NEWSLETTER
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Malaysian HTA Section

MaHTAS

NEWS

LAUNCHING OF CLINICAL PRACTICE GUIDELINES MANAGEMENT OF PSORIASIS VULGARIS

Psoriasis is a systemic chronic inflammatory disease that affects 1 - 3 % of the general population worldwide. In the Malaysian Psoriasis Registry 2013, plaque psoriasis is the commonest form (85%) while psoriatic arthritis occurs in 16% of the patients. Psoriatic patients do not only have to deal with their highly visible skin disease, but also endure psychological problems such as low self-esteem and depression.

Due to the disease burden and wide variety of clinical practice in the treatment of psoriasis, an evidence-based Clinical Practice Guideline (CPG) on the condition has been developed. Recommendations in the CPG include assessment of physical severity and quality of life, screening of metabolic syndrome and other classic risk factors of cardiovascular diseases, and regular assessments for associated arthritis for timely referrals to the rheumatologists. Although there is no cure for psoriasis, skin clearance can occur with appropriate treatments which include topical therapies, phototherapy and systemic medications. Treatment goals and the choice of treatment should be individualised based on disease severity, patient's preferences and co-morbidities.

The newly-approved CPG entitled Management of Psoriasis Vulgaris was officially launched by YB. Datuk Dr. S. Subramaniam, Minister of Health Malaysia, on 13 October 2013 at Istana Hotel, Kuala Lumpur. The event was jointly conducted by MaHTAS and Dermatological Society of Malaysia. It was attended by about 100 participants who were mainly dermatologists, family medicine specialists and other healthcare providers involved in the management of psoriasis from both public and private sectors.

The launching ceremony was preceded by a continuous medical education on selected CPG topics which was delivered by the CPG development group members themselves. The aim of the launching was to create awareness of the CPG existence which will help to increase its utilisation. In his launching speech, the minister stressed on optimising the treatment of psoriasis by not just reducing skin-related morbidity but also preventing related co-morbidities. The minister also presented CPG packages consisting of the CPG and Quick Reference (QR) to representatives from the state health department, medical faculty and professional society. This is a symbolic mandate for them to implement the CPG at their respective institutions. A press conference was held after that.

Participants of the CPG launching ceremony

Overview of CPG Management of Psoriasis Vulgaris

Presentation of the CPG to the audience and media

All the HTA and TR reports, and CPGs are accessible online at **http://www.moh.gov.my**

PUBLICATIONS IN 2013

All CPGs, Health Technology Assessment (HTA) reports and Technology Review (TR) reports, endorsed in HTA and CPG Council Meeting 1/2013 and 2/2013 are listed in Table 1, Table 2 and Table 3, respectively.

Table 1: Clinical Practice Guidelines approved in 2013

No	Title
1	Management of Psoriasis Vulgaris
2	Prevention and Treatment of Venous Thromboembolism
3	Management of Anterior Crossbite in Mixed Dentition (2nd Edition).
4	Management of Osteoarthritis (2nd Edition)
5	Management of Hypertension (4th Edition)

Table 2: Health Technology Assessment Reports approved in 2013

No	Title
1	Nutritional Therapy for Diabetes and Hypertension
2	Single Use Dialyser versus Reuse Dialyser

Table 3: Technology Review Reports 2013

No	Title
	CARDIOVASCULAR DISEASES
1	Aquadex FlexFlow Ultrafiltration System
2	Mobile Phone with Portable Electrocardiogram (ECG) Device (EPI Life)
	DIAGNOSTIC PROCEDURES, SCREENING
3	NH2 Drug Lab (DrugKop)
4	Symptoms Checker
	DISORDERS OF ENVIRONMENTAL ORIGIN
5	EndoQuat™ Disinfectant and Sanitizer as Low Level Disinfectant
6	EndoStat™ Antimicrobial Treatment as Low Level Disinfectant
7	EndoSan™ Ecological Disinfectant as Low Level Disinfectant
8	Ultraviolet Germicidal Irradiation (UVGI) Indoor Air Purifier: An Update
9	Virusolve: An Update (for High Level Disinfectant)
	INFECTIOUS DISEASES
10	Auto-Destruct Mini Syringe
11	QuantiFERON® TB Gold for Detection of Latent Tuberculosis Infection
	MISCELLANEOUS
12	INJEX Needle Free Drug Delivery System
	MUSCULOSKELETAL DISEASES
13	Platelet Rich Plasma for Treatment of Osteoarthritis
	NEOPLASM
14	Haifu® Model – JC Focused Ultrasound Tumor Therapeutic System: An Update
	SURGICAL PROCEDURES, OPERATIVE
15	Autologous Peripheral Blood Stem Cells for Articular Cartilage Repair
16	X Collar versus Conventional Cervical Collar

TR REPORTS IN BRIEF

VACCINE

A vaccine is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened (attenuated) or killed forms of the microbe, its toxin or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters.

