



# MaHTAS

Volume 16 JULY-DEC 2014 MALAYSIAN HEALTH TECHNOLOGY ASSESSMENT SECTION

## HORIZON SCANNING OF HEALTH TECHNOLOGIES

## NEWS

Innovation in health technologies is important to meet the challenges in improving quality of health care and patient outcomes. Rapid development and adoption of health technologies and premature introduction of new technologies may increase health care expenditure. Thus, selection of the potential health technologies is crucial to improve patient outcomes and refine health system efficiency, and should be based on scientific evidence.

Horizon Scanning of health technologies or also known as early awareness and alert (EAA) system is the systematic identification of new and emerging health technologies that have the potential impact on health, health services, and/or society; and which might be considered for health technology assessment.

The system can also identify health technologies that are becoming obsolete. The aim is to provide timely advice to allow appropriate implementation and/or adoption of health technologies, and to facilitate timely budgetary planning. The system will help in decisions on undertaking primary and secondary researches. Emerging technologies identified will also be monitored when the evidence is inadequate.

The main difference between Health Technology Assessment (HTA) and horizon scanning system is that the later focuses on technologies early in the life cycle while HTA focuses on technologies that have already diffused into clinical practice. Horizon scanning systems are sometimes viewed as the first stage of a comprehensive HTA process. New technologies identified through horizon scanning system which require further

evaluation will be prioritised for HTA.

Horizon Scanning systems had been practised in many developed countries such as the United Kingdom, Canada, Spain, Italy, France, Switzerland, Australia and New Zealand.

It is part of the regular approval process in many countries worldwide. A survey of International Network of Agencies for HTA (INAHTA) members in 1998 showed that 30% of HTA agencies have continued and structured EAA activities.

MaHTAS is setting up horizon scanning system for Ministry of Health (MOH) Malaysia. In September 2014, a proposal for horizon scanning activity was presented and approved at Mesyuarat Khas Ketua Pengarah Kesihatan Bil. 4/2014.

Following the approval, MaHTAS organised a Horizon Scanning Workshop: Manual Development from 13 - 15 October 2014 at Kings Green Hotel, Malacca. The objectives of the course were to expose the participants on the conduct of horizon scanning and to develop a horizon scanning manual. A total of 31 participants comprising of Clinical Specialists, Public Health Physicians, Medical Officers, Dentists, Pharmacists and other health care professionals from MOH and other related agencies such as SIRIM, MIDA and BioTech Corporation attended the workshop.



Participants of Horizon Scanning Workshop: Manual Development

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**PUBLICATIONS IN 2014**

**Table 1: CPG and HTA Reports approved in HTA-CPG Council Meeting 1/2014 and 2/2014**

|  |
|--|
| <b>Clinical Practice Guidelines (CPG)</b>  |
| <ol style="list-style-type: none"> <li>1. Management of Bipolar Disorder in Adults</li> <li>2. Management of Autism Spectrum Disorder in Children and Adolescents</li> <li>3. Management of Acute ST Segment Elevation Myocardial Infarction (STEMI) (Third Edition)</li> <li>4. Management of Heart Failure (Third Edition)</li> <li>5. Management of Neonatal Jaundice (Second Edition)</li> </ol> |
| <b>Health Technology Assessment (HTA)</b>  |
| <ol style="list-style-type: none"> <li>1. Pneumococcal Conjugate Vaccine for Children below 5 years old</li> <li>2. Continuous Intrathecal Baclofen (ITB) Infusion for Severe Spasticity and Dystonia</li> </ol>   |

