



MINISTRY OF HEALTH MALAYSIA

MALAYSIA'S HEALTH 2008

Foreword



The right to health is being recognised as a basic human right in the WHO Constitution. It is increasingly acknowledged that health is not just a result of development and poverty reduction, but also a precondition for development. Investing in health is investing in development. The Ministry of Health has over the years introduced various health programmes to improve patient safety and the population's health. The actual implementation and their success depend on the rigourity of the planning processes and the quality of plans. In turn, this is dependent on the comprehensiveness and accuracy of information available for use at all levels.

This edition of the report attempts to provide information on a comprehensive range of topics relating to health care services, population health, health system management and research undertaken by the Ministry of Health. It is broad ranging and attempts to not only provide a brief overview of the issues and challenges faced by the various programmes in their implementation, but also on the latest initiatives and their potential benefits. For example, the principles of primary health care have been universally accepted and yet the implementation varies widely throughout the world. How we have fared and where we move from here is shared in this edition. Other topics covered include overviews of newer initiatives such as Stem Cell research and the introduction of computer based multiple risk factor intervention in the prevention of cardiovascular and chronic kidney diseases (CORFIS). Prevention of non-communicable diseases (NCD) and their subsequent management remains a concern and challenge. There is much room for improvement and we need to revisit the way we have done things and be innovative. The work done on CORFIS is an attempt towards this.

In our pursuit to provide the best care possible to the Malaysian population, it is my hope that the valuable information shared in this report will provide a better understanding of the health issues surrounding us and also the various endeavours that the Ministry has undertaken.

A stylized, handwritten signature in black ink, likely belonging to Dato' Sri Dr. Hasan Bin Abdul Rahman.

DATO' SRI DR HASAN BIN ABDUL RAHMAN
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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Vision for Health

Mission of the Ministry of Health

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Part 1

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Chapter 1

HEALTH CARE SERVICES

SUSTAINING THE INTEGRATED SCHOOL-BASED FISSURE SEALANT PROGRAMME

SUMMARY

Fissure sealants play an important role in caries prevention because they can protect caries susceptible surfaces, specifically the occlusal pits and fissures. The integrated school-based fissure sealant programme in Malaysia has been implemented for more than 10 years and has been reviewed from time to time. A targeting strategy has been employed for this programme, targeting schoolchildren considered “at high risk” to occlusal caries. Over the last 5 years, the percentage of children and teeth in need of fissure sealant rendered treatment increased annually. This means unmet fissure sealant need has decreased yearly. A longitudinal study on school-based fissure sealant programme showed that the programme is effective in preventing dental caries. This programme can be effectively carried out by dental officers and dental nurses at mobile dental team settings, irrespective of materials used. The aim of the programme is that all children and all teeth in need of fissure sealants will receive fissure sealants. Survey data showed oral health status of 12-year-old Malaysian schoolchildren has improved over the years. The National Oral Health Goal 2010 of having a mean decayed, missing and filled teeth (mean DMFT) less than 1.5 and 60% of schoolchildren with caries free permanent dentition has been met. This signifies Malaysia is among countries with very low caries level based on World Health Organisation (WHO) classification. To further improve the oral health of schoolchildren, the school-based fissure sealant programme need to be continued, strengthened and sustained.

Introduction

Fissure sealants are materials commonly placed on occlusal fissures and palatal/buccal pits of permanent molar teeth to prevent the occurrence of dental caries. There are two main types of fissure sealant materials, namely resin-based sealants and glass ionomer cement (GIC) sealants.

Fissure sealants prevent occlusal caries

Fissure sealants play an important role in caries prevention, protecting the susceptible caries surfaces in the occlusal pits and fissures that are least protected by fluoride. Pits and fissures are surfaces most prone to dental caries compared to other tooth surfaces due to their morphological characteristics.

Strong evidence on effectiveness of fissure sealants



A number of systematic reviews had found strong evidence of effectiveness of fissure sealant in preventing dental caries amongst children and adolescents. The Cochrane Review in 2008 showed over 50% reduction in dental caries in fissure-sealed teeth compared to teeth without sealants after four years. Another study by Griffin and co-workers found dental sealants reducing caries in pits and fissures by 60%, from two to five years after placement. Truman and colleagues also showed that exposure to school-based or school-linked sealant delivery programmes was associated with a median relative decrease in dental caries of 60% (range 5% - 93%) with follow-up periods between 2 to 5 years.

Background

In Malaysia, fissure sealant programme has been implemented for more than 20 years. The programme was started as a pilot project in the Federal Territory of Kuala Lumpur in 1987-1988. Subsequently, this was extended to other states. Data from several surveys on schoolchildren in Malaysia have shown a decline in caries prevalence and severity over the last forty years. However the National Oral Health Survey of Schoolchildren in 1997 (NOHSS'97) found that the majority of caries were on the occlusal surfaces.

*Pilot programme in
FT Kuala Lumpur*

On the strength of this evidence and current literature on fissure sealants at that time, the Oral Health Division of the Ministry of Health (MOH) implemented an integrated school-based fissure-sealant programme in 1999. The programme has been undertaken by teams of dental officers and dental nurses as part of the 'outreach' incremental dental care programme. A review of the programme resulted in a revised guideline in 2002, which emphasised on the need for evaluation on the impact of the national programme, and suggesting a longitudinal study of fissure sealant on a cohort of schoolchildren.

*Integrated school-
based Fissure
Sealant Programme*



Objectives

The objectives of the integrated school-based fissure sealants programme are :

1. To implement a school-based fissure sealant programme starting at year 1 primary school children upwards as part of the Incremental Dental Care programme.
2. To monitor performance in terms of need for fissure sealant and fissure sealant rendered.
3. To assess trends of occlusal caries occurrence in relation to total tooth decay for 12 year-olds.

Strategy

From a public health point of view and best use of resources, a targeted strategy was adopted whereby schoolchildren considered “at high risk” to occlusal caries are the targeted clients. Based on this strategy, programme managers at the local level need to prioritise schools and children with high risk of dental caries (children with special needs, the physically, medically and mentally compromised children, as well as the social and economic disadvantage groups).

*Targeted population
strategy*

Monitoring and Evaluation

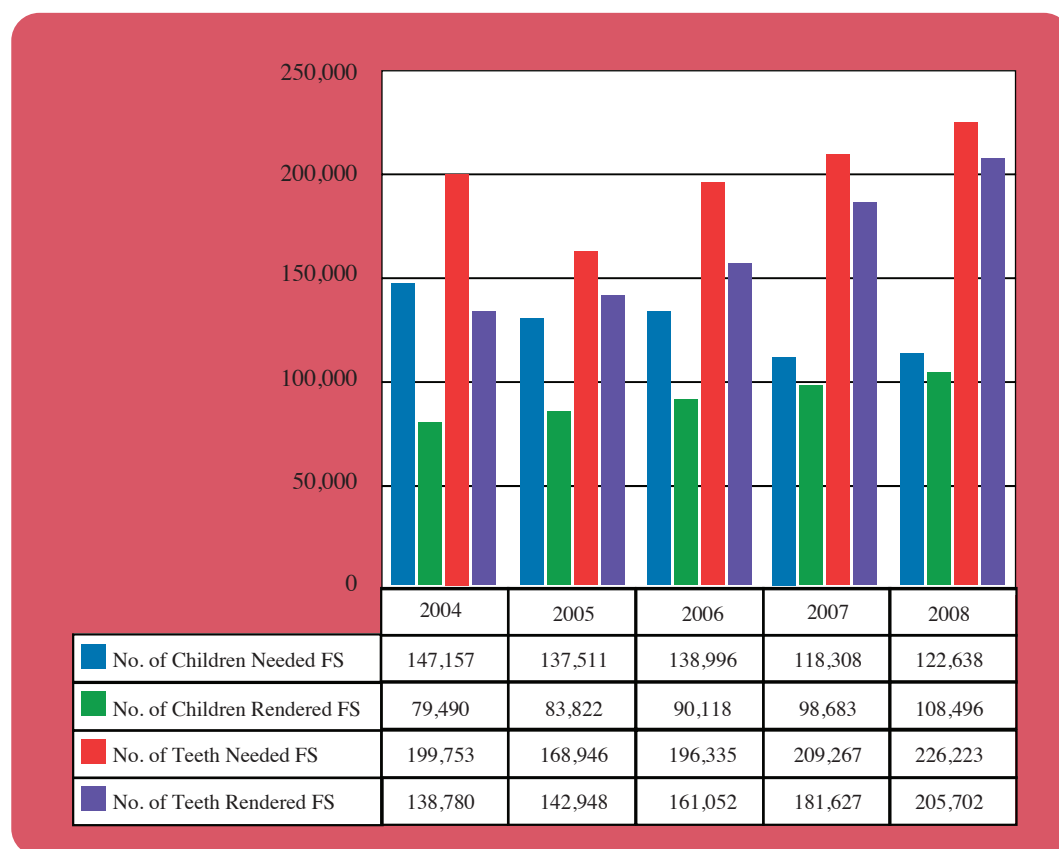
Monitoring and evaluation of the programme are continually being carried out by local dental officers in-charge, district dental officers and the state deputy directors of health (oral health) through the existing Health Information Management System (HIMS)

*Monitoring and
evaluation through
HMIS*

An evaluation on the programme was carried out using data from HMIS and from a five-year longitudinal study conducted from year 2003-2007. Adequacy of the programme was measured by the number of primary schoolchildren and the number of teeth rendered fissure sealant. Generally, the number of schoolchildren and teeth treated with fissure sealant increased annually from 2004 to 2008 (Figure 1). It showed an increasing number of high risk children and teeth benefiting from the programme yearly.



Figure 1: Provision of Fissure sealant Year 2004-2008



The percentage of children rendered fissure sealant increased annually over the last five years, from 54.0% in year 2004 to 88.5% in 2008, while the percentage of teeth needing and rendered fissure sealant also increased, from 69.5% in 2004 to 90.9% in 2008 (Table 1). This indicated unmet fissure sealant need for both high risk schoolchildren and teeth had decreased annually.

*Increase numbers
receiving sealant
treatment*

Trend data on decayed teeth among selected year 6 schoolchildren for the same period indicated that 66.0% to 71.9% of caries were in the posterior teeth, of which 58.4% to 63.9% involved only occlusal surfaces (Table 2).



Table 1: Provision of Fissure sealant Year 2004-2008

YEAR	NO. OF CHILDREN			NO. OF TEETH		
	Needed FISSURE SEALANT	Rendered FISSURE SEALANT		Needed FISSURE SEALANT	Rendered FISSURE SEALANT	
	n	n	%	n	n	%
2004	147,157	79,490	54.0	199,753	138,780	69.5
2005	137,511	83,822	61.0	168,946	142,948	84.6
2006	138,996	90,118	64.8	196,335	161,052	82.0
2007	118,308	98,683	83.4	209,267	181,627	86.8
2008	122,638	108,496	88.5	226,223	205,702	90.9

Source: Annual Reports, Oral Health Division

Table 2: Trend Data of Decayed Teeth among Year 6 Schoolchildren, 2004-2009

YEAR	No. of Teeth with Caries Experience (* D + F) (include all teeth)	No. of Teeth with occlusal caries experience (D + F)			
		All type (** Class I and II)		Class I only	
		n	%	n	%
2004	436,840	288,382	66.0	255,270	58.4
2005	450,665	313,757	69.6	277,151	61.5
2006	455,964	323,174	70.9	291,583	63.9
2007	414,610	289,671	69.9	260,901	62.9
2008	571,156	410,477	71.9	364,661	63.8

Source: Oral Health Divisions , 2008

* D: Carious tooth F : Filled tooth

** Class I : Caries involves only the occlusal surface of the posterior tooth

Class II :Caries involves other surfaces and/or occlusal of the posterior tooth



Findings from a longitudinal study on school-based fissure sealants programme showed that school-based fissure sealant programme was effective in preventing dental caries. This programme can be effectively carried out by dental officers and dental nurses at mobile dental teams setting irrespective of materials used.

*Longitudinal study
on school-based
fissure sealants
programme*

Training

School-based fissure sealant programme must provide high-quality sealants, and achieve high coverage for children at high risk for dental caries to ensure its effectiveness. With the advent of newer materials and treatment modalities, repeated trainings and updates are needed for dental officers and nurses in clinical preventive techniques. Subjects covered include:

*Regular updates and
training needed*

- Current knowledge on caries risk assessment,
- Indications of fissure sealant application (patient-selection criteria, tooth-selection criteria)
- Application technique and type of materials use based on current evidence
- Methods for monitoring and evaluation

Future direction

There are a number of advantages in having a school-based fissure sealant programme. These include timely access to children corresponding to eruption times of first and second permanent molars; integration and reinforcement of dental health education; and introduction of oral healthcare to younger children in a non-threatening way.

*Advantages of
school-based sealant
programme*

The findings from the longitudinal study on school-based fissure sealants programme support recommendations for continued training and utilisation of dental nurses for fissure sealant application in mobile dental settings in terms of caries prevention. The equivocal results in terms of caries outcome also support the use of both resin-based material and Glass Ionomer Cements (GIC) for fissure sealant. In fact, there are merits in extending the use of GIC, in particular those with fluoride releasing properties. This option is

*Utilising dental
nurses for fissure
sealant programme*

Merits of using GIC



strongly based on its cost-effectiveness, additional benefit on caries prevention due to fluoride released properties and ease of application that requires less stringent moisture control in a mobile dental setting.

It is strongly recommended that school-based sealant programmes be part of a comprehensive community strategy to prevent dental caries. The aim is to ensure all children and all teeth in need of fissure sealants will be rendered fissure sealants.

Conclusion

The integrated school-based fissure sealant programme is an effective public health approach in the prevention of pit and fissure caries of posterior teeth. The success of this programme has contributed to improvements on the oral health status of schoolchildren in the country. The National Oral Health Survey for School Children 2007 (NOHSS 2007) showed that dental caries levels among 12-year-olds Malaysian schoolchildren was 1.12, a 41% reduction compared to 1997 (mean DMFT of 1.9). Malaysia is currently among those countries with very low caries level, according to World Health Organisation (WHO) classification. The 2010 National Oral Health Goal of having a mean decayed, missing and filled teeth (DMFT) of less than 1.5 and 60% of school children with caries free permanent dentition has thus, been met.

School-based fissure sealant programme is an effective public health strategy

Malaysia among countries with low caries level

The school-based fissure sealant programme needs to be continued, strengthened and sustained to protect the most caries susceptible tooth surfaces (occlusal/buccal pits and fissures) that are least benefitted by other preventive modalities like the community water fluoridation programme.

School-based fissure sealant programme should be continued



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INITIATING THE PROVISION OF ANTI-RETROVIRAL (ARV) TREATMENT AS PART OF THE PREVENTION AND CONTROL HIV/AIDS PROGRAMMES IN MALAYSIAN PRISONS

SUMMARY

HIV/AIDS in prisons poses both a serious public health threat and challenge for health authorities and governments worldwide. Risk behaviour practices among prisoners like drug injecting, sexual practices, tattooing, lack of awareness and education, overcrowding and higher incidence of other infectious diseases are some of the factors contributing to higher prevalence of HIV/AIDS in prisons. The Ministry of Health together with the Prison Department of Malaysia, embarked on a programme to provide anti-retroviral treatment for HIV positive prisoners in the 2007. Some of the challenges in making this programme a success include providing a continuum care to prisoners upon their release from the prisons; adherence to the treatment; the presence of co-morbidities and capacity building for the prison staff. Cooperation from all the key stakeholders is vital to make this programme a success.

Introduction

HIV/AIDS is a serious health threat for prison populations, and presents significant challenges for prison and public health authorities and government worldwide. Globally, the level of HIV infection among prisoners tend to be much higher than in the general population. The higher incidence of HIV/AIDS in incarcerated settings is often accompanied and exacerbated by high rates of other infectious disease such Hepatitis B, C, Tuberculosis and Syphilis. In French prisons, HIV prevalence was estimated to be 10 times higher than that of the general population and to be 2% among Irish prisoners. A WHO report in 2001 indicated the HIV prevalence among prisoners in Brazil was 13.4%, while in Eastern Europe, it ranged from 0.03% to 6%.

HIV/AIDS in prisons – a challenge for health authorities and governments

Many of those who are HIV positive were already infected before they were sent to the prisons. The prisoners came from segments of populations that are categorised as most-at-risk (MARPS) or vulnerable populations to HIV infection and carry a heavier than average burden of HIV/AIDS infection. Many of them (prisoners)

Prisoners are “most-at-risk” population



are there because of drug use. In Malaysia, it is estimated that the percentage of prisoners infected with HIV infection is around 5% to 8% at any one time.

Prisons and prisoners are part of the broader community. Health threats of HIV within and outside prisons are inextricably linked and demand coordinated actions. Experiences around the world have shown that a lot can be done to check the spread of HIV among the prisoners while they are inside these institutions or upon release.

Prisoners and the community

Locally, there is a lack of statistics to gauge the prevalence of prisoners practicing male-to-male sex (MSM) or engaging in some form of drug use whilst still undergoing rehabilitation.

Conditions for spread

Prison populations are very fluid, moving in and out of prisons. Several factors can be attributed to the reasons why the prevalence of HIV/AIDS continues to be higher than the general public:

Prison populations are very mobile

- a) Practice of drug injection
- b) Sex among prisoners, whether consensual or forced,
- c) Practice of tattooing or skin piercing
- d) Lack of education, information and medical care,
- e) Overcrowding

Factors for high prevalence of HIV/AIDS among prisoners

National Response to HIV/AIDS in Prisons

In the absence of interventions, there is a real danger of HIV/AIDS among prisoners progressing into a generalised epidemic in the Malaysian prisons. It is therefore critical that HIV/AIDS in prisons and incarcerated populations be addressed as an integral part of the national strategic plan on HIV/AIDS control and prevention. The successful response to such an epidemic requires strong political commitment and leadership at the highest level.

Danger of progression to generalised epidemic



Realising the importance of adopting universal access to ARV treatment as part of the national strategy for the prevention and control of HIV/AIDS, a major decision was made in October 2007 to extend such treatments to all prisoners with HIV/AIDS in the country. This “breakthrough decision” was made at the cabinet meeting on HIV/AIDS chaired by the Deputy Prime Minister.

*ARV treatment
for HIV infected
prisoners*

With such a decision, there is now a comprehensive package of HIV care in prisons which include counseling, testing, ARV treatment and treatment for other HIV related opportunistic infections as well as the involvement of infectious disease physicians and family medicine specialists in their care. This is also in line with the 6th strategy of the Malaysian Strategic Plan of Action on HIV/AIDS, namely the provision of treatment, care and support to HIV infected individuals without discrimination against HIV infected prisoners.

*Comprehensive
package for HIV
care in prisons*

In addition, HIV/AIDS education and training of staff involved in the management of prisoners with HIV/AIDS have also been introduced in a plan drawn up by the Ministry of Health and the Prisons Department. These prison staff undergo a 2 week attachment training in hospitals treating HIV/AIDS patients under the supervision of infectious disease physicians and HIV nurse counselors. They are introduced to preventive measures, counseling and drug dependence treatment and rehabilitation. A manual on management of HIV/AIDS in the prisons’ settings has also been jointly developed between the Ministry of Health and the Prisons Department.

*HIV/AIDS education
and training for
prison staff*

As of December 2008, staff of Kajang Prison in Selangor have benefitted from this programme. Nevertheless, a lot more needs to be done. It is hoped that by 2010, the provision of ARV treatment to prisoners will become a standard practice to all prisons, including the states of Sabah and Sarawak. This will ensure prisoners will have continued access to essential HIV/AIDS prevention, treatment and care services eventually linking to services available to the wider community outside the prison walls.

*Access to ARV
Treatment*



Lessons Learnt, Overcoming Barriers, Recommendations and Policy Implications

The exercise of providing ARV treatment to prisoners provided insight into the standard practice of care to HIV prisoners in the country. From data gathered, it is realized that campaign intervention programmes against HIV/AIDS in prisons must not be targeted at the prisoners alone, but to include prison staff and officials, hospital and clinic staff as well as the entire community. Support from NGOs and other non-health sectors are also crucial.

*HIV/AIDS
intervention
programmes
in prisons must
include prison staff
and others*

The following lessons were learnt while implementing this policy decision:

a) **Towards Universal Access: The Provision of “Standard”, Continuum of Health, Treatment, Care and Support to Prisoners**

Effective HIV/AIDS prevention for prisoners requires a collaborative and comprehensive approach. This involves bringing together correctional systems, public health agencies, and community-based organisations to design an array of prevention and support services for inmates and ex-offenders. To ensure continued risk reduction, linkages must be established within communities. Those who are released from prisons need assistance in gaining access to educational services and referrals. Above all, public health authorities and the prison departments have to work closely together to plan and formulate policies to meet the specific needs of the diverse groups of prisoners.

*Collaborative and
comprehensive
approach*

There is much that can be done to reduce the spread of HIV inside or outside the prison. Prisoners must be given the necessary information, education and resources to avoid being infected. Being the “captive population, opportunity for education as well as dissemination of material and information on HIV prevention, treatment, support and care will be much easier.

*Education and
information
for prisoners
on HIV/AIDS*

Health outcomes for prisoners can be much worse than those in the general population. Stigma against drug users among health care workers, law enforcement personnel, social workers, community and probably families play a

*Need for
multiple services*



part in contributing to poor health outcomes. There is a need to have multiple services and not just from the perspective of medical and health outcomes. There is a need to provide services by the religious authorities, non-governmental organisations and others.

b) Adherence to Treatment

A key aspect in obtaining the greatest benefit from ARV treatment is full adherence to the prescribed regimen. The majority of prisoners would eventually be released and return to the community. Therefore, reducing the transmission of HIV in prisons is an integral part of reducing the spread of infection in the broader society. Any disease contracted in prison, or any medical condition made worse by poor conditions in the prison will become issues of public health for the wider society when these people are being released.

*Adherence
to treatment*

Poor adherence leads to the development of drug resistance. This will become not just a failure primarily for the prisoner (especially if they are also drug users) but also the failure of the health system to provide appropriate adherence interventions. Evidence indicates that effectiveness for adherence reminders, adherence counseling, contingency management, supervised therapy, opioid substitution therapy and ancillary services are equally important components to ensure prisoners follow the guidelines, be it inside or outside the incarcerated environment.

*Strategies to
enhance drug
adherence*

The challenge for the Ministry of Health and the Prisons Department is how best to assist these HIV infected prisoners to fully adhere to anti-retroviral regimens. This is a complex issue and involves the entire health care team, in which counselors and NGOs play key roles especially when prisoners are released into the community



c) Supporting The Parole System, Community, and Follow-Up of Ex-Prisoners

Many countries have taken steps to address the issue of HIV/AIDS in prisons. These experiences are valuable and should be examined while developing our own national responses. It is important that prisoners who are on ARV treatment have proper and adequate discharge planning, with pre- and post-test counseling (HIV) and have good support from their families as well as the community.

Adequate discharge planning

Although new drug regimens are easier to take, non-adherence or compliance may still pose a problem. Therefore, pre-release counseling is a final critical opportunity to reinforce and remind those about to be released of ways to reduce risk when they return to familiar risky environments. The provision of HIV prevention messages and behavioural interventions for inmates is an important mission for prisons and other correctional institutions including the drug rehabilitation centres.

Pre-release counseling

d) The Presence of Co-Morbidities and Infection of HIV

Any type of co-morbidity such as mental health problems, Hepatitis and on-going illicit drug use may require increased health care supervision. Alcohol dependence should not be used as reasons to withhold treatment. It is thus a huge challenge for the health care providers to streamline the multiple services being provided to the prisoners as well to coordinate various infections suffered by these MARPS. Such concomitant clinical manifestations can make the choice of ARV combination difficult.

Co-morbidities

e) Capacity Building for the Prison Staff

As treatment programmes are expanded, additional evidences from research will be needed to guide decision makers. Advocacy efforts need to be given priority to ensure prisons are adequately staffed and intervention programmes adequately funded.

Adequate staff and funding



Meaningful rehabilitation activities should be put in place, including pre-release re-integration programmes. Prison staff should be trained on how to deal with HIV/AIDS cases in prisons and on the needs of HIV-infected prisoners. Periodic retraining should be provided, covering aspects on sexuality, sexually transmitted disease, family planning, all aspects of HIV/AIDS, drug abuse, sexual behavior and others to both male and female prison staff. ARV therapy and improved hygiene, sanitation and diets for HIV-infected prisoners should be provided.

*Periodic re-training
needed*

CONCLUSION

Anti-retroviral treatment provision in prisons feasible and crucial. Establishing effective linkages between prison-based and community services is essential in implementing a comprehensive HIV/AIDS prevention and control strategy in prisons. Programs and services for the prisoners should draw on experiences of community health and available evidences, and adapted to the prison environment. This is vital for the success of prevention of HIV/AIDS in prisons and the community at large.



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PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV INFECTION IN MALAYSIA – A PROGRAMME REVIEW

SUMMARY

The Ministry of Health (MOH), Malaysia initiated a national prevention of mother-to-child transmission (PMTCT) Programme in 1998. To identify lessons from the current Programme, and to update policy recommendations and implementation strategies, we undertook a comprehensive review based on the ‘four-pronged’ strategic approach to PMTCT recommended by the Joint UN Programme on HIV and AIDS was done.

Findings for the review noted current strategies for PMTCT in Malaysia focus on timely detection of HIV infection and commencement of ARV prophylaxis during pregnancy, excellent early neonatal follow-up, and support for replacement feeding. Recommendations are proposed for strengthening the programme

Introduction

Worldwide, the Joint United Nations Programme on HIV (UNAIDS) estimated that 420,000 children became infected with human immunodeficiency virus (HIV) during 2006.

Mother-to-child transmission (MTCT) is the most common and important source of HIV infection in children. In the absence of any intervention, between 30% and 45% of children born to HIV infected mothers will themselves become infected with HIV during pregnancy, labour or delivery, or through breast feeding.

*Risks and
Consequences of
Mother-to-Child
Transmission of HIV*

In heavily burdened countries, HIV infection in women and children is reversing many of the gains in child survival achieved over the last 25 years, reducing the ability of those countries to achieve the health- and infant mortality-related Millennium Development Goals.



The risk of MTCT can be reduced by interventions that include antiretroviral (ARV) prophylaxis for the mother during pregnancy and labour and for the infant during the neonatal period, obstetric interventions to avoid infant exposure to infected maternal secretions (including elective caesarean section prior to the onset of labour and rupture of membranes), and complete avoidance of breast feeding. Selecting the most appropriate method of feeding for infants of HIV-infected mothers may be problematic in societies or families where breast feeding is the norm and replacement feeding is neither acceptable, feasible, affordable, sustainable or safe.

*Reducing
transmission risk*

Voluntary HIV counselling and testing (VCT) in Malaysia takes place predominantly through government and private health facilities, where some level of counselling services may be available. Specialist counselling services (e.g. medical social worker, clinical psychologist) are available at the State level but may not be readily available at District or community level health services.

*HIV Testing and
Counselling Policies
and Approaches in
Malaysia*

Testing facilities

Testing at government facilities is free, while private facilities may charge a fee for HIV-related services. VCT for most at-risk populations (MARPs; see Table 1) – including more comprehensive lifestyle-related counselling and harm reduction services – are available free through selected non-government organisations (NGOs) that are funded by the Malaysian AIDS Council (MAC), a predominantly government financed umbrella organisation for 42 affiliated partner organisations.

HIV screening

Screening is also routinely done for blood donors, pregnant women (option out), injecting drug users (IDUs) resident in drug rehabilitation centres, prisoners serving custodial sentences, individuals diagnosed with tuberculosis or a sexually transmissible infection (STI), individuals named as a contact of somebody with confirmed HIV infection, and patients with a clinical presentation suggestive of an HIV-related diagnosis. HIV counselling and referral for screening is required of all Muslim couples and later extended to anybody who wants to be tested before marriage.

Public sector primary care centres, antenatal clinics and hospitals currently use qualitative rapid screening test for HIV-1 and HIV-2. These tests are procured through Government tender and accredited by the Institute for Medical Research (IMR) Department of Virology, Kuala Lumpur. The manufacturers of both tests report

Rapid screening test



their sensitivity as 99.9% (95% Confidence Intervals [CI]: 99.4-100%) and their specificity as 99.8% (95% CI: 99.5-99.9%).

Following a reactive screening test, a second specimen is sent to the nearest accredited testing laboratory for confirmation using a recommended two-step protocol, i.e. enzyme linked immunosorbent assay (ELISA) followed by a highly specific particle agglutination test (Serodia®, Fujirebo; specificity 100%, 95% CI 98.5-100%) [WHO1999]. For quality control, testing laboratories are required to submit all positive and discordant specimens and a 10% random sample of negative specimens to IMR to undergo re-testing.

National PMTCT Programme

The Ministry of Health (MOH), Malaysia initiated a national prevention of mother-to-child transmission (PMTCT) Programme in 1998, based around the perinatal and infant feeding interventions described above and operating through government hospitals and health facilities.

*Description of the
National PMTCT
Programme*

Within the context of the Programme, HIV screening is offered routinely on an 'opt-out' basis to antenatal mothers, for whom pre-test counselling takes place on a group basis. Should a screening test be reactive, individual 'intra-test' counselling is provided prior to collection of a second specimen for confirmation.

The national PMTCT Programme encompasses four core strategies: a) early detection of HIV infection using a rapid screening test, with confirmatory testing if indicated; b) provision of counselling for infected mothers and their partners; c) provision of oral zidovudine (ZDV) to infected mothers according to the Paediatric AIDS Clinical Trials Group 0764 (PACTG-0764) protocol, i.e. from as early as possible in the second trimester of pregnancy until the onset of labour, switching to intravenous ZDV during labour, and with oral ZDV for the baby for the first 6 weeks of life; and d) early detection of HIV infection among babies born to HIV infected mothers. The strategy also emphasises contact tracing of partners of HIV infected women and training of clinical staff.

Core strategies

*Strategies for
reducing risks*

Provision exists for immediate screening using rapid test for women who present in labour with no record of antenatal care or HIV testing. The infants of women found to have a reactive HIV rapid



test in labour are managed according to the post-natal component of the PACTG-0764 protocol. These strategies are supplemented by safer modes of delivery (generally caesarean section) and MOH support for replacement feeding of infants born to HIV positive mothers until the infant is 6 months of age.

Longer term paediatric follow-up is by sequential antigen-based testing (HIV proviral DNA, p24 antigen) by polymerase chain reaction (PCR) at around 2 weeks, at 6-8 weeks and at 3 months of age (sometimes more frequently). If the initial tests are negative, antigen-based screening continues three-monthly until HIV infection is either confirmed or excluded by antibody-based testing by ELISA, particle agglutination and Western Blot at 18 months of age.

Rationale for the Review

Following the UN General Assembly Special Session on HIV/AIDS (UNGASS) in 2001, UNAIDS and its co-sponsor agencies recommended a more comprehensive, ‘four-pronged’ strategic approach to achieving the goal of reducing HIV infection in children by 50% by 2010. This approach includes: (1) primary prevention of HIV infection in women of reproductive age, (2) secondary prevention of unintended pregnancy in HIV-infected women, (3) prevention of MTCT of HIV infection during pregnancy, labour, delivery and infant feeding, and (4) provision of care, treatment and support (CT&S) to HIV-infected parents, infants and families. Recent evidence suggests that refinement of the third strategic ‘prong’ can reduce the risk of MTCT to less than 2%, while exclusive breast feeding during the early months of life may be associated with longer survival rates among infants born to HIV-infected mothers than either replacement or mixed feeding. These reviews enables for further update on policy recommendations.

Rationale for the review

METHODS

We structured the review of strategic and operational aspects of the Programme around the comprehensive, ‘four-pronged’ strategic approach recommended by UNAIDS. Table 1 summarises the components of the Review and the UN strategic ‘prong’ addressed by each one.

Review structured



Table 1: Components of the Review of the PMTCT Programme in Malaysia with UN strategy addressed by each one

COMPONENT	PRIMARILY ADDRESSING UN 'PRONG'	SECONDARILY ADDRESSING
Background description of national HIV programme	1	Prong 3 , 4; context
Background description of national PMTCT programme	2, 3	Context
Descriptive study based on PMTCT data base	2, 3	Programme outcomes
Descriptive epidemiology of other perinatally acquired STIs	2	Context, data validity
Paediatrician survey, 'key informant' interviews	2, 3	Data validity
Review of Laboratory / IMR data	3	Data validity
Social research (Focus Group Discussions) among HIV infected mothers	3	Prong 2 , 4
<i>Analysis of HIV Knowledge, Attitudes and Risk Behaviour study, 2006</i>	1	Prong 2
Review of behavioural surveillance among commercial sex workers conducted in 2003-2004	2	Prong 1, 4
<i>Review of Technical Report of the Director-General of Health</i>	1	Prong 2, 3, 4; sexual and reproductive health context
Survey of HIV- and PMTCT- related knowledge and practices among health care workers	2, 3	Prong 1 ,4
Focused 'key informant' interviews with obstetricians	3	Prong 2 ,4
Mapping of non-government VCT facilities	2	Prong 1
Focused investigation of services for children affected by AIDS in institutional or foster care settings	4	-



First, the descriptive epidemiology of HIV infection in Malaysia and outcomes among mothers enrolled in the PMTCT Programme was updated by reviewing and analysing the national HIV and MTCT data bases, which are based on statutory clinician and laboratory notifications and maintained by the MOH. To determine the incidence of other perinatally acquired infections, we also examined the national registry of sexually transmissible infections (STIs) for notified cases of early and late congenital syphilis and gonococcal ophthalmia neonatorum.

*Descriptive
epidemiology*

To examine primary prevention, the vulnerability of women to HIV infection and their reproductive health status, we used three existing published sources of data: a Nationwide Survey of HIV-related knowledge, attitudes, practices and behaviour (KAPB) conducted in 2006 [Health Education Division 2006]; behavioural surveillance among commercial sex workers conducted in 2003-04; and the 2001 Technical Report of the Director-General of Health.

Data review

To further examine women's HIV-related knowledge and their experience of PMTCT services, we undertook focus group discussions (FGD) and interviews based on an open-ended questionnaire with a sample of 66 urban and 64 rural women from Kelantan, Penang and Selangor; the sample included HIV-infected and non-infected antenatal mothers and HIV-infected women with either HIV-infected or non-infected infants. Ethical clearance for the study was obtained from the Universiti Sains Malaysia Research and Ethics Committee, and informed consent obtained from all participants. Data from the FGDs and interviews were transcribed and imported into the NVIVO 2 qualitative data analysis software [QSR international], and analysed using the "framework" method developed for systematic analysis of qualitative data. Descriptive statistics on socio-demographic characteristics of study participants were analysed using SPSS software.

*Focus Group
Discussion*

To examine provider perspectives of the national programme, we conducted a cross-sectional survey among a sample of 96 staff nurses from Perak, Negeri Sembilan and Terengganu who were directly involved in PMTCT in primary care settings. An open-ended questionnaire sought information on their HIV- and MTCT-related knowledge and their clinical knowledge and practice in relation to antenatal screening and counselling, treatment compliance, infant feeding practices, safer sexual practices, family planning, and prevention in health care settings. Open-ended

*Cross-sectional
survey among nurses*



responses were coded into subcategories and descriptive statistics and cross-tabulations performed.

To ascertain the current and potential future role of private medical providers in VCT for HIV and the provision of antenatal care outside the government system, we conducted a nation-wide telephone and postal survey of the testing and antenatal care services provided by private medical practices and laboratories recorded on the Malaysian Medical Council data base. Data were recorded and frequency tables generated. We also reviewed the compliance of government testing laboratories with the national quality assurance scheme, which is coordinated by the Institute for Medical Research (IMR), Kuala Lumpur.

*National telephone
and postal survey*

We undertook key informant interviews with obstetricians and, to identify children whose mothers may not have had contact with the PMTCT programme, with infectious diseases paediatricians responsible for the clinical care of HIV-infected infants and children.

*Key informant
interviewers*

Finally, to examine the CT&S available to MARPs, PLHIV, their families and their children, we visited clinical facilities and interviewed hospital- and community-based clinical service providers in Kuala Lumpur, Kuantan, Alor Setar and Kuala Terengganu. We also identified NGOs registered with the Malaysian AIDS Council to provide CT&S for HIV-infected mothers and their children and conducted key informant interviews during site visits to selected facilities.

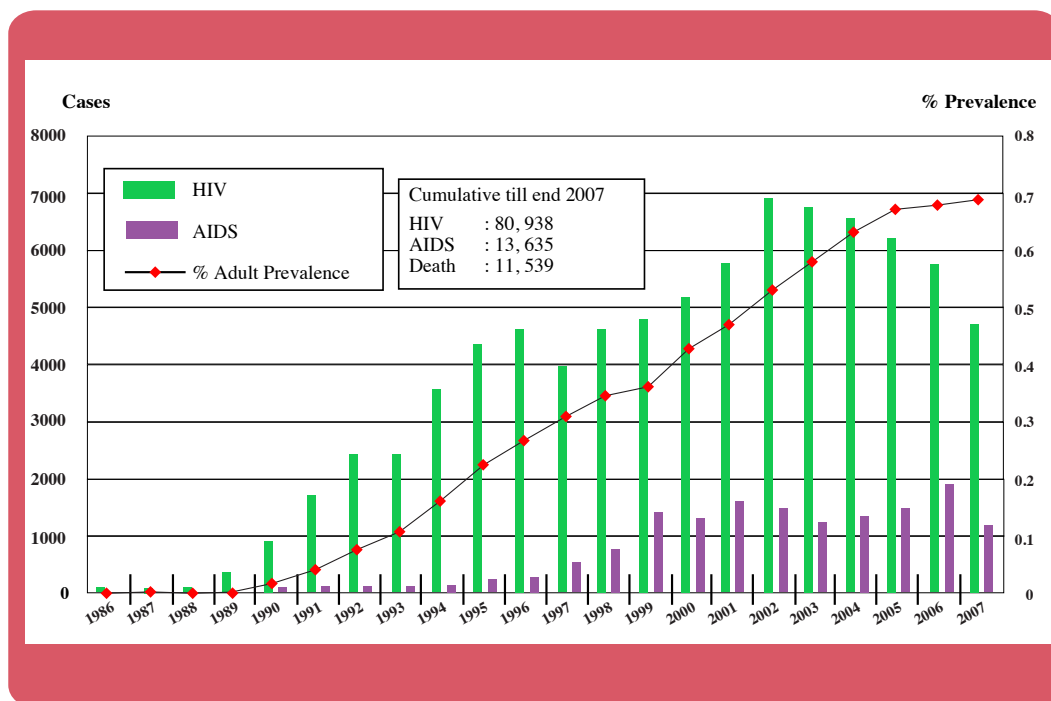
FINDINGS AND RESULTS

From the first notification of HIV in 1986 to end 2007, a cumulative total of 80,938 HIV infections and 13,635 cases of AIDS have been reported to the MOH Malaysia (Figure 1)

*Background
Epidemiology of
HIV Infection in
Malaysia*



Figure 1: Cumulative reported cases of HIV and AIDS, Malaysia, 1986 - 2007

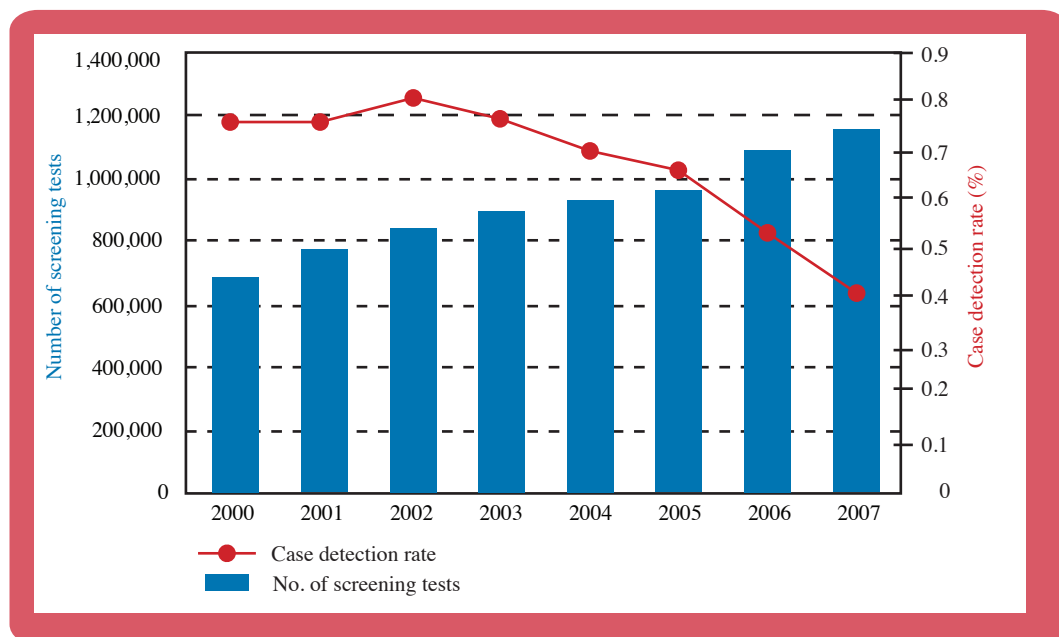


Among the 1,098,403 tests conducted in 2006 and 1,139,256 tests conducted in 2007, 5,830 new HIV infections were detected in 2006 and 4,549 in 2007 which gave case detection rate of 0.53% and 0.40% respectively (Figure 2).

Case Detection Rate



Figure 2: Screening and case detection rate, 2000 - 2007



The most at-risk populations include: i) IDUs; (more than 75% of cumulative reported cases, with an estimated prevalence rate of 16.8%); ii) heterosexual transmission among partners of IDUs and other MARPs (almost 20% of reported cases, and steadily increasing); iii) transmission between men who have sex with men (MSM); and iv) MTCT. Between 2002 and 2007, the proportion of infections acquired through heterosexual transmission doubled. Table 2 summarises the transmission risk factors among new infections notified during 1995 - 2007.

*Most at risk
populations*



Table 2: Transmission risk factors among new infections notified during 1995 - 2007.

Transmission Risk Factors	YEAR												
	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Injecting Drugs Users	3,187	3,800	3,014	3,592	3,374	3,815	4,724	5,176	4,796	4,478	4,038	3,127	2,601
Homosexual / Bisexual	17	47	58	33	43	62	44	51	151	222	209	263	184
Heterosexual	310	344	400	653	824	902	834	1,218	1,307	1,271	1,356	1,599	1,315
Vertical Transmission	4	20	19	34	44	82	57	60	62	67	75	81	70
Blood Recipients	0	0	0	0	0	2	1	5	1	0	3	1	0
Organ Recipients	0	1	0	0	0	0	0	0	0	0	0	0	0
No Data	680	385	433	312	407	244	278	468	439	389	439	759	379
TOTAL	4,198	4,597	3,924	4,624	4,692	5,107	5,938	6,978	6,756	6,427	6,120	5,830	4,549

The proportion acquired through injecting drug use fell from a mean of more than 75% of all cases during the period 1990–2003 [UNAIDS UNGASS Country Report 2005] to 53.6% in 2007. During 2006, 170 of 384,027 women screened through government antenatal facilities tested positive for HIV infection (crude HIV prevalence rate 0.044%).

*HIV cases and
Transmission risk
factors*

Routine premarital screening among Muslim couples through government facilities in eight States indicates a prevalence rate in that population of 0.1-0.2% (e.g. the prevalence rate among a total of 77,493 people tested in the state of Johor from 2001 to 2004 was 0.16%)

Premarital screening

From 1998 to 2006, 35 HIV-infected babies were born to 1,042 HIV-positive mothers identified in government facilities and managed according to the national perinatal PMTCT protocol, representing a crude vertical transmission rate of 3.2% (Figure 3).

*Outcomes of
Pregnancies affected
by HIV*



Figure 3: PMTCT performance 1998 – 2007.



However, there are an estimated 6,000 to 14,000 children affected by AIDS (CABA; i.e. HIV infected, orphaned, abandoned or otherwise vulnerable) in institutional or foster care – far more than the above estimates of antenatal HIV prevalence and perinatal transmission would suggest.

Estimated CABA

Up to December 2007, about 500 HIV-infected children were receiving care, treatment and follow-up through infectious diseases paediatricians. The number currently on follow-up is estimated to be approaching 500, with more than 400 on ART. Less than 20% of these children were detected through the PMTCT Programme – the majority were identified and referred for treatment from outside the programme following investigation of failure to thrive or clinical presentation with an opportunistic infection or other signs suggestive of immune deficiency.

Paediatric cases on ART



Among 2,541 infants of HIV-infected mothers whose sera were submitted to the IMR for confirmatory testing from 1992 to 2006, 411 (16.2%) were confirmed as infected with HIV. This, again, is a greater number and higher seroconversion rate than reported by the PMTCT data base; it probably reflects additional cases detected through the routine screening of abandoned babies (whose mothers may not have accessed antenatal PMTCT services) or the private sector (from where data are not routinely submitted to the Registry).

*Cases outside
PMTCT programme*

There are other perinatally-acquired sexually transmissible infections. Table 3 and Figure 4 present the number of cases of other perinatally acquired Syphilis of infancy (early congenital syphilis and late congenital syphilis) reported to the national STI data base from 2002 to 2007 and reported syphilis, gonorrhoea and chancroid.

*Other Perinatally-
Acquired Sexually
Transmissible
Infections*

Table 3: Percentage of Antenatal Screening for Syphilis and confirmed cases and number of congenital syphilis (2002 - 2007)

YEAR	2002	2003	2004	2005	2006	2007
% ANC SCREENED FOR SYPHILIS	62.95	74.73	79.09	77.12	80.20	95.90
% CONFIRMED SYPHILIS	0.08	0.09	0.09	0.10	0.09	0.08
CONGENITAL SYPHILIS	0	0	0	0	0	0



Figure 4: Number of Notified Syphilis, Gonorrhea and Chancroid, Malaysia (1993 - 2007)



Although males account for more than 91.6% of cumulative HIV infections, the proportion of new cases reported among females is increasing rapidly: from 1.4% of notified cases in 1990 to 8.4% in 2000 and 16.4% in 2007. Among women, 64% of HIV infections are classified as occurring through heterosexual contact and 20% through IDU.

Vulnerability and Prevention of HIV Infection among Women

A high proportion (96%) of respondents in the 2006 Nationwide Behavioural Survey were aware that sharing injection equipment with an HIV-infected individual carried a risk of HIV transmission, while 94.5% were aware of sexual transmission and 87% were aware of antenatal and intrapartum MTCT; there was no difference in the awareness of males and females of these routes of transmission. Only 57% of respondents (but significantly more females than males) were aware of MTCT through breast feeding.

Significantly fewer female than male respondents (82% cf 85.9%; $p < 0.05$) were aware that using a condom during sex could prevent HIV infection. Knowledge of HIV prevention among both males and females increased significantly with increasing educational

Knowledge and condom practices



status ($p < 0.001$), but showed no variation by ethnicity or urban or rural place of residence.

Overall, only 26.6% of respondents (with no significant gender differences) knew that the risk of HIV transmission from an HIV-infected pregnant woman to her fetus could be reduced

Antenatal Care Attendance and Infant Feeding Practices

The antenatal period presents opportunities for reaching pregnant women with interventions that may be vital to their health and wellbeing. The WHO recommends a minimum of four antenatal visits based on a review of the effectiveness of different models of antenatal care. The WHO guidelines are specific on the content of antenatal care visits, which should include:

Antenatal care

- blood pressure measurement;
- urine testing for bacteriuria & proteinuria;
- blood testing to detect syphilis & severe anemia; and
- weight/height measurement (optional)

Four antenatal visits will ensure that the pregnant women receive important services, such as tetanus vaccinations, screening and treatment for infections and health promotion and prevention advice on warning signs during pregnancy. Thus, antenatal visits help identify and treat illnesses which place pregnant women at high risk of maternal death due to indirect causes. Although Malaysian women make more than one visit for antenatal care, antenatal care is monitored for only the first visit. Antenatal care coverage (First Visit) has been increasing from 78 per cent in 1990 to more than 90 per cent since 2006. In Malaysia 97% of births are attended by a skilled birth attendant.

Coverage

Although a majority (88.6%) of mothers initiate breast feeding, the overall prevalence of exclusive breast feeding (including delivery of expressed breast milk by bottle) to four months of age is 29% (95% CI 26.7-31.3%). There is a higher prevalence of exclusive breast feeding among Malay mothers than among other ethnic groups, but

Breast feeding practices



no difference by urban or rural place of residence. Mixed infant feeding before the age of four months is common, with 10.0% predominantly breast fed and 46.9% receiving both breast milk and complementary feeds.

Vulnerability to HIV Infection and STIs among At-Risk Women

Health workers providing antenatal care through government facilities report difficulty reaching female members of MARPs with PMTCT and other HIV-related services and care. These groups include: those with identified risk behaviours (especially female IDUs and commercial sex workers; CSWs); immigrant populations (both legally registered migrant workers and informal immigrants); occupationally and socially mobile groups and individuals; and individuals with lower socio-economic status.

MARPs among female

Among 420 female CSWs surveyed in 2004, only 35.4% “often” used a condom with clients and 21.2% used a condom “most of the time” [MOH and WHO 2004] – a similar proportion to that found in a 2001 study [MOH 2001]; 7.3% “never” used a condom [MOH and WHO 2004]. More than half (57.4%) “never” used a condom with non-paying sexual partners.

Survey among CSW

Drug use was admitted by 17.9% of CSW respondents; among these, about 60% had injected heroin or morphine during the month prior to the survey.

Drug use among CSW

The overall prevalence of HIV infection among female CSWs in 2001 was 6.94%; 16.67% had reactive syphilis serology.

Disease prevalence among CSW

Experience of HIV-Infected Pregnant Women enrolled in the PMTCT Programme

HIV infected women enrolled in the PMTCT Programme reported variable quality of counselling and other aspects of service provision (consistent with the findings of the health worker study, below) and a high level of HIV-related stigma (including self-stigmatisation and stigmatisation in health care settings). Pre-test counselling was either incidental or conducted in group settings, while post-test counselling generally contained appropriate information and was of better quality. Rural women were less

Pre and post test counselling



comfortable with group approaches to counselling than urban residents. HIV infected women in their second or subsequent pregnancy noted a poorer quality of counselling, and reported assumptions within the health service that they “should know [about HIV and PMTCT] already”.

The majority of respondents reported a high level of trust and confidence that health workers would maintain confidentiality about their infection with HIV.

Trust on services

Respondents from rural areas identified distance from primary and specialist care and the cost of transport as important factors compromising regularity and continuity of antenatal care.

Informed discussion of mode of delivery was uncommon, with most respondents delivering by caesarean section. Where vaginal delivery occurred, this was generally following premature onset of labour.

Delivery options

Knowledge of the risks associated with different patterns of infant feeding was variable and generally poor. Respondents indicated that supplies of breast milk substitutes through health facilities were inconsistent; complete avoidance of breast feeding would therefore be associated with significant expense to most mothers, and lead to pressure from family members due to the cost of maintaining replacement feeding for the baby after 6 months of age. These factors led to almost universal mixed feeding by HIV infected mothers.

Feeding practices

Adherence to antenatal ARV and opportunistic infection (OI) prophylaxis and the chosen method of infant feeding relies heavily on the woman’s own understanding and motivation. Paediatricians are rarely involved in the care of HIV positive pregnant women during the antenatal period; they generally only meet mothers and babies postnatally or on referral from a community facility.

Treatment adherence

A further obstacle to complete avoidance of breast feeding was that social disapproval would be likely, and that there would always be the potential for others to infer that the mother had HIV infection.

Social disapproval

There are limited mechanisms for community based care and support and, in provincial centres, no involvement of PLHIV in peer support.



Availability of Testing and Counselling through Non-Government Providers

Malaysia has an estimated annual birth cohort of approximately 560,000. As more than 400,000 women attended government antenatal facilities in 2007, we assume that about 160,000 pregnant women each year either seek antenatal care through non-government providers or do not attend antenatal clinic at all.

Antenatal coverage

Among 791 private practices and laboratories contacted, only 291 (36.8%) responded to the survey. However, a relatively high proportion (>50%) of those private health facilities that provided antenatal care to pregnant women also offered routine antenatal HIV screening.

Survey among private practice

Highly variable testing protocols were used. Only 40% of the respondents used standard, MOH-accredited primary screening by ELISA and secondary testing with a highly specific particle agglutination test. Only 50% provided pre-test counselling, and 40% provided any post-test counselling.

HIV testing activities in private facilities

The survey methods were not able to estimate the number of women attending the private facilities that responded to the questionnaire.

Laboratory Quality Control and Quality Assurance

Only 30 of 55 HIV testing laboratories currently implement the two-stage ELISA and particle agglutination testing according to the IMR protocol. About 25 laboratories use only particle agglutination for primary screening.