The effectiveness of vaccination has been widely studied and verified; for example, the influenza vaccine, the human papillomavirus (HPV) vaccine and the chicken pox vaccine. Stimulating immune responses with an infectious agent is known as immunization. Vaccination includes various ways of administering immunogens which may be oral, by injection (intramuscular, intradermal, subcutaneous), by puncture, transdermal or intranasal.

Two reviews on vaccine namely BCG revaccination and Cervical Cancer Vaccine have been published by MaHTAS and the findings are discussed below.

1. BCG REVACCINATION

Tuberculosis (TB) is a contagious airborne disease posing major public health problem worldwide and has been declared as a global emergency by WHO in 1993. Control of this disease relies upon prevention through Bacillus Calmette-Guérin (BCG) vaccination or chemoprophylaxis, ascertainment and treatment of the cases by employing the "directly observed therapy short course" (DOTS) approach. BCG vaccine has been used worldwide as a neonatal vaccination against severe forms of TB for around 80 years. The efficacy of BCG vaccination in newborns (primary BCG vaccination) is well recognized against disseminated TB. BCG revaccination is frequently given to children between six to fourteen years of age. However, there is considerable uncertainty as to the efficacy and extent of protection offered by booster of BCG vaccine (revaccination) against TB in these older children.

There was fair to good level of evidence to show that BCG revaccination did not provide additional protection when given to children with scar. BCG revaccination was not cost effective in low incidence TB country given the lack of protection provided by the second dose.

2. CERVICAL CANCER VACCINE: GARDASIL® AND CERVARIX®

Cervical cancer is one of the deadly cancers among woman. It is usually linked to genital infection with human papillomavirus (HPV). There are more than 130 subtypes of HPV and about 70 subtypes infect human. Out of these, about 40 different genotypes of HPV can infect the ano-genital area in men and women. These have been classified into high-risk and low-risk genotypes indicating their level of association with cervical cancer.

In cervical cancer, Papanicolaou smear remains the main screening form, as it has been proven to reduce the incidence by 43%. However, the sensitivity varies from 30-87%. Vaccination is an alternative to prevent the disease.

There was good level of evidence to show that both Gardasil® (quadrivalent) and Cervarix® (bivalent) were efficacious to prevent cervical cancer in young women. There was fair level of evidence to show that these vaccines were safe. Although deaths were reported but direct temporal relationship with the use of Gardasil® cannot be determined. Adverse events such as headache, fatigue, fever, and joint pains were reported in the clinical trials in those who received these vaccines. There was good level of evidence to show that vaccination program using Gardasil® and Cervarix® for prevention of cervical cancer was cost-effective compared to screening program alone. However, Gardasil® was more cost-effective compared to Cervarix® due to its additional benefit in reducing genital warts.

HTA REPORTS IN BRIEF

1. Nutritional Therapy for Diabetes and Hypertension

Nutraceuticals are pharmaceutical products (pills, powders, capsules, etc.) containing a concentrated form of a presumed bioactive phytochemical or zoochemical agent (metabolites) from a food. They are used with the purpose of enhancing health. These metabolites have low potency when compared to pharmaceutical drugs. Legislature in most countries categorises nutraceuticals as dietary supplements and therefore, regulation, is not as stringent as for drugs. Hence, they are widely available and minimally monitored. Currently there is inadequate policy on the use of oral nutritional supplements or vitamin-mineral supplements or nutraceuticals in the treatment of hypertension and diabetes in Malaysia. Therefore, a systematic review was conducted to review the evidences on the efficacy/effectiveness, safety, cost effectiveness and organizational aspects of oral nutritional supplements or vitamin-mineral supplements or nutraceuticals as a complement for diabetes and hypertension. Twenty one studies were included in this review.

