MaHTAS NEWSLETTER
Volume 17 JAN - JUNE 2015 MALAYSIAN HEALTH TECHNOLOGY ASSESSMENT SECTION

NEWS

Establishing a cost-effectiveness threshold value for health technologies

Cost-effectiveness threshold is generally defined as the estimation of affordability to pay for an individual treatment. However, there is no standardized method in deciding this value. The different methods used include human capital approach using gross domestic product (GDP) per capita or preference elicitation through willingness to pay (WTP) studies. World Health Organization (WHO) recommended the threshold between one to three gross domestic products (GDP) per capita which is based on the concept of human capital that depends on the total income of the country.

Among the importance of cost-effectiveness threshold value are to promote the use of cost-effective intervention, to improve allocation of the healthcare resources, to promote transparency and consistency in decision making and to facilitate the negotiation of health technologies pricing.

A collaborative work on economic evaluation for health technologies has been initiated between Ministry of Health and various local academic institutions such as Monash University, University of Malaya, University Sains Malaysia and National University of Malaysia to strengthen the component of economic evaluation for health technologies. This committee is known as Technical Advisory Committee for Health Technologies Economic Evaluation (TACHTEE) with one of the earliest roles of recommending the acceptable cost-effectiveness threshold value for health technologies.

Following this, a brief presentation on the recommended cost-effectiveness threshold value of one GDP per capita was presented and approved in KPK Khas Meeting 2/2015 in April 2015. Further discussion and collaborative work on economic evaluation for health technologies will be carried out soon to refine the implementation of the cost-effectiveness threshold value.

New CPGs Developed and Technologies Assessed

Four Clinical Practice Guidelines (CPGs) and two Health Technology Assessment (HTA) reports were approved in the Health Technology Assessment and Clinical Practice Guidelines Council Meeting 1/2015 held on 2 June 2015 (see Table 1). Ten technology review reports were also endorsed (see Table 2).

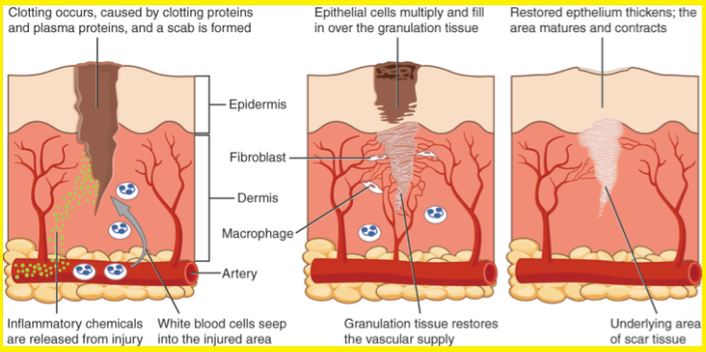
Table 1. Clinical Practice Guidelines and Health Technology Assessment reports approved in HTA-CPG Council meeting 1/2015

Clinical Practice Guidelines (CPG)	
1	Management of Cervical Cancer (2th Edition)
2	Management of Multiple Sclerosis
3	Management of Type II Diabetes Mellitus (5th Edition)
4	Management of Ameloblastoma
Health Technology Assessment (HTA)	
1	Breast Cancer Risk Prediction Model for Health Risk Assessment Module (HRA)
2	Capsule Endoscopy for Colorectal Cancer Screening

Table 2. Technology Review reports endorsed in HTA-CPG Council meeting 1/2015

Cardiovascular Diseases
• Extracorporeal Shockwave Myocardial Revascularization (ESMR)
• Piston Type Mechanical Chest Compression
Congenital, Hereditary, Neonatal Diseases and Abnormalities
• Kangaroo Mother Care
• Pulse Oximetry Screening for Critical Congenital Heart Disease in Newborn Infants
Infectious Diseases
• TB.SPOT.TB Assay - An Update
• Rapid Blood Test Device for HIV, HBV, HCV and Syphilis
Musculoskeletal Diseases
• Computer Assisted Surgery for Unicondylar and Total Knee Replacement
Female Genital Diseases and Pregnancy Complications
• Inexscreen as a Screening Test for Ectopic Pregnancy and Miscarriage
Wellness/Traditional Complementary Medicine
• Acupuncture for Chemotherapy-Induced Nausea and Vomiting in Cancer Patients
Skin and Connective Tissue Diseases
• Ultrasonic Wound Debridement Device

