN THE PREVENTION AND CONTROL OF HIV/AIDS

SUMMARY

Harm Reduction Program should be viewed as a comprehensive community-based package of measures, which include Need Syringe Exchange Programme, to prevent HIV spread as well as to remedy the drug addiction situation among injection drug users. The programme is particularly appropriate for Malaysia as its HIV epidemic is mainly contributed through spread by sharing of contaminated needles while injection drugs. Harm Reduction approach is consistent with the spirit embodied within United Nation's 'Declaration of Commitment on HIV/AIDS which was adopted by United Nation General Assembly Special Session on HIV/AIDS (UNGASS) in 2001

Introduction

Drug use and HIV/AIDS in Malaysia

Sharing of syringes and needles is associated with HIV transmission among injecting drug users (IDUs). It is estimated currently, that there are at least 5.5 million and possibly up to 10 million injecting drug users, across 128 countries globally. Malaysia is one of the many countries whose HIV epidemic has been driven by IDUs.

Injection drug use contributes to the epidemic's spread far beyond the circle of IDVUs. People who have sex with an IDU are also at risk of being infected with HIV, and children born to mothers who contracted HIV through sharing of needles or having sex with an IDU may also become infected. This disturbing trend appears to be continuing. HIV infection is currently occurring at 18 new cases per day in the country.

As of December 2004, out of 64,439 cumulative individual reportedly infected with HIV in the country, 48,369 (75.1%) were injecting drug users. Heterosexual route of infection has increased from 4.8% in 1990 to 19.8% in 2004, while during the same period, HIV infection among women jumped from 1.2% to 10.8%.

Studies conducted in relation to IDUs and HIV infection in Malaysia

Multi-centre drug rehabilitation survey

A study conducted among 1,932 inmates from 26 *Pusat Serenti* (drug rehabilitation centres) in 1998 revealed that; 64.6% of the respondents were IDUs, of whom 77% admitted they injected drugs more than 3 times per day and shared needles with more than 5 others. Of the 1,139 (18%) drug users infected with HIV, 92.4% were IDUs, and 81% shared needles. The risk of being infected with HIV among those sharing needles is 7 times higher than among those who do not share needles. 77.6% of HIV infected drug users were sexually active, while only 18.7% of them used condom

Collaborative study between MOH and UUM

A study conducted by the AIDS/STI Section of the Ministry of Health (MOH) in collaboration with *Universiti Utara Malaysia* (UUM) in 2003, estimated that there were 897,624 drug users in the country, of whom 117,955 were IDUs (13.15%). Knowing that the HIV prevalence among IDUs is about 20%, it is estimated that about 23,600 have already been infected with HIV in 2003. However, only 4,792 IDUs were reported as HIV positive for that year. This indicated that possibly, there were about 18,800 IDUs infected with HIV virus that were not reported or worst, they may not even realised that they had been infected with HIV.

Why Harm Reduction ?

The United Nation Declaration of Commitment on HIV/AIDS

Recognizing that it is the sharing of contaminated needles and unsafe sex behaviour among the IDUs that continuously fuel the spread of HIV in the country, and in response to 'The Declaration of Commitment on HIV/AIDS' adopted by United Nation General Assembly Special Session on HIV/AIDS (UNGASS) in 2001, which specially indicated that by 2005, "a wide range of prevention programs including *Harm Reduction* efforts related to drug use would be made available by all member states". Thus, the plan by Malaysia to introduce *Harm Reduction* as a strategic approach for reversing the HIV epidemic is in accordance with UNGASS recommendation.

What is Harm Reduction?

Concept of harm reduction

Harm Reduction is about making dangerous behaviour less dangerous. It is less dangerous to inject the drug with one's own clean needle as opposed to share needle with others. However, the concept of harm reduction is not just exchanging clean needle and syringe with

a dirty one. While Needle Syringe Exchange Program (SNEP) is an important component of harm reduction activities, it is by no means the only crucial activity. In fact, its major role is more on functioning as a driving force towards a wider range of harm reduction related activities, which include Information, Education and Communication (IEC) on risk-reduction; HIV testing and counselling; Methadone Substitution Therapy (MST); condom promotion; psycho-spiritual support; live-skill counselling/training; and Anti-retroviral treatment (ART). Therefore, *Harm Reduction* Program should be viewed as a comprehensive package of measures that prevent the spread of HIV infection as well as remedy to drug addiction among IDVUs, and thus enhancing the quality of life of injecting drug users.

Needle Exchange Program (NEP)

Goals

The goals are firstly, to help the uninfected IDUs stay that way. Secondly, it is to help infected IDUs stay healthy and thirdly, to help infected IDUs initiate and sustain behaviours that prevent HIV transmission to others.

One-for-one exchange program

The NEP is a community-based 'one-for-one exchange' program, specifically targeted for: the hard-core IDUs who cannot or will not stop injecting drugs, and those who are not accessing to available health services. They are very vulnerable of being infected with HIV as well as at very high risk of infecting others.

Program structure

It is a program that reaches out at the IDUs through outreach points and drop-in centres, which are characterised by peer education run by authorised and trained NGOs. The program is guided by clear operational policies, standard operating procedures, monitoring and evaluation protocol, and security guidelines; This is fundamentally accompanied by communication and bridges the participating drug users to primary health care services, HIV testing and counselling, STD / ART & other AIDS related treatment, Methadone Substitution Therapy, and psycho-social services / support.

The basis of NEP service is to provide an avenue for drug users to exchange dirty needles with clean one. For the programme to succeed, it must have the support and full participation of the local community, especially community leaders, the police, anti-drug agency and health clinics. No single element of NEP activities will be effective if practiced on its own.

Conclusion

The reality is that HIV still continues to attack our youth and; many more remain to be detected with HIV as a result of sharing contaminated needles and engaging in unprotected sex. The Australian government invested Aus$130 million in their Needle Exchange Program during 1991-2000 to prevent 25,000 people from being infected with HIV, and saved Aus$2.4 billion of treatment cost. If no to the Needle Exchange Program, do we have a better alternative?

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SUICIDE PREVENTION IN MALAYSIA

SUMMARY

In recent decades, suicide has emerged as a major public health problem, especially among teenagers and young adults. It has been estimated that there is 30% under-reporting of suicide in developed countries, and in Malaysia the magnitude of under-reporting is substantially higher. It is estimated that more than 2,500 persons commit suicide every year in Malaysia but this is probably an underestimate. Malaysia's annual crude suicide rate from 1990 to 2000 is estimated to range from 10.5 - 13.5 per 100,000 (for Peninsular Malaysia). Statistics on suicidal behaviour show that the number of persons making non-fatal suicide attempts may be at least 15 times higher than the number of suicides. Many of these are serious enough to require medical attention, often resulting in irreversible physical or psychosocial disability. For every person who commits or attempts suicide, about 20 other people are emotionally affected. Some would be affected seriously enough to resort to suicidal behaviour themselves. Suicide prevention remains a challenging and complex task, which requires consistent, sustained and collaborative approaches across all levels of government and the community.

Introduction

Among the wide range of mental health problems, the most tragic is perhaps suicide. It is not only a manifestation of a wilful loss of life, it leaves in its wake feelings of grief, guilt and anger among the people known to the person. Suicidal behaviour, both fatal and non-fatal, can have profound and lasting emotional effects on family, friends and peers.

Suicide and suicidal attempts - a major public health and social issue

The prevalence of non-fatal suicidal behaviour may be up to 15 times higher than fatal suicidal behaviour. From the economic point of view, suicidal behaviour places a considerable drain on the resources of the healthcare system (Schmidtke, 1997). Hence, suicide and suicidal attempts are now increasingly recognised as a major public health and social issue, and suicide prevention has become an important concern in many countries of the world.

Suicide prevention remains a challenging and complex task, which is likely to benefit from a consistent, sustained and collaborative approach

across all levels of government and community. This paper reports on the approach for suicide prevention helmed by the Ministry of Health (MOH) in Malaysia.

Magnitude of the problem

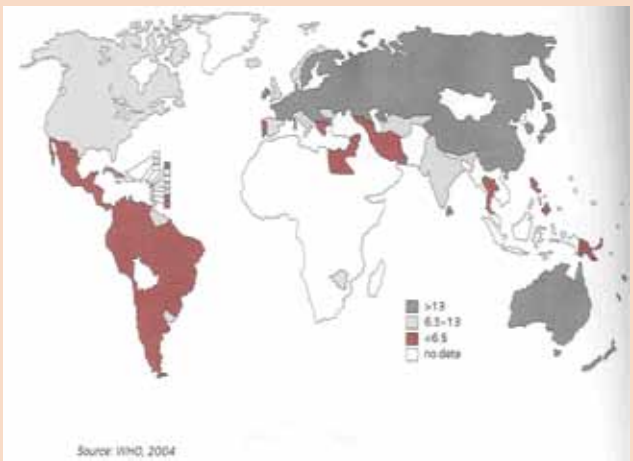
Suicide rates

Suicide is among the 10 leading causes of death for all ages in many countries. In some countries, such as China, Hong Kong and the European Region (Albania, Austria, Bulgaria, Finland, Germany, Spain and United Kingdom), suicide is among the top three causes of death for people aged 15 – 34 years (World Health Report 2001). Currently, suicide is the leading cause of death among young adults for both males and females, and the second leading cause of death among adolescents.

The World Health Organization (WHO) and the International Association for Suicide Prevention estimate that close to 1 million people commit suicide every year, that is, about 1 suicide every 40 seconds.

In 2000, the WHO (WHO 2001) reported a global estimate of mortality due to suicide as 14.5 per 100 000 population. The suicide rate was 24.0 per 100 000 for males and 6.8 per 100 000 for females. Suicide rate of 53 countries reported to WHO shows that the highest suicides rates (more than 13 deaths per 100,000 persons) are in the European Region and Australia. In the Asian region, countries like Japan and Thailand show suicide rate of less than 6.5 deaths per 100,000 population **(Figure 1). Nevertheless, countries like Hong Kong and Korea demonstrate**

Figure 1 : Map of Suicide Rates (per 100,00 persons) from most recent available data (March 2002)

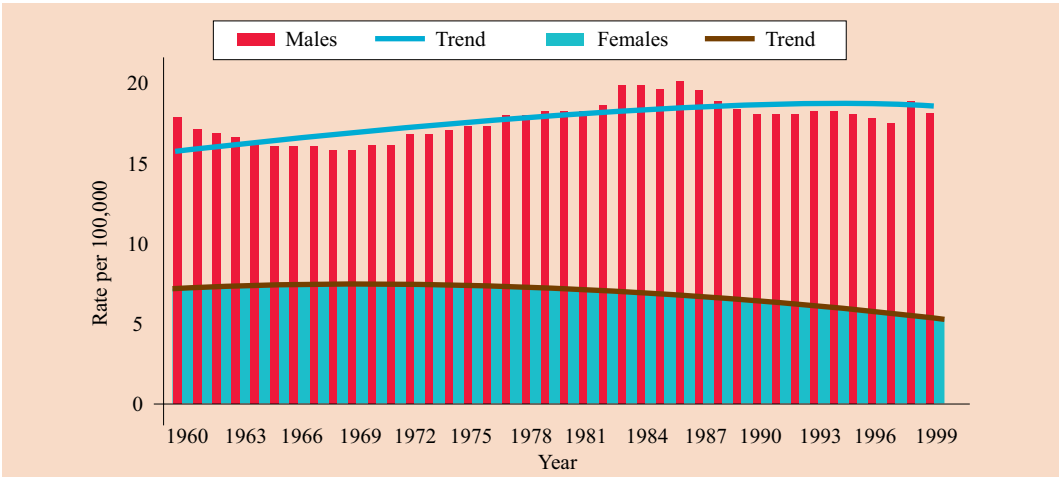


increased suicide rate over the past two decades, of which Hong Kong (9.6 to 16.6 deaths per 100,000 population from 1981 to 2003) was above the global estimate, while Korea showed an increase in 6% from year 1983 to 2003.

Rising male suicide rates

At the global level, suicide mortality for males has increased by 7% over the last four decades with rates at their highest point during the 1980's while in females, there has been a 27% decline in rates since the 1960's **(Figure 2).**

Figure 2 : Global Suicide Trends, 1960 – 1999

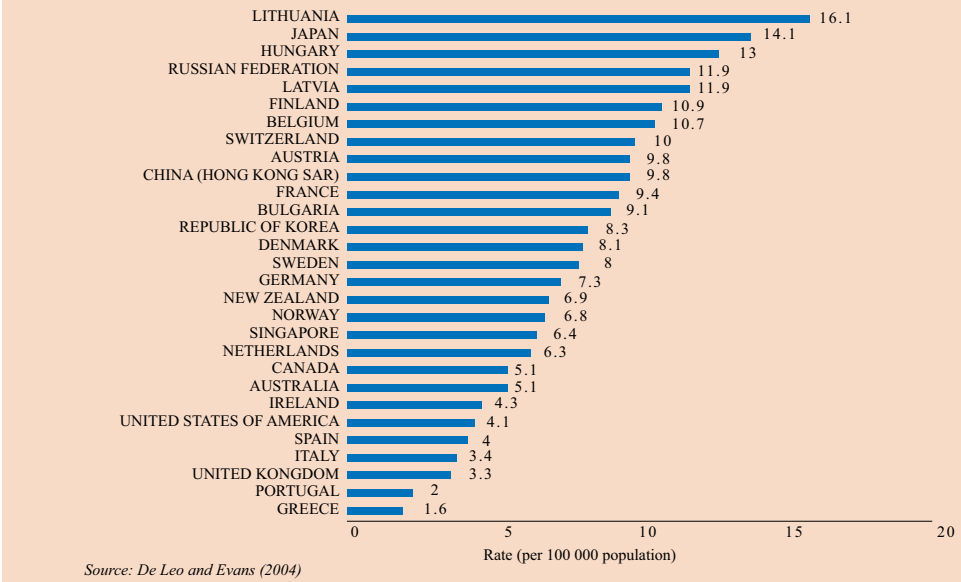


Source:International Suicide Rates and Prevention Strategies 2004

Global trends

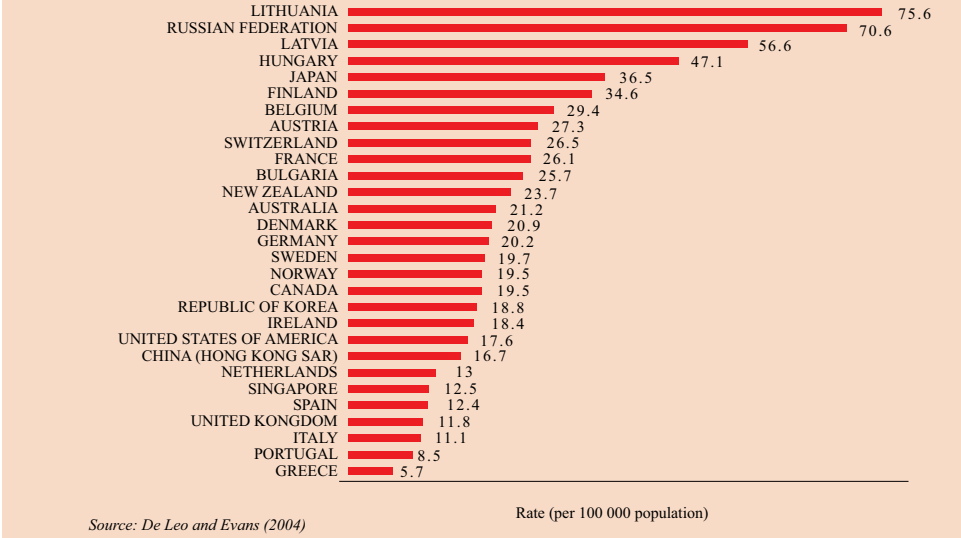
Figures 3 and 4 show year 2001 suicide rates for males and females from selected countries. While each country maintained relatively consistent ranking for male and female suicide rates, four of the five highest-ranking countries were in the Eastern European Region. Japan, which had rates comparable to the Eastern European countries, has shown a steady decline in suicide rates in the past decades (De Leo & Evans,2004).

Figure 3 : Suicide Rates for Males from Selected Countries, 2001



Source: De Leo and Evans (2004)

Figure 4 : Suicide Rates for Females from Selected Countries, 2001



Source: De Leo and Evans (2004)

National Trends

In Malaysia, the Ministry of Health (MOH) Report in 1999 showed a suicide rate of 6.3 per 100,000 population. However, in 2004, the suicide rate was later estimated to be between 9 - 12 per 100,000 population (Consensus meeting with International Association For Suicide Prevention, IASP Consultant, 2003).

Suicide mortality estimate for Malaysia

There is difficulty in obtaining correct statistics for suicidal mortality, as there is no co-ordinating agency for data collection. Local research indicates substantial under-reporting of suicides. Estimates of the corrected crude suicide rate for Peninsular Malaysia in the 1980s were between 8 to 13 per 100,000 population, while for the period 1990 to 2000 it was estimated at 10.5 to 13.5 per 100,000.

In 2002, it is estimated that about 7 suicides occurred everyday amounting to more than 2,500 deaths per year. Therefore, about 30,000 family members and friends will be directly or indirectly affected by suicide each year.

General under-reporting

Generally, it is widely acknowledged that official mortality figures under-estimate the true extent of suicide mortality (Sainsbury & Jenkins, 1982) and Malaysia is no exception. This is attributed to several reasons. One is the stigma attached to suicide as it may be considered a religious contravention or a grave sin. Another important contributing factor in Malaysia is the legal penalties for suicide and attempted suicide being enforced by the legal system. Death by suicide is considered a crime under the Malaysian Penal Code, and attempting suicide is against the law and punishable by imprisonment. Abetting suicide is a crime and punishable by imprisonment while abetting suicide of a mentally ill person is punishable by death. Under Malaysian law, all suicides are classified as "unnatural deaths" and mandatory to be reported to the police.

Problems of establishing a database

There is no available co-ordinating body for compiling, analysing and disseminating information on suicide in Malaysia. Suicide mortality data are at three sources - the Ministry of Health (MOH), the Police Department and the Statistics Department. There is possibility of overlap and duplication of data, but under-reporting is still the major problem.

One local study indicates that there is a major problem in the reporting of *certified deaths* as suicides because of poor certification procedures. Underlying causes of deaths due to poisoning or drowning or fall from heights are often not properly documented, resulting in many of these

deaths being clustered under the rubric of *deaths due to undetermined violence or other violence* (Maniam, 1995).

MOH suicide registry based on autopsies

This crucial issue needs immediate attention. There is a great need to establish standard reporting of deaths and a centralized co-ordinating system to collect suicide statistics to facilitate planning and effective implementation of specific interventions and prevention programmes for suicide. A database on suicide mortality based on autopsies from all MOH hospitals was initiated recently in 2004. This suicide registry is jointly undertaken by the Department of Public Health, MOH and the Psychiatric Department of Kuala Lumpur Hospital and will be piloted in three hospitals in Johor, Pahang and Kuala Lumpur.

Improving quality of data on suicide

Recommendations

To improve quality of suicide data, it is recommended that specialists supervise doctors reporting on causes of death to ensure full and accurate reporting. Medical schools could place emphasis on teaching students proper reporting procedures. Sometimes, family members prevail upon the authorities to report suicides as accidental deaths to avoid stigma or to avoid legal issues. A way to circumvent this may be to develop a "Dual Reporting Method" for suicide mortality where actual cause of death is only reported to the authorities, while the family gets a death certificate stating medical causes.

Establishing a Suicide Surveillance System

A Suicide Surveillance System is the process of collecting information about suicide mortality and morbidity resulting from suicidal behaviour. This includes information on suicide mortality, morbidity of suicidal behaviour, characteristics of victims, precipitating events, adequacy of social support and health services, and cost of injuries related to suicidal behaviour. The MOH could be the main player with experts from the Universities and the Police or other relevant agencies, to establish a Suicide Surveillance System for the country.