**Table 2: TR Reports endorsed in HTA-CPG Council Meeting 1/2014 and 2/2014**

|   |  |
|---|--|
| <b>Cardiovascular Diseases</b>  | <b>Cerebrovascular Diseases</b>  |
| Chlorthalidone for Hypertensive Patients  | Transcranial Doppler Ultrasound (TCD US) and Cerebral Computed Tomography Perfusion (CTP) for Aneurysmal Subarachnoid Haemorrhage (aSAH) |
| <b>Nervous System Diseases</b>  | <b>Digestive System Diseases</b>   |
| Ketogenic Diet Treatment for Epilepsy   | Colorec Bowel Aid with Perianal Support  |
| <b>Neoplasms</b>  | <b>Skin and Connective Tissue Diseases</b>   |
| Epidermal Growth Factor Receptor (EGFR) Mutation Test for Patients with Non-Small Cell Lung Cancer (NSCLC)                                  | Disposable Vacuum Wound Therapy  |
| Avemar Granulate as Dietary Food/Special Purpose Food for Cancer  | Antimicrobial Dressing with Activated Carbon Fibre (ACF)   |
| Photodynamic Therapy for Cancer Treatment – An update   | <b>Eye Diseases</b>  |
| OncoE6™ Cervical Screening Test Kit   | Intraocular Lens (IOL) Implantation and Opacification-An update  |
| Infrared Regulation Thermography for Cancer   | <b>Organisational</b>  |
| <b>Infectious Diseases</b>  | Effect of Promoting Formula Milk for Toddler and Pregnant as well as Breastfeeding Mothers on the Breastfeeding Practice                 |
| Screening Patients with Diabetes Mellitus for Tuberculosis  | <b>Wellness/ Traditional and Complementary Medicine</b>  |
| Enercel® for Patients with Infectious Diseases and Motor Neuron Disease   | Placenta for Cosmetic Purpose and Cell Regeneration  |
| Typhoid Carrier Test (Typhidot-C)   | Collagen for Anti-aging Treatment, Enhance Cell Regeneration and Boosting for Immune System  |
| <b>Respiratory Diseases</b>   | Colostrum for Cosmetic Purpose and Cell Regeneration   |
| Bronchial Thermoplasty  | <b>Stomatognathic Diseases</b>   |
| NOSK Nasal Filter   | Cone Beam Computed Tomography  |
| <b>Female Genital Diseases and Pregnancy Complications</b>  |  |
| Water birth   |  |
| Screening of Pregnant Women Aged 40 years and above for Cardiac Abnormalities Using Electrocardiography (ECG) to Prevent Maternal Mortality |  |

*All HTA and TR reports, and CPGs are accessible online at <http://www.moh.gov.my> and myMaHTAS mobile apps*

# Dietary Food for Special Medical Purposes

Dietary foods for special medical purposes are a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of patients. The foods may be used only under medical supervision. They are intended for exclusive or partial feeding of patients with a limited or impaired capacity to take, digest, absorb or metabolised ordinary foodstuffs or certain nutrients contained therein. They are also dedicated for those who have other special medically-determined nutrient requirements,

whose dietary management cannot be achieved only by modification to the normal diet, by other foods for special dietary uses, or by a combination of the two (CODEX STAN 180-1991).

The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated by scientific evidence, to be safe and beneficial.

## 1 Ketogenic Diet Treatment for Epilepsy



Example of ketogenic diet

Ketogenic diet is a high-fat, adequate-protein, low-carbohydrate diet that is used primarily to treat difficult-to-control (refractory) epilepsy in children. The diet forces the body to burn fats rather than carbohydrates which then converted into fatty acids and ketone bodies. The ketone bodies enter the brain and replace glucose as an energy source. An elevated level of ketone bodies in the blood, a state known as ketosis, leads to a reduction in the frequency of epileptic seizures.

A systematic review was conducted to review evidence on the efficacy, safety, and cost effectiveness of a ready-to-drink liquid formula ketogenic diet available commercially for infant and young children with epilepsy. The main raw materials are refined olive oil, soybean oil, whey protein concentrate, sodium caseinate and PE-30A (emulsion stabiliser).

There was limited but good level of retrievable evidence on the effectiveness of ketogenic diet treatment for epilepsy in infant and young children. All studies seemed to show more than 50% reduction in seizure compared to their comparative controls at three months, and this response was maintained for up to a year. However, the studies had small sample sizes and of short duration. The randomisation process was not specified and none were blinded. Outcome measures relating to seizure control such as seizure reduction were not well-defined and specified. There was no retrievable evidence on United States Food and Drug Administration (US FDA) approval or CE mark for this product. Some studies recorded a range of side effects, the most prevalent being gastrointestinal effects. Based on the review, ketogenic diet can be recommended to be used as a treatment for epilepsy in infant and young children.