WOUND HEALING



Wound healing is an intricate process where the skin or other tissue repairs itself after injury. In normal skin, the epidermis (surface layer) and dermis (deeper layer) form a protective barrier against the external environment. When the barrier is broken, an orchestrated cascade of biochemical events quickly set into motion to repair the damage. This process is divided into predictable phases which are blood clotting (haemostasis), inflammation, the growth of new tissue (proliferation), and the remodeling of tissue (maturation).

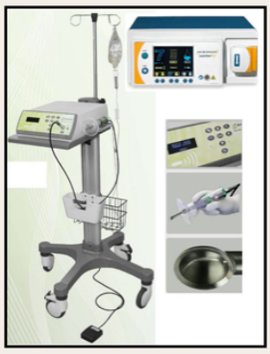
Several new technologies have been introduced for wound management and MaHTAS has assessed five of the technologies as follows;

i Disposable Negative Pressure Wound Therapy

Negative pressure wound therapy (NPWT) or vacuum assisted closure (VAC), which has been developed as an alternative to the standard forms of wound management, incorporates the use of negative pressure to optimise conditions for wound healing.

There was good level of evidence retrieved to show that negative pressure wound therapy was effective to accelerate wound healing in diabetic foot. However, negative pressure wound therapy for other wounds such as pressure ulcer, venous leg ulcer, necrotising fasciitis, grafts and burn were inconclusive and require more high quality evidence. While considering other costs involved and hospital stay, the NPWT may be cost-effective compared to conventional method. However, practitioners have to be cautious of the adverse events related to NPWT.

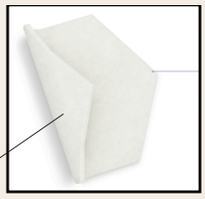
ii Ultrasonic Wound Debridement Device



Low frequency ultrasound is claimed to provide a debridement alternative to, for example, surgical debridement. Ultrasonic waves are also claimed to lead to destruction of bacteria and disruption of biofilms. There was limited evidence retrieved to show that this device was not associated with major complications. However, mild pain was one of the reported adverse events. It seemed to have potential benefit as an adjunct to standard treatment for chronic wounds such as diabetic foot ulcers, venous ulcers and pressure ulcers. However, there was lack of good quality evidence. Hence, more quality evidence is required.

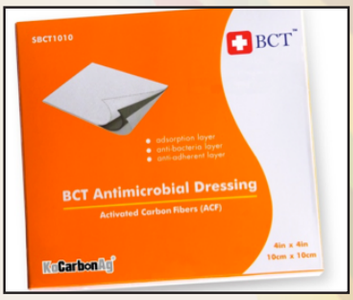
iii Enhanced Wound Care Product

We assessed a group of enhanced wound care solutions and products produced by a company, for the treatment of chronic and surgical wounds, and the control of bleeding. The potential for matrix wound dressing was promising and the outcomes were encouraging for treatment of chronic wounds. However, a large prospective evaluation is warranted to provide further scientific evidence on its effectiveness.