Types of suicide mortality

Means and methods for suicidal mortality

In many countries, including Malaysia, the commonest method for suicide death is poisoning (ingestion of pesticides or other poisons such as paracetamol). Other methods include hanging and jumping off heights, which is increasing in urban areas. There are also reports of carbon monoxide poisoning from exhaust gases of motor vehicles, which appears to be an increasingly common method in recent years. There is some evidence that sensational and detailed reporting of these

fatal methods influences the decisions of distressed people to take the fatal step and their choice of method.

Limiting access to means

Availability of, and access to, the methods are major determining factors resulting in mortality. Limiting access to means is an approach to suicide prevention that has the strongest evidence for efficacy in suicide prevention (Gunnell and Frankel, 1994) and is a core component of most National Suicide Prevention Strategies. Beneficial activities include reducing the availability and accessibility of pesticides, as well as lethal amounts of prescription and non-prescription drugs over the counters.

Reducing availability and accessibility to pesticides

Pesticides are responsible for about one third of suicides worldwide. Sri Lanka has started a "Secure Access to Pesticides" Programme where all pesticides are required to be kept double-locked in a box with access only to two different members of the family, usually the father and the mother. The programme which ensured that no one member of the family has access to the poison in a fit of impulsive anger, sorrow or grief, has shown encouraging preliminary results in reducing suicide. This inexpensive preventive strategy, recently introduced as a national programme is now being studied in detail.

Suicide methods in Malaysia

In Malaysia, the most common methods are poisoning, with mainly pesticides and other poisons including paracetamol, and hanging. Paraquat, a lethal pesticide commonly used in plantation farms and estates, is highly toxic and causes high fatality rate. Over the last 10 years (1987 to 1997), paraquat has been the source of 700 poisoning cases in Malaysia and 3% of paraquat ingestion is suicidal cases. Despite the announcement of a ban on paraquat in August 2002, there were steps taken recently by the Ministry of Agriculture to review the ban, and paraquat will still be available in the market up to November 2007.

Paracetamol has emerged as a major choice of deliberate overdosing. Since it is harmful in higher doses, some countries have initiated steps to restrict its availability by introducing by-laws to limit the number of tablets in packaging.

Advocacy on suicide prevention

Creating awareness among

In tandem with the global advocacy on suicide prevention, the MOH in October 2003 began activities to increase awareness on suicide and prevention of suicide. A seminar and workshop was jointly organized

healthcare providers

by the Family Health Division of the Public Health Department, MOH and the Department of Psychiatry, Faculty of Medicine, National University of Malaysia (UKM) and held with the assistance of the International Association for Suicide Prevention. The objectives were to create awareness among healthcare providers on suicidality and suicide prevention, and to establish national networking and collaboration. About 80 participants from various agencies including the MOH, the Ministry of Education, the Department of Social Welfare, Universities, the media and "The Befrienders" (a non-government organisation or NGO) attended the forum.

Educating for responsible media reporting

Since the theme for World Suicide Prevention 2004 was **"Media Advocacy in Suicide Prevention"**, special exhibits highlighting newspaper cuttings on suicide reporting from local newspapers were developed. The aim was to highlight the negative and sensational media statements to educate on the need for responsible reporting.

Need to monitor Media reporting

A workshop on suicide prevention was also conducted for 60 media representatives. A most useful part of this workshop was the preparation of media guidelines by representatives of the media, which was launched in September 2005. What is needed now is a monitoring body with representation from the media to assess how well reporting conforms to these guidelines.

The MOH Community Mental Health Programme

Strengthening efforts to destigmatise mental problems

The MOH Community Mental Health programme undertakes mental health promotion activities since its establishment in 1997. The programme aims to reduce stigma and discrimination of people with mental illnesses. It is hoped that the campaigns will have an indirect impact on suicide mortality and behaviour by increasing community awareness, reducing the overall negative view on mental health problems and illnesses, and increasing the likelihood and acceptability of sufferers to seek help. Many mental health promotion activities, such as health talks and advertorials through the media, public health forums and talks, exhibitions, and press conferences have been held during World Mental Health Month since 1997 and during the Suicide Prevention Month since 2003 onwards.

These efforts to increase destigmatisation of mental illness have included production and dissemination of Health Information, Education and Communication (IEC) materials such as pamphlets, posters, exhibits, info-kits, calendars and collaterals on mental health

and early treatment of mental illness such as depression, anxiety bipolar disorders and schizophrenia.

Improving detection and treatment of depression

Managing depression

Detection and management of depression is another important component of suicide prevention. The Malaysian Psychiatric Association has started training general practitioners to detect and manage depression since 2001. The training has included Family Medicine Specialists at primary healthcare level since 2003.

The psychiatric departments of MOH hospitals have conducted ongoing training of health personnel to strengthen their knowledge and skills in management of psychiatric disorders.

Development of training modul

To address depression, anxiety and other emotional and behavioural disorders among children and adolescent, a training module on Child and Adolescent Mental Health for Specialists was developed in 2003. The aim is to strengthen detection and early intervention. Training using this module has been undertaken annually. Another module on Child and Adolescent Mental Health for Primary Health Care workers was developed in 2004. Training for healthcare providers, school counsellors, teachers and lay counsellors from relevant NGOs will be carried out in 2006 onwards using the same module.

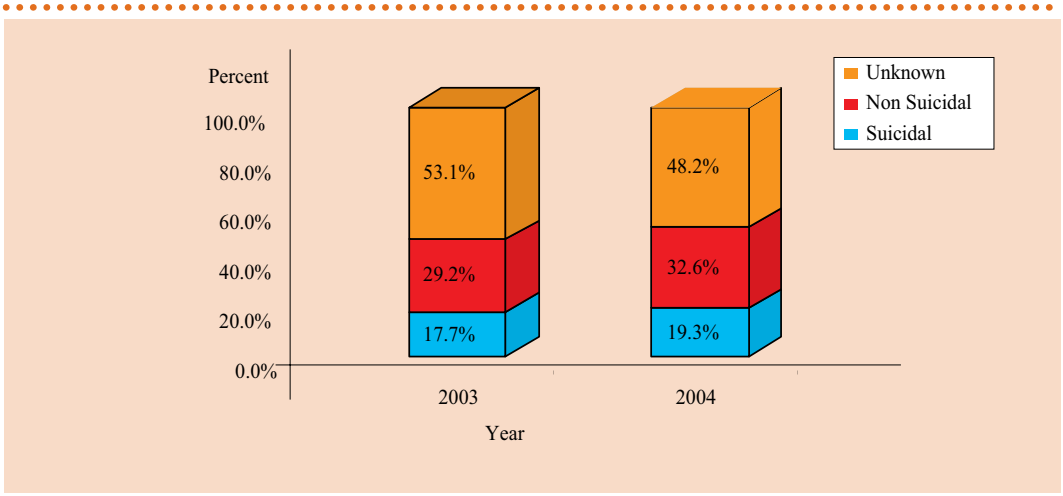
Capacity building

Involvement of primary healthcare personnel, school counsellors, social workers and the media is important to enhance public awareness and promote suicide prevention activities. They can play a major role in providing emotional support to those experiencing depression and anxiety as well as mental health problems. Training for journalists and media personnel had already begun as early as 2003 by the "Befrienders" and the MOH followed suit the two consecutive years.

Counselling and Help Line services

Non-governmental organizations (NGOs) play an important role in suicide prevention. However, there are not many NGOs providing suicide prevention activities in Malaysia at present. The "Befrienders", run by 80 trained volunteers, has been actively providing 24-hour counselling. Since it was established in 1970 it has been the only NGO, which provides support in the form of counselling, help lines, public forums and talks. The 'Befrienders' received a total of 6,201 calls in 2003 and 5,370 calls in 2004, of which 17.7% to 19.3% had suicidal thought respectively **(Figure 5)**
Data from the 'Befrienders' also showed that there were more female

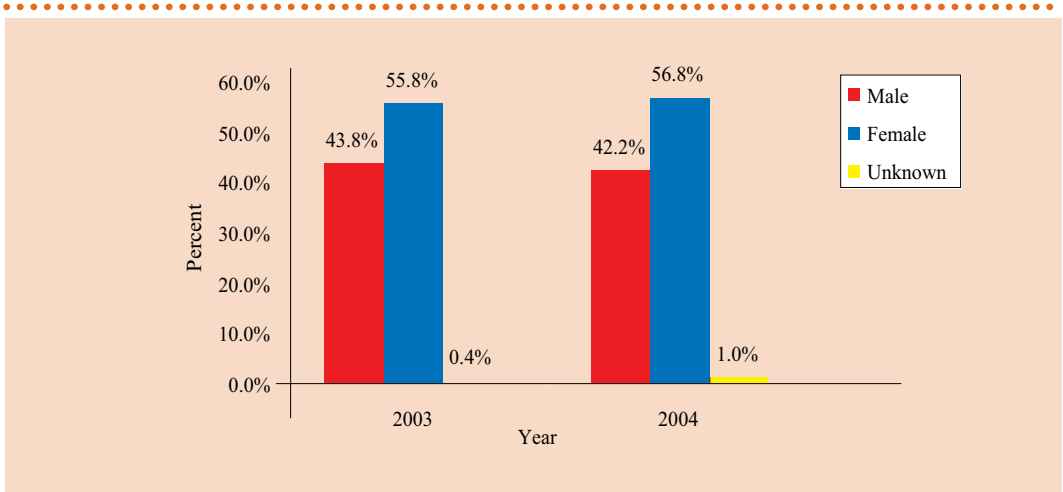
Figure 5 : Types of Callers to Befrienders" in 2003 and 2004



than male callers **(Figure 6)**.

Callers by gender

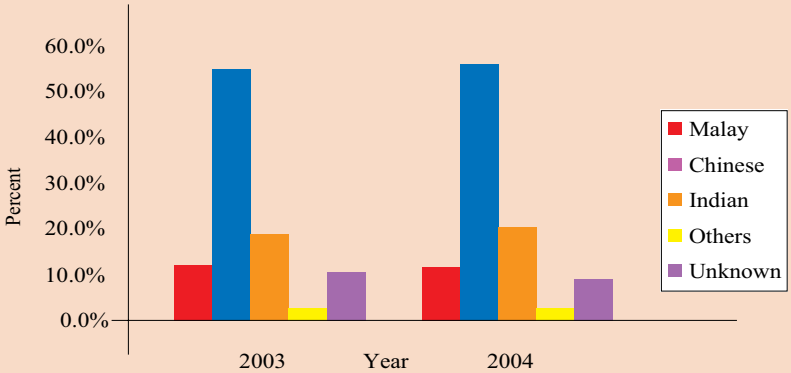
Figure 6 : Distribution of Callers by Gender, 2003 and 2004



Chinese contributed to more than 50% of the calls for both years **(Figure 7)**. Although Indians had the highest number of suicidal mortality in 2000-2004, not many of them sought help for their problems. Only an average of 20% of callers was Indians. The majority of callers were in the those aged between 21 – 30 years, contributing to an average of

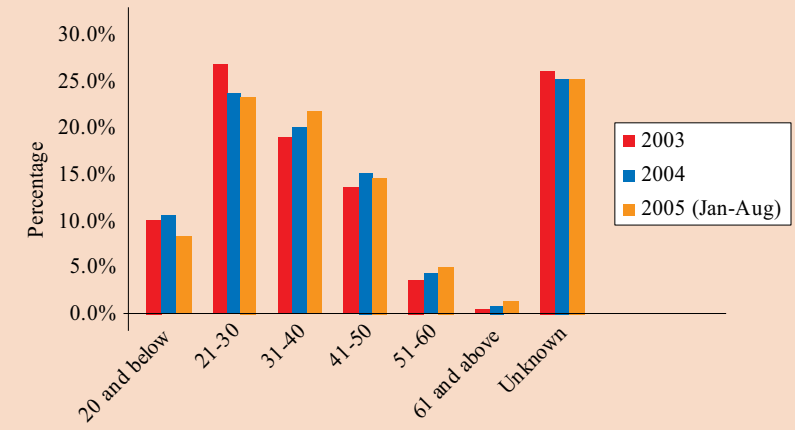
Callers by ethic group

Figure 7 : Distribution of Callers by Ethnic Group, 2003 and 2004



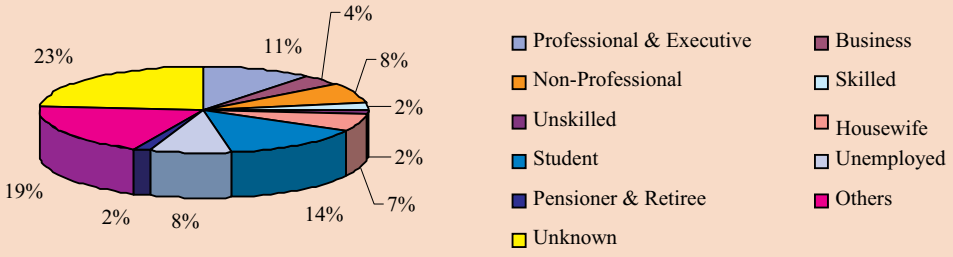
25% of the total callers, followed by those in the 31-40 year age group which contribute to about 20% of the total **(Figure 8).**

Figure 8: Distribution of Callers by Age Group, 2003 – 2005 (Jan-Aug)



Among the callers, 14% were students, 11% were professionals and executives while calls from the unemployed were about 8% **(Figure 9).**

Figure 9: Distribution of Callers based on Occupation, 2004



Key elements to suicide prevention

In response to growing concern over suicidal behaviour, in 1996, the United Nations published guidelines to assist and stimulate countries to develop national strategies aimed at reducing mortality, morbidity and other consequences of suicidal behaviour. The guidelines emphasized the need for inter-sectoral collaboration, multi-disciplinary approaches and continued evaluation and review.

Six key elements for effective suicide prevention strategies include:

- Support from government policy
- A conceptual framework
- Well-established aims and goals
- Measurable objectives
- Identification of organizations capable of implementing objectives
- Ongoing monitoring and evaluation

Suicide prevention strategies in Malaysia

Public health approach

While mental health problems are a core risk factor for suicide, suicide prevention requires an integrated and multifaceted approach.

Recognising the interrelatedness of all risk and protective factors for suicide, Malaysia's approach to suicide prevention targets at a broader public health perspective, both at individual and population levels.

The Malaysian National Suicide Prevention Strategy operates at three levels - universal, selective level and indicative levels. The components of the proposed strategies at various levels are as follows:

Universal level

Promotion of mental health awareness including encouragement of help-seeking behaviour.

- Development of a mandatory supervised reporting system for suicide
- Implementation of National Media Guidelines for Suicide
- Improvement of collaboration among different service providers
- Establishing networking with general practitioners
- Discourage the use of paraquat or alternatively ensure secure access to such has been described in the case of Sri Lanka.
- Procurement of counsellors to be placed at the primary healthcare facilities

Selective level

- Active outreach of individuals with the risk of suicide, for example individual with depressive illness or psychosis
- Counselling and rehabilitation services

Indicative level

The following objectives have been adopted :

- To promote awareness on suicide through the schools, health institutions and media with emphasis on recognition of mental health disorders and suicidal behaviour
- To promote human resource development and training
- To enhance multi-sectoral collaboration in providing counselling and help-line services
- To reduce the availability and accessibility of pesticides
- To reduce the availability of lethal amounts of prescription and non-prescription drugs

A draft of the National Suicide Prevention Strategy has been developed

with the objectives mentioned above. A Technical Working Group formulated this draft with the assistance of IASP experts and the National University of Malaysia (UKM). This proposed action plan aims to promote positive emotional and spiritual well-being of Malaysian society through continuous multi-sectoral collaboration.

Conclusion

Mental health problems represent a major, but rarely the only, precursor to suicide and suicidal behaviour. While a majority of countries, including Malaysia have enacted programmes to address mental health, only some aspects of the mental health programmes may be beneficial to suicide prevention and their limited usefulness does not provide a sufficient response to suicide. Suicide needs to be addressed thorough policies and strategies that acknowledge the interrelatedness of all risk and protective factors for suicide, including socioeconomic, cultural, and mental health problems.

Several countries have well-established national suicide prevention strategies, and many others have either recently established one or are in the process of doing so. Whatever the status may be, it is important that the prevention strategies have a positive impact on the suicide rate or trend.

As resources, in terms of manpower and funding are made available, the MOH has in the pipeline, plans to implement suicide prevention programme in the Ninth Malaysia Plan. The programme will include the prevention strategies outlined above and will take a multi-sectorial, holistic and comprehensive approach. A Suicide Prevention Policy and Guidelines will need to be developed as blue print for suicide prevention in Malaysia.

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Chapter 3

HEALTH SYSTEM MANAGEMENT

THE NEW GENERATION HOSPITALS – IT HOSPITALS

SUMMARY

The Future Healthcare System is set to harness the power of information and multimedia technologies to transform the delivery of healthcare services in the country towards improving health and health outcomes in the population. Demands on the healthcare system to provide safe, effective, efficient, seamless, timely and quality health care service, through access to the right information at the right place and time, has necessitated that health information be provided in an integrated and holistic manner. The Electronic Medical Record (EMR) is the most important component for information management in a computerized and Integrated Healthcare system. The "rebirth" of hospitals in the 21st century into a new paradigm of healthcare delivery, makes it imperative for this new generation of hospitals to adopt Hospital Information System solutions to meet the above objectives.

Introduction

In line with the government's *Vision 2020* to achieve developed country status by the year 2020, the Ministry of Health formulated its *Vision and Mission for Health*, and identified eight health service goals to ensure realization of the National Health Vision.

Future health system

The attainment of the future healthcare system requires reshaping and transforming a system that has thus far largely focused on illness, facilities and healthcare providers, into one focused on wellness, catering to future generation of informed persons and ICT environment, as well as having the capacity to provided integrated and seamless healthcare services across all sectors.

Earlier hospitals

Through the various five year National Development Plans (Malaysia Plan), hospitals have been built using templates of standard and one-off plans, based on the traditional way of healthcare provision which is provider focused. From the 7th Malaysia Plan period onwards, there was a conscious effort to develop hospitals into the new ways of working by leveraging on Information and Communication Technology (ICT).

New generation hospitals

The new 21st century hospitals have to harness the strengths of information and multimedia technologies to enhance efficiency in hospital management, improve patient care through better documentation and record keeping, and bringing together all patient information to support continuity of care. It is patient focused rather than provider focused, providing coordinated continuous and seamless care through a "network of care" concept . This is the "rebirth of hospitals" into new ways of working and providing care using ICT to generate, manage and retrieve health care information.

Hospital Information System (HIS)

Definition of HIS

Hospital Information system (HIS) refers to an electronic information system that would support the core business of patient care and enable the hospital to run as a facility / organization . In the Malaysian context, the HIS should have the minimum functionalities to meet the Eight Health Services Goals **(Table 1)**. The system should be able to improve healthcare delivery so as to meet service requirement, ensure continuity of care, improve efficiency and productivity, improve patient safety, improve quality of care and health outcomes as well as empower healthcare providers and consumers.

Table 1 : Eight Health Service Goals

Goals of Health Service	*Description of goals*
1. Wellness focus	Provide services that promote individual wellness throughout life
2. Person focus	Focus services on the person and ensure services are available when and where required
3. Informed person	Provide accurate and timely information and make informed decisions
4. Self help	Empower and enable individuals and families to manage health through knowledge and skills transfer
5. Care provided at home or close to home	Provide services into rural and metropolitan homes, health settings and community centres

6. Seamless Continuous care	Manage and integrate health care delivery across care settings, episodes of care and throughout life
7. Services tailored as much as possible	Customise services to meet individual and group needs and special circumstances
8. Effective, Efficient and affordable services	Provide enhanced access , integration and timely delivery of high quality services at reasonable cost.

Other benefits of HIS

In addition, the Health Information System should also be able to generate various health system reports for local management and planning, as well as contribute to the national population health database from individual Lifetime Health Records (LHR). The LHR repository will be the focal point for integration of all electronic health records (hospital and clinic visit summaries) to ensure continuity of care across the health sector.

The HIS should have the following minimum functionalities as depicted in **Table 2.**

Table 2 : Minimum Functionalities in a Hospital Information System

• Person management • Patient Accounting • Patient appointment/ scheduling • Order / report management • Laboratory Management • Pharmacy management • Discharge Summary • Medical Records management & document tracking	Manage and integrate health care delivery across care settings, episodes of care and throughout life Customise services to meet individual and group needs and special circumstances Provide enhanced access , integration and timely delivery of high quality services at reasonable cost.