A. Nutraceutical therapy for diabetes:

These nutraceuticals (fish oil, bitter melon, high dose vitamin C, and a combination of vitamin C & E, high doses of vitamin B6, B12, cinnamon and vitamin E) cannot be recommended as a complement therapy for diabetes until further scientific evidence is obtained to establish their effectiveness and safety. More research with larger, high quality randomised clinical trials is warranted to provide more scientific evidence on the long term safety and effectiveness of nutraceuticals such as fenugreek, chromium, vitamin E, thiamine, acetyl-L-carnitine and alpha lipoic acid before these can be recommended as a complementary therapy for diabetes in Malaysia.

B. Nutraceutical therapy for hypertension :

Vitamins C (1000 mg) and E (400 IU) supplementation in this dose combination may be associated with an increased risk of premature rupture of the membranes (PROM) and preterm premature rupture of the membranes (PPROM). Therefore, this combination is not recommended for pregnant hypertensive patients. An adequate intake of calcium has been shown to reduce both systolic blood pressure (SBP) and diastolic blood pressure (DBP). Calcium supplementation during pregnancy reduced risk of pre-eclampsia, the risk of maternal mortality/severe morbidity, reduction in risk of pre-term birth. Therefore, calcium may be recommended for the prevention of hypertension in appropriate therapeutic doses. Oral L-arginine, garlic preparations and magnesium supplementation can only be recommended for further research before they can be established as nutraceuticals to be used as a complement therapy for hypertension.

2. Single Use Dialyser versus Reuse Dialyser

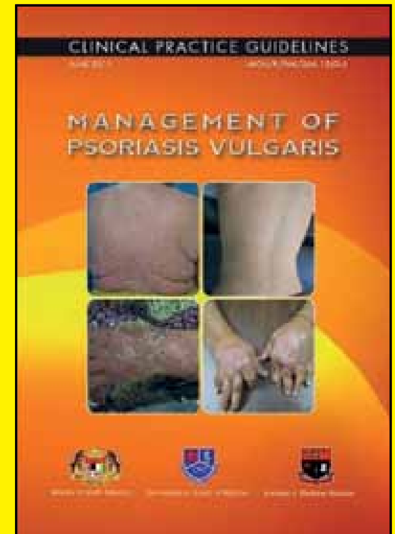
The number of haemodialysis centres in Malaysia increased from 208 in 2001 to 581 in 2010. In Malaysia, 90% of patients undergoing haemodialysis use reuse dialysers and 19% of these patients used their dialysers for at least 13 times, in 2010. Dialyser reuse has historically been practised in light of perceived potential benefits for the dialysis provider and the patient. However, the availability of cheaper high-flux dialysers for single use means that the traditional benefit of the ability to reuse such dialysers no longer holds true. Potential errors and breakdowns in the reuse process are continuing concerns. The risk may move beyond bacteria into the realm of viruses and prions. Therefore, there is a need to reassess the dialyser reprocessing practice in Ministry of Health haemodialysis units through systematic review of literature and local economic evaluation.

Studies were identified by searching electronic databases through the Ovid interface and PubMed. Thirty full text articles comprising one systematic review, two randomised controlled trial, three cross over design, five cohort studies, one pre and post-intervention study, eleven cross sectional studies, three case series, one cost-utility analysis, two cost analysis and one cost minimisation analysis, were included. Local economic evaluation was designed from the provider (Ministry of Health) perspective based on haemodialysis unit in general public hospital. The evaluation was conducted using Markov cohort analysis where the average five years' costs and consequences (quality adjusted life years) for the patient who received either type of dialyzer were evaluated.

There was fair level of evidence to suggest that single use dialyser is as effective as reuse dialyser in terms of mortality. However, dialyser reuse was associated with higher rates of hospitalisation. Reuse of dialyser has the potential to increase the risk of infections. Dialyser performance may be reduced with reuse. Separation practices and ban on reuse of dialyser lower the incidence of hepatitis B or hepatitis C infection among patients. From the local economic evaluation, single use was found to be more expensive but more effective than reuse. However, the incremental cost-effectiveness ratio was found to be above the threshold of cost-effectiveness (RM 4 983 655). Single use dialyser should be used for those with infectious diseases such as hepatitis B, hepatitis C, hepatitis B & C co-infection or human immunodeficiency virus infection, subjected to the availability of resource. In line with the Ministry of Health guidance on Haemodialysis Quality and Standards and the Report of the Malaysian Dialysis and Transplant Registry where manual dialyser reprocessing system reported significantly higher risk for hepatitis C virus seroconversion. Hence, automated reprocessing system for reuse of dialyser is advocated.

