



MAHTAS

MALAYSIAN HEALTH TECHNOLOGY ASSESSMENT SECTION
E-NEWSLETTER

The HTAi 2022 Annual Meeting 25 – 29 June 2022 Utrecht, Netherlands *By Dr. Syaquirah Akmal*



This reputable yearly event had been held in Utrecht, Netherlands and gathered experts in health technologies assessment (HTA) to discuss on various issues. The focus this time was on **'Lifecycle Approach: Coming Together to Make It Happen'**. The sharing sessions involved continuous dialogue and the exchange of knowledge between HTA organisations, industries, patient group and other stakeholders to ensure better outcomes for patients as a central focus of the activities of HTA bodies.

For this year, the Head of MaHTAS, Dr. Izzuna Mudla Mohamed Ghazali was invited as a speaker in a plenary session on **Plenary 1 - Adopting a Lifecycle Approach in HTA: Consequences for Pricing Setting and International Collaboration** for this prestigious event. She also presented two panel sessions on horizon scanning and patient participation in HTA.



Health Technology Assessment international (HTAi) is a global, non-profit, scientific and professional society for all those who produce, use or have interest in HTA. It has 82 organisations and over 2,500 individual members from 65 countries including Malaysia. The members include researchers, policymakers, industry players, academicians, health service providers, agencies and patients. They contribute to a balanced conversation on HTA across different areas of practice and jurisdictions.

The collaboration or involvement is important to ensure HTA in Malaysia are at par with the international standard and for the betterment of health services.



Lifecycle approach
Dr. Izzuna Mudla Mohamed Ghazali

- Lifecycle approach
 - Optimise the value of patient care
 - Accelerate access
 - Improve quality of patient care
 - Improve population health
 - Dynamic reimbursement decisions
 - Use of real-world evidence
 - Multistakeholder involvement

June 25-29, 2022 | www.htai2022.org | #HTAi2022Utrecht

Health Technology Assessment (HTA) and Clinical Practice Guidelines (CPG) Council Meeting 2/2021

By Matron Wong Wai Chee

Chairperson

YBhg. Tan Sri Dato' Seri Dr. Noor Hisham Abdullah
Director General, Ministry of Health Malaysia



Reports and CPGs presented at Council Meeting

Technology Review (TR)

1. Proton Beam Therapy for the Treatment of Cancer - an Update
2. First Line Targeted Therapy for Advanced Hepatocellular Carcinoma (HCC)
3. REZUM Therapy for the Management of Benign Prostatic Hyperplasia (BPH)
4. 5-Aminolevulinic Acid (5-ALA) for Brain Tumour
5. Single Dose Rifampicin for Leprosy Contacts
6. Versajet Hydrosurgery System for Wound Debridement - an Update
1. Transcutaneous Oxygen Pressure Monitoring (TcPO₂)
2. Sublingual Immunotherapy (SLIT) for Atopy (Allergic, Rhinitis, Eczema and Asthma)
3. Mesenchymal Stem Cell for Treatment of Retinitis Pigmentosa and Other Degenerative Disease

Health Technology Assessment (HTA)

Early Cancer Detection Test for Lung (Early CDT-Lung)

Clinical Practice Guidelines (CPG)

1. Management of Acne Vulgaris (Second Edition)
2. Management of Osteoporosis (Third Edition)
3. Management of Menopause

Horizon Scanning (HS) TechBrief

1. Tezepelumab for Severe Uncontrolled Asthma
2. Abrelcimab for Prevention of Venous Thrombo-embolism

HTA Highlights in Brief: Early Cancer Detection Test for Lung (EarlyCDT-Lung)

By En. Syful Azlie Md Fuzie

EarlyCDT-Lung

Introduction

- Assess the malignancy risk of solid lung nodules.
- Measure autoantibodies to a panel of seven lung cancer-associated antigens (p53, NY-ESO-1, CAGE, GBU4-5, HuD, MAGE A4, and SOX2).

How it works?

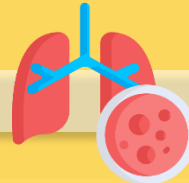
Enzyme-linked immunosorbent assay (ELISA) principle - test results are based on a comparison of relative autoantibody levels to fixed thresholds.