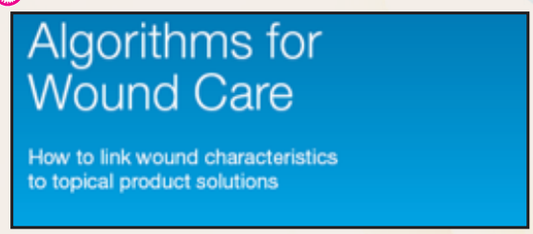
Protease Modulating Matrix composed of 55% collagen, 45% ORC

iv Antimicrobial Dressing with Activated Carbon Fibre (ACF)

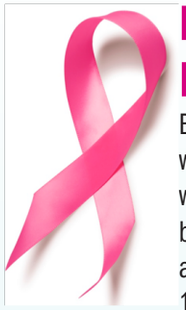


The new development in wound dressing includes the impregnation of silver to Activated Carbon Fibre (ACF) which was claimed to support the silver component and produce a suitable wound dressing with good antimicrobial properties that also reduces cell cytotoxic affection. There was very limited and fair quality of retrievable evidence from the scientific databases to suggest that the use of Antimicrobial Dressing with ACF is effective in wound care. There was no report of adverse events on the use of this technology. However, it has been approved by United States Food and Drug Administration (US FDA) and classified as class II and class IIb medical device in Canada and Taiwan respectively.

v ALGORITHMS for Wound Care



The Algorithms for Wound Care is a set of visual guidelines designed to help general health care professionals assess the wound characteristics that affect subsequent goal identification and treatment. There was fair level of evidence to suggest the use of the Algorithm was effective in the management of wound care. Although there was no retrievable evidence on cost-effectiveness, direct cost showed that the Algorithm seemed to be cheaper than traditional care (ointment and gauze) with or without a standardised wound management algorithm. However, the user of this algorithm must be well trained in the assessment of the chronic wound. The effectiveness, safety and cost-effectiveness of the solutions and dressings were not included in this review.



Breast Cancer Risk Prediction Model for Health Risk Assessment Module

Breast cancer is the commonest cancer among women and the commonest cause of cancer death worldwide. Similarly, in Malaysia, it was reported to be the commonest cancer in women with an overall age standardized incidence rate (ASR) of 29.1 per 100,000 population (National Cancer Registry 2007), higher than incidence in other developing countries (ASR of 20 per 100,000 population). About 30 to 40% of Malaysian women presented at a later stage of breast cancer (stage III and IV). Hence, affordable and effective approaches in cancer control are needed for early detection, diagnosis and treatment of breast cancer. In addition, the growing public awareness of breast cancer and its risk factors, with availability of medical and surgical risk reduction options has led consultation of many women on their breast cancer risk. Considerable effort has been directed at identifying risk factors and developing risk prediction models for breast cancer. A risk prediction model is a mathematical equation (statistical tool) which uses multiple predictors designed to quantify the risk an individual woman would develop a particular cancer in a defined period. It provides an estimation of disease risk that can be used to guide management for women at all levels of risks. Reliable, accurate prediction models can inform future disease burdens, health policies, individual decisions on future screening behaviour and adoption of risk reduction strategies, counsel those at risk, design prevention strategies for at risk populations and plan intervention trials. Subsequently, the adoption of such models should guide decision-making, improve patient outcomes and the cost-effectiveness of care. In Malaysia, currently there is no risk prediction model for breast cancer in existing cancer control approaches. The review demonstrated that the models studied had good calibration and moderate discriminative ability. However, further validation of the model need to be done until a well-fitted model with better predictive ability tailored to Malaysian population established. This model also needs to be continually validated to determine the consistency of its performance.

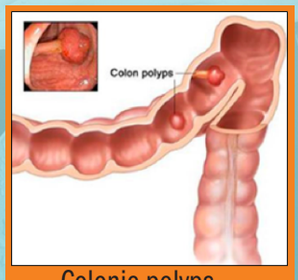
Capsule Endoscopy for Colorectal Cancer (CRC) Screening

Colorectal cancer (CRC) develops slowly from a growth of tissue or polyp on the inner lining of the colon or rectum. According to the latest report of the National Cancer Registry (NCR) in Malaysia 2007, colorectal cancer (CRC) is the commonest cancer among men and the second most common cancer among women. Most of the patients presented late and many cancer cases are diagnosed from symptomatic patients. At present, we relied on opportunistic screening program using various methods including faecal occult blood test (FOBT), flexible sigmoidoscopy and colonoscopy since mass population screening is not yet available. Low compliance to colonoscopy has been reported and these can be attributed to fear of pain, embarrassment and requiring sedation.