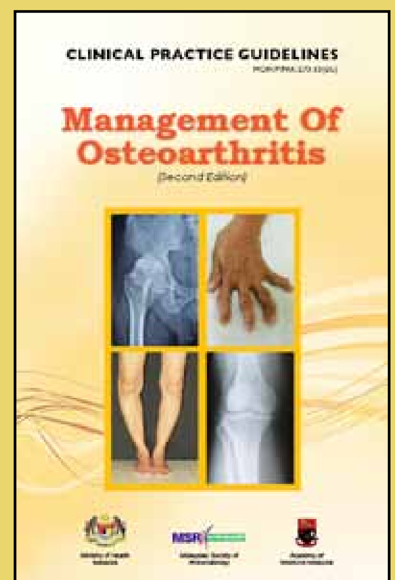
CPG KEY MESSAGES

MANAGEMENT OF PSORIASIS VULGARIS



i. Psoriasis is a genetically determined, systemic immune-mediated chronic inflammatory disease that affects primarily the skin and joints.
ii. Psoriasis vulgaris is characterised by well-demarcated erythematous plaques with silvery scales on elbows, knees, lumbosacral region and scalp, and nail changes.
iii. Erythrodermic psoriasis affects more than 80% body surface area.
iv. Generalised pustular psoriasis is widespread erythema studded with superficial pustules which may coalesce to form lakes of pus.
v. Psoriasis can be as mentally and physically disabling as cancer, heart disease, diabetes, hypertension, arthritis and depression.
vi. Psoriatic arthritis affects about 16% of Malaysians with psoriasis. Early recognition and treatment prevent deformities. Assessment should be performed at least annually by looking for relevant signs and symptoms:-
   - Joint swelling
   - Dactylitis
   - Significant early morning stiffness >1/2 hour
vii. Psoriasis patients are more prone to cardiovascular disease, lymphoma and non-melanoma skin cancers, and increased mortality.
viii. Psoriasis patients should be screened for metabolic syndrome and risk factors of atherosclerosis-related diseases.
ix. Assess physical severity of psoriasis with Psoriasis Area and Severity Index (PASI) or Body Surface Area (BSA). Assess the impact of psoriasis on the quality of life of patients with Dermatology Life Quality Index (DLQI)
x. Choice of treatment for pregnant and lactating women should benefit the mother and pose minimal risk to the fetus/baby.

MANAGEMENT OF OSTEOARTHRITIS



i. Osteoarthritis (OA) is a progressive joint disease due to failure in repair of joint damage & is one of the major causes of disability in adults.
ii. Identifying the modifiable risk factors may help in prevention of OA & its progression.
iii. Diagnosis of OA is mainly clinical. Blood investigations & synovial fluid analysis are seldom required.
iv. Plain radiography is the standard imaging for disease assessment. Classical features include narrowed joint space, subchondral bone sclerosis, osteophytes & subchondral cysts.
v. Patient education should form an integral part of OA management.
vi. Lifestyle modification such as weight reduction, physical activity & exercise is beneficial in hip & knee OA.
vii. The aim of pharmacological treatments in OA is for symptom relief. The medications include simple analgesic, non-steroidal anti-inflammatory drugs (NSAIDs), cyclo-oxygenase-2 (COX-2) inhibitors, glucosamine and diacerein.
viii. NSAIDs or COX-2 inhibitors should be avoided in patients with previous gastrointestinal complications & used with caution in the elderly & those with hypertension, cardiovascular disease, renal or hepatic impairment.
ix. Surgery is considered if the symptoms of the affected joints significantly affect patient's quality of life & interfere with the activity of daily living despite medical therapy.
x. Expert opinion should be sought for evaluation of arthritis with unclear diagnosis.

INTERNATIONAL PARTICIPATIONS

1. 2013 HTAi ASIA POLICY FORUM HTA AND DECISION MAKING IN ASIA

Date: 13 – 14 Jun 2013
Venue: Coex Seoul, Korea

Datin Dr. Rugayah Bakri participated in the forum. The forum provides opportunity for senior people from public and private sector organisation involved with HTA to meet one another for strategic discussion about the present state of HTA, its development and implications for health care systems, industry, patients and other stakeholders.