Source: Planning and Development Division, Ministry of Health Malaysia 2004: 9MP Technical Working Group Paper: Transforming Healthcare Services through ICT: The Way Forward.

Health informatics

Health informatics, is a term used for healthcare information management, originating in the systemic use of data to manage and provide health services. It contains elements of "acquisition, organization, analysis, evaluation, synthesis, management, communication and dissemination of information".

Health informatics, the basis for HIS

With advances in computing and communications technology, it is feasible to store, assemble and retrieve electronic patient records from different systems, thus allowing clinicians to have an integrated view of a patient's life-long health record at the point of care. The electronic health record is the single most important component for information management in computerized integrated healthcare systems.

Advancements in health informatics

The use of health informatics will help coordinate and manage patient data more efficiently through electronic means. The development of shared health information systems and technology infrastructures in networking and patient databases will integrate the healthcare enterprise and thus improve the quality of patient care. The new generation hospitals with HIS systems have to be well versed with health informatics.

The Malaysian experience in HIS

The use of information technology is not totally new in Malaysia. In the 1980's, an in-patient administration system [*Sistem Pengurusan Pesakit Dalam* (SPPD)] was implemented in 14 hospitals throughout the country to manage in-patient billing and revenue collection. Furthermore, an outpatient management system [*Sistem Pengurusan Pesakit Luar* (SPPL)] was also introduced in two of the above hospitals with similar financial objectives. Both these systems which were developed in-house are independent stand-alone systems. In addition, there are several other "stand-alone" systems which have been implemented in the existing hospitals, by the end user clients, to meet the functional requirements of the respective clinical disciplines.

SPPD / SPPL

In the 6th Malaysia Plan (6 MP, 1991-1995), it was proposed that all hospitals (new and existing hospitals) shall be equipped with electronic Hospital Information Systems. Selayang Hospital was the test bed for a hospital-wide IT solution called Total Hospital Information System (THIS) in 1998, followed by Putrajaya Hospital and Putrajaya Health Clinic in 8th Malaysia Plan (2001-2005). However, these systems are

Selayang Hospital – the first THIS hospital

yet to be integrated across the health care enterprise, meaning between institutions.

The implementation of a fully integrated facility information system called Total Hospital Information System (THIS), encapsulates the integration between clinical including imaging and critical care, financial and administration systems. The challenge is in adopting the best working method as well as innovations in forming electronic work process in all aspects of patient flow to achieve the notion of seamless and continuous patient care.

Basic and Intermediate HIS

The years 2004 -2005 saw the implementation of two other IT hospital models namely, the Basic Hospital Information System (BHIS) at Kepala Batas Hospital in Seberang Prai Utara district of Pulau Pinang, and the Intermediate Hospital Information System (IHIS) at Lahad Datu Hospital in the state of Sabah. Figure 1 depicts the incremental relationship between the various levels of the Hospital Information systems that were hitherto outlined in 7th Malaysia Plan.

Figure 1 : Levels of Hospital Information Systems in 7 MP

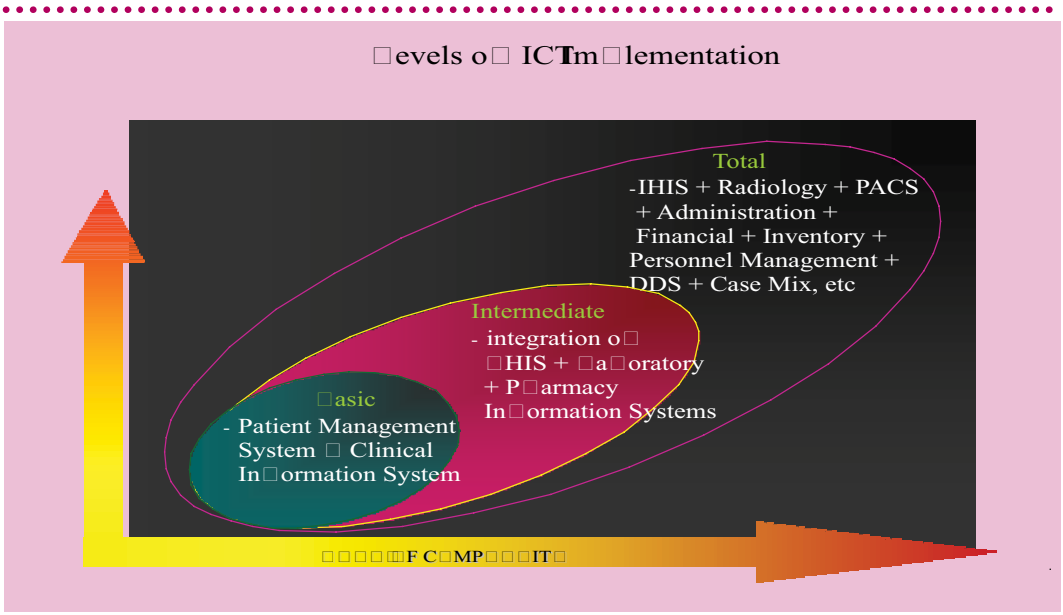


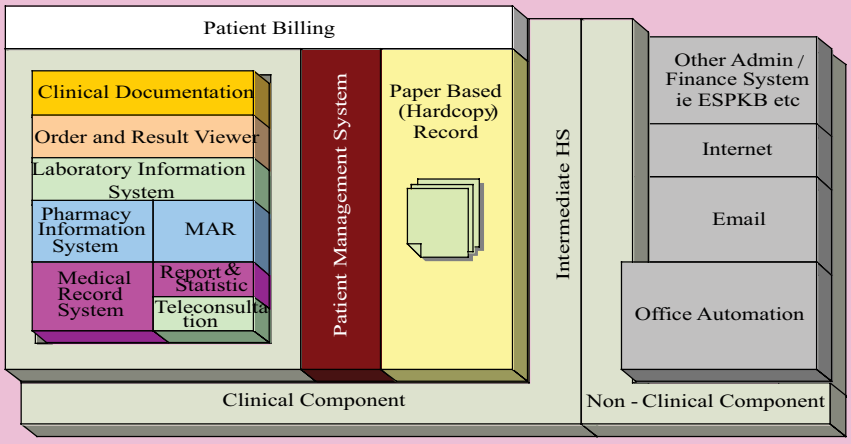
Figure 1 : Levels of Hospital Information Systems in 7 MP

Various levels of Hospital Information Systems

The Basic Hospital Information System comprises of modules for person management, computerized physician order entry and result reporting and a clinical discharge summary. The Intermediate level Hospital Information System has in addition, a computerized Laboratory Information System and an electronic Pharmacy Information System.

Figure 2 depicts the scope of the Intermediate Hospital Information System (IHIS) that was implemented in Lahad Datu Hospital, a 268 bedded replacement hospital in Sabah.

Figure 2 : Scope of the Intermediate Hospital Information System (IHIS) in Lahad Datu Hospital



The scope of the Intermediate Hospital Information System (IHIS) at Hospital Lahad Datu

Source: Lahad Datu Hospital 2005

Standardizing data sets

Recognising the need for development of standardized data elements and customization of the application software to fulfill all information requirements for the provision of seamless patient care service, a central "THIS Core Team" comprising of health care professionals was set up in 2002 by the Ministry of Health. This was a multi disciplinary team with a mix of personnel with varied expertise of HIS systems. This team was also entrusted with the task of ensuring compliance and

consistency with other E government initiatives and guidelines. The HIS implementation also took cognizance of the need to share data and information where appropriate for the purpose of the delivery of continuous and seamless care. The central THIS Core Team was supported by the Telehealth Division of the Ministry of Health which was responsible for the development of Health Informatics Standards.

Evaluation of HIS

End-user surveys

End-user surveys and evaluation of the HIS System at Selayang Hospital for the development of the Strategic Information System Plan for Selayang Hospital, as well as surveys and evaluations of HIS Systems in Putrajaya and Kepala Batas hospitals had been conducted. The findings of these evaluations provided much needed evidence to improve future implementations of HIS solutions.

Selayang Hospital experience

In a case study report on Hospital Selayang in 2002, 3 years after it started service, user satisfaction survey indicated widespread approval of THIS, where 64% to 71% of the users rated the IT work processes as being very good to excellent. More significantly, 93% of those surveyed indicated they preferred working in a paperless environment versus a traditional paper-based hospital[3].

Comparison with HTAR Klang

The same report also recorded results of a benefit study comparing Selayang Hospital with Tengku Ampuan Rahimah Hospital in Klang. Among others, it showed that comparatively, there was a 11.3% reduction time in patient registration; 36.7% time reduction in admission procedures; 73% time reduction following portable x-ray reporting; 80% reduction in time to view the patient's medical records; and 51.6% efficiency gain in scheduling patients.

Lahad Datu Hospital experience

In the Lahad Datu hospital experience there is concrete evidence of tangible benefits primarily in the areas of patient safety, minimization of drug errors, elimination of transcription errors, improvements in resource utilization and optimization, improvements in efficiency and effectiveness, quantifiable reduction of financial losses resulting from "expired drugs", improvement in quality of care, and, turn around times.

Intangible benefits

Intangible benefits have also been realized in the area of appropriate bed allocations and minimization of non-clinical transfer of patients between bed classes, in the online clinic scheduling feature, and in

improved quality of patient care through appropriate and timely interventions and seamless care across a continuum. Production of real-time management reports as system outputs has produced an unquantifiable benefit in terms of savings of man-hours spent to produce the reports as well as the accuracy of data and information.

Future directions for the new generation HIS hospitals : the challenges ahead

Implementation of HIS systems

Leadership

Drawing from the experience of Selayang, Putrajaya and Lahad Datu hospital, the critical success factors that contribute to successful deployment of a HIS solution, among others, are good leadership, strategic planning, user motivation and commitment, and, involvement of the clinicians (clinician buy-in). A strong, well read and empowered leadership with effective decision making skills (to resolve problems as they arise) is crucial to project success.

System deployment

In system deployment and roll out - there is no perfection, no tried and true method for implementation. It is a journey of "pilot and improve, rollout and improve", and one should be prepared to make changes as the need arises. It is critical to "fix the bugs" before further roll out. One must also be aware that it is impossible to completely replicate the production use of a system in a test environment – hence the end-user will always a "beta tester".

"Easy wins"

As with any innovative initiative in a socio-technical environment (healthcare), it is important to get customer feed back and use it. Problems, especially those that affect patient safety should be resolved quickly. Confidence can be enhanced by "looking for the opportunity and quick wins" especially in fine tweaking of the system to get value and benefits.

Training

It has been proven that the training never ends and implementation never really ends. Clinician efficiency comes first - if a clinician is saddled with many tasks at go live, the clinician may never learn the system well enough to achieve a good level of comfort and efficiency. The application software should be kept simple. Content should support efficiency and it has to be managed and maintained.

Operations and maintenance

Data integrity and security

Sustenance of operations and continued maintenance of the system in terms of managing the system hardware, software, and the

enhancements, upgrades and content management are key challenge areas in the deployment of HIS systems. Data volume, flexibility and scalability of the system, data integrity and security are some of the critical areas that have to be addressed.

Maintenance budget

In the Malaysian context, it is vital to allocate adequate budget to ensure continuity and efficient sustenance of the system operations. As a rule of thumb based on the experience of deployment of HIS solutions in the 3 hospitals, it would be prudent to allocate an operations and maintenance budget equivalent to 15 – 20% of the capital expenditure. There should be timely scheduling of the operations and maintenance contracts so that there is a smooth transition from the project completion phase into the operational phase. An added advantage would be to ensure that the operations team is "on board" during the project completion phase, as it will facilitate the Operations and Maintenance (O&M) training of the personnel as well as the transfer of technology (TOT). This O&M training and TOT are vital to ensuring efficient and effective functioning of the hospital.

The Chief Information Officer (CIO)

Need for Chief Information Officer (CIO

The need for a new genre of specialized medical personnel, the Chief Information Officer (CIO).has crystallized as we move into the era where Health Information Technology is the core of every significant business process in a hospital and is a critical success factor for innovation and enterprise success. The CIO has to be "one step ahead of the curve" and become an irreplaceable part of their organisation's success.

Conclusion

Benefits of HIS

Hospital Information System (HIS) provides the environment for better patient care and safety. It has the potential to improve patient outcome through better clinical governance and continuity of care. Management of clinical data, medical records and hospital resources can be made more efficient, contributing towards better control of hospital cost in the long run. From the patient's perspective, the HIS will enable access to timely, appropriate and accurate information for management of his health.

HIS set to be utilized in future generation

With the successful adoption of HIS in the first few Ministry of Health hospitals, future generation hospitals are set to utilize more of HIS in the years to come. The experience gained from implementation

of different levels of Hospital IT systems ranging from basic to Total Hospital Information System (THIS) has provided many useful insights into the functional and operational requirements of an "IT hospital." These would be useful in helping the Ministry of Health in developing the next generation "IT hospitals" in the future.

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CONTROL OF UNREGISTERED DRUGS AND HEALTHCARE PRODUCTS IN MALAYSIA

SUMMARY

Poor quality drugs and healthcare products can threaten the health of the public. The Pharmaceutical Services Division plays an important role in protecting the health and safety of the public through enforcement of pharmacy laws and regulations pertaining to unregistered drugs and healthcare products. Activities such as registration of products, licensing, adverse drug reaction monitoring, post-market surveillance, raiding, investigation, prosecution, consumer education and hologram introduction are imperative to ensure the safety, efficacy and quality of drugs and healthcare products for the consumer.

Introduction

Need for regulation

In Malaysia, the lucrative healthcare industry is considered one of government's priorities and various schemes have been introduced to help boost the pharmaceutical and healthcare industry. The sector is highly regulated by the Drug Control Authority (DCA), through the *Sales of Drugs Act 1952 (Revised 1989)* and *the Control of Drugs and Cosmetics Regulations 1984*. Recent fatalities due to consumption of unregistered drugs have escalated activities within the Ministry of Health (MOH) against illegal pharmaceutical drugs and healthcare products.

Regulating bodies

The vision of the Pharmaceutical Services Division (PSD) of the MOH is to provide the best pharmacy services for the health and well being of the nation so as to achieve definite outcomes and improve quality of life. The National Pharmaceutical Control Bureau (NPCB) as the secretariat and executive arm of the DCA ensures that pharmaceutical and healthcare products produced locally or imported conform to standards of quality, safety and efficacy before they are registered. The NPCB also ensures that all manufacturers, importers and wholesalers of these products comply with the required standards until the products reach the public. The Pharmaceutical Enforcement Branch (PEB) under the PSD has the responsibility to ensure that the manufacture, importation, sale, supply, management and use of pharmaceuticals and healthcare products are conducted according to the existing acts and regulations.

Regulation of registered drugs and healthcare products

Registration of products

A registered drug is one that is approved by the DCA for sale and use in Malaysia. The DCA requires the registration of any drug in a pharmaceutical dosage form, intended to be used, or capable or purported or claimed to be capable of being used on humans or any animals, whether internally or externally, for a medicinal purpose. The registered drug must be evaluated for efficacy and safety. Registration of products ensures medications and healthcare products are effective and are not contaminated with lead, mercury, arsenic, steroids or any scheduled poisons listed under the Poison List Order. By the year 2005, a total of 32,456 drugs have been registered, not including cosmetics. Cumulative data on products registered are shown in **Table 1.**

Table 1: Cumulative Number of Products Registered (2003-2005)

Year	Cumulative Data				
	Prescrip-tion drugs	Over-the-Counter (OTC) products	Traditional medicines	Cosmetics	Total
2003	9,659	7,206	12,107	6,656	35,538
2004	10,012	7,432	13,077	47,418	77,939
2005	10,339	7,732	14,385	83,430	115,886

Source: National Pharmaceutical Control Bureau

Licensing

Manufacturers, importers and wholesalers are licensed, monitored and audited to ensure all premises and practices employed to manufacture, store and distribute these products comply with the guidelines issued by the NPCB. A total of 1,891 licenses were issued for the year 2005 **(Table 2).**

Table 2: Licenses Issued To Manufacturers, Importers And Wholesalers (2003-2005)

Year	Manufacturers	Importers	Wholesalers	Total
2003	217	316	875	1,408
2004	227	456	864	1,547
2005	296	652	943	1,891

Source: National Pharmaceutical Control Bureau

Adverse drug reaction monitoring

Monitoring for adverse drug reaction (ADR) arising from the use of medications is handled by the Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) under the NPCB. Manufacturers, importers and wholesalers, as well as healthcare professionals, are required to submit ADR reports to the MADRAC.

Post-market surveillance

Monitoring the quality of registered drug and healthcare products is done through post-market surveillance. Samples tested at the NPCB laboratories are either for registration, surveillance or enforcement activities. The NPCB will test products for compliance with required standards in Malaysia.

Enforcement on unregistered drugs

Centrally-driven programme

In 2005, more than RM 9.5 million worth of unregistered products was seized by the PEB, compared to over RM 20 million seized in 2004. Items seized in 2005, however, were much higher than those seized in previous years.

In 2004, a national programme was implemented to combat unregistered products. States were required to conduct major operations according to schedule. As a result, the number of items seized escalated compared to previous years. One seizure valued at RM 13.7 million involved a syndicate illegally manufacturing and distributing locally-produced unregistered products claimed to be imported from United Kingdom **(Table 3)**, of which RM 10 million were seized in Selangor.

Table 3: Seizure of unregistered drugs by states (2003-2005)

State	2003		2004		2005	
	Items seized	Value(RM)	Items seized	Value(RM	Items seized	Value(RM)
Perlis	32	9,230	33	9,350	160	64,271
Kedah	207	147,519	563	1,484,975	212	99,541
Penang	315	52,517	290	289,334	263	1,155,573
Perak	371	620,671	312	1,329,708	566	300,167
Selangor	654	2,267,247	470	13,725,858	4,170	2,429,770
K.Lumpur	684	1,912,920	735	1,342,592	1,265	2,626,299
N.Sembilan	152	22,286	1,367	159,536	126	54,421
Malacca	231	165,180	790	894,750	1,152	521,898
Johor	471	180,108	729	94,119	649	418,594
Pahang	142	43,460	1,041	148,533	518	62,938
Terengganu	299	129,890	183	111,225	1,324	195,775
Kelantan	717	477,150	614	699,132	431	1,026,870
Sarawak	1163	312,164	389	162,859	1,053	490,903
Sabah	233	88,539	132	146,326	208	150,534
Labuan	16	3,127	56	4,815	145	6,058
Malaysia	**5,687**	**6,432,008**	**7,704**	**20,623,112**	**12,169**	**9,598,809**

Source: Pharmaceutical Services Division

Seizure of unregistered products

Unregistered products seized from night markets, unlicensed premises, direct selling outlets and from Internet sales consisted of products containing scheduled poisons, non-poison over-the-counter (OTC) products, traditional medicines and cosmetics. Most of the products seized were traditional medicines and health supplements, of which sex stimulants contributed the largest item. In 2005, a total of 4,575 unregistered traditional medicines items valued at more than RM 4.9 million were seized **(Table 4)**. The products were from manufacturers without Good Manufacturing Practices (GMP) certification to guarantee safety, efficacy and quality. The PEB also encountered a few cases of imitation products which did not meet quality requirements.

Investigation and prosecution

In 2005, 458 cases were investigated under the Control of Drugs and Cosmetics Regulations 1984, and 244 cases were brought to court for prosecution with collected fines of RM 680,950 **(Table 5)**. Many of the cases were in the Klang Valley region.