Capsule endoscopy (CE) is a new technology which offers an alternative non-invasive technique that allows exploration of the colon without requiring sedation and air insufflations. Therefore, a Health Technology Assessment (HTA) was conducted to assess the diagnostic accuracy, safety, effectiveness and cost-effectiveness of capsule endoscopy for CRC screening in the adult population.

The first generation colon capsule endoscopy (CCE-1) uses a small, wireless camera contained in an easy-to-swallow and disposable capsule specifically designed to visualize the colon. The capsule has two imagers that enable it to acquire video images from both ends at an angle of 156º. The second generation colon capsule endoscopy (CCE-2) is similar to CCE-1 except it consists of a slightly bigger, ingestible video capsule. It is also provided with a new portable wireless data recorder and user-friendly interface to send active, customised reminders to the patient.

The accuracy of CCE-1 was found to be suboptimal as compared to colonoscopy. There were wide variations in the sensitivity, specificity, positive predictive value and negative predictive value of CCE-1 reported in the studies. The sensitivity of CCE-2 was found to be comparable to the sensitivity of colonoscopy although the specificity was slightly low. There was no retrievable evidence on mortality rate, survival rate and quality of life related to screening CRC using capsule endoscopy in the general population. Most of the adverse events related to CCE were reported as mild and related to bowel preparation. Regarding cost-effectiveness of CCE-1 in screening for CRC, the evidence was limited. According to simulation using a Markov model, an increase of 30% in compliance to CCE-1 compared to colonoscopy, has resulted CCE-1 to be the more cost–effective option for CRC screening. As CCE is currently not being used yet in Malaysian health care facilities, the cost per capsule can be estimated from the cost reported in the US, to be around RM 1688.25 (USD 500; 1 USD = RM 3.37).



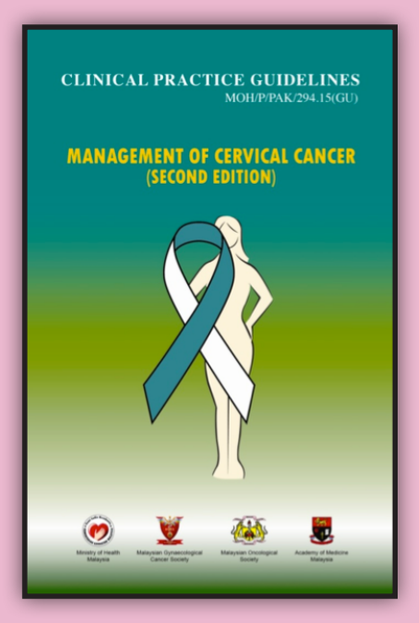
Colonic polyps

Capsule endoscopy

Based on this review, CCE-2 may be considered as a diagnostic tool to identify colonic polyps or CRC among patients with average or increased risk of CRC, particularly among those who are unwilling to undergo colonoscopy, have contraindication for colonoscopy and have history of incomplete colonoscopy. However, for general population screening for CRC, capsule endoscopy cannot be recommended yet until further quality evidence is available.

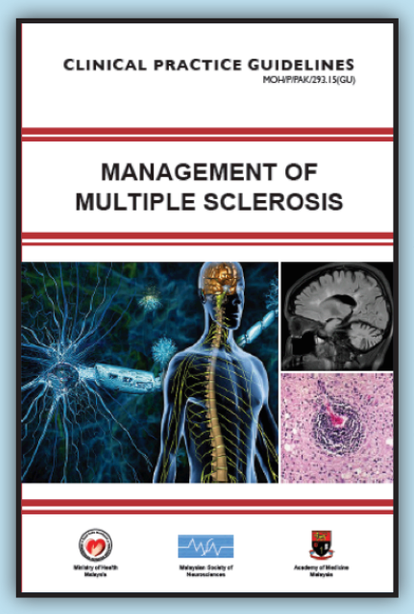
CPG KEY MESSAGES

MANAGEMENT OF CERVICAL CANCER (SECOND EDITION)