## 2 Avemar Granulate as Dietary Food/Special Food for Cancer



Wheat germ

Separated wheat germ is traditionally included in healthy foods, and consumed or served as raw material for extracts rich in vitamin E. During the 1990s, a new, fermented wheat germ extract for human consumption was invented by Professor Máté Hidvégi in Hungary. The standardised manufacturing technology included the extraction of wheat germ, the fermentation of the extract, followed by separation of the fermentation liquid, microencapsulation, drying, and granulation. The resulting powder was named Avemar pulvis (or simply Avemar), and the granulate is known as Avemar.

A systematic review was conducted to review the evidence on the efficacy, safety and cost effectiveness of Avemar granulate as a dietary food/special purpose food for cancer before it can be imported and used routinely in Malaysia.

Five non-randomised clinical trials and comparative studies were included in this review. Based on the review, benefits to patients with colorectal cancer, head and neck cancer as well as post surgical cancer patients cannot be determined as the evidence are limited and of poor quality of evidence. Hence, further research into the role of Avemar as a dietary food / special purpose food in these areas is warranted.

**CPG Management of Neonatal Jaundice (Second Edition)**

Neonatal Jaundice (NNJ) or neonatal hyperbilirubinaemia is one of the most common medical conditions in newborn babies. All babies have a transient rise in serum bilirubin but only about 75% are visibly jaundiced. Jaundice is clinically detectable when the serum bilirubin levels are  $>85 \mu\text{mol/L}$  (5 mg/dl). NNJ is more common among Asian babies and varies with races. There are also other risk factors that may be associated with severe jaundice including prematurity, G6PD deficiency and ABO incompatibility. Due to improving survival rates of preterm babies, and better identification of risk factors over the years, there is a need to address the management of jaundice in this group of babies.

Hyperbilirubinaemia is either unconjugated or conjugated. Without treatment, high levels of unconjugated bilirubin may lead to acute and chronic bilirubin encephalopathy. This may cause neurodevelopmental problems including athetoid cerebral palsy, hearing loss and visual impairment.

The CPG on the Management of Jaundice in Healthy Term Newborns was developed in 2003 as a guide to clinical practice, based on the best available evidence at that time. Since then, novel techniques in the assessment of jaundice, different modalities of treatment and newer concepts of prevention have been introduced. Based on the recent evidence, this updated CPG aims to assist healthcare providers in clinical decision-making and to provide a standard framework for the management of NNJ in the country. Among others, it features algorithms on management of NNJ and predischarge screening, tables on phototherapy and exchange transfusion levels, and advices to both parents/carers and healthcare providers on NNJ. To assist in the implementation of the CPG, a clinical audit indicator for quality management based on the incidence of severe NNJ (TSB  $\geq 20 \text{ mg/dL}$  or  $\geq 342 \mu\text{mol/L}$ ) has been proposed. The CPG will be followed by its implementation strategies such as a Quick Reference and a Training Module.

..... **KEY MESSAGES** .....

**1** NNJ is common in newborn babies. Severe NNJ can lead to acute and chronic bilirubin encephalopathy.

**2** NNJ within 24 hours of life is abnormal and needs urgent attention.

**3** Assess all babies for jaundice at every opportunity. Methods include visual assessment, transcutaneous bilirubinometer (TcB) or total serum bilirubin (TSB).

**4** The adequacy of breastfeeding, weight and hydration status of all babies should be assessed during the first week of life. Refer babies with weight loss  $\geq 7\%$  of birth weight for further evaluation.

**5** Screen all babies for Glucose-6-phosphate dehydrogenase (G6PD) deficiency. Babies with G6PD deficient should be admitted for the first five days of life.