Table 4: Types of unregistered products seized (2005)

	Item	Value (RM)
Scheduled poisons	1,675	938,838
OTC (non-poisons)	1,531	1,439,020
Traditional medicines	4,575	4,911,386
Cosmetics	1,222	529,497

Source: Pharmaceutical Services Division

Table 5: Investigations & prosecutions of unregistered products 2005

State	Investigations		Prosecutions
	2004	2005	2005
Perlis	3	2	2
Kedah	5	28	3
Penang	22	19	14
Perak	57	46	13
Selangor	90	71	40
K. Lumpur	35	32	52
N. Sembilan	8	15	18
Melaka	50	66	7
Johor	5	32	40
Pahang	29	42	4
Terengganu	16	4	18
Kelantan	34	40	17
Sarawak	15	34	5
Sabah	33	27	11
Labuan	0	0	0
Malaysia	402	458	244
Total fines collected (RM)			**680,950**

Source: Pharmaceutical Services Division

Steps taken to control unregistered drugs and healthcare products

Need of Hologram

Besides strict enforcement on unregistered products, the PSD has been enacting deterrent legislation and enforcing mandatory security hologram labels since 1 May 2005. The hologram is introduced to curb imitation, counterfeit or unregistered health products on the market. All products including traditional medicines, food supplements and imported or locally manufactured drugs registered with the DCA, are required to bear the hologram labels. The seals authenticate the contents of the products. External personal care (EPC) products such as medicated soaps, shampoos and cosmetics are exempted from the hologram ruling, although these are still required to be registered with the DCA.

The role of the consumer to inform the PSD of suspicious products

The tendency for self-medication and the obsession to enhance sexual performances or to have a svelte body has boosted the health supplements and traditional medicines industry. Hence, consumer education is important for health and safety. Publishing enforcement activities and adverse effects cases, holding exhibitions and lectures and distributing pamphlets are ways to raise consumer awareness. The public must be educated to check for expiry dates, registration numbers, manufacturer's names and addresses, and hologram labels. However, such public education activities are limited, due to budgetary constraint.

The role of retailers

Enforcement alone, without an informed public, is inadequate to overcome problems of use of unregistered products. The Public can obtain useful information from the PSD website at www.pharmacy.gov.my for current enforcement activities or lodge any complaint or provide any information via e-mail to the Pharmacy Division in Ministry of Health at pharmacy1@pharmacy.gov.my.

Retailers must also exercise diligence in maintaining proper record and keep inventories of their stocks with regards to batch numbers, manufacturing and expiry dates especially for the traditional medicines that have short shelf lives of 2 – 3 years similar to the modern medicines.

Increase surveillance activities

Unregistered products may be brought into Malaysia either by authorization of the Director-General of Health, or as part of personal luggage in a quantity that does not exceed one month's use by a person. Such provision can be misused by syndicates to bring in unregistered products from abroad. Intensifying enforcement activities and

surveillance at the entry point will curb smuggling activities across the border and ports of entry. This is an on-going activity of the PEB and is being actively pursued.

Products registration holder

Pharmaceutical and healthcare products are one of the most highly regulated industries in the world. All registered products should bear the name and address of the actual manufacturer. Foreign companies who wish to market health products in Malaysia must appoint a local agent to be products registration holder. The appointed agent would thus be accountable for all matters pertaining to the registration of the products.

Monitoring direct selling

The resurgence in interest of the public in biotechnology and alternative medicines has stimulated expansion of direct selling businesses. The PSD is monitoring direct selling companies that are using contract manufacturers to produce health products to ensure that registered products are from valid and licensed manufacturing sites to avoid breach of product quality, safety and efficacy.

Conclusion

The Pharmaceutical Services Division plays an important role in safeguarding the health and safety of the public through combating illegal health products in Malaysia. The Division will continue to intensify its national programme to increase surveillance and operation activities, as well as study and promulgate deterrent laws from time to time to achieve its vision and mission. However, with large numbers of unregistered and illegal products flooding the market, consumer education and surveillance of retailers assume greater importance.

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INFORMATION VERSUS ADVERTISING

SUMMARY

The use of traditional print or electronic media for the propagation of health information or advertising of products and services is well established. The advent of the global information highway and newer interactive information technology has revolutionised the way health information is presented to the consumer. Medical advertisements now are highly sophisticated and consequently, promotional strategies adopted by advertisers have resulted in the blurring of the once-clear demarcation between health information and medical advertisements. Without question, medical advertisements empower consumers by providing valuable health information towards more rational decisions. However, abuses must be curbed. It is for this reason that the Medicine Advertisement Board (MAB) scrutinises all information on medical advertisements before publication. At the same time, recognising changes in the field of advertising, the MAB has introduced measures aimed at liberalising many aspects of medical advertisements.

Introduction

Information exploration

Information explosion has been the hallmark of modern day innovations and health information is no exception. Technological breakthroughs have permitted consumers to access medical information in unprecedented volume. The arrival of media like the internet has forever changed the landscape resulting in an urgent need for regulators all over the world to redefine borders.

Information through advertisements

In the early days, manufacturers of potions and pills and other purveyors of human health fought for consumer attention with large, often outrageous promises and colourful, dramatic advertisements. Although many of these advertisements were not truthful or were misleading, they played the traditional role of providing so-called health information to the consumers. However, dubious products and services have resulted in consumer movements to regulate the medical advertisement industry.

Medical science has since made strident progress with the discoveries of new products and treatment options that not only save lives but also enhance the quality of life. The reality today is that information about these products and services constantly vie for our attention through various media that includes the internet.

This article reports on the role of the Malaysian Medicine Advertisement Board (MAB) in exercising control and balance on health and medical information and advertisement.

Advertisement today

Few would question the enormity of the advertising machine that runs within our society. Advertisements are omnipresent and totally pervasive in our modern day culture. Despite or because of its ubiquity, advertising is not an easy term to define. Usually, advertisements attempt to persuade their audience to purchase a product or service. Thus, there is constant clamour from consumer groups that advertisers should not be given free reign and that there should be stricter vetting of information that goes into an advertisement.

Most governments of the world realise that consumer vulnerability to deceptive advertising is particularly acute in the area of health products and services. Such advertisements are often the result of complex promotional strategies and they wield enormous persuasive power over unsuspecting individuals who have very little knowledge of the information provided. Because of this great inequality of bargaining power, governments often back up consumers with protective laws.

Today, advertisements of medical products and services are one of the most highly regulated aspects of our life. It has been argued that this is rightly so, as medical product and services are different from that of other commodities. Medical products and services are by definition and nature intended to have therapeutic effect, and influence the health status of the sector of the population that has very little capacity to evaluate the information presented.

Advertisement and information: the pros and cons

Exaggerated information in advertisement

Detractors of medical product advertisements have argued that despite governmental controls and self-regulation by the industry, most of the advertisements present information in an exaggerated manner designed to exploit the consumers' lack of knowledge in medical matters. They claim that these advertisements are very likely to arouse unwarranted and unrealistic expectations leading to dangerous self-diagnosing.Studies have shown that in the absence of proper controls, advertisers of medical products tend to omit facts, downplay risks, publish unsubstantiated claims and mislead consumers.

Raising consumer

In the midst of these controversies, one pertinent question is whether advertisements themselves might serve a more positive purpose.

awareness

Proponents of medical advertisements argue that advertisements serve to bring information to the people and thereby confer considerable health benefit to the consumer. This is exemplified by Direct-to-Consumer advertisements in countries that allow them, where one of the main benefits is raising people's awareness of disease states and the treatment options available1. As a result, the argument continues, patients become better educated, better equipped to discuss their treatment with doctors, and better prepared to maintain the treatment regime they determine jointly with their doctors.

Seeking publicity through media

In the case of health services, similar views have been put forward. The Malaysian Medical Council (MMC) holds the traditional view that doctors should not resort to blatant publicity in the media in the guise of providing health information to the public. It believes that doctors have distinct ethical obligations to the public. These obligations include professional competency, integrity, honesty, confidentiality, objectivity and any attempts to dilute these values by promoting their own professional advantage is considered an affront to the nobility of the profession.

Bodies like the MMC have defined borders that serve as warning when overstepped when it comes to information and advertisements. It defines these two terms in the following manner[2] :

Defining 'Information''

Information - P*roviding information in relation to the medical profession is the act by which a registered medical practitioner as a health care provider, disseminates factual information to the public generally on health promotion and specifically on diseases, their prevention, control and treatment, and on any other aspects related to these modalities, without the practitioner contravening the ethical codes of professional conduct, or without any designs to obtaining patients, profiting financially or materially, or, appearing directly or indirectly, to promoting his own professional advantage or product, or appearing to be for these purposes.*

Defining 'Advertising'

Advertising - *The word 'advertising' in relation to the medical profession must be taken in its broadest sense, to include all those ways by which a person is made publicly known, either by himself or by others, without objection on his part, in any manner or channel which can be fairly regarded as for the purpose of obtaining patients, or promoting his own professional advantage, or as appearing to be for these purposes.*

The practices of touting or canvassing for patients are considered to fall under the definition of advertising and are unethical.

Thin line between information and advertising

The above definitions highlight the fine line between 'advertising' and 'information'. Admittedly, at the extreme ends of the spectrum, advertisements and information are clearly distinguishable. The issue is when advertisers present information masked with indirect, innovative references which leave trails that ultimately lead consumers directly to the product owners or service providers. In such cases, when does information stop and advertisement begin?.

Treading the fine line

Matters become complicated with the entry of a third party - the advertising agency. Today's advertising industry is highly sophisticated. The most striking development is its ability to devise highly subtle advertisements. The modern advertisers' ability to blend aspects of product information and health information into a highly entertaining advertisement has been hailed as one of the finest example of the industries' contribution towards creativity, and its ultimate success in providing one of the fundamental pillars of the modern day advertising business.

Advertising ingenuity

Many examples abound. Institutional advertising with emphasis on neither product nor service is meant to enhance corporate reputation, thereby indirectly ensuring credibility and loyalty for their products and services. Disease awareness campaigns that are in vogue in recent years are another example. There are arguments that disease awareness campaigns sponsored by pharmaceutical companies are thinly veiled attempts to advertise a particular health product. Hence, the collapse of barriers between product information and advertisement has been a significant development within the medical advertisement industry. There is no discounting the fact that modern media is a uniquely versatile medium for dissemination of health information whether in the form of advertisement or not.

The Medicine Advertisement Board

Regulating medicine advertisement

The Medicine Advertisement Board (MAB) under the chairmanship of the Director General of Health takes on a more pragmatic view of what constitutes an advertisement and how much control is exercised on information that is placed in an advertisement. It is aware of the winds of change that is sweeping the entire world in the field of advertisements and is mindful of the effects of globalisation that has brought on these changes. The Board tries to strike a balance between stakeholders. These range from advertisers who believe healthcare legislation that limits medical advertisements is outdated to consumer groups that believe that uncontrolled advertisements present a recipe for an impending health disaster.

Key points in advertising control

While the MAB does not impose any restrictions on *bona* fide medical information or news that is not associated with any particular product or health services rendered by a health institution or clinic, it considers any promotional attempts of specific products and services as clear advertisements and therefore subject to control under the Medicine (Advertisement and Sale) Act 1956. The following are some of the key points adopted by the MAB in its control of medical advertisements.

- The MAB does not impose restrictions on information directed exclusively to healthcare professionals.
- Editorial contents, *bona fide* health information and news of public interest that is not associated with any commercial product or service are not subjected to any regulatory control.
- Commercial sponsorship must not influence articles and editorial contents purporting to provide heath information. Editorial contents and health articles must be clearly discernible from advertisements.

Information must be reliable, accurate, truthful, balanced and up to date

The MAB expects information concerning medicinal products and services to be reliable, accurate, truthful and informative, balanced, up to date, capable of substantiation and consistent with claims approved by the Drug Control Authority if they are registered medicinal products. It can be hard to judge the accuracy and credibility of medical information that appears in the form advertisements in the mass media. Even people with medical background sometimes find this a daunting task.

While MAB is mindful of the World Health Organisation's stand on self-medication, it takes special interest in ensuring information appearing in advertisements do not result in consumers forsaking timely professional intervention for serious ailments.

Allowing advertisements by healthcare providers

Since mid-2005, the MAB has introduced major changes to information allowed in advertisements by healthcare providers. Health facilities like private hospitals and clinics are now allowed to advertise freely in newspapers and magazines, pamphlets and brochures and even on the internet. Restrictions on frequency of publication in the case of print media and distribution points in the case of pamphlets and brochures have been lifted allowing more meaningful and easier access to consumers. More importantly, the Board now allows medical practitioners to publish in advertisements their photographs, qualifications and areas of specialisaton and services offered.

Conclusion

It is acknowledged that health information must reach the consumer untainted by any bias or apparent self-interest. Skewed information that accrues monetary gains in some form ceases to be information per se but takes on a new role as an advertisement. There is consensus that health information in the mass media must be more responsible. In the case of advertisements, they must avail themselves to scrutiny and control by the relevant authorities so that information provided is accurate, fair and not misleading to consumers.

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HEALTH TECHNOLOGY ASSESSMENT IN MALAYSIA

SUMMARY

Health Technology Assessment (HTA) aims at promoting the adoption and use of appropriate, safe and cost-effective technologies in the provision of healthcare service. The establishment of the HTA Unit in the Ministry of Health in 1995 has created greater awareness on proper technology assessments before their adoption, and demand for such service at the top management level. Besides conducting technology assessments and reviews to support evidence-based policy decisions, the Unit also develops clinical practice guidelines and clinical pathways. The HTA Unit has been designated as a WHO Collaborating Center for Evidence Based Health Care Practice for the Asia Pacific Region for four years effective from 27 July 2004. With rapid growth and development of medical technologies globally, the HTA Unit faces many challenges, the most crucial being capacity building to cope with increasing need and demand for its core services. While health technology assessments have been initiated in the public sector, in particular the Ministry of Health, there is a need to promote such practices in the private sector to optimize use of resources and enhance the quality of patient care service.

Introduction

Establishment of HTA Unit

The ever increasing demand for technologies, and a need to ensure the safety, effectiveness and cost-effectiveness of such technologies, has led to the establishment of a Health Technology Assessment (HTA) Unit in the Medical Development Division at Ministry of Health Malaysia in August 1995. The Unit caters to the health technology assessment needs for all Divisions and Programs in the Ministry of Health (MOH). Requests from the private sector are currently restricted to those received from members of the HTA Council and those sent through MOH policy-makers in the Ministry of Health. In addition, rapid assessments (referred to as technology reviews) to meet the needs of top policy-makers and various technical divisions, are carried out based on requests. For these technology reviews, reports are usually made available within a month or two after receipt of the issue. Reports on technology reviews and health technology assessments, after approval by HTA-CPG-Council are sent to the requesting units and relevant departments or agencies, which are inputs to formulation of the policies for implementation.

Mandatory HTA requirements

To ensure quality of health care through use of safe, effective and appropriate technology, MOH has made mandatory that all medical equipment within MOH hospitals using new technologies costing more than RM 200,000 per unit, should undergo a health technology assessment prior to acquisition.

CPGs came under the purview of HTA Unit

Since April 2001, clinical practice guidelines have been brought under the purview of the Health Technology Assessment Unit. Efforts have since been made to have clinical practice guidelines (CPG) on a more evidence-based footing. CPG's are assisting healthcare used as a means of translating policy to practice, assist healthcare providers in managing some of the common medical conditions seen in the clinical setting so that inappropriate decisions can be reduced, if not totally avoided.

Mission

To encourage the appropriate use of health technology by providing input to decision-makers through collection, analysis, dissemination of information on the safety, effectiveness, cost-effectiveness and health impact of technologies.

Function, core activities and other activities

Functions

The function of the Health Technology Assessment (HTA) unit include:

- providing input for policy making on adoption or use of technology;
- disseminating HTA information to healthcare providers; providing HTA expertise to healthcare facilities; advising on standards and norms;
- acting as a clearing house for HTA; and
- coordinating the formulation and implementation of evidence-based clinical practice guidelines.

Core activities

The core activities of the Health Technology Assessment (HTA) Unit include conducting technology assessment on prioritized issues at national as well as hospital level, carry out technology reviews and facilitate/coordinate the development of evidence-based clinical practice guidelines.

Other activities

Other activities include production of HTA newsletters, training on systematic reviews for development of CPG/s and conduct of HTA for clinical specialists and other allied personnel, co-coordinating

research activities for MOH Medical Program, provide consultancy on matters relating to technology assessment and CPG development, and networking with other HTA and CPG related organizations at regional and international level.

Creating awareness in evidence-based policy making

Strengthening evidence-based policy making

Many changes have taken place since the introduction of health technology assessment in the Ministry of Health. The immediate benefit is greater awareness amongst policy makers and health professionals on the importance of health technology assessment consideration in the formulation of health policies. There has been an increasing number of requests from top management in various Divisions of the Ministry of Health (MOH), as well as from outside the MOH to carry out health technology assessments, for example in the introduction of new programme, activity or service that utilizes a certain technology, purchase of expensive drugs and equipment, and others.

Mechanism for HTA

Expert committee

The process of health technology assessment starts with receival of requests from various sources and at various levels, including from the Health Minister and the Director-General of Health. Identified issues are prioritized using a set of criteria, adopted from other international HTA organizations.

Prior to conduct of an HTA issue, an appointed expert committee will be formed. Such expert committees are multidisciplinary, involving all those related to the issue. The scope and scale of the assessment will depend on the nature of the problem, the availability of resources, the expert committee capabilities in reviewing and interpreting evidence. The completed HTA report is then forwarded to the HTA Technical Advisory Committee. This committee then examines the methodology and technical content. If acceptable, it is then forwarded to the HTA-CPG Council, chaired by the Director-General of Health for approval. The approved reports are then forwarded to the requesting department or agencies.

Development of Clinical Practice Guidelines (CPG)

Technical advisory

A new work process has been drawn up, which among others, involves establishing a mechanism for clinicians to identify topics for CPG

development; the setting up of a Technical Advisory Committee to vet the quality of CPG; and formal approval of all new guidelines by the HTA-CPG Council chaired by the Director-General of Health before release.

committee on CPG

To improve acceptability of CPG, members of the expert committees responsible for developing CPGs are recommended to be as multidisciplinary as possible, involving healthcare providers from all sectors namely public, academic and private sectors. Draft CPGs are uploaded in the MOH website to invite feedbacks and comments. Where necessary, the draft CPG's will also be sent to external reviewers for further comments on the content of the CPG's.

Multi-disciplinary members

Clinical pathways

Implementation of CPG has always posed a problem, and this is compounded by the fact that there is no effective strategy to monitor the degree of utilization of the guidelines. Questionnaires on utilization would inevitably produce positive responses. These, however, may not reflect the actual situation. It is felt that this can best be achieved through the use of clinical pathways. It is expected that clinical pathways would eventually replace the current case notes. This will assist in providing data for auditing purposes. Using clinical pathways encourages adherence to the guidelines and change in practice. The clinical pathways that have been introduced in MOH hospitals are based on MOH evidence-based CPG's which takes into account local practices and constraints, in the management of individual patients.

Use of clinical pathways

Training

It has been identified that creating awareness on HTA is a crucial strategy in propagating the evidence-based approach amongst our health care professionals. An annual training course has been organized for the past ten years. Training on the conduct of health technology assessment is provided to specialists, hospital directors and other allied MOH personnel. Each year about 45 personnel are trained in one course.

Annual training course

To assist in the development of evidence based CPG, systematic review workshops were introduced in 2002. Two workshops are planned each year, with about 40 participants per course.

Systemic review workshops

The 1st Asian Regional Conference in Health Technology Assessment

Regional

was held in 2000 is jointly organized by the Ministry of Health of Malaysia in collaboration with the Malaysian Society of Quality in Health. Subsequently, the Ministry of Health in collaboration with the Malaysian Society of Health Technology Assessment organized the 2nd Asian Regional Conference in Health Technology Assessment in 2003. Both conferences had an overwhelming response with about 300 participants both internationally and locally. In September 2003 MOH once again with the Malaysian Society of Health Technology Assessment organized the first Evidence Based Nursing Conference in the ASEAN Region.

conferences on HTA in Malaysia

Hence, from 1996 to 2005, 10 health technology assessment courses were conducted and 347 clinicians and allied health personnel were trained. Since 2002 until 2005, 6 systematic review workshops were conducted and 286 clinicians were trained.