1. Cervical cancer is the second most common cancer among women in Malaysia and is potentially curable.
2. A definitive diagnosis of cervical cancer is made by histopathological examination of cervical tissue.
3. Histopathological reports of cervical cancer should include core histological data, following standards and datasets for reporting cancers (Dataset for histological reporting of cervical neoplasia - 3rd Edition).
4. All newly diagnosed cervical cancer should be clinically staged according to the Revised FIGO Cervical Cancer Staging 2009 before initiating treatment. Radiological imaging may be offered to provide additional information on nodal status and systemic spread.
5. In the management of cervical cancer, patients should be thoroughly counselled & involved in the decision-making process.
6. In early stage cervical cancer (up to FIGO stage IIA, excluding bulky disease stage IB2 & IIA2), surgery is the preferred modality of treatment. Definitive concurrent chemoradiation therapy (CCRT) is an alternative to surgery. Adjuvant chemoradiotherapy should be considered in patients with high risk of recurrence.
7. In locally advanced cervical cancer (FIGO stage IIB to IVA, including bulky disease stage IB2 & IIA2), CCRT is the primary modality in which treatment time should not exceed 8 weeks.
8. Post-treatment cervical cancer patients may be followed up every 3 months in the first year, 4 months in the second year, 6 months in the third to fifth year & annually thereafter.
9. The treatment of cervical cancer in pregnancy should be individualised with multi-disciplinary team involvement.
10. Cervical cancer patients should receive palliative care especially in advanced disease & preferably referred to a palliative care team.
11. Psychosocial assessment & psychoeducation should be offered for cervical cancer patients.

MANAGEMENT OF MULTIPLE SCLEROSIS



1. Multiple sclerosis (MS) is an idiopathic inflammatory demyelinating disorder characterised by neuroinflammation & neurodegeneration. The hallmark of MS is attacks or exacerbations affecting different parts of the central nervous system (CNS) which are separated in time & space in the absence of any other better explanation. It is a disease of the young (20s to 40s) & commoner among women.
2. An attack/relapse/exacerbation in MS is defined as a patient-reported symptom or objectively observed signs typical of an acute inflammatory demyelinating event within the CNS either current or historical of at least 24 hours in the absence of fever or infection.
3. Clinically isolated syndrome (CIS) is the first clinical episode in which a patient has symptoms & signs suggestive of an inflammatory demyelinating disorder of the CNS. Patients with CIS need to be stratified according to risk of conversion to Clinically Definite Multiple Sclerosis (CDMS).
4. The commonest type of MS is relapsing-remitting disease (85%).
5. The McDonald criteria 2010 should be used in the diagnosis of MS.
6. Magnetic resonance imaging (MRI) of the brain & spine utilising the MRI Diagnostic Criteria should be used in the diagnosis of MS. Cerebrospinal fluid oligoclonal bands & evoked potentials may be useful in the diagnostic workup.
7. In the diagnosis of MS, it is important to rule out other possible mimickers of MS [idiopathic inflammatory demyelinating disease such as neuromyelitis optica spectrum disorder, vasculitis, sarcoidosis and small vessel disease] & identify the “Red Flags” that may suggest an alternative diagnosis to MS.
8. Patients with clinical features highly suggestive of MS should be referred to a neurologist.
9. Disease progression in MS should be assessed clinically by using Kurtzke’s Expanded Disability Status Scale upon diagnosis & follow-up. MRI should be done at baseline, annually & earlier if clinically indicated. Neuroimaging parameters in monitoring MS disease activity are T2-weighted & gadolinium-enhancing T1-weighted lesions.
10. The management of MS involves:
    - treatment of acute attacks (this includes CIS & relapses in CDMS)
    - prevention of relapses
    - multidisciplinary interventions for MS-related symptoms

Health Technology Assessment Course in Kuching, Sarawak

Group photo of all participants

As the continuous training for health technology assessment, a course was conducted in Hotel Grand Continental, Kuching, Sarawak from 8 to 9 April 2015. A total of 32 participants consisting of hospital directors, family medicine specialists, public health specialists, dental officers, pharmacists from Sarawak and Federal Territory of Labuan attended this course. The participants were first underwent the ice-breaking session, followed by a jam-packed days of lectures. During the lectures, the participants were exposed to the framework, the work process and the usage of health technology assessment. The participants were then divided into groups for critical appraisal exercise and later presented the outcome of their discussion.