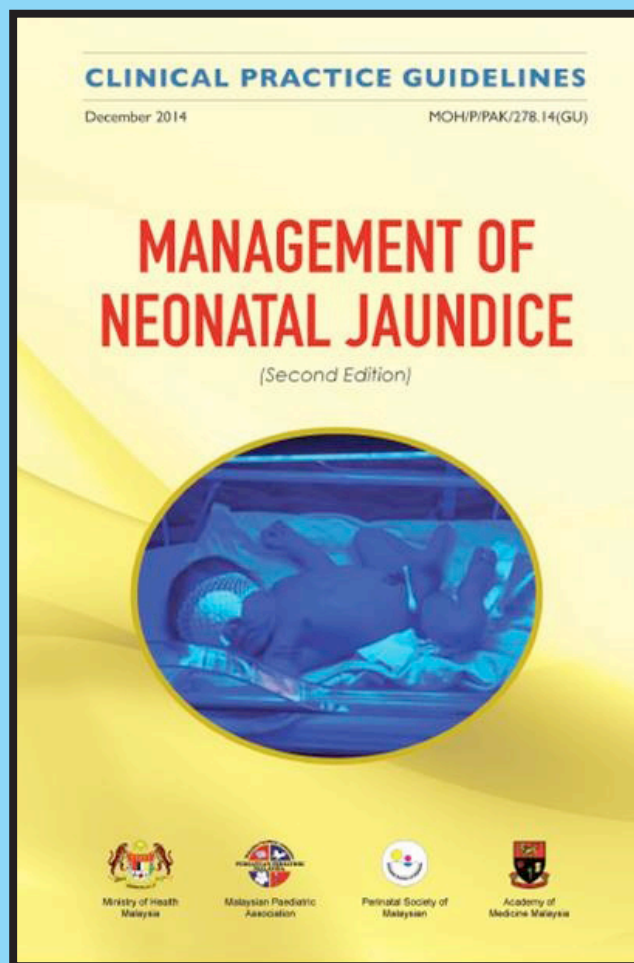
**6** Start phototherapy when TSB reaches the phototherapy threshold. The threshold is lower in preterm and low birth weight babies.

**7** Consider exchange transfusion (ET) when TSB reaches the ET threshold. This should follow a standardised protocol and be supervised by experienced personnel.

**8** Babies discharged  $<48$  hours after birth should be seen by a healthcare provider in an ambulatory setting or at home within 24 hours of discharge.

**9** Continue breastfeeding in babies with jaundice. Provide adequate lactation support to all mothers, particularly those with preterm babies.

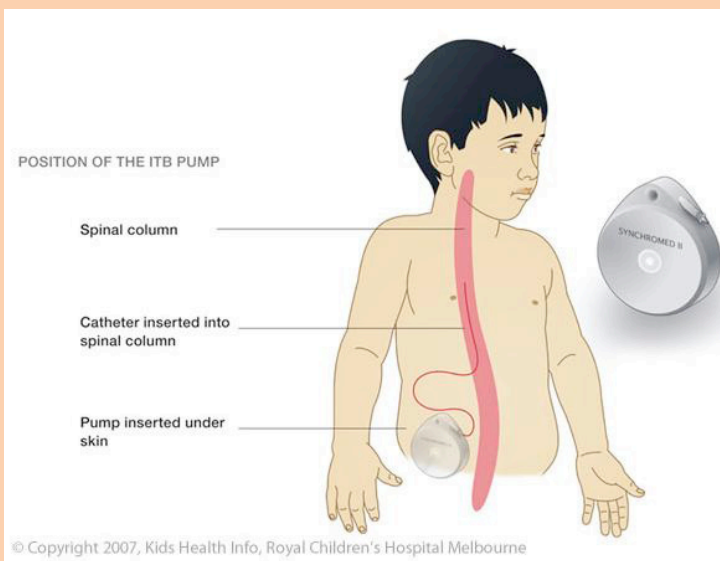
**10** Babies with acute bilirubin encephalopathy (ABE) should have long-term follow-up to monitor for neurodevelopmental sequelae. Auditory Brainstem Response testing should be done within the first three months of life.



## Continuous Intrathecal Baclofen (ITB) Infusion for Severe Spasticity and Dystonia

Spasticity is a common problem in many conditions that affect motor function, such as stroke, traumatic brain injury (TBI), spinal cord injury, multiple sclerosis, and cerebral palsy (CP). Severe, uncontrolled spasticity impairs ambulation and self-care of patients. Dystonia has been classified as primary, primary plus, secondary, and heredo-degenerative. Secondary dystonia is the most common type due to its association with two frequent conditions: CP and TBI. It is typically generalised and causes progressive disability, discomfort and deformity. Intrathecal delivery of baclofen has been used to control spasticity in cases in which oral medications have failed to bring about the expected results. However, continuous ITB infusion has not been practised in any government hospitals in Malaysia. Therefore, there is a need to assess the feasibility of using continuous ITB infusion for treatment of patients with severe spasticity, severe dystonia or having both conditions which are uncontrolled by conventional treatment.