International recognition

One of the proudest achievements of the HTA Unit in MOH is its designation as a WHO Collaborating Center for Evidence Based Health Care Practice for the Asia Pacific Region, effective from 27 July 2004 for 4 years. The term of reference for this collaborating center is as follows:-

HTA Unit as WHO collaborating centre

- to contribute to creating awareness on the importance and application of evidence-based health service provision, health services evaluation and health technology assessment (HTA) in the Asia Pacific Region;

- to provide training in evidence-based health service provision, for example, through the use evidence-based clinical practice guidelines (CPG), health service evaluation and HTA;

- to provide technical advice and support in evidence-based health service provision, health service evaluation and HTA for countries in the Asia Pacific region, and to assist in setting up evaluation, HTA and CPG programmes or in strengthening existing ones;

- to provide opportunities for work attachments at the HTA Unit in Malaysia for countries in the Asia Pacific region;

- to carry out activities in collaboration with WHO to further strengthen existing evidence-based health service provision or

- health technology assessment activities;

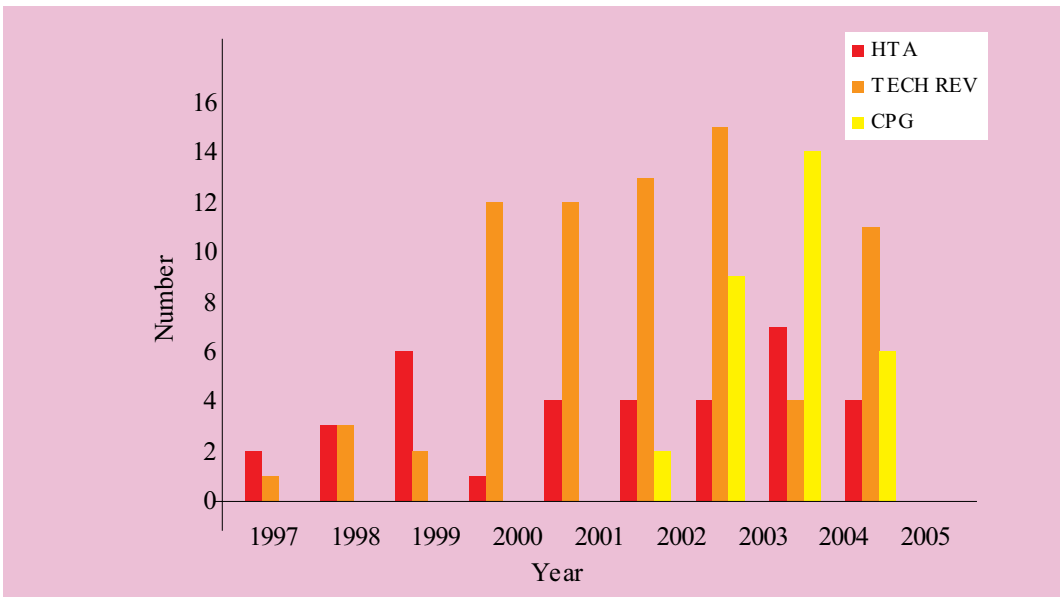
- to work with WHO to set up network for collaboration in health services evaluation, evidence-based practice of health technology assessment and CPG; and

- to collaborate with WHO and other associations to strengthen evidence-based policy-making in countries in Asia Pacific region.

HTA performances

Since the establishment of the Health Technology Assessment Unit in 1995 until 2005, HTA has produced 43 HTA reports, 85 technology reviews, 31 evidence-based CPGs and 3 clinical pathways **(figure 1).**

Figure 1 : HTA performances, Min. of Health,1997-2005



In year 2000 a web page for Health Technology Assessment unit was developed. This web page contains outputs of the HTA unit namely, HTA reports, CPGs and technology reviews. This web page is attached to the MOH main web page. The address is http://www.moh.gov.my.

Challenges in health technology assessment

1. ***Strengthening HTA capacity to support evidence-based decision making in 9MP development plans***

With the 9MP being planned, HTA unit is expected to play a bigger role in providing evidences for the development of services and facilities in the 9MP. HTA demands that personnel be skilled and have expertise in key areas like evidence search, critical appraisal, analysis and synthesis of data. Apart from carrying out technology assessment, HTA unit staff has to guide members of expert committees and provide formal teaching at related workshops / seminars. While in-house training is being provided, they would also benefit from training overseas and attending international conferences. The latter is constrained by limitation of funds. To enhance the credibility of the trainers it is proposed that more exposure such as overseas training for staff on conduct of HTA and CPG development as well as implementation based on evidence-based approach should be offered. This will ensure maintenance of the current high standards in all activities including the conduct of health technology assessment and training.

2. ***Sustaining HTA capacity***

Efforts by the HTA Unit in creating awareness amongst healthcare professionals and training given to them has yielded results in that evidence-based approach in decision making are being adopted in the hospitals and other health institutions. The existing critical mass of trained professionals in HTA should act as ambassadors to advocate the evidence based approach on the conduct of health technology. Knowledge and skill in the conduct of HTA can be inculcated through continuous medical education and establishing health technology assessment units in their settings.

3. ***Engaging the private sector in health technology assessments***

With rapid introduction of new technologies in the global market, coupled with the absence of regulation on medical devices in the country currently, it is important to ensure that Malaysia does not become a dumping ground for obsolete, unproven or unsafe technologies. While an organized health technology assessment mechanism exists in the public sector, especially in the Ministry of Health, this is not so in the private sector where adoption of

new technologies is largely left to individual hospitals based on market forces and economic considerations. Hence, there is a real need to transfer skills in HTA to the private sector, especially at the management level, to ensure all technologies used in the provision of patient care are safe and cost-effective.

4. ***Strengthening the implementation of CPG through clinical pathways***

   As is a common feature in most parts of the world, application and use of the guidelines pose a great challenge. Apart from areas of suggested improvement mentioned above, there needs to be a concerted drive towards producing clinical pathways based on CPG. This involves adaptation of the general recommendations of the CPG into specific work process reflecting the practice and preferences of the individual health professionals in the local setting. It is envisaged that these clinical pathways can be used in place of patients case notes since they would involve total management of the patient, and can allow for computerization as well.

5. ***Local research data for policy formulation through HTA and CPG***

   The lack of local data pertaining to technologies is another challenge that is frequently faced when carrying out a health technology assessments. Data on the epidemiology of common diseases are frequently not available. In addition, information on current practices and procedures, types of equipment being utilized, and existence of specific types of equipment, are also not readily available. More research on these areas should be carried out locally to fill the knowledge gaps and ensure that evidences used in the HTA reflects the local context.

Conclusion

Rapid advancements in medical technologies and pressure imposed by end users to introduce new technologies in the market pose a great challenge to the Health Technology Assessment Unit. Decisions on whether to disengage an old technology, continue using existing technologies, or introduce new technologies require careful consideration to ensure adoption of appropriate, cost-effective and safe technologies in our Malaysian health care system. This is crucial in ensuring the most efficient and cost-effective use of resources,

especially where resources are always limited while demands are never ending, in delivering good quality and affordable health care services to the population.

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DEVELOPMENT AND IMPLEMENTATION OF MEDICAL DEVICES REGULATION IN MALAYSIA

SUMMARY

Medical devices have always been the integral part and indispensable tools in medical diagnosis and therapy. However, these devices pose public health and safety issues and issues related to trade. This article provides an overview on the development and implementation of medical devices regulation to manage and address issues related to medical devices. It outlines the rationales for the development and implementation of medical devices regulation in Malaysia; the framework and the scope of the regulation; the important aspects in ensuring safety and effectiveness of medical devices; as well as the activities involved in medical devices regulation. This article also outlines how the regulation can help the Malaysian medical devices manufacturers to position themselves in the global arena. Finally, this article provides a brief account on the progress in the development and implementation of medical devices regulation in Malaysia.

Introduction

Definition of medical device

The term medical device refers to medical technology, supplies and equipment. It encompasses a very broad range of healthcare products used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but exclude drugs. In contrast with medicinal products the intended primary mode of medical device action to human body is not metabolic, immunological or pharmacological.

The Global Harmonisation Task Force (GHTF)* defines medical device as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article;

i) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of :

- diagnosis, prevention, monitoring, treatment or alleviation of diseases;
- diagnosis, monitoring, treatment, alleviation of or compensation for injury;

- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body; and

ii) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means [1].

In the provision of healthcare, the use of medical devices has always been an integral part and often indispensable tools in medical diagnosis and therapy. Medical devices encompass a wide array of products with myriad use. In 2001, it was reported that more than 50,000 different types of medical devices are available on the global market[2] ranging from simple contact lenses to precise robotic arm and sophisticated computed tomography machines, radiation-emitting equipment, lasers, implanted hip joints, defibrillators and heart valves. These devices can be categorised into 12 categories according to the Global Medical Devices Nomenclature (GMDN)* system[3].

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Footnote :-

** GHTF is a voluntary body which was established in 1993 by the governments and industry representatives of Australia, Canada, Japan, the EU and the USA in an effort to harmonise the regulatory practices to ensure safety and effectiveness of medical devices. The objective of the GHTF is to encourage convergence in the evolution of medical devices regulatory system at the global level. The regulatory system is aimed at protecting of public health and safety and facilitating trade.*

[7] GMDN is a nomenclature system developed to classify medical devices on the market developed by the European Standards Body CEN and sponsored by the European Commission, with full participation and parallel acceptance by the ISO. It is the only nomenclature system in use within the European Economic Area and is being endorsed by many legislators. It is endorsed by the GHTF as the global nomenclature system.

Rationales for Medical Devices Regulation

Medical devices market

It was estimated that in the year 2000, more than RM 500 billion worth of medical devices were available on the global market. With innovation and the rapid advancement of technologies, the global market figure for 2006 is expected to exceed RM 960 billion[4]. Malaysia imported about RM 1.8 billion worth of medical devices[5] in 2004 and approximately RM 300 million was spent annually to maintain and service these devices. The demand for medical devices will continue to grow due to the growing population, longer life expectancy, rising living standards, growing affluence and increasing consumer awareness. This growing trend will also take place in Malaysia with the implementation of upgrading and replacement programmes under the Ninth Malaysia Plan.

Issues related to medical devices

Medical devices pose a number of issues ranging from accessibility to safety, appropriate use as well as issues related to trade. The pace of innovation and increasing use of medical devices have caused many countries in the world to come up with regulatory controls designed to protect public health and safety and at the same time facilitate technological advancement and advances in patient care.

Public health and safety issues

Public health and safety

The safety and effectiveness of medical devices are important aspects that need to be addressed as all medical devices carry certain degree of risks and safety implications. Some of the public health and safety issues associated with medical devices in Malaysia are;

i) Unavailability of pre-market control to assess safety, effectiveness and quality of medical devices resulting in the dumping for sub-standard, unsafe and ineffective devices.

ii) Inadequate information for the public and health professionals to make informed choices on medical devices. This will deprive the patients from getting appropriate treatment and may even result in patient or user injury.

iii) Lack of control over the usage of various medical devices, the usage of various medical devices without appropriate training by non-medical professionals and the usage of medical devices that have not been properly maintained and calibrated.

iv) The absence of formal post-market reporting system to identify and monitor medical devices with problems in the market. Neither manufacturers nor importers are currently required to keep distribution records of medical devices or report adverse incidents related to medical devices to the authority.

Medical devices manufacturing, a national strategic industry

The Government has identified the medical devices industry as one of the strategic industries for economic growth in Malaysia. Various incentives have been introduced to attract companies to invest in this industry. Malaysia is currently a gateway to Asia's market, the fastest growing economy where 75% of the world's population resides. Asia's healthcare market constitutes approximately 34% of the global healthcare market and this share has increased to 45% by 2005. A diverse range of medical equipment and products are imported to cater the Asian growing healthcare needs. In ASEAN alone, the market constitutes a combined GDP of about RM 2,800 billion and a total trade of RM 2,700 billion[6].

Malaysia, world leading manufacturer of rubber-based products

Malaysia is the world's leading manufacturer of rubber-based products such as medical gloves, condoms and catheters. In total, these 3 products accounted for approximately 85% of the total exports[7]. In addition, Malaysian manufacturers also produce syringes, needles, procedure kits, surgical and dental instruments.

Today, the industry is currently shifting into manufacturing products made from plastics, silicone and metal alloys. There is also a huge potential for the industry to move into the manufacturing of more sophisticated devices such as those used in cardiovascular, orthopaedic, transplants, ultrasound imaging and patient monitoring systems. It is envisaged that many more downstream and non-manufacturing services related to medical devices industry will also be created along with the manufacturing sector.

Investments in medical devices manufacturing in Malaysia

In 2005, there were 159 medical devices manufacturers in Malaysia with a total investment of RM 6.3 billion, of which 40% was domestic investment whilst the remaining 60% was foreign. The exports of medical devices grew by 23% to RM 4.8 billion during the period of January to November 2005 compared to RM 3.9 billion during the corresponding period in 2004.

With this trend, it is natural for the Malaysian medical devices industry to be cautious and concern about ensuing competition with the rest of the world. To reduce trade barrier and to facilitate our local

manufacturers to market their products globally. Development of and compliance to regulation that is based on internationally acceptable standards is of paramount important

Regulating medical devices in Malaysia

Medical devices regulatory framework

In February 2005, the Ministry of Health was given the task to develop and implement a regulatory framework for the control of medical devices in this country. This framework will encompass the following;

i) Formulation of Medical Devices Act and its subsidiary legislations to provide legislative support for medical devices regulatory programme;
ii) Establishment of an appropriate agency to implement and enforce medical devices regulation;
iii) Appropriate training and capacity building to develop competent and trained manpower to ensure effective implementation of the regulation;
iv) Development of appropriate infrastructures and mechanisms for effective and efficient implementation of medical devices regulation;
v) Development of Medical Devices Registration and Surveillance/ Vigilance System; and
vi) Financial requirements for the development and implementation of regulatory programme.

Aims of medical devices regulation

Aims of regulation

The medical devices regulation is generally aimed at providing an appropriate framework for ensuring public health safety and facilitating trade. In the context of safety, the regulation will ensure the timely availability and access to only safe and state-of-the-art technologies in diagnosis and treatment modalities. At the same time the regulation will prevent sub-standard, unsafe and ineffective devices from reaching the market. In the context of trade, the regulation will provide a favourable environment to stimulate the development of the medical devices industry by ensuring safeguard mechanisms are put in place for fair and rules-based trade harmonisation with Malaysian trading partners.

Classification and level of control

Four risk classes

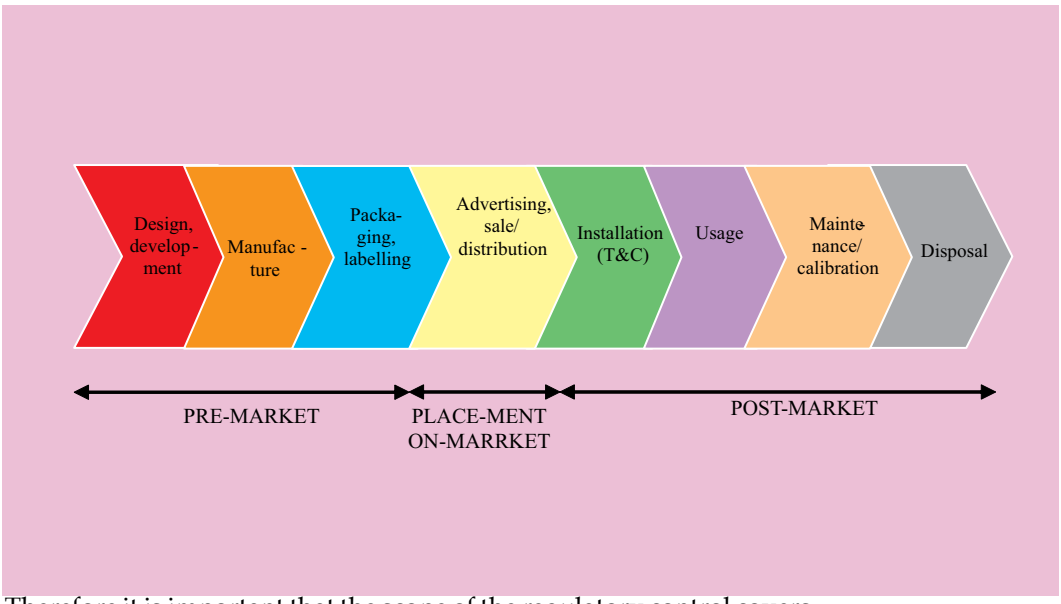
All medical devices carry certain level of risks depending on the intended purposes. The effectiveness of the applied risk management

techniques during design, manufacture and use will also contribute to the amount of risks associated with the devices. In regulating these devices, the degree of control should be proportional to the level of the associated risks, taking into account the benefits offered by use of the devices. Based on a set of rules, medical devices are classified into four risk classes. In general, low-risks devices are those that are applied external to the body; and if applied correctly, involve minimum risk to the patients. The higher risk devices are those that penetrate the human body, and involve a high- energy source, or used to sustain life[8].

Scope of medical devices regulation

The life span of a medical device is calculated from its design and development to manufacture and its subsequent disposal. These phases can be divided into three common stages, namely pre-market, placement on-market and post-market stages as illustrated in **Figure 1.** Each of these phases of the life span may affect its safety and performance.

Figure 1: The phases and corresponding stages in the l ife span of a medical device([4])



Therefore it is important that the scope of the regulatory control covers the manufacturing process, the device, the representation of the device, the manufacturer or local authorised representative (of foreign

manufacturer of imported medical device) and the user (including those involve in maintaining/calibrating the device).

Factors affecting safety and performance of medical devices and the corresponding regulatory activities

Pre-market stage

Concept, design and development

At the pre-market stage the concept, design, development and testing (including verification, validation and clinical evaluation) require the scrutiny of scientific experts to ensure that design parameters and performance characteristics do not impose unwarranted risks[4,12].

Manufacturing process

Good management of the manufacturing process is important in the production of medical devices[9]. Poor manufacturing management may bring about inconsistency in the quality of products even when the original prototype has been well designed.

Packaging and delivery

Following its manufacture, ensuring the delivery of clean, sterile and protected medical devices to the point of use through a well developed packaging system will be important. Proper labelling including the relevant hazard warnings or cautions and clear instructions are crucial in identifying a medical device and specifying instructions for its proper use[10]. Mislabelling of medical devices can result in serious consequences for the users[4]. In addition, the address of manufacturer or local authorised representative (of foreign manufacturer) must be available.

Pre-market review to ensure safety and quality

Pre-market review of a medical device is performed to ensure that a medical device satisfies not only safety and performance but also quality system and labelling requirements before market clearance is given. The degree of scrutiny during pre-market review depends on the potential risks of the device according to the risk-based classification system[4,9].

Registration only if complied with requirements

Thus, only products that have complied with the above requirements will be registered. It is the responsibility of manufacturers or local authorised representatives to demonstrate that their devices meet the requirements for product registration.

Placement on-market stage

Regulating vendor activities

When a medical device is placed on the market, advertisement has the potential to create expectations and influence the belief in the capabilities of the device. Misleading or fraudulent advertising of a medical device may deprive patient of more appropriate treatment and could lead to injury. For this, the vendors play a critical role and there is a need to regulate their activities. Registering the local vendors will enable authorities to track the responsible parties in the event of difficulty or emergency situation associated with medical devices. This control also enables the authority to carry out regular inspections and audits to ensure ongoing compliance[4,9].

Registration of local manufacturers and importers

All local manufacturers involved in the manufacture, alteration or re-packaging of medical devices to be sold in Malaysia and local authorised representatives of imported devices need to be regulated and registered. Local authorised representatives for imported medical devices must maintain linkage with their foreign manufacturers and should be able to obtain the support of their foreign manufacturers whenever required. To ensure correct product representation and to prevent misleading or fraudulent advertisements or claims, advertisement control is performed.

Post-market stage

Familiarity of users with technology

Assuring medical devices safety entails more than the functioning of the device, it requires oversight of the use of the devices at the post-market stage. Unfamiliarity with a certain technology or operating procedure, and the use of a device for clinical indications outside its scope can cause device failure even in the absence of inherent design or manufacturing defects. In addition, the re-use of disposable devices not in accordance with the instructions, and without proper control or precautions for minimising associated risks, can be detrimental.