Compliance to HIV testing protocol

Among 6,759 samples submitted for confirmatory testing over the last 5 years, 5,013 (74.2%) yielded a positive result by Western Blot. Laboratories generally do not send any negative specimens for quality control.

HIV testing Quality Control

Under the IMR's external quality assurance scheme (EQAS), 5 "blinded" specimens and one specimen to confirm the precision of ELISA testing (where available) are sent out 6 monthly. All testing laboratories able to perform ELISA participate satisfactorily in this EQAS, with acceptable performance and rapid turn-around of results.



The IMR itself participates in the EQAS managed by the National Serology Reference Laboratory, Melbourne, Australia and the HIV Reference Laboratory at the Centers for Disease Prevention and Control, Atlanta, United States.

Care and Support and Referral for Treatment for MARPs, PLHIV and CABA

First line ART and OI prophylaxis for adults and children is fully funded by the MOH, and the MAC provides some financial support for second line ART for selected individuals. ART is currently prescribed and monitored through specialist infectious diseases physicians in Provincial centres and, increasingly, through family medicine specialists working from community health centres. By end of 2007, there were 6203 patient on ARV compared to an estimated 15,000 PLHIV who would meet the criteria for commencing ART. Currently available paediatric formulations of ARVs are limited to first line drugs.

ART

The MOH, Royal Malaysian Police, National Anti-Drug Agency and MAC have collaborated to establish a pilot harm reduction programme for IDUs in three centres (with plans to expand to another three sites). The harm reduction programme incorporates needle and syringe exchange, opiate replacement therapy, psychosocial support and counselling, and the promotion and provision of male condoms.

*Pilot project of
Harm Reduction
Programme*

In the more urbanised Klang Valley, harm reduction programmes for IDUs and support services for MARPs are relatively disconnected from sexual and reproductive health (SRH) and clinical HIV CT&S and PMTCT services. Drop-in centres provide food, shelter and variable levels of counselling and support; however, clients must travel to other facilities for SRH services (other than provision of condoms), VCT for HIV and other STIs, antenatal care, PMTCT services or ART and clinical monitoring.

*Harm reduction
programme*

Coverage and “reach” of services to MARPs outside the Klang Valley are very variable and, again, relatively disconnected from CT&S services. In many provincial centres, there is no involvement of PLHIV in peer support.



Shelter and emergency housing for PLHIV – including approximately 240 CABA – are currently available through 16 faith-based organisations (FBOs) and non-denominational NGOs in Kuala Lumpur and 6 other Provincial centres. These organisations derive most of their funding through the MAC.

DISCUSSION

This paper is the first to provide information about the strategies employed for PMTCT of HIV infection in Malaysia, the outcomes of pregnancies in HIV infected women, and factors that potentially limit the effectiveness and “reach” of the Programme. Recent observed increases in heterosexual transmission and the prevalence of HIV infection in women in Malaysia provide warning about the potential for an epidemic of HIV infection in their children. The cost and limited availability of paediatric formulations of ARVs and the ongoing costs of clinical monitoring, care and support present a strong argument for a comprehensive, prevention based approach.

In many countries, interventions to reduce MTCT of HIV have historically targeted the higher risk peripartum period. The PMTCT Programme in Malaysia is based strongly around ARV prophylaxis for mother and baby, safer modes of delivery and safer infant feeding practices (i.e. UNGASS “Prong 3”) and partly on detection of HIV infection during the antenatal period (i.e. “Prong 2”) – strategies that rely on early antenatal presentation and confirmation of HIV status, timely commencement of ARV prophylaxis and excellent early neonatal follow-up. Primary prevention of HIV in women (“Prong 1”) and extended community-based care and support for families living with and affected by HIV (“Prong 4”) are not strongly integrated into the Programme.

PMTCT intervention

Less than 70% of the expected annual birth cohort was recorded in the PMTCT data base for 2007. The HIV prevalence rate recorded among antenatal attendees (0.04%) is lower than expected from other population prevalence data, rates of perinatal transmission (3.2%) are also lower than expected (8.3% with the current ARV protocol; 8.6% if maternal ZDV prophylaxis does not commence until the third trimester. The majority of children affected by AIDS have been identified and referred for care and treatment from outside the PMTCT Programme. These findings all suggest that the Programme is only reaching more highly motivated mothers and/or those at lower risk of acquiring HIV infection.

Vertical transmission prevalence rate



PMTCT services, SRH services, maternal and neonatal health services and adult and paediatric CT&S programmes generally function independently of each other, without natural coordination or linkages. Additional barriers to PLHIV accessing CT &S services include feelings of shame and self-stigmatisation and a lack of coordination between harm reduction and other services for MARPs and clinical PMTCT and HIV medicine services.

MTCT of HIV infection is dramatically reduced by complete avoidance of breast feeding. However, in communities with high infant mortality rates from other causes, breast feeding provides significant benefit by reducing mortality associated with gastrointestinal and other infections acquired from contaminated water, including in infants of HIV-infected mothers. In Malaysia, mixed breast and replacement feeding of infants is common in both the general population and MARPs, and represents an additional risk for postnatal transmission of HIV.

*Breast feeding and
replacement feeding*

There are significant gaps in knowledge, attitudes and practices among both the general population and MARPs in relation to HIV transmission and its consequences, and in the KAPB of health care workers in relation to HIV counselling and testing, PMTCT and infant feeding. Because respondents to our surveys were principally located in larger population centres, these studies probably present a 'best case' scenario and it is not possible to extrapolate to the level of care available in more remote population centres.

KAP

It is also likely that opportunities for diagnosing HIV infection in women of reproductive age and their partners are being missed – for two reasons. First, the manufacturers of both screening tests in common use in Malaysia report their sensitivity as 99.9% (range 99.4-100%); this means that, among 1,000 positive specimens, the screening tests may report between 0 and 6 specimens as HIV non-reactive. Second, only 30 of 55 HIV testing laboratories currently implement testing according to the national IMR protocol. In particular, some use only the Serodia® particle agglutination test for confirmation – although highly specific, this test is not recommended by the World Health Organization (WHO) to be used in isolation (reported sensitivity 100%; 95% CI 98.5-100%).

*Variability of testing
methodology*



CONCLUSIONS

The consequences of HIV infection and acquired immunodeficiency syndrome (AIDS) in young children are serious. The untreated mortality among HIV positive children is about one-third by the first birthday and about 50% at 2 years of age; survival to 5 years of age is uncommon.

*Consequences of
HIV infection*

While behaviour change communication, interventions targeting sex workers and prompt treatment of STIs represent the “best buys” for reducing HIV transmission, PMTCT interventions are also regarded as cost effective by international criteria. If ART and treatment for OIs are readily available, the majority of deaths can also be prevented. Evidence is now emerging that early identification of HIV infection and initiation of ART may achieve a 75% reduction in infant mortality, irrespective of CD4 lymphocyte count.

*Role of early HIV
testing and treatment*

RECOMMENDATIONS

Based on the above observations, the following recommendations for re-aligning and strengthening the national PMTCT Programme are proposed:

- i) The Programme must be re-oriented around the four UNGASS “prongs”. There should be a strong emphasis on engagement of women who are members of MARPs, with a particular focus on primary prevention of HIV in women of reproductive age (“Prong 1”) and prevention of unintended pregnancy in women infected with HIV (“Prong 2”, including those who are not aware of their status).

*Reorientation of
PMTCT programme*

In particular, because the HIV epidemic in Malaysia remains predominantly “concentrated” among MARPs, the linkages between HIV prevention (including harm reduction, SRH services and PMTCT), care (including shelter and livelihood support), treatment (including antiretroviral therapy) and peer support services for PLHIV and MARPs must be greatly strengthened, with these services co-located wherever possible. Integrating HIV-related CT&S into maternal and neonatal health services and linking the mother’s HIV status to the

*Involvement of
MARPS*

Integration activities



child's follow-up and health records are essential for HIV-infected mothers and HIV-exposed children to receive appropriate follow-up and treatment. In Malaysia, linkages may be fostered by: a) integrating PMTCT services, VCT and community based aspects of HIV-related care and support into existing maternal and neonatal health services and harm reduction services for IDUs, CSWs and other MARPs; and b) identifying community-based organisations, community workers, lay counsellors and volunteers who can guide and support women through the testing and counselling process, monitor adherence to any prophylactic medication for HIV or OIs, and assist them in accessing maternal and neonatal health and harm reduction services.

- ii) The VCT services must be strengthened by ensuring compliance of both government and non-government testing facilities with IMR standard protocols for testing, and strengthening SRH, pre-test and post-test counselling services linked to HIV testing. The low response rate to our survey by private facilities and the limited services they provide are further evidence of lost opportunities to reach those HIV positive mothers who seek antenatal care outside the government system, and remind us of the need for stronger engagement with the private sector.
- iii) Improvements in the detection of HIV infection during pregnancy and in the management of HIV infected pregnant women and their infants can result in further reductions in the incidence of HIV infection in children. WHO has developed evidence based guidelines which can be adapted readily for use in both well-resourced and resource limited settings in Malaysia. Our third recommendation is therefore to accelerate the introduction of new Clinical Practice Guidelines for managing HIV infection in pregnant women and clinical management and follow-up of their children, using the WHO-recommended multi-drug ARV prophylaxis regimens to reduce the risk of perinatal transmission and minimise the risk of emergence of ARV-resistant strains of HIV that are associated with single-drug protocols.

Compliance to HIV testing strategy

New PMTCT guideline



- iv) Depending on the family and community context, it is important that health workers promote, support and supervise exclusive breast feeding or (if acceptable, feasible, affordable, sustainable and safe) exclusive replacement feeding for infants of HIV infected mothers during the first 4-6 months of life. Mothers and families must be counselled on the need for strict avoidance of mixed feeding. At the discretion of the attending paediatrician or family medicine specialist, subsidised infant feeding support should be extended beyond 6 months of age for vulnerable children.

Infant feeding

To assist Programme monitoring, the MOH should ensure that all government, non-government and civil society organisations involved in VCT and care for pregnant women infected with HIV are well orientated regarding data collection for the PMTCT data base. The MOH should also establish active surveillance of the reporting compliance of partner agencies and private practitioners and laboratories.

*Involvement in
PMTCT*

- iv) To disseminate information about the new, stronger programme and Clinical Practice Guidelines to health workers, civil society organisations and other stakeholders, it will be necessary to develop a comprehensive communications strategy. This will include stronger engagement with private medical practitioners providing obstetric care and VCT for HIV, and with NGOs providing CT&S services for PLHIV and MARPs.

*Communication
strategy*

Religious leaders can also be very influential on the attitudes of their communities to PLHIV and MARPs, and it is important that the communication strategy continues to pursue engagement with FBOs. Important experiences and lessons may be learned from the Buddhist Leadership Initiative in Thailand and other Mekong countries, and in the work of Islamic leaders in harm reduction approaches to HIV prevention in the Xinjiang Uygur Autonomous Region of China.

*Involvement of
religious leaders*



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QUALITY OF DIABETIC CARE IN PRIMARY HEALTH CARE SETTINGS

SUMMARY

In ensuring quality of diabetic care, strengthening of its management should be done at all levels of the health system to ensure that appropriate attention is given to primary prevention, effective quality management, monitoring and research.

As primary care is the first level of contact with the health system, it is important that the quality of medical care provided at this level is *par excellence*. The effort to achieve this requires that diabetes care and management be integrated into the existing primary care services. Training of suitable health care personnel and making available related manuals, guidelines and SOPs are also essential.

A strong commitment from national leaders, policy makers, health care organisations, community leaders, health care personnel, patients and families is needed to ensure quality of care at the primary care level. Emphasis should be placed on a shift from curative to preventive and community based primary health care.

Introduction

Primary Health Care in Malaysia

P rimary Health Care is essential health care based on practical, scientifically sound and socially acceptable methods and technology. It should be accessible to individuals and families in the community and at a cost that is affordable and sustainable at every stage of their development as embodied in the spirit of self – reliance and self determination. It is also the first level of contact of individuals, the family and community with the health system, bringing health care as close as possible to where people live and work and constitutes the first element of a continuing health care process. Up till now, Primary Health Care is the best vehicle to ensure availability, accessibility and equitability of health for the whole community.



Primary Health Care when first formally introduced in 1978 in the Alma Ata Declaration required the basic packages of eight essential areas of care to be made available to every individual. Primary Health Care now also provides services for the older person, adolescents, female adults, male adults and children. Prevention and control of locally endemic diseases has expanded to encompass non infectious and chronic diseases such as heart diseases, hypertension, diabetes, cancer and injuries.

*Alma Ata
Declaration*

Recently, the Ministry of Health introduced the Integrated Health Care or Reviewed Approach (REAP) of health services provided in Primary Health Care, where the management of illness and wellness is carried out comprehensively. It functions holistically in a package of 4 implementable services which includes wellness, illness, support services and emergency (WISE). Mental health is also now being incorporated into Primary Health Care. By adopting Primary Health Care as the thrust of the health care system, not only has the Ministry of Health increased the number of modern healthcare facilities to improve physical and geographical coverage, it has also expanded the range of services provided. These services now include promotive, preventive, curative and rehabilitative care, far beyond the few basic elements of primary health care services originally envisaged by the Alma Ata Declaration.

*Integrated Services
or the Reviewed
Approach (REAP)*

Chronic Diseases in Malaysia

The disease profile of the world is changing at an alarming rate. Chronic diseases include heart disease, stroke, cancers, chronic respiratory disease, diabetes and mental disorders which now account for 47% of the global burden of disease and 60% of all deaths. World Health Organisation (WHO) in its report Preventing Chronic Diseases: a Vital Investment states that 80% percent of chronic disease deaths occurred in the low and middle income countries and 50% of these deaths occurred prematurely in people under 70 years of age, disputing the long-held notion that chronic diseases are mainly affecting affluent countries and older generations.

Globalisation, urbanisation, an ageing population, as well as changing environmental ecology has been identified as the underlying determinants responsible for the changing pattern of diseases in developing countries. Malaysia is no exception in terms of the effect of urbanisation, as an estimated 63% of



Malaysians now live in urban areas. Although only 6.6% of Malaysians are aged 60 years and above, the ageing population is projected to gradually rise as the life expectancy at birth for both males and females has increased over the years to 70.6 years for males and 76.4 for females in 2005.

In Malaysia, the Burden Of Disease study conducted in 2004 reported for non-communicable diseases such as Hypertension, Diabetes and Cardiovascular Diseases contributed more than two thirds to the Burden of Disease. Communicable diseases, maternal and perinatal conditions and nutritional disorders contributed to 20% of the burden.

Burden of Disease

The total years of life lost for the Malaysian population was 1.7 million years with almost two-thirds of this burden of premature deaths resulting from chronic diseases. Of the total burden of disease measured using Disability Adjusted Life Years (DALYs), approximately 69% was contributed by chronic diseases.

Data from the Malaysian Non-Communicable Disease (NCD) Surveillance for 2005/06 estimated that approximately 11.6 million Malaysian adults aged 25-64 years had at least one risk factor for chronic diseases and only about 3% did not have any risk factor.

Prevalence of Diabetes in Malaysia

Diabetes mellitus is an important public health concern. Globally there is a rising trend in the prevalence of diabetes due to many factors including increasing prevalence of obesity and physical inactivity. The International Diabetes Federation (IDF) predicts that by the year 2025, the South East Asia Region would have the highest prevalence of diabetes. The World Health Organisation (WHO) has estimated that in the year 2030, Malaysia would have a total of 2.48 million people with diabetes.

The First National Health and Morbidity Survey (NHMS I) conducted in 1986 reported a prevalence of diabetes of 6.3% and in the Second National Health and Morbidity Survey (NHMS II) in 1996, this had risen to 8.3%.

National Health and Morbidity Survey (NHMS)

The third National Health and Morbidity Survey (NHMSIII) in 2006 determined the prevalence of diabetes mellitus and impaired fasting glycemia (IFG) in the Malaysian population. The national



prevalence of diabetes was 11.6% in those above 18 years and 14.9% in those above 30 years. The prevalence of known diabetes, newly diagnosed diabetes and IFG amongst Malaysians above 18 years was 7.0%, 4.5% and 4.2% respectively.

Managing Diabetes in Primary Health Care

The primary health care sector under the Ministry of Health is the main service provider. Significant progress has been made by the Ministry of Health in terms of infrastructure. In 2008 there were 802 Health Clinics, 1,927 Community Health Clinics, 95 Maternal and Child Health Clinics, and 193 Mobile Clinics sprawled all over the country. Services are highly subsidised at minimal or no cost to the patients and are delivered by team members comprising of doctors, paramedics, nurses and other support staff. In Malaysia, most people with chronic diseases receive their medical care at the primary care level.

Efforts are being made in the public primary care sector to manage chronic diseases in a more systematic and holistic way, using the integrated approach of care. Currently, there are 172 Family Medicine Specialists (FMS) posted in 151 Health Clinics. The Ministry of Health has also started placing nutritionists at the primary care level to provide a more comprehensive approach of managing people with diabetes.

a) Screening, Early detection and Early Intervention of Diabetes

Most people were not aware that they have diabetes. The prevalence on undiagnosed diabetes in Malaysia was 2.5% (NHMS II) and increased to 4.5% in 2006 (NHMSIII). People with diabetes are prone to develop complications. Thus, it is important to detect diabetic cases as early as possible.

In promoting early detection of diabetic, opportunistic screenings were conducted in health clinics since 1996. Screening was carried out especially among those with high risk factors which included those aged 35 years and above, obesity with BMI>30, family history of diabetes, history of gestational diabetes, history of big baby,

High Risk Screening

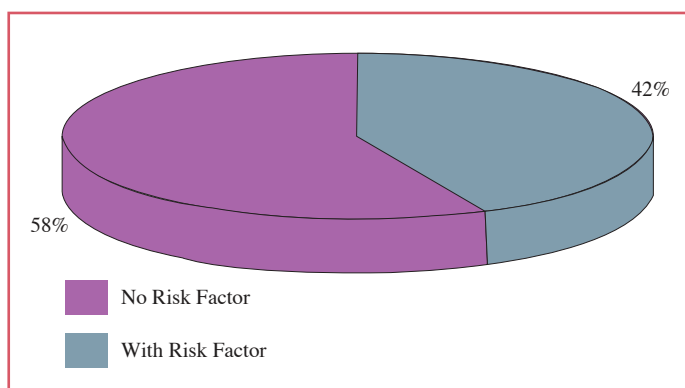


hypertension and hyperlipidaemia, as recommended by Diabetes Clinical Practice Guidelines.

However since 2008, the Ministry of Health has introduced integrated screening involving all age groups. A standardized format for health status Screening or known as BSSK forms (*Borang Saringan Status Kesihatan*) has been developed to facilitate this screening activity.

Integrated Screening

Figure 1: Integrated Screening Activity at Health Clinics



A total of 13,422 clients were screened with 58% or 7,804 clients having at least one risk factor. Among those with risk factors, 10% were smokers, 8% with high blood pressure (BP>140/90mmHg), 7% were overweight and physically inactive, 5% were obese, 4% with abnormal glucose and 2% with abnormal lipid levels.

Those found with risk factors were referred for further intervention. This included sessions on health education, dietary advice, weight management and counseling.

b) Diabetic Care Management and Monitoring

Intensive glycaemic control can delay the onset and progression of the early stages of diabetic retinopathy, nephropathy and neuropathy in diabetic patients. Thus, monitoring is an essential part in diabetes management.

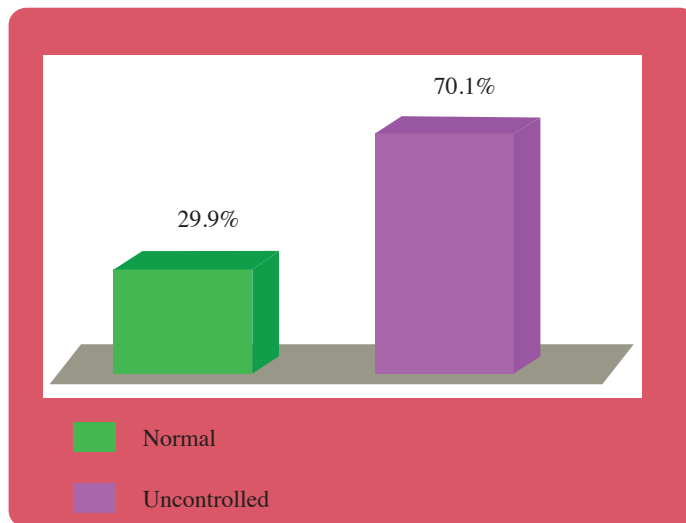
Diabetics attending health clinics are routinely monitored for fasting blood glucose (FBG). However, since 2001,



glycated haemoglobin or HbA1c has been used for more accurate assessment of metabolic control. Tests using HbA1c provide information to the average glycaemic control over the past 3 months is a better indicator of diabetic control.

For the year 2007, 214,145 HbA1c tests were done with 70.1% (150,113 cases) have HbA1c >6.5%.

Figure 2: Status of Diabetes Control



c) Screening for Diabetes Complications

Diabetic patients were screened for complications as scheduled including fundoscopic examination, foot examination, cardiac status, peripheral neuropathy and renal status.

Since 2001, several health clinics were equipped with fundus camera to assist in detection of retinopathy. At present, there are 66 Health Clinics with fundus camera, mainly those clinics with in-house Family Medicine Specialist (FMS). The fundus photograph taken will be seen and graded by the FMS. If needed, patients are referred to the Ophthalmologist for further management.

*Diabetes
Complications*

Diabetic nephropathy is one of the more common complications. Data from the Malaysian Renal Registry



showed an increasing number of diabetic patients requiring dialysis (from 40% in 1999, 45% in 2000 and 54% in 2004). In 2008, it was reported that 55% of all new patients for dialysis had end stage renal failure (ESRF) due to Diabetes.

Detecting early signs is essential for managing renal complications among diabetic patients. In health clinics, diabetic patients are screened for urine albumin annually.

Quality of Diabetic Care in Primary Health Care Setting.

The Family Health Development Division has initiated the quality assurance (QA) program for diabetes as a modified NIA or Modified National Indicator Assurance Programme in 1996. The purpose of this QA programme is to monitor the appropriateness of diabetic management at the primary care level by health care providers. This initiative uses the principle of continuous quality improvement that focuses on the process and not only outcome. The work process follows the model of good care with reference at every critical point so that any shortfall in the service outcome can be easily traced.

QAP Diabetes in Primary Care

The indicator identified for this QAP program is the percentage of diabetic patients receiving appropriate management at the health clinic. Advantage of this indicator includes:

- a) Ensuring health personnel constantly upgrade their knowledge.
- b) Ensuring usage of Diabetes CPG.
- c) Indicating whether the present practice of diabetic management is adequate.
- d) Identification of areas to be strengthened



Training

Training is an on-going activity at the primary care level where doctors, paramedic and allied health staff are trained regularly to update their knowledge and skills in diabetic management.

Since 2004, the Ministry of Health has started post-basic training in Diabetes Management for paramedical staff. This post-basic training is a 6-months course which is held in the training schools for Assistant Medical Officers in Kedah and Sabah. Each year, 2 batches of students attend this course with an average of 30 students per intake.

Standard Operating Procedures and Clinical Guidelines

Management of diabetes at the primary care level follows what is stated in the Clinical Practice Guidelines for Diabetes (Diabetes CPG). The Ministry of Health has come out with regular Diabetes CPG updates since 1996. The last guideline was produced in 2004 (3rd Edition) and for the year 2008, work has started on the 4th Edition of the Diabetes CPG.

*Clinical Practice
Guidelines for
Diabetes*

Health Promotion and Education

More efforts are being given to the primary prevention and health promotion. This includes the use of the media in publicity campaigns, the production and distribution of educational materials, and the education of diabetic patients, their family and carer.

Health education at the health clinics has been done either on an individual basis or as a group activity. It covers a wide range of topics from information about diabetes as a disease, its risk factors, elements on diet, exercise and on to how to lead a normal active life with diabetes.

Future Plans

- i. To have a structured annual diabetic clinical audit in primary health care, as an additional assessment tool in measuring the quality of diabetic management. This will provide the mechanism for reviewing the



quality of daily care. The audit process will also provide information about the aspects of diabetic care that has been audited and how to improve it.

- ii. To have an outcome indicator of glycaemic control by using HbA1c level. The objective of this indicator is to assess the quality of care of diabetic patients in primary health care by using HbA1c level as the proxy.

Conclusion

As the diabetic prevalence rate in Malaysia has risen much faster than expected, efforts in prevention and control should be stepped up. As primary care is the first level of contact for individuals, the family and the community, it is vital that good quality medical care is delivered to our diabetic patients at the primary care level.

A strong commitment from national leaders and policy makers, health care organisations, community leaders, health care personnel, patients and families are needed to ensure quality of care at the primary care level.

Emphasis should be given to shift from curative to preventive and community based primary health care. Strengthening of diabetes care should be done at all levels of the health system to ensure that appropriate attention is given.



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FIRST GLOBAL PATIENT SAFETY CHALLENGE IN MOH HOSPITALS: 'CLEAN CARE SAFER CARE'

SUMMARY

The First Global Patient Safety Challenge initiated by WHO in 2005 with the theme 'Clean Care Safer Care' was an international movement aimed at improving patient safety through the simple act of performing proper hand hygiene at point of care by health care workers. Malaysia joined the alliance in 2006, and strategies to implement hand hygiene using alcohol based hand rub at point of care were laid down. The hand hygiene compliance surveillance was started in 2008 in the state hospitals and hospitals with specialists and will be a part of the monitoring system in the infection control program of the MOH.

The outcome of the implementation will be monitored through the healthcare associated infections rates and the alert organism infection rates in the hospitals. Though the hospitals faced multiple challenges during the implementation, the rate of hand hygiene compliance was recorded at 56% at the beginning of the surveillance in June 2008 as compared to a compliance of less than 50% from previous surveys. Future evaluation and interventions aim to improve the hand hygiene compliance surveillance in relation to the hospital healthcare associated infection and the rate of alert organism infections will be monitored.

Introduction

Hand hygiene has always been considered by the experts as the undisputed and single most effective infection control measure. Effective hand hygiene practice among health care providers reduces the rate of healthcare associated infections (HCAI) and the rate of alert organisms, Methicillin Resistance Staphylococcus aureus (MRSA) or Extended Spectrum Beta Lactamase (ESBL) Klebsiella rates in the hospitals.

*Hand hygiene
effective in
controlling infection*

The hands of health-care workers are the most common vehicle for the transmission of micro-organisms from one patient to another, from one body site to another within the same patient, and from a contaminated environment to patients. Importantly, health-care workers' hands become progressively colonized with microorganisms including potential pathogens during patient care. In the absence of hand hygiene practice, the longer the duration



of care, the higher is the degree of hand contamination.

However, the adherence of health-care workers' to good hand hygiene practice is extremely low. A number of studies in the past have demonstrated moderate to poor compliance to hand hygiene practices of 20% to 50% only. In critical care situations where there are severe time constraints and the workload is higher, adherence to good practices is even lower. The challenge is to motivate healthcare personnel to undertake this very basic professional responsibility.

*Low compliance
in hand hygiene
practice*

The initiation of the hand hygiene practice change with the use of alcohol based hand rub (ABHR) in the effort to ease hand hygiene at point of care in hospitals began with the Ministry of Health (MOH) Malaysia's commitment and participation of the WHO First Global Patient Safety Challenge themed "Clean Care is Safer Care" in May, 2006. Following this, 'The Hand Hygiene Handbook' was developed and distributed to all MOH hospitals in the same year.

*ABHR for Hand
Hygiene*

Key Strategies for Implementation

The strategies that were laid for the hand hygiene challenge were as follows:

*Strategies of hospital
hand hygiene
implementation*

- i. National Hand Hygiene Guidelines was produced in 2006 (Adapted from the WHO document)



- ii. Hand Hygiene Campaigns, conducted at national level (2006) and State level (2007) contributed to the increasing awareness on the importance of hand hygiene compliance and practice.



- iii. Continuous training on hand hygiene in all hospitals as regular or routine activities of the infection control units.
- iv. Continuous financial allocation for alcohol-based hand rubs.
- v. Distribution of educational materials on the techniques of hand hygiene and “5 moments in hand hygiene”.
- vi. Training on hand hygiene observation/audit which is a component from WHO Multi-modal Hand Hygiene Strategies and Tools, in 2007 and early 2008.
- vii. Surveillance of hand hygiene compliance rate in hospitals.

Hand Hygiene Campaigns

The use of ABHR started in the middle of 2006 in critical care service areas of the State hospitals. The hand hygiene practice change activities continued in 2007 with the expansion of ABHR usage hospital-wide. With a budgetary allocation from the Medical Development Division, MOH, state hospitals and hospitals with specialists in the country continued to conduct hand hygiene campaigns in 2007 and 2008.

Hand hygiene campaigns

The campaigns highlighted the importance and proper technique of hand washing and hand rubbing, as well as encouraging the practice change of using the ABHR among health care provider. ABHR was made freely available in all hospital wards and clinics



Pahang State Health launching of campaign in its state hospital 2007.





Hand hygiene training session in Hospital Ipoh.

Training in WHO Multimodal Implementation strategies

Key elements in the multimodal strategies for hand hygiene as outlined in the implementation guide by the WHO includes staff education and motivation programmes, adoption of alcohol-based hand rub as the gold standard, use of performance indicators, and strong commitment by all stakeholders, such as front-line staff, managers and health-care leaders

*Adoption of
WHO multimodal
strategies*

In November 2007, training on the WHO's '5 moments in hand hygiene' was conducted at national level for all infection control personnel, infection control nurses and selected infection control link nurses in the state hospitals. The training sessions included observation technique for hand hygiene compliance and calculation involved in the monitoring of hand hygiene compliance, adapted from the WHO hand hygiene implementation guide.

*Practice and
observation
technique of the '5
Moments in Hand
Hygiene'*

The "5 moments" adopted constitutes the fundamental temporal reference points for health-care workers, and designate the moments when hand hygiene is required in order to effectively interrupt microbial transmission during care:

- i. Before patient contact
- ii. Before aseptic task
- iii. After body fluid exposure risk
- iv. After patient contact
- v. After contact with patient surroundings



The state hospital infection control doctor and nurses who attended the national training then conducted 'echo training' for all categories of health care providers in each State hospital from February to April, 2008.

*Information,
Education and
Communication
(IEC)*

Posters and education materials were produced at national level and distributed to the States. Some hospitals, to their credit, developed education materials and posters on their own to be used in their hospitals during the campaign and for future training.

The key messages in the training and education materials were the usage of alcohol based hand rub in the practice of hand hygiene at point of care, practice change of hand hygiene from hand washing to hand rub at point of care and the practice of hand hygiene following the "5 moments".

Hand Hygiene Implementation Project

In an effort to assess the success of hand hygiene practice change, and also to show that hand hygiene with ABHR improves hand hygiene compliance rate in hospitals, a multi-site hand hygiene implementation project was conducted in April 2008. The monitoring of hand hygiene is to be continued in 2009 in all State hospitals.

*Multisite hand
hygiene compliance
in state hospitals.*

The hand hygiene observation/audit used is a component from WHO Multi-modal Hand Hygiene Strategies and Tools (adopted in 2007). Trained infection control nurses, had to observe at least 200 opportunities of hand hygiene moments in the month of April, May and June of 2008 among healthcare workers in their hospitals.

The objective of the project was to compare the hand hygiene compliance rates before and after a hand hygiene practice change with the introduction of alcohol based hand rub in all public state hospitals and ultimately to assess the hospital MRSA rates and other HCAI following the practice change in the following years.



Hand Hygiene Performance and Hospital Infection Surveillance.

Prior to the hand hygiene compliance observation, health care workers were surveyed for their perception and practice of hand hygiene. 90.2% of the participants have had formal hand hygiene training, and 94.8% informed that the alcohol-based hand rub was available in their hospitals.

*Perception of
personnel to hand
hygiene practice*

73.0% of the health care workers believed that the impact of HCAI on patient outcome was high or very high and that hand hygiene was highly or very highly effective in preventing HCAI (89.9%). Almost 90% of them believed that hand hygiene is an important issue for the governing body of their hospitals and 69.4 % thought that their co-workers performed hand hygiene at least 50% of the time.

The hand hygiene compliance observation was conducted between May and June in 2008. There were 6924 opportunities observed with more than half of it done on nurses and midwives. The overall hand hygiene compliance rate was only 56.85% with nurses/ midwife and auxiliary nurses showing 63.0% and 58.0% compliance respectively

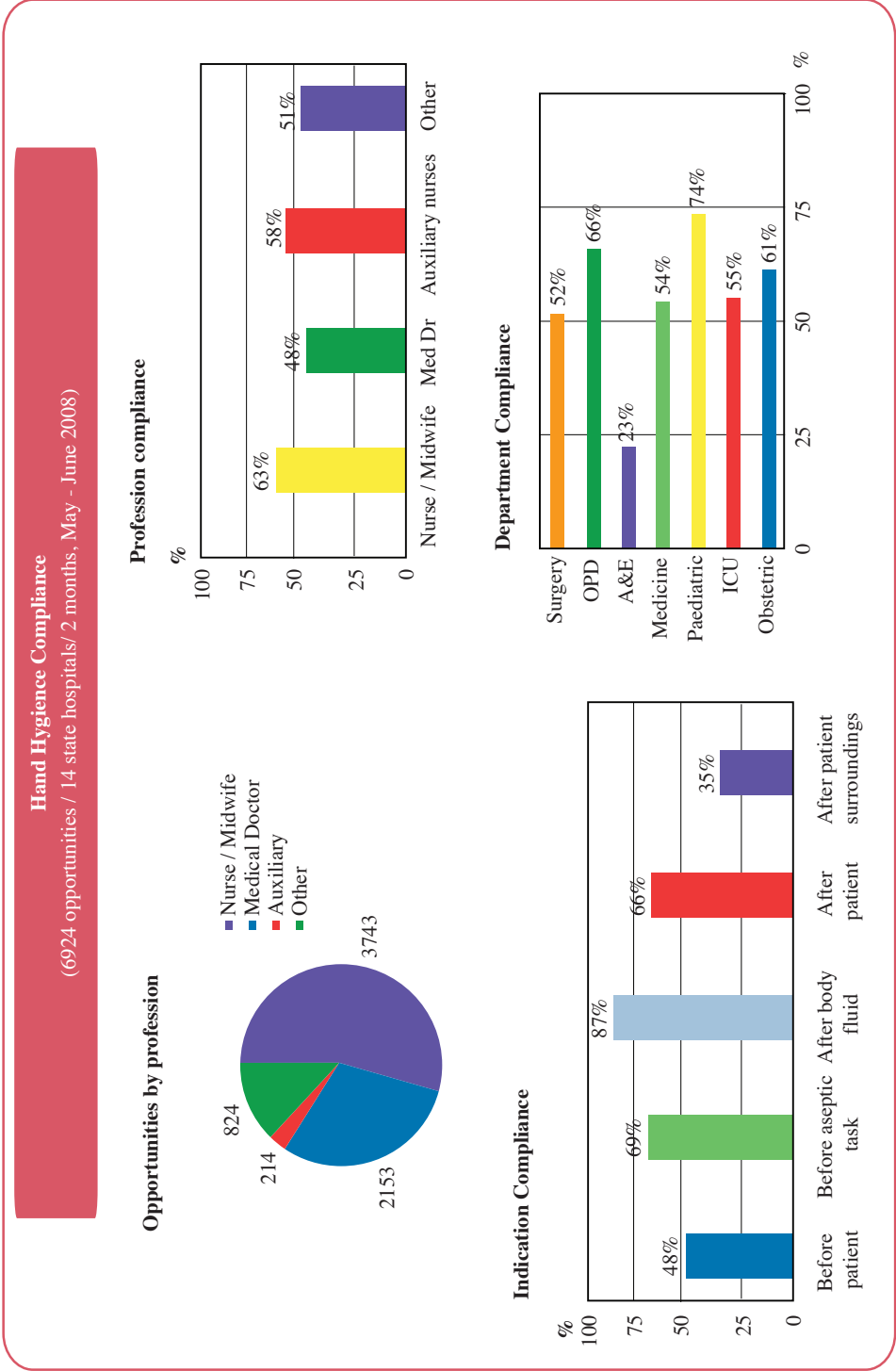
*Results of first hand
hygiene compliance
survey*

Among the 5 moments or indication used during the observation audit, hand hygiene compliance rate was highest on the indication of 'after exposure to body fluid' (87%) and lowest on the indication of 'after contact with patient surrounding's (35%).

Among the hospital departments, the highest hand hygiene compliance rate was seen in the Pediatric (74.0%), followed by Outpatient (66.0%), Obstetric (61.0%), Intensive Care Unit (55.0%), Medical (54.0%) and Surgical (52%). In the Emergency Department the hand hygiene compliance rate was 23.0%, with data collected from only 2 State hospitals. All departments used more hand wash than hand rub with more than 70.0% preferring hand wash to hand rub in the Intensive Care Unit, Pediatric and Obstetric Departments



Figure 1: The hand hygiene compliance of healthcare worker by profession, indication and department in state hospitals.

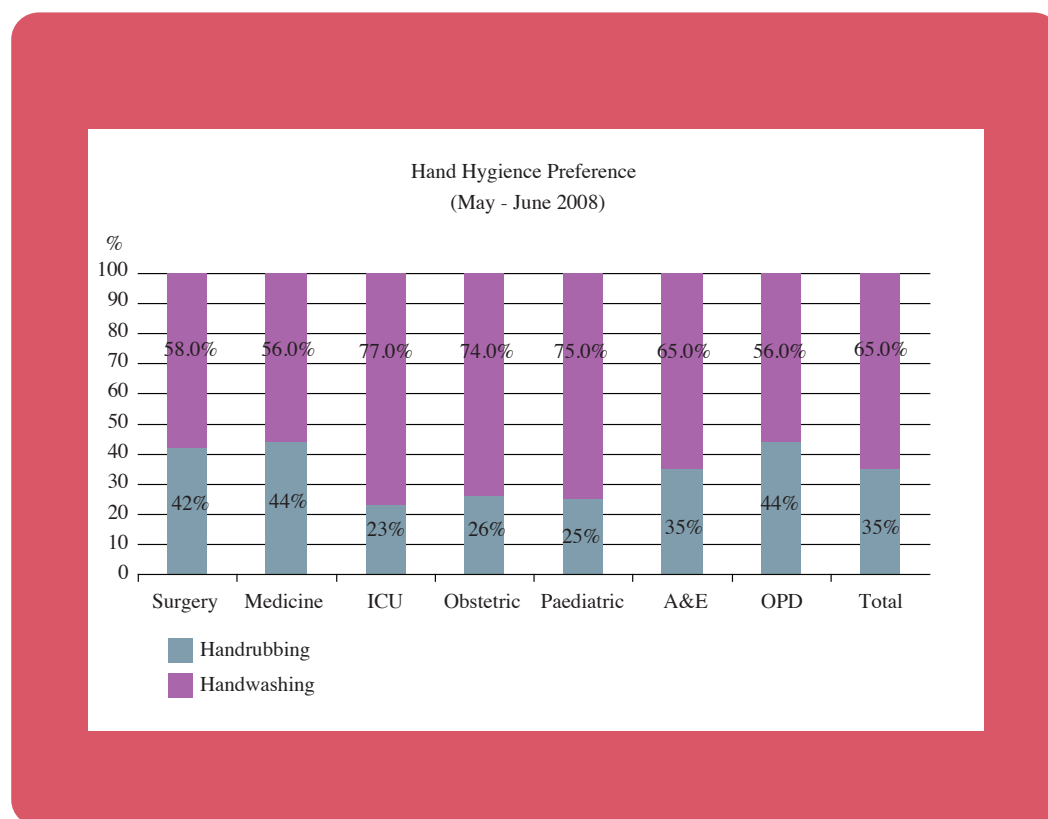


The practice change by introducing ABHR as an alternative to hand washing at point care was gradually introduced to healthcare workers in all State hospitals in 2007 and 2008. Although the rate of hand hygiene (washing or hand rubbing) compliance was not quite satisfactory among health care workers, it was noted that the majority of healthcare workers still preferred to hand wash rather than hand rub with ABHR.

Hand hygiene preference –wash or rub?

This is shown in this survey where 40% of the healthcare workers from the different departments were still not comfortable with alcohol hand rub with less staff using ABHR as their choice for hand hygiene

Figure 2: Hand Hygiene Preference (wash or rub) by hospital departments.



Challenges And Lessons Learnt During the Implementation

Leadership by example, like having the consultants practising hand rub during rounds or medical procedures in the ward and

Leadership by example



constantly reminding their staff to do the same will enhance hand hygiene practice in the department. In addition, hospitals are also to continuously train healthcare providers on hand hygiene at entry point, in refresher courses or as and when infection control courses are conducted in the hospital.

The training of hand hygiene observers in the infection control unit to ensure the reliability of observation was conducted at national level and 'echoed' to selected staff in hospitals. However, sustaining staff trained for observation of hand hygiene performance is difficult due to movement of staff following promotional exercises, transfer or retirement. Hand hygiene training is regularly conducted by hospital infection control units for new hospital staff and in the post basic infection control training, participants is trained as observers.

Sustaining trained personnel on the programme

Therefore infection control nurses (ICN) need to be constantly trained in hand hygiene observation technique nationally and within each State. Hospitals are to ensure that there are sufficient infection control nurses (1 ICN: 110 beds) to perform infection control activities which include observation of hand hygiene compliance in wards. This is in compliance with the international recommendation.

Sufficient infection control nurses

Patients are aware of the practice change of performing hand hygiene using ABHR. They are given the reason for such action when they ask. The set back of patient education is the disappearance of ABHR from the wards when patients are discharged!

*Patient education in hand hygiene.
Sufficient supply of ABHR*

Access to ABHR is made easier by hanging the ABHR on the wall near the patient's bed, besides having them on the medical trolley during ward rounds. Yearly budgetary allocation is made to all hospitals from the Medical Development Division to ensure sufficient supply in the hospitals. Hospitals are to plan their procurement of ABHR accordingly each year.

Relationship of HCAI and hand hygiene in hospitals

Hand hygiene compliance rate of the hospital in relation to alert organism surveillance and HCAI is also one of the main agenda in the hospital, state and national infection and antibiotic control committee meetings. Active and continuous hand hygiene training nationally and in the states, encouraging practice change and continuous hand hygiene observation audit in the hospitals is



some of the factors that can contribute to the reduction of hospital infections.

Conclusion

The hand hygiene compliance rate was noted to have improved with the introduction of ABHR for hand hygiene. However, the preference for hand wash was noted to be high among the healthcare workers as compared to hand rub when performing hand hygiene.

With continuous on-going training and availability of ABHR in hospital wards and clinic, the practice change from hand washing to hand rub and increased compliance to hand hygiene among health care worker is possible. It is hoped that future trending and evaluation of hand hygiene compliance and hospital infections will show such improvement.



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FUTURE CHALLENGES IN THE DEVELOPMENT OF FORENSIC MEDICINE SERVICES AT MINISTRY OF HEALTH HOSPITALS

SUMMARY

Over the years, Forensic Medicine Services provided by the Ministry of Health has attracted increasing public interest due to the nature of the cases under its purview. From the initial 9 Forensic Medicine Specialists serving the Ministry of Health hospitals throughout the country, there are now twenty Specialists, 6 of whom have obtained Subspeciality Degrees. The types of deaths for post mortem are of varying complexity and thus pose a great deal of challenges to the Forensic Medicine Specialists. The scope of Forensic Medicine Services has widened to include post mortems, crime scene investigations and toxicology

Introduction

During the early years, Forensic Medicine Services had been in the shadow of Pathology Services. The concept of a National Institute of Forensic Medicine (NIFM) was approved during the Policy and Development Committee Meeting 2002 but it has not materialised till the present day due to financial constraints and other medical service priorities. The Ministry of Health (MOH) has acknowledged the importance of Forensic Medicine Services and has developed the service in stages starting at the State hospitals. The district hospitals were provided with minimal requirements for Forensic Medicine Services so as to ensure easy accessibility of the services to all levels of the population throughout the country.

Early development of Forensic Medicine Services

Defining Forensic Medicine Services and Specialty

Forensic Medicine, also known as legal medicine, applies medical knowledge to criminal and civil law. It includes Forensic Pathology, Clinical Forensic Medicine, Forensic Medical Laboratory, Forensic Anthropology, Forensic Odontology, Forensic Histopathology and Forensic Radiology. There are three (3) main areas in Forensic Medicine:

Defining Forensic Medicine



- i. Forensic Pathology (relating to dead bodies including post mortems)
- ii. Clinical Forensics (examination of live patients for medical-legal purposes)
- iii. Forensic Medical Laboratory (analysis of forensic specimens)

Delivery of Forensic Medicine Services

Forensic Medicine Service is an integral functional division of the clinical directorate of the MOH. Delivery of Forensic Medicine services is provided by the Departments of Forensic Medicine at the State Hospitals and tertiary hospitals or the Forensic Medicine Units at the other categories of MOH hospitals.

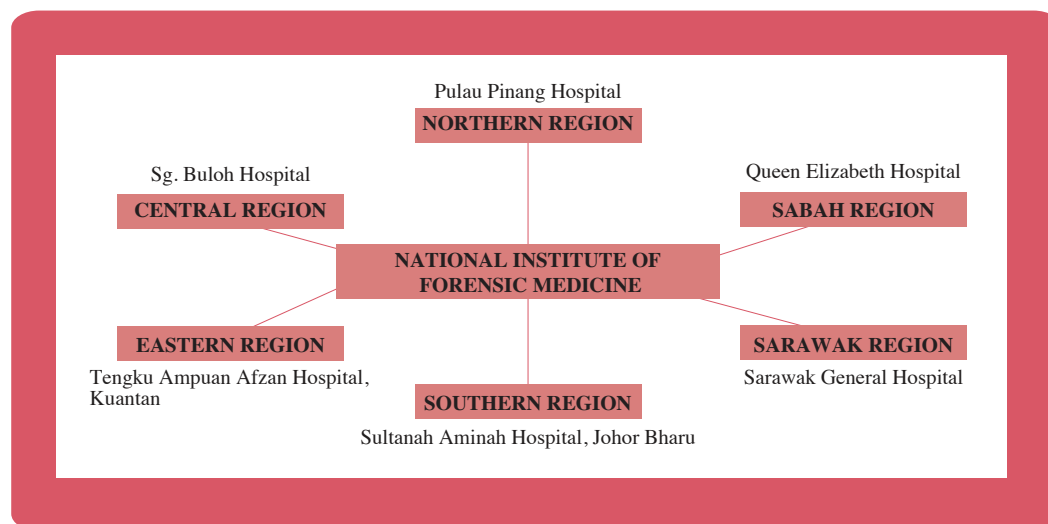
*Organisational
Structure of Delivery
of Service*

The Department of Forensic Medicine in Kuala Lumpur Hospital (HKL) also functions as the NIFM and acts as the National Referral Centre. The Department of Forensic Medicine was established in the year 2002 after its official separation from the Department of Pathology. The scope of service was to provide Forensic Medical Services which encompassed primarily the field of forensic pathology and clinical forensic medicine. The NIFM is headed by a Director who also functions as the National Advisor of Forensic Medicine Services, MOH.

Due to the shortage of Forensic Medicine Specialists currently, the delivery and monitoring of the services is via six (6 Forensic Regional Centres throughout the country. Each Regional Centre is headed by the Resident Forensic Medical Specialist based in the designated State Hospitals as shown below:



Figure 1: Organizational Structure of Forensic Medicine Services



Scope of Services Available

Currently, there is at least one Forensic Medical Specialist at all the state hospitals except for the states of Terengganu and Perlis. Forensic cases in Terengganu and Perlis are referred to the resident Forensic Medical Specialists in Tengku Ampuan Afzan Hospital, Kuantan and Sultanah Bahiyah Hospital, Alor Setar respectively.

Scope of Services

Routine medicolegal autopsy cases such as accidents, suicides and natural deaths at the peripheral hospitals are conducted by the medical officers at the respective hospitals. Where necessary, forensic consultations and case referrals are made to the respective state hospitals's Forensic Medicine Specialist.

The following services are available at hospitals with Forensic Medical Specialist:

- Management of dead bodies – receive, register and release bodies to the next of kin and disposal of unclaimed bodies
- Storage of bodies
- Provision of autopsy services
- Provision of clinical forensic services



- Management of medico legal specimens
- Crime scene investigations
- Provision of forensic medicine laboratory services
- Provision of medico legal consultation
- Provision of expert testimony in court
- Special services - Management of fatalities in mass disaster and infectious disease and unknown agents outbreak
- Provision of forensic training, education and research

Hospitals without Forensic Medicine Specialist, unless the case are referred to a specialist, can offer these services:

- Storage of bodies
- Provision of autopsy services
- Management of medico legal specimens
- Provision of professional testimony in court

Standardisation of Service Delivery

Medical services provided by MOH Malaysia are governed by the principles of quality as well as safe and efficient delivery of services. This also applies to the services provided by Forensic Medicine Specialty at the hospitals.

*Standardisation of
delivery of services*

Thus to ensure uniformity in providing the services, two (2) guidelines have been published as a Director General's Circular and distributed for use. These are:



- a. Director General Of Health, Circular No. 5/2008:
 “Guidelines on Distribution of Unclaimed Bodies at Ministry Of Health Hospitals to The Faculty Of Medicine In The Country For The Purpose of Education or Medical Research” (reference MOH/P/PAK/164.08(GU) Mei 2008)



- b. Director General Of Health, Circular No. 17/2008
 “Guidelines on Post Mortem On Dead Bodies at Ministry Of Health Hospitals” (reference MOH/P/PAK/170.08 (CL) October 2008)



Future Development And Challenges

a) Provision of Services

Recently, the Forensic Medicine Services have been under close scrutiny both locally and internationally, indicating a great

Provision of Services



awareness regarding medico-legal issues amongst our Malaysian community as well as overseas. NIFM will continue to maintain and improve further the provision of quality services to our customers.

NIFM will also continue to promote and recruit more trainees in order to train more specialists who can be posted to forensic centers based on workload and demand.

Subspecialty services are available at the following forensic centers; Forensic Anthropology at HKL and Melaka Hospital; Clinical Forensic Medicine at HKL, Tengku Ampuan Afzan Hospital, Kuantan and Seremban Hospital and Forensic Histopathology at Sultanah Bahiyah Hospital, Alor Setar and Queen Elizabeth Hospital.

In any event of a disaster or major incident that involves many fatalities, NIFM is able to coordinate the management through the network of 20 Forensic Pathologists nationwide. NIFM is also responsible and ready to handle autopsy of high risk cases in any event of outbreak of infections due to unknown agents. Most of the Forensic Medicine specialists have had hands-on experience in managing deaths from the previous SARS outbreak.

Clinical Forensic Medicine cases such as assault cases (child abuse, maid abuse and sexual offences) are sometimes referred to the Forensic Medicine Specialists. NIFM realizes the importance of this subspecialty and have trained 2 Forensic Medicine Specialists in this field. The combined management of these clinical forensic cases amongst the Emergency Department (ED) doctors, gynecologists and surgeons has substantially improved the handling of these cases at the One Stop Crisis Centre located in the ED.

NIFM is hoping to develop the Forensic Medicine Laboratory in further supporting the subspecialty services of Forensic Anthropology, Forensic Histopathology and Clinical Forensic Medicine services. At present NIFM is developing and strengthening the 2 laboratories; one in Sungai Buloh Hospital and the other in Sultan Ismail Hospital, Pandan.



b) Human Resource

Currently there are only 20 Forensic Medicine Specialists serving the MOH hospitals throughout the country (Table 1).

Table 1: Distribution of Forensic Medicine Specialists in Ministry of Health, Malaysia 2008

No	State	No. of Hospitals	No. of Forensic Medicine Specialists
1	Perlis	1	0
2	Kedah	9	1
3	Perak	14	1
4	Pulau Pinang	6	1
5	Selangor	10	4
6	Wilayah Persekutuan Kuala Lumpur / Putrajaya	2	5
7	Negeri Sembilan	6	1
8	Melaka	3	1
9	Johor	11	1
10	Pahang	10	1
11	Terengganu	6	0
12	Kelantan	9	1
13	Sabah (including Labuan)	24	1
14	Sarawak	19	2
Total		130	20

Note: *Subspecialty: Clinical Forensic Medicine = 2 persons*
 Forensic Anthropology = 2 persons
 Forensic Histopathology = 2 persons

An ideal number of specialists would be a minimum of 3 specialists for each state and 8 specialists with the NIFM. It is a great challenge to recruit and encourage junior doctors to pursue Forensic Medicine as their postgraduate area of interest. With ongoing short



courses in Forensic Medicine conducted in all states, positive support from MOH and more placement allocation by the local universities, this effort would be expected to attract more trainees to enroll for postgraduate training in Forensic Medicine. The introduction of the new ‘Rotational System’ will be more attractive and standardized as compared to the ‘close’ and ‘open’ system for the local Masters Programme in Forensic Medicine.