Participants of the forum

2. 10th HTAi SEOUL 2013 ANNUAL MEETING

Date: 15 – 16 June 2013
Venue: Seoul, Korea

MaHTAS participated actively in the 10th HTAi SEOUL 2013. Four delegates from MaHTAS attended the pre-conference as well as the main conference. They also presented one oral presentation and five posters were presented during the conference. In addition, several side meetings were organised in conjuction with the conference.

a. **Pre-conference Workshops**
MaHTAS delegates participated in four pre-conference workshops. Datin Dr. Rugayah was one of the speakers in pre-conference workshop on “Assessing the impact of HTA on Policy and Practice”.

Pre-conference workshop on ‘Filtration and Prioritisation of Emerging Health Technologies from Simplicity to Complexity’. Different approaches and examples from the United Kingdom, Australia, Italy, Austria and Spain were discussed.

Pre-conference workshop on ‘Capturing and Measuring the Impact of Patient and Public Involvement in HTA: Current Practice and Future Evidence Based’.

Pre-Conference Workshop On Methodological Developments In Advanced Biblopgraphic Searching And Assessment Research Impact.

b. **Scientific Presentations**
MaHTAS had four presentations during the conference. Dr. Izzuna Mudla presented an oral presentation entitled “Drug Eluting Balloon for Coronary Heart Disease”. The three poster presentations were “Bakri Balloon Tamponade in Postpartum Haemorrhage – An Update” by Madam Ku Nurhasni, “Solution@ Algorithm for Wound Care” by Madam Sin Lian Thye and “Malaysia (MaHTAS) Health Technology Assessment Performance Evaluation” by Dr Roza Sarimin.

Poster presentations during the conference

c. Datin Dr. Rugayah co-chaired symposium on Decision-Making in the Real World and participated in WHO Round Table Meeting on “The Role of Health Technology Accessment in Achieving Universal Coverage”. The WHO Round Table Meeting was chaired by Dr. Shin Young-Soo, Regional Director for the Western Pacific Region.

Participants of WHO Round Table Meeting-Seoul 2013

Datin Dr. Rugayah Bakri co-chaired the symposium

3. 2nd HTAsiaLink ANNUAL CONFERENCE

Date: 13 – 15 May 2013
Venue: Universiti Sains Malaysia, Penang

Six MaHTAS officers participated in the conference. Four of them presented an oral presentation entitled 'MaHTAS Present and Future', 'GD-EOB-DTPA-liver specific magnetic resonance imaging contrast agent', Autologous peripheral blood stem cells for articular repair' and VERSAJET^{TM} Hydrosurgery system'. One of the presentations won the second best oral presentation.

4. 2nd ANNUAL ASIAN PATIENT ACCESS LEADER FORUM

Date: 23 – 24 July 2013
Venue: Swissotel Merchant Court, Singapore

Dr Izzuna was invited to give a talk on "The role of regulators and HTAs in Malaysia and how they make their decisions. She also involved in a panel discussion on "How to enhance decision making via more accurate HTA & economic modelling". The forum was organised by Next Level® Pharma, Singapore. The forum was attended by leaders in pharmaceuticals and medical device industries.

Dr. Izzuna Mudla delivered her talk.

5. ERASMUS SUMMER PROGRAMME

Taking notes during lecture on meta-analysis

Date: 12 – 23 August 2013
Venue: Erasmus University Medical Center, Rotterdam, Netherlands

For the second time, MaHTAS send two officers to attend the Erasmus Summer Programme to strengthen their knowledge in related topics thus increase their capacity building. The courses attended were meta-analysis, global public health, methods of clinical research and pharmaco-epidemiology.

Lecture presentation during groupwork

6. 6th ASIA PACIFIC FUTURE TRENDS FORUM "FINANCING AND REFORM FOR HEALTH SYSTEM SUSTAINABILITY'

Date: 18 – 19 October 2013
Venue: Asian Institute of Management, Manila, Filipina

Dr. Junainah Sabirin presented a paper on 'Using HTA to Balance Access, Equity and Affordability in Malaysia" during the forum.