Training of Core Trainers (ToT) on CPG Management of Bipolar Disorder in Adults

The CPG entitled Management of Bipolar Disorder in Adults was published in July 2014. A training module was developed out of it with the purpose to actively disseminate the content of the CPG by training healthcare providers on it. The ToT using the module was conducted successfully at Hilton Kuala Lumpur Hotel on 22 - 24 April 2015. A total of 55 participants nationwide consisting of psychiatrists and family medicine specialists attended the training.

Chairman of the CPG giving the ToT briefing

Systematic Review Workshop on Evidence-Based CPG Development & Implementation 1/2015

Lecture on retrieval of evidence

Group work on critical appraisal

The first workshop of the year for the annual systematic review training was successfully held at Hotel Bayview, Melaka from 27 - 30 April 2015. A total of 33 participants attended the workshop consisting mainly the Development Group members of CPG on Management of Asthma in Adults (Second Edition) and CPG on Management of Diabetes in Pregnancy. They were multidisciplinary healthcare professionals from the specialties of Respiratory Medicine, General Medicine, Emergency Medicine, Endocrinology, Obstetrics & Gynaecology, Family Medicine and others.

The objectives of the workshop were to provide knowledge and develop skills in the development of evidence-based CPG, and to encourage its implementation. The workshop was made up of lectures on relevant topics followed by various group works and presentations by the participants. The participants actively participated in the training and gave an overall good rating of it.

4th HTAsiaLink Annual Conference

Datin Dr. Rugayah Bakri as a panelist in a forum entitled Experiences and Difficulties in Developing HTA

The 4th HTAsiaLink Annual Conference was held by Center for Drug Evaluation (CDE), Taiwan on 13 -15 May, 2015. The main theme of the conference was "Sharing Experiences of HTA for Universal Health Coverage (UHC) in Asia."

On 12 May 2015, at the Pre-Conference workshop, Datin Dr. Rugayah shared Malaysia experiences about the success and failure in implementing HTA for policy making in a plenary session entitled: Overview of the use of HTA in Health Policy: Asian Experiences. On 13 May 2015, Datin Dr. Rugayah Bakri was one of the panelists for a forum session entitled: Experiences and Difficulties in Developing HTA. In the Health System Research oral presentation session, Puan Noormah Mohd Darus presented two technology review topics entitled: VNUS Radiofrequency Ablation (RFA) for Varicose Veins (on behalf of Mr Syful Azlie Md Fuzi) and T.SPOT.TB Assay. Datin Dr. Rugayah Bakri became one of the moderators for the Economic Evaluation session. During lunch on the last day, there was an HTAsiaLink Board meeting which was attended by both Datin Dr. Rugayah and Puan Noormah Mohd Darus. Among the issues brought up was to have the next HTAsiaLink 2016 conference which was suggested to be held in Singapore.

MaHTAS Roadshow

Since its inception in 1995, MaHTAS has released products such as the Health Technology Assessment (Health Technology Assessment Report), mini Health Technology Assessment (Technology Review) and others to help the ministry to make decisions or policies related to health technology. MaHTAS also published Clinical Practice Guidelines to ensure that the medical care we provide are evidence-based. However, the understanding of the role of MaHTAS and its products among the employees of Ministry of Health (MOH) needs to be improved. Since February 2015, the section started to conduct roadshows to the divisions within MOH, state health offices and some hospitals/institutes in Malaysia, to promote its work and products. Up to June 2015, we have visited of 18 MOH offices, including 8 divisions, 6 state health offices and 4 hospitals/ institutes to give awareness on MaHTAS to 826 health personnels.