Proper installation

To ensure devices function properly, there is a need for proper installation (including testing and commissioning) prior to usage and scheduled maintenance and calibration. The lack of, or inappropriate, testing, maintenance and calibration of such devices may jeopardise their safety and performance. The disposal of devices should follow specific safety rules as the possibility of their contamination can present hazards to the public and the environment.

Post-market

Post-market control is essential after market clearance. Monitoring

the performance and reporting the problems associated with the use of medical devices are important components of regulatory control as failures or incidents arising from the use of a device could not be predicted or totally prevented during the pre-market stage. At the post-market stage, manufacturers or local authorised representatives are required to perform two major activities, namely post-market surveillance study and adverse event reporting.

surveillance

In post-market surveillance study, manufacturers are required to establish a system to collect post-market surveillance data of medical devices.

Adverse event reporting is important to carry out timely intervention and it provides an opportunity for identification and remedial action for problematic medical device such as modification or product recall. It also allows for timely dissemination of information that is necessary to prevent recurrence of similar incident. Adverse incident reporting requires manufacturers or local authorised representatives to report adverse incidents that reasonably suggest that death or serious injury has been caused or contributed by the use of a medical device. The manufacturers or their representatives are required to investigate and carry out follow-up actions, such as product recall, and report the results to the authority. Healthcare professionals are also encouraged to notify manufacturers or local authorised representatives of adverse incidents. Injuries arising from the use of medical devices by non-health professionals should also be reported[4,9,11].

Reporting of adverse events

Operation and usage

Some sophisticated medical devices require specialised and trained personnel to ensure their safe operation and performance. The objective of operation and usage control is to prevent unnecessary harms or complications arising from the improper use of medical devices.

Trained operators

Thus, owners and users of such sophisticated devices are required to get the approval to possess and use these devices. In addition, they must also undertake to comply with a set of requirements which include requirements for qualification and training, safety precautions and maintenance/calibration.

Quality system

The key advantage of a quality system is it represents a preventive

Quality system

approach to assuring medical device quality. The introduction of a quality system has been proven to be more efficient and cost effective in controlling manufacturing processes and maintaining medical device quality.

to ensure device quality and safety

A quality system identifies the organisational structure, responsibilities, procedures, processes and resources required to implement quality management. It imposes strict quality assurance on every aspect of the production of medical devices. By complying, this reduces the likelihood of non-conforming products, ensures consistency in the quality of a device and provides the basis for greater reliability in its safety and performance[4,12]. The quality system is subject to periodic audits and management reviews by the authority or third party agencies[4,9].

Harmonisation and the use of standards

Harmonisation of medical devices regulatory requirements

In developing the Malaysian medical devices regulatory framework, the Ministry of Health will be guided by the current global harmonisation trend as promoted by the GHTF and Asian Harmonisation Working Party (AHWP)[7] and supported by the World Health Organisation (WHO)[4]. The harmonised system supports the commitment of the ASEAN Economic Ministers for the development of a common system for medical devices in ASEAN by the end of 2006. A common system for medical devices is one of the identified measures to realise the vision of the ASEAN leaders on the establishment of the ASEAN Economic Community (AEC) by the year 2020. The AEC is envisaged as a single market and production base with free flow of goods, services, investment, skilled labour and free flow of capital.[13]

The harmonised system encourages convergence in standards and regulatory practices and hence minimises regulatory barriers, facilitates international trade and reduces the cost of implementing the regulations. It also promotes technological innovation and more importantly enables our products to gain access and compete in the global market.

Footnote :-

[7] *AHWP is an informal group of experts from medical devices regulatory authorities and the medical device industry from the Asian region. It was formed around 1996–97 to work towards a harmonised medical devices regulatory system in Asia in line with the GHTF approach*

Conformity to national and international standards

Standards are widely used to demonstrate conformance to essential principles of safety and performance of medical devices[14]. This includes conformity to process, product and management standards. The use of national or international standards in establishing medical devices regulation is essential as it helps in simplifying the regulatory process and promoting the global harmonisation efforts.

Industry assistance and international relations

Regulatory control to facilitate local manufacturing industry

The Government recognises the contribution of the medical devices industry to the growth of the Malaysian economy. One of the essential requirements to be a global player in the production of medical devices is to ensure that the devices produced are in compliance with the international standards for safety, quality and effectiveness. In this context, the Ministry of Health will formulate appropriate regulation to facilitate local manufacturers to position themselves in the global arena.

Besides developing the regulatory framework, the Ministry of Health has initiated bilateral and multilateral negotiations with other countries. This is an important step to help the Malaysian medical devices industry to broaden the global market access. The Ministry of Health is taking the lead role in the AHWP and the Medical Device Product Working Group (MDPWG) under the ASEAN Consultative Committee for Standards and Quality (ACCSQ)[7] to spearhead the harmonisation of medical devices regulatory requirements in the ASEAN and Asian regions. Both the ASEAN and Asian groups are embarking on various projects towards harmonisation, one of which is the development of a common submission dossier template for medical devices product approval within the ASEAN and Asian regions

Progress in the development and implementation of medical devices regulation

Policy in the control of medical devices and legislative support

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Footnote :-

[7] MDPWG was formed in 2005 as a result of the decision of the ASEAN Leaders on the establishment of the AEC by the year 2020 and fast-track integration of eleven priority sectors including healthcare sector. MDPWG assists the ACCSQ in implementing specific measures to facilitate the integration of the medical devices sector under the ASEAN Roadmap for Healthcare Integration

The policy and the framework for medical devices regulatory programme was approved by the Cabinet in February 2005. A core team known as the Medical Devices Bureau has been established for this purpose. The responsibility of this Bureau in addition to developing the regulatory framework, is also to formulate policies, undertake planning, registration and licensing, activities monitoring and surveillance, provide industry assistance and seek international relations.

Establishment of Medical Devices Bureau

The policy will be supported by *Medical Devices Act*. The object of this Act is to provide for the establishment, implementation and maintenance of a system of control related to performance and safety of medical devices. The *Medical Devices Act* is targeted for promulgation by the end of 2006.

Standards and guidance documents

Development, adoption and adaptation of standards related to medical devices are undertaken by the Industrial Standard Committee for Medical Devices (ISC R) which was established in collaboration with the Standards and Industrial Research Institute of Malaysia (SIRIM) and Department of Standards Malaysia. ISC R has identified various international standards to be adopted and adapted as Malaysian standards.

Establishment of the Industrial Standard Committee for Medical Devices (ISC R)

Guidance documents form a set of references for the regulatory system. The documents elucidate various aspects of the regulation in greater detail. These include amongst others, details of the regulatory requirements, the implementation mechanisms, the regulatory tools, the roles and responsibilities of the authority and all the parties involved. The drafting of guidance documents is undertaken by the Medical Devices Technical Committee of the Ministry of Health with the assistance of three working groups, namely Working Group on Pre-Market Assessment, Quality System and Auditing, Working Group on Post-Market Surveillance and Vigilance and Working Group on Proper Usage of Medical Devices.

Guidance documents for regulatory system

Registration and surveillance / vigilance

Registration of medical devices and their manufacturers or local authorised representatives is considered to be the first and most important component in medical devices regulatory control. A medical device will only be listed in a registry after it has complied with

Registration – first stage of regulatory control

the essential requirements for safety and performance. For medical devices manufacturers, listing in the registry is an important means to demonstrate that their devices have undergone the scrutiny of the competent authority in pre-market review and have complied with the essential requirements for safety and performance.

Info for public

A registration system must contain all the relevant information discussed in the earlier sections. In addition, a list of medical devices that have obtained market clearance will be made available for public and clinical community to assist them in making informed choices on medical devices that are safe and effective to treat or diagnose health problems.

Traceability

In the post-market stage, traceability is crucial as it allows immediate corrective actions to be taken. A post-market surveillance/ vigilance system includes major post-market components such as distribution record, recall procedures, reporting and complaint handling.

Regislation and surveillance/ vigilance system by 2008

The design and development of registration and surveillance/ vigilance systems will be done in stages and are expected to be ready for implementation by the end of 2008. A centre that receives and manages information from all sources will be established. The system will provide facility for information sharing with local users as well as users from other countries.

Voluntary Registration Scheme for Medical Devices Establishment (MeDVER)

Launching of MeDVER

An important milestone in the development and implementation of medical devices regulatory programme in Malaysia is the implementation of the voluntary registration scheme for medical devices (MeDVER). The latter which was launched on 12th January 2006 was introduced for the following purposes:

i) to familiarise all the affected parties with the registration process;
ii) to gauge the readiness of medical devices establishments in conforming to the regulatory requirements;
iii) to prepare a smooth transition into the mandatory phase and full enforcement of medical devices regulation in Malaysia;
iv) to obtain a profile of the Malaysian medical devices industry. MeDVER is an on-line voluntary registration scheme and those dealing with medical devices in Malaysia are encouraged to voluntarily register their establishments and list their medical

devices with the Ministry of Health Malaysia[15].

Conclusion

The need to develop and implement the medical devices regulation in this country is recognised by the Government. The aims of the regulation are to protect public health and ensure safety from the risks arising from the use of medical devices and to facilitate trade. The proposed regulation is in line with current global harmonisation approach. It encompasses the entire life cycle of a medical device and it covers the device itself, the manufacturing process, the representation of the device and the manufacturer. Various activities in the development of the regulation have been initiated. The launching of MeDVER was an important step towards achieving the full implementation and enforcement of medical devices regulation by 2008.

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Chapter 4

RESEARCH AND DEVELOPMENT

MEETING OUTPATIENT EXPECTATIONS AT PUBLIC HOSPITAL SPECIALIST CLINICS IN PENINSULAR MALAYSIA

SUMMARY

The health care industry has undergone tremendous improvements and changes in recent years. Providers have gone beyond satisfaction; attempting to delight their consumers by meeting their wants or unarticulated needs. The objective of this study was to measure the extent of meeting such needs through services provided at the specialist clinics. Using the self administered questionnaire (SERVQUAL), 14 hospitals with specialists were selected by stratified random sampling. Only 8.0% of patients were unhappy with the services provided. However, the participating hospitals had not been able to meet 73.9% of the patients' expectation. There appeared to be significant association between patient satisfaction and age, ethnicity and educational level. Younger patients were more dissatisfied than the older age group, whilst the higher the educational level achieved, the more dissatisfied they were. Most dissatisfied dimension as reported from the SERVQUAL questionnaire was for Reliability. Patients were not happy with the waiting time at the specialist clinic and with staff promptness. Besides recruiting more staff, the management must develop strategies to create a conducive waiting environment to reduce the agony of waiting.

Introduction

Definition

The health care industry has undergone tremendous improvements and changes in recent years. Many organizations are now focusing on continuously improving the quality of the services that they provide in order to attain patient satisfaction. One of the earlier definitions of patient satisfaction was developed by Linder-Pelz in 1982 who defined patient satisfaction as the *"individual's positive evaluations of distinct dimensions of health care"*[1].

In recent times, health care providers have attempted to go beyond ensuring patient satisfaction. According to Carson et al[2], providers can ultimately delight consumers by meeting their wants or unarticulated needs. "Delighted" customers are those whose expectations or needs were not only met, but have been exceeded. The purpose of this study was to explore the capacity of the specialist clinics in government

facilities to meeting such needs and expectations. Local study[3] had found the were more problems at the outpatient department in hospital with specialist as compare to outpatient department in hospitals without specialist. Courtesy was found to be less practiced at specialist clinics.

Methods

SERVQUAL

To measure patient satisfaction, the study had used the self-administered SERVQUAL[4] which assessed satisfaction through 5 dimensions namely:

(i) Tangibles	Physical facilities, equipment, and appearance of personnel
(ii) Reliability	Ability to perform the promised service dependably and accurately
(iii) Responsiveness	Willingness to help customers and provide prompt service
(iv) Assurance	Knowledge and courtesy of employees and their ability to inspire trust and confidence
(v) Empathy	Caring, individualized attention

Study Instrument

The instrument was modified by the researcher to accommodate our local setting. Additional dimensions were further added to the instrument by the researcher.

SERVQUAL

- Tangible Q1+Q2+Q3
- Reliable Q4+Q5+Q6
- Responsiveness Q7+Q8+Q9
- Assurance Q10+Q11+Q12
- Empathy Q13+Q14+Q15

Outcome

- Outcome Q16 (treatment)

Corporate Culture

- Caring Service Q4+Q8+Q9+Q12
- Teamwork Q11+Q18
- Professionalism Q3+Q6+Q16+Q19+Q20

Sampling and analysis

A cross-sectional study was conducted amongst government hospitals with specialists. A two-phased sampling strategy was used. Using stratified random sampling, 14 hospitals from a total of 39 hospitals with specialists were selected. The EPI INFO software programme was used to calculate the patient sample size needed and patient selection done using systematic random sampling. Self-administered questionnaires were given to the study respondents at the pharmacy. The "Statistical Package for Social Sciences" (SPSS) was used for analysis.

Findings

A total of 7,417 patients from 14 hospitals were selected. Their mean age was 36.08 years, with the majority of the respondents being Malays (74.5%) as shown below **(Table 1)**.

Table 1 : Respondents' characteristics

Ethnicity	Malay	5443 (74.5%)
	Chinese	1049 (14.4%)
	Indian	709 (9.7%)
	Others	108 (1.5%)
	Total	7,309 (100.0%)
Gender	Male	3263 (44.5%)
	Female	4062 (55.5%)
	Total	7,325 (100.0%)
Marital Status	Single	1608 (22.0%)
	Married	5694 (78.0%)
	Total	7302 (100.0%)
Education level	No formal	389 (5.4%)
	Primary	1529 (21.2%)
	Secondary	3843 (53.2%)
	Tertiary	1465 (20.3%)
	Total	7226 (100.0%)

Considering perception alone, about 8.0% of patients were dissatisfied with the services provided by the hospitals at the specialist clinics. However using SERVQUAL, the dissatisfaction rate increased to 73.9%; with only 20.2% and 3.3% being moderately and severely dissatisfied respectively **(Table 2).**

Table 2 : Level Of Patient Satisfaction

Satisfaction level	Frequency	Percent
Most satisfied	5	-0.10%
Moderately satisfied	27	-0.40%
Mildly satisfied	1838	-25.60%
Mildly dissatisfied	3627	-50.40%
Moderately dissatisfied	1455	-20.20%
Severely dissatisfied	240	-3.30%
Total	**7192**	**-100%**

There appeared to be a significant association between patient satisfaction and age (p = 0.002), ethnicity (p = 0.000), occupation (p = 0.000) and educational level (p = 0.000).

Younger patients, Malays, those with higher educational status and working in the public sector were more dissatisfied **(Table 3, Table 4, Table 5** and **Table 6** respectively). About 38% of the workers in the public sector had tertiary education compared with 23% of private sector workers **(table 7).**

Table 3 : Age Group And Patient Satisfaction

Age group	Satisfied	Not satisfied	Total
< 40 years	949 (24.4%)	2939 (75.6%)	3888 (100%)
40 – 55 years	437 (24.1%)	1374 (75.9%)	1811 (100%)
>/= 56 yearse	329 (29.4%)	791 (70.6%)	1120 (100%)

P=0.002

Table 4 : Ethnicity And Patient Satisfaction

Ethnic group	Satisfied	Not satisfied	Total
Malay	1269 (24.0%)	4010 (76.0%)	5279 (100%)
Chinese	297 (29.3%)	718 (70.7%)	1015 (100%)
Indian	229 (33.1%)	463 (66.9%)	692 (100%)
Others	32 (30.2%)	74 (69.8%)	106 (100%)

P=0.000

Table 5 : Education And Patient Satisfaction

Education Level	Satisfied	Not satisfied	Total
No formal education	135 (35.4%)	246 (64.6%)	381 (100%)
Primary education	463 (31.0%)	1032 (69.0%)	1495 (100%)
Secondary education	948 (25.5%)	2770 (74.5%)	3718 (100%)
Tertiary education	254 (17.9%)	1168 (82.1%)	1422 (100%)

P=0.000

Table 6: Occupation And Patient Satisfaction

Occupation	Satisfied	Not satisfied	Total
Public sector	325 (20.5%)	1257 (79.5%)	1582 (100%)
Private sector	406 (24.3%)	1263 (75.7%)	1669 (100%)
Self employed	319 (31.2%)	704 (68.8%)	1023 (100%)
Others (Housewife, student, pensioner, etc)	399 (30.8%)	895 (69.2%)	1294 (100%)

P=0.000

Table 7 : Education Level And Working Sector

	Public sector	Private sector	Self employed	Others
No formal education	12 (0.7%)	22 (1.3%)	85 (8.3%)	147 (11.2%)
Primary education	133 (8.2%)	246 (14.4%)	342 (33.2%)	347 (26.4%)
Secondary education	862 (53.0%)	1043 (61.2%)	511 (49.7%)	638 (48.6%)
Tertiary education	619 (38.1%)	393 (23.1%)	91 (8.8%)	181 (13.8%)
Total	**1626 (100%)**	**1704 (100%)**	**1029 (100%)**	**1313 (100%)**

P=0.000

In addition, it was also observed that the more times the patient visited the specialist clinics, the more dissatisfied they were as shown in **table 8** below.

Table 8: Patient Satisfaction And Frequency Of Visits To Specialist Clinic

Education Level	Satisfied	Not satisfied	Total
No. of visit	Satisfied	Not satisfied	Total
First time	510 (30.7%)	1151 (69.3%)	1661 (100%)
Second time	377 (28.2%)	961 (71.8%)	1338 (100%)
Third time	177(25.2%)	526(74.8%)	703 (100%)
More than three times	645 (21.1%)	2405 (78.9%)	3050(100%)

P=0.000

The mean for patient satisfaction score in this study was -0.5651 **(table 9).** With regard to the dimension of SERVQUAL, least dissatisfaction was in the dimension of "Assurance" and the greatest dissatisfaction was for the dimension on "Reliability". In the dimension concerning the Ministry of Health Corporate Culture, *the least dissatisfaction was reported for the dimension on "Professionalism" and the greatest dissatisfaction was in the dimension of "Caring".*

Considering the individual questions **(table 10)**, out of the three questions under the dimension of "Reliability" (Q4, Q5 & Q6) which obtained the greatest dissatisfaction, Q5 had the highest negative

value. Q5, *Waiting times in Hospital are appropriate* obtained a score of -0.7833. Among the twenty questions, Q8 *It is realistic for patients to expect prompt service from hospital staff*, obtained the highest negative score (-0.8343). However Q3 *Hospital staff always appear neat*, obtained the lowest negative score (-0.3578).

Table 9: Satisfaction Score According To Dimension/Grouping

	Dimension/ Grouping	Mean	Std. Error of Mean	Std Deviation
1	Tangible	-0.5327	0.00930	0.79806
2	Reliability	-0.6420	0.01104	0.94709
3	Responsiveness	-0.6189	0.00975	0.83646
4	Assurance	-0.5080	0.00863	0.74074
5	Empathy	-0.5693	0.00975	0.83638
6	Outcome	-0.4747	0.00956	0.82131
7	Caring service	-0.6428	0.00961	0.82258
8	Teamwork	-0.4927	0.00843	0.72320
9	Professionalism	-0.4656	0.00767	0.65656
10	**Total**	**-0.5651**	**0.00813**	**0.68963**

Discussion

Dissatisfaction

For our study, dissatisfaction was defined as n*ot being able to meet patients' expectations*. Hence, following this definition, only 8.0% of patients were dissatisfied with the services provided by the specialist clinics. Nevertheless using SERVQUAL, our services had not been able to meet the expectations of 74.7% of the patients. In the USA, Scardina[5], using the same instrument to measure levels of satisfaction with nursing care, also found low levels of satisfaction. Similar findings were also reported by Fayek[6] in their study of the quality of NHS health care in a survey of 174 patients in the UK. Hart[7], attributed his low level of satisfaction findings to the methodology used in the calculation of satisfaction. Nevertheless, other researchers using different sets of instrument, have come up with different findings. In a meta-analysis of 221 studies, Hall[8] found patient satisfaction to be moderately high ranging between 76% and 84% of all patients studied. Calnan and colleagues[9] also found high levels of satisfaction amongst those receiving in-patient care in hospitals in UK. Carmel[10], using her own instrument, found that 80% of patients in her hospital in Israel, were satisfied with the services provided.