A transient acute shortage of medical officers due to the implementation of the new housemanship training program of two years duration has affected many district hospitals that rely on medical officers to perform medico legal autopsies on non-complicated cases. Due to the nature of services and small number of cases, it is not cost effective to post a permanent medical officer to a Forensic Medicine Unit of every Hospital without a Forensic Medicine Specialist. However, it is the prerogative of the Hospital Director to ensure the provision of autopsy services when the need arises. A better alternative to maximize the utilization of medical officers in order to further improve the service is to create a minimum of 2 specific posts of Forensic Medicine Medical Officer (UD44-UD48) in all District Hospitals; the Hospital Director can also utilize these officers to support any other clinical disciplines based on their workload.

At present there are 22 Forensic Science Officers employed in various MOH Hospitals. However there are only 2 Forensic Medicine Laboratories in the process of being set up, in Sungai Buloh Hospital and in Sultan Ismail Hospital, Pandan. NIFM has adequate number of Forensic Science Officers to support the Forensic Medicine Services and the future setting up of 6 regional Forensic Medicine Laboratories will ensure much better quality services. These laboratories are in keeping with the current availability of subspecialties in Forensic Medicine namely Clinical Forensic Medicine, Forensic Anthropology, Forensic Histopathology and Forensic Toxicology.

Trained Assistant Medical Officers (AMO) and Medical Attendants are still short in most of the forensic centers nationwide. The ongoing 6 months post-basic course (Forensics) for the AMO and the Level 3 (Forensics) course for the Medical Attendants will ensure an adequate number of trained staff in all forensic centers in the country. The development of Clinical Forensic Medicine services would also require new posts for the nurses to support this important service.



c) Physical Resource: Infrastructure and Medical Equipment

At present, the Department of Forensic Medicine HKL also functions as NIFM. It is timely for NIFM to have its own building complex in order to focus on future development in line with its vision, mission and values to meet customer requirements. NIFM is expected to counsel, advise, train, steer, support and enable all the Forensic Medicine centers in the country.

Infrastructure and equipments

Some centers require new buildings or upgrading and others need new or replacement equipment that would further improve the quality of services provided.

d) Financial Allocation

Financial constraint is another challenge for the future development of Forensic Medicine Services. By 2008, Forensic Medicine was granted its own activity code for budgetary allocation. This was a move towards self management of allocation separated from or independent of the Pathology Services. It has also contributed to a more efficient and coordinated distribution of funding and expenditure for all the Forensic Medicine Departments/Units via their respective hospitals.

Budgetary Allocation

e) Information And Communication Technology

NIFM has taken the initiative to have the Forensic Medicine Information System (FMIS) installed at fourteen (14) Forensic Medicine Departments with the allocation granted through the New Policy Projects and also through Ministry of Science, Technology and Innovation (MOSTI) Innofund (Innovation Fund) project.

Information and Technology

NIFM will have a very important tool through FMIS in capturing national data for death statistics and also workload statistics of Forensic Medicine Services. These data will be very useful to MOH in planning future health policy and preventive programmes based on the yearly data series. NIFM will continue to expand this facility and technology in stages to be installed in most, if not all, MOH hospitals.



f) Training

Continuous and on-going training is a major focus of NIFM. NIFM had recently proposed through MOH to the Ministry of Higher Learning for universities to standardise the Forensic Medicine curriculum for undergraduates at all local Medical Schools (public and private universities). It has been the intention for the doctors-to-be who graduated from our local universities to be equipped with the necessary knowledge on management of the dead in preparation for posting to MOH hospitals without Forensic Medicine Specialists.

From next year onwards, the MPath (Forensics) will be incorporated with a 6 months of Clinical Forensic Medicine module.

The other categories of staff, for example, the Assistant Medical Officers and nurses involved in provision of Forensic Medicine Services are required to undergo relevant training as scheduled under their respective professional bodies.

g) Research Activities

The National Suicide Registry is a joint effort by the Forensic Medicine Services and the Psychiatry and Mental Health Services. The registry was started in 2007 and several reports have been published showing the importance of this registry to monitor changing trends of suicide in Malaysia.

Research

The FMIS is now installed at 14 state Forensic Medicine Departments and will capture numerous data on almost all deaths in the country. Death statistics will be a very useful asset and tool for MOH in formulating health promotion and preventive programmes for the country. It will also be useful in human resource planning.

Under the initiative of MOH, Malaysia is the first country in South East Asia that has procured a 64 Multi-Sliced Computerized Tomography (CT) Scanner for the CT Scan Assisted Post Mortem Project, which is due to be operational by June 2010. This postmortem CT facility based in HKL will be a pilot project in spearheading the research activity on deaths due to motor-vehicle accidents. It will provide NIFM staff with a high end technology and cutting edge tool to promote research activities in Forensic Medicine. It has even



generated great interest amongst the radiologists from the local universities. NIFM will explore future international collaboration in research activities in postmortem CT. NIFM also plan to organize training in postmortem CT technology for local and international participants.

Conclusion

In summary, the planning for future development of Forensic Medicine Services will focus its activities and efforts to face the present and possible future challenges. MOH and NIFM will continue to maximize productivity by optimizing all available resources; physical, financial, information and communication technology, and human resource. The objectives of MOH Forensic Medicine Services are aimed at providing a professional, effective, efficient and quality Forensic Medicine Services to support the judicial system in the country; with the hope that the future of the medico legal services will be further strengthened to achieve justice for the people.



DEALING WITH ADOLESCENTS USING THE HEADSS ASSESSMENT

SUMMARY

Most adolescent health problems are psychosocial and arise from the consequences of health risk behaviors, developmental difficulties and exposure to social and environmental risks factors. Yet, adolescents rarely choose to see health care providers for psychosocial issues such as substance use, sexual health, mental health, school or family problems. Adolescents often present to the clinics with relatively minor complaints. By exploring beyond the presenting complaints, the health care provider can assess the young person's psychosocial background and detect underlying health concerns and risk factors. This increases the chance of providing timely intervention, preventive education and counseling. The HEADSS screening tool is a structured framework for conducting a comprehensive biopsychosocial assessment of the young person. It provides information about the young person in key areas of their life: H - Home; E- Education/Eating/Exercise; A- Activities and Peer Relationships; D- Drug Use/ Cigarettes/ Alcohol; S- Sexuality / Spirituality; S- Suicide/ Depression/ Mood. This report explains the HEADSS assessment tool and its application in the Malaysian context.

Introduction

Adolescents form one fifth or 20% of the Malaysian population totaling 5 million (2009). They have relatively low morbidities and mortalities compared to other age groups but specific morbidities are high. Psychosocial problems such as accidental injuries, unprotected sexual intercourse, smoking, alcohol and substance abuse are high among adolescents which are most of the time undetected in the current routine management of patients. Adolescents will not reveal their problems unless they trust the adult or health care provider and the confidentiality of the information provided are assured. Many present with physical conditions, therefore if underlying psychosocial conditions are not explored, a lot of risk behaviour and mental health problems may be missed.

The National Health Morbidity Survey 2 (1996) showed school going adolescents (aged 13 to 18 years) participating in various risk behaviours. The prevalence of adolescent smoking was 16.7%;



9% consumed alcohol and 2.2% used drugs (heroin, hallucinogen, glue sniffing, cough mixture and other drugs). The prevalence of adolescents involved in sexual activity was 1.8% and majority of these adolescents were heterosexual (63.2%); homosexual (19.9%); and 9.4% utilised commercial sex workers.

*Adolescent health
status and risk
behaviours*

The NHMS 3 (2006) revealed the prevalence of psychiatric morbidity among children and adolescents (aged 5-15 years) have increased from 13.0% in 1996 to 20.3% in 2006. The National Population and Family Life Survey reported an increase in sexual activity among adolescents from 0.9% in 1994 to 2.1% in 2004. Problems widely reported by the media recently including teen pregnancies, unwanted babies, child abandonment and abortion are of great concern. Many of the psychosocial issues are sensitive in nature, thus all service providers dealing with adolescents require special training on how to engage and further explore their health issues.

The HEADSS Assessment

The HEADSS is a psychosocial screening tool designed by Dr Henry Berman in the USA and further developed by Drs Goldenring and Cohen in 1989. The HEADSS screening tool is a structured framework for conducting a comprehensive biopsychosocial assessment of the young person. It provides information about the young person's functioning in key areas of their life:

What is HEADSS

- H- Home
- E- Education/ Employment/ Eating/ Exercise
- A- Activities and Peer Relationship
- D- Drug Use/ Cigarettes / Alcohol
- S- Sexuality/ Spirituality/ Safety
- S- Suicide / Depression/ Mood

The HEADSS psychosocial screening tool was designed to discover the context of the presenting complainant to the health care provider. It is a useful tool to develop rapport with the young

Why need HEADSS



people while at the same time, systematically gathering information about their world- their family, peers, school and inner world. The HEADSS framework also helps to engage young people in a therapeutic relationship, to explore their risk and protective factors and utilize the information to help form a strength-based management plan with the young person.

The first impression a health care provider strikes at the outset of the assessment interview may affect the entire outcome. Thus, before starting the interview it is important to introduce yourself, establish rapport, show genuine concern and maintain eye contact with the adolescent. It is important that the health care providers clarify their own belief system and try not to be judgmental as the adolescent's values and belief system may differ from theirs.

Preparing for the interview

Explain and reassure the young person and their families about confidentiality at the beginning of the interview. The confidentiality statement or "verbal confidentiality contract" states that all information discussed is confidential except in 3 situations: where the adolescent may harm himself or herself, he or she may harm others, or others may harm the adolescent. In these situations, confidentiality may be breached in the best interest of the young person. Parents, family members or other adults accompanying the adolescent should not be present during the HEADSS assessment unless the adolescent specifically gives permission or asks for it.

Confidentiality requirement

A thorough understanding and discussion of the confidentiality requirement with both parents and adolescents underpins the process of building trust in the patient-doctor relationship and is essential in effectively assessing health risk behaviours and providing appropriate management to the clients.

There are many different approaches to taking a psychosocial history either through self administered questionnaires or through interview using the mnemonic HEADSS framework (See Appendix 1). HEADSS assessment is arranged so that one can progress from less sensitive questions such as home, education, activities to more sensitive questions such as sexuality, suicide and safety as the interview progresses. Rather than using HEADSS as a checklist to be rattled off, the real value of HEADSS lies in its feasibility in being incorporated within the clinical history that is context specific and customize to the age and development of the patient. There is no evidence that inquiring about sensitive questions such as sexual

Approach to HEADSS assessment



activity or suicide will promote such behaviours. In contrast, there is significant evidence to suggest that young people do not disclose sensitive information unless directly asked.

Health care providers need to be flexible in applying HEADSS assessment. Let the interview flow naturally in an interactive style and come back to an area not covered. It is useful to use open ended questions or third person approach as this normalises the process and lessens the impact of sensitive questions. Listen carefully and note the young person's verbal and non verbal responses. Any areas of ambiguity or matters pertaining to risky behavior need to be further explored. When asking sensitive questions such as drug use and sexual activity, it is important to request permission and reassure the adolescent that it's all right if they do not wish to answer the question.

Asking sensitive questions

Adolescent Health Services in Malaysia

The Adolescent Health Unit was first established in the Ministry of Health, Malaysia in 1996 as an expanded scope of the Maternal and Child Health Programme. Services for adolescents are provided at the clinics/hospitals, schools and community settings. Various government agencies, non-governmental organizations and private sector entities provide health services to adolescents in varying degrees. The main service provider is the Ministry of Health through its network of health facilities throughout the country. The health services provided to adolescents include promotive, preventive, curative and rehabilitative care. At the primary health care level, the services include health promotion and education, screening for risk behaviour, advice, counseling and curative care. Adolescents who require further management are referred to relevant agencies.

Background of adolescent health services

During the early phase of developing the adolescent health programme, several pilot projects were conducted to provide valuable inputs into the real need of the adolescents. In 2005, Ministry of Health developed a guideline on implementation of the adolescent health services at the primary health care level which consisted of adolescent health screening tools and standard operating procedures on managing common adolescent health problems. However, regular feedback from service providers showed that they required more skills in dealing and exploring further problems highlighted by the adolescent screening tools.



Applying HEADSS in Malaysia

In 2005, a group of officers comprising of a Family Health Physician, a Family Medicine Specialist and a paramedic went on a WHO Fellowship Study Visit to the Center of Adolescent Health Melbourne, Australia. The officers were exposed to the Australian model of providing adolescent friendly health services at the primary health care level as well as at the secondary and tertiary care level. As part of the undergraduate curriculum, medical students were taught on how to utilise HEADSS Assessment in dealing with adolescents.

*WHO Fellowship
Study Visit*

*Developing the
HEADSS Module*

Following the WHO study visit, the Family Health Development Division, Ministry of Health took the initiative to introduce the HEADSS Assessment in Malaysia and develop the Engaging the Adolescent Module Using HEADSS Framework. Several workshops and meetings were conducted to develop the draft module. In 2007, Professor Dr Susan Sawyer from the Center of Adolescent Health Melbourne, Australia was invited to train a group of Malaysian health care providers on using the HEADSS Assessment as well as provide valuable input into the final draft of the HEADSS Module. Since 2006, about 200 health care providers comprising of specialists in various fields, paramedics, counselors and psychologists have been exposed and trained on the HEADSS psychosocial assessment. It is hoped they will act as resource persons for future echo training at state and district levels to further improve the knowledge and skills of service providers.

*Contents of the
“Engaging the
Adolescent Module
Using HEADSS
Framework”*

The Engaging the Adolescent Module Using HEADSS Framework incorporate relevant and important aspects in managing adolescents which include overview of adolescent health issues and challenges, understanding the adolescents, improving communication skills, engaging the adolescent using HEADSS framework and how service providers can further enhance their confidence in dealing with the adolescents.

The module consists of five units; Unit 1: Overview of Adolescent Health; Unit 2: Understanding the Adolescent Development, Environment and Culture; Unit 3: Communication, Confidentiality, Rapport, Empathy and Trust (CRET); Unit 4: Using HEADSS Framework and Unit 5: Face Your Fears.



The module comprises of a guidebook with a set of videos and power point slides to facilitate echo training at the state and district levels. It is based on input from experts locally and abroad. It is primarily intended to be used for in-service training of all health care providers involved in managing the adolescents. However, this module is also useful to those dealing with adolescents in general.

Issues and Challenges

The issues and challenges can be categorised from the perspective of the adolescent, the service providers, facility, policy and work processes. Introducing the HEADSS assessment in Malaysia, has received a mixed response from the health care providers. Some find it useful while others find it difficult and time consuming.

In a busy clinic setting, applying the HEADSS interview may be challenging. Thus the challenge is to convince the health care providers to utilise the HEADSS assessment in their daily management of adolescents as and when required. Service providers need to be trained on how best to appreciate and apply HEADSS with special emphasis on how to establish rapport, maintain confidentiality, empathy and trust among the young clients.

Issues related to service providers

Many adolescents are reluctant to reveal their problems unless they trust the service providers and are assured of confidentiality. To facilitate adolescents to open up and seek help, it is essential that the health care provider and the whole clinic team maintains a positive and non judgmental attitude towards the adolescent and reassure confidentiality in the best interests of the young people.

Issues related to the adolescents

Since 2006, the Family Health Development Division has worked closely with the Institute of Public Health to conduct Training of Trainers on Engaging the Adolescent Using HEADSS Module. A total of 50 health care providers from various categories were trained annually. Budgets have been allocated for states to conduct echo training but due to competing priorities some states do not conduct echo training regularly.

Training requirements and related issues



Findings from pilot projects conducted in the early phase of the Adolescent Health Programme development revealed that the physical layout of the clinic, its policies and work process are also important in improving adolescent access to the clinics. To this end, national guidelines and standard operating procedures on the provision of adolescent friendly health services have been developed. To further strengthen the quality of health services at the primary health care facility, a circular from the Director General of Health Malaysia was circulated on Reviewed Approach (REAP), requesting all health clinics to provide comprehensive integrated services, including utilization of the health risk assessment forms. Whilst physical access is emphasized, efforts must also be made by local level managers to make all Ministry of Health clinics psychologically accessible by ensuring staff are friendly, caring, can be trusted to maintain confidentiality, professional and address the real needs of the adolescents.

Issues related to the facilities, policies and work process

Conclusion

It is hoped that in years to come, all health clinics will provide comprehensive adolescent friendly health services which are physically and psychologically accessible, equitable, appropriate to age and customised to the specific needs of the adolescent. To achieve this, more health care providers need to be trained on the HEADSS psychosocial assessment as well as empowered with the appropriate knowledge and skills for effective interventions.

Provision of comprehensive adolescent friendly services

There is now increasing evidence from longitudinal studies that identification of psychosocial issues followed by counseling can positively affect young people's lifestyles and behaviours. The early identification of such high risk behaviours and mental health problems through routine assessment of psychosocial health is the first step towards reducing adolescent morbidity and mortality. Universities and training colleges could also incorporate the HEADSS psychosocial assessment as part of the undergraduate or post graduate training in advancing the field of adolescent health and development in Malaysia.

Need for expansion of HEADSS assessment for in-service training and university curriculum.



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APPENDIX 1

The HEADSS Framework for Psychosocial Health Assessment (Adapted from Goldenring & Cohen)

The following are some questions as a guide to conducting HEADSS assessment

ASSESSMENT AREA	QUESTIONS
H-Home	<p>Where do you live?</p> <p>Who do you live with?</p> <p>How do you get along with each member of the family?</p> <p>Who could you go to if you needed help with a problem?</p> <p>Have there been recent changes?</p>
E-Education& Employment	<p>What do you like about school / work?</p> <p>What are you good / not good at?</p> <p>How do you get along with teachers/ employers and other students or colleagues?</p> <p>Is there any adult you can talk to at school and how do you feel?</p> <p>Have your grades changed recently?</p> <p>Many young people experience bullying at school/ work, have you ever had to put up with this?</p> <p>What are your future plans?</p> <p>Do you have meals with your family? How often?</p>



ASSESSMENT AREA	QUESTIONS
E- Eating	Is anyone worried about your weight? Are you happy with your weight?
E- Exercise	How do you get to school or work? Do you exercise? How frequent and for how long each session last? Do you play sport?
A- Activities & Peers	What do you like to do for fun? What do you do in your spare time? Who do you hang out with? What sort of things do you like to do with friends? Tell me about parties. Do you belong to any clubs, groups, etc? How much TV do you watch each night? Do you use a computer for talking to people?
D-Drugs	Are you on any regular medication? Anybody in your family smokes cigarettes, takes drugs or drinks alcohol frequently? Have any of your friends tried alcohol, drugs or cigarettes? How about you, have you tried any? Explore What effects do drug taking, smoking or alcohol have on them/ you?



ASSESSMENT AREA	QUESTIONS
D-Drugs	<p>Do they / you have any regrets about taking drugs?</p> <p>How much are you taking, how often and has your use increased recently?</p>
S- Sexuality	<p>Many young people your age become interested in sexual relationships. Have you ever had sexual experience with a boy or a girl?</p> <p>Have anyone touched you in a way that made you feel uncomfortable or forced you into a sexual relationship?</p> <p>How do you feel about relationship in general and about your own sexuality?</p>
S- Suicide	<p>How do you feel in yourself at the moment on a scale of 1 to 10?</p> <p>What sort of things do you do if you feel angry / sad/ or hurt?</p> <p>Is there anyone you can talk to?</p> <p>Do you feel this way often?</p> <p>Some people who feel really down often feel like hurting themselves or even killing themselves. Have you ever felt this way?</p> <p>Have you ever tried to hurt yourself?</p> <p>What prevented you from doing so?</p> <p>Do you feel the same now?</p> <p>Do you have a plan?</p>



ASSESSMENT AREA	QUESTIONS
S- Safety	<p>Sometime when people are drunk, they do not think about what they are doing. Have you ever driven a car / motorbike when you are drunk?</p> <p>Have you ever been in a car with a driver who was drunk or high?</p> <p>Have you ever felt the need to carry a knife or other weapons to protect yourself?</p> <p>Have you ever been bullied/ abused?</p> <p>Have you had any immunizations?</p>
S- Strengths / Spirituality	<p>How would you describe yourself?</p> <p>What are you best at?</p> <p>How would your best friend describe you?</p> <p>Do you pray regularly?</p> <p>Who do you talk to when you feel upset about something/ when you feel really happy about something?</p>





Chapter 2

POPULATION HEALTH

DEVELOPING COMPETENCIES FOR FIELD EPIDEMIOLOGY – THE EIP WAY

SUMMARY

The Epidemic Intelligence Programme (EIP) Malaysia was established in 2000 under a mandate from the Cabinet. Its learning by doing concept has broadened and helped strengthen the capacity of public health professionals in surveillance and outbreak responses at the local level. The fellows and graduates of EIP are called to an event as an expert or trainee depending on the needs of the situation. A set of criteria has been established to differentiate their involvement from that of the District Medical Officer in charge.

EIP Malaysia is a member of TEPHINET and one of 43 countries with similar field epidemiology training programmes. In 2008, Malaysia hosted the 5th Global TEPHINET Scientific Conference where 70% of the delegates were from overseas. EIP Malaysia is also the focal point for WHO-GOARN

Introduction

There are many public health training models available at present – both within the country and abroad; short courses in epidemiology, clinical epidemiology, Masters in Public Health (Epidemiology), Masters in Science (Epidemiology), Doctorate in Public Health and many more. Since epidemiology is becoming increasingly complex and specialized, the graduates are thus equipped with theoretical knowledge in epidemiology but with limited focus field training and understanding of service needs.

Training models

‘Field epidemiology or applied epidemiology’ is the application of epidemiological methods for action. In field based training model – the site of education is the actual work place and the trainee conducts learning scenarios with very limited and scarce resources but which require urgent decision making and a desired outcome. Thus the knowledge of applied epidemiology and the skill acquired during training will equip the EIP graduates to handle the real life needs of the workplace.

Field Epidemiology Training Programme



‘Capacity development’, the EIP way is defined as the deliberate effort to strengthen the ability of the public health service through ‘learning by doing’ in order to produce desirable outcomes. The EIP programme can deliver two desirable outcomes; one at the service level and the other at the individual level. By focusing on the actual needs of the workplace, the trainee is able to respond effectively and deliver quality health services relevant to the ever changing community needs; and conduct operational research so as to provide evidence based on research findings for appropriate action. On the individual level, the trainee will have acquired the skills and knowledge to be a competent field epidemiologist.

Epidemic Intelligence Programme

Epidemic Intelligence Programme (EIP) Malaysia (www.eipmalaysia.gov.my)

The positive experience with the US CDC Epidemic Intelligence Service (EIS) during the Nipah encephalitis outbreak in 1997-1998, prompted the Ministry of Health Malaysia (MOH) to start a similar programme. Thus following the Memorandum Cabinet No: 623/129/99, the Field Epidemic Training Programme in Malaysia was developed and later renamed as Epidemic Intelligence Programme (EIP) Malaysia. This programme was carried out through a collaborative effort between the Institute for Medical Research and the Disease Control Division MOH and later included the Institute for Public Health. A WHO consultant assisted during the initial drafting of the FETP Malaysia blue print and EIP Malaysia was then formalised through the *Mesyuarat Khas KPK* on 24th March 2002.

Birth of EIP Malaysia

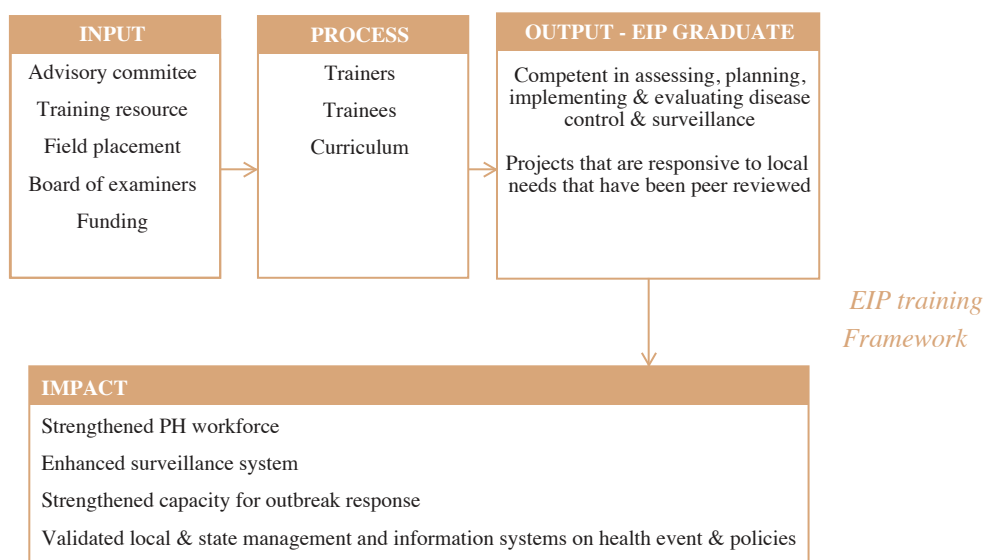
The programme is a blend between the highly successful US CDC EIS programme and the Field Epidemiology Training Programme (FETP) where 60% of the training comprised of fieldwork under the guidance of a mentor. The unique characteristic of the programme is the ‘shoe-leather epidemiology or learning by doing’ concept whereby the training is conducted within the context and constraints of the resources prevailing in the study locality. The study projects are identified according to the needs of the local authorities i.e. district, state or national and not prescribed by an outside institution or trainee’s personal preferences.



In 2009, the Training programme in Epidemiology and Public Health Interventions Networks (TEPHINET website: www.tephinet.org) reported over 43 countries worldwide with similar training programmes. These programmes are affiliated with TEPHINET and EIP Malaysia has been a member of TEPHINET since 2005. EIP Malaysia remains the only training programme within TEPHINET member countries that has no external permanent technical assistance either as a Technical Advisor from the US CDC or other agencies. EIP Malaysia utilizes the existing expertise in the country within and outside MOH. However, for continuous improvement, programme performance is evaluated by the TEPHINET evaluation committee. TEPHINET is a professional network that carries out the FETP/ EIP training programme with the aim of strengthening public health capacity by training field epidemiologists through an applied apprenticeship programme.

Although the curriculum in general addresses communicable disease control i.e. outbreak investigation and disease surveillance, the principles and application of epidemiological and statistical methods can be translated into non-communicable diseases and the environmental health training module.

Figure 1: Strengthening individual & national capacity in PH surveillance and response



EIP's role in strengthening MOH capacity

To demonstrate that trainees have acquired a competency in an area, they must actually implement the activity appropriately in the field. As a graduate of EIP, they are outbreak investigator experts. They can be called to the event as a team or as individuals depending on the severity of the incident and also upon request at State or National level. To differentiate their role from the District Medical Officer, the following criteria requiring their involvement has been formulated:

During outbreak / event that is

- Unusual occurrence of event e.g. death or long duration
- Occurring in more than one state / district
- Unusual clusters (There have been instances where EIP was asked to investigate unknown death in a private hospital)
- Highly contagious or with high fatality rate
- Request from higher authority or state

*EIP as backbone
for outbreak
response*

A directive has been issued to all States to use the following criteria to get assistance from EIP trained officers:

- Priority is given to an EIP from the same state / district where the outbreak has occurred
- Mobilise within short notice.
- When an outbreak is within one state, it is the prerogative of the state to mobilise their EIP fellows. The State Director can request the assistance of an EIP outside their state if there is a specific area of expertise EIP can provide.
- When an outbreak occurs in more than 1 state, it is the prerogative of EIP Malaysia to offer assistance in virtue of their expertise with the advice from Deputy Director General (Public Health) / Director of Disease Control.



- The Office of EIP Malaysia can send fellow EIP trainees to outbreak sites as a learning experience and provide assistance.

Nevertheless, implementing the programme is not without its limitations and there is a constant need for improvement and upgrading of the EIP Strategic Training Plan.

EIP Achievements and Success Stories

Since its inception, three (3) cohorts of EIP fellows have graduated and are working in various disciplines; service and institutions. EIP also conducted short courses for District Health Officers under the 'EIP Gives Back' programme. These initiatives have received positive responses and have broadened the EIP concept of strengthening public health capacity at district level in line with the requirements of the International Health regulations (2005) on Public Health Emergency of International Concern (PHEIC).

*EIP sets
its marking at
international level*

EIP fellows have presented projects and won prizes both at local and international conferences. (See Table 1). The biggest achievement was in 2007 when 20 out of 21 abstracts sent to the 4th Regional TEPHINET Conference in Taipei, Taiwan were accepted. EIP fellows have presented their projects at several Regional and Global TEPHINET Conferences and other local and international conferences. The EIP graduates have also published their studies in local and international journals. An e-journal was created for FETP/ EIP to publish their projects and share their experience and (<http://www.osirjournal.net>).



Table 1: Prize winning papers presented at National and International Conferences

No	Title of project	Type of presentation/ Award	Place of event
1.	An experimental study to compare the effectiveness of modified fogging and routine fogging in controlling dengue outbreak	Poster (Special Jury award)	2th Regional TEPHINET Conference, Baracay Island, Philippines 2004)
2.	Leptospirosis surveillance during flooding in Johor	Oral (First prize)	Infectious Disease Conference, Penang, 2007
3.	Antibiotic usage in a basic specialist service hospital	Oral (Third prize)	Infectious Disease Conference, Penang, 2007
4.	Food poisoning outbreak in a religious high school, Johor Bahru, 16 March 2007	Oral (Third prize)	4th Regional TEPHINET Conference, Taipei, Taiwan
5.	Paedrus Dermatitis among children in Terengganu, 2005	Poster (First prize)	Infectious Disease Conference, Penang, 2007
6.	Cholera outbreak in a tourist frequented village, Melaka, Malaysia, 2007	Poster (First prize)	4th Regional TEPHINET Conference, Taipei, Taiwan
7.	Syndrom Surveillance - Why bother	Poster (Third)	Infectious Disease Conference, Penang, 2007
8.	The in - patient cost of hospital acquired infection to patients and the Ministry of Health Malaysia, 2006	Poster (Sixth)	4th Regional TEPHINET Conference, Taipei, Taiwan
9.	First document case of Q fever in Penang, 2008	Oral (First Five)	5th Regional TEPHINET Conference, Seoul, South Korea



In 2008, EIP Malaysia was given the honor of hosting the 5th Global TEPHINET Scientific Conference with a budget of RM 1.2 million approved by the Cabinet. More than 1000 participants, 70% being foreign participants from TEPHINET member countries and related agencies attended the conference. A total of 256 oral free papers or posters were presented.

Besides TEPHINET, EIP Malaysia is also the focal point for Global Outbreak Alert and Response Network (GOARN), a collaborative unit under WHO for surveillance and response. EIP Malaysia works closely with WHO and US CDC in enhancing capacity building and hands on training.



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7. US CDC - Center for Disease Control and Prevention, USA
8. WHO - World Health Organisation





Malaysia - Japan - Australia



Briefing on Flight Food Catering



Learning by doing - EIP way



Together we succeed



EIP in Beijing



5th Global TEPHINET Conference





Acheh



International participation



EIP Malaysia - FETP Thailand



Epidemiology for Action



30 YEARS AFTER ALMA ATA TOWARDS A NEW OUTLOOK ON MALAYSIA'S PRIMARY HEALTH CARE

SUMMARY

As governments attempt to focus more intently on how to deal with the health disadvantage and inequities between the rural and urban as well as the have and have-nots, an approach was developed to enforce investing on the building of health clinics in the rural areas. This commitment has resulted with the early inception of the Rural Health Services (RHS) in Malaysia in 1959, paving its way to provide better access of care focusing on mother and child. Over time, in the early 1970's there were further enhancement to the RHS with curative "primary care services" manned by "dressers", or assistant medical assistant they are called today, to attend to urgent acute needs of the local community.

The progress made in providing these rudimentary but effective services has made significant impressions in the delivery of "equitable" and "efficient" health care in Malaysia. This model, which has its proponent practiced by many countries such as Sri Lanka, Cuba to name a few, was further developed by the World Health Organisation culminating with the historical advent of the concept of Primary Health Care, which made its entry in 1978 in the World Health Assembly, 30 years ago in Alma Ata. Today, the New Outlook of PHC in Malaysia still holds strongly "More Than Ever" on to the principles that were laid, only differing in the approach and delivery mechanism. From a dichotomous system, Malaysia is looking at optimising the network of various health care institutions into a unified and integrated more efficient delivery, making care closer to home.

Introduction

Primary Health Care: A philosophical approach to health and health care

This approach is characterised by a holistic understanding of health as wellbeing, rather than the absence of disease. The presence of good health is dependent upon multiple determinants; health services are important but so too are housing, education, public works, industry, agriculture, communication and other services. The health status of communities is both a function of and a reflection of development in those communities. The locus of control is important in PHC; health services should reflect local

Equity is a crucial part of PHC; health services must strive to address inequity and prioritise services to the most needy



needs and involve communities and individuals at all levels of planning and provision of services. Services and technology should be affordable and acceptable to communities. Through health promotion and preventive care, PHC aims to eliminate causes of ill health. Equity is a crucial part of PHC; health services must strive to address inequity and prioritise services to the most needy. Finally, PHC should be based upon social, biomedical and health services research in order to provide effective health care: WHO 1978.

Primary health care, as defined in the Alma-Ata Declaration, sets a very demanding standard for health care. This has led to various changes and modifications in adopting the original ideal, much due to the process of accommodating to available resources within the country. In the first three decades from the 1950s to the 1980s, Malaysia, similar with other countries submits to the concept of Selective Primary Health Care. Services were introduced as program based, started with antenatal care, childhood immunisation, management of diarrhoeal & acute respiratory diseases prevention. The concerns on diseases such as Leprosy, Malaria, Filaria, and Tuberculosis were given equal attention as these diseases were raving significant proportion of the population. Due to the limited resources, this selectiveness in approach or almost vertical programmes that were introduced was necessary to ensure focussed efforts in making accelerated reduction of the morbidity and mortality it causes.

The selective approach has also created “vertical” ownerships of the various programs. These “owners” were given the authority to introduce, and monitor as well as managing budget and resources to ensure effective implementation. The result showed astounding success achieving the coverage or targets that were set.

During the 60 and 70s, the primary health care delivery services then paid attention to the promotion of health amongst mothers and children, prevention of childhood illnesses and in pregnancy to improve birth outcomes, and to combat against infectious diseases. The successes were pronounced which led to better promises to further expansion of public health activities.

Over the years the continued encouraging outcomes led to further development of delivery points to the population as public service via static health clinics as well as mobile clinics. There was conscious effort to focus on reduction of maternal and infant mortality. To hasten the decline, access to care were enhanced by having delivery



centres near to the homes. Alternative Birthing Centres were set-up. It was a deliberate policy to create higher quality rural delivery outlets.

ALTERNATIVE BIRTHING CENTRES (ABC)

Alternative Birthing Centres (ABC) offer an alternative to conventional birthing centres in hospitals for women without known or predictable obstetric risk factors. Such centres are managed by trained staff without compromising established standards of obstetric care. Careful selection of mothers using predetermined protocols with ready access to referral centres in emergency situations makes such centres a solution to avoid crowding in urban hospitals and an alternative for more marginalised populations in certain areas. The ABC provides for a home-like environment by facilitating the 'baby friendly' and 'husband friendly' approaches.

Concurrently, the Risk Approach was also introduced to facilitate referral system from the community and primary care in rural areas to secondary and tertiary centres. It plays a triaging role taking into consideration the limited availability of staff. With this approach only those with white tags or no apparent risk can deliver at home or be conducted by a nurse. Mothers with other colour tags namely green, yellow and red will find themselves attended by more skilled staff not less than a medical doctor. These strategies developed are worth mentioning as it has helped in significant drop in maternal mortality, where socioeconomic alone would not have allowed it to happen in isolation.

The Primary Health Care Delivery Network

The overall picture of public primary healthcare delivery system can be summarised as a two-tier system comprising one health clinic and its network of community clinics. The operational area of each health clinic covers a population of 20,000 while each community clinic is designed to cover a population of 2000-4000. In the remote areas of the country, where the population density is low, rural clinics cover even smaller populations and coverage of health services is extended through mobile health services (terrestrial, riverine or 'flying doctor services').

The extensive network has also been supported with an organised system of referral into 2 levels namely primary care and secondary

*The Extensive
Network Has Also
Been Supported
With An Organised
System Of Referral*



and tertiary care the later two are termed as specialised services. The Primary care level being first level care, is close to where people live and involves front line health workers who have well developed generalist skills and who maintain regular contact with individuals/ families/ local communities with a broad range of health issues. The services in this level provide most of the anticipatory preventive care and early detection of and intervention for risk factors and curative services care for common time limited health problems, the ongoing care of multiple chronic health problems, and rehabilitative services as follow-up from those discharged from hospitals.

The primary care providers act as a filter role, in relation to the specialised services and facilitate the referral of only those patients/ clients that meet relevant access criteria. The specialised level aims to provide services for individuals/ families/ communities with specific health conditions or more complex and multiple needs. Criteria for accessing these services are restricted to people who are at risk or are affected by the conditions.

The governance of the delivery system at the operational level is lead by the District Health Office. It orchestrates not only the delivery of PHC but ensures its integration with various community preventive programmes, to include, communicable diseases control, vector-borne diseases control, as well as environmental sanitation.

The Private Primary care Sector

In the private sector, the general medical practitioners or GPs as they are frequently called, are partners in providing access to quality medical services. Studied however mostly in the urban settings, they provide comprehensive primary medical services as first point of contact with access fees affordable by average earners.

The private General Practitioners (GPs) have early beginnings in Malaysia even before independence

The private General Practitioners (GPs) have early beginnings in Malaysia even before independence. Traditionally, GP has been the preserve of those doctors who did not specialise. Their type of service could be described as episodic and curative in outlook. Since the early 1970's there was a rethink towards the development of family practice designed to provide comprehensive and continuing care to individuals and their families. Using their own discipline of GP, which has a wide range of clinical competencies in medicine, GPs aim to incorporate newer dimensions of care to forge a sophisticated form



of primary care that will meet the present and future needs of the community. This culminated the formation of the Academy of Family Physician in 1973. Since then several more than 700 GPs, the challenge is to reach the majority engaged.

Currently there are more than 6500 private GPs registered. They are mostly located in the urban areas and hence accessible only to those who are economically advantaged. It is estimated that these Private GPs which makes up 80% of the PHC doctors caters to about 62% of the health needs of the population compared with the 1200 public doctors covering health needs of the other 38% of the rest (NHMSII and III).

Community Participation

PRIMARY HEALTH CARE VOLUNTEERS IN THE CONTROL OF MALARIA IN SABAH

The Alma Ata Declaration 1978 emphasised disease prevention and community participation towards 'Health for All by the Year 2000'. In Sabah, the Primary Health Care Volunteer (PHCV) is an adjunct to the current anti-malaria measures to promote active community participation in the control of malaria. The PHCV is usually a villager who receives basic training, and who is then permitted to assist in malaria surveillance activities under close supervision of the malaria health personnel. This smart partnership has proven a 'win-win' situation for all parties concerned in the fight against malaria in the state. Sabah is now seeing rapid decline of malaria cases since the early 1990s due in part to the role played by the PHCV. There has been a tremendous drop in malaria cases from 49,865 cases in 1995 to 1,777 cases in 2003. However, there is no room for complacency. Much remains to be done to sustain the gains achieved so far.

Another area that needs mentioning is community participation and the involvement of non-governmental organisations (NGOs). Together they have contributed tremendous successes in the implementation of many of the health programmes. The village health teams in Sarawak, the PHC Volunteers in Sabah and Advisory Panel to Health Clinics in peninsular have significant role in the community helping along to modify some of the health approaches to make it locale-friendly. They also helped in its execution and monitoring of outcome. This includes early recognition through signs and symptoms of some of the infectious disease and child and maternal health problems. There are more than hundreds of NGOs which are actively complementing the work of the MOH, from child health to elderly health. Each

They also help in its execution and monitor outcome



has their strengths and levels of contributions, but collectively has made significant progress in improving health promotion and health practices.

Achievements Amongst Many

Some of the achievements through PHC approach are worthy of mention. The increased coverage for immunisation against immunisable diseases, namely, Tuberculosis, Polio, Tetanus, Diphtheria and Pertussis, to a level exceeding the WHO's target of 85%. The country eradicated polio in 1995; and eliminated leprosy in the same year. Currently, Malaysia is working towards elimination of Filaria and Measles. Significant progress has been made to control other communicable diseases such as Malaria, Typhoid, Hepatitis A and B, and Tuberculosis; through improved sanitation facilities, increased access to safe drinking water, provision of essential medicines, improved dental health and availability of basic laboratory test at point of care. The resurgence of some communicable diseases as a result of rural-urban and international transmigration; and the spread of AIDS, are being addressed. New programmes have also been instituted to address the challenges posed by increased incidence of non-communicable diseases, for example, lifestyle-related illnesses, environmental health and occupational diseases. Health promotion activities emphasise on advertising and marketing positive health behaviour through the Health Ministry's annual Healthy Life Style Campaigns. The recent approach focussed on the 4 areas of concern namely nutrition, exercise, smoking and mental health.

The country eradicated polio in 1995; and eliminated leprosy in the same year

Moving Forward From Selective To Comprehensive

In the mid 1995, with the introduction of many programs with specific targets, created a plethora of activities at the clinic level, aiming to achieve comprehensiveness in the delivery at first point of contact. The earlier focus on maternal and child health has extended to include adolescent, adult and elderly health. The Family Medicine Specialist (FMS) introduced in 1997 brought with it higher quality services and meeting a substantial coverage of community needs. From simple cases to chronic conditions including care of the hospital discharges which needs follow-up and rehabilitative services are now a common feature in most health clinics.

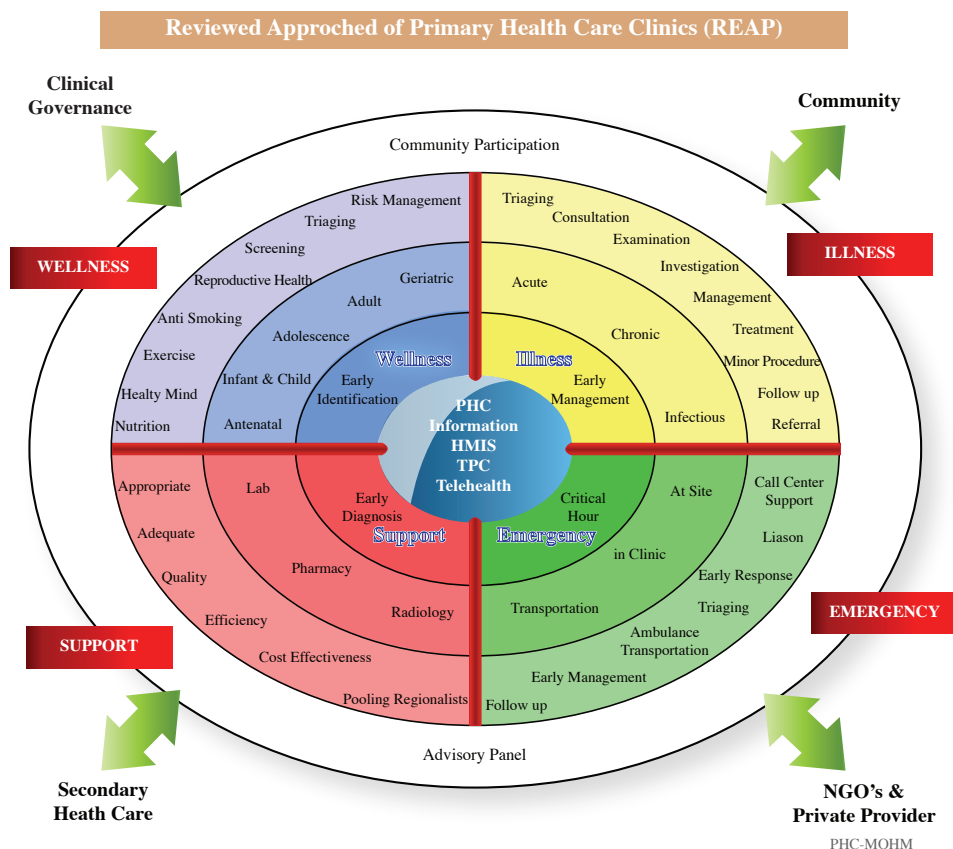
The introduction of so many programs with specific targets, created a plethora of activities at the clinic level



With such expansion, the need for integration was critical as the number of staff in each clinic were not increasing in tandem with increase of activities. A more strategic approach has to be incorporated to ensure more efficient use of resources. The Reviewed Approach (REAP) was developed and introduced in 2006, and is currently being implemented throughout the country. The main objective of the reviewed approach (REAP) policy is integrating the health services, looking at comprehensiveness of the delivery of primary care and working with the various stakeholders in the external environment. Primary health care services of the future will be able to address the wellness screening and intervention of the population at large but at the same time managing those with illness in an integrated package. This will allow for a holistic and comprehensive health care management at first point of contact.

The acronym WISE has been given to represent Wellness, Illness, Support (clinical), Emergency and Information. The various components of the services are illustrated in Figure 1 below.

Figure 1: Reviewed Approach



The Respond and Resources

The number of patients seen by the Public Primary healthcare team, in the clinics, schools and homes (via land, water and air) reaches close to 40 million encounters in 2008. The operational budget allocated for these services is RM1.2 billion. However these services are served and supervised by about 1200 medical doctors and family medicine specialists spread across the countries' health clinics. They are heavily supported by assistant medical officers, nurses, pharmacists, assistant pharmacists, radiographer, medical lab technologist amongst many others in all providing low-cost but quality healthcare, despite the challenges of catering to the high volume of workload. Team approach in PHC has often been cited as the most cost-effective strategy in health delivery.

Team approach in PHC has often been cited as the most cost-effective strategy in health delivery.

Health Services for the Underserved Populations

Maintaining universal access remains high in the MOH agenda. The health services of the underserved and remote locations are reached through mobile services by land, water and air. The "Flying Doctor Service" programme was started in 1973, with the combined effort of the Sarawak state government, Royal Air Force and the State Health Department. To date the Ministry hires 5 helicopters to fly the FDS team and for emergency medical evacuation. In 2008, the FDS covers 51 and 970 locations in Sabah and Sarawak, respectively. Kelantan, Pahang and Perak the larger states in Peninsula do not as yet have a formalised FDS, although the Royal Air force does offer assistance for the *Orang Asli* health services. The average patient attendances per year range from 75,000 to 95,000 and average MEDEVAC (medical evacuation) cases are 300-400 per year. The main bulk of referrals is for the medical, surgical, obstetric and gynaecology, orthopaedic and paediatric disciplines. There were 193 mobile health teams in the country providing outreach services to the remote population.

There were 193 mobile health teams providing outreach services to the remote population.

ICT in Primary Care

The role of ICT in health has been taken with lukewarm response except for few projects or pilot sites. The delay of making it available in all work stations of service provider with the appropriate system has often been associated for its high cost. Currently in the public sector, ICT was introduced to address the need to access specialist

The system links primary to secondary healthcare, allowing healthcare



care. In 2005, the Teleprimary Care (TPC) project was established starting with 57 sites and is currently extended to 73 health clinics, 4 specialist outpatients' clinics in hospitals and 10 district health offices in the states of Johor, Sarawak, Perlis, Selangor and Federal Territory Kuala Lumpur. The system links primary to secondary healthcare, allowing healthcare providers to consult specialists on patient management thus reducing physical referrals.

providers to consult specialists on patient management thus reducing physical referrals

In the private sector, ICT have seen greater utilisation however as isolated standalone system. This works well to improve especially the financial and office automation of the GPs. It however will be of little help for strategic and national health care data sharing that would be the idealism in Health ICT that many countries dream to have.

PHC Financing

Primary health care services at public health clinics are delivered almost free of charge, excluding opportunity and access costs, whereby each patient is charged a nominal fee of RM 1 (equivalent to US\$0.31 in 2007) for each outpatient visit and RM5 (USD1.55), inclusive of medical consultation, investigation and drugs received. The Fees (Medical) Order 1976 also provides an exemption clause such that those who cannot afford to pay will be given free treatment whether at primary care, secondary and tertiary care levels.

Primary health care services at public health clinics are delivered almost free of charge

Payment for services in the private sector is usually fee for service with out of pocket payment, employer- provided insurance with panel doctors and health maintenance organisations and private medical insurance. Private sector providers work mainly on fee-for-service. Although not compulsory, the fee schedule developed by the Malaysian Medical Association (MMA) apparently acts as a benchmark to prices charged by private practitioners. Some large employer groups and insurance companies may also set their own fee schedule, other than defining the benefits package that is covered.

Proposed Health System Transformation: A New Outlook

The private healthcare system is fragmented and there is no effective system of gate-keeping or referral. The private market is apparently competitive especially in PHC. The recent initiative of the MOH to



increase the payment rate for locum work in MOH facilities from RM40 to RM80 an hour has raised concern in the market. Nevertheless, most private providers take cognisance of the ministry's initiatives to foster more public-private integration and wait with mixed reactions for any health care financing reforms. The proposed restructuring of Primary Health Care is the integration of services between the public and private sectors. The idea is to make available a more responsive health care to meet the needs and expectation of the population. An overriding value in primary health care which needs to be maintained in health restructuring is equity, where people will receive health care services based on their needs, irrespective of their ability to pay, geographical access to care.

Private healthcare system is fragmented and there is no effective system of gate-keeping or referral

The restructuring of PHC requires new administrative structures perhaps autonomous health care providers for both primary and higher care facilities and formation of monitoring and evaluating bodies. The new organisational framework may need to be synchronised with the existing structure at every level. There may or may not be major changes of the existing structure depending upon the newly expected or proposed mandates, roles and functions. The other foreseeable significant changes would be on the physical layout, finishes & equipping of existing public facilities. The health facilities need to be upgraded to meet the requirements in the PHFS Act 1998 and Regulations 2006. Furthermore, there may be a need for a new act to be enacted to cater for the new service arrangements while related existing laws may have to be reviewed and amended or even repealed if necessary.

Conclusion

30 years after Alma Ata has seen the Malaysian Primary Health System evolve achieving increasing universality and equity. However the changing environment and economic climate is straining the existing resources with imbalance in the delivery system. The need of an integrated system between private and public is paramount. The potential benefits for the public/consumer include improved access; care closer to home, increase in choice to care providers and better quality of services. The benefits for the providers are reduced uneven workload and improved contact providers' time, and for the GPs, improved distributive income and competition. The benefits for the government, the opportunity of a holistic data collection supporting strategic approach towards holistic and integrated primary

Benefits for the public/consumer include improved access; care closer to home, increase in choice to care providers and better quality of services



healthcare system and management in respect of better control of health expenditures, equity and health status improvements. The experience also allows feasibility study for the development of the much discussed about national health financing mechanism (NHFM). The challenge for payment rate and mechanisms is to strike a balance in risk sharing and cost sharing. This should include built-in incentives for GPs as well as payment for performance towards improvements in the population health status.

The New Outlook is a reality in the making. In it promises strategies to better use of resources, and a fresh change in health behaviour by the community towards self-care through a progressive health system using PHC as the platform.



EXPERIENCE OF FRONT-LINERS IN HANDLING EMERGENCY MENTAL HEALTH CASES IN PENINSULAR MALAYSIA

SUMMARY

This report highlights aspects of a study conducted by the Institute for Health Management in 2007 to assess the level of knowledge, attitude and skills of front-liners in handling emergency mental health cases. The study covered front-liners from four government agencies in Peninsular Malaysia, namely: the Police, Fire and Rescue Services, Civil Defence Department and Ministry of Health hospitals. The study indicated that a large proportion of first-line responders had no experience in handling mental health emergency cases and felt inadequate in managing such cases. Most also viewed such cases as being dangerous and need to be physically restrained. Except for the Ministry of Health front-liners, knowledge on causes and awareness on the legal aspect in dealing with such cases were lacking in other agency front-liners, while training in handling emergency mental health cases were also very lacking. There is a great need to provide appropriate training to equip front-liners in handling emergency mental health cases to ensure such cases are handled with care and dignity, and to safeguard the safety of the front-liners.

Introduction

Persons with mental health crises can go into full-fledged emergencies, with possibilities of endangering themselves and those around them if proper interventions are not instituted. In such situations, it is important that these people receive care and help in a way that is acceptable to their family, care takers and society in general, as well as in avoiding inflicting more traumas to the distressed persons.

*Mental health
emergencies*

A mental health emergency is an urgent, serious emotional disturbance of behaviour, affect, or thought that makes a person unable to cope with his life situation and interpersonal relationships. Common mental health emergencies are suicidal attempts, post-trauma reactions, depression, alcohol abuse and other drug related problems.



In Malaysia, the first point of contact for mental health emergencies is usually the police, ambulance personnel and emergency department staff. All front-liners must be able to recognize mental illness cases, how to deal with them, and how to handle violence or potential violence among these persons in a dignified way.