• Oral Health Division

• Hospital Rehabilitasi Cheras

• Hospital Kuala Lumpur

• Pharmaceutical Services Division

• Institut Kanser Negara

• National Blood Centre

• Melaka State Health Department

2015 INAHTA Congress

Photo of the "INAHTA family" taken at the Congress

The Congress theme is *The INAHTA Family: Building Trust & Strengthening Connections*. The Congress was held at the Voksenasen Hotel & Conference Centre Oslo Norway from 17 to 18 June 2015. The Congress was attended by Dr. Junainah Sabirin and Dr. Roza Sarimin.

12th HTAi Annual Meeting 2015

The HTAi 2015 Annual meeting was conducted in Oslo, Norway. The focus was on 'Global Efforts in Knowledge Transfer: HTA to Health Policy and Practice'. Two participants from MaHTAS attended the meeting and were involved in the poster, oral and panel presentations.

Dr. Roza Sarimin presenting on Pneumococcal Conjugate Vaccines for Children Below 5 Years Old

Dr. Junainah Sabirin with other panelists from HTAsiaLink (Thailand, Taiwan, Korea and Singapore) during the panel session on HTA Role in Ensuring Universal Health Coverage in Asia Pacific Region

• Traditional and Complementary Medicine Division

Awareness and Utilisation of Clinical Practice Guidelines 'Management of Dengue Infection in Adults: revised 2nd Edition' among Malaysian Doctors

A cross-sectional study was conducted among registered medical practitioners practicing in public and private Health Clinics and Hospitals in Malaysia, to evaluate the level of awareness and utilisation of CPG Management of Dengue Infection in Adults (revised 2nd edition). This study was commenced with collaboration from Malaysian Health Technology Assessment (MaHTAS), Medical Development Division; Vector Control Sector, Disease Control Division, Ministry of Health and Social and Preventive Medicine Department, Faculty of Medicine, University of Malaya. A multistage proportionate random sampling according to region (Central, Northern, Southern, Eastern, Sabah and Sarawak) was performed to select study participants. This study used a self-administered questionnaire as the study instrument. A total of 860 validated self-administered questionnaires were distributed and collected from all participants either by hand, post or fax between January and November 2014.

Response rate was 84% vs 82% (public hospitals vs private hospitals), and lower for clinics (70% vs 64% for public clinics vs private clinics), respectively. Majority (76%) of the respondents were medical officers with a mean length of service of 14 years. This study demonstrated that higher percentages of doctors from public facilities (99%) were aware of the CPG compared to those in private facilities (84%). The proportion of doctors utilising the CPG were also higher (98%) in public facilities compared to private facilities (86%). A high proportion of doctors used the CPG in both public (97%) and private (94%) hospitals were also observed. However, only 69% of doctors in private clinics utilised the CPG compared to doctors in public clinics (98%). Therefore, there is a need to increase the level of CPG utilisation among doctors especially those practicing in the private clinics.