Dr. Junainah Sabirin at the forum

7. 2nd GULF CONFERENCE ON COMPLEMENTARY MEDICINE

Date: 24 – 26 November 2013
Venue: King Faisal Conference Hall, Riyadh Intercontinental Hotel, Riyadh, Saudi Arabia

Madam Noormah was invited to present two topics entitled 'Ozone therapy scientific evidence and the role of HTA unit' and 'Overview of Traditional and Complementary Medicine in Malaysia' during the conference.

Madam Noormah at the conference

LOCAL ACTIVITIES

1. TRAINING OF TRAINERS ON GRADING RECOMMENDATION ASSESSMENT, DEVELOPMENT AND EVALUATION (GRADE)

Date: 30 September - 4 October 2013
Venue: The Best Western Hotel, Kuala Lumpur
Number of Participants: 42

Judgements on scientific evidence and related recommendations in healthcare are complex. Because of limited resources, there is also a need to decide whether any incremental health benefits are worth any additional costs. The uncertainty associated with the tradeoff between benefits and risks or burdens will determine the strength of an evidence-based recommendation. To worsen the issues, there are various systems in grading the quality of evidence and strength of recommendations employed by guidelines or health technology assessment agencies worldwide. These cause further confusion and impede effective communication among the potential users of the documents.

A systematic and explicit approach in solving the above matters is required. Thus, the GRADE working group started in 2000 as an informal collaboration of people with an interest in addressing the shortcomings of present grading systems in healthcare. Their aim was to develop a common and sensible approach on the matter. They had suggested that factors that need to be considered when grading a recommendation was the methodological quality of the evidence, the tradeoff between benefit and harm/burden, patients' values and preferences, and resource implications. Many related agencies, including the World Health Organization (WHO) have adopted GRADE framework in their work process.

In view of the development, Training of the Trainers on GRADE was organised by MaHTAS in collaboration with WHO at The Best Western Hotel, Kuala Lumpur. Dr. Jan Brozek, an Assistant Professor at Department of Clinical Epidemiology & Biostatistics of Mc Master University, Canada was invited exclusively to be the consultant for the training.

The objectives of the training were to gain understanding and experience in applying the GRADE approach for formulating health care recommendations for evidence-based CPG and HTA. Forty two participants attended the training, comprising of MaHTAS staffs, other Ministry of Health officers and foreign participants from Singapore, Thailand, Brunei and Taiwan. MaHTAS will start adopting GRADE in its work and continue having related training for its staff to master in the approach.

Dr. Jan Brozek was delivering his talk

Participants of Training of Trainers on GRADE

Closing Remarks by Dato' Dr. Azmi Shapie, Director of Medical Development Division

2. PRE CONFERENCE WORKSHOP: HEALTH TECHNOLOGY ASSESSMENT FOR PUBLIC HEALTH INTERVENTION DURING 3rd INTERNATIONAL PUBLIC HEALTH CONFERENCE AND 20th NATIONAL PUBLIC HEALTH COLLOQIUM

Date: 27 August 2013
Venue: Riverside Majestic Hotel, Kuching, Sarawak.

Four MaHTAS officers involved in a pre conference workshop entitled 'Health Technology Assessment for Public Health Intervention'. There were 15 participants consisted of clinical experts, public health specialists, medical officers and science officers attended the workshop.

3. 3rd INTERNATIONAL PUBLIC HEALTH CONFERENCE AND 20th NATIONAL PUBLIC HEALTH COLLOQIUM

Date: 28 August 2013
Venue: Riverside Majestic Hotel, Kuching, Sarawak.

Dr. Junainah Sabirin presented a talk on 'New Health Technologies for Non-Communicable Disease (NCDS): How safe and effective' during the main conference.

COURSES AND WORKSHOPS CONDUCTED FROM JULY – DECEMBER 2013

HTA Course For Expert Committee and Central Region
4 - 6 September 2013

HTA Training For Northern Zone
28 - 30 October 2013

Systematic Review for Evidence-Based Clinical Practice Guidelines Development and Implementation Workshop 2/2013
11 - 14 November 2013

COURSES AND WORKSHOPS PLANNED JANUARY – JUNE 2014

Systematic Review for Evidence-Based Clinical Practice Guideline Development and Implementation Workshop 1/2014
7 - 9 April 2014

Training on CPG Adaptation
28 - 30 April 2014

TURNOVER OF MaHTAS STAFFS – THOSE WHO NEWLY JOINED

Dr. Ana Fizalinda Abdullah Sani
Medical Officer UD52
Start: 15 July 2013

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