Seventy six articles fulfilled the inclusion and exclusion criteria and were included in this review. There was fair level of retrievable evidence to suggest that continuous ITB infusion was safe and effective in reducing dystonia, and spasticity apart from improving function and quality of life in patients with severe spasticity, severe dystonia or having



both spasticity and dystonia who were unresponsive or cannot tolerate oral baclofen. Patients and caregivers were satisfied with the treatment. Although there was risk of adverse events related to continuous ITB infusion, the treatment is considered relatively safe, minimally invasive and reversible.

Continuous ITB infusion for treatment of patients with severe spasticity seemed to be cost-effective in some countries. However, there was no retrievable evidence on the cost-effectiveness of continuous ITB infusion for treatment of patients with severe dystonia or having both spasticity and dystonia. This treatment system requires long term monitoring by an experienced healthcare team. Besides proper training for the healthcare teams, education for patients and caregivers is critical in avoiding severe consequences of ITB withdrawal. Despite large upfront cost for the procedure, the long-term effects can be potentially money saving.

Continuous ITB infusion may be utilised in patients with severe spasticity or severe dystonia or having both conditions who are unresponsive or cannot tolerate oral baclofen, by trained multidisciplinary healthcare teams. Criteria for patient selection should be developed. Records of patients on continuous ITB infusion should be maintained by the treating physicians. Patient's outcome research on a long term basis is warranted.

## INTERNATIONAL PARTICIPATIONS

### Asia-Pacific Regional Capacity Building for HTA (ARCH) Initiative



Dr. Izzuna as one of the panelist in a panel session on The Current Stakeholder Landscape: Barriers and Facilitators to HTA

The second workshop of Asia-Pacific Regional Capacity Building for HTA (ARCH) Initiative was held in Bali, Indonesia on 28 - 29 August 2014. Eleven countries in the region namely Malaysia, Singapore, Philippines, Indonesia, Thailand, Laos, Cambodia, Vietnam, China, Taiwan and Japan participated in the workshop. The workshop focused on the conduct of economic evaluation for Tobacco Control. Mr Matthew Glover from Brunel University, United Kingdom shared his team experience in developing a Tobacco Return on Investment Tool for National Institutes for Health and Care Excellence (NICE), United Kingdom.

ARCH Initiative for 2014 ended with ARCH Initiative Conference on Health Technology Assessment and Tobacco Control on 21 November 2014 in Singapore. Building on the momentum from the technical training workshops in Manila and Bali, the conference focused on education and advocacy for incorporating HTA into decision making and the mutual development of better methods to assess value for money of investments, focusing on tobacco control and including examples of its successes in APEC economies and other regions.

Dr. Izzuna was one of the panelist in a panel session on "The Current Stakeholder Landscape: Barriers and Facilitators to HTA" and Madam Sin Lian Thye presented on "Evaluating Tobacco Alternatives: e-cigarettes and Shisha".

**INTERNATIONAL PARTICIPATIONS**

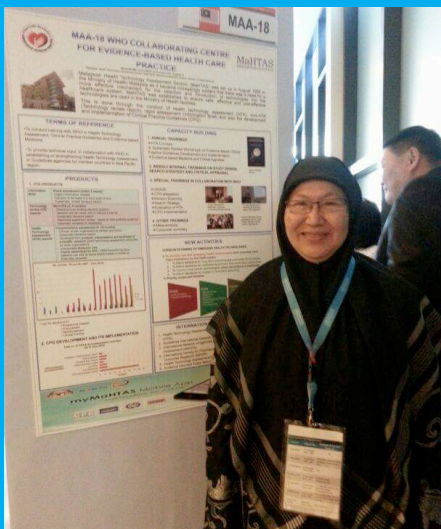
**G-I-N Conference Melbourne 2014**



MaHTAS was one of the 340 delegates from 42 countries participating in the Guidelines-International-Network (GIN) Conference at Melbourne Convention and Exhibition Centre from 20 - 23 August 2014. The theme of the convention was Creation and Innovation: Guidelines in the Digital Age. Interesting plenary presentations and discussions, and short oral and poster presentations plus Pre-Conference Workshops and GIN Annual General Meeting were conducted.