*Front-liners in
MOH*

This report is based on a study conducted by the Institute for Health Management (IHM) on the management of emergency mental health cases by front-liners in four lead agencies. The report focuses on their perception on mental health emergency cases, their knowledge and skills in dealing with such cases, and the training received by them.

Methodology

This was a cross-sectional study conducted from September to November 2007 using a self-administered questionnaire. The study involved all front liners from four agencies:

*Four agencies
involved*

- Ministry of Health hospitals (MOH) – Emergency Departments and ambulance staff
- Royal Malaysian Police (Police) – Police stations and mobile units
- Fire & Rescue Services – Operation units
- Civil Defence (*Jabatan Pertahanan Awam, JPA3*) - Operation Units

A front-liner in this study was defined as the first person in contact with emergency mental health cases. For the hospitals, they cover all categories of staff at the Emergency Department and ambulance dispatch team.

*Definition of
front-liner*

Fifty districts were randomly selected from all the states in Peninsular Malaysia including the Federal Territory of Kuala Lumpur. Coordinators for each district were appointed for each of the agencies, and given one-day training on the selection of front-liners, on the questionnaire and the process of administering the questionnaire. Copies of the questionnaire were distributed to those identified as front-liners based on the agreed definition. Upon completion, they were collected and posted back to the IHM for analysis.

*Sampling method
and data collection*



Data were coded and analyzed using Statistical Packages for Social Sciences (SPSS) Version 15.0.

Data analysis

Findings

The overall response rate was 63.0%, with the Fire and Rescue Services having the highest response rate at 77.0% and JPA3 the lowest at 41.0% (Table 1). Majority of the respondents were less than 5 years in service (Table 2).

Response rate

Table 1: Response rate by agency

Agency	Total no.of eligible respondents	No. of respondents	Response rate
Police	7,967	4,861	61.0%
Fire & Rescue Services	3,301	2,542	77.0%
MOH	3,565	2,059	57.8%
Civil Defense	500	205	41.0%
Total	15,333	9,667	63.0%

Table 2 : Duration of service of front-liners by Agency

Duration of service (years)	Police	Fire & Rescue	MOH	JPA3	Total
	n=4,862	n=2,542	n=2,059	n=205	n=9,667
< 5 years	51.3%	50.3%	47.7%	85.4%	51.0%
5 - 10 years	20.8%	15.9%	24.7%	7.8%	20.1%
11 - 15 years	5.6%	10.3%	8.9%	1.5%	7.5%
16 - 20 years	5.5%	4.6%	6.0%	1.5%	5.3%
> 20 years	16.7%	18.8%	12.6%	0.5%	16.1%

Duration of service

The Ministry of Health and the Police were the agencies that were more frequently involved in handling emergency mental health cases. However, as a first responder, the Police was the main agency in cases of suicidal attempts; self-afflicted injuries or shooting, and cases of running amok. For suicidal attempts involving jumping from heights, the Fire and Rescue Service was the main agency (Table 3).

Main responders in types of mental health emergencies



Table 3 : Involvement in handling emergency mental health cases

	Propotion of respondents by Agency				
	Police	MOH	Fire & Rescue	JPA3	Others
Involving in handling emergency mental health cases	57.7%	58.5%	43.2%	42.1%	-
Main agency in managing cases of mental health emergencies					
Suicidal attempt (jump from height)	35.1%	3.5%	58.1%	1.8%	1.5%
Suicidal attempt (self afflicted injuries)	91.3%	2.2%	4.5%	0.8%	1.2%
Suicidal attempt (shooting)	96.5%	0.9%	1.5%	0.1%	1.0%
Cases of running <i>Amok</i> *	94.6%	1.0%	3.2%	0.5%	0.6%

**Amok*- Malay word to mean running berserk with uncontrollable rage

Most of the front-liners from all the agencies perceived emergency mental health cases to be dangerous (91.3% to 93.9%). A high proportion of respondents from the Police were of the opinion that such patients needed to be physically restrained (73.5%) while this was least with the Ministry of Health respondents (Table 4).

Perception of front-liners

Table 4 : Perception of front-liners on emergency mental health cases

Perception on mental emergency cases	% Agree / Strongly Agree			
	Police	MOH	Fire & Rescue	JPA3
Some of the cases are dangerous	93.9%	93.4%	91.3%	93.5%
Patients have to be hancuffed / tied down	73.5%	41.2%	54.6%	52.1%



For knowledge and awareness, the MOH front-liners had the highest scores in being able to recognize people with mental health problems (60.9%) and in being aware of the Mental Disorder Ordinance 1952 for dealing with mental health emergency cases although.

Knowledge and awareness

In general, most of the front-liners from all the agencies knew that mental health emergencies could be caused by drug abuse, and mental disorders but less than half of them, including those from the Ministry of Health, were aware that this could be a manifestation of dementia or physical illness, (Table 5).

Table 5 : Knowledge and Awareness on Mental Health Emergency Cases

Knowledge and Awareness	% Agree / Strongly Agree			
	Police	MOH	Fire & Rescue	JPA3
I can recognize people with mental health problem	44.6%	60.9%	34.0%	37.7%
Awareness of Mental Health & Mental Disorder Ordinance 1952	37.8%	55.8%	26.8%	37.4%
Knowledge on causes of mental health emergencies				
<i>a) Due to drug abuse</i>	85.8%	88.8%	85.2%	84.0%
<i>b) Due to schizophrenia, bipolar disorder, or depression</i>	84.0%	90.4%	75.4%	84.5%
<i>c) Due to senility or dementia</i>	40.1%	49.9%	45.2%	41.9%
<i>d) Due to physical illness</i>	29.3%	41.8%	33.8%	22.6%



Only between 17.7% to 31.1% of the front-liners had experience in handling mental health emergency cases. Except for the MOH front-liners, most of those from other agencies felt that they did not have the skills in handling emergency mental health cases. For the Police, the first responder for most mental health emergencies, 76.3% felt that they did not have the skills needed, and only 32.6% of them felt they were confident in handling such cases (Table 6).

*Experience, skills
and confidence*

Table 6 : Perceived experience, skills and confidence in handling emergency mental health cases

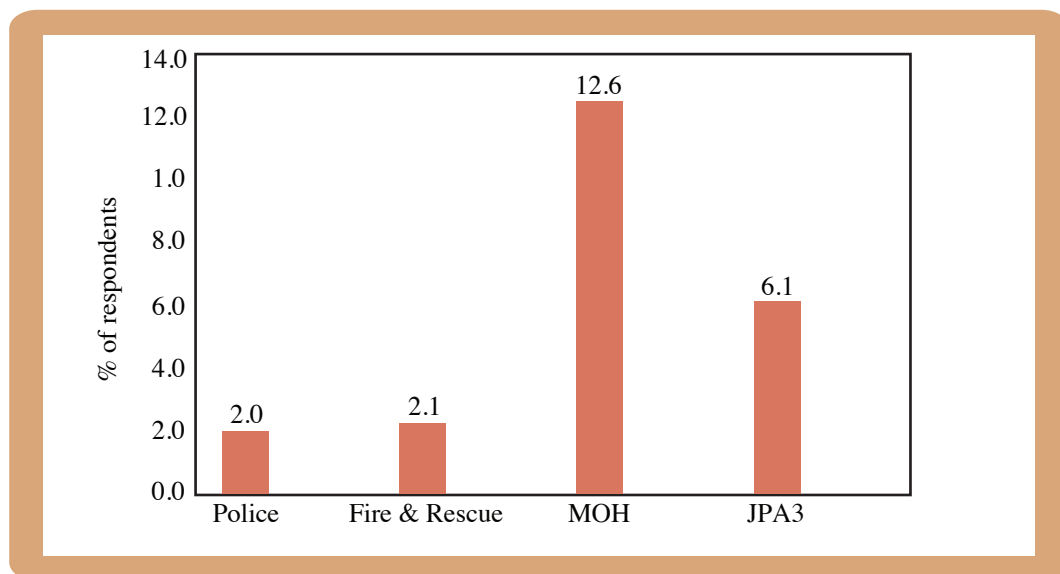
Experience, skill, confidence	% Agree / Strongly Agree			
	Police	MOH	Fire & Rescue	JPA3
I have experience in managing mental health emergency cases	24.4%	31.1%	17.7%	20.1%
My experience is based on “hands - on experience”	69.1%	69.3%	59.7%	48.1%
I do not have the skill in handling mental health emergency cases	76.3%	56.3%	82.5%	66.3%
I am confident in managing mental health emergency cases	32.6%	38.1%	22.2%	16.2%

The Ministry of Health had the biggest proportion of front-liners who having attended courses dealing with emergency mental health cases compared to only about 2% for the Police and the Fire and Rescue Services. (Fig. 1).

*Attended training
course*



Figure 1 : Proportion respondents who attended training courses on emergency mental health cases by agency



Discussion

Mental health emergencies range from situations where a patient is at risk because of intense personal distress, suicidal intention, or self neglect to those where a patient places others at risk. Some patients may behave in an aggressive manner, make threats, or act violently. Such behaviour may produce physical or psychological injury to other people or damage property. Although studies have shown that persons with serious mental illness are more likely to be violent compared to those without, it is also shown that there is no difference in the risk of violence between treated patients and those without a psychiatric disorder. Hence, disturbed behaviours of people with mental illness are usually the result of non-treatment, inadequate treatment or poor compliance to treatment.

Emergency mental health situations

Serious grievous hurt or homicide caused by mentally disturbed persons get reported in the media and intensify the fear of such people. These reports increase public perception of the mentally ill as being unpredictable and dangerous.

Media reports

In Malaysia, aside from para-suicide cases, emergency mental health cases brought to the hospital by the police generally belong to 2 groups of people - those where police help is being sought by family

Two groups of emergency mental health cases



members due to unmanageable disturbing behaviours at home, and those called in by the public due to unacceptable public behaviours. It is hence not surprising for front-line personnel to view mental health emergency cases as being dangerous.

Aggression or violent behaviour of mentally disturbed person can be directed to objects or people due to provoked anger or delusion. Removal from such threat or provocation sometimes causes the cessation of such behaviours. Mechanical restraint aggravates the anger or threat and therefore should only be used as a last resort as patients can be injured in the process. Management of mental health emergencies require calm, confidence, empathy and respect for the patients' dignity.

Aggressive or violent behaviours

Therefore, it is important for the front-liners to understand this fact so that they do not provoke further violence in the process of dealing with such patients. In this study, almost three quarters of the police believed that mental health emergency cases had to be physically restrained by tying them down or handcuffing them. Fear of personal injury and a lack of understanding and empathy on the part of the officers, combined with the difficulty or reluctance to comply with instructions on the part of the person with mental illness, were the leading causes of violent confrontation between the two.

Use of mechanical restraints

On the other hand, studies have also shown that the front-line officers like the police, trainees and staff at psychiatric units and facilities are at risk of assaultive behaviours of patients prior to, or at the time of admission. Hence, it is important for the front-line officers to be aware of safety measures in dealing with emergency mental health cases.

Safety of front-liners

In the MOH hospitals, the assistant medical officers (AMOs) are the core personnel and first-line officers at the Emergency Departments. AMOs receive training in psychiatry in theory and attachment training in psychiatric wards in their basic training programme while nurses receive only classroom teaching. Hence, front-liners in the MOH are more experienced and knowledgeable in dealing with mental health emergencies compared to those from the other Agencies.

AMOs in MOH

While 80% to 90% of the front-liners were aware that mental health emergencies could happen due to drug abuse or mental disorders, less than 50% of them were aware that dementia or physical illness could mimic mental disturbances. Although uncommon, it is important for front-liners to be aware of this point especially dealing with older

Knowledge on causes of mental health emergencies



people and people with a febrile illness so that appropriate care for the physical illness is not delayed.

Only about 2% of the front-liners from the Police and the Fire and Rescue Services had undergone any course related to mental health emergencies. For the Fire and Rescue Services, their involvement is mainly for attempted suicide cases involving jumping from heights.

Lack of training

The Police Department is the main agency called to deal with cases of Amok. More than three-quarters of the personnel professed not to have the skill in handling mental health emergency cases. Except for the Ministry of Health front-liners, less than one-third of the front-liners felt confident in dealing with them. Although handling mental health emergencies may not be a frequent function of the police personnel, they need to know how to deal with such situations confidently and in a way that protects their own safety.

Need for Police to be trained

Training needs for front-liners from different agencies differ slightly depending on their role. For example, front-liners from the Fire and Rescue Services require more in-depth knowledge on dealing with para-suicide cases involving jumping from heights, while the police front-liners need more knowledge in dealing with violent mentally disturbed people. However, basic knowledge on mental disorders, mental health emergency situations, their causes and dealing with such emergencies in an appropriate manner with safety of the persons and themselves in mind should be common to all. Basic crisis communication skills and violence risk assessments are also necessary.

Training needs differ for different Agencies

Ideally, there should be a dedicated mobile crisis intervention team in bigger districts or cities that can respond to any mental health emergencies at their familiar home environment rather than being transported to the hospital. This collaborative effort between the police and the hospital has been successfully implemented in many parts of the world. These specially trained personnel carry out their role professionally to avert the crisis and help reduce hospital admissions.

Crisis intervention team

In Malaysia, several of the hospitals with larger psychiatric departments have some form of community crisis intervention service, the CAT or Community Assertive Treatment team. However, the



team only responds to patients registered with it due to medico-legal implications and covers only a limited area. Hence, such a model may not be effectively available to many instances of mental health emergencies outside these boundaries.

Conclusion

Knowledge on proper management of mental health emergencies is important for front-liners in the Police, hospitals and Fire and Rescue services as well as Civil Defence to ensure such persons are handled with dignity while ensuring the safety of front-liners and persons concerned. There is a need to study in greater detail the prevalence, type and distribution of emergency mental health cases in order to prepare a more strategic plan in the management of emergency mental health cases in the country and to improve coordination among the agencies involved.

Essential for front-liners to know how to handle emergency mental health cases.

Meanwhile, basic training on the management of mental health emergencies should be initiated, in particular, for the police who are the key front-line responders for violent mentally disturbed persons, throughout the country and on a continual basis. This will help to enhance the level of mental health emergency service in the country.

Training is needed.



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FOOD POISONING IN MALAYSIA 2008 – ISSUES AND CHALLENGES

SUMMARY

In 2008, 17,322 food poisoning cases were notified throughout the country, giving an incidence of 62 cases per 100,000 populations. There were 420 episodes of food poisoning reported throughout 2008, of which 263 episodes (62.6%) occurred in schools. Of all the episodes in school, 229 episodes (88.1%) were in schools under the administration of the Ministry of Education. Most of the contributory factors identified were related to poor food safety practices among food handlers. The food poisoning cases identified by routine reporting might be a small fraction of the true number. True burden of the illness need to be evaluated. Preventive measures require multi sectoral coordination involving a number of stakeholders. The measures should also include a wide range of strategies, from promoting food safety practices among food handlers, to enforcement of laws and regulations by health authorities

Introduction

Foodborne diseases are terms applied to illness acquired through consumption of contaminated food which includes food contaminated with toxins produced by microorganism, plant or animal and food contaminated with bacteria, virus or parasite. These are frequently referred to as food poisoning although this relation is not really accurate. More appropriately food poisoning should exclusively refer to food contaminated with toxins only. However, clinically it is difficult to differentiate between illness caused by food contaminated with toxins and foodborne infections.

Definitions

Since food poisoning is usually a mild illness and does not require medical attention, diagnosis is usually clinical and does not require confirmatory laboratory test.

This report provides the current situation of food poisoning in Malaysia as well as issues and challenges related to this illness.

Objective of the report



Food poisoning surveillance in Malaysia

Food poisoning is one of the 5 food and waterborne diseases where notification is required under the Communicable Disease Prevention Act 1988(Act 342). The others include Typhoid, Cholera, Hepatitis A and Dysentery.

Notification of food poisoning is mandatory.

Food poisoning case is defined as an acute onset of vomiting or diarrhea or other symptoms associated with ingestion of food. Food poisoning may also present with other systemic symptoms like neurological symptoms such as paresthesias, motor weakness and cranial nerve palsies.

All the notified cases of food poisoning are registered into The CDCIS (*Communicable Diseases Control Information System*), an electronic database system of notification of communicable diseases which was introduced in 2002. Laboratory confirmation is not required for diagnosis of food poisoning as well as for registration into this surveillance database.

An outbreak of food poisoning is defined as two or more people with the illness associated with a common food or meal, as well as epidemiologically related in time, place or person. Since most of the outbreaks are very brief and confined to a small area such as institution or mass gathering, a food poisoning outbreak is also referred to as a **food poisoning episode**.

A food poisoning episode or outbreak is usually identified from individual case notification when there are a cluster of cases identified from the CDCIS or from rumours surveillance such as reports from institution, public, health personnel etc. Outbreak surveillance and management are carried out by the respective District Health Office, whereas the preliminary report should reach the National Head Quarters within 24 hours of the notification.

Food Poisoning Trend in Malaysia

As shown in figure 1, a dramatic increase of food poisoning episodes and incidence were recorded in 2007. This was however not a true increase but rather reflected an improvement in reporting and registration of the illness.

Improvement in reporting and registration system

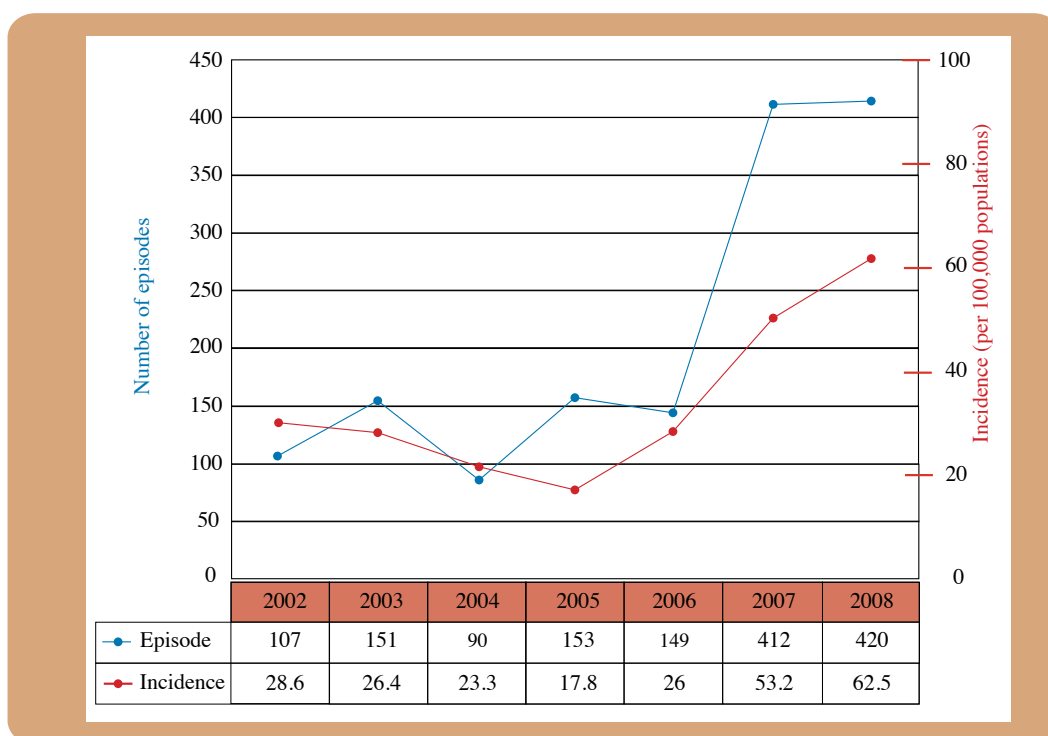


A new guideline was introduced in 2006 which required reporting and investigation of any episode of food poisoning or any incidence of two or more people with the illness associated with a common food or meal. Prior to this only selected episodes which met the following criteria were reported as a food poisoning episodes:

- involving 10 or more cases, or
- any of cases was admitted to ward, or
- any recurrent outbreak in same locality, or
- any deaths attributed to food poisoning

Furthermore, the establishment of the Crisis Preparedness and Response Center (CPRC) in May 2007 had also improved the food poisoning reporting system, so that more food poisoning episodes and cases were registered.

Figure 1: Episode and Incidence of Food Poisoning in Malaysia, 2002 – 2008.



Food Poisoning Situation in 2008

In 2008, 17,322 food poisoning cases were notified throughout the country. These represented an incidence of 62.5 cases per 100,000 population, which was also recorded as the 3rd highest of all the notifiable diseases incidence, i.e. after Dengue (167.8 cases per 100,000 populations) and Tuberculosis (62.5 cases per 100,000 populations).

*Food poisoning
incidence and
episodes*

There were 420 episodes of food poisoning reported throughout the year 2008, an increase of 8 episodes (1.9%) from the previous year.

Figure 2: Food Poisoning Trend 2008, Number of Episodes By Epid Week

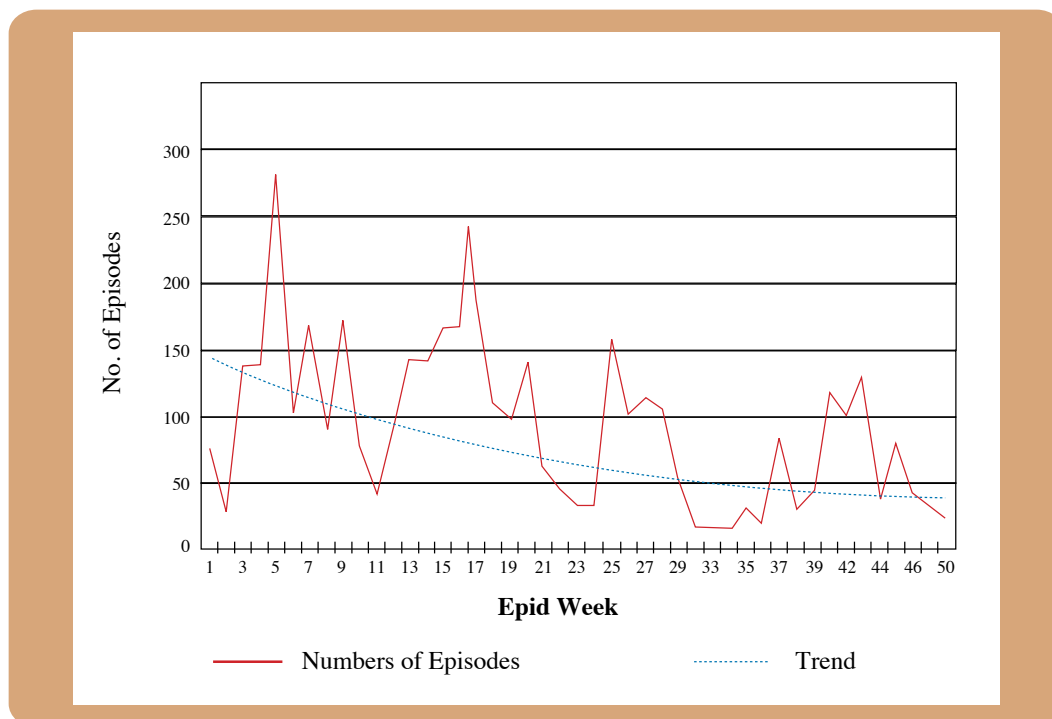
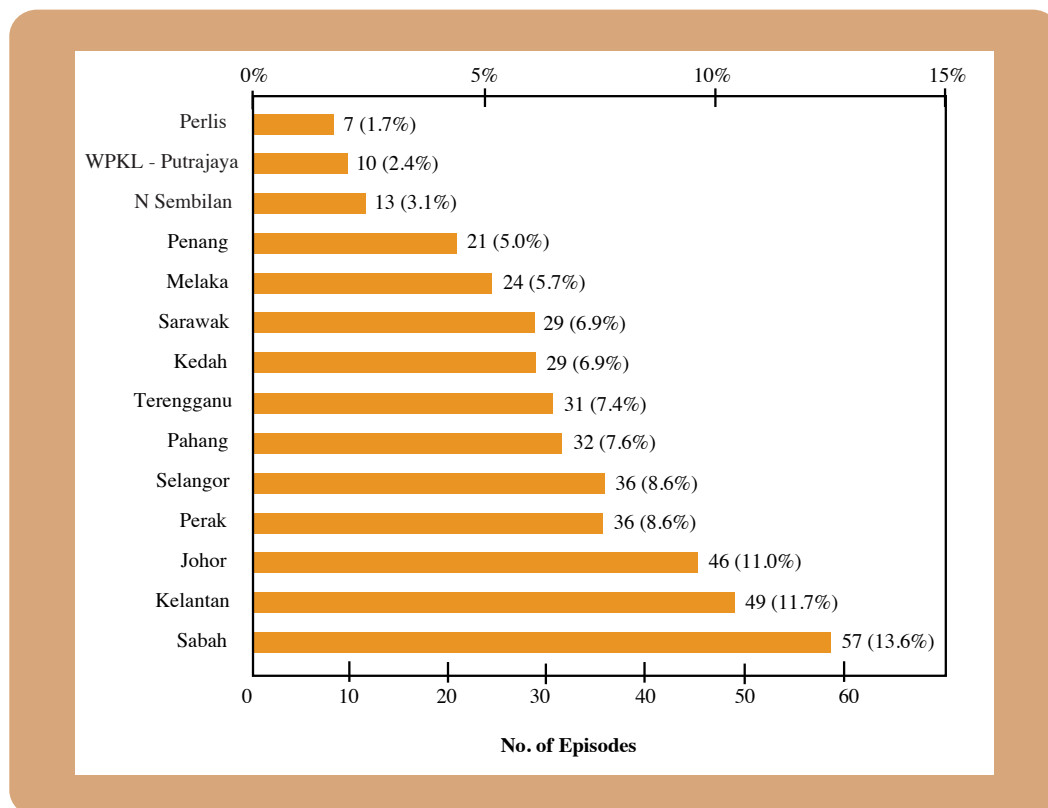


Figure 2 showed that decreasing trend of food poisoning episodes in 2008. Lower episodes were reported mainly during the school holidays (i.e. week 11, 22, 23, 34 and 47 onwards) and suggested that the overall number of episodes was influenced by the number of episodes in schools.



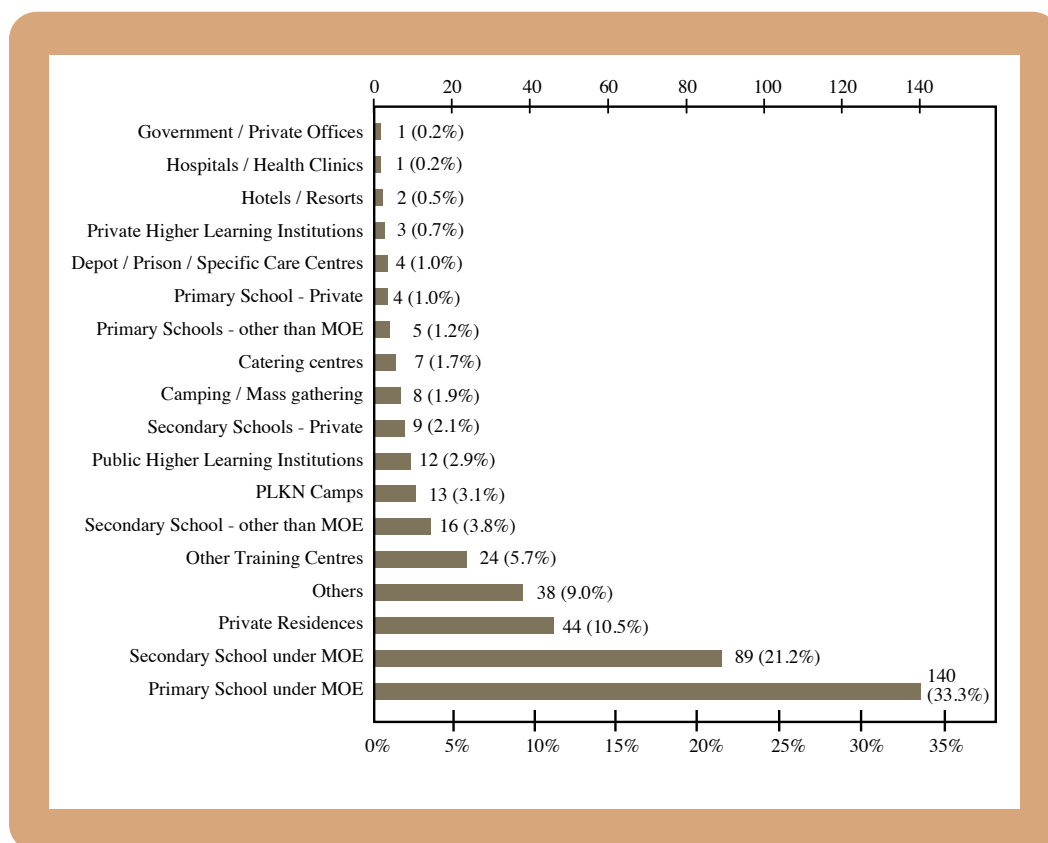
Figure 3: Food Poisoning Episode 2008 by States



Of the 420 food poisoning episodes reported in 2008, the top 5 states were Sabah with 57 episodes (13.6%), followed by Kelantan with 49 episodes (11.7%), Johor with 46 episodes (11.0%), Perak 36 episodes (8.6%), Selangor 36 episodes (8.6%) and Pahang 32 episodes (7.6%).



Figure 4: Food Poisoning By Place of Occurrence



Schools accounted for the majority of food poisoning episodes in 2008 (Figure 4). Schools were classified into primary and secondary and these were further classified into schools under the administration of the Ministry of Education, and schools under the administration of other agencies and private schools. Of the 420 food poisoning episodes in 2008, 263 episodes (62.6%) occurred in schools and 229 (88.1%) of these schools were under the administration of the Ministry of Education (Table 1).

School accounted for majority of food poisoning episodes in this country.

From all of these episodes, 219 (83.3%) involved premises within the school compound such as the school canteen and the hostel kitchen.



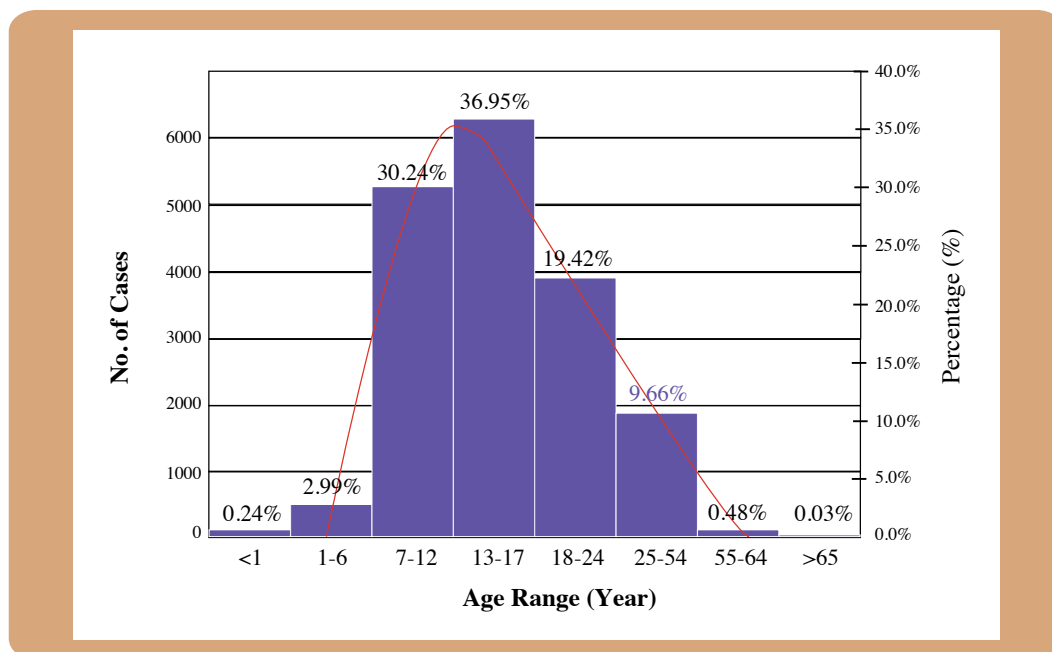
Table 1: Food Poisoning 2008 By Place Of Occurrence

Type of Schools	Frequency	Percentages	Sources from internal premises (Canteen / Hostel Kitchen)		Sources from External Premises (Home/public food outlet etc)	
			freq	%	freq	%
Primary Schools under MOE	140	53.2%	118	84.3%	22	15.7%
Primary Schools- other than MOE	5	1.9%	4	80.0%	1	20.0%
Primary Schools- Private	4	1.5%	3	75.0%	1	25.0%
Secondary Schools under MOE	89	33.8%	73	82.0%	16	18.0%
Secondary Schools- other than MOE	16	6.1%	15	93.8%	1	6.3%
Secondary Schools- Private	9	3.4%	6	66.7%	3	33.3%
Total	263	100.0%	219	83.3%	44	16.7%

The school going age group has a greater risk of food poisoning compared to the other age groups. As shown in figure 5, the majority of food poisoning cases reported in 2008 were among the school going age groups (7 to 17 years old). Secondary school going age groups (13 to 17 years old) recorded the highest cases of food poisoning (36.95%), followed by primary school going age groups (7 to 12 years old) (30.24%). Children less than 7 years old accounted for only 3.23% of overall food poisoning cases, whereas adult working groups accounted for 9.66% of all cases.



Figure 5: Distribution of Food Poisoning cases by age group.



Contributing Factors to Food Poisoning

Contributing factors were classified into 3 categories according to how the food was contaminated along the food chain process. Contamination during storage, transportation and serving of food was found to be a major contributing factor and accounted for 47.8% of all the factors identified, followed by general contamination (24.6%), contamination during cooking/secondary to processing technique (15.0%) and contamination of raw materials (12.6%).

Most of contributing factors carried by food handlers

Most of the contributory factors identified were related to poor food safety practices among the food handlers such poor personal hygiene of food handlers, inadequate holding time and inadequate holding temperature. The unsafe food safety practices among the food handlers could be due to their lack of knowledge on food safety. Inspection of 592 food handlers from 87 premises in schools found that only 157 of them (26.5%) were trained in designated food handlers training institutions. Out of the 87 premises, only 14 premises (16.1%) have all or 100% of their food handlers trained.



Table 2: Contributing Factors for Food Poisoning 2008

CATEGORIES	CONTRIBUTING FACTORS	FREQUENCY (PERCENTAGE)	
Contamination of raw materials	Contaminated raw material	56 (5.9%)	119 (12.6%)
	Unsafe thawing process	10 (1.1%)	
	Contaminated water	46 (4.9%)	
	etc	7 (0.7%)	
Contamination during cooking/ secondary to processing technique	Inadequate cooking (undercooked)	9 (1.0%)	142 (15.0%)
	Inadequate reheating	10 (1.1%)	
	etc	123 (13.0%)	
Contamination during storage, transportation, serving	Inadequate holding temperature	121 (12.8%)	452 (47.8%)
	Inadequate holding time	137 (14.5%)	
	Cros contamination from raw material	129 (13.6%)	
	Contaminated utensils	13 (1.4%)	
	Unsafe pckaging / detect in packaging	1 (0.1%)	
	Poor storage	5 (0.5%)	
	etc	46 (4.9%)	
General contamination (contamination along the food chain process)	Unhygienic premises	23 (2.4%)	233 (24.6%)
	Untrained food handlers	22 (2.3%)	
	Unhygienic food handlers	156 (16.5%)	
	Ill food handlers	1 (0.1%)	
	Cross contamination from consumers	5 (0.5%)	
	etc	26 (2.7%)	
Total		946 (100%)	

An episode could be contributed by one of more factors.



Food Poisoning Issues and challenges

i. Food Poisoning Surveillance

Many countries define food poisoning as foodborne illnesses which include illness acquired through consumption of food contaminated with toxins produced by microorganism, plant or animal, and food contaminated by bacteria, virus or parasite. In Malaysia however, food poisoning usually refer to food borne illnesses of unspecific causes, and do not include other notifiable foodborne diseases i.e. Cholera, Typhoid, Hepatitis A and any Dysenteric producing organism such as Shigellosis, E. Coli O157, *Entamoeba histolytica* etc. Because of the differences in definition, local food poisoning data cannot be used to compare with other countries.

Issues and challenges include surveillance, multi sectoral coordination, health promotion as well as law and legislation.

The foodborne diseases surveillance in this country needs to be improved so that the data can be compared with other countries. This may require reclassification or redefinition of the disease according to international ICD 10 standard.

The food poisoning cases identified by routine reporting may be a small fraction of the true number. The result is a surveillance pyramid in which the number of reported cases, represented by the peak, is much smaller than the number of all illnesses that are occurring in the population. In one hand since food poisoning is usually mild and do not require medical attention, most of the sporadic cases may not be reported. On the other hand, any food poisoning in an institution particularly in a school always draws public attention so that it gets reported to the health authorities.

Estimation of true burden of foodborne diseases including poisoning is very important to allow prioritisation and evaluation of the effectiveness of food safety intervention. Estimation of true burden of foodborne diseases requires a standard protocol so that it can be compared with other countries. Recognising the



current data gaps, WHO convened a group of international scientists at the “WHO Consultation to Develop a Strategy to Estimate the Global Burden of Foodborne Disease” in September 2006. The consultation provided the strategic framework for the assessment of burden of foodborne diseases, including a roadmap for assembling existing information on the disease burden and a time frame outlining the individual strategic activities.

Food poisoning in the home is usually related to more serious cases of the illness. An analysis of food poisoning outbreak surveillance data in England and Wales from 1992 to 1999 showed that although food poisoning outbreaks in the home accounted for only 226 (5%) of the 4604 outbreaks reported, the risk of hospitalisation was higher than outbreak related to other premises (0.045 v 0.016; risk ratio 2.66; 95% confidence interval 2.31 to 3.06). In Malaysia, from the 420 food poisoning episodes reported in 2008, only 44 episodes (10.5%) occurred in the home or private residence (Figure 4). However, of the 86 cases who were admitted, 30 cases (34%) were related to outbreak in the home. Furthermore, of the 17,322 food poisoning cases reported in 2008, all the 3 deaths were related to outbreaks at home. Two of the deaths were due to tetrodotoxin poisoning from puffer fish whereas another death was due to the eating of a poisonous frog.

ii. Multi Sectoral Coordination

Preventing foodborne diseases including food poisoning is a multi factorial process, with no simple or universal solution. It involves a number of stakeholders, including primary producers, food handlers, processors and traders along the food chain, official food control services, and consumers. It is essential to understand the underlying mechanism by which contamination and disease transmission occur in order to interrupt the chain of events. Meeting these complex challenges requires collaboration and coordinated effort of multiple regulatory agencies, service providers and food producers.

Multi Sectoral Coordination



As shown in figure 5, most of the food poisoning episodes occurred in institutions, both government and private. Over the years, food poisoning in schools contributed to 60 to 70% of overall food poisoning episodes reported in Malaysia. In 2008, 62% of the food poisoning episodes occurred in schools.

As most schools were government schools particularly those under the administration of the Ministry of Education, the government schools contributed to most of the food poisoning episodes in this country. Although these data might only represent a small fraction of all food poisoning cases, and many more cases which were not related to schools were probably not reported, focusing of preventive measures in schools could still cause a great reduction in overall episodes in this country. Recognising this, a joint committee between the Ministry of Health and the Ministry of Education was established in 2008 to coordinate food safety activities in schools.

Food handlers working in food industries need to understand the principles of food safety, so that the risk of foodborne diseases from food handlers can be minimized. The unsafe food safety practices among food handlers may be attributed to their inadequate knowledge on food safety. This was shown in the finding that only 26% of 592 food handlers examined had been trained and only 16.1% of the premises had all or 100% of their food handlers trained. In response to these findings, the Government had issued a circular to its Agencies, to ensure all food handlers working in the Government facilities had adequate and appropriate training.

iii. Health Promotion

Agents that cause disease (pathogens) can be transmitted to human by a number of routes; via animals, equipments, food handlers themselves as well as the consumers. As shown in table 2, poor food safety practices among food handlers such as unhygienic food handlers, inadequate holding time and inadequate holding temperature were major contributing factors to food poisoning in 2008. Although the consumer can also



transmit the pathogen to the food, such as through improper hands washing, the consequence is usually minimal and limited to the affected consumer only. On the other hand, if the transmission is from a food handler, the disease can spread extensively.

Promoting food safety should focus on improving food safety practices among food handlers and selecting safe food and food premises among consumers. In addition, training institutions must ensure that the food premises within their premises practice good food safety practices.

iv. Law and Legislation

Although good food safety practices can be cultivated among food handlers through health promotion, laws and legislations are still required particularly to ensure food safety practices in this country are comparable with standards of other developed countries. Recognizing this, The Food Hygiene Regulations 2009 were gazetted in early 2009. Under these Regulations, several requirements are imposed on all food handlers which include food handlers training, food premises registration, food handlers' medical examination as well as vaccination. The challenge is for the health authorities to enforce the regulations.

Enforcement of Food Hygiene Regulators

Conclusion

Food poisoning is a major public health problem in this country. The reported cases may be a small fraction of the true number, and the true burden of the illness need to be evaluated. Preventive measures require multi sectoral coordination involving a number of stakeholders. The measures should also include a wide range of strategies and modalities, from promoting food safety practice among food handlers, to enforcement of laws and regulations by health authorities.



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Chapter 3

HEALTH SYSTEM MANAGEMENT

CONSOLIDATING THE PHARMACEUTICAL SECTOR THROUGH THE MALAYSIAN NATIONAL MEDICINES POLICY (DUNAS)

SUMMARY

The Malaysian National Medicines Policy (MNMP) or its *Bahasa Malaysia* equivalent, *Dasar Ubat Nasional* (DUNAS) forges the direction for ensuring quality, safety, efficacy, availability, affordability and quality use of medicines. DUNAS sets the platform for human resource development, research and development, and also international co-operation in relevant fields. The Policy brings together all major stakeholders in the pharmaceutical sector and provides the framework for conduct and coordination of activities. It also sets priorities for medium- and long-term goals of the sector. All activities under DUNAS are based on a master plan of action (2006-2012), whereby the mid-term review of the policy will be held in 2009 and the full-term review of policy in 2012. The full-term review of the policy is essential to strengthen all processes in the pharmaceutical sector to meet the needs of the nation.

Introduction

The Malaysian National Medicines Policy (MNMP) or *Dasar Ubat Nasional* (DUNAS), drafted according to the framework of the World Health Organisation (WHO) and endorsed by the Malaysian Cabinet, is the way forward for the Pharmaceutical Services Division Ministry of Health (PSD) to ensure good drug management for improved health outcomes of Malaysians.

*DUNAS to ensure
Good Drug
Management*

DUNAS serves as a commitment by all stakeholders in the pharmaceutical sector to meet country objectives related to medicines. The policy document underwent a series of consultation with stakeholders before being presented to the Cabinet and approved on 11 October 2006. The introduction of DUNAS is timely in view of the growth rate of the pharmaceutical sector in Malaysia, estimated to range from RM4.12 billion in 2008 to RM5.96 billion in 2013. It will greatly assist all stakeholders (including health professionals, policy makers, industries and consumers) to work together to support the healthcare needs of the country.



The objectives of DUNAS are to ensure Malaysians have equitable and affordable access to medicines, including essential drugs; to maintain the quality, safety and efficacy of all medicines; and to promote the rational use of medicines by health professionals and consumers. The objectives and strategies remain major challenges for stakeholders. While timely access and availability of medicines constitute important factors in maintaining good healthcare, this has to be balanced with affordable costs to consumers. In this regard, the rational use of medicines by health professionals and consumers is particularly important in determining the success of DUNAS.

*Objectives of
DUNAS*

BACKGROUND OF THE PHARMACEUTICAL SECTOR

Malaysia's healthcare system is acknowledged internationally as a successful, modern, well-managed health system that provides effective health services. Major developments in procurement, distribution, practice, marketing, community participation, manufacturing, academia, research, regulation and enforcement have changed the entire landscape of the local pharmaceutical sector.

*Development of the
Pharmaceutical
Sector*

According to the New Sabah Times, the pharmaceutical sector, valued at RM3.5 billion in 2007 grew to RM3.8 billion in 2008, and is estimated to increase to RM5.96 billion in 2013. Driven by changing demographics, a growing middle-class and rising expectations, the domestic industry is projected to grow at an annual compound rate of 10 per cent. As a result, the number of medicines on the market has increased dramatically in the last two decades, posing challenges in regulating the quality and monitoring the rational use of medicines. Domestic manufacturers dominate the scene for generics and over-the-counter (OTC) products while multi-national companies (MNCs) reign strong in branded/innovator medicines.

The introduction of new medicines has become a major driver of healthcare expenditure. The expenditure for pharmaceuticals in the Ministry of Health Malaysia (MOH) has more than doubled between 2000 and 2008. Up to 2008, the Drug Control Authority (DCA) had approved 12,214 prescription medicines, 9,370 OTC items and 19,153 traditional products. The DCA had also licensed 257 manufacturers, 397 importers and 1,089 wholesalers in 2008.

*New Medicines –
a Major Drive of
Health Expenditure*



The MOH total medicines expenditure hit RM1.3 billion in 2007 and RM1.5 billion in 2008. In 2008, the private sector share of drug expenditure was estimated at RM1.1 billion while the non-MOH public sector spent about RM354 million. The per capita expenditure in 2008 was approximately RM106. This figure is modest as there is no data on drug expenditure from some of the public statutory bodies.

In tandem with the rapid development of the sector, the number of registered pharmacists has also increased. Registered pharmacist numbers have reached 6,594 (2008) from 5,977 in 2007. The number of pharmacies and drug outlets (public and private) has also increased to 15,431 in 2008 from 11,409 in 2007. The norm of 1 pharmacist to 2000 population is likely to be achieved by 2016.

Reflecting the growing emphasis of the pharmaceutical sector as a whole, DUNAS requires continuous support and cooperation from all stakeholders to ensure the development of a truly sustainable health system for Malaysians.

OVERVIEW OF DUNAS

The monitoring and evaluation of all activities under DUNAS, which was approved by the Cabinet and implemented in 2006, are based on a Master Plan of Action (POA) whereby progress of the activities outlined in the policy strategies will be monitored and comparisons made every 3 years. There are eight components in DUNAS. A full evaluation of the policy will be done in the 6th year, after 5 years of implementation. DUNAS will be conducting its mid-term review in 2009 and the full evaluation of the policy in 2012. The impact of these activities, to be implemented by various parties, is monitored through the collection of data based on indicators stated for each activity. All indicators were either directly adopted from the World Health Organisation (WHO) or tailored to the needs of the country.

*Strategies for
Implementation of
DUNAS*

DUNAS is strengthened by a Steering Committee headed by the Director-General of Health and this committee is supported by a Monitoring Committee and five other Technical Committees (TC); TC on Quality, Safety and Efficacy of Drugs, TC on Drug Availability, TC on Drug Affordability, TC on Quality Use of Drugs and TC on Human Resources Development, Research and Development and



Technical Co-operation. Members of these TCs were selected from various government and private institutions. To ensure the successful implementation of DUNAS, a secretariat, 'Unit DUNAS' was established at the PSD to co-ordinate and monitor the implementation of the policy.

QUALITY, SAFETY AND EFFICACY OF DRUGS

The aim of this policy component is to ensure that only safe, efficacious and quality drugs that meet approved standards and specifications are registered and made available for sale and use in Malaysia. This is to be achieved through a comprehensive drug legislation framework with a strengthened drug regulatory system, and enhancement of pharmaceutical quality assurance (QA) measures. Effective and comprehensive drug legislation will not only ensure full implementation of this component but also satisfy the country's obligation under international treaties. Drug legislation and regulations are managed through rational and transparent criteria and processes.

*Need for Effective
Drug Legislation
and QA Measures*

Drug Registration

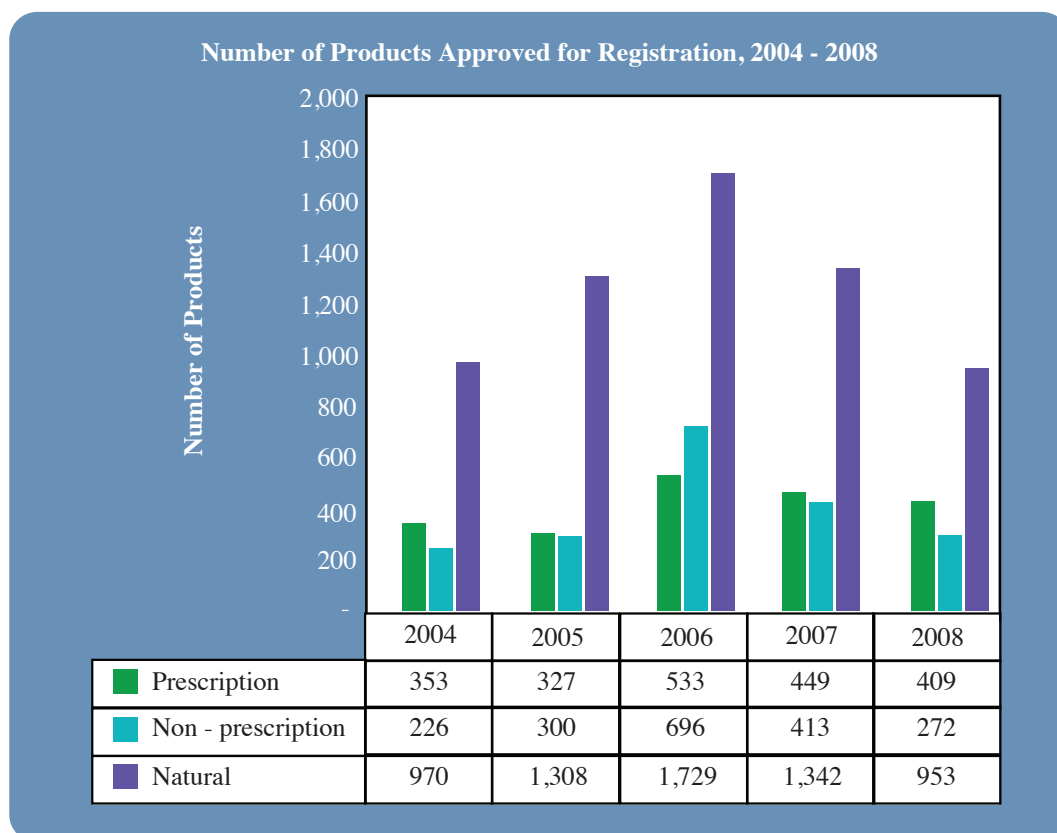
The Drug Control Authority (DCA), established in 1985, is entrusted to ensure that marketed pharmaceutical and healthcare products comply with specified standards and technical requirements. The DCA not only ensures quality, safety and efficacy of pharmaceutical products but also the quality and safety of natural products in the market. The National Pharmaceutical Control Bureau (NPCB) as secretariat to the DCA is responsible for the registration of prescription, non-prescription, veterinary, health supplements and natural products. Registration of products are valid for specified periods deemed appropriate by the DCA, after which every drug is required to be re-evaluated for re-registration.

*Rigorous
Evaluation for Drug
Registration*

The number of products approved for registration declined from 2006 (the highest number of products approved for registration within a 5-year time frame) to 2008 (Figure 1). A total of 2,249 applications for product registration were tabled to the DCA in 2008, but only 1,634 products consisting of new chemical entities (NCEs), biotechnology, prescription, non-prescription, natural and supplement products were approved and registered by the end of December 2008.



Figure 1: Number of Products Approved for Registration, 2004-2008



Licensing of Premises Licensing of Premises

Only licensed manufacturers, importers and wholesalers handle registered pharmaceutical products. The manufacturing, import and wholesale trading of controlled medicines are undertaken by licensed pharmacists at addresses specified on their licenses. These activities are conducted in accordance with Good Manufacturing Practice (GMP), Good Storage Practice (GSP) and other additional requirements as stipulated by the law.

*Licensing Premises
under the Law*

As also stipulated in the law, retail sale of controlled medicines must also be in licensed premises by licensed pharmacists. Dispensing of medicines is carried out by registered pharmacists while registered medical and dental practitioners may dispense drugs for the treatment and use of their patients only. The sale of registered products other than controlled medicines must also only be made through licensed premises.



Inspection

Adequate and effective professional inspections ensure that all activities in the drug manufacturing and supply chain comply with the requirements of the relevant licenses and regulations. Pharmacy enforcement officers undertake inspections of healthcare facilities in relation to medicines, while inspections of manufacturing facilities and wholesale premises are conducted by GMP/GSP auditors. Inspection is also extended to drug quality control laboratories and clinical trial centres to ensure compliance with current Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) respectively.

*The Need for
Effective Inspection*

Quality Control

Quality control is one of the activities under the NPCB. The Bureau ensures the quality and safety of pharmaceutical, traditional and cosmetic products through two important activities, namely the 1) evaluation of the product's protocol of analysis and analytical method validation data, and 2) the laboratory testing of these products. Evaluating the product's analysis protocol ensures that the methods used to test the products are suitable for its intended purpose, thus enabling testing of pre- and post-registration samples, complaint samples as well as samples, under suspicion of adulteration, received from the Pharmacy Enforcement Division.

*Quality Control
under the NPCB*

One of the WHO process indicators (PR 4) is used to assess the capacity of inspectors to collect samples on a routine basis. The collection of samples for analysis is an important means of controlling the quality of drugs and ensures that drugs reaching the patient are safe and efficacious.

*Evaluating the
Capacity of
Inspectors*

Figure 2 below shows the percentage routinely collected out of total number of planned collected samples. Routine samples indicate the actual number of collected samples based on the inspection reports of NPCB and Pharmacy Enforcement Division, while planned samples refer to the targeted number of samples determined for collection in a particular year.

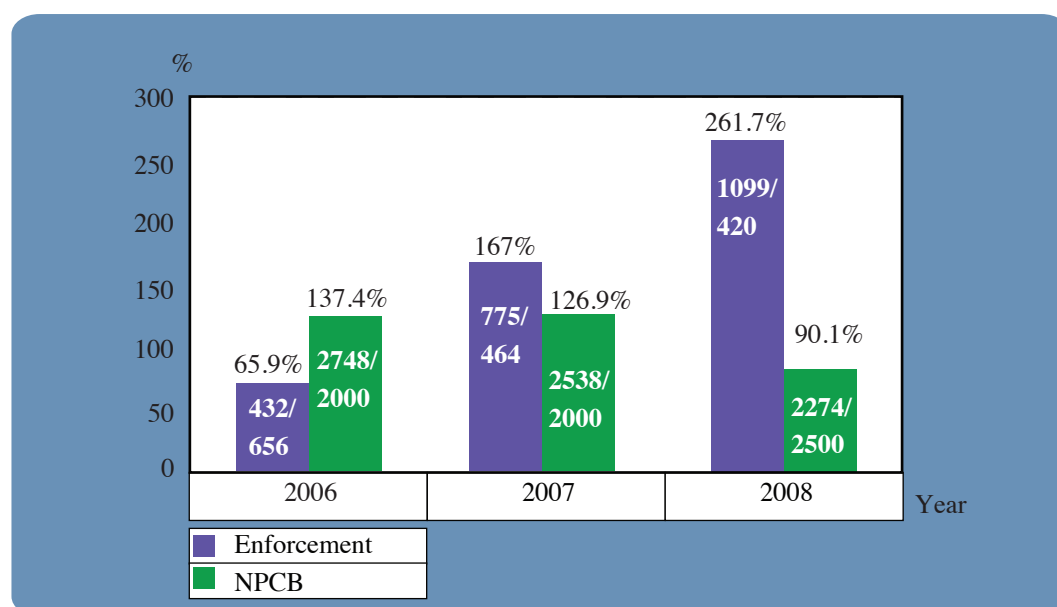
A total of 1,099 samples were collected in 2008 by the enforcement team, compared to only 420 planned sample collections. The number of planned collected samples in 2008 was lower compared to the previous two years. This was because in 2008, the Pharmacy



Enforcement Division has made a requirement for the officers to collect samples based on the intelligent sampling method, instead of random sample collections. Intelligence samples were defined as product samples from the complaints received and those collected from the pre-operation surveillances conducted.

The percentage of samples collected by NPCB showed a decrease from 2007 to 2008 which is from 126.9% to 90.1%. This is because the denominator value i.e. total number of planned collected samples for 2008 had increased to 2500 from 2000 in year 2007.

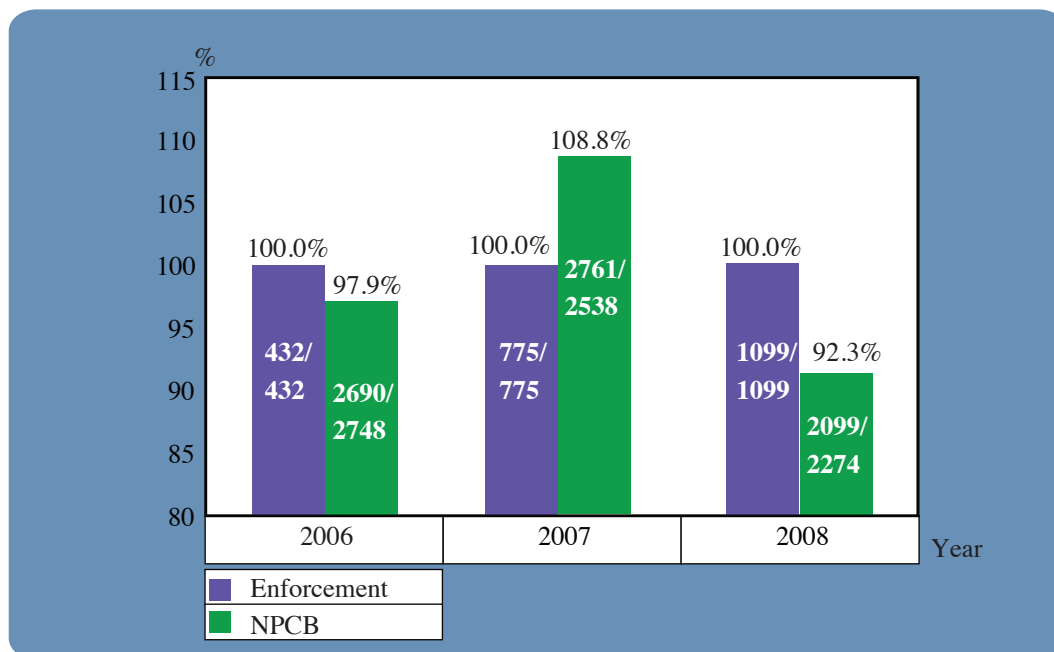
Figure 2: Percentage of Samples Routinely Collected Out of Total Number of Planned Collected Samples, 2006-2008



Another WHO indicator (PR 5) is used to assess the efficacy of the drug quality control laboratory or in the absence of a national quality control laboratory, the efficacy of any system implemented to control the quality of pharmaceutical products. The quality control of pharmaceutical products is a major aspect of DUNAS and is part of the overall QA system. Figure 3 shows the percentage of samples tested out of the number collected. In 2007, the number of samples tested by NPCB were more than the number of samples collected. This was due to the number of certain backlog samples from year 2006 which were only tested in 2007.

*Evaluating the
Quality Control
Laboratory*

Figure 3: Percentage of Samples Tested Out of Samples Collected, 2006-2008



Post-Marketing Surveillance

Post-marketing surveillance is an on-going activity to ensure drug quality, safety and efficacy. The DCA in collaboration with the pharmacy enforcement officers are responsible to ensure products on the market are duly registered and comply with the conditions of registration.

*Ensuring Marketed
Drug Quality*

DRUG AVAILABILITY

This policy component states that an efficient and integrated drug management and supply network must be maintained. The aim is to ensure an equitable, adequate and continuous availability of safe, effective and quality essential drugs for the population. This can be achieved through the careful selection of medicines, improvement of the management of drug procurement and the supply chain, and true optimal utilisation of available financial resources.

*The Need for
Integrated Drug
Management*



Domestic Medicines Production

Domestic production of medicines in sufficient quantities is encouraged especially for drugs on the National Essential Drug List (NEDL). This is to stimulate expansion of a viable domestic pharmaceutical industry and manufacturing capacity in the production of medicines towards national self-sufficiency and reduced dependence on imports. Domestic manufacturers may be eligible for incentives subject to fulfilment of criteria of the government. Export of locally produced medicines is greatly encouraged.

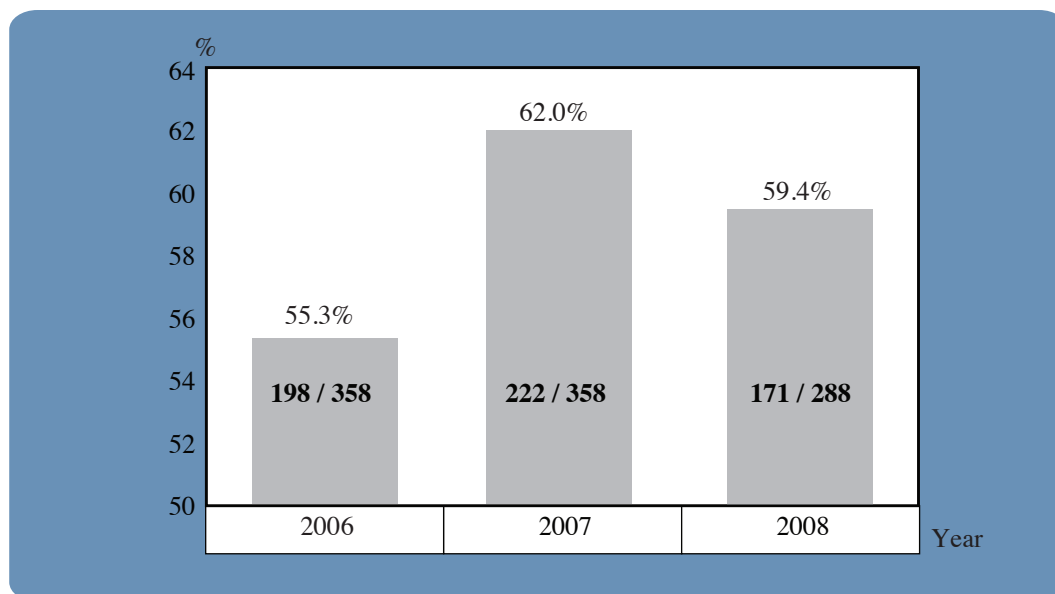
*Encouraging
Domestic Medicines
Industry*

Another WHO indicator (PR 11) is used to assess compliance of the local drug industry with the NEDL. This indicator provides an indication of the NEDL and DUNAS on the drug sector, as local manufacturers should prioritise drugs on the NEDL.

*Assessing Local
Drug Industry
Compliance*

Figure 4 shows the percentage of locally manufactured drugs in the NEDL sold in the country out of the total number of drugs in the list. The total number of drugs in the NEDL was 358 for 2006-2007, but this has declined to 288 for 2008. In year 2008, 59.4% of the drugs in the NEDL were produced locally and sold in the country. The number on the NEDL was revised in 2008 by a panel that reviews the list (revised at the *Mesyuarat Panel Kajisemula Senarai Ubat-ubatan KKM Bil. 3/2008*).

Figure 4: Percentage of Locally Manufactured Drugs of Total Number of Drugs in the NEDL Sold in Malaysia, 2006-2008



Procurement, Distribution, Storage & Disposal

The drug procurement system in the MOH ensures adequate and timely availability of the most cost-effective medicines nationwide. The long-term goal is to achieve self-reliance through an increasing shift from imported to local products. Order quantities are based on reliable estimates of actual needs. Drug procurement is guided by the NEDL and procurement documents list drugs by their generic names (International Non-Proprietary Names or INN)

*Need for Effective
Drug Procurement
and Supply System*

As MOH is the biggest spender of drugs, an effective procurement and distribution mechanism has to be put in place. The current system includes three processes (the central tendering system, supply by concession company and local purchase at institutional level).

An effective procurement and supply system and economical distribution network is important to ensure prompt distribution of adequate quantities of quality essential medicines to all healthcare facilities. Storage, inventory control and QA in facilities must comply with GSP requirements to ensure maintenance of quality and security of drugs through the storage period. Disposal of expired or obsolete drugs is carried out in accordance with prevailing environmental laws and regulations.

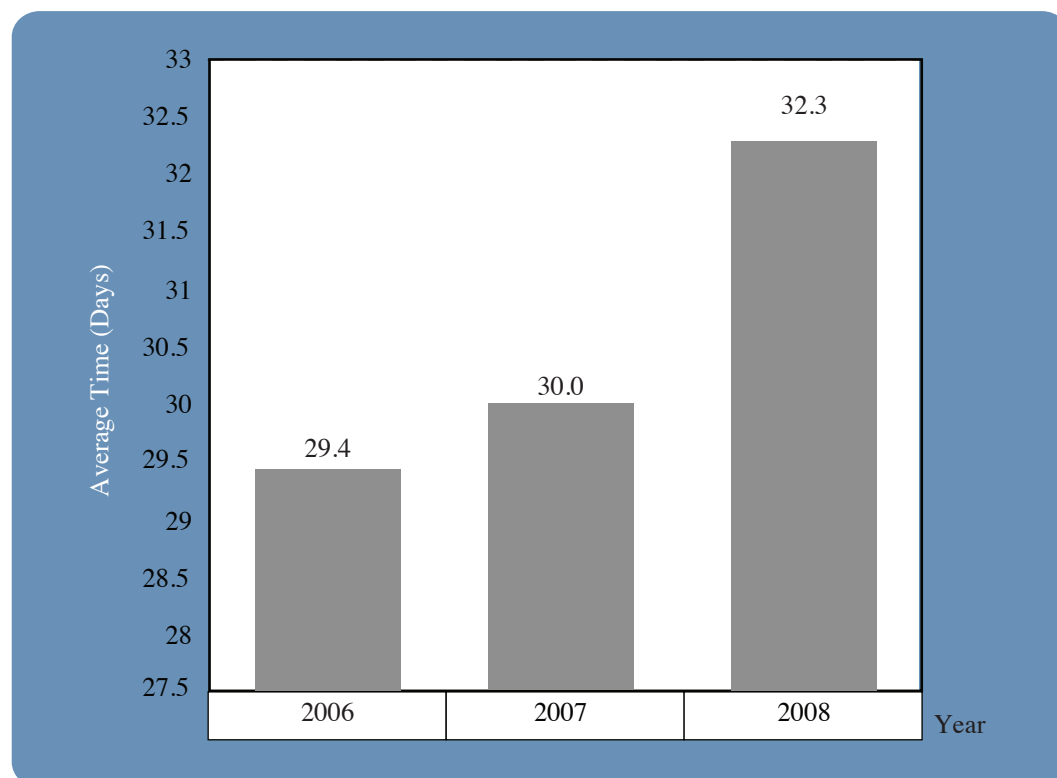
PR 27 is a process indicator that assesses the performance of the distribution system in the public sector. In an effective distribution system, the time between order and delivery should approximately be the same for each order and should be as short as possible, depending on the distance and the number of intermediate levels. The indicator measures the average time (in days) between order and delivery from central store to remote facilities in the last year, out of the average time between order and delivery in the past three years. If there are improvements in the distribution system, the rate will be less than 100%.

*Assessing Public
Sector Distribution
System*

However, there were no data available on the time between order and delivery for the past 3 years for year 2006 to 2008. Thus, the average time between order and delivery in the past 3 years could not be calculated. Only the time between order and delivery for each particular year is available and showed in Figure 5. The exact PR 27 indicator will be collected starting only in year 2009.



Figure 5: Time (Days) Between Order and Delivery from Central Store to Remote Facilities, 2006-2008



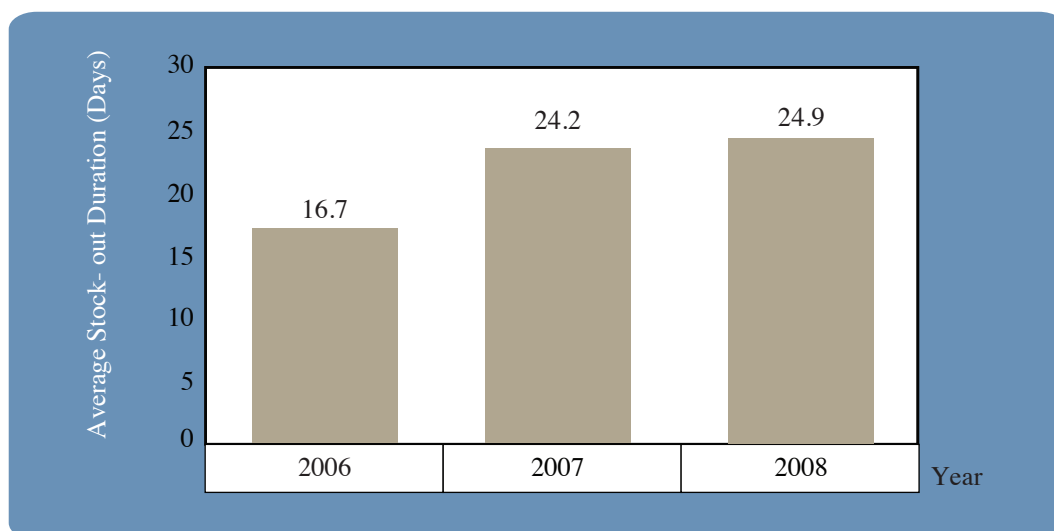
Another WHO indicator (PR 28) is used to assess the efficacy of the stock management of drugs at central and/or regional warehouses. If drugs are managed properly, they should be in stock most of the time. PR 28 measures the average stock-out duration (in days) for a basket of drugs in the central and/or regional stores in the last year out of the average stock-out duration for the same basket in the past 3 years. Basket of drugs is a representative number of drugs selected to obtain specific information. In this case it is a selection of drugs used to measure the stock-out duration. If stock management has improved, the rate will be lower than 100%.

Assessing the Drugs Stock Management

However, there were no data available on the stock-out duration for a basket of drugs in the central and/or regional store for the past 3 years for year 2006 until 2008. Only data on the stock-out duration for each particular year is available as showed in Figure 6. Thus, the average stock-out duration in the past 3 years could not be calculated. The exact PR 28 indicator will be collected starting only in year 2009.



Figure 6: Stock-out Duration (In Days) for a Basket of Drugs in the Central and/or Regional Stores, 2006-2008



Drug Supply in Emergency Situations and Drug Donations

Drug supply in emergency situations and drug donations are based on expressed needs as recommended by the WHO Guidelines. In Malaysia, there are national warehouses, which store stockpiles for antiviral drugs and Personal Protective Equipment (PPE) in preparation for any outbreaks of pandemic diseases.

*Stockpiling Drugs
for Emergencies*

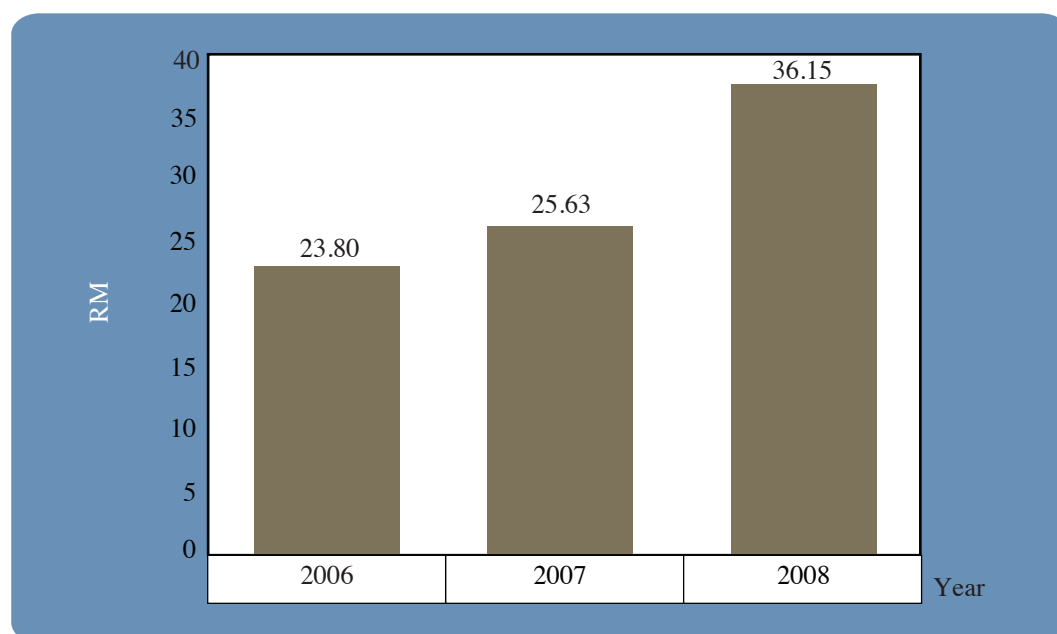
DRUG AFFORDABILITY

Medicine pricing issues have always been of great concern for developed and developing countries due to the high cost incurred for pharmaceuticals. Malaysia's healthcare system is facing challenges with increasing medicines cost. The survey done by the PSD on 10 NEDL items indicates increasing medicines cost. The median expenditure per prescription (RM) rose from RM23.80 in 2006 to RM36.15 in 2008 (Figure 7).

*Rising Medicine
Prices*



Figure 7: Median Expenditure per Prescription (RM), 2006-2008



Medicines price is an issue that should be addressed systematically. The PSD has set up a **Medicines Price Unit** to monitor prices and develop a database. The Unit has undertaken a number of initiatives, aimed at enabling the MOH to ensure continuous equitability and timely access to affordable, good quality medicines.

Monitoring Drug Prices

Price monitoring activities started with the objective of getting an overview of medicines price trends in Malaysia. A Medicines Price Monitoring Survey was done in 2006 for 100 types of medicines consisting of 711 brands. The survey involved 93 premises - 44 MOH, 46 private premises and 3 University Hospitals in Peninsular and East Malaysia. The findings of the survey showed that:

- The overall prices of medicines in the public and private sectors were 1% and 9% higher in East Malaysia respectively compared to Peninsular Malaysia
- The original brands were 3.7% more expensive than the generic brands in the public sector
- The original brands were 2 times more (100% more expensive) than the generic brands in the private sector



- In the public sector, medicines price differences were fairly acceptable as the median price ratio was found to be 1.02 times higher than the International Reference Pricing (IRP)
- The overall median price ratio for the private sector was found to be 4.9, that is, prices of medicines were 4.9 times higher compared to the IRP
- There were no specific patterns of an increase or a decrease of medicines prices in Malaysia in 2006.

The findings of the survey have been published in the 1st and 2nd editions of **My MedPrice** Bulletin.

At present, the compilation of medicines price data is by reference to public and private wholesale price lists, private retail price lists and private recommended retail price lists. A comprehensive national medicines price database will be developed which will include Manufacturer Sale Prices and General Practitioner Retail Prices. The national database from various sources in Malaysia will provide useful information about the true pricing scenario of the local pharmaceutical industry. By providing pertinent facts and figures about medicines usage, expenditure and prices, the database can contribute tremendously towards medicines price transparency. Data can also generate output of price trending, price mark-ups and price variation by state, zone and region.

*Towards
Transparency of
Medicines Prices*

Under DUNAS, efforts will be taken to disseminate independent and objective information on prices of medicines to health professionals and consumers. Several publications on medicines prices have been produced such as the Recommended Retail Prices (RRPs) for NEDL 2008, and data from the Public and Private Sector Medicine Wholesale Price Surveys 2008. One of the Plan of Action is the implementation of labelling requirements for RRP on ready-to-dispense packages and the enforcement of itemised billing for each item purchased or supplied by retail pharmacies, hospitals and private medical/dental practitioners.

To encourage healthy competition in drug pricing, medicines procurement in the MOH is done through open tender by generic name most of the time. For medicines supplied under the concession agreement, the concession company, *Pharmaniaga*

*Regulating
Medicines Prices in
Malaysia*



Logistics conducts a similar open tender system. Direct price negotiations are sometimes necessary when there are no competing distributors or suppliers. Through bulk purchase and open tender system, the MOH indirectly brings down the prices of medicine. The PSD is also collaborating with the WHO to study other suitable mechanisms to regulate medicines price in Malaysia.

QUALITY USE OF DRUGS

Quality use of drugs is another essential component in assuring cost containment and appropriate spending for medicines. According to WHO, rational use of drugs means that patients must receive medicines appropriate for their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

*Realising Rational
Use of Medicines*

WHO reports inappropriate use of drugs as a major global problem. Irrational use of medicines includes over-treatment of a mild illness, inadequate treatment of a serious illness, misuse of anti-infective drugs and over-use of injections. It is of great concern that irrational use of medicines not only occurs among consumers and patients, but also among prescribers and dispensers of drugs. The policy on Quality Use of Drugs has to be implemented by all players in the pharmaceutical sector (health professionals, industry and media) for quality of care, cost-effective therapy, rational prescribing and appropriate use of medicines by both professionals and consumers.

A wide range of strategies is necessary for effective implementation of this policy. The strategies outlined under DUNAS encompass training and education, provision of neutral and evidence-based drug information, the establishment of standard treatment guidelines, ethical promotion of drugs and defining the distinct roles of health professionals. Drugs and Therapeutics Committees should also play an effective role in healthcare institutions in both the public and private sectors.



Education and Training of Healthcare Providers

While basic qualifications of healthcare providers and allied health personnel is a prerequisite for appropriate drug utilisation, the policy emphasises the need for the concept of essential medicines and rational drug use to be part of the core curriculum of training programmes in all undergraduate schools or faculties. Simultaneously, continuing professional development is another journey to better prescribing, dispensing and drug management practices among practicing healthcare professionals.

*Skills Training for
Rational Drug Use -
Providers*

Skills training of pharmacists involve overseas stints and attachments at local health institutions under supervision of trained preceptors. One of the areas identified as contributing towards quality use of drugs is the establishment of medication management initiatives run by pharmacists in health institutions - in particular the Medication Therapy Adherence Clinics or MTAC, and Clinical Pharmacy activities. The main target of the MTAC in 14 major hospitals is the management of chronic diseases, such as diabetes mellitus, HIV/AIDS, warfarin use and asthma, to ensure effective self-management and compliance towards pharmacotherapy and other interventions.

Education of the General Public

Partnership and collaboration of the MOH with non-governmental organizations (NGOs), academia, professional associations, the pharmaceutical industry, consumer and community groups have been established to promote the quality use of drugs by the public. The emphasis is to provide objective and practical information on drugs and their proper use, develop a more discerning attitude to advertising and commercial information, encourage informed decision-making on drug use based on adequate scientific information, encourage responsible self-medication and build consumer confidence to interact with healthcare providers.

*Promoting Rational
Drug Use by the
Public*

As an initiative under DUNAS, a three-year project, the Comprehensive National Project on Quality Use of Medicine - Consumers (QUM-C) was jointly organised by the MOH and the Federation of Malaysian Consumers Associations (FOMCA) with active participation from the universities and the Malaysian Pharmaceutical Society. QUM-C aims to create awareness, increase knowledge and provide education to consumers on rational use of medicines.



It comprises the “Know Your Medicine Campaign” and the “National Survey on the Use of Medicines (NSUM) by Malaysian Consumers”. Activities carried out to the public include seminars, exhibitions and talks (Table 1).

Table 1: Campaign Activities Conducted, 2007-2008

Year	Exhibitions	Seminars/ Radio Seminars	TOT	Dialogues/ Quizzes	Launch of Campaign	Total No. of Campaign Activities
2007	54	28	-	2	2	86
2008	267	307	18	-	9	601

The survey yielded baseline data on consumer awareness and knowledge about medicines. The results show that about 32% of consumers currently use medicines to treat their chronic diseases, 43% use health supplements and 26% use traditional medicines. Although a third of Malaysians are on chronic medications, the level of understanding on proper use was only slightly more than half (56%). More than two-thirds do not know their medicine name(s) (66%) and 56% were not aware of the common side effects of their medicines. These results reveal that much more is needed to educate the general public to be more discerning and responsible towards medicines and this can only be done through collaboration and partnership between all stakeholders.

*Need to Further
Educate the Public*

Drug Information

Drug information plays a vital role in this policy as it ensures the availability of accurate, unbiased and relevant information understandable by all healthcare providers, patients and the general public. Drug information services at public hospitals have been established for many years, but some still lack updated resources due to sporadic provision of allocation to maintain the service. The function of a Drug Information Centre (DIC) is to disseminate relevant information on drugs and pharmaceuticals to health professionals and the public. The DICs not only act as information centres but also as adverse drug reaction (ADR) reporting centres for the health facility.

*Establishing Drug
Information Centres*



For a drug information service to function effectively there must be sufficient resources to respond to queries. The networking of all information centres is also very important to overcome the shortcomings and inadequacy of resources. Another measure is to develop a National Pharmacy Information Centre to provide support to centres with inadequate resources and this initiative has already been undertaken from 2008.

There have been increasing numbers of queries received by MOH hospital pharmacies and a total of 43,861 were received in 2008 (Table 2). The DICs also facilitated the reporting of cases of Adverse Drugs Reactions (ADR) to the Malaysian Adverse Drug Reaction Advisory Committee (MADRAC). There have been increasing reports of ADR cases since 2006.

Table 2: Number of Drug Information Enquiries and ADRs Received, 2006-2008

Year	Total No. of Enquires Received	Total No. of ADRs Reported
2006	25,061	1,718
2007	30,485	2,340
2008	43,861	2,844

ROLE OF PHARMACISTS

Dispensing of medicines is the central role of pharmacists. Through dispensing, pharmacists can further institute medication counselling. This is a patient-centred activity that will not only provide drug information but can also identify pharmaceutical care issues faced by patients as well as identify options to overcome these problems. The policy is very clear on the role of health professionals whereby medical and dental practitioners prescribe while pharmacists dispense medicines. To achieve quality use of medicines these distinct roles need to be adhered to.

Defining Role of Pharmacists

Medication counselling through individual, discharge and group sessions is carried out by pharmacists to help patients achieve intended health outcomes through better compliance and handling of



adverse drug events that may arise from their medication use. The number of patients counselled on their medications has increased to 376,584 in 2008 in MOH facilities (Table 3).

Table 3: Number of Patients Counsellled, 2006-2008

Year	Total no. of patients counselled
2006	253,142
2007	312,439
2008	376,584

The policy specifies that Drug and Therapeutic Committees of hospitals and state health offices should co-ordinate the development of Standard Treatment Guidelines and adopt the NEDL according to in-house policies and local needs. Pharmacists have an important role in mobilizing this effort by providing cost and good quality drug utilisation data. The promotion of NEDL in the private sector is very important to ensure that medicines that are necessary to treat the most common conditions in the country are available to all citizens at affordable costs.

There is also an urgent need for evidence-based Standard Treatment Guidelines to harmonise with existing clinical practice guidelines as one of the measures towards quality prescribing and cost containment. This needs collaborative efforts involving experts in related disciplines, to include general practitioners and community pharmacists, and should be coordinated by the National Drug And Therapeutic Committee. The Standard Treatment Guidelines should indicate the most cost-effective therapeutic approach on the basis of clinical evidence and define the desired prescribing and drug use behaviour.

*Harmonising
Treatment and
Practice Guidelines*



MEDICINES ADVERTISEMENT AND PROMOTION

The Medicines (Advertisement and Sale) Act 1956 (Act 290) and its Regulations control advertisements of medicines, appliances, remedies, skills and services that relate to medical and health claims. Such regulation of products and services aims to protect the public from false and fictitious claims by unscrupulous traders. The policy advocates ethical and truthful promotion and marketing activities. To strengthen promotion of medicines, a document on Good Governance of Medicines has been developed. Two process indicators (PR 6 and 7) measure the effectiveness of the regulation and enforcement under the Act (**Table 4**).

*Violations
in Medicine
Advertisements*

Table 4: Process Indicators (PR 6 & PR7) Values (%), 2006-2008

Indicator	Description	2006	2007	2008
PR 6	% of advertisements in violation of regulations out of total no. advertisements monitored	365 / 2013 (18.0%)	288 / 2433 (11.8%)	127 / 1737 (7.3%)
PR 7	% of sanctions on advertisements in violation of regulations out of no. of violations identified	365 / 365 (100%)	288 / 288 (100%)	127 / 127 (100%)

The results above showed a decline in the rate of advertisements violating the regulations from 2006 to 2008. Meanwhile, punitive actions such as sanctions or administrative measures were taken for all the violations encountered throughout the three years.

SUPPORTING COMPONENTS OF DUNAS

There are four supporting components of DUNAS, namely Human Resource Development, Research and Development, Technical Cooperation and Management of DUNAS. Their importance cannot be understated as these are the pillars that support the implementation of the core components of DUNAS.

*Four Supporting
Components of
DUNAS*



Major researches on drug use and drug expenditure have been conducted with grants from the MOH. The findings of these studies will provide the tools for future policy decision-making in DUNAS as well as for funding of pharmaceuticals.

In the area of technical co-operation, the NPCB plays an important role in the international arena. It has been designated as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals since 1996 and has been a member of the Pharmaceutical Co-operation Scheme (PIC/S) since January 2002.

CONCLUSION

The Malaysian National Medicines Policy (DUNAS) is a very much needed policy to ensure better healthcare of the people. The successful implementation of DUNAS requires national acceptance, recognition and commitment by all stakeholders, including the highest political level, in order to achieve the goals of the pharmaceutical sector in Malaysia. The Pharmaceutical Services Division, as lead agency, will co-ordinate and monitor all activities undertaken under DUNAS. As lead agency, the Division has managed to bring all stakeholders together to discuss and agree on all activities meant to be implemented by the various agencies, the government and private sector.

DUNAS will provide the direction for the pharmaceutical sector to plan and implement health activities and unify all efforts towards improving the health status and quality of life of Malaysians. All activities, which have been conducted, will be used as guidelines for future decision-making to meet the objectives of the policy. DUNAS is very much in line with the overall philosophy of the government and specifically of the MOH, to ensure that the population has access to good and affordable healthcare when required.



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IMPROVING THE DRUG DELIVERY SYSTEM IN HOSPITALS AND HEALTH CLINICS

SUMMARY

Drug dispensing is one of the basic activities of pharmacy practice carried out throughout the world. In hospitals and health clinics under the Ministry of Health (MOH), dispensing of drugs on long term prescriptions for outpatients is done in a staggered manner to enable better monitoring of long term adverse effects, reduce drug wastage and indirectly to enable better management of the annual drug budget. Realising the problems encountered by patients who need to come regularly to MOH facilities solely for the purpose of receiving their repeat medications, the Pharmaceutical Services Division has endeavoured to introduce new initiatives towards further improving the drug delivery system. In order to satisfy the needs and wants of patients, strategies which have been introduced to improve the drug delivery in the outpatient pharmacy setting include the Integrated Drug Dispensing System, Drive through Pharmacy, “SMS and Take” and the appointment card system. These systems have enabled patients to collect repeat medications at their own convenience. The introduction of these systems have also helped to ease the congestion at the out-patient pharmacies and reduce waiting time especially during peak hours.

Introduction

It is common practice for patients with chronic illnesses who have been stabilised on their medications to be given prescriptions for a long duration without the need for them to be seen by the attending physician between appointments. Medicines are supplied in full by the pharmacy in accordance with the prescription but for long term prescriptions, the quantity supplied is normally on a monthly basis. This approach has been taken by pharmacies in facilities under the Ministry of Health for several reasons. Firstly, it allows for better monitoring of adverse events especially those which occur as a result of long term or chronic use as patients can easily inform the pharmacists and seek advice when they come to get their repeat medications. It also helps to minimise medication errors on the part of patients who may be having many drugs. The quality of medicines supplied can be ensured as patients may not always store their medicines properly at home. Through partial supply of medicines on a monthly basis, wastage of medicines

*Partial supply
of medicines by
pharmacies under
MOH*

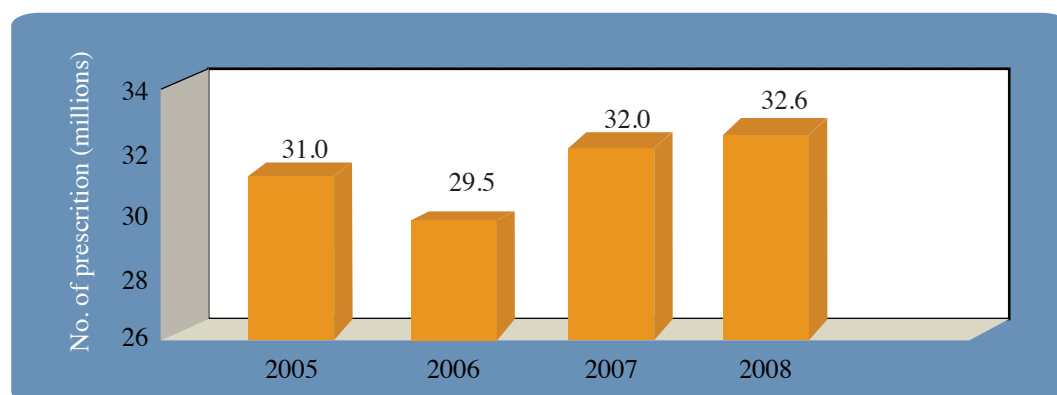


can be reduced as patients who may have some remaining stock at home may not come so frequently to collect their medicines. As government facilities have a pre-determined budget for purchasing of drugs and the stocks held should not exceed the quantity required for three months, staggering the supply of long term prescriptions allows for better store management.

The disadvantage, however, of this system is that patients have to come repeatedly to the outpatient pharmacy to get their prescriptions refilled at regular intervals. This practice inconveniences the patients, increases workload for the pharmacy, worsens the congestion at peak hours and lengthens the waiting time for all other patients as well. Patients living in different areas who have been referred to these facilities for their treatment may encounter problems due to distance and travelling costs. There is also the possibility that patients may not comply with their medication regimens properly and may even ultimately stop taking their medicines when they run out of stock. Patients may also absent themselves from work on days when they have to pick up their medicines and this will ultimately affect the productivity of the country.

The number of out-patient prescriptions received by the pharmacies in hospitals and clinics under MOH has been escalating over the years (Figure 1). Whilst the staggered supply system has its advantages, workable mechanisms have had to be introduced to address the problems faced by the patients and their care-givers.

Figure 1: Number of outpatient prescriptions (in millions) in MOH hospitals and health clinic from 2005 to 2008



Integrated Drug Dispensing System (SPUB)

Previously, government-run hospitals and clinics would supply medicines based on prescriptions issued from their own facilities only. There was no structured system or policy in place which enabled patients to collect medicines from facilities other than those where they sought treatment initially. With the development of healthcare in the country, there was an increasing trend for patients to be referred from primary healthcare facilities and district hospitals to secondary and tertiary care centres for treatment of complicated illnesses and follow-up treatment. Patients had little choice but to go back to these facilities to collect their medicines for as long as they were on these drugs.

In order to overcome problems faced by patients, in April 1999, a working paper entitled “Integrated Pharmaceutical Care in the Health System” was presented by the Pharmaceutical Services Division (PSD), MOH at the Conference of Directors, Ministry of Health held in Penang with the theme Towards Integrated Health Care System. The goal of this system was aimed at optimising pharmacotherapy and improving clinical outcomes through improved accessibility to drugs and the provision of better pharmaceutical care services. The proposal to have an Integrated Drug Dispensing System (IDDS) or “*Sistem Pendispensan Ubat-ubatan Bersepadu* (SPUB)” was accepted and a concept paper was subsequently developed by the PSD.

Integrated Pharmaceutical Care

The aim of SPUB was to provide an option for patients, particularly follow-up cases, to collect their medications from health facilities nearest to their homes through an integrated supply system. This system will especially benefit patients who stay in remote areas.

Aim of SPUB

The implementation of an integrated pharmaceutical care service was also a strategy developed to ensure continuous, comprehensive, equitable, accessible, quality health care for all. This was in line with the goals of health services in the 21st century which emphasises seamless care and care close to home.

A pilot project was conducted during the period December 2001-May 2002 in seven states namely Johor, Malacca, Negeri Sembilan, Pahang, Perak, Selangor and Federal Territory of Kuala Lumpur. Following the success of the pilot project, SPUB was implemented nationwide on 1st June 2003.

Pilot project

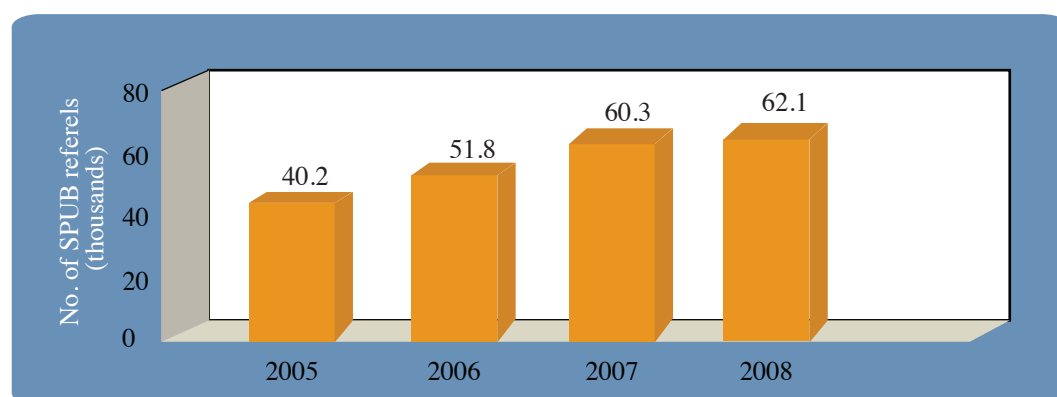


Through this system, patients are required to collect their initial supply of medicines from the facility where they sought treatment. For subsequent supplies, patients have the option of collecting it from a MOH health facility conveniently accessible to them which is listed in the SPUB directory. The pharmacy will make a certified copy of the prescription, indicate the referral for SPUB and the name of facility chosen, and return the prescription to the patient. The SPUB form with the relevant patient particulars and a copy of the prescription will be sent by the referring hospital/clinic to the facility of the patient's choice. Upon receipt of the SPUB form, it is the responsibility of the second facility to ensure that adequate stocks are available to fulfil the patient's prescription. Besides making it convenient for patients, the system would ensure the continuity of medicines supply and improve patient's compliance to their medications.

When the system was first introduced, initial hiccups were encountered. This was mainly due to the fact that the health clinics did not have sufficient funding to purchase the medicines prescribed as they were often specialist items which were not stocked in these facilities. There was also a shortage of pharmacists in the health clinics who could undertake to make the necessary arrangements to either purchase the drugs or obtain them from other facilities before the patient was due to come. The lack of understanding on the part of patients who would walk in to a facility without having gone through the proper referral system also created problems.

Through better management of the system, the number of SPUB cases has been increasing steadily over the years since its inception and involves both intra- and inter-state referrals (Figure 2). The system has received good response from the patients as it enables them to save time, travel expenses and has brought healthcare closer to home.

Figure 2: Number of SPUB referrals 2005-2008



The SPUB transaction from 2005 to 2008 is tabulated in Table 1.

Table 1: SPUB Transactions (2005 -2008)

	2005			2006			2007			2008		
	Intra State	Inter State	Total	Intra State	Inter State	Total	Intra State	Inter State	Total	Intra State	Inter State	Total
Total No. of Prescription	28,705	11,474	40,179	39,670	14,092	51,762	44,502	15,752	60,245	48,113	14,060	62,119
Total No. of Category Items	25,868	12,868	38,736	30,936	12,419	43,355	42,047	13,618	55,665	55,830	16,107	71,937
Total No. of Category B & C Items Total	50,845	23,561	74,406	56,590	29,654	95,171	89,172	36,232	125,404	127,573	36,367	163,940
Cost for Category A Items (RM Millions)	1.3	0.5	1.8	1.0	0.7	1.7	2.2	1.1	3.3	3.4	1.1	4.5
Total Cost for Category B & C Items (RM Millions)	0.4	0.2	0.6	0.5	0.3	0.8	0.9	0.4	1.3	1.1	0.4	1.5
Total Items Cost (RM Millions)	1.7	0.7	2.4	1.5	1.0	2.5	3.1	1.5	44.6	4.5	1.5	6.0

Source: Pharmaceutical Services Division, MOH



However, from Figures 3 and 4, it can be seen that there is no significant increase in drug expenditure. In the year 2008, only 0.4% of the drug cost involved SPUB cases.

Figure 3: Cost of SPUB DRug Supplied by Drug Category

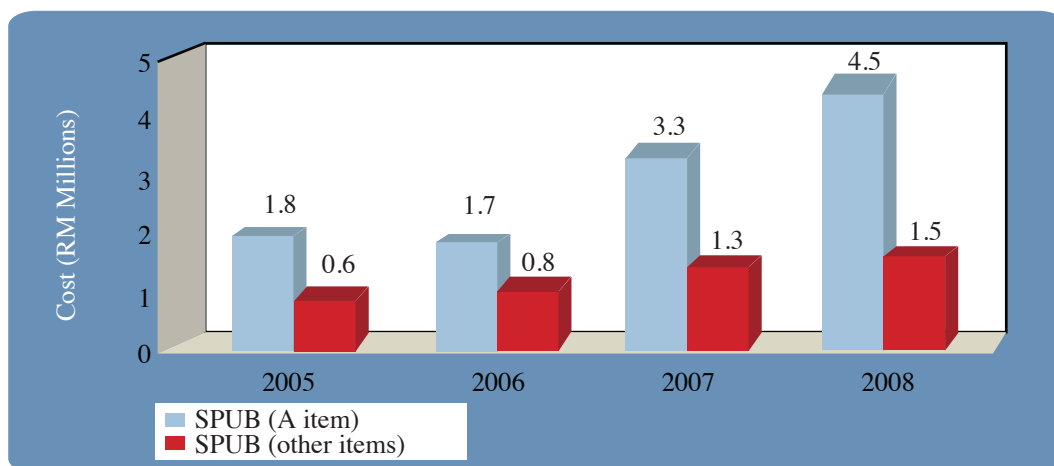
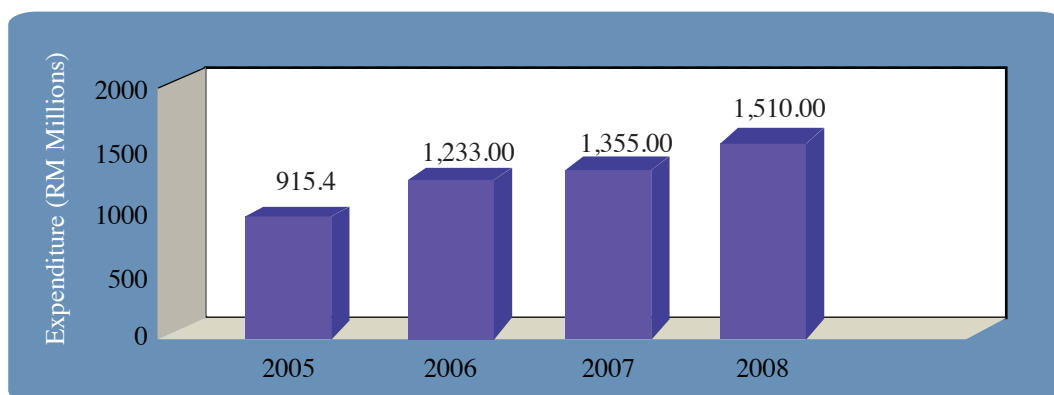


Figure 4: MOH Drug Expenditure 2005-2008



Appointment Dispensing System

Many pharmacies in hospital and health clinics have introduced the use of an appointment card system through which patients are given an appointment date and encouraged to come during non-peak hours to get their prescriptions refilled. Their medicines are prepared in advance and patients can collect them on the appointment day from pre-assigned counters thus reducing waiting time for themselves and others.

Appointment Card System



With the increasing use of mobile phones and SMS in Malaysia, several hospitals and health clinics have used this to their advantage and evolved the appointment card system into the “SMS & Take” System.

Patients who have to collect repeat prescriptions now only need to send a SMS to the pharmacy giving their details, date and time when they plan to come to collect their repeat medications. The introduction of this system has been well received by patients as it gives them the flexibility of choosing when they would like to come to collect their medicines. As the cost incurred to MOH is minimal, the Pharmaceutical Services Division plans to expand it to all hospitals and health clinics in the country especially where waiting time is a problem.

SMS & Take system

Implementation of the various appointment systems for collection of medicines is shown in Table 2.

Table 2: Number of Hospitals and Health Clinics Implementing Appointment Dispensing System

States	Number of Hospitals				Number of Health Clinics			
	Appointment Card	SMS & Take	Telephone	Others	Appointment Card	SMS & Take	Telephone	Others
Perlis	1	-	-	-	-	-	-	-
Kedah	1	1	-	-	-	-	-	-
Penang	4	1	-	1 (Drive Thru)	-	-	-	-
Perak	5	1	2	-	1	-	-	-
HKL	1	-	-	-	-	-	-	-
JKWP & Putrajaya	1	1	1	-	1	-	-	-
Johor	-	12	-	-	-	10	-	-
Pahang	1	-	-	-	-	-	-	-
Terengganu	1	1	2	-	-	-	-	-
Sabah	-	23	-	-	-	5	-	-



“Drive Through Pharmacy”

Despite the introduction of appointment and SMS systems, patients still encounter problems picking up their medicines due the perpetual problem of insufficient parking space in most major hospitals.

The Pharmacy Department of the Penang Hospital undertook a project called the ‘Drive-Through Pharmacy Counter’ as part of their Customer Service Initiative to create a more accessible, user-friendly method of dispensing monthly medications to their clients.

The Drive Through Pharmacy was launched in July 2008 with the main objective of improving waiting time in Out Patient Pharmacy which was a major source of complaints. The drive-through concept also created a friendlier yet more efficient method of medication collection for especially for the elderly, special-needs and disabled patients who have difficulty accessing the current walk-in premises. Also, it also helps the care givers who can now save time by not having to bother about parking and can also listen in to advice provided by the pharmacists when the medicines are being dispensed.

*Drive Through
Pharmacy Counter’
Launched in Penang
Hospital*

Patients who opt for this system need to come to the Drive Through Pharmacy on the appointment day and their medicines which have been pre-packed are dispensed by pharmacists manning these counters. This system has steadily gained popularity among the patients as it is efficient, hassle-free and the quality of dispensing has not been compromised. Total number of patients recruited and percentage of patients attendance are shown in Table 3 and Table 4.

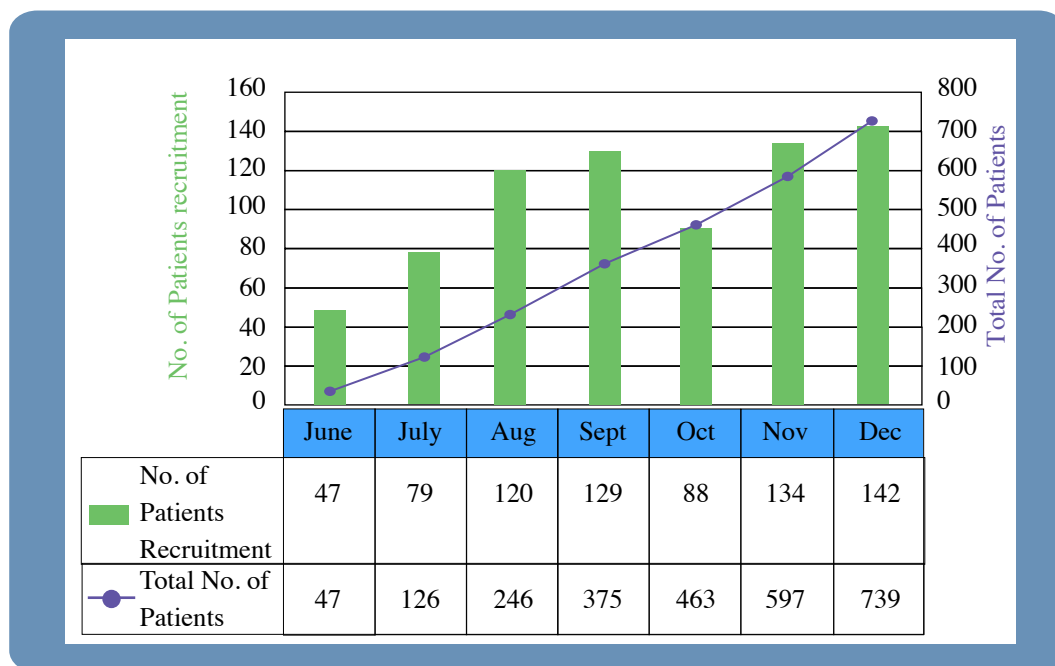
As the Drive Through Counter is located away from the main hospital, it has helped to ease not only congestion and waiting time, but to certain extent has reduced the traffic and parking woes for others.

Penang Hospital’s “Drive through Pharmacy” has gained recognition not only locally but internationally as well at the Asian Hospital Management Award 2008 in Manila, Philippines.

*International
Recognition*



Table 3: Number of Patients Recruited for “Drive through Pharmacy” in Penang Hospital 2008



The Way Forward

Improving drug delivery systems in the ambulatory setting is a major concern for MOH. Gaining patients’ satisfaction for the services provided by the pharmacy services in terms of adequate supply of quality medicines, proper patient education, timely drug delivery whilst looking after their needs and comfort is of utmost importance towards achieving the PSD’s vision in optimising pharmaceutical care. Much effort has been focused on improving the pharmacy services particularly in the outpatient setting. Integrated Drug Dispensing System, Appointment Dispensing system such as SMS & Take, Appointment Card system and Drive through Pharmacy have been implemented to give options to patients who are on long term prescriptions.

Improving Drug Delivery System

These systems will be further expanded and extended to involve all hospitals and health clinics in the country. An amalgamation of the various systems is currently being studied so that patients will have a choice of choosing the option which suits them best.