Table 10 : Mean Of Satisfaction For Individual Question

No.	Parameter	Mean	Std. Error of Mean
1	*Hospital always has up-to-date equipment.*	-0.6637	0.01225
2	*Facilities at the waiting area are visually appealing*	-0.5750	0.01238
3	*Hospital staff always appear neat*	-0.3578	0.00897
4	*Hospitals provide their services at the time they. promise to do so*	-0.6438	0.01298
5	*Waiting time in Hospital are appropriate.*	-0.7833	0.01426
6	*Hospital performs the services right every time.*	-0.4976	0.01091
7	*Hospital staff tells patients exactly when services will be performed.*	-0.4775	0.01119
8	*It is realistic for patients to expect prompt service. from hospital staff*	-0.8343	0.01331
9	*When patients have problems, hospital staff will be willing to help with sincere interest.*	-0.5397	0.01049
10	*Relevant hospital staff gives clear information about the illness suffered by the patient.*	-0.4720	0.01006
11	*Hospital staff is knowledgeable.*	-0.5031	0.00995
12	*Hospital staff is polite.*	-0.5482	0.01102
13	*Hospital staff will always understand the. patients' needs*	-0.5404	0.01144
14	*Hospital staff gives patients personal attention.*	-0.5770	0.01123
15	*Hospital has patients' best interest at heart.*	-0.5884	0.01084
16	*Hospital will give effective treatment.*	-0.4747	0.00956
17	*Public toilets in Hospital are clean.*	-0.6582	0.01249
18	*Hospital staff works together among them in giving treatment.*	-0.4796	0.00977
19	*Hospital staff displays good work discipline.*	-0.4709	0.00975
20	*Hospital staff does their jobs with high commitment.*	-0.5277	0.01030

The mean for patient satisfaction score in this study was -0.5651. Fayek[6] in his study of the quality of NHS health care found the overall mean SERVQUAL score was -0.9950. However this does not mean that our hospitals are better than NHS. These findings suggest that the patients obtaining services from NHS were more dissatisfied than those in our study. Possible reasons for the differences may be attributed to differing patient characteristics and expectations between the two sites.

The younger patients in our study had been reported to be more

dissatisfied that the older age group. Our findings were supported by those by Pascoe[11], Young[12] and Breemhaar[13] whom all reported older patients as being more satisfied.

There were no significant relationship between satisfaction and gender in this study. Studies on the relationship between gender and satisfaction had varying results. Similar findings to our study were reported also by Carmel[10], Hall[15] and Weiss[16]. However, Pascoe[11] and Zastovny[14] identified women as being more satisfied than men.

Among the ethnic groups, the Malays were more dissatisfied in contrast to findings by Weiss16 and Hall[15] both found no relationship between satisfaction and ethnic group. Our study also reported an association between educational level and satisfaction. This phenomenon was fairly well documented in other studies. Linn[17], Hall[15] and Anderson[18], all came to a similar conclusion where they all found dissatisfaction greatest among the more educated.

Our study also reported those serving in the public sector were more dissatisfied than others. Probably this may also be attributed to educational status as more than one-third of the workers in the public sector had tertiary education. Further, probably the more times the patient visited the specialist clinic the more dissatisfied they were as they may have discovered or experienced more negative things following these visits.

Using SERVQUAL, our study reported least dissatisfaction for the dimension of "Assurance" and the greatest dissatisfaction was in the dimension of "Reliability". Similar findings had been reported by Fayek6 on NHS hospitals. Our study indicated that the patients were dissatisfied with the waiting time at the specialist clinics because Q5, *(Waiting times in Hospital are appropriate)* obtained the second highest negative score. Usually long waiting times are caused by (i) the system not functioning (ii) too many patients (iii) shortage of staff.

The "staggered appointment system" can sometimes jeopardise the system. The patient comes at 10.00am according to her appointment but is only seen by the doctor at 11.30am is worse off than a patient who comes at 8.30am, takes a number and waits for her turn, finally being seen by the doctor at 12.30pm. Patients often perceive it as normal to wait for their turn even though they have to wait for several hours. Patients also perceive unresponsiveness as not only delay on taking

action but also when proper explanation was not given at the time the services were not provided as promised. For example, if the doctors came late to the clinic because of urgent and important matters in the wards, patients should be informed. However it is not professional if clinics always started late and all sort of excuses are given frequently. If a clinic starts late, the backlog will be felt at the pharmacy, where there will be overcrowding of patients waiting to get medicine before lunch time. Sometimes, doctors come late to the clinic because of grand ward rounds. A way around this is for one or two doctors to start the clinic running before the grand rounds are finished. Apart from ineffective system, there were too many patients and the hospital does not have the required staff to provide prompt services. Other than recruiting more staff, management should develop a strategy to create a conducive waiting environment to reduce the agony of waiting.

The next dissatisfaction was in the dimension of "Responsiveness". Patients were also not happy with the staff promptness in giving services as evidence from Q8 *(It is realistic for patients to expect prompt service from hospital staff)*, obtained the highest negative score. Management should identify the delay in service delivery were due to manpower shortage or staff attitude. Management must ensure that all staffs are given the opportunity to undergo training that can improve their competency and capability to perform their daily work effectively. Problematic staff should be sent for counseling.

Conclusion

The SERVQUAL was a useful instrument to be used for the measurement of patients' expectations. The 5 dimensions assessed in this instrument will facilitate the identification of strengths and weakness; and it is hoped that health care facilities nationwide will learn to use this instrument to further help improve the quality of services provided.

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JOB SATISFACTION AMONG STAFF IN SELAYANG HOSPITAL

SUMMARY

The purpose of this study was to document job satisfaction level and issues arising from the information technology (IT) environment in Selayang Hospital. This cross-sectional study utilised a self-administered questionnaire involving all staff at the hospital. About 60% of staff professed job satisfaction. However, there were a high proportion of doctors claiming job dissatisfaction, heavy workload and severe work stress. There was a significant association between perceptions of job satisfaction, overwork, and stress at work. Staff who perceived to be overworked were likely to perceive being under severe stress, and were more likely to be dissatisfied with their job. The main factors that contribute to job dissatisfaction were inadequate support service, demanding patients and bad attitude among staff. In terms of the Total Hospital Information System (THIS), majority agreed the system has many benefits, but that too much time was spent entering data than in communicating with patients. There was unhappiness with the response time to solve IT problems. These problems had contributed to longer waiting times for patients.

Introduction

Defining job satisfaction

Locke (1976)[1] defines job satisfaction as an emotional reaction that "results from perception that one's job fulfils or allows the fulfilment of one's important job values, providing and to the degree that those values are congruent with one's needs". Not every employee is happy with his or her job. Overwork can cause stress. Job dissatisfaction is sometimes associated with overwork and stress. Studies have also shown that overwork leads to stress[2]. Although a little stress is motivational, severe stress can lead to job dissatisfaction and burnout. It all depends on how someone takes it'. However, severe stress is associated with job dissatisfaction and health problems[3-5].

Current challenges in the MOH

There are many challenges in the Ministry of Health (MOH) that put a strain on its personnel. Due to bureaucracy, the decision-making process in the MOH is slow. Lack of resources, especially manpower, and an increasing number of patients using public health facilities also overload current facilities. An increasingly educated community has led to more complaints if individual rights are not met.

Increasngly too, MOH hospitals are based on information technology (IT). Selayang Hospital was the first hospital built with the Total Hospital Information System (THIS). The purpose of this study was to document the level of job satisfaction among staff working in the IT environment of Selayang Hospital. The study also sought to identify issues of staff working with THIS, and where possible, to develop strategies to address these issues.

Methodology

Sampling and use of questionnaire

This is a cross-sectional study using a self-administered questionnaire developed by the research group. The questionnaire was pre-tested to test its validity. The dependent variables were job satisfaction, stress and workload. The study involved all staff working in Selayang Hospital. Staff were given a week to complete the questionnaire and reminders were sent to their immediate supervisors to increase the response rate. Descriptive analysis of data was undertaken using the Statistical Package for Social Sciences (SPSS).

Findings

Profile of respondents

There was 1,853 staff working in Selayang Hospital and 81.2% (1,515) responded. However, there were several non-responses to individual items in the questionnaire with only 1,494 responding to job category and ethnic grouping **(Table 1)**. The respondents were mainly nurses (65%) and more than 90% were Malays **(Table 1).**

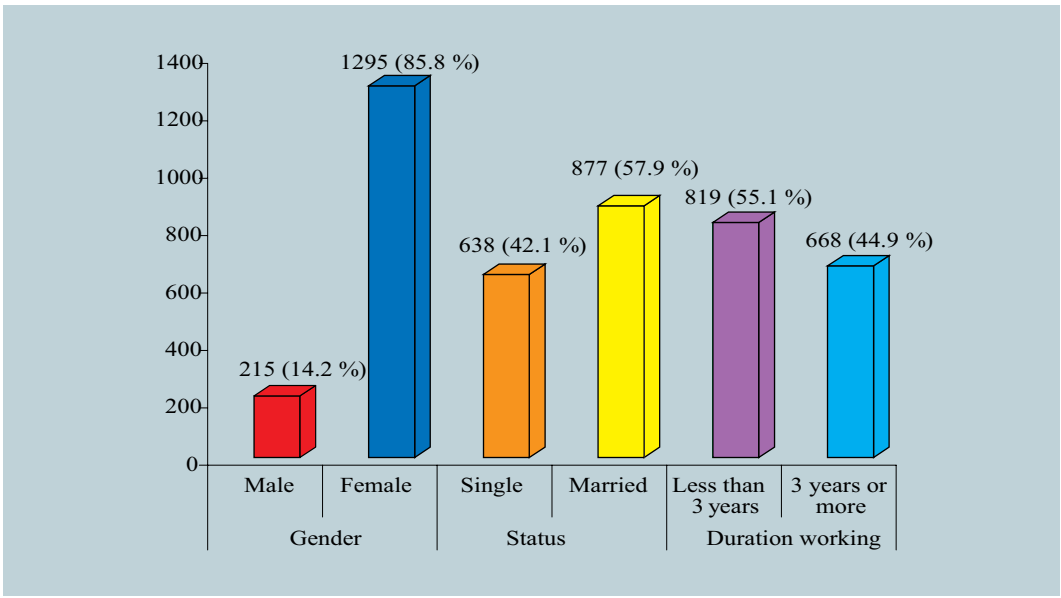
Table 1 : Job Category and Ethnicity of Respondents in Selayang Hospital

Category	Malays	Chinese	IndianOthers		Total
Specialist	29 (1.9%)	10 (0.7%)	8 (0.5%)	1 (0.1%)	48 (3.2%)
Medical Officer	83 (5.6%)	16 (1.1%)	16 (1.1%)	1 (0.1%)	116 (7.8%)
Nurse	928 62.1%)	11 (0.7%)	26 (1.7%)	6 (0.4%)	971 (65%)
Medical Assistant	47 (3.1%)	1 (0.1%)	5 (0.3%)	0	53 (3.5%)
Others	266 17.8%)	10 (0.7%)	28 (1.9%)	2 (0.1%)	306 (20.5%)
Total	**1,353 (90.6%)**	**48 (3.2%)**	**83 (5.6%)**	**10 (0.7%)**	**1,494 (100%)**

21 respondents did not state their occupation

Mean age was 29.4 years. Majority were females, married and had being working in Selayang Hospital for less than 3 years **(Figure 1).**

Figure 1: Profile of Respondents



Level of job satisfaction

More than 60% of staff was happy with their job **(Table 2).** However, only half of doctors were satisfied (49.7%) and this was significantly different from others (p=0.001). However, there appeared to be no significant association between job satisfaction and gender, marital status, ethnicity or educational level.

Table 2 : Job Satisfaction Among Staff

Job Satisfaction Level	Doctor	Nurse	Others	Total
Satisfied	80 (49.7%)	600 (62.3%)	251 (66.9%)	931 (62.1%)
Dissatisfied	33 (20.5%)	134 (13.9%)	58 (15.5%)	225 (15%)
Uncertain	48 (29.8%)	229 (23.8%)	66 (17.6%)	343 (22.9%)
Total	**161 (100%)**	**963 (100%)**	**375 (100%)**	**1,499 (100%)**

16 did not respond

Perception on workload

In terms of workload, 57.7% of doctors perceived they were overworked **(Table 3)**, a higher proportion than other categories. Apart from occupation, there appeared to be no significant association between workload and gender, marital status or ethnicity.

Table 3: Perception on Workload among Staff

Perceived Overwork	Doctor	Nurse	Others	Total
Yes	94 (57.7%)	355 (36.7%)	139 (37.0%)	588 (39.0%)
No	44 (27.0%)	352 (36.4%)	157 (41.8%)	553 (36.7%)
Uncertain	25 (15.3%)	260 (26.9%)	80 (21.3%)	365 (24.2%)
Total	**163 (100%)**	**967 (100%)**	**376 (100%)**	**1,506 (100%)**

9 did not respond

Perception on work stress

More than 45% of doctors claimed having severe work stress **(Table 4),** followed closely by nurses (43%). Apart from category of occupation, there appeared to be no significant association between severe work stress and gender, marital status or ethnicity.

Table 4 : Perception of Work Stress among Staff

Perceived work stress	Doctor	Nurse	Others	Total
Yes	73 (45.1%)	326 (43.0%)	117 (31.3%)	516 (34.5%)
No	57 (35.2%)	420 (43.8%)	189 (50.5%)	666 (44.5%)
Uncertain	32 (19.8%)	213 (22.2%)	68 (18.2%)	313 (20.9%)
Total	**162 (100%)**	**959 (100%)**	**374 (100%)**	**1,495 (100%)**

20 did not respond

Overwork and work stress

There seems to be a relationship between perception of being overworked and working under severe stress (p=0.000). Staff who perceived themselves to be overworked were also likely to claim being under severe stress **(Table 5).**

Table 5 : Overwork and Working under Severe Stress Among Staff

Perceived overwork	Perceived under severe stress			
	No	Yes	Uncertain	Total
No	465 (70.2%)	30 (5.8%)	54 (17.3%)	549 (36.8%)
Yes	88 (13.3%)	423 (82%)	72 (23.1%)	583 (39.1%)
Uncertain	109 (16.5%)	63 (12.2%)	186 (59.6%)	358 (24.0%)
Total	**662 (100%)**	**516 (100%)**	**312 (100%)**	**1,490 (100%)**

P = 0.000

Overwork and job dissatisfaction

There also seems to be a relationship between overwork and job satisfaction level (p=0.000). Staff who perceived themselves to be overworked were also likely to have job dissatisfaction **(Table 6).**

Table 6 : Overwork and Job Satisfaction Among Staff

Perceived overwork	Job Satisfaction			
	No	Yes	Uncertain	Total
No	493 (53.3%)	14 (6.2%)	43 (12.5%)	550 (36.8%)
Yes	229 (24.8%)	180 (80.0%)	170 (49.6%)	579 (38.8%)
Uncertain	203 (21.9%)	31 (13.8%)	130 (37.9%)	364 (24.4%)
Total	**925 (100%)**	**225 (100%)**	**343 (100%)**	**1,493 (100%)**

P = 0.000

Severe stress and job satisfaction

Perception of working under severe stress also seemed to be associated with job satisfaction (p=0.000). Staff who perceived themselves under severe stress was also likely to have job dissatisfaction **(Table 7).**

Table 7 : Severe Stress And Job Satisfaction Among Staff

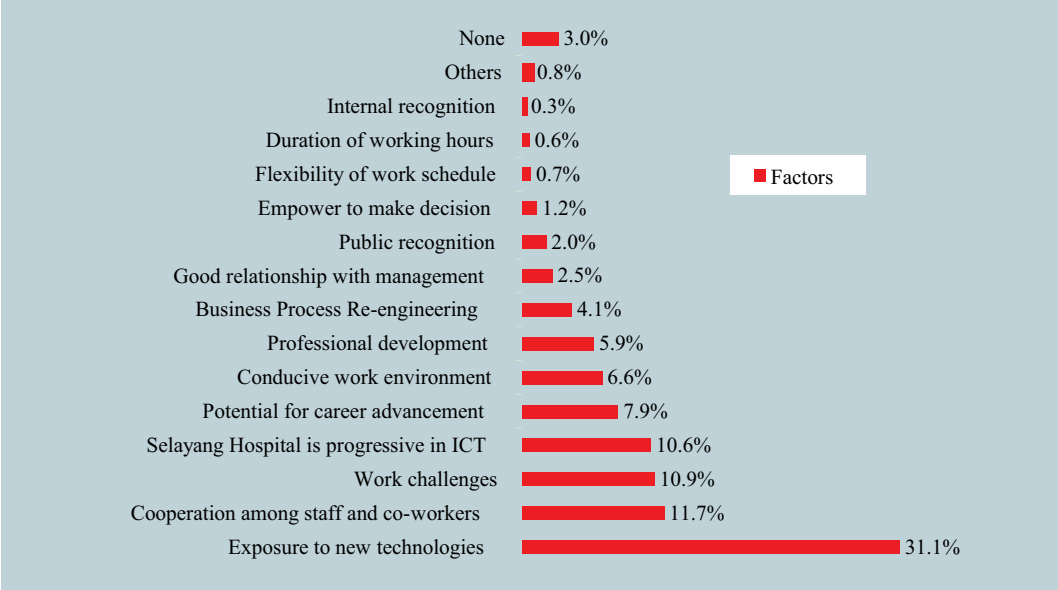
Perceived severe stress	Job Satisfaction			
	No	Yes	Uncertain	Total
No	585 (63.4%)	21 (9.5%)	60 (17.5%)	666 (44.8%)
Yes	174 (18.9%)	176 (79.3%)	159 (46.4%)	509 (34.2%)
Uncertain	163 (17.7%)	25 (11.3%)	124 (36.2%)	312 (21.0%)
Total	**922 (100%)**	**222 (100%)**	**343 (100%)**	**1,487 (100%)**

P = 0.000

Factors that influence job satisfaction

When asked on factors that contribute to job satisfaction, exposure to new technologies was cited as the main factor that accounted for job satisfaction **(Figure 2).** The other positive factors for job satisfaction were co-operative staff and co-workers, and work challenges. .