**First Regional Forum of WHO Collaborating Centres**

The first Regional Forum of WHO Collaborating Centres was held in Manila, Philippines on 13 - 14 November 2014. There are 184 WHOCCS out of total 812, located in 10 member states in the Western Pacific region. WHOCC aims to build partnerships and mobilise technical resources in helping WHO implement its mandated normative and programmatic work as reflected in its Strategic and Operational Plans. During the meeting there were discussions on current WHO activities and future initiatives of WHO. There was also sharing of experiences on effective collaborative work that can be followed by other WHO collaborating centres. There were also discussions on innovations to strengthen the role of WHO and WHOCC centres.



Madam Noormah representing MaHTAS in the First Regional Forum of WHO Collaborating Centres

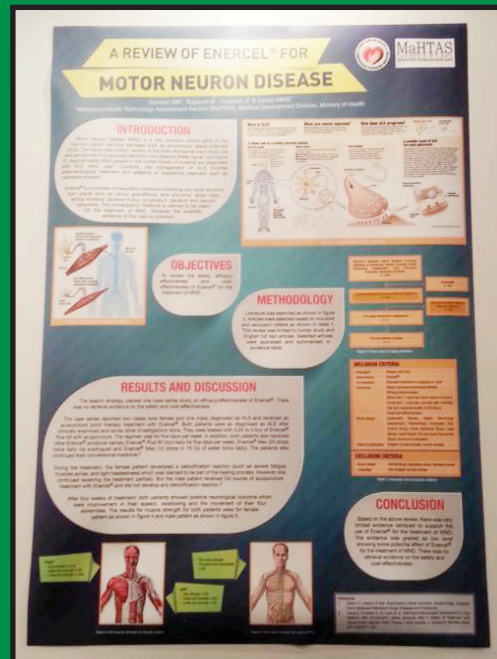
**Second Intercountry Meeting on HTA**



Datin Dr. Rugayah presenting "HTA in Malaysia"

Datin Dr. Rugayah Bakri attended Second Intercountry Meeting on HTA: Guidelines on Establishment of Programmes within National Health Systems in Cairo on 2 - 4 December 2014 at EMRO WHO Office. She gave a talk on "HTA in Malaysia" during the meeting.

**8<sup>th</sup> International Traditional and Complementary Medicine (INTRACOM) Conference**



A poster entitled "A Review on Enercel for Motor Neuron Disease" presented by MaHTAS during the conference

Madam Noormah Darus was invited to present a talk on "Nutritional Therapy as a Complement for Diabetes and Hypertension" during the 8<sup>th</sup> International Traditional and Complementary Medicine (INTRACOM) Conference. The conference was held in Sunway Pyramid Convention Centre on 30 October - 2 November 2014. MaHTAS also had one poster presentation entitled "A Review on Enercel® for Motor Neuron Disease" which was presented by Madam Asmirah Md Redzuan.

## Systematic Review on Evidence-Based Clinical Practice Guidelines (CPG) Development & Implementation Workshop 2/2014



Group discussion on critical appraisal

A Systematic Review on Evidence-Based CPG Development & Implementation Workshop 2/2014 was successfully held at Hotel Premiere, Kelang on 3 - 6 November 2014. It was attended by 45 participants consisted mainly multidisciplinary Development Group of CPGs on Management of Colorectal Cancer,

Management of Nasopharyngeal Cancer and Management of Primary Open Angle Glaucoma. The objectives of the workshop were to create awareness and provide knowledge on the development of evidence-based CPG and to encourage the implementation of such documents. The training was given by MaHTAS staff themselves.