Expanding services



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PATIENT SAFETY – IDENTIFYING THE RESEARCH AGENDA FOR MOH IN THE 9TH MALAYSIA PLAN

SUMMARY

Internationally, it is recognized that knowledge is required to improve patient safety. In addition, the global community had stated its concern that the increase in publications in patient safety had not shown measurable improvement.

MOH approached the Malaysia patient safety R & D agenda by calling for concerted research to identify threats to patient safety, as well as design and test effective strategies to address national needs. The health research priority's call for research in patient safety resulted in an explicit process of prioritisation to identify crucial areas to meet these requirements.

This article attempts to delineate the processes taken to identify MOH's research agenda for patient safety.

Research in Patient Safety

In 2005, half a decade after the landmark report “*To Err is Human: Building a Safer Health System*” by the Institute of Medicine (IOM), the 1st meeting of the Global Research Program for Patient Safety WHO World Alliance for Patient Safety in collaboration with AHRQ¹ produced a report called “*Knowledge Is the Enemy of Unsafe Care*”, emphasizing the need for information in Research & Development (R&D). Additional concerns raised were on health care beyond the hospital, systemic approach versus the human hazard/hero, and the undeniable fact that though publications had increased tremendously, improvement in patient safety had not.

Global research directions

“Research is a means to an end”, and cognizant of this, the Secretariat for Patient Safety Council Malaysia (PSCM) had advanced the MOH research agenda to encompass not merely identifying threats to patient safety, but to also design and test effective strategies, research priorities also recommended by AHRQ.

Malaysian vision

1 AHRQ: The Agency for Healthcare Research and Quality, USA.



Health Research Priority

In the 9th Malaysia Plan (9MP) health research priority, the National Institutes of Health (NIH), Malaysia issued a call to improve patient safety, stating:

...a big knowledge gap in the understanding of the magnitude of the problem, the risk factors and the causes that leads to adverse events both in the public and the private health sector. These findings will provide valuable evidence to assist the Patient Safety Council Malaysia in decision-making and policy development, and development of a safe healthcare system in Malaysia ...

Recognising the need for patient safety research.

Prioritizing Patient Safety Areas for Research

Step #1: The Knowledge Gap – What is of concern in the international arena?

To determine areas requiring research, international perspectives and challenges identified for Patient Safety were reviewed and listed. Notably the concerns came from:

Identifying the knowledge gap – areas that international research addresses

- World Health Organization (WHO) GLOBAL Patient Safety Challenge 2005-2006
- WHO GLOBAL ALLIANCE For Patient Safety
- World Alliance documents
- The Joint Commission International Center for Patient Safety
- the landmark documents from Institutes of Medicine (IOM)
- other international publications on patient safety

Step #2: The Knowledge Gap – What is of concern at national level?

Key stakeholders from the PSCM Secretariat, clinician activists



with vested interest in improving healthcare, researchers involved in patient safety research from NIH and the Institute for Health Systems Research (IHSR) pooled resources to set about identifying this knowledge gap.

Areas of possible concern – national perspective

Brainstorming sessions, review of current available issues/evidence in patient safety and expert group meetings were held to identify national needs.

Step #3: The List – All Areas of Concern

A list of areas requiring research that covered issues from the international arena as well as local needs was identified. Included were the safety of blood, injections, disposables/needle reuse, immunization, clinical procedures, wrong site/wrong procedure/wrong person surgery, safe water and sanitation, infection control, laboratory medicine, patient identification, hand-off communication, catheter and tubing misconnections, preventing kernicterus, inpatient falls (amongst elderly), medication, failure to recognize deteriorating condition, complementary/alternative care, discharge at-own-risk (AOR), injuries, accessibility (available, affordable) to emergency care, community safety, transplant safety, medical devices and equipment, chemical safety, making pregnancy safer, accessibility to health care (e.g. marginalized group - indigenous, refugees), patients' role for patient safety, reporting tools/systems, analytical & investigative tools and patient safety solutions.

Possible research areas – from international and national perspective

Step #4: The List – Collecting Information prior to Prioritization

The team then explored each identified area. Areas were described, as far as possible, in terms of its problem statement, current scenario in Malaysia, impact, burden (mortality or morbidity) as well as the strategies available for improvement.

Impact & burden to country of various patient safety areas

In addition, methods of researching patient safety were included as well, and researchers previously involved in patient safety studies had been invited to join the team.

Methodologies for patient safety research



Step #5: The List – Prioritizing Process

An explicit priority setting exercise took place between stakeholders, mainly of the PSCM Secretariat, clinicians and researchers.

*Prioritising areas
for research*

Three (3) criteria were adopted for prioritisation. They were each allocated marks according to importance in the prioritisation process, in which a criterion of greater consequence had a higher maximum score achievable. Higher scores signifying higher priority.

*Criteria for
prioritising*

Criteria used and the allocated marks for prioritisation were (range of possible scores in parenthesis):

- impact/magnitude of issue/burden of problem/seriousness of issue (1-10),
- preventable/ remedial actions / corrections possible? (1-8)
- and feasibility of conducting the study (1-5)

Members considered impact/magnitude of an issue the most important criterion in the prioritisation process, whereas feasibility of conducting the study was deemed least important. This was because members held the view that capacity gaps, timelines and methodological issues should not be as important a deterrent.

Rating for each area and criterion was done in a group, enriched with discussions of pros and cons for each. This approach was preferred over that of individual rating as group discussion enriched the process, in particular, for areas with minimal information available. Attempts were made to reach a consensus score.

*The rating process
in prioritising*

Scores were then totaled, and areas with the highest scores reviewed. High priority areas resulting from this explicit rating process were discussed in depth by all members, in terms of the criteria used for rating and other issues unique to each research area. Following this, members collectively agreed upon the prioritised area to be researched. The identified areas, in order of priority, are in Table 1.

*Identifying the
prioritised areas*



Table 1: Research Priority Areas for Patient Safety for MOH in the 9MP

	Area
1.	Patients For Patient Safety
2.	Hand - Off Communication / Handling Over
3.	Errors In Laboratory Medicine
4.	Patient Falls - Magnitude Of Problem, Infrastructure
5.	Immunisation Safety / Vaccine Efficacy
6.	Infection Control - Provider Practice
7.	Hand Washing - Preventions
8.	Blood Safety
9.	Clinical Procedures - Medical Errors In Executed Wrongly / Skill / Staff / Wrong Choice Of Procedures (Primary Care & Ipatients)
10.	Reporting Tools / Systems, Analytical & Investigative Tools, To Reporting Incidents Etc, Leading To Underreporting, Resentment / Burden, No Improvement
11.	Staff Safety - Clinical Governance / Accountability / Supervisor & Management Commitment To Safety / attitude / Behaviours / Universal Precaution / Psychological / Trauma Counselling / Rehabilitation / Injuries / Work Conditions
12.	Disposables Reuse; Reuse Of Devices Of Single Use
13.	Medical Waste Disposal
14.	Catheter And Tubing Misconnections
15.	Injection Safety (Inappropriate Use, Unsafe, Infections,Wrong Side)
16.	Basic Training - Patient Safety Issues
17.	Organizational Efforts For In-Service Training Pertaining To Patient Safety
18.	Patient Identification (a cross cutting areas)

Step #6: The Investigators

For each selected priority area, principal investigators (PI) were identified based on expertise in the relevant field and willingness to carry the torch forward for service improvement.

*Identifying
the principal
investigators*



Challenges and Gains: A Reflection

The prioritisation process conducted was painful in its tediousness, yet invigorating with the wealth of discussions that took place over several days. The explicit process attempted to eliminate bias in the choice of areas to study.

*Explicit
prioritisation
process*

Nevertheless the members present could not comprehensively represent all health care sectors/programmes. Some bias did exist due to the inherent preference of some members involved in the voting process, though care had been taken to ensure most disciplines and sectors (public health/hospital) were represented.

*Inherent bias
-preference of voters*

Stakeholder involvement at MOH level was crucial for the success of the prioritisation process. They provided direction, crucial information, as well as instilled a sense of ownership and worth to the whole endeavour.

*Stakeholder
involvement*

Obtaining information prior to actual prioritisation process necessitated an extensive search for evidence, and information, mainly through local and international literature. The challenge remains in how to ease this process in future as local sources of information remain mostly as grey literature, with its retrievability sometimes a time-consuming process.

*Gathering the
requisite information*

Conclusion

Setting national research agenda in an explicit manner provides clear goals and directions for both researchers and stakeholders whilst simultaneously focusing research resources on the nation's needs, and not a researcher's individual agendas. The compelling MOH leadership demonstrated in the process improves chances of research findings utilization towards improvement in care. Concerted effort such as this is crucial in our journey to improve patient safety, a concern that all nations grapple with, yet none have come near to solving.

Concerted efforts



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EXTENDED HOURS IN PRIMARY CARE - IS THE POLICY EFFECTIVE?

SUMMARY

Extended Hours Service in health clinics was introduced in January 2008, following an administrative circular No.8/2007 by Director General of Health. The objective was to reduce congestion of “cold cases” seen at Emergency Department of the nearby hospital. There were 16 health clinics identified throughout the country and these clinics were situated nearby the state hospital. The number of attendances during extended hours, type of cases and category of staff involved were monitored. The number of attendance at the nearby hospital was also compared to see whether the objective was achieved. Preliminary observations noted that there was a tremendous increase in number of attendances utilizing the services over one year period. The majority were non-emergency cases. There was not much reduction in the number of attendances at the nearby hospital. Further evaluation is needed before expanding the service to more clinics.

Introduction

Extended hours service, also called after office hours service is defined as an extension of service hours beyond normal hours at identified health clinics. Health clinics in rural areas usually provide service after office hours but it is only for emergency cases and managed by the health clinic staff who carry out call duties on rotational basis namely Medical Doctors, Assistant Medical Officers and Nurses.

Extended Hours

The Emergency Department in several hospitals reported that many non-emergency cases (‘cold cases’) were seen to seek care at the department after office hours. In 2006, Emergency Department recorded 4.9 million attendances, of which 60% cases were non critical. This has contributed to the heavy attendance at the department, causing congestion and long waiting hours as well as an increased burden for staff at the department treating those “perceived” emergency cases.

*Emergency &
Trauma Department*

“Cold Cases”

The hospital management introduced a new policy of having government doctors to do locum at Emergency Department from

Locum



9.00 pm till 12.00 midnight and be paid on an hourly basis. However it still did not solve the long waiting hours. Therefore, the Ministry of Health decided to introduce an extension of service hours to health clinics which were near hospitals from 5 pm to 9.30 pm. By decongesting the workload, hopefully the healthcare providers would be able to provide more efficient and prompt treatment to those who need emergency treatment.

Selection Criteria

The health clinics for extended hours were identified based on the following criteria:

*Outpatient
Department*

- a) It must be situated near hospitals which do not have an outpatient department.
- b) High workload at Emergency Department of the hospital, i.e. more than 200 patients per day.

Scope Of Services

*Critical
Non-critical
Medico-legal*

The type of cases seen at the extended hours clinic is either critical or non-critical except for medico-legal cases and cases which require integrated services by One Stop Crisis Center (OSCC) teams. Such cases need to be referred to hospital. Critical cases shall also be referred to the hospital for further management.

There were 16 health clinics identified, gazetted officially and as listed in Table 1.

Gazette health clinic

A Director General of Health Circular No. 8/2007 was issued on 10 December 2007 and the service was commenced with the aim to reduce congestion of “cold cases” at Emergency Department in hospitals. The 16 health clinics extended their operational hours from 5.00 pm to 9.30 pm on weekdays and from 8.00 am to 12 noon on Saturdays. Only a small number of clinics were chosen at the beginning because there were constraints for additional funding.

*Director General of
Health Circular*



Table 1: Distribution Of Extended Hour Clinics By States

No	States	Hospital	Health Clinic
1.	Kedah	Alor Setar	KK Alor Setar
2.	Perak	Ipoh	KK Greentown
3.	Selangor	HTAR, Klang	KK Anika
		Selayang	KK Selayang Baru
4.	Negeri Sembilan	Seremban	KK Seremban
5.	Melaka	Melaka	KK Peringgit
6.	Johor	HSAJB	KK Mahmoodiah
		Sultanah Aminah Muar	KK Bandar Maharani
7.	Pahang	HTAA, Kuantan	KK Kuantan
8.	Terengganu	Sultanah Nur Zahirah, Kuala Terengganu	KK Kuala Terengganu
9.	Kelantan	Raja Perempuan Zainab, Kota Bharu	KK Bandar Kota Bharu
10.	Sarawak	Umum Sarawak	KK Jln Masjid
11.	Sabah	Duchess of Kent	KK Sandakan
12.	WP Kuala Lumpur	Hospital Putrajaya	KK Putrajaya

Human resource

In most clinics, the extended hours service was manned by a very minimum number of staff. They were the “key-staff” i.e. one from each category:

- Medical Officer
- Assistant Medical Officer
- Staff Nurse



- Community Nurses
- Assistant Pharmacist
- Medical Laboratory Technologist
- Health Attendant
- Driver

Key staff

Since there was no additional staff, the clinic and district health managers were given flexibility to deploy staff within the district to assist in the implementation to ensure efficient services. The staff were given overtime allowance according to their eligibility and the medical officer was paid RM 80.00 per hour.

Financial support

A gross budget was calculated for additional financial support for a year per health clinic and estimated as below:

No	Item	Cost per year per clinic (RM)
1.	Utility bill	78,787.80
2.	Pharmacy/ drugs	155,952.00
3.	Overtime and allowance for staff	216,055.29
	Total	450,795.09

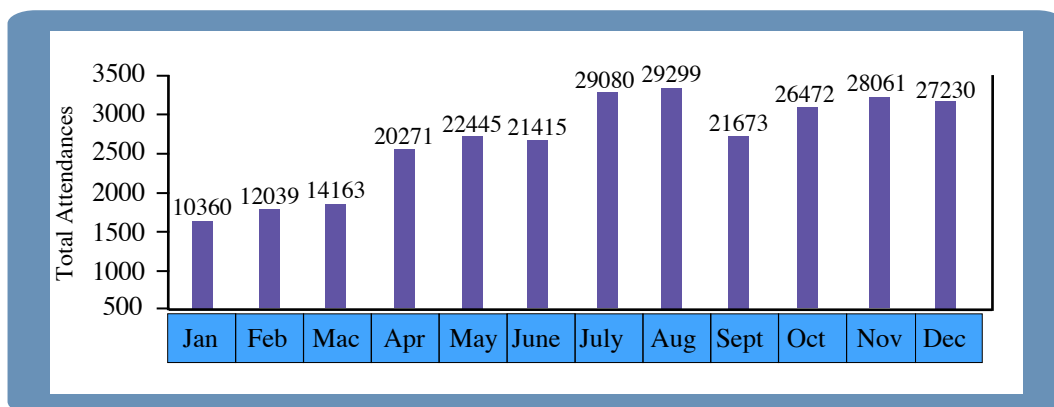
Overtime allowance and incentive

Results

The figure 1 shows performance over one year in 2008.



Figure 1: Total attendances to clinics during extended hours from January- December 2008



Source: Annual Report, Family Health Development Division, Ministry of Health, 2008.

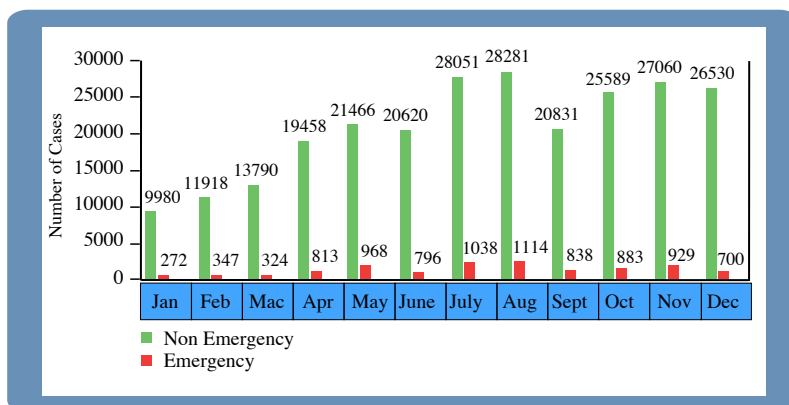
A total of 476,653 attendances were recorded utilizing the service throughout the year. Figure 1 showed the monthly performance. There was an increasing trend of attendances. The number of cases seen in January was initially low i.e. 10,360 but it gradually picked up and almost doubled to 20,271 over 4 months. It continued to increase and almost tripled in July and August. There was a slight reduction in September. This could be due to the fasting month and long holidays for *Hari Raya* celebration. Attendances picked up again in November and December.

Overall, the service seems to have received very good response from the public in utilizing the extended hours service in health clinics.

The majority of cases seen were non-emergency cases. Out of 476,653 attendances, only 13,580 (2.8%) were emergency cases and a small percentage of referrals were made to hospital. The proportion of emergency vs. non emergency in each month is as shown in Figure 2.



Figure 2: Proportion of Emergency vs Non Emergency Jan- Dec 2008



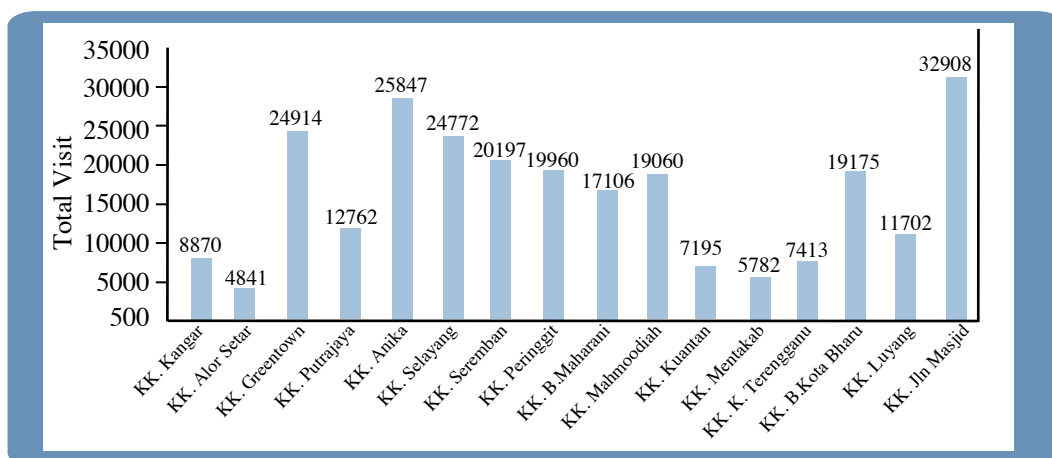
*Emergency And
Non-Emergency*

Hospital Referral

Source: Annual Report, Family Health Development Division, Ministry of Health, 2008.

Performance by each individual clinic is shown in Figure 3

Figure 3: Total visits to each health clinic January – December 2008



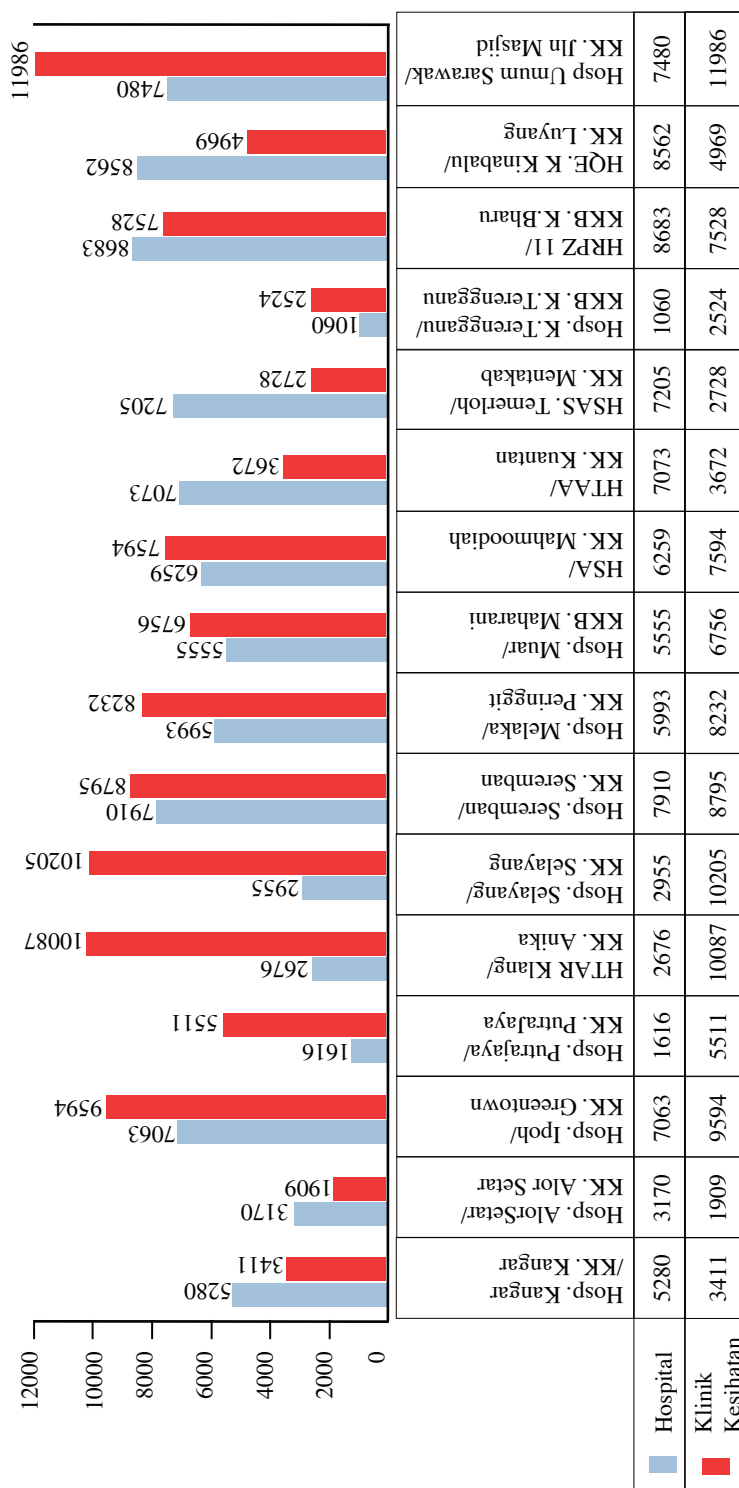
Source: Annual Report, Family Health Development Division, Ministry of Health, 2008.

Amongst the 16 clinics, KK Jalan Masjid in Sarawak recorded the highest attendance, followed by KK Anika, Selangor and KK Greentown, Perak. Other clinics namely KK Selayang, KK Seremban, KK Mahmoodiah in Johor and KK Bandar Kota Bharu also recorded high attendances.

The number of visits to hospitals and health clinics was also noted (Figure 4). It varied. Some health clinics noted lower attendances than nearby hospitals. Health clinics in urban areas were noted to have higher attendances than hospitals as compared to health clinics in smaller towns.



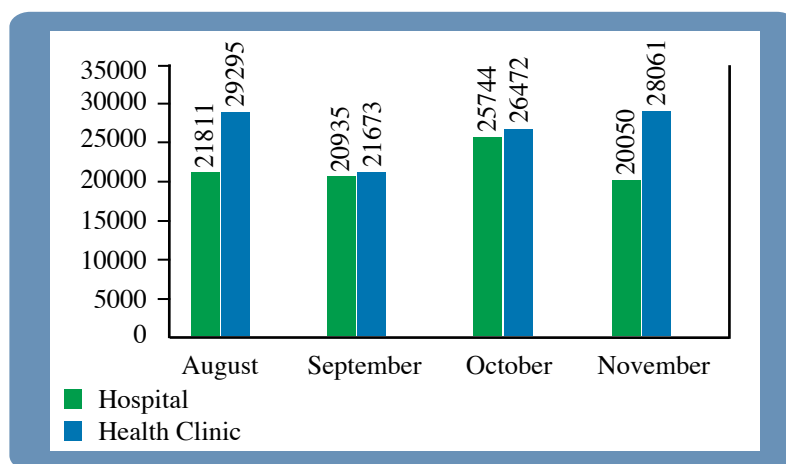
Figure 4: Total Attendance To Hospital & Health Clinic for August to November 2008



Source: Family Health Development Division and Medical Development Division, MOH, 2008

Further assessment was done to see whether there was really a reduction in the attendances of cold cases to the Emergency & Trauma Department of the hospital once the nearby clinic introduced extended hours service. The data from August to November were compared and is shown below.

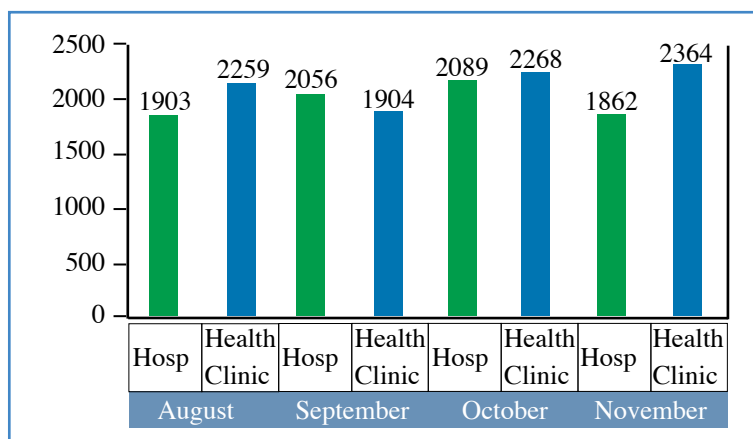
Figure 5: Total Attendance of Hospitals and Health Clinics for Aug – Nov 2008



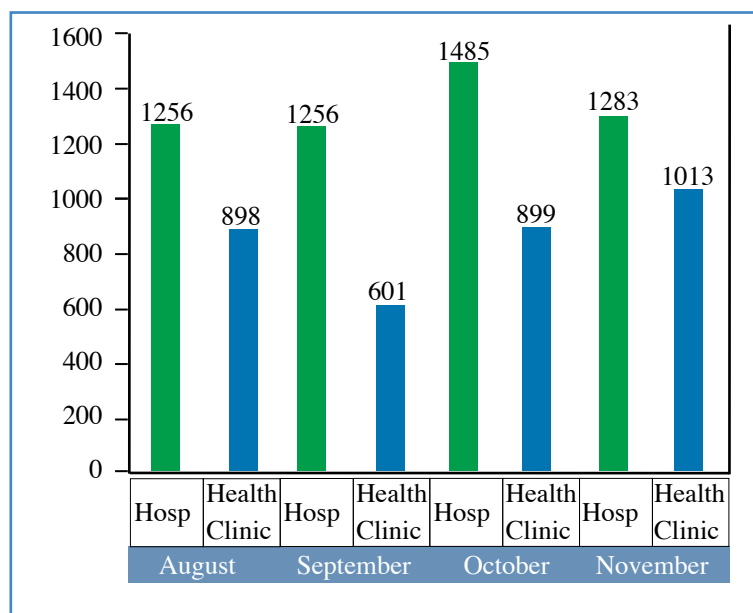
Source: Report from Medical Development Division, MOH and Family Health Development Division, MOH

There was no definite pattern seen. The duration may have been too short for any valid comparison. Only four months data were gathered from respective hospitals. There seemed to be no reduction in the pattern of attendances at the Emergency Department in the respective hospitals from August to December 2008 even though the nearby health clinics were opened to provide after office hours service. Individual analysis was also done in a few clinics and hospitals and the result is shown below.





KK Seremban vs Hospital Seremban

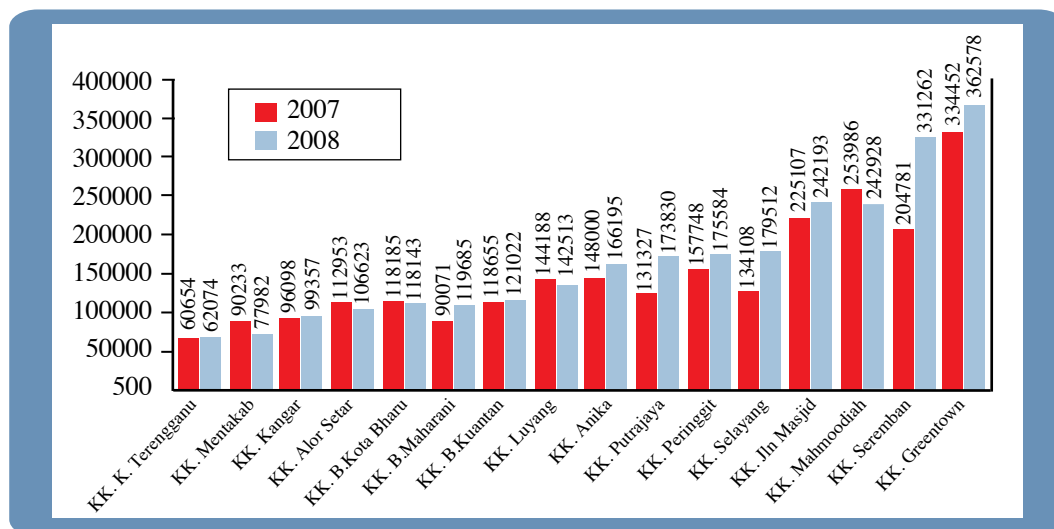


KK Kangar vs Hospital Kangar

In some clinics, there seems to be a reduction in hospital attendances whilst the clinic attendances increased.

Another comparison was made to see whether attendances at the outpatient unit of the health clinic during office hours i.e. from 8 am – 5pm were reduced, resulting the client to attend the clinic after office hours. The number of visits to outpatient units during office hours in 2007 were compared with same data in 2008 (Figure 6).

Figure 6: Comparison of outpatient attendance during office hours in 16 clinics for 2007 and 2008



There were no reduction in outpatient attendances during office hours in 2008 as compared to 2007 in the same clinic after the introduction of extended hours services.

Discussion

The introduction of extended hours service in 16 health clinics is a welcome move in the effort to facilitate access for public to seek healthcare. The choice of health clinics, the majority of which are situated in urban areas, make it very conducive for the urban population to utilise the services after working hours although there is still the option for private facilities. This can be seen from the increasing attendance to the clinics. The global economic down turn could also have deterred customer from spending out of pocket (OOP) at the private facilities to a cheaper RM 1.00 in government facilities.



Preliminary findings have shown that the service has received good response from the public. There was no reduction “seen” in attendances at Emergency Department of the ‘respective’ hospitals and also no reduction in attendances during office hours at the clinic itself. There is a possibility that different types of populations are using the service.

However, there are **constraints and challenges** such as:

- **Increased Workload:** Since the operation hours are longer, there will be increased attendances to the clinic.
- **Long working hours:** This could cause physical, mental and psychological stress to the staff since there was no additional manpower to the clinic. This is worrying because it can lead to inefficiency and a downgrade in the performance.
- **Inadequate number of staff:** The same staff is working extra hours. Hence, staff mobilization is important, especially single staff such as Medical Laboratory Technologist and Assistant Pharmacist. The responsibility will have to be shouldered together with other similar staff in the district.
- **Abuse of system:** Although it is a good move, explicit consideration should be given to avoid “inappropriate” use of after office hours service. Close monitoring will need to be carried out so that there is no abuse in overtime and allowance claims
- **Cost implication:** Definitely the operational cost to the clinic will be increased. The budget required should be considered. Estimated cost for lab, drugs, utility usage and allowance per clinic will have to be provided for to ensure optimum running of the service.
- **Customer expectation.** Because the clinic is manned by minimal staff, the scope of services also needs to be limited during extended hours. It is unreasonable to expect consultation with a specialist during such clinics.



Conclusion:

The introduction of extended hours service has excited planners and users and gave immediate benefit to the latter. By providing this service, it created an opportunity for public to utilise services at their convenient time especially those who were working during day time. This is in line with the government aspiration of “People First, Performance Now” and *Kami Sedia Membantu* (“Ready to Serve”). However the service can be improved with further provision of resources.

Future Plan

It is still very early to evaluate the policy because it has only been implemented for one year. More supporting data from hospitals is needed for detailed analysis in order to support the policy made and give guidance for further expansion. The current economic turmoil could have been a compounding factor for the results. A detailed study on impact and cost analysis would be helpful before deciding to expand this policy to more health clinics.



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Chapter 4

RESEARCH AND DEVELOPMENT

SHOWCASING MULTISECTORAL COLLABORATION: THE ORAL CANCER RESEARCH AND COORDINATING CENTRE (OCRCC) IN MALAYSIA

SUMMARY

Oral cancer is the eighth most common cancers worldwide. Incidence and mortality rates have either been stable or increasing in the last four decade. In Malaysia, most cases of oral cancer were detected late at diagnosis thus making best available treatment impossible. Realizing the growing burden of the disease there is a need for a shift in the approach of cancer research in Malaysia. To do this, a multidisciplinary partnership in conducting research was initiated. As a step towards sustaining this collaborative initiative, the Oral Cancer Research and Coordinating Centre (OCRCC) based in University Malaya had been established. Participating organisations include: the University of Malaya (UM), the Ministry of Health Malaysia (MOH), Universiti Sains Malaysia (USM), Cancer Research Initiatives Foundation (CARIF), University Kebangsaan Malaysia (UKM) and Universiti Teknologi Mara (UiTM). The mission of the OCRCC is to advance knowledge and learning in oral cancer through quality research and education for the nation and for humanity; with a vision to be an internationally renowned research centre in oral cancer. The Centre is actively conducting research activities, training, continuing education and promotion. Currently, partners in OCRCC are at a stage of developing its governing body called the Central Advisory Committee (CAC) which would consist of representatives of all the stakeholders and independent scientific experts to ensure the sustainability of this collaborative effort.

Introduction

Oral cancer management requires interdisciplinary participation. Early detection and understanding of the disease demands for interdisciplinary research that integrates two or more disciplines that may seem to be unrelated but are needed as strategies for success in research. This need led to the establishment of the Oral Cancer Research and Coordinating Centre (OCRCC) based in University Malaya in year 2005. The vision is to establish an internationally-renowned research centre in oral cancer that emplaces data and tissue sharing for research. The aspiration is for successful translation of basic research into clinical practice which will lead to excellence in innovation, publication and teaching. The aim of this paper is to share the experience of developing and sustaining partnership in managing oral cancer research in this country.



About Oral Cancer

Globally, oral cancer is the eighth most common malignancy. In many countries, incidence rates varies from 1 to 10 per 100 000 population. In South Central-Asia, cancer of the oral cavity ranks among the three most common types of cancer. For the past four decades, oral cancer incidence and mortality rates have been found to be either stable or increasing. There seems to be a sharp increase in the incidence rates of oral cancer in several countries and regions such as Denmark, France, Germany, Scotland, Central and Eastern Europe, and to a lesser extent in Australia, Japan, New Zealand and the USA.

Global Incidence of Oral Cancer

In Malaysia, oral cancer is not one of the top ten most common cancers, but it nevertheless is prevalent among ethnic Indians.

Oral Cancer Incidence in Malaysia

Preliminary data presented in 2007 on 156 cases showed that the majority of Malaysian oral cancer patients (62.3%) were at stage IV of the disease, giving a 1-year survival rate of only 47.4%.

Past data from the Ministry of Health (MOH) facilities reported oral cancer accounting for 7.1% of cancer deaths in 1998. A 1998 report on retrospective records from a large public hospital showed that lip and oral cancer accounted for about 3% of hospital admissions with more than 80% presenting at stages III and IV. In 1985, the Stomatology Unit of the Institute for Medical Research (IMR) reported an annual number of 150-200 cases and it was suggested that the numbers are probably 1.5-2 times higher as there are other hospitals and laboratories managing cancers. With oral cancer cited at a prevalence of 0.04%, the percentage of cancer admissions and deaths attributed to oral cancers confirm high morbidity and mortality.

Tobacco use and excessive alcohol consumption have been estimated to account for about 90% of cancers in the oral cavity. Oral cancer risk increases when tobacco is used in combination with alcohol or areca nut. The evidence on smokeless tobacco as a risk factor for oral cancer was confirmed by the International Agency for Research on Cancer. These associated risk habits are common among the Malaysian population and are in fact high in certain communities.

Risk Habits Associated With Oral Cancer

It is generally accepted that most cases of oral cancers are preceded by precursor lesions aptly termed 'potentially malignant' lesions. The progression of these lesions to malignancy is believed to be caused by accumulation of genetic changes in the epithelial cells that

Potentially Malignant Lesions



eventually reach a critical point to acquire the malignant phenotype. In Malaysia, it has been reported that there are variations in the occurrence of oral pre-malignancies among ethnic groups with the indigenous people of Sabah and Sarawak showing a high prevalence of 15.4%.

Recently, there has been increasing concerns regarding cases of oral cancer in healthy patients with no history of risk habits, and also in younger age groups in different populations. This indicates that several other aetiological factors such as viral infection, dietary habits and inherent genetic susceptibility may have a role in the process of cancer transformations. Data from OCRCC showed evidence that some oral cancer cases in Malaysia fall under this category.

There is thus a need to shift the approach in cancer research in Malaysia to reduce this growing burden. A multidisciplinary partnership in the form of OCRCC was initiated as a positive step towards the successful translation of research into evidence-based decision-making that will benefit oral cancer sufferers in this country.

Pre-Establishment Of The Oral Cancer Research And Coordinating Centre (OCRCC)

The idea of a partnership originated from a group of interested researchers from different institutions who were concerned with the direction of oral cancer research in Malaysia and realised the need for a partnership to strengthen the national capacity for oral cancer research. This need arose from the fact that oral cancer is a major emerging health problem and that many studies on oral cancer in Malaysia are conducted using small samples with insufficient follow-up data. These can only be considered as pilot studies which do not directly address national needs. Strengthening national capacity will add to the knowledge base and improve the oral health and quality of life of the community.

*The need for
multidisciplinary
partnership*

Cancer, including oral cancer, has been identified as a priority research area. The National Council on Higher Education (MPTN) also calls for the strengthening of research efforts and outputs. Support, especially in terms of funding sources, paves the way for accelerated research in this area. In addition, there is currently a strong drive towards international recognition through research, where the Ministry of Science, Technology & Innovation Malaysia (MOSTI) awards

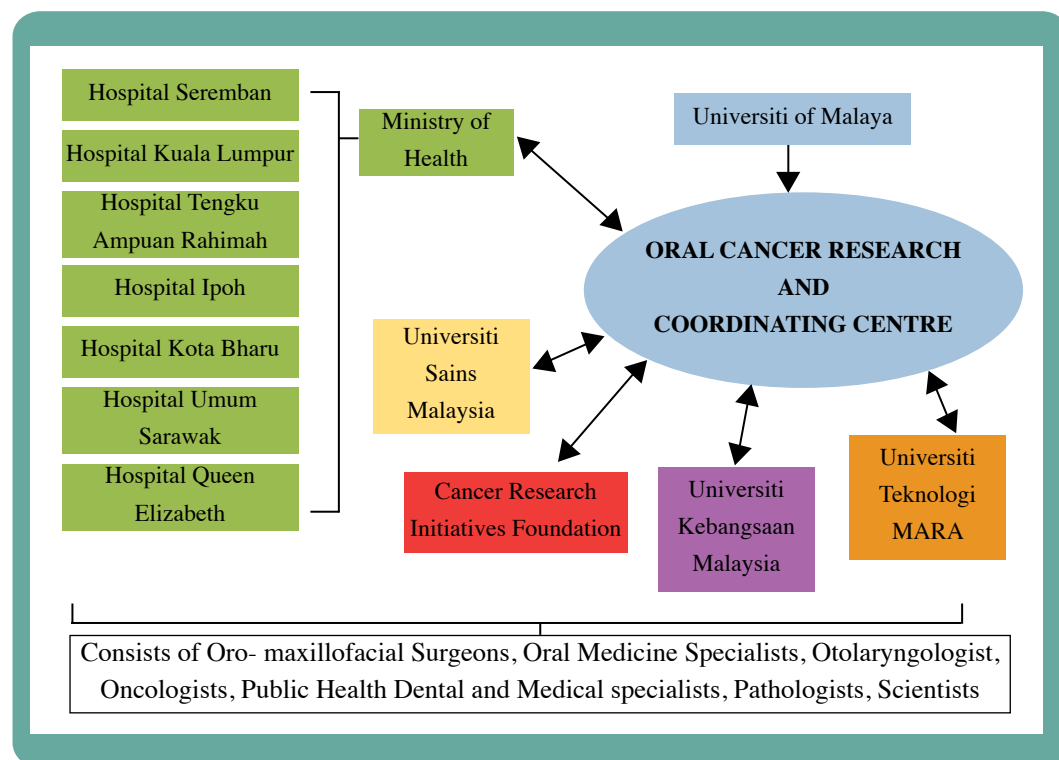


large grants to institutions for the advancement of multidisciplinary research. Furthermore, the existence of research-based organisations within the academic structure and research-based Non-Governmental Organisations (NGOs) also contribute towards the existence of a wide range of expertise in various disciplines.

The Processes Of Collaboration

Organisations that were either conducting research in oral cancer or were involved in the management of these patients had been approached and a shared mission developed. The initial set-up comprised of the University of Malaya (UM), Universiti Sains Malaysia (USM), the Ministry of Health, Malaysia (MOH) and the Cancer Research Initiatives Foundation (CARIF). The National University of Malaysia (UKM) joined the partnership at a later stage while Universiti Teknologi Mara (UiTM) is the latest member to align itself with this group (Figure 1).

Figure 1. The Institutions In The Partnership For Oral Cancer Research In Malaysia



The shared vision is to provide a framework for oral cancer research in Malaysia through the collection and sharing of data and tissues to ensure successful translation of basic research into policy decision-making in patient care. The mission is

Shared Vision and Mission

- To enhance relevant on-going local and regional efforts in research strategies and
- To develop new strategies in predicting and preventing oral cancer, improving quality of life of oral cancer patients, intervention of potentially malignant lesions and management of oral cancer.

These research areas coincide with the three operational interlinked categories of biomedical, health services and behavioural research described as the **health research triangle**.

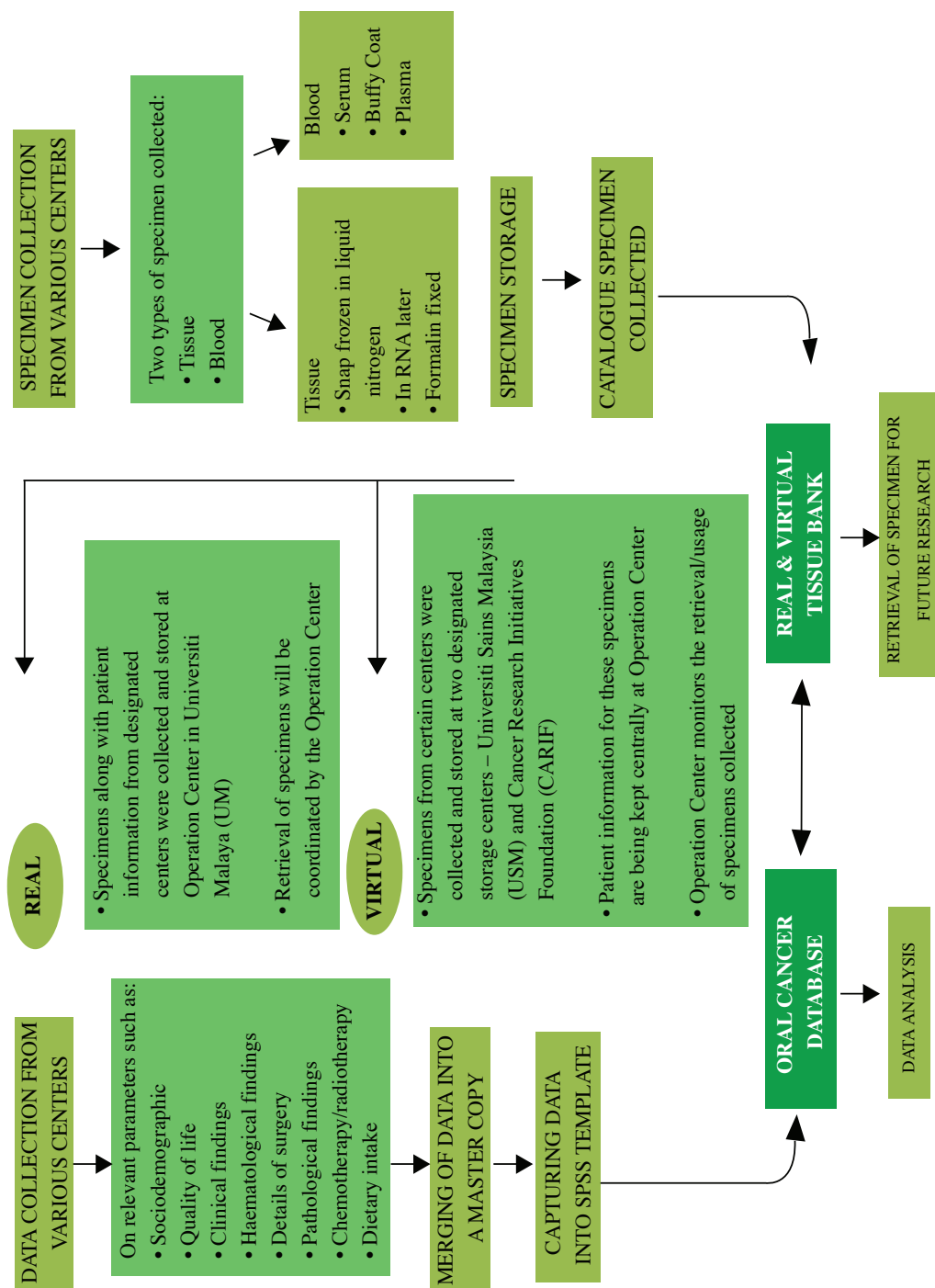
In 2003, the group obtained initial funding from MOSTI. With this funding, the group established a network of nine hospitals where oral cancer management is routine. Activities in this phase included procurement of equipment, hiring of human resource for each centre and conduct of training and motivational workshops. Training was conducted by the group leader at each of the participating centres. The emphasis was on the concept of sharing and collaborating with different institution. These trainings had been successful in harnessing the involvement of many practitioners, surgeons, oncologists, pathologists and their support staff to work together with the scientists and academicians.

Establishing Networks

Since receiving the grant in February 2003, the Malaysian Oral Cancer Database and Tissue Bank System (MOCDTBS) was developed to store the massive information and specimens collected over time. This system involves the identification of patients, collection of information and specimens at each centre, processing, storing and transportation of the data/specimens at the coordinating centre for data analysis and future research (Figure 2). The system demands the commitment of surgeons with the assistance of research coordinators at each participating centre to ensure proper management of the oral cancer patients. These research coordinators under the supervision of the surgeons are solely responsible for the activities at the respective centres. The availability of the system eases access to information and specimen among the partners, a prerequisite for online collaborative work, and establishes distant communication to discuss or exchange information and expertise.

*Establishing Networks
Establishing the Oral Cancer Database and Tissue Bank*

Figure 2. The Malaysia Oral Cancer Database & Tissue Bank System (MOCDTBS)



Projects directly related to the MOC DTBS and satellite projects were developed and eventually became the basis for postgraduate training. With increasing maturity of the MOC DTBS, more satellite projects are currently being developed with an increase in the number of participants. These projects include simple audits of clinico-pathologic parameters to determine treatment outcomes, quality of life, risk factors including studies on genetic polymorphisms, molecular biology with initial studies on cell cycle proteins and telomerase activity, and risk predictions via conventional statistical methods and artificial intelligence. The MOC DTBS has also been instrumental in the development of the Malaysian oral cancer cell lines and cell bank at CARIF. The set-up of this system has been published and presented locally and internationally.

Establishment Of The Oral Cancer Research And Coordinating Centre (OCRCC)

The dependency of these projects on this system requires sustainable partnership. For this to happen, there is a need to have a governing body where constitutions can be developed and monitored. Such a governing body would be responsible for developing policies on usage of data and tissues. The establishment of OCRCC based in UM in August 2005 was a step towards sustaining these collaborative activities.

The vision of the OCRCC is to be an internationally renowned research centre in oral cancer through data and tissue sharing for research, such that there is successful translation of basic research into clinical practice leading to excellence in innovation, publication and teaching.

*Vision,
Mission and
Objectives of
OCRCC*

The mission of the OCRCC is to advance knowledge and learning in oral cancer through quality research and education for the nation and for humanity.



The main objectives of the centre are as follows;

1. To develop and maintain the system of data and specimen (tissue, blood, DNA, etc) collection, processing and storage through the MOCDTBS
2. To coordinate research activities on oral cancer in Malaysia
3. To create a conducive environment in sharing information from the database and optimising the use of specimens
4. To be a resource centre for oral cancer
5. To conduct training in clinical expertise and research with other institutions within the country and internationally
6. To disseminate information and create awareness among the Malaysian public on risk factors of oral cancer.

OCRCC Activities

The main activity of OCRCC is the continuous collection of data and specimens for research purposes from oral cancer patients from all the participating hospital-based centres in the country. OCRCC comprises of a renowned team of experts in the management and care of oral cancer patients such as surgeons, oncologists, pathologists, epidemiologists and scientists all working together for the common goal of reducing the burden and impact of this disease on the Malaysian population. The MOCDTBS has successfully established systematic data and specimen collection, processing and storage procedures at all the participating centres. To date, data on more than 500 oral cancer patients and almost 300 controls have been entered and specimens such as tissue and blood have been collected from more than 350 patients at these participating centres.

Currently, OCRCC is actively conducting research activities headed by several renowned academics. The research projects cover a wide range of areas: molecular biology, genomics, proteomics, cytogenetics, epidemiology, quality of life and possible anticancerchemotherapeutic targets. Findings from the work on molecular biology and genomics have interestingly revealed that there are specific genes and



biomarkers that are commonly found in oral cancer patients which could be targeted for personalised treatment.

Majority of the research activities are through collaborations and partnerships with other research institutions, both local and abroad in an effort to make OCRCC a resource centre for oral cancer in the Asia Pacific region. Apart from developing collaborations with experts from five national institutions, OCRCC has also developed linkages through research endeavours with four international partners from Taiwan, Indonesia, New Zealand and Australia.

*Expanding
Internationally*

Apart from accelerating research in the field of oral cancer in the Malaysian context, OCRCC has also contributed to human resources development. There are currently 20 students attached to this Centre pursuing postgraduate studies on various aspects of oral cancer research such as molecular biology, genomics, cytogenetics, proteomics and epidemiology. Preliminary results of research have also been presented at more than 18 international and 17 national conferences where team members have won 19 national and eight international awards for their work.

In addition to research activities, OCRCC is also actively organising seminars and training workshops in the quest to improve and enhance knowledge in the field of oral cancer, bringing regional and international speakers and involving local (mainly MOH) and regional participants.

In addition, OCRCC has been actively advocating increased oral cancer awareness among the public. The 'Mouth Cancer Awareness Week' was started in 2006 and now annually ensues for a week in mid-November. Various activities such as mouth screening and exposure/information on oral cancer through the mass media have been actively carried out.



Future Direction

To ensure the sustainability of this collaborative effort, partners in OCRCC is now at a stage of developing its governing body - the Central Advisory Committee (CAC), comprising of representatives from all the stakeholders and independent scientific experts. The CAC will ensure that the aims and objectives are clear and agreed upon by members, formal Standard Operating Procedures (SOPs) are developed for decision-making and solving disputes, undertake assessment of project applications for data and specimen usage, and that there is accountability by partners to their funders. Thus, CAC will continue to promote the process of building partnership within a framework of mutual trust, shared decision-making and consensus-building to assure a win-win outcome for all partners. Future plans in this partnership include establishing international networking and collaboration as part of the ongoing global effort to create a healthier world and to achieve equity in global health.

*Formation of
Central Advisory
Committee*



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STEM CELL RESEARCH IN MINISTRY OF HEALTH

SUMMARY

The Ministry of Health (MOH) actively encourages the development of research capabilities in stem cell research, an area with the potential for new therapeutic approaches for cell and tissue replacement therapy. The plurality of the Malaysian population offers opportunities to derive genetically-diverse human embryonic stem cell lines and make them available for future research and clinical purposes. However, government intervention and regulation are required to ensure standards of safety to protect public health. To this end, the MOH has developed national guidelines and standards for the conduct of stem cell research and therapy. The establishment of a National Stem Cell Laboratory is crucial for new research capabilities. In Phase 1, the Institute for Medical Research (IMR) will embark on stem cell cultures from commercially available stem cell lines, following which, in Phase II, there are plans to invite collaboration from local and international institutions to develop protocols that support the characterisation of molecular, cellular and genetic characteristics of stem cells.

Introduction

Stem cell research has drawn attention from enthusiastic researchers in Malaysia, especially in areas relating to regenerative medicine. This area of research offers vast potential for new therapeutic approaches in cell and tissue replacement therapy. The Ministry of Health (MOH) actively encourages the development of such research capabilities.

*Enhancing Stem
Cell Research*

Many local institutions have already embarked on stem cell research with funding from the MOH or the Ministry of Science, Technology and Innovation (MOSTI). Researchers from the Institute for Medical Research (IMR), Universiti Kebangsaan Malaysia (UKM), University Malaya Medical Centre (UMMC), Universiti Putra Malaysia (UPM), Universiti Sains Malaysia (USM) and other institutions are studying the biology of stem cells, their characterisation and genetic stability, as well as their differentiation into many different cell types, including heart muscles, neurons, liver cells, kidney cells and also cartilage. There are also institutions that are working on joint research with the stem cell industry on possible manufacturing opportunities.



Despite the current controversies surrounding stem cell research and therapy, it is still crucial for local scientists and clinicians to be involved in this area of research within the ethical guidelines that have been agreed upon. MOH has strongly urged the private sector to conduct studies on new indications for stem cell therapy under clinical trial conditions, with ethical approvals and patient-informed consents, before trying to market them. While research into stem cell therapy should be at the forefront, it is important that ethics and the safety of patients are never compromised.

*Ensuring Safety,
Quality and Efficacy*

The MOH has developed national guidelines and standards for the conduct of stem cell research and therapy. The guidelines were launched in 2009. Stem cell therapy in Malaysia has been established in MOH and university hospitals. This has seen increasing number of patients receiving bone marrow and stem cell transplantations for leukaemia's and solid tumours over the years.

The proven modalities of treatment include stem cell transplantations for leukaemia's, lymphomas, some genetic conditions and some solid tumours. Those that are in the developmental stage include stem cell treatments for heart failure, stroke, spinal cord injuries, and organ failures. These latter forms of experimental stem cell therapies must be approved by the institutional research and ethics committees, and the use of cell-based therapies for these conditions must be undertaken strictly as clinical trials. Before the clinical trials, there must be sufficient evidence to show safety, quality and efficacy. Practitioners must strictly follow the guidelines for Good Clinical Practice (GCP), while those involved in the processing and handling of the stem cells must ensure that their facilities follow Good Laboratory Practice (GLP).

Current Good Manufacturing Practices

A clean room facility at the Cancer Research Centre of IMR is ready for use to support several projects and activities funded by the National Institutes of Health (NIH), MOH under the strengthening of the stem cell and cord blood banking services in the IMR. This facility will cover all relevant aspects of cell manipulation process including acquisition of the starting cell population, cellular isolation, processing, storage, transportation and administration. Each step must incorporate procedures that ensure integrity of the cellular end product. Stringent requirements for the entire processing of

*Meeting
Requirements of
cGMP*



stem cell products specific for cell-based therapies must follow standard protocols and procedures. These must be linked to high-level quality systems to meet the code of clean Good Manufacturing Practices (cGMP). Hence, this facility will seek accreditation in relation to cGMP guidelines and international standards.

The MOH has initiated the co-ordination of stem cell research by developing and circulating the '**Guidelines on Stem Cell Research and Therapy**'. A stem cell laboratory has been built at the IMR (Figure 1) to support research in stem cells that have tremendous potential for therapy involving replacement and repair of tissues and organ. This laboratory is situated at the Haematology Unit, Cancer Research Centre. The facility will be upgraded to cGMP status where stem cells will be comprehensively tested for safety, quality and efficacy before they can be used in clinical trials involving human subjects.

IMR initially embarked on stem cell cultures from stem cell lines. Under its research expansion programme, collaboration with local and international institutions has witnessed the development of protocols that support the characterisation of molecular, cellular and genetic characteristics of stem cells including the use of monoclonal antibodies, qPCR, transfection, flowcytometry, PCR techniques, FISH and karyotype analysis. Ongoing stem cell research projects include the following:

*Stem Cell Research
in IMR*

1. Propagation and expansion of human embryonic stem cell lines
2. Cultivation of limbal cells for clinical application in severe ocular surface disorders
3. Isolation, expansion and characterisation of mesenchymal stem cells (MSC) from various tissues for therapeutic applications
4. Derivation of human embryonic stem cell lines



Figure 1: The Stem Cell Laboratory, IMR



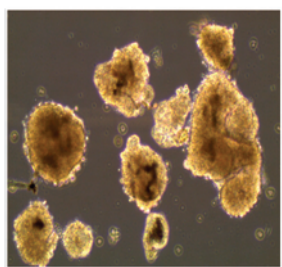
Propagation and Expansion of Human Embryonic Stem Cells

This project aims to optimise and standardise culture protocols for stem cells expansion (Figure 2a) in the laboratory and define appropriate cell markers for stem cell identification and characterisation. The following embryonic markers were determined via immunofluorescence staining for characterisation of human embryonic stem cells at undifferentiated stage:- nuclear markers - NANOG (Figure 2b), Brachyury, OCT3/4, GATA4 and SOX2; cytoskeletal markers - SMA, MAP2 and Nestin (Figure 2c), cell surface markers - SSEA1, SSEA4 and Tra-1-81; and cytoplasmic marker – Troponin.

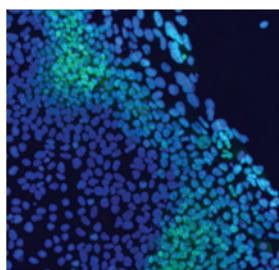
Human Embryonic Stem Cells

Other methods like qPCR, transfection and FACs analysis will be adopted to improve the reliability of the cell lines for a comprehensive characterisation scheme for hES cells. A safe and efficient 'scale-up' methodology for enriched stem cell populations is still in the developmental stage. For future studies, the differentiation and development of hES cells will be conducted for future cell-based transplantation e.g. in degenerative diseases.

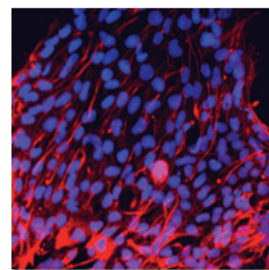
Figure 2: Human Embryonic Stem Cells



(a) Undifferentiated Human Stem Cell Colonies



(b) NANOG, Nuclear Marker in Undifferentiated Human Stem Cells



(c) Nestin, Marker for Neural Progenitor Cells in Differentiated Human Stem Cells

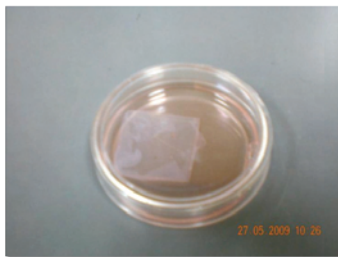


Cultivation of Limbal Cells for Clinical Application in Severe Ocular Surface Disorders

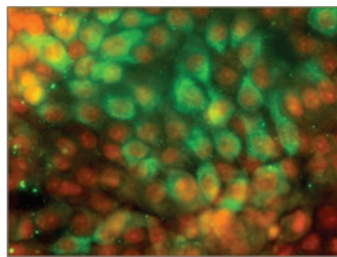
Limbal Stem Cells

Cultivated limbal epithelium transplantation is one of the advanced treatments for severe ocular surface disease (Figure 3a) which applies bio-engineered tissue generated from amniotic membranes and limbal biopsies. In this study, an established method to generate this bioengineered tissue was adopted and characterisation of the cultivated cells (Figure 3b) was done by various methods. Human limbal biopsies were cultivated on denuded amniotic membranes (Figure 3c). After three weeks of culture, the phenotypes of cultivated cells were analyzed by immunohistochemistry (Figure 3d), and real-time RT-PCR for the expression of a panel of specific markers.

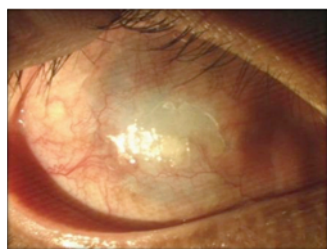
Figure 3: Limbal Stem Cells



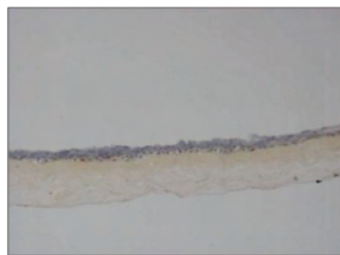
(a) Ocular Surface Disease caused by Limbal Stem Cell Deficiency



(b) Cross section of Cultivated Limbal Epithelium (200x)



(c) Limbal Biopsy Cultivated on Amniotic Membrane



(d) Limbal Epithelial Stem Cells (400x)

Cultivated limbal epitheliums were also analyzed by scanning (SEM) and transmission (TEM) electron microscopy. Sterility tests and mycoplasma assays were also conducted for the safety of products. A confluent layer of polygonal cells was formed in 2 weeks time and 1-3 stratified layers of cells were observed after three weeks of culture. Cultivated cells were positive for p63, cytokeratins (K) 3, K19,



and involucrin but negative for K14, integrin $\alpha 9$ and ABCG2 when analyzed by immunohistochemistry. Expression of molecular markers was detectable with real-time RT-PCR. SEM showed multilayer of flat squamous polygonal epithelial cells. Desmosomal and hemidesmosomal were evident when analyzed by TEM. A small percentage of contamination by fungi occurred during the culture period. The bio-engineered ocular surface tissue was successfully generated in this study. This study showed that cultivated limbal epithelium consists of limbal progenitors as well as differentiated corneal epithelial cells. SEM and TEM analysis showed cultivated cells demonstrated typical features of corneal epithelium.

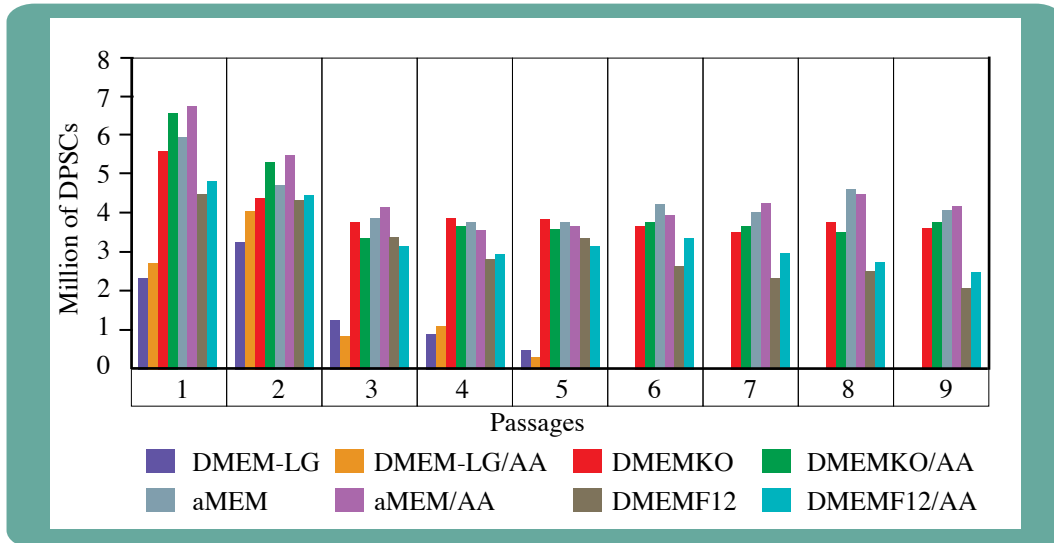
Isolation, Expansion and Characterisation of Mesenchymal Stem Cells (MSC) from Various Tissues for Therapeutic Applications

Many researchers believe that mesenchymal stem cell (MSC) treatments have the potential to change the face of human diseases and alleviate suffering. The MSC project has successfully produced 70 vials of dental pulp MSC lines (Figure 4a and 4b), 85 vials of umbilical cord MSC lines and 73 vials of adipose derived MSC lines. This project is collaboration between IMR and Stempeutics Research Malaysia Sdn. Bhd. The cell lines were derived from 25 dental pulp samples, 12 umbilical cord samples and 5 adipose tissues samples (with informed consent). Characterisation works such as growth kinetics, proliferation rate, flow cytometry analysis, immunocytochemistry, karyotyping, differential potential into adipogenic and osteogenic tissues and reverse transcription –polymerase chain reaction have been performed. Interestingly, embryoid bodies have also been discovered in umbilical cord derived from MSC. For future studies, differentiation potential of MSC from tissues such as neurogenic and pancreatic islet cells will be tested out.

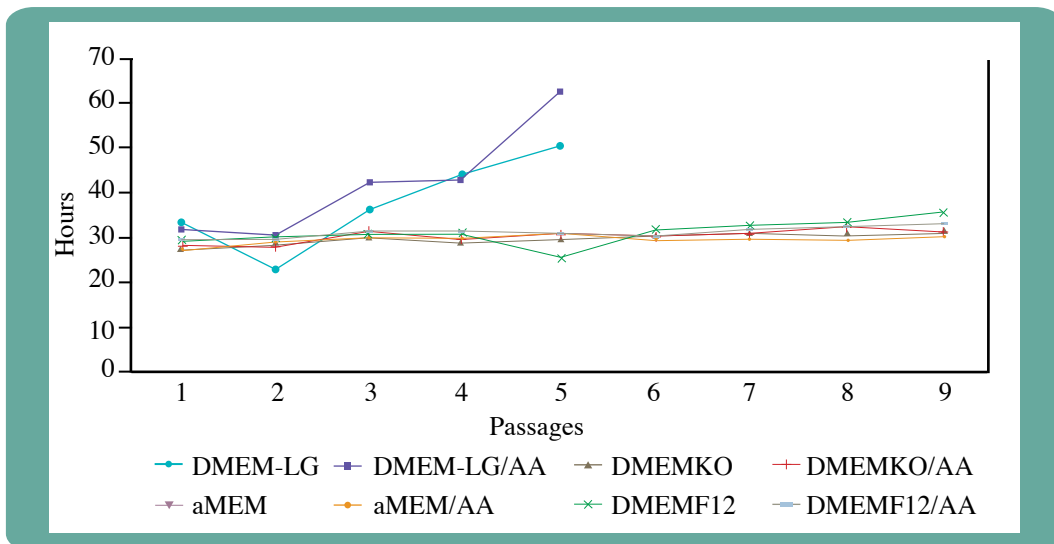
Mesenchymal Stem Cells



Figure 4: Dental Pulp Stem Cells



(a) Proliferation rate of dental pulp stem cells in various growth media



(b) Population doubling time of dental pulp stem cells in various growth media

Derivation Of Human Embryonic Stem Cell Lines

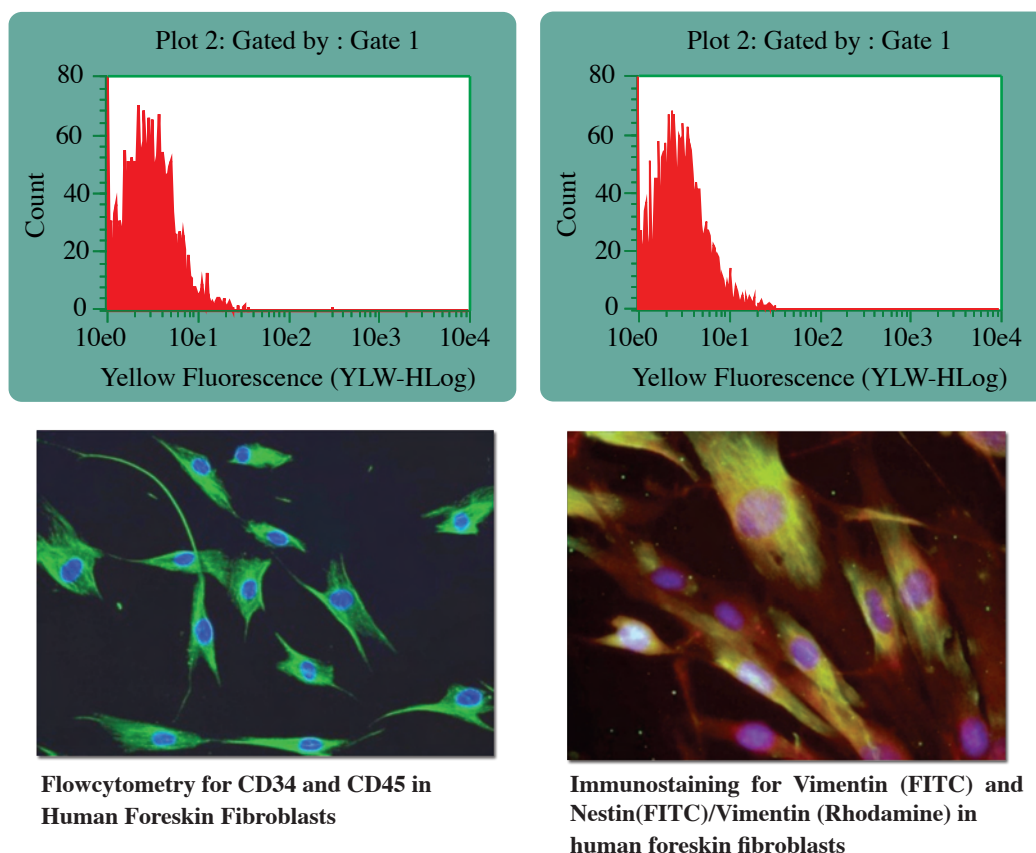
This project is intended to derive new human embryonic stem cell (hESC) lines from genetically diverse population that could be used for clinical applications. This work has been initiated by IMR and Stempeutics Research Malaysia Sdn. Bhd. Five batches of human foreskin fibroblasts (HFF) were prepared for the growth of hESC.

*Derivation of
Human Embryonic
Stem Cell Lines*



Twelve IVF surplus embryos have been received with informed consent from the donors. Characterisation of inactivated HFF to support hESC maintenance was done by immunochemistry and RT-PCR analysis using commercially available HUES-7 cell line (Figures 5a and 5b). Embryoid bodies at day 5, 10, 15, and 20 were analysed at molecular, protein levels and compared with undifferentiated cells. Future plans for this project will involve isolation of more hESC, expansion of hESC using xeno-free culture conditions and characterisation of hESC using cellular markers, immunophenotyping, real-time PCR, differentiation markers, karyotyping, genotyping, HLA isotyping, teratoma formation and differentiation and drug testing of hESC lines.

Figure 5: Characterisation of Inactivated Human Foreskin Fibroblasts



Induced Pluripotent Adult Stem Cell

Researchers are enthusiastic in the stem cell progress and are confident that we will be able to treat, maybe someday cure, heart disease, diabetes, spinal cord injury and other disorders. But the excitement is not generated by stem cells harvested from human embryos alone. Researchers believe that results can be almost as good from adult stem cells taken from the patient's own bone marrow or belly fat, or even from full-fledged adult cells from muscle tissues or skin. This new development in the field of stem cell research is the "induced pluripotent adult stem cell." Currently, adult stem cells have been injected around a patient's heart to help heal a heart attack, and adult cells are being applied around injured spinal cords in hopes of restoring movement. Using adult cells avoids the controversy of destroying embryos, and, coming from the patient's own body, will avoid the risk of rejection.

Conclusion

The potential use of stem cell technology to treat many present day illnesses has brought new hopes to society. However, the technology needs to be subjected to the usual research protocols, and the effectiveness and safety of such therapies need to be established before they can be accepted as standard medical practice. Cellular products, including stem cell-based therapies, are considered as biological. Hence, like most other biological or drugs, they have both risks and benefits. Government intervention and regulation are required to protect public health, and the standards of safety for such biological need to be higher than those for other products.



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ACCURACY OF DIAGNOSIS: IMPLICATIONS ON HEALTHCARE FINANCING

SUMMARY

Quality of data and information on diseases are dependent on diagnoses written by doctors in patient case notes. Errors in documenting diagnosis will result in coding errors which will seriously impact financing, reimbursement systems, public health surveillance and health research. The objective of this study was to gauge the accuracy of diagnoses made by doctors responsible for writing the 'diagnosis on discharge' in the case notes of patients. This simple study describes the type and quantum of errors made by doctors in recording the 'diagnosis on discharge'. The percentage of inaccurate diagnosis ranged from 3.4% in Orthopedics to 14.4% in General Medicine. The entire process of documenting diagnosis by the doctor and transcribing data by medical record officers needs to be audited.

Introduction

Complex modern healthcare systems require accuracy in providing disease information for disease coding. Disease coding underpins diagnosis-based provider reimbursement systems, provides a key component of public health surveillance, and constitutes a major data source for health research. Case mix¹ is a system which classifies types of patients treated, and costs each category to enable consistent pricing for each patient. The Ministry of Health (MOH) has decided to use case-mix to categorize patients into discrete groups based on clinical information obtained from patient charts in an attempt to identify clinical and cost difference among these groups.

*Function and
Purpose of Case Mix*

Aggregations of patients are meant to be clinically homogeneous and have similar cost profiles. The diagnosis-related group (DRG) case mix system is an example of a successful case mix system and variants have been adopted in many countries. DRG has been used in the US since 1983 to reimburse hospitals for the services provided to inpatients under the Federal Government's Medicare programme for the aged and disabled. In Europe, several countries with predominantly government-financed and controlled hospital systems, notably Portugal, Sweden and Norway are now using DRG extensively to allocate funds to hospitals.

*Diagnosis-related
Group (DRG)*

¹ There is a need to differentiate between the function and purpose of case mix system. The function of case mix systems is to categorize patients into discrete groups based on detailed clinical information extracted from the patient chart, while the purpose is to recognize clinical or cost differences in patient mix.



Concept and Principles

Diagnosis is the principal determinant of the DRG result. The doctor who is responsible for the treatment of the patient is the person who determines the principal diagnosis.

Principal Diagnosis

The Principal Diagnosis² is used to determine the Major Diagnostic Category (MDC). These categories correspond to the main body organ systems. Interpretation of 'Principal Diagnosis' can make a significant difference to the amount of payment reimbursement. If there is a choice of principal diagnosis, then the hospital can gain by choosing the diagnosis that produces the higher payment.

Evaluating the Accuracy of Diagnoses

In the MOH, disease information has been regularly provided by the Health Management Information System (HMIS) since the early 1980s. The quality of this information has rarely been studied. It was decided that a simple study be undertaken to evaluate the accuracy of diagnosis, the basis of reliable disease information. The study was conducted in Hospital Kuala Lumpur (HKL) from 1 – 5 December 2008.

Rationale

The objective of the study was to gauge the accuracy of diagnosis made by the doctor responsible for writing the diagnosis on discharge in the case notes of the patient.

Objective

Consecutive case notes of patients admitted to HKL in July 2008 from the disciplines of General Medicine, General Surgery, Obstetrics & Gynecology (O&G), Pediatrics and Orthopedic Surgery were examined for accuracy of diagnosis. The number of cases notes for each discipline reflected the proportion of admissions per discipline for the hospital. The case notes were examined initially by professional staff of the National Health Financing Unit (NHF) of the Planning and Development Division, MOH. Specialists from the specialty concerned were recruited to assist in the study. Case notes in which the diagnosis on discharge did not fit with the history, physical examination, investigations or treatment were referred to the specialists for opinion. The specialists either agreed or disagreed on the diagnosis on discharge. If the diagnosis was incorrect, the specialist provided the correct or most appropriate diagnosis.

Study Design

² The Principal Diagnosis

The principal diagnosis is the principal determinant of the DRG result - defined as the diagnosis established to be chiefly responsible for occasioning the patient's episode of care in the hospital (AIHW). The doctor who is responsible for the treatment of the patient is the person who determines the principal diagnosis.



The percentage of inaccurate diagnosis ranged from 3.4% in Orthopedics to 14.4% in General Medicine (Table 1).

Results

Table 1: Percentage Inaccuracy in Diagnosis

Discipline	Total	Inaccurate	% inaccurate
Pediatrics	307	30	9.8
O&G	98	10	10.2
Orthopedics	205	7	3.4
Surgery	202	25	12.4
Medicine	306	44	14.4

There were many types of errors, the most common being diagnostic (pure error) (Table 2). There were five cases which had no diagnosis and notes were not sent back for rectification by the record office.

Analysis of Inaccuracies

Discussion

Patient information is the key building block for case mix, and data quality is vital. Disease coding errors in claims data can cause serious problems for financing, reimbursement systems, public health surveillance and health research.

Impact of Diagnostic Errors

Errors in recording the correct diagnoses will also result in errors in the reported epidemiology of diseases amongst those admitted for treatment into a hospital. In addition, it will result in coding error for purpose of case mix, and subsequently the costs incurred in treating the cases. Interpretation of 'Principal Diagnosis' can make a significant difference to the amount of payment reimbursement. If there is a choice of 'principal diagnosis' then hospitals will attempt to gain by choosing the diagnosis that produces the higher payment (optimising the DRG). This issue must be addressed to create greater accountability. Secondary and additional diagnoses (complications and/or co-morbidities) are likely to result in significantly greater resource consumption.



Table 2: Classification of Errors

Classificatio of error	Diagnosis on Discharge	Diagnosis after review
Diagnostic (pure error)	Acute gastroenteritis	Acute pharyngitis
Purpose of admission instead of disease	To rule out appendicitis To rule out PTB	Abdominal colic (insufficient data in the case notes to pin down diagnosis) Well child
Disease instead of purpose of admission	End-stage renal failure	Admitted to AVF operation
Symptom instead of diagnosis	Dizziness (non-specific) Post-menopausal bleeding	Hypotension (due to anti- hypertensive) Ovarian tumour
Sign instead of diagnosis	Left axillary swelling	Infected sebaceous cyst
No diagnosis	-	Acute renal failure
Procedure instead of diagnosis	Left salphingo-oophorectomy and Right tubal ligation	Left ovarian cyst
Secondary condition instead of primary reason	HPT and IHD	Acute gastroenteritis
Two diagnosis instead of one	Acute pharyngo-tonsillitis	Acute pharyngitis
Unrelated existing condition	Neurofibrotosis Cardio-fascio-cutaneouse syndrome	Acute phryngitis bronchopneumonia
Error within same disease group (ICD 9)	Infantile spasm	West's syndrome



The process of churning out disease data goes through a series of steps that need to be scrutinised, recording by the doctor on discharge being the first, followed by transcription and interpretation by the record officer.

Conclusion

This simple study indicates the existence of errors made by doctors in recording the diagnosis on discharge. In many cases, the diagnosis can be obtained by going through the case notes indicating that the patient was given correct treatment. To ensure minimal errors, there needs to be a system of verification of diagnoses by a senior doctor, either by the bedside on discharge or before the case notes are dispatched. There should be consensus on the manner of listing existing chronic illnesses that did not receive treatment during an admission and the listing of an incidental finding of another illness. All these will contribute towards correct classification of patients treated and accurate costing for each category of care to enable consistent pricing.

Recommendations for Improvement

Acknowledgement

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CASE MIX IN PRIMARY CARE IN MALAYSIA

SUMMARY

The Ministry of Health's Teleprimary Care (TPC), Malaysia's first home-grown enterprise-wide electronic medical record developed specifically for primary care in 2005, is a rich source of health information. This huge database was utilised for a case-mix study to look into efficiency in resource allocation for primary care services in the Ministry of Health.

In 2006, through a WHO funded project, the Johns Hopkins University ACG® System was applied in both government clinics and the private sector, to provide an indication on the quality and efficiency of primary health care delivery in Malaysia. The focus was on data quality; morbidity profile of individual clinics and regions; and on developing the necessary underlying infrastructure to support adjustments in the formulation of risk adjusted capitation schemes for primary care.

The successful completion of the first evaluation project in 2007 has resulted in an appreciation on the value of TPC database, as well as increased knowledge on the morbidity profile of the Malaysian population. It indicated that morbidity pattern was influenced by age, gender, region and ethnicity. The profiling of providers on a regional basis served as a first step towards evaluating the viability of a morbidity-based capitation formula. It also indicated that before the national capitation scheme can be developed, a better understanding on the differences in service delivery between the public and private sector is necessary.

Subsequent studies in 2008 further refined the process by validating new micro-costing information and increasing the quality of diagnostic information recorded. In addition, clinic profile reports and high-risk patient identification lists were developed, and treatment information was added to the mix.

The next steps include studies to predict high-risk patients for inclusion in care management programs, and addressing equitable allocation of resources and efficient provider practices. Additionally, plans are in place to develop fair provider payment mechanism for the proposed national health financing system.



Introduction

Information and Communication Technology (ICT) development in primary health care was introduced in the Ministry of Health with the aim of improving accessibility to health care, increasing specialist access and coverage, reducing professional isolation and providing borderless and seamless health care.

Objective of ICT in primary health care

It started with the development of a clinic information system at Putrajaya Health Clinic, the first paperless government clinic in Malaysia's multimedia super corridor highway. This was closely followed by the development of Teleprimary Care (TPC), Malaysia's first home-grown enterprise-wide electronic medical record system, developed specifically for primary care with linkage to secondary care in the hospital. Launched in 2005, TPC currently operates in 5 states, namely Johor, Sarawak, Perlis, Selangor and Federal Territory of Kuala Lumpur. It covers a total of 73 health clinics, 4 hospitals and 10 district health offices.

Development of IT systems in primary care

The introduction of TPC has provided a wealth of health information for data mining which is readily available to policy makers, and healthcare managers in the Ministry of Health (MOH), in particular the Primary Health Care Subdivision of the Family Health Development Division.

TPC database

Utilising this rich source of health information offered by the TPC electronic database, a case-mix project was undertaken to look into efficiency of resource allocation for primary care services in the Ministry of Health, in 2006. This is in line with the Ministry's initiative to reform the national health system for a more effective and efficient delivery of primary care service.

Using TPC data for case-mix project

WHY CASE-MIX?

Case-mix enables us to know the utilisation and morbidity pattern of the population, which is not homogenous throughout the country, even differing by district and clinic. Hence, resources required will differ and should ideally be distributed according to needs.

Morbidity and resource needs differ



The practice of financial distribution in the MOH has traditionally been dependent on historical information of past performances with additional increments based on arbitrary predictions of the consumer index or inflation. A more appropriate distribution formula should not only encompass the volume of patients, but also take into consideration the morbidity profiles of these populations. A better understanding on the costs of health care delivery, as well as the expected needs are necessary before significant progress can be achieved in risk adjusted budgeting.

*Risk adjusted
budgeting versus
historical budgeting*

WHY THE ACG SYSTEM?

When the Ministry was looking into utilising TPC data for resource allocation in 2006, the only case-mix application found to be suitable for primary care was the ACG (Adjusted Clinical Groups) System. The John Hopkins ACG System is a clinical-based system developed from research in the early 1980s and is one of the first methodologies in the world categorising ICD (International Classification of Disease) diagnostic codes outside of hospitals. Because of its distinction of being developed, tested and supported by a world-renowned academic and medical research institution, the ACG System's transparency and academic credibility were critical plus points in choosing this over others system demonstrated that clustering of morbidity is a better predictor of health services resource use, rather than the presence of specific diseases. Clustering of morbidity forms the basis of the current ACG System and remains the fundamental concept that differentiates the ACG System from other case-mix adjustment methodologies.

*ACG system as
primary care case-
mix application*

Easily adaptable

The system can be easily adapted to unique local circumstances. It is used in more than 300 sites over more than a dozen countries. Presently, health care of over 60 million patients are being actively managed and monitored using the ACG System across several continents.

*Morbidity clustering
as predictor of
resource use*

Malaysia has earned tremendous learning experience from the transfer of technology from the JHU-ACG Team, backed by their more than 20 years track record in deploying the System globally. The ACG System offers a widely used and rigorous health-based risk adjustment approach. Used by healthcare providers, health plans and public-sector agencies, the ACG System has a uniquely clinical perspective on person health that emphasises inter-relationship of multiple diseases to explain healthcare utilization, both retrospectively and

*Statistically valid
and industry
benchmark*



prospectively. ACGs have withstood financial and clinical pressures of the healthcare market place to become a statistically valid and industry benchmark in risk adjustment and predictive modelling method.

PHASES OF MALAYSIAN ACG PROJECT

Since 2007, the Ministry of Health has completed three projects using the ACG system, and is currently entering into the fourth project.

Project I: Development of Teleprimary Care (TPC) Data Set using the Johns Hopkins ACG® system in Malaysia, 2007

Project 1

The first evaluation project undertaken was to determine the feasibility of utilising TPC data, as well as electronic data from the Putrajaya health clinic and a general practitioner (GP), for the ACG System. Funded by a RM100,000 grant from the World Health Organisation, the project successfully demonstrated the interoperability of the Malaysian electronic databases with the ACG System.

*Feasibility of
utilising local
electronic data*

The project demonstrated the feasibility of applying readily available diagnostic and other clinical information to develop state-of-the-art case-mix measures relevant to medical and fiscal management activities using the TPC database. It also offered an example of how risk adjustment tools can be used to monitor the TPC data collection process.

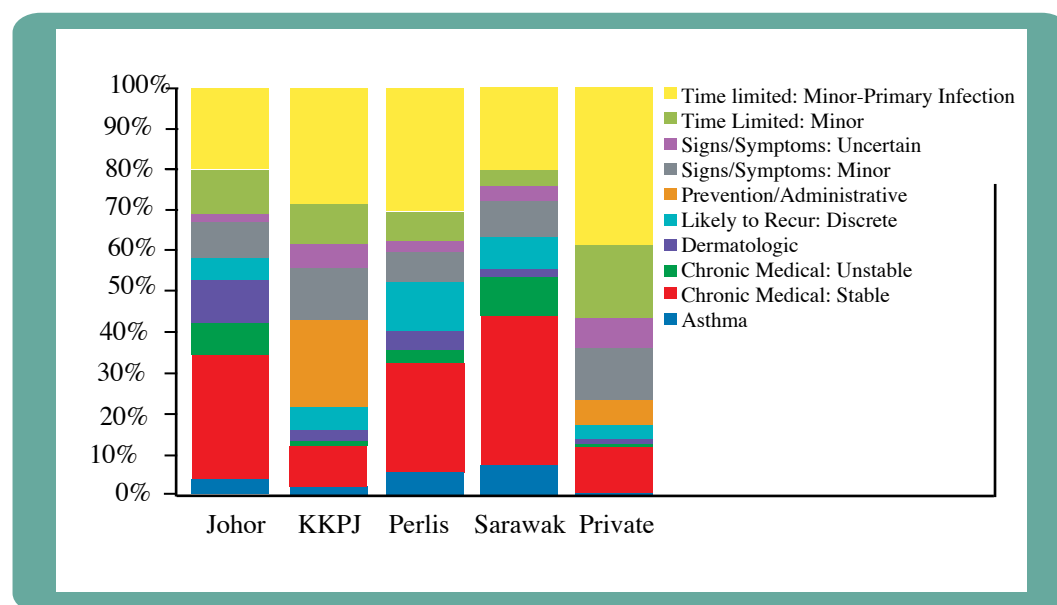
*Successful
application of TPC
data to case mix
measures*

Specifically, Project I illustrated that the Malaysian population does vary in their need for health care resources across states, geographic regions as well as at the individual clinic level, as shown in Figure 1 below. Comparisons to assess the disease burden and health care resource needs of the population indicated that morbidity patterns seemed to be influenced by age, gender, and ethnicity.

*Variation in
morbidity and health
care resource needs*



Figure1: Morbidity by Region



Project II: Ambulatory Case-mix Measurement using Johns Hopkins University's ACG® method in Primary Care in Malaysia, 2008

Project II

In 2008, the National Institutes for Health, Ministry of Health Malaysia funded Project II at a cost of RM 304,045. It furthered the process by validating new micro-costing information; assessing the ability to link patient information across providers; increasing the quality of the diagnostic information recorded and provided a better understanding of the impact of the private sector, as well as reassessing the morbidity profile provided by the new information. Information from the private sector was further expanded with the incorporation of data from a private health insurance company.

Validating micro-costing, linking patient information across providers, increasing quality of data and impact of private sector

The results of Project II showed that the micro-costing data works for the TPC population and provides a better understanding on differences in resource allocation and needs. The 2008 Total Visits model was extremely predictive. However, cost data for health clinics need to be improved before the model can be used to predict costs. The profiling of providers on a regional basis as the initial step towards determining the viability of a morbidity-based capitation formula was successful.

Micro-costing data works



Adjusted coefficients of determination (R^2) were calculated to compare the performance of various models. P-values <0.05 were taken to be significant. The goal of this assessment was to assess whether co-morbidities could be used to predict Total Visits. The set of predictors (age, gender, number of major Adjusted Diagnosis Groups, number of Adjusted Diagnosis Groups, number of Major Expanded Diagnosis Clusters, number of Expanded Diagnosis Clusters and Resource Utilisation Bands) were recreated for 2006 to 2008 for Total Visits.

*Improved diagnoses
quality and
completeness
improves prediction
model*

Table 1 below shows huge increases in the adjusted R^2 for Total Visits models using the TPC data from 2006 to 2008. From a dismal adjusted R^2 value of 0.064 for all states in 2006, the R^2 climbed to 0.654 in 2007, and even higher to 0.932 in 2008.

This means that for the 2008 data, 93% of the variance in the Total Visits can be explained by the model. This achievement was likely due to improvements in diagnosis quality and completeness. In 2008, all 3 states achieved adjusted R^2 of 0.9 or higher reflecting that diagnosis quality is very high and can be used to predict Total Visits in that year.

Table 1: Explanatory Power for Model to Predict Visit Rates

Adjusted R^2 Values			
Year	2006	2007	2008
Overall	0.064	0.654	0.932
Perlis	0.414	0.728	0.942
Johor	0.010	0.584	0.901
Sarawak	0.058	0.670	0.912

Project II also addressed the gaps identified in Project I and successfully demonstrated the success of coding quality training to ensure continued improved data quality in TPC over time. However, the data quality was not uniform across the TPC regions. Where data quality was better, the predictive modelling improved in tandem. The data quality was sufficiently high to conduct predictive model analysis to identify “high risk” patients or “high cost” patients.



Project II also showed that the Malaysian Identification Card, *MyKad* & *MyKid* could be used as a unique patient identifier number. Health data contained in the cards could be used to capture services consumed from multiple providers. This ability to link data across providers, especially between public and private sector, allows for better understanding of the differences in service delivery which is imperative before a national capitation scheme is possible. This study showed that less than 5% of the population utilised more than one health facility for their health needs. However, if they were hospital patients, 45% would utilise more than one healthcare facility, presumably on discharge to the primary care clinic.

*Malaysian IC as
unique patient
identifier*

Project III: Using Teleprimarycare(TPC) to improve the delivery of Primary Health Care in Malaysia: Application of the Johns Hopkins ACG® System to improve data quality, financing and efficiency

Project III

Project III will be funded by a research grant of RM 221,978 from the National Institutes for Health, Ministry of Health Malaysia in 2009. It will build on the information gained from the first two projects and further refined the process towards introducing the Malaysian case-mix in Primary Care. It will address important aspects to better understand the Malaysian TPC database, the cost structure in the provision of health care in Malaysia, as well as the morbidity profile of the Malaysian population. The final goal is in the development of a morbidity-based capitation formula for primary care providers.

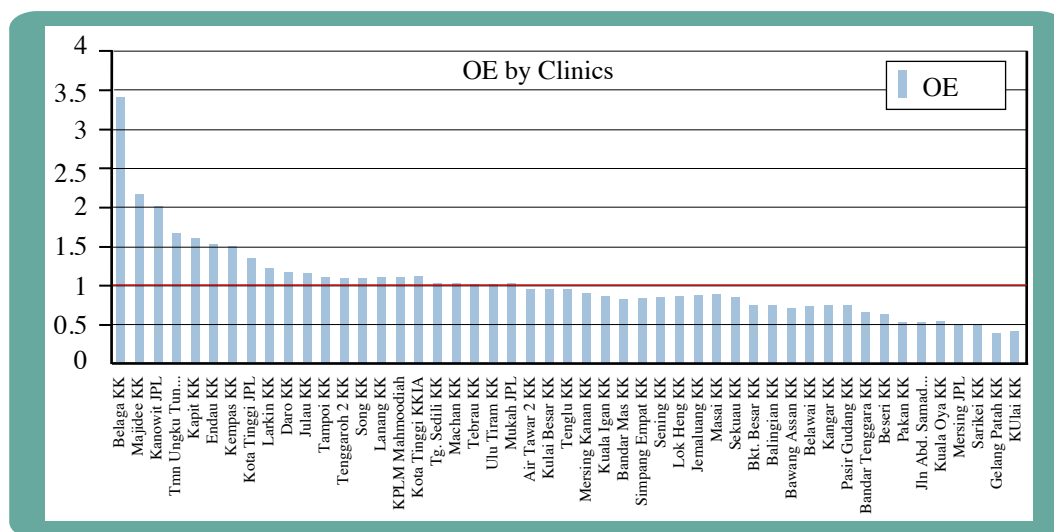
*Furthered process
towards case-mix*

Project III successfully developed profiling reports, which could not only be used to understand differences in morbidity burden; but also to potentially affect resource allocation in the future. Figure 2 below shows a comparison of cost per capita for all 49 TPC clinics using the O/E (observed to expected) ratio, a proxy measure of efficiency index. Utilising these measures, it is possible to assess the provider and the appropriate level of resources to be allocated. Providers with many patients with more serious morbidity are anticipated to use, and therefore should receive more resources. In this analysis, the variables measured were cost which comprised of 5 components namely, cost of drugs, laboratory cost, cost of procedures, consultation cost and registration cost. The facility cost was not included as the cost between the recently built facilities and the old clinics was not comparable. The population comparison can be done at various levels, between states, between clinics or within clinics.

*Development of
profiling reports*



Figure 2: List of O/E Ratio for Clinics in Year 2008



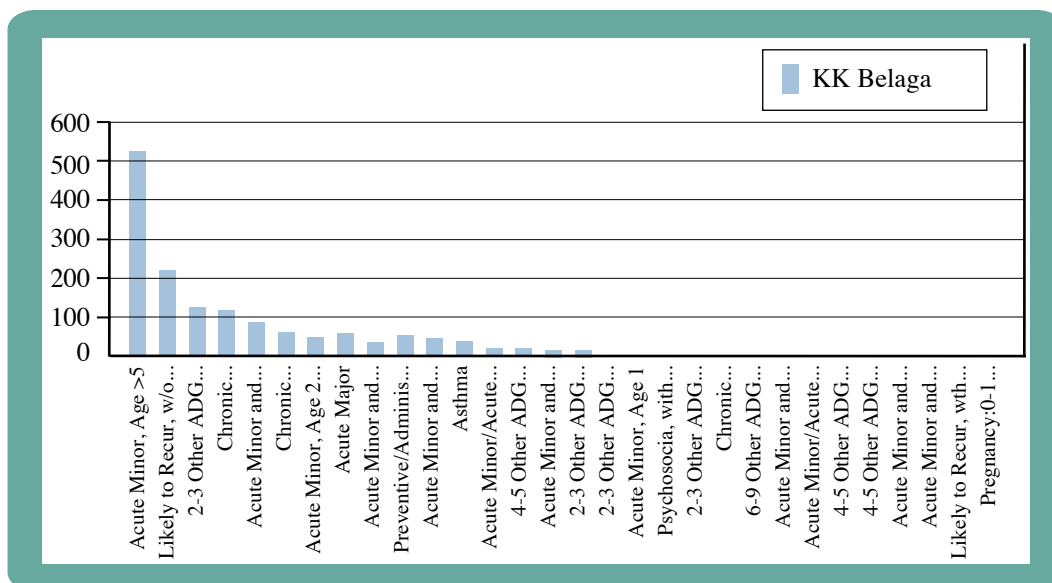
Eleven clinics were noted to have O/E ratio >1. This indicate that the 11 clinics are operating at much higher cost as compared to what is expected based on the morbidity of the population. KK Belaga in Sarawak had the highest O/E ratio at 3.4, followed by KK Majidee in Johor (O/E ratio of 2.1) and KK Kanowit in Sarawak (O/E ratio of 1.9). Further analysis to evaluate the profile of the population, morbidity pattern of patients, and resource use efficiency was carried out to try explain the high O/E ratio noted.

The higher costs incurred could be due to high utilisation of the clinic, especially in remote locations, by the catchment population for the full range of services offered. This include procedures not normally provided in the more urban setting, for example intra-partum service. The case-mix of the population, especially chronic disease conditions such as Hypertension and Diabetes, could have also contributed to the higher cost, as shown in the ACG distribution of KK Belaga in Figure 3 below. It indicated that clinics in remote areas incur higher costs for delivery of health services

Comparing efficiency indices of clinics



Figure 3: ACG for KK Belaga, 2008



Project III showed that population profiling by means of assessing the probability high total cost could be applied on TPC data. Probability high total cost is the probability that a patient will have high total costs (including pharmacy costs) in the year following the observation period. Usually, only a small percentage of individuals (typically less than 5%) will have probability scores greater than 0.5, and approximately 10 percent of the population will have scores greater than 0.10. The distribution and categorisation of the population predicted to have a high total cost in the following year can be carried out at any level, from national level to the clinic level. In this study, the pattern of distribution of probability score was similar in all the three states, with higher proportion of low probability score (<0.1).

The characteristics of patients with high probability score (> 0.5) can be analysed at the clinic level. This high risk patient identification can provide the clinician with a better understanding of how such reports could be used to identify at-risk individuals for targeted interventions to improve individual patient management. High risk patient identification can also be used by public health physicians to develop targeted interventions at the population level.

*Probability high
total cost*

As an example, an analysis of high risk patients was carried out for KK Kempas, an urban clinic, manned by 43 staff and headed by a



medical & health officer. The Family Medicine Specialist visited the clinic monthly to supervise and manage complicated cases by referral. The average daily attendance was 450 patients. At this clinic, 128 patients were identified to have high probability score of more than 0.5. The majority were female and the mean age was 62 years. The youngest patient was a 14 year old Malay male suffering from acute leukaemia (ACG 800, ADG 32, EDC MAL16) while the oldest was an 88 year old Malay female with hypertension (ACG 900, ADG 10, EDC CAR14).

High risk patient identification

Pharmacy cost contributed the biggest proportion of total cost, generally more than 75%. The highest total cost in the study was RM 959.48, with 84% contributed by pharmacy cost. The patient with the highest total cost was a 56 year old Malay male who visited the clinic thrice, and was diagnosed with Type 2 diabetes and exanthema (ACG 2300, ADG 2, 10, EDC END 06, SKN 09). The probability score was 0.66, interpreted as 66% more likely to have high total cost the following year.

High risk patient identification in KK Kempas

From this analysis, it was clear that high total cost was related to the morbidity pattern of the population. As expected, management of chronic disease required more resources, and co-morbidities were more prevalent among the older age groups. The findings also illustrated the usefulness of probability score as one of the screening parameters that could assist health managers in allocating scarce resources more efficiently.

Total cost related to morbidity pattern and probability score as screening parameter

Project III further showed improvement in linking costs with morbidity, and a pharmacy-based model was successfully applied as an adjunct to currently inadequately recorded information on diagnosis. Focus was given to determining the ability to apply the ACG Rx-MG methodology to the available Malaysian pharmaceutical information, which uses the Malaysian Drug Code which was converted to ATC (Anatomical Therapeutic Chemical classification system) compatible Rx codes.

Application of ACG Rx-MG to Malaysian pharmaceutical information

In general Rx MG (pharmacy based morbidity group) sourced from prescriptions, managed to capture more patient morbidity than EDC (a tool used to select patients with a specific condition or combination of conditions), sourced from diagnosis, as shown in Figure 4 below. Through Rx-MGs, one can narrow down to see which state, clinic or provider has specific coding/prescribing patterns. This is generally

Prescriptions versus diagnoses data in capturing patient morbidity

TPC pharmacy module compatible with ACG

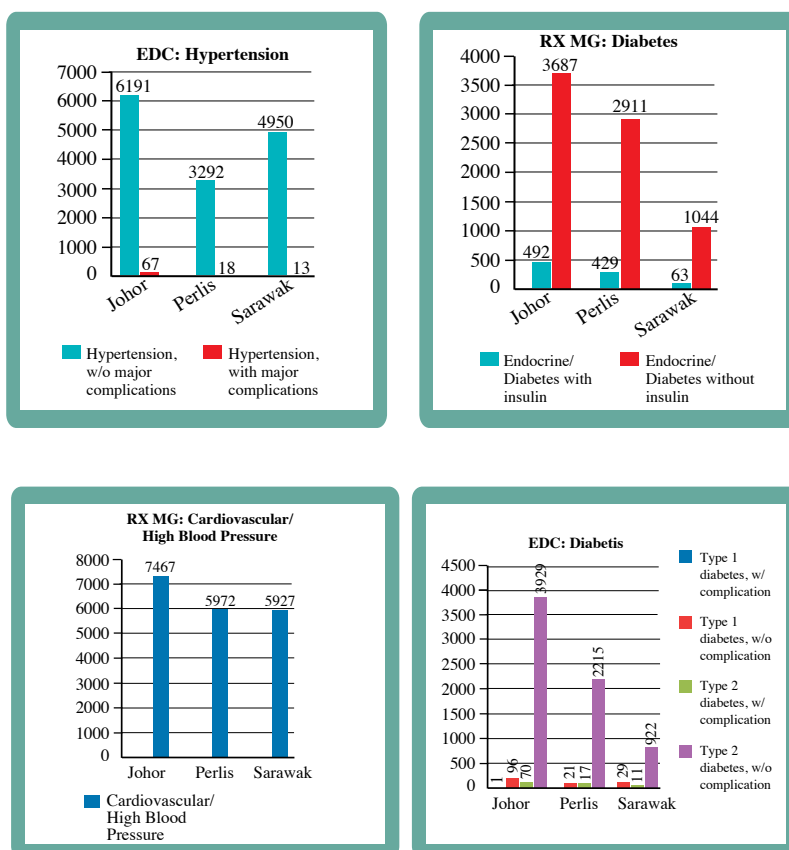


used when diagnosis information is unavailable, thus complementing the diagnosis-based model.

The ability to capture additional information through the use of the pharmacy model should be explored further, especially in light of the incomplete recording of diagnoses.

*Prescription data
complementary*

Figure 4: Comparison of patient morbidity from EDC and RxMG – Hypertension and Diabetes



*Better understanding
of Malaysian
database with ACG*

*Integrating case-
mix into Malaysian
healthcare system*

This project revealed several important findings:

- a. ATC codes contained in the TPC pharmacy module were compatible with the ACG System. In fact, the MDC code (Malaysian Drug Code) which is more extensive, may supply additional information in future research projects. *Rx-MG as tool to gauge data quality*
- b. Rx MG is complementary to diagnosis based (EDC) groupings.
- c. Rx MG is more robust and can be used as a tool to gauge data quality and coding patterns among clinicians.

While this project has highlighted necessary improvements in the pharmacy module within the TPC System, recognizing the deficiencies enables its improvement. In addition, the study showed that not all clinics were using the TPC pharmacy module and steps are now able to be taken to correct this.

CONCLUSION

Experience with the ACG System has been invaluable in providing a better understanding of the Malaysian health database, the morbidity profile of the Malaysian population as well as cost structure in the provision of primary health care in Malaysia. This information is crucial to ensure that efforts in providing a primary care system that is fair, efficient and sustainable will be realised. *Resource use measures*

To make full and effective use of TPC, a resource-use measure based on micro-costing information must be developed and validated. The three projects represented the initial first steps in a multi-stage process to demonstrate the benefits of integrating case-mix into the Malaysian health care system.

There is much opportunity to improve existing input data in terms of complete entry and accuracy so that high quality output can be generated. This will ensure case mix research output is credible and allow better uptake of the research outcome into policy and practice. Applying case-mix and health information technology in primary care can further improve the delivery of health services in the country towards better health for our population.



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COMMUNITY-BASED CARDIOVASCULAR RISK FACTORS INTERVENTION STRATEGY (CORFIS) IN MANAGING CHRONIC DISEASES

SUMMARY

Hypertension, diabetes mellitus and hyperlipidaemia are emerging global health problems, and they continue to be poorly managed and controlled. The aim of this community trial was to assess the efficacy of a chronic disease management strategy – the Community-Based Cardiovascular Risk Factors Intervention Strategy (CORFIS) – in the treatment of these three conditions. A target enrolment of 75 General Practices were randomly selected to provide participants for either CORFIS Care (chronic disease management programme) or conventional care (‘control’) for 6 months. Participants with known cases of, and treated for, Hypertension, Diabetes Mellitus and hyperlipidaemia were enrolled. The results of the study showed significant improvement in chronic disease control among participants under the CORFIS programme. The programme has potential as a comprehensive chronic disease care model for Malaysia.

Introduction

The prevalence of chronic diseases is increasing at an alarming rate. The World Health Organisation (WHO) estimates that 46% of the global disease burden is attributed to chronic diseases and this will increase to 60% by year 2020. The three most prevalent chronic diseases in Malaysia are hypertension (HPT), diabetes mellitus (DM) and hyperlipidaemia (HLP). Together with smoking, they account for the increasing burden of cardiovascular diseases (CVD), the commonest causes of death in Malaysia. The country also has the highest incidence of chronic kidney diseases (CKD) attributable to DM in the world.