Regulatory approval

- USFDA (2012)
- CE mark (2017) as a general in vitro diagnostic; update 2019



RESULT



Efficacy

- EarlyCDT-Lung has **low to moderate sensitivity but good specificity** as serum diagnostic biomarkers of lung cancer in population screening among high-risk group.
- Compared with standard clinical care, a positive EarlyCDT-Lung test followed by low-dose computed tomography **reduced the numbers of late-stage lung cancers and increased early-stage disease being diagnosed**. There were no significant differences in lung cancer mortality and all-cause mortality.

Economic Implication

- Economic evaluation conducted in countries that implemented low-dose computed tomography as a screening tool with **an addition of EarlyCDT-Lung was cost-effective**.
- Economic evaluation based on Malaysia situation comparing EarlyCDT-Lung followed by low-dose computed tomography and biopsy with no screening showed **an ICER of RM37,169.04**.

Safety

No severe adverse events directly related to the test were reported and all were considered minor.

Conclusion

- EarlyCDT-Lung **has the potential to be used** to complement low-dose computed tomography in population screening for early lung cancer detection among high-risk group in Malaysia.
- However, its use should take into consideration the availability and acceptability of low-dose computed tomography as a screening tool.
- **Competitive price** of EarlyCDT-Lung₃ may improve the cost-effectiveness of this screening strategy.

Proton Beam Therapy for the Treatment of Cancer – an Update

By En. Lee Sit Wai



The challenge in using high-energy x-rays to treat cancer is that the x-rays pass through the thickness of the body, depositing an entrance and an exit dose to healthy organs. The unavoidable dose to healthy organs limits the dose that can be safely administered to the tumour. Radiation oncologists constantly find the optimal balance between a high-enough dose to prevent cancer recurrence and a low-enough dose to avoid injury to healthy organs. Proton beam therapy (PBT) offers an option for obtaining that balance.

Effectiveness: Since last review in 2006, there was **no new high level evidence** in determining the safety and effectiveness of PBT for cancer treatment. **No significant differences** were noticed from the outcome of the studies.

Safety: Compared with photon therapy, PBT may result in **fewer adverse event** but similar overall survival and progression-free survival in children with brain tumours, adults with oesophageal cancer, head and neck cancer, and prostate cancer. However, **the quality of the evidence is low to very low.**

Economic Impact: The minimum setting for the facility includes a building, a proton accelerator and a multi-ion accelerator. Current proton therapy facilities with three to four treatment rooms may cost well **over a \$100 million.**

Conclusion: Proton beam therapy **may be used for treatment of selected cancer** like brain, oesophageal, head and neck, and prostate cancer. Further research is proposed for its use to treat other cancer types in providing more quality evidence on the safety, effectiveness and cost-effectiveness.

Rezūm Therapy for the Management of Benign Prostatic Hyperplasia

By Dr. Erni Zurina Romli

An innovative method of minimally invasive surgical treatments (MIST) on the prostate provides a potential treatment option aiming to relieve the symptoms with less perioperative risks, as well as less sexual dysfunction. Rezūm is a novel MIST using a convective thermal ablation therapy, also known as water vapour thermal therapy.

EFFECTIVENESS

Rezūm therapy had shown to improve urologic symptoms and quality of life as early as 6 months post-procedure and remained durable through 5 years follow-up

SAFETY

Rezūm therapy was considered safe. Most reported adverse events were minor adverse events (CDC I-II) with transient effects

ECONOMIC IMPACT

Rezūm therapy was shown to be a cost-saving procedure in comparison to other MISTs and invasive benign prostatic hyperplasia surgeries (**holmium laser enucleation of the prostate** and **transurethral resection of prostate**)

CONCLUSION

Rezūm therapy may be used as alternative treatment option for moderate to severe lower urinary tract symptoms in men with benign prostatic hyperplasia



5-Aminolevulinic Acid (5-ALA) for Brain Tumour

By Pn. Maharita Ab Rahman

14 scientific evidence included:

- 5 Systematic Reviews
- 1 Randomised Controlled Trials
- 6 Cohort studies
- 2 Case-control studies

Caution on transient elevation of liver enzyme and skin