## Economic Evaluation in Healthcare Workshop



Participants of Economic Evaluation in Healthcare Workshop at Institute for Health Management, Kuala Lumpur

A workshop on Economic Evaluation in Healthcare was organised by MaHTAS on 8 - 9 October 2014 at Institute for Health Management, Ministry of Health Malaysia in Kuala Lumpur. A total of 36 participants consisting of top level managers and MaHTAS staffs attended it. Associate Professor Dr. Asrul Akmal Shafie, from the School of Pharmaceutical Sciences, Universiti Sains Malaysia was invited to conduct the training. The objectives of the workshop were to provide knowledge on the principles of

economic evaluation of health care and to improve skills in appraising articles on economic evaluation. Participants were exposed to the importance of pharmacoeconomic, overview of various types of economic evaluation (cost-benefit, cost-effectiveness and cost-utility analyses) and methods to analyse them. The workshop was conducted successfully. It was particularly useful to MaHTAS staffs in conducting health technology assessments and clinical practice guidelines.

## LOCAL ACTIVITIES

### Training of Core Trainers (TOT) on CPG Management of Osteoarthritis (Second Edition)



Message delivered by CPG chairman

As part of the implementation strategies, MaHTAS conducted training for the core trainers (TOT) on CPG Management of Osteoarthritis (Second Edition) at Thistle Hotel, Port Dickson on 9 - 10 November 2014. A total of 57 participants nationwide consisting of Rheumatologists, General Physicians, Orthopaedic Surgeons and Family Medicine Specialists attended the training. The lectures and case studies were delivered by the members of CPG Development Group. With better understanding of the CPG, the core trainers should be able to do the echo training well at their respective states.

### Health Technology Assessment Course for East Malaysia Sabah



Participants of Health Technology Assessment Course for East Malaysia-Sabah

A course on Health Technology Assessment was organised by MaHTAS on 20 - 22 August 2014 at Grand Borneo Hotel, Sabah. A total of 29 participants consisting of Directors and Deputy Directors of hospitals, Public Health and Family Medicine Specialists, pharmacists and other healthcare providers attended it. The objectives of the course were to provide knowledge to the healthcare professionals on the basic concept of HTA, HTA work process and impact of HTA report in decision making. Other than that, this course aimed to enhance the skills of the participants in the development of HTA reports. Small group exercises were conducted to enhance the understanding of HTA. The course was beneficial to the participants.

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### CONTACT

Malaysian Health Technology  
 Assessment Section (MaHTAS)  
 Medical Development Division  
 Ministry of Health Malaysia  
 Level 4, Block E1, Precint 1  
 62590 Putrajaya, Malaysia



+603-88831245/6



+603-88831230



htamalaysia@moh.gov.my



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## Training, Workshop, Courses Conducted from July - December 2014

|    |  |                    |
|----|--|--------------------|
| 1. | Health Technology Assessment Course for East Malaysia Sabah                            | 20-22 August 2014  |
| 2. | Economic Evaluation in Health Care Workshop  | 8-9 October 2014   |
| 3. | Horizon Scanning Workshop : Manual Development   | 13-15 October 2014 |
| 4. | Systematic Review Workshop on Evidence-based CPG Development and Implementation 2/2014 | 3-6 November 2014  |
| 5. | Training for Core Trainers on CPG Management of Osteoarthritis                         | 9-10 November 2014 |

## Training, Workshop, Courses Planned for January - June 2015

|    |  |                  |
|----|--|------------------|
| 1. | Health Technology Assessment Training for East Malaysia Sarawak                        | 8-10 April 2015  |
| 2. | Systematic Review Workshop on Evidence-based CPG Development and Implementation 1/2015 | 27-30 April 2015 |
| 3. | Training for Core Trainers on CPG Management of Bipolar Disorder in Adults             | 22-23 April 2015 |

## Turnover of MaHTAS Staffs

We are pleased to introduce



Dr. Nafisah Ahmad Lutfi  
 Medical Officer UD44  
 Joined MaHTAS on  
 25 August 2014



Mr. Badrul Hisham Awang  
 Assistant Medical Officer U32  
 Joined MaHTAS on  
 4 August 2014

## Thank you for your contribution



Madam Zalina Ahmad  
 Clinical Nurse U41  
 Left MaHTAS on  
 24 March 2014



Madam Rosnah Siran  
 Nurse Manager U42  
 Retired on  
 10 November 2014