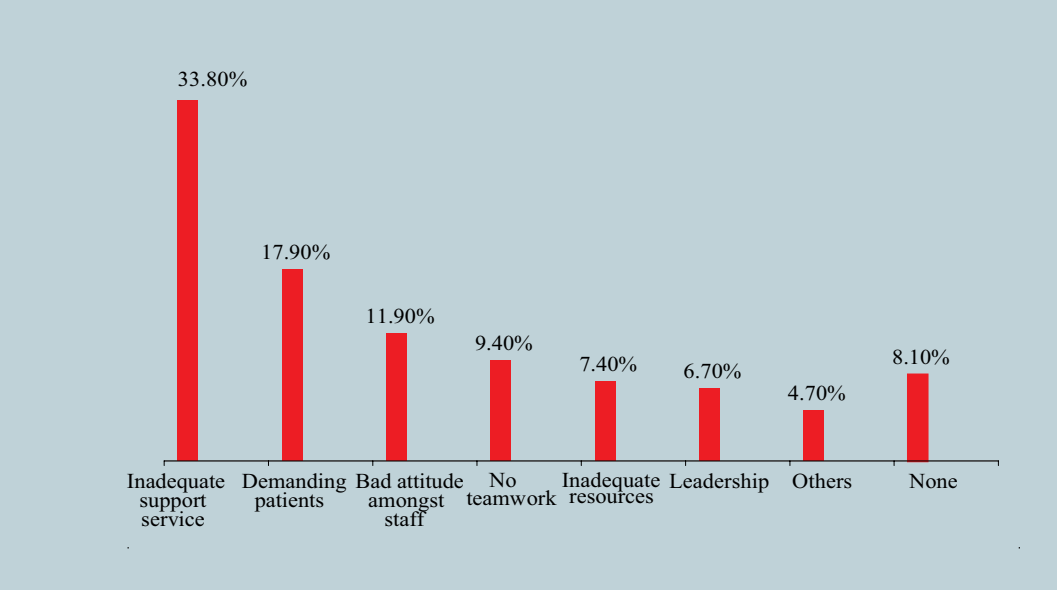
Figure 2: Factors that contri butes to staff job satisfaction



Factors that contribute to job dissatisfaction

The main factors cited to contribute to job dissatisfaction were inadequate support service, demanding patients, bad attitude among staff, no teamwork, inadequate resources and leadership problems **(Figure 3).**

Figure 3 : Factors that contributes to staff job dissatisfaction



Total Hospital Information System (THIS) in Selayang Hospital

Perception on THIS among staff

Nearly 60% of staff agreed that THIS in Selayang Hospital facilitates daily work by easing retrieval of patient data. They also agreed that the system facilitates integration and interfacing of clinical work among departments. However, 25.5% of clinical specialists and more than 30% of medical officers felt that the system did not ease their workload **(Table 8).**

Table 8 : Perception of Workload and THIS in Hospital Selayang

Eases workload	Clinical Specialist	Medical Officer	Nurses	Medical Assistant	Others	Total
Yes	22 (46.8%)	46 (40.4%)	577 (59.7%)	35 (66.0%)	184 (60.7%)	864 (58.2%)
No	12 (25.5%)	35 (30.7%)	171 (17.7%)	9 (17.0%)	66 (21/8%)	293 (19.7%)
Uncertain	13 (27.7%)	33 (28.9%)	219 (22.6%)	9 (17.0%)	53 (17.5%)	327 (22.0%)
Total	**47 (100%)**	**114 (100%)**	**967 (100%)**	**53 (100%)**	**303 (100%)**	**1,484 (100%)**

31 did not respond

Further, less than half of staff perceived that THIS in Selayang Hospital is user-friendly **(Table 9).**

Perception on ease of use

Table 9 : Perception of THIS as User-friendly in Selayang Hospital

Eases friendly	Clinical Specialist	Medical Officer	Nurses	Medical Assistant	Others	Total
Yes	16 (33.3%)	42 (36.2%)	438 (45.6%)	24 (46.2%)	159 (53.0%)	679 (46.0%)
No	20 (41.7%)	40 (34.5%)	146 (15.2%)	12 (23.1%)	40 (13.3%)	258 (17.5%)
Uncertain	12 (25%)	34 (29.3%)	377 (39.2%)	16 (30.8%)	101 (33.7%)	540 (36.6%)
Total	**48 (100%)**	**116 (100%)**	**961 (100%)**	**52 (100%)**	**300 (100%)**	**1,477 (100%)**

31 did not respond

Majority of staff (60.7%) claimed that they spend more time entering data into the system than communicating with patients. This was more pronounced among the medical officers compared to other staff **(Table 10).**

Decreased interaction with patients

Table 10 : IT and Patient Communication

More time entering data than communi-cating with patient	Clinical Specialist	Medical Officer	Nurses	Medical Assistant	Others	Total
Yes	28 (59.6%)	85 (73.3%)	600 (62.2%)	30 (57.7%)	147 (51.2%)	890 (60.7%)
No	15 (31.9%)	20 (17.2%)	167 (17.3%)	13 (25.0%)	31 (10.8%)	246 (16.8%)
Uncertain	4 (0.3%)	11 (9.5%)	198 (20.5%)	9 (17.3%)	109 (38.0%)	331 (22.6%)
Total	**47 (100%)**	**116 (100%)**	**965 (100%)**	**52 (100%)**	**287 (100%)**	**1,467 (100%)**

48 did not respond

Majority of doctors were not happy with support services in terms of the time taken to solve problems related to ICT **(Table 11).**

Solving IT downtime

Table 11 : Perception on Response Time to Solve ICT Problems

Good respond time	Clinical Specialist	Medical Officer	Nurses	Medical Assistant	Others	Total
Yes	14 (29.2%)	35 (30.7%)	443 (45.9%)	19 (35.8%)	122 (39.9%)	633 (42.6%)
No	21 (43.8%)	61 (53.3%)	283 (29.3%)	22 (41.5%)	95 (31.0%)	482 (32.4%)
Uncertain	13 (27.1%)	18 (15.8%)	239 (24.8%)	12 (22.6%)	89 (29.1%)	371 (25.0%)
Total	**48 (100%)**	**114 (100%)**	**965 (100%)**	**53 (100%)**	**306 (100%)**	**1,486 (100%)**

29 did not respond

Majority of staff agreed that on-the-job training using THIS is adequate for them to improve their skills in operating the ICT system **(Table 12).**

Adequacy of hands-on training

Table 12 : Perception on THIS On-the-job Training

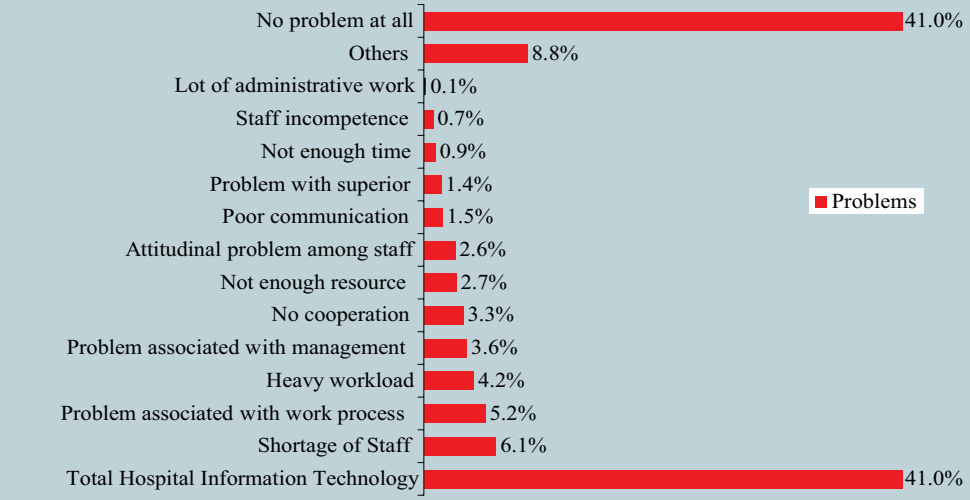
Adequate on-the-job training	Clinical Specialist	Medical Officer	Nurses	Medical Assistant	Others	Total
Yes	23 (47.9%)	52 (44.8%)	610 (63.1%)	29 (55.8%)	167 (54.8%)	881 (59.2%)
No	15 (31.3%)	41 (35.3%)	195 (20.2%)	16 30.8%)	68 (22.3%)	335 (22.5%)
Uncertain	10 (20.8%)	23 (19.8%)	162 (16.8%)	7 (13.5%)	70 (23.0%)	272 (18.3%)
Total	**48 (100%)**	**116 (100%)**	**967 (100%)**	**52 (100%)**	**305 (100%)**	**1,488 (100%)**

27 did not respond

Majority of the problems (41%) faced by the staff were, overwhelmingly related to information technology **(Figure 4),** while an equal 41% perceived no problems at all.

Problems faced by staff

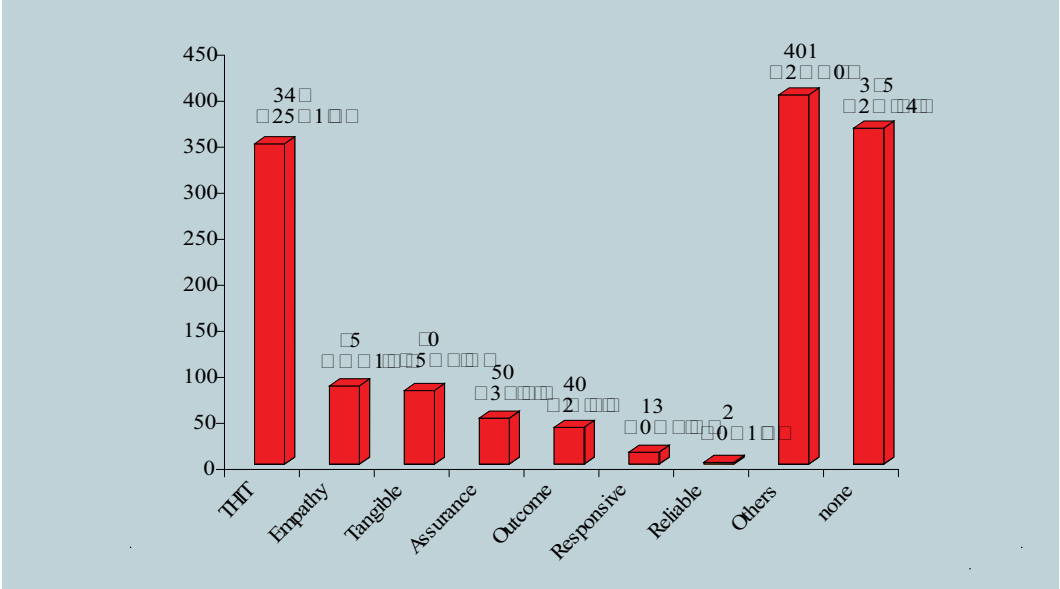
Figure 4 : Problems faced by staff



If given a chance to change or improve condition, 25.1% of the respondents would like to improve the conditions related to THIS **(Figure 5).**

Hypothetical change to system

Figure 5: Changes That Staff Would Like to Make (Grouped Under Dimension)



Discussion

Job dissatisfaction among doctors

There was a good response rate from staff of Selayang Hospital. Althoug, almost two-thirds of staff had job satisfaction, a high proportion of doctors professed job dissatisfaction, heavy workload and severe work stress. The results of a national survey on job satisfaction among general practitioners in England reported about 22% of doctors intending to quit6. The intention to quit was due mainly to a reduction in job satisfaction. Based on workshops with doctors in the United States and United Kingdom, Nigel Edwards et al. (2002)7 concluded that heavy workload and low pay were obvious causes of unhappiness among doctors. In this study, the main factors that contribute to job dissatisfaction were inadequate support service, demanding patients and bad attitude among staff.

Association between overwork, stress and job dissatisfaction

This study also found an association between perceived overwork and severe stress. Staff who perceived to be overworked and under severe stress were also likely to have job dissatisfaction. The results concur with that of a survey conducted by Rasidah et al. (2006)8 on medical doctors working in public hospitals in Malaysia. Other studies have also linked increased stress and reduced job satisfaction with high nursing workloads[9-11].

Disadvantages of THIS

Although the majority was of the opinion that THIS has many benefits, staff, especially doctors, also felt that too much time is spent on entering data than communicating with patients. Majority of problems faced were related to IT. Personnel were not happy with the response time from the ICT support team to solve IT problems. These problems had contributed to longer waiting times for patients. There is therefore, a need for more stringent monitoring of the vendor responsible to maintain and to solve the ICT problems in reasonable time.

Need to address issues

Hospital management should focus on doctors' claims of being overworked and under severe stress. Stress management should be introduced to increase coping skills. Some work processes may also need to be reviewed or re-engineered to address this issue.

Conclusion

This study found advantages and disadvantages of the THIS in Selayang Hospital from the perspective of staff. While the IT-based system is seen to increase integration and interfacing between departments, it is also seen to detract from communication time with

patients due to the need to enter data real-time. Many of the problems cited seem to be associated with the need for more timely responses to solve IT problems.

Many of the factors that contribute to perceptions of job dissatisfaction, overwork and stress may or may not be associated with the IT-based system per se, as these factors may apply equally to other staff in other healthcare facilities. It is recommended that the hospital management of Selayang Hospital address issues within control such as introducing stress coping skills, reviewing and re-engineering processes and exercising more stringent control and monitoring of the ICT vendor responsible for maintenance of the system.

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NATIONAL LABORATORY BIOSAFETY

SUMMARY

Public concern has increased regarding the use of biological materials as agents of terrorism and as potential risk of spread from the laboratory to the public, or environment due to inappropriate handling and practices. However, these same agents are essential in clinical and research microbiology laboratories. Traditional biosafety guidelines for laboratories have emphasized use of optimal work practices, appropriate containment equipment, well-designed facilities, and administrative controls to minimize risk of worker injury and to safeguards against laboratory contamination. In Malaysia, although there are various public health laws they are mainly for the prevention and control of infectious diseases, the issue of laboratory biosafety need to be addressed as a matter of urgency. The National Laboratory Biosafety and Biosecurity Committee has been set up by the Ministry of Health to formulate a national biosafety policy and address local biosafety issues. A national biosafety policy, under the Ministry of Health will renew the commitment of the government, in ensuring adequate levels of protection in biomedical laboratories, to ensure that there will be no adverse effects on human health and the environment.

Introduction

Biohazardous materials in laboratories

Biological materials, pathogenic and nonpathogenic, are used and cultured in many laboratory procedures. These biological materials include but are not limited to bacteria, virus, parasites, fungi, prions, recombinant products, allergens, cultured animal cells, infected clinical specimens and tissue from experimental animals. These agents are termed biohazardous because they are capable of producing deleterious effects to the health of the individual exposed to the agent. Laboratories handling biohazardous agents have a unique work environment and may pose infectious disease risk to person in or near them, to the environment and public should the material escape the containment procedures established for the laboratory.

Recent new emerging infectious diseases

Over the last decade, the scientific community has witnessed the emergence of new infectious agents, for example Nipah and SARS corona virus. These agents post a threat to laboratory personnel working in laboratories with inadequate containment facilities.

Considerable information has been compiled in recent years from a variety of sources concerning the accidental infection of laboratory workers working with pathogenic microorganisms[1,2].

Concern over Safey of laboratory personnel

Global events in the recent past have also highlighted the need to protect laboratory personnel and materials. When the SARS epidemic ended in July 2003, the World Health Organization was worried about a new epidemic emerging from SARS samples stored in many laboratories working with the virus. Those fears were confirmed by three laboratory accidents documented in Singapore (August 2003), Taiwan (December 2003) and in China (March 2004)[3].

Principles Of Biosafety

Containment of biohazard materials in laboratories

Laboratory biosafety is a term used to describe containment principles, technologies and practices that are implemented to prevent accidental exposure to pathogens and toxins. "Containment" is used in describing safe methods for managing infectious materials in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents. The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or potentially infected materials must be aware of potential hazards, and must be trained and proficient in the practices and techniques required to handle such material safely.

Biosafety and biocontainment are important international issues

Despite a great awareness of biosafety and biocontainment practices, handling infectious micro-organism remain a source of infection or even mortality among laboratory workers. The World Health Organisation (WHO) has long recognized that safety, including biological safety, are important international issues. The WHO in their three editions of "Laboratory Biosafety Manual" has encouraged countries to accept and implement basic concepts of biological safety and to develop a national code of practice for the safe handling of pathogenic micro-organism in laboratories [4].

National Laboratory Biosafety

The Government of Malaysia has various laws in place for the prevention and control of infectious diseases in Malaysia. These include, Prevention and Control of Infectious Diseases Act 1988, Malaysia Civil Aviation Regulation 1996, Environmental Protection

Act 1990, Occupational Safety and Health Administration (OSHA) Act 1994 and Regulation (2000).

Guidelines on import and export of micro-organisms

Recently, there is an increase in the number of government public health laboratories, research institutions, universities and private laboratories handling microbiological agents and pathological specimens. These institutions also import microorganisms and infectious materials for research and commercial purposes. Understanding the threat that these may pose to the spread of infectious diseases, the Disease Control Division, Ministry of Health (MOH) in 2001, revised the guidelines for the import and export of infectious materials. These guidelines outline the procedures involved in the safe handling, packaging for the import and export of microorganism, and also assist in the issuance of license permit to the relevant authorities.

Occupational Safety and Health Act 2000

The OSHA regulation 2000 provides the means whereby the associated occupational safety and health legislations and approved industry codes of practice operate in combination with the provisions of the Act designed to maintain or improve the standards of safety and health. The Act also ensures personnel protection at the place of work with control of risks to safety or health arising out of their activities at work. It also promotes an occupational environment for persons at work which is adapted to their physiological and psychological needs. Although these laws related to safety are in place, there is still an urgent need to address laboratory biosafety.

The WHO at the 58th World Health Assembly on 25 May 2005 urged member states to "review the safety of their laboratories and their existing protocol for the safe handling of microbiological agents and toxins consistent with WHO biosafety guidance"[5].

National Laboratory Biosafety and Biosecurity Committee.

The Director General of Health Malaysia, Datuk Dr. Hj Mohd Ismail Merican convened a meeting on 10 May 2005 to set up the National Laboratory Biosafety and Biosecurity Committee. The proterm committee comprised of heads of government departments, senior government officers and representatives from local universities **(table 1)**. National Biosafety and Biosecurity issues were discussed at the meeting. The committee agreed in principle that biosafety is an issue of national importance.

The Terms of Reference (TOR) are :

i) To develop and establish a National Laboratory Biosafety & Biosecurity Policy

ii) To assess the biosafety and biosecurity capability of all laboratories that handle biological agents and toxin
iii) To raise awareness on the importance of biosafety amongst personnel working in diagnostic and biomedical research laboratories
iv) To provide appropriate training programs for upgrading skills and competencies of laboratory personnel particularly those handling pathogens of high risk (BSL-3 and BSL-4)
v) To formulate the National Biological Agents and Toxins Act

Three sub-committees were set-up under the main committee:

Committee members

(1) Policy and Act: Chairman: Director of National Institute for Natural Product, Vaccines and Biological (NINPVB)
(2) Assess capability: Chairman: Director of Medical Development Division
(3) Education and training: Chairman: Directors of IMR & NINPVB

Table 1: List of members for the National Laboratory Biosafety and Biosecurity Committee (NLBBC)

Chairman	Director General of Health Malaysia
Secretary	Director, NINPVB
Members	Ministry of Health : Institute for Medical Research Disease Control Division National Public Health Laboratory Hospital Development Division Ministry of Education : University of Malaya (UM) Universiti Kebangsaan Malaysia (UKM) University of Science Malaysia (USM) University Malaysia Sarawak (UNIMAS) University Islam Malaysia (UIA)

Ministry of Agriculture :
Malaysian Agricultural Research and Development Institute (MARDI)
Veterinary Research Institute (VRI)

Ministry of Natural Resource and Environment:
Forest Research Institute Malaysia (FRIM)
Secretariat for Biosafety

Ministry of Defense :
Malaysia Palm Oil Board (PORIM)

The sub-committee for Biosafety Policy and Act would be formulating the National Biosafety Policy and later, the Biologicals and Toxins Act. The Education and Training sub-committee would develop educational programmes on biosafety for laboratory personnel in biomedical facilities in the form of printed material to enable them to understand their rights, roles and responsibilities and to carry out their duties in a safe manner. The role of the sub-committee on the assessment of laboratory capabilities is to have an active database on all biomedical laboratories in Malaysia.

Scope of activities of NLBBC

The scope of activities for the National Laboratory Biosafety and Biosecurity Committee would cover all Ministry of Health employees who could reasonably be anticipated to face contact with potentially infectious materials as a result of performing their job duties occupational exposure; BSL3 and BSL4 laboratory workers and managers and trainers on biosafety and biosecurity. This is to ensure that the people involved in biosafety decision-making are competent and confident to handle specific training needs of the department. The scope would also include all diagnostic and biomedical research laboratories personnel, including universities, private laboratories and Army (MINDEF).

Conclusion

The WHO recommends each laboratory organization to have a comprehensive safety policy, a safety manual and supporting programmes which are specific to the institution needs. Most biomedical laboratories in Malaysia adhere to these and have implemented their local guidelines on biosafety with biosafety policies and programme which are specific to the scope of activities in their laboratories.

Local biosafety guidelines are mostly adopted from international guidelines for example the WHO Laboratory Biosafety Manual and the Centre for Disease Control, United States (6). A National Biosafety Framework, involving all biomedical laboratories, government and non-government is important to address technical, scientific, legal and socio-economic and political issues governing biosafety in Malaysia. It is apparent that a National Laboratory Biosafety Policy, under the Ministry of Health will renew the commitment of the government, in ensuring adequate levels of protection in biomedical laboratories; to ensure that there will be no adverse effects on human health and the environment, based on international biosafety guidelines, for the benefit of the present and future generations. This policy would support all related legislation and biosafety policies and programmes existing in biomedical institutions and is intended to be complementary and not to replace or undermine them.

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