Prevalence of Chronic Diseases

These chronic diseases are poorly managed and controlled in the Malaysian population. Findings from the National Health & Morbidity Survey III in 2006 (NHMS III, 2006) showed that 92% of patients with Type 2 DM were aware of their condition but only 86% were on treatment, of whom only one-third achieved glycaemic control. Only 33% of patients with HPT were aware of their condition, of which 23% were on anti-hypertensive treatment, with just 26% of these patients achieving blood pressure control. As for patients with HLP, only 19.7% were aware that they had such a condition, of which only



44.1% received treatment, and with only 69% of that group achieving control. Similar findings of unsatisfactory DM management have been documented in the United States, Canada, Europe and Asian countries like China and India.

Over the years, there have been considerable advances in the understanding and management of chronic diseases. The Chronic Care Model (CCM) developed by Wagner et al. (2001, 2004) is the most widely accepted approach, and the WHO has adapted it as the framework for chronic disease care. The CCM states that optimal chronic care can be achieved when a proactive healthcare team interacts productively with an informed, motivated patient who wants to take charge of his/her own health. This requires six essential elements:

*CORFIS based on
the Chronic Care
Model (CCM)*

1. Overall healthcare organisation
2. Re-design of the delivery system
3. Decision support
4. Clinical information systems
5. Self-management support for patients and
6. Links to available community resources.

Hence, the Community-based Cardiovascular Risk Factors Intervention Strategy (CORFIS), built around the CCM, was tested for efficacy in short-term control of the three conditions in a Malaysian setting.

Research Design And Methods For CORFIS

A prospective, open label community trial was conducted on a target of 75 general practice clinics (GP) in Malaysia. The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) requirements. The local institutional review board approved the protocol, and all patients gave their written informed consent.

*Community
Intervention Trial*



Study Patients, General Practices and Randomisation

Patients were recruited from the 75 participating GPs. The GPs were randomised centrally in a two-to-one ratio to be assigned as 'Intervention' or 'Control'. The inclusion criteria were patients aged 18 years and above and diagnosed by the participating GP as having Type 2 DM and/or HPT and/or HLP, and currently on drug treatment for one or more of these conditions.

Inclusion & Exclusion Criteria

The exclusion criteria were pregnant or nursing women, and those with history of unstable angina, acute myocardial infarction, coronary revascularisation procedure, heart failure, stroke or serum creatinine $>150 \mu\text{mol/l}$ in the preceding 6 months, and clinically significant valvular heart disease.

Study Intervention

The study intervention, the CORFIS programme, incorporates elements of the CCM. Its specific components are:

Elements of CORFIS

1. Primary care delivery system reform
2. Decision support tools based on current clinical practice guidelines (CPGs)
3. Multidisciplinary care team
4. Patient-centred care with emphasis on self-empowerment
5. Information technology to facilitate information dissemination among healthcare providers
6. Community support and target organ screening, and
7. Incentives for healthcare providers to engage in chronic disease management and care.



Study Control

The control arm constituted patients who were receiving conventional routine care by their attending GP without any CORFIS intervention from the team. Routine care in this context was defined by the standard healthcare services provided by the GPs.

Study Control Criteria

For both arms, the decision to adjust medication dosage was at the GPs' discretion.

Study Assessments and Endpoints

For the intervention arm, study visits occurred 30 days after the initial enrolment and baseline investigation, followed by monthly visits thereafter for 6 months, a total of 7 visits. For the control arm, patients were followed-up on a 2-monthly basis from baseline, making it a total of 4 visits. At each visit, study assessments were conducted and patients' adherence to the programme and medication were measured. The primary outcome for diabetic patients was defined as the proportion of patients who were able to reach treatment goals as defined by HbA_{1c} of $\leq 7\%$ and fasting blood glucose of 4.4 - 6.1 mmol/l. BP target is defined as $<140/90$ mmHg for patients without DM and CKD or $<130/80$ mmHg for those with DM and CKD.

Monitoring Endpoints

Statistical Methods

Continuous variables were described by summary statistics such as mean, median, standard deviation, maximum and minimum values. Categorical (nominal/ordinal) variables were described by the frequencies and percentages of each category. In terms of the efficacy analysis, a Chi-square test was used to assess the difference in the proportion of patients who were able to reach treatment goals. Other statistical tests used in the analysis included Fisher's Exact Test, Mann-Whitney Test, Independent T-Test and One-sample Proportion Test. In all the statistical analyses, a p-value of less than 0.05 is considered significant. The primary analysis set was the intention-to-treat (ITT) population, who had at least one efficacy assessment. Subjects with missing data on the primary efficacy variable had their data imputed by method of Last Observation Carried Forward (LOCF).

Statistical Analysis Plan

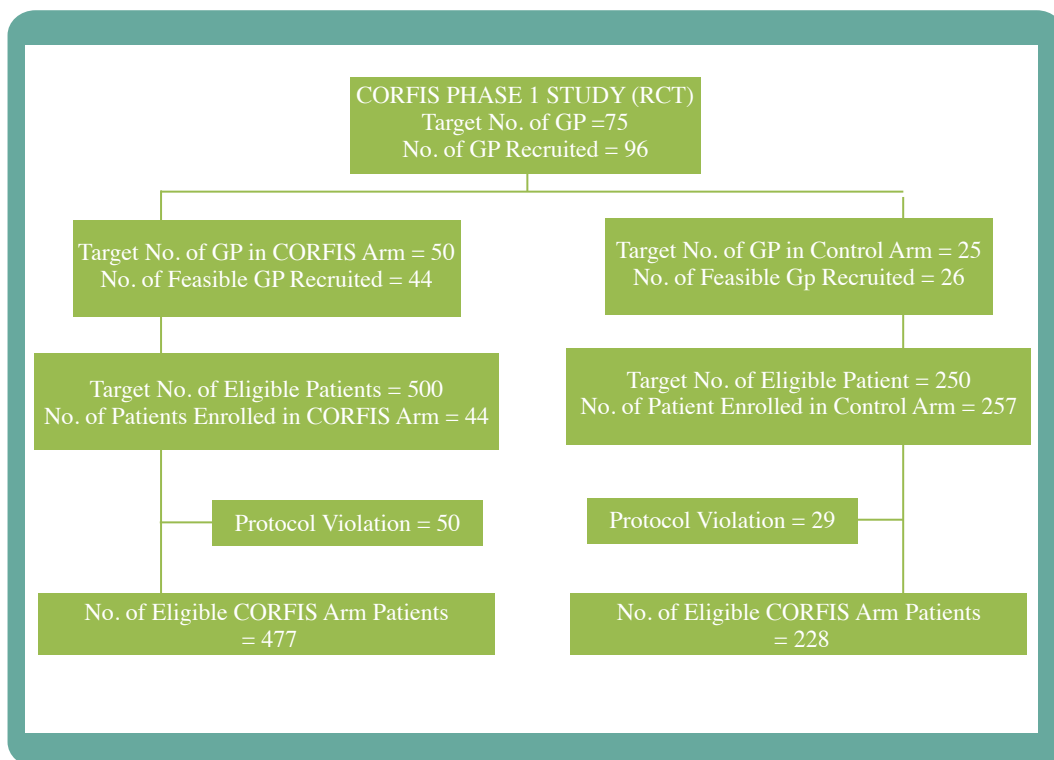


Results

Seventy eligible GPs were recruited to participate in the trial. Forty four GPs were randomised to the CORFIS arm (intervention) and these enrolled 527 patients, while 26 GPs were randomised to usual care (control) with 257 patients enrolled (Figure 1).

Trial Profile

Figure 1: Trial Profile



Fifty patients in the CORFIS group and 29 in the 'control' were excluded for protocol violation as they withdrew consent (n=18) or did not complete baseline assessment (n=61). Results analyses were divided into three sub-groups using the number of patients within each group (Table 1).

Attrition of Subjects



Table 1: Sub-Group Analysis Profile

Variable	Intervention Arm N=477			Control Arm N=228		
	HPT	DM	HLP	HPT	DM	HLP
N at Baseline	320 (67.1%)	268 (56.2%)	299 (62.7%)	177 (77.6%)	106 (46.5%)	128 (56.1%)
Withdrawn/ Loss to Follow-up	42 (13.1%)	42 (15.7%)	42 (15.1%)	30 (16.9%)	15 (14.2%)	18 (14.1%)
N at 6-months	278	226	254	147	91	110

HPT=Hypertension, DM= Diabetes Mellitus, HLP= Hyperlipidaemia

DM Sub-Group Analysis

A total of 268 patients in the CORFIS arm and 106 in the control arm had Type 2 DM at entry and were included in this analysis. The characteristics of the study population at baseline were similar between the two groups.

DM Patients' Profile

Of these patients, 42 (15.7%) in the CORFIS arm were excluded - minor protocol violations (2 patients), loss to follow-up (31 patients), other non-specific reasons (5 patients), and administrative reasons (4 patients). For the control, 15 (14.2%) were excluded - loss to follow-up (13 patients), other non-specific reasons (1 patient) and administrative reasons (1 patient). Therefore, 374 patients were included in the intention to treat (ITT) analysis, while 317 patients who completed the trial were included in the per-protocol (PP) analysis.

Baseline HbA_{1c} level showed uncontrolled blood glucose in both groups with a median of 7.6% (4.9-14.0) and 8.1% (5.1-13.8) in the intervention and control arms respectively (Table 2). After the 6-month period, reductions in HbA_{1c} were 0.7% (intervention) and 0.2% (control) (p=0.002).

Monitoring HbA_{1c} Levels



Table 2: Efficacy Analysis for Diabetes Mellitus (Intention-to-Treat Analysis)

Variable	Intervention Arm N=268			Control Arm N=106			P-value
	Median	Min	Max	Median	Min	Max	
HbA _{1C} %							
At Baseline	7.6	4.9	14.0	8.1	5.1	113.8	0.792
At Visit 6	6.7	5.1	12.8	7.3	4.8	15.1	0.007
Change at 6 months from baseline	-0.7	-7.8	2.3	-0.2	-5.9	3.0	0.002
Blood Glucose, mmol							
At Baseline	7.1	4.0	21.4	7.1	3.1	23.7	0.520
At Visit 6	6.5	3.5	21.2	7.1	4.4	27.0	0.027
Change at 6 months from baseline	-0.4	-16.4	11.6	0.1	-11.2	19.8	0.004
No. of diabetic achieve target HbA _{1C} control at 6-month;n (%)	143 (58%)			38 (42%)			0.002
Total number of diabetic patients with uncontrolled HbA _{1C} at baseline achieved target at 6-month; n (%)	70 (43%)			14 (23%)			0.004
Total number of diabetic patients with uncontrolled HbA _{1C} at baseline at 6-month; n (%)	73 (87%)			24 (86%)			1.000

***Intention-To-Treat (ITT) Set**

For fasting blood glucose (FBG), the median value for the intervention arm fell from 7.1 mmol (4.0-21.4) to 6.5 mmol (3.5-21.2) over 6 months, while the median value for the 'control' remained unchanged (7.1mmol) - a significant difference in FBG change between the

*Fasting Blood
Glucose (FBG)*



two groups ($p=0.004$) (Table 2). Overall, more subjects (58%) in the intervention arm achieved their glycaemic target compared to the control arm (42%) ($p=0.002$). Of the 162 uncontrolled diabetic patients in the intervention arm, 70 (43%) achieved their HbA_{1c} target, compared to 23% in the control arm ($p=0.004$). In both groups, patients were able to maintain their blood glucose control once they had achieved good control at the beginning ($p=1.000$).

HPT Sub-Group Analysis

A total of 320 and 1,777 patients with HPT at entry were included in the CORFIS and control arms respectively. The characteristics of the study population at baseline were similar between the two groups. Of these, 42 on the CORFIS arm were withdrawn - minor protocol violations (4 patients), loss to follow-up (28 patients), other non-specific reasons (6 patients), and administrative reasons (4 patients). In the control arm, 28 were withdrawn - minor protocol violations (3 patients), loss to follow-up (22 patients), other non-specific reasons (2 patients) and administrative reasons (1 patient). Thus, 497 patients were included in the ITT analysis, while 427 patients were in the PP analysis.

HPT Patient Profile

The overall decrease in median systolic blood pressure (SBP) after 6 months in the intervention arm was 9 mmHg, compared to 2 mmHg in the control arm ($p=0.003$), while the decrease in median diastolic blood pressure (DBP) was 6 mmHg in the intervention arm and 0 mmHg in the 'control' ($p<0.001$) (Table 3).

Descriptive Clinical Analysis HPT Patient

Among the uncontrolled hypertensive patients at baseline, 57% achieved their BP target in the intervention arm, compared to 34% in the control arm ($p=0.001$). In both groups, patients were able to maintain BP control once they had achieved good control at the beginning ($p=0.633$). Based on this ITT analysis on hypertensive patients, the CORFIS intervention programme is found to be superior compared to management by the GP alone.



Table 3: Efficacy Analysis for HPT (Intention-to-Treat Analysis)

Variable	Intervention Arm N=320			Control Arm N=177			P value
	Median n	Min	Max	Median n	Min	Max	
SBP at Baseline	134	92	196	130	110	210	0.632
SBP at 6 month	128	87	181	130	98	193	<0.001
Change in SBP at 6 month from baseline	-9	-60	50	-2	-50	48	0.003
DBP at baseline	85	58	118	82	58	130	0.838
DBP at 6-month	80	52	111	83	51	120	<0.001
Change in DBP at 6 month from baseline	-6	-53	30	0	-42	30	<0.001
No. of Hypertensive achieve target BP at 6-month	216 (68%)			102 (58%)			0.028
No. of Uncontrolled BP at baseline achieve target BP at 6-month	90 (57%)			30 (34%)			0.001
No. of Controlled BP at baseline achieve target BP at 6-month	125 (83%)			72 (81%)			0.633

***Intention-To-Treat (ITT) Set**

The authors conducted a sub-group analysis on HPT patients who achieved target BP after 6 months. The target BP levels were <130/80 mmHg (HPT with CKD and with or without DM) and <140/90 mmHg (HPT without CKD DM). After 6 months, 87% of patients with HPT without CKD and with or without DM achieved target BP on CORFIS intervention, compared to 49% in the control arm ($p<0.001$). Similar, but less pronounced results were observed among patients with HPT and CKD and with or without DM mellitus (42% CORFIS Intervention versus 25% Control; $p=0.042$).

Achieving BP
Control



HLP Sub-Group Analysis

A total of 299 and 128 patients on the CORFIS and control arms, respectively, had HLP at entry and were included in this analysis. The characteristics of the study population at baseline are similar between the two groups. In the CORFIS arm, 45 patients (15%) were withdrawn [minor protocol violations (5 patients), loss to follow-up (36 patients), significant improvement such that study treatment was no longer required (1 patient), and administrative reasons (3 patients)]. On the control arm, 18 were withdrawn [minor protocol violations (3 patients), loss to follow-up (13 patients), and administrative reasons (2 patients)]. Thus, 427 patients were included in the ITT analysis, and 364 patients were included in the PP analysis.

HLP Patient Profile

The efficacy analyses of fasting low density lipoprotein-cholesterol (LDL-C) for patients with HLP is shown in Table 4. The two study groups were similar at baseline but were significantly different at the end of the 6-month trial. After 6 months, the median value for LDL-C in the intervention group was 2.6 (0.3-4.9), a reduction of 0.3 mmol/l from baseline compared to 0.1 mmol/l reduction in the control group ($p=0.001$) (Table 4). Among all patients with HLP, there was no significant difference in target LDL-C achievement after 6 months. However, when a detailed analysis was conducted on patients with poor LDL-C control at baseline, a significant proportion of patients in the intervention arm (50%) achieved LDL-C target after 6 months, compared to the control arm (32%) ($p=0.027$). A sub-group analysis on HLP patients with 2 or more cardiovascular risk factors also showed significant differences in the number achieving target LDL-C control (71% intervention versus 29% control; $p=0.003$). No differences were observed between both study arms when patients already had good serum lipid control at baseline.

Descriptive Clinical Analysis HLP Patient



Table 4: Efficacy Analysis for Hyperlipidaemia (Intention-to-Treat Analysis)

Variable	Intervention Arm N=299			Control Arm N=128			P value
	Median n	Min	Max	Median n	Min	Max	
LDL at Baseline	3.1	0.7	7.5	2.9	1.3	6.5	0.447
LDL at 6 month	2.6	0.3	4.9	2.8	1.0	6.3	0.066
Change in LDL at 6 month from baseline	-0.3	-3.9	2.5	-0.1	-2.3	1.6	0.001
No. of Hyperlipidaemic achieve target LDL at 6-month	187 (63%)			75 (59%)			0.4427
No. of Uncontrolled Hyperlipidaemic at baseline achieve target LDL at 6-month	74 (50%)			16 (32%)			0.027
No. of Controlled Hyperlipidaemic at baseline achieve target LDL at 6-month	113 (82%)			59 (83%)			0.946

Discussion

This is the first community trial on chronic disease management in Malaysia. The study provided encouraging results on the effects of a comprehensive chronic disease management strategy for the treatment of chronic diseases such as DM, HPT and HLP compared to routine care delivered by independent GPs or family physicians.

Sentinel Community Trial

The authors hypothesised that the effectiveness of CORFIS may be mediated in part through increased prescription and improved adherence. However, both arms displayed similar trends of increased prescription as well as good level of medication adherence after 6 months. The Hawthorne effect most likely explains this, as this was an open label trial for both investigators and subjects.



Since the effects of increased prescription and improved adherence do not explain the difference in outcomes between the intervention and control arm, the authors hypothesised that other CCM elements such as therapeutic lifestyle modification, patient empowerment, multidisciplinary care and the use of IT technology play an important role in disease control among patients diagnosed with DM, HPT and HLP. This hypothesis is consistent with studies conducted by Piatt et al. (2006) and Gaede et al. (2008) which reported a significant reduction of HbA_{1c} after going through a multifaceted intervention based on the chronic care model. Their results showed HbA_{1c} reduction ranging from 0.6%-0.7%.

Three non-multidisciplinary studies by McGhee et al. (1994), Rachmani et al. (2002) and Zillich et al. (2005), which provided structured consultation based on CPGs and continuous patient follow-up on medication compliance, revealed some degree of blood pressure improvement (reduction of SBP and DBP by approximately 3 – 6 mmHg; $P < 0.05$). In contrast to studies of HPT management by multidisciplinary team focusing on therapeutic lifestyle changes (TLC), there were significantly higher reductions in BP readings in the intervention group compared to conventional care (mean SBP reduction of -2 to -14 mmHg in the intervention arm compared to zero to -3 mmHg reduction in the control. Kim et al. (2006) also reported that patients who received continuous follow-up on behavioural change and conducted home self-monitoring achieved target BP control of $<130/80$ mmHg after 6 months compared to usual care. Similar efficacy outcomes were reported by Lim et al. (2002) and Wood et al. (2008) where higher percentages of patients ($>10\%$) achieved target BP control on receiving multidisciplinary counselling and patient empowerment.

Other studies had reported significant efficacy outcomes in HLP treatment using pharmacist-led disease management programme focusing on pharmaceutical care and TLC. Their results show LDL reductions ranging from 0.6-1.3 mmol/l with 57-72% of patients achieving recommended target serum LDL-C level. Similar findings were also observed in studies that utilised nurses or case managers to provide case management services and therapeutic lifestyle counselling. A study conducted by Shaffer et al. (1995) had demonstrated that patients are four times more likely (Relative Risk = 4.1; $p < 0.001$) to achieve serum cholesterol control through multidisciplinary care by physicians, nurses, pharmacists and dieticians.



There were many challenges faced during this pilot study, some of which are lessons for future programme development. These included the need to stratify patients based on cardiovascular risk factors and disease control, extremely long counselling sessions by the multidisciplinary team, relatively non-conducive environment to provide optimal chronic disease management in the majority of GP clinics, lack of optimal pharmaceutical services due to multiple sources of medication prescription, and lack of leadership among primary healthcare team.

Challenges for the CORFIS pilot

Conclusion

Although a short term (6 months) community intervention trial, this pilot study provides valuable inputs on programme design and execution of chronic disease management in the Malaysian setting, with the researchers having the leverage to advocate for the adoption of the CORFIS programme.

Hence, the CORFIS programme has great potential as a comprehensive chronic disease care model for Malaysia. Results of the pilot study on patients with hypertension, diabetes, and hyperlipidaemia singly or in combination and with/without other co-morbidities, show that multifaceted chronic care intervention can demonstrate significant improvements in target disease control. However, in cognisance of some the challenges faced in the pilot study, there is a need to consider all perspectives, especially 'real world' factors in proposing any community intervention programme.



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TOTAL ARSENIC EXPOSURE THROUGH DIETARY INTAKE IN THE ADULT MALAYSIAN POPULATION

SUMMARY

The first Malaysian Total Diet Study on the exposure of total arsenic through dietary intake in the adult Malaysian population was carried out in 2006. Foods were purchased randomly in 14 Malaysian states from supermarkets and grocery shops as would normally be practiced by consumers. There were 11 food groups consisting of 86 food samples. Samples were composited and analyzed based on 25 food subgroups. Analysis of total arsenic was carried out at the National Public Health Laboratory using Inductively Coupled Plasma-Optical Emission Spectrometer (ICP-OES). The results showed that Fish and Fish Products had the highest concentration of total arsenic ranging from 0.79 to 3.83 µg/g. The estimated dietary exposure of total arsenic showed that plain water was the major contributor to the total arsenic exposure which is 0 – 28 % of Provisional Tolerable Weekly Intake (PTWI). This result was contributed by the highest amount of water consumption and the highest level of detection. The second major contributor to the exposure of total arsenic was Fish and Fish Products. Within this group, sea fish (13 – 13.5 µg/kg.bw/week) and fresh cuttlefish (5 – 5.5 µg/kg.bw/week) was the highest contributor to exposure of total arsenic which equaled to 3.7 – 3.9 % and 1.6 % of PTWI respectively. From the whole diet, the total weekly exposure to total arsenic for an average adult in Malaysia, with an average body weight of 63 kg, was estimated to be 47.23 – 281.21 µg/kg.bw/week. This was equal to 13.5 - 80.3 % of PTWI for total arsenic.

Introduction

Malaysia Total Diet Study (MTDS)

In the past, the safety of the food supply was being determined using conventional methods i.e. by monitoring individual foods for compliance with national and international regulatory standards. However, monitoring of this type of data will focus on individual chemicals in raw commodities, and may not provide a direct link to the health assessment of the population.

*Conventional
monitoring tools*



The alternative method of ensuring safety of national diet is by using total diet studies. It provides a clear picture of the condition, safety and quality of the food supply. A key characteristic of such study is that foods are prepared ready for consumption, so this provides the best means of assessing the risk to consumers in contrast to commodity based surveys. It measures the actual dietary exposure to these chemicals by the population, and compares these exposures with toxicological reference points set by the World Health Organisation (WHO) such as the Acceptable Daily Intake (ADI) or Provisional Tolerable Weekly Intake (PTWI). These comparisons provide a direct link to the health of the population, and total diet studies are the most reliable way to estimate the dietary intake of toxicants by large population groups. Therefore, total diet studies are essential to answer the fundamental question of whether or not the national diet is safe. And if not, which regions, age, sex, ethnic groups, or food groups/ foods are most at risk.

Alternatives method

The 1st Malaysian Total Diet Study (MTDS) was conducted in 2006 and focused on total arsenic. The MTDS differs from other surveys of contaminant levels in the following ways:

1st Malaysia Total Diet Study

- a) The MTDS monitors the level of certain substances in the total diet to determine whether they pose an unacceptable risk to human health. Other surveys examine the level of residues and contaminants in individual raw agricultural commodities or foods to determine compliance with the law but do not carry out a comprehensive examination of their significance in the diet.
- b) The MTDS contrasts with other national surveys in that all MTDS food samples are prepared to a 'table-ready' state before they are analysed, that is, they are subjected to documented preparation or processing steps. Food preparation varies with the type of food. For example, fruits may be peeled if they are usually eaten without their skins, while beef may be dry fried or otherwise cooked because this food is nearly always consumed after cooking. As food preparation is known to affect the concentration of residues or contaminants in the food, an analysis of prepared foods more accurately reflects the levels of residues or contaminants that are likely to be consumed.



MTDS consists of purchasing foods commonly consumed, processed for consumption, combined into food composites or aggregates, homogenised, and analysed for toxic chemicals. The concentration data obtained were multiplied by the food consumption for the composites of the corresponding food group to give estimates of dietary exposure of the contaminants.

Components of TDS

Since the national food consumption pattern is only available for adult, MTDS will focus on the adult diet. With the current analytical capability, resources and expertise available, MTDS 2006 focused on analysis of heavy metals. The National Public Health Laboratory, Sungai Buloh is the laboratory responsible for such analysis.

Contamination of Arsenic

Arsenic occurs naturally in both organic and inorganic forms. In the past, arsenic compounds were commonly used in drugs, but the main uses today are in pesticides, veterinary drugs and industrial applications. Most food contains low levels of arsenic due to its wide distribution in the environment and, to some extent; to its use in agriculture. Dietary exposure of arsenic represents the major source of arsenic exposure for most of the population. Some types of seafood contain up to 10 times the level of arsenic compared to other foods. People consuming large amounts of seafood may therefore ingest significant amounts of arsenic (primarily in organic form). It should be noted, however, that inorganic arsenic is much more toxic than organic arsenic.

Arsenic in foods

Source of Arsenic

Arsenic can enter the environment from natural sources, such as rocks and sediments, and as a result of human activities such as coal burning, copper smelting and the processing of mineral ores. Levels of arsenic are higher in the aquatic environment than on land and arsenic is known to accumulate in fish and some shellfish, such as crabs and whelks. Fish contains relatively high levels of arsenic compared to other foods and is the most significant source of arsenic in the United Kingdom (UK) diet. In the 1997 UK Total Diet Study, the fish group contained the highest average concentrations of arsenic (4.4 mg/kg) and contributed 94 % of the average population dietary exposure to arsenic.

Toxicity of Arsenic



Arsenic is present in food in different forms which vary in toxicity, with inorganic forms being the most toxic. Most of the arsenic in the diet is present in the organic form. Inorganic arsenic is typically found in food at a level of 1 to 3 percent. Fish and seafood, which are the most significant sources of arsenic in the diet, predominantly contain organic arsenic. The main organic arsenic in fish (more than 90 per cent of total arsenic) is in the form of arsenobetaine which is also the main form found in crustaceans and bi-valve molluscs.

The objective of this study was to estimate the total arsenic exposure from consumption of the whole diet among the adult population in Malaysia

Objective of this study

Materials and Methods

Selection of Food Sample

A list of 86 foods selected for the survey were categorised into the following 11 groups which were Cereal and cereal products, Meat and meat products, Fish and fish products, Egg, Nuts, Milk and milk products, Vegetables, Fruits, Drinks, Flavours and Others.

The food list was constructed based on the Malaysian Food Consumption Survey for Adults (18 – 59 years) conducted by The Family Health Development Division, Ministry of Health (MOH) in 2002. All foods reported in the surveys were aggregated into approximately 11 groups based on similarity of nutrient content, major ingredients and food uses. A list of foods (> 50% of population consumed) was selected for each of the 11 food groups. Appendix 1 showed the list of foods analysed for the 2006 MTDS. They were grouped into 25 food subgroups for the purpose of compositing and analyses (Table 1). The selection was based on the ‘most commonly purchased food item’ decided by the Purchasing Officer.

Food list



Table 1: Food Subgroups

No	Food Subgroup	No	Food Subgroup
1.	Cereal I	14.	Vegetable III
2.	Cereal II	15.	Vegetable IV
3.	Cereal III	16.	Fruit I
4.	Meat	17.	Fruit II
5.	Fish I	18.	Fruit III
6.	Fish II	19.	Fruit IV
7.	Egg I	20.	Fruit V
8.	Egg II	21.	Drink I
9.	Egg III	22.	Drink II
10.	Nut	23.	Drink III
11.	Milk and Milk Product	24.	Flavour
12.	Vegetable I	25.	Others
13.	Vegetable II		

Sample Purchasing

The sampling point was randomly selected in the capital cities of the various states covering all the 14 Malaysian states. Food samples were purchased from supermarkets and grocery shops as would normally be practiced by consumers. Sampling should be ideally done where consumers would most commonly purchase the items in one shop or if that was not possible, at the nearby shop.

Sampling plan

The food samples were packed into insulated containers, chilled where necessary and dispatched to the 12 Food Safety and Quality Laboratories and Public Health Laboratories for composite sample preparation. The prepared composite samples were then sent to the National Public Health Laboratory for sample analysis.

Transporting of food samples



Sample Preparation

The food samples were prepared in accordance with normal practice before analysis. The food preparation was based on the guidelines prepared by Food Safety and Quality Division (FSQD). The cooking methods used were baking, grilling or boiling. Distilled water was used in the food preparation. Food samples from the same food subgroup were blended and homogenised to prepare a composite sample.

*Sample preparation
instructions*

Sample Analysis

All 25 food subgroups composites from each of 14 states were analysed for total arsenic at the National Public Health Laboratory using Inductively Coupled Plasma-Optical Emission Spectrometer (ICP-OES). The reference test method was Doc No. H04-002.

*Analysis of total
arsenic*

Dealing with 'Not Detected' Results

When the analytical value was below the Limit of Detection (LOD), the true value of total arsenic in the food samples could be anywhere between zero and the LOD. It may not be appropriate to assume a zero concentration for all samples with analytical values below LOD. In dealing with the 'Not Detected' (ND) results, the theoretical approach was used where the upper bound and lower bound value is based on the LOD. If the LOD is high, the possibility of high concentration was calculated. The upper bound range represents a worst case conservative estimate. The treatment for these results was particularly important when a large percentage of the analytical results of a particular food group fell below the LOD.

*Theoretical
approach*

In this study, a value of 0, $\frac{1}{2}$ -LOD and LOD were assigned to all results below LOD as lower, middle and upper bounds. The dietary exposure to total arsenic was calculated based on the lower, middle and upper bounds (GEMS/Food-EURO, 1995).

Estimating Dietary Exposures

The purpose of the MTDS was to estimate the dietary exposure of the Malaysian population to a range of contaminants that can be found in their food supply. These exposures were estimated by multiplying

Exposure assessment



the mean level of contaminant in each food and the respective amount of food consumed. Total dietary exposure for each contaminant was estimated by adding together all contributions from the various foods in the Malaysian diet. The estimated exposure levels were then compared with the Reference Health Standard i.e. Provisional Tolerable Weekly Intake (PTWI) established by WHO. In this study, the PTWI for total arsenic is 350 $\mu\text{g}/\text{kg}$.

All analytical results are expressed in micrograms per gram ($\mu\text{g}/\text{g}$) of the edible portion of food prepared for consumption. Dietary exposure estimates for total arsenic contamination was presented as micrograms per kilogram body weight per week ($\mu\text{g}/\text{kg.bw}/\text{week}$).

Results and Discussion

Level of Total Arsenic in Food Samples

This MTDS analysed total arsenic in 25 food subgroups in 14 states. The concentration data is summarized as in Table 2 using the lower, middle and upper bounds approach since arsenic was not detected in almost 15% of the samples which means that the analytical values are lower than the LOD. So the theoretical approach was used in reporting the concentration data and calculating estimated dietary exposure.

Total arsenic in 25 food subgroups

The results showed that Fish and Fish Products had the highest concentration of total arsenic where the major contributor is the Fish III group (cockle, fresh prawn, fresh cuttlefish and crab) which is 3.83 $\mu\text{g}/\text{g}$. Fish I group (sea fish) was the second highest contributor for total arsenic which ranged from 1.92 – 2.00 $\mu\text{g}/\text{g}$ and followed by Fish II group (fresh water fish, anchovy, canned fish, dried fish, fish ball/ fish cake and raw keropok lekor) where the results ranged from 0.79 – 1.08 $\mu\text{g}/\text{g}$. As expected, fish and sea foods are the major source of total arsenic exposure to humans. Fish and sea foods can accumulate arsenic from their environment where water often contains arsenic and extremely high levels may be found in groundwater from areas with geothermal activity and with arsenic rich rock. However, it is well recognised that most of the arsenic contamination in fish and

Major contributor for total arsenic



Table 2: Concentration Data of Total Arsenic in Foods

Bil	Food Subgroup	Concentration (mg/kg)		
		Lower bound	Middle bound	Upper bound
1.	Cereal I	0.25	0.48	0.71
2.	Cereal II	0.00	0.29	0.58
3.	Cereal III	0.08	0.35	0.62
4.	Meat	0.19	0.43	0.68
5.	Fish I	1.92	1.96	2.00
6.	Fish II	0.79	0.94	1.08
7.	Egg I	3.83	3.83	3.83
8.	Egg II	0.00	0.29	0.58
9.	Egg III	0.28	0.49	0.70
10.	Nut	0.37	0.57	0.78
11.	Milk and Milk Product	0.12	0.39	0.66
12.	Vegetable I	0.00	0.29	0.58
13.	Vegetable II	0.04	0.31	0.58
14.	Vegetable III	0.00	0.29	0.58
15.	Vegetable IV	0.00	0.29	0.58
16.	Fruit I	0.00	0.29	0.58
17.	Fruit II	0.00	0.29	0.58
18.	Fruit III	0.00	0.29	0.58
19.	Fruit IV	0.00	0.29	0.58
20.	Fruit V	0.00	0.29	0.58
21.	Drink I	0.00	0.29	0.58
22.	Drink II	0.00	0.29	0.58
23.	Drink III	0.10	0.37	0.64
24.	Flavour	0.11	0.39	0.65
25.	Others	0.00	0.29	0.58



seafood is in the organic form which is less toxic than the inorganic form. Generally only 0.5 – 10% of total arsenic in fish and seafood is in the inorganic form.

The Nuts and Cereal I (rice, porridge) also contained a higher concentration of total arsenic which ranged from 0.37 – 0.78 $\mu\text{g/g}$ and 0.25 – 0.71 $\mu\text{g/g}$ respectively. The arsenic content of plants is usually determined by the arsenic content of the soil, water, fertilizers and other chemicals.

*Other contributors
for total arsenic*

Estimated Dietary Exposures by Each Food Samples Consumption

The estimated dietary exposure of total arsenic is given in Table 3. It shows that the highest estimated dietary exposure of total arsenic was from plain water which ranged from 0 – 97.91 $\mu\text{g/kg.bw/week}$, equal to 0 – 28 % of PTWI for total arsenic. The estimated dietary exposure was influenced by the amount of food consumed and the concentration level. Even though the concentration of total arsenic was low in plain water, the exposure was the highest due to high consumption of plain water (1519.24 g/day). The theoretical approach of using LOD instead of ND value, also affected the estimated dietary exposures as the high value of LOD will contribute to the high estimated dietary exposure.

*Highest estimated
dietary exposure of
total arsenic*

The estimated dietary exposure was also higher in other Drinks Group which included tea (0 – 15.89 $\mu\text{g/kg.bw/week}$), coffee (0 – 10.99 $\mu\text{g/kg.bw/week}$), chocolate drinks (0 – 8.24 $\mu\text{g/kg.bw/week}$) and cordial syrup (1 – 7.23 $\mu\text{g/kg.bw/week}$). All these estimated dietary exposure used the theoretical approach which may be a very conservative overestimate approach.

*Total Estimated
Dietary Exposure*

The exposure to total arsenic through the consumption of rice is 8 – 22.76 $\mu\text{g/kg.bw/week}$ which equal to 2.3 – 6.5 % of PTWI. This was due to the high intake of rice (289.68 g/day) for Malaysian Adults since consumption is one of the major factors in exposure assessment.



Table 3: Estimated exposure of total arsenic

Bil	Food Subgroup	Exposure, $\mu\text{g/kg.bw/week}$			% PTWI		
		LB	MB	UB	LB	MB	UB
1.	Cereal I	8.88	16.9	24.97	2.5	4.8	7.1
2.	Cereal II	0	6.86	13.72	0.0	2.0	3.9
3.	Cereal III	0.5	2.27	4.04	0.1	0.6	1.2
4.	Meat	1.5	2.8	4.41	0.3	0.8	1.3
5.	Fish I	12.9	13.2	13.5	3.7	3.8	3.9
6.	Fish II	3.45	4.08	4.71	1.0	1.2	1.3
7.	Fish III	10.5	10.5	10.4	3.0	3.0	3.0
8.	Egg I	0.00	0.81	1.62	0.0	0.2	0.5
9.	Egg II	0.16	0.27	0.39	0.0	0.1	0.1
10.	Nut	5.16	8.08	11	1.5	2.3	3.1
11.	Milk and Milk Product	0.44	1.45	2.45	0.1	0.4	0.7
12.	Vege I	0	2.8	5.6	0.0	0.8	1.6
13.	Vege II	0.26	1.89	3.52	0.1	0.5	1.0
14.	Vege III	0	1.01	2.02	0.0	0.3	0.6
15.	Vege IV	0.00	0.32	0.64	0.0	0.1	0.2
16.	Fruit I	0	5.55	11.1	0.0	1.6	3.2
17.	Fruit II	0	3.03	6.06	0.0	0.9	1.7
18.	Fruit III	0	0.46	0.93	0.0	0.1	0.3
19.	Fruit IV	0.00	0.05	0.09	0.0	0.0	0.0
20.	Fruit V	0.00	0.12	0.24	0.0	0.0	0.1
21.	Drink I	0.00	48.9	97.91	0.00	14.0	28.0
22.	Drink II	0	17.6	35.11	0.00	5.0	10.0
23.	Drink III	3.15	11.8	20.9	0.9	3.4	5.9
24.	Flavour	0.63	2.12	3.57	0.2	0.6	1.0
25.	Others	0	1.33	2.65	0.00	0.4	0.8

Estimated dietary exposure in the Drinks Group and rice

Analytical results of Fish and Fish Products

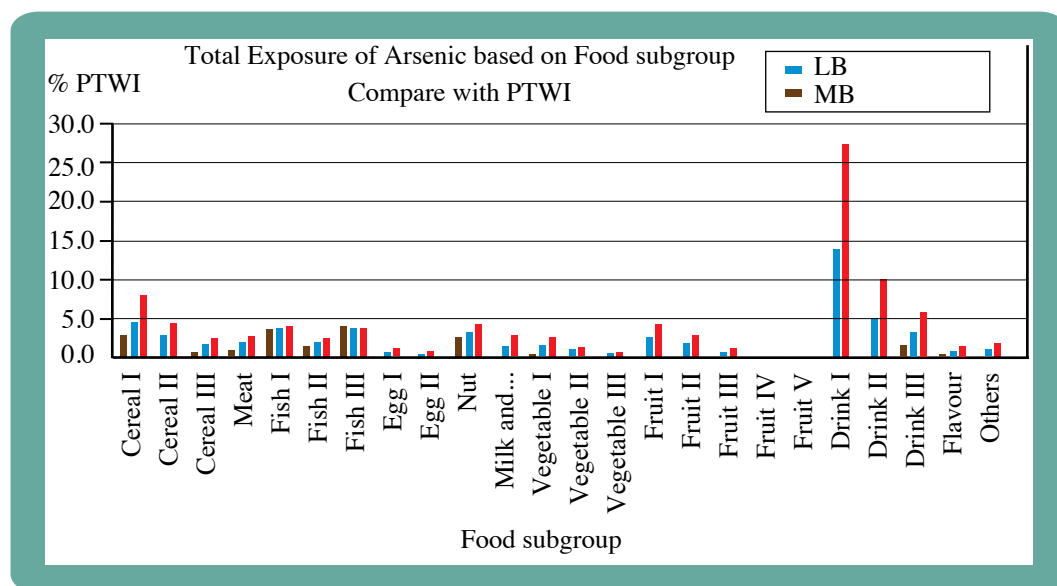


For the Fish and Fish Products, the actual value of the analytical results was used as almost all the results had a value above the LOD. Even though the concentration data showed the highest concentration of total arsenic was found in Fish and Fish Products, it is not necessarily true that these products had high estimated dietary exposure of total arsenic. This was due to the low consumption intake of Fish and Fish Products compared to plain water, drinks and rice. The exposure of total arsenic from Fish and Fish Products was mostly contributed by sea fish ($13 - 13.5 \mu\text{g/kg.bw/week}$) and fresh cuttlefish ($5 - 5.5 \mu\text{g/kg.bw/week}$), which equal to 3.7 – 3.9 % and 1.6 % of PTWI.

Estimated Dietary Exposures of the Whole Diet

The total estimated weekly dietary exposure to total arsenic and the comparison with PTWI based on food subgroup is shown in Figure 1. It showed the total exposure for total arsenic was in the range of 0 – 28 % PTWI. All the food subgroups were below the 5 % PTWI except for Drink I, Drink II, Drink III and Cereal I. Exposure of total arsenic for all food subgroups were found to be below the WHO PTWI established by taking into consideration the safety factor.

Figure 1: Total Exposure of Arsenic based on Food Subgroup Compared with PTWI



From the whole diet which included Cereal and Cereal Products, Meat and Meat Products, Fish and Fish Products, Egg, Nut, Milk and Milk Products, Vegetables, Fruits, Drinks, Flavours and others, the total weekly exposure to total arsenic for an average adult in Malaysia, with an average body weight of 63 kg, was estimated to be 47.23 – 281.21 $\mu\text{g/kg.bw/week}$. This was equal to 13.5 - 80.3% of PTWI for total arsenic. There was a large difference between the lower and upper bound values of estimated dietary exposure of the whole diet. This is due to the use of the theoretical approach based on LOD value. The higher LOD will contribute to the big differences between the lower and upper bounds of the estimated dietary exposure.

Conclusions

The level of total arsenic was highest in the Fish and Fish Products group which included cockles, fresh prawn, fresh cuttlefish, crab, sea fish, fresh water fish, anchovy, canned fish, dried fish, fish ball/fish cake and raw keropok lekor. The total arsenic concentration of Fish and Fish Products was 21.98 – 23.80 $\mu\text{g/g}$. It showed that fish and seafood were the major sources of total arsenic contamination in adults in Malaysia.

The highest estimated weekly dietary exposure was from plain water (0 – 97.91 $\mu\text{g/kg.bw/week}$) and this result was based on the theoretical approach.

The estimated weekly dietary exposure for Fish and Fish Products was the most representative of the actual situation as the calculation was based on the actual analytical results. It showed that the estimated weekly dietary exposure for Fish and Fish Products was 26.84 – 28.66 $\mu\text{g/kg.bw/week}$ which equal to 7.7 – 8.2 % of PTWI.

This study indicated that there was no appreciable risk for arsenic consumption. The dietary exposures were lower when compared to the PTWI. As such, the MTDS concluded that with respect to arsenic there are no health concerns to adults in Malaysia, consuming the Malaysian diet.

Total arsenic is composed of the organic and inorganic form and the inorganic is more toxic. However, 90% of the total arsenic in foods is in the organic form. If we make an assumption that 10% of total arsenic is inorganic, the estimated dietary exposure of inorganic arsenic through food intake showed that there is no health concern.



This main benefit of the MTDS is the knowledge and experience gained that will help improve future studies.

Recommendations

The main reason for the high degree of uncertainty in the exposure estimates is the high limit of detection. It is important to formulate a theoretical approach for calculating dietary exposure when considering the LOD. For future TDS projects, it is proposed that a lower LOD value has to be achieved to ensure that the exposure assessment calculation using the theoretical approach is more realistic. Lower LOD can be achieved by increasing the sensitivity of the technique and the instrument.

Continuous surveillance and monitoring of total arsenic and inorganic arsenic in fish and seafood should be conducted to ensure the safety of consumer.

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SOCIAL MARKETING: ANTI SMOKING MEDIA CAMPAIGN

SUMMARY

Mass media campaign (MMC) is used in social marketing campaigns because it can reach a diverse and vast audience. In order to use the media in anti-smoking campaign, we need to have very clear objectives. These objectives should be measurable, specific and realistic. For example, in trying to influence smokers or non smokers, we have to be able to measure the impact of the campaign. It is important to have a realistic aim and to recognise that even the best campaign cannot achieve its aim in a short time. For anti smoking campaign to be effective, it is important to integrate the MMC with other approaches namely school and peer education, enforcement, interpersonal intervention and, anti-smoking outreach programme. An important part of any campaign is to identify the factors and effects of cigarettes among the targeted group. Targeted campaigns are more effective than those adopting a blanket approach. Targeting involves segmenting the population according to relevant variables. Type of messages such as fear appeals, emotional appeals, rational appeals are frequently used in anti smoking campaign, however they may increase the undesired behaviour, and make it more resistant to change. When communicating about smoking, one factor to consider is the credibility of the source. This determines the degree to which the source is perceived as being an expert and believable by the audiences. The choice of channels for a campaign depends on the audience. It is possible to use multiple channels such as radio, television, outdoor events and print media.

Introduction

Public health education is a critical component of successful comprehensive tobacco control programmes. The scientific evidence on the effectiveness of public education campaigns is strong and will continue to grow as more countries implement campaigns and evaluate their effectiveness.

The U.S. Guide to Community Preventive Services studied the impact of mass media campaigns and other tobacco prevention and cessation methods on prevention of tobacco use and cessation. The Task Force found “strong evidence” that mass media education campaigns featuring long-term, high intensity counter-advertising, combined with other interventions, are effective in reducing tobacco use initiation and consumption of tobacco products, and in increasing cessation among tobacco users.

Model for successful and comprehensive tobacco control program



Social marketing may broadly be defined as the application of marketing techniques to social problems. It covers a wide variety of disciplines including health education, advertising, economics, business management, scientific research, systems analysis, community organization, psychology and epidemiology. Social marketing aims to persuade or motivate people to adopt specific courses of action or behaviour which are generally accepted as being beneficial. It is “the design, implementation and control of programs seeking to increase the acceptability of a social idea or practice in a target group(s)” (Kotler 1975). It cannot create the behaviour, it can only help to gain acceptance and a willingness to adopt the behaviour. According to Ward (1986) the health planner or social marketer must consider each of the four marketing elements: **product, price, place and promotion.**

*Application
of marketing
techniques*

*The marketing
elements*

*Product, price, Place
and promotion*

The Tak Nak Anti-smoking Media Campaign

Smoking is considered one of the worst enemies of public health, because its consequences are devastating. In fact, half of all regular smokers die of smoking-related illness and half of these individuals will die in the middle age (between 35 and 69 years).

*Defining the
Problem*

It is now evident that tobacco promotions have positive influence on smoking prevalence. The increase in smoking uptake rates among children and youth occur proportionately with the intensity of tobacco industry promotions carried out. On the other hand, total ban on tobacco promotions as well as counter-advertising campaigns implemented independently or jointly are capable of reducing smoking prevalence especially among children and youth.

Competitive Analysis

Smoke-free and quitting messages compete with the tobacco industry's promotion of its products. Although tobacco advertising and sponsorship are banned in Malaysia, the tobacco industry continues to market its products using below-the-line marketing techniques. Audiences, particularly the young audiences, continue to encounter substantial media content depicting smoking across virtually all media channels. Much of this content is non-promotional, incidental portrayals of tobacco. For many smokers, the call to stop smoking competes with the smokers addiction to nicotine, the pleasure of smoking, and family and peer smoking influences.

*Tobacco industry's
promotion*



Contextual Analysis

It is important to ensure that all members of the community are aware of the harm caused by tobacco and the measures that they can take personally and collectively to reduce that harm. Young people in schools and community settings are a high priority to reach, as they are potential future smokers. Parents and carers can play an important role in preventing uptake, and the community generally needs to be informed about the need for tobacco control measures.

Aware of the harm caused by tobacco

The mass media provides a cost-effective way to encourage smokers throughout the country to take action to stop smoking, to promote the most effective ways to quit, and to promote the support services available for help. Through the use of both paid and unpaid media, information reaches most people, including smokers, in ways that can be personally relevant and motivate action.

Use of mass media to stop smoking

Ministry of Health, Malaysia has implemented the *Tak Nak* anti-smoking media campaign since 2004 to increase public awareness on the dangers of smoking.

This *Tak Nak* anti smoking media campaign aims to reduce the major burden of tobacco-related diseases.

Reduce the major burden of tobacco-related disease

Aims and Objectives

Through the *Tak Nak* anti smoking media campaign, MOH hopes to have Malaysians free from the smoking habit by not starting (to smoke), knowing the method to quit smoking, making the decision to stop smoking, quit smoking and maintain the status of non-smokers after quitting. The following specific goals have been set for smokers and non-smokers respectively.

Free from smoking habits

a) Specific goals for smokers

1. At least 90% of the target group are exposed to the materials/messages at least once or more within the campaign period.

*AIDA marketing model –
Attention, Interest,
Desire, Action*



2. At least 85% of those exposed to the campaign messages understand the messages (diseases related to smoking, benefits of not smoking, methods to quit smoking, facilities provided to quit smoking and how to maintain the status of non-smoker).
3. At least 50% of smokers who understood the messages have / stated intention to quit smoking.
4. At least 50% of those exposed to the campaign messages have taken action to quit smoking

b) Specific goals for non-smokers

1. At least 90% of the target groups are exposed to the materials / messages.
2. At least 90% of those exposed to the campaign messages understand the messages.
3. At least 95% of the target group that understand the messages state intention not to start smoking.

Four-phase campaign and Media campaign message

The *Tak Nak* campaign phases and concentration were: Phase 1 (2004-2005), focused on building awareness on the dangers of smoking and to brand the campaign. Phase 2 (2006-2007), focused on prevention –to stop teenagers from picking up the smoking habit, rehabilitation, capacity building- i.e, provide training and the building of quit smoking services. Phase 3 (2008-2009), focused on efforts on the health risks of tobacco use which include health warning on tobacco packages, diseases related to smoking and methods to quit smoking and reinforcing messages for the target group. Phase 4 (2010), focused on passive smokers and continue with the key messages that were delivered in 2009 “ If you don’t smoke, DON’T START”.

*Four-phase
campaign and Media
campaign message*

The *Tak Nak* anti-smoking campaign provides consistent messages from many sources, repeatedly and over a long period, and portray tobacco as a product that is deadly for everyone. The campaign focuses on developing ways to present cessation messages as news.



A new message gets noticed, gets attention, is remembered, and affects decision-making. This includes new understanding about health risks and new information about quitting.

The audience needs to be continuously presented with news about smoking and quitting, which may put extra pressure on the creative development process and budget. Messages about the health effects of tobacco use to the smoker are effective only if the information or perspective is new. Although smokers report that they know all about the health risks of smoking, cessation messages that present the risks in a new way may cause smokers to reconsider the risks and put quitting on their agenda. These messages may also help ex-smokers remain tobacco-free, providing important reinforcement on an ongoing basis.

Research and Evaluation

Comprehensive research, evaluation and monitoring help us to ensure that our policies and programmes are appropriate and effective and that we are achieving our objectives.

The objective of the evaluation is to measure the effectiveness of the *Tak Nak* media campaign and cover the following elements:-

- i. Measuring the specific objectives set for the campaign
- ii. Measure awareness of the campaign
- iii. Measure the effectiveness of the campaign through the respondent's understanding of the campaign/key message, future attitude towards smoking and intention to change behaviour.
- iv. Understanding the impact the advertisement campaign has on the specific target groups.



The *Tak Nak* smoking campaign has however been a necessary first step in equipping the population with the knowledge required for them to make informed decisions with regards to smoking as well as encouraging smokers to smoke less. They have been successful in the following:

- Shifting the attitudes of smokers – smokers became more aware and concerned of the danger of smoking and the impact of secondary smoking to others.
- Smokers became more open to possibility of quitting smoking with plans to do so.
- The *Tak Nak* anti smoking campaign also reinforces attitudes of non-smokers towards maintaining their status quo and improving the knowledge of the population on the hazards of smoking.

Achievement of the specific objectives of the campaign:

Non Smokers

1. 95% of the target groups have been exposed to the materials / messages.
2. 100% of those exposed to the campaign message understood the messages.
3. 100% of the target group that understood the message have/ stated intention not to start smoking.

Smokers

1. 96% of the target group have been exposed to the materials / messages at least once or more within campaign period.
2. 100% of those exposed to the campaign message understood the messages
3. At least 29% of smokers who understood the messages have / stated intention to quit smoking.
4. 75% of those exposed to the campaign message had taken action to quit smoking.

*Declare intention
to quit smoking and
action taken to quit
smoking*



Lessons learned

Social marketing can be effectively applied as an important tool for behavioural change. It is important to develop specific and measurable objectives in the early stages of planning a media campaign. For the *Tak Nak* anti-smoking media campaign, specific and measurable objectives were formulated, allowing the campaign team to monitor each of the objectives.

Lesson learned

Conclusion

We found that comprehensive, synergistic media campaigns are effective. Successful campaigns have been comprehensive from a media standpoint, working in synergy with other parts of the overall tobacco control programs to create stronger results.

This media campaign works within an overall strategy that seeks to de-normalise smoking by using multiple media channels to reach consumers with messages about why and how to quit smoking and by engaging non-smokers as well.

Nevertheless, this campaign has to continue to further improve the knowledge level of the population with regards to health risks of smoking and the ways in which one can seek help to quit smoking. Although the *Tak Nak* anti-smoking campaign has not reduced the population of smokers, it has however been a necessary step in equipping the population with the knowledge required for them to make an informed decision with regards to smoking.



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ACKNOWLEDGEMENT



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