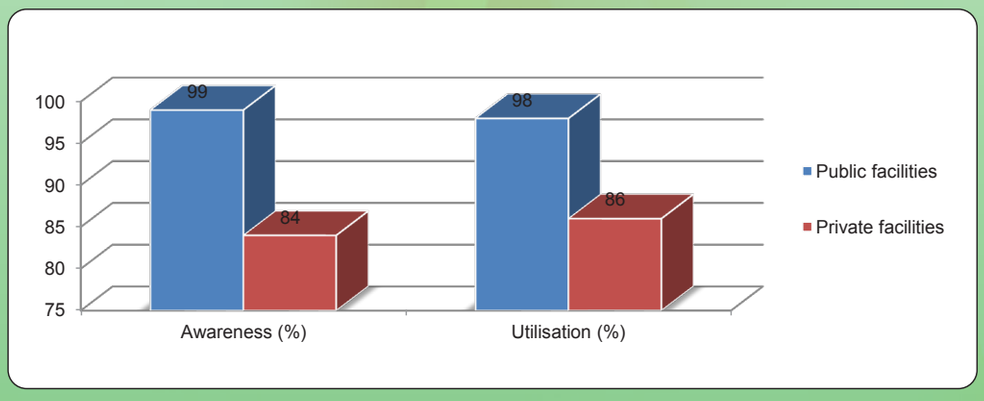
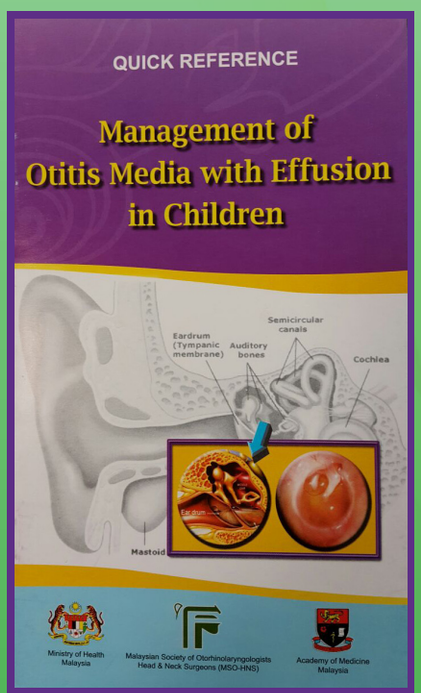


Figure 1: Percentage of awareness and utilisation of CPG Management of Dengue Infection in Adults (revised 2nd Edition)

Quick Reference Utilisation Survey 1/2015 - Management of Otitis Media with Effusion in Children

Monitoring and evaluation of CPG implementation activities has been started in year 2011 and has been continued biannually since then. The monitoring was done by a survey to targeted respondents using Quick Reference (QR) Utilisation Feedback Form distributed to selected Ministry of Health (MOH) facilities. In the first survey for 2015, CPG Management of Otitis Media with Effusion has been selected. A total of 292 respondents from 51 selected healthcare facilities participated in this survey (83.4% response rate).

The survey found an acceptable level of awareness and utilisation with 72.3% of respondent used the QR in their practice. They found this Quick Reference was useful as a reference material, as a tool to assist in decision making as well as a guide in further understanding of the disease.



MaHTAS
NEWSLETTER

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Courses and Workshops Conducted from January until June 2015

Courses / Workshops	Date
• Health Technology Assessment Training for East Malaysia, Sarawak	8 - 10 April 2015
• Training for Core Trainers on CPG Management of Bipolar Disorder in Adults	22 - 24 April 2015
• Systematic Review on Evidence-based CPG Development and Implementation Workshop 1/2015	28 - 30 April 2015

Courses and Workshops Planned from July until December 2015

Courses / Workshops	Date
• Budget Impact Analysis Workshop 2015	8 October 2015
• Systematic Review on Evidence-based CPG Development and Implementation Workshop 2/2015	20 - 22 October 2015
• Training for Core Trainers on CPG Management of Neonatal Jaundice (Second Edition)	26 - 27 October 2015
• Health Technology Assessment Training for Expert Committee and Dental Officers	2 - 4 November 2015
• Basic Applied Statistics for Medical Research Workshop	11 - 12 November 2015

Turnover of MaHTAS Staffs

We are pleased to introduce

Mr. Syful Azlie Md Fuzi
Scientific Officer C48
Joined MaHTAS on
2 January 2015

Mr. Mohd Tholib Ibrahim
Medical Assistant Officer U32
Joined MaHTAS on
12 January 2015

Mdm. Maria Ja'afar
Pharmacist U48
Joined MaHTAS on
30 March 2015

Mdm. Rosnani Abdul Latip
Nurse U32
Joined MaHTAS on
6 April 2015

Thank you for your contribution

Mdm. Asmirah Md. Redzuan
Pharmacist U44
Left MaHTAS on
30 March 2015

Mdm. Sin Lian Tye
Nurse U44
Left MaHTAS on
17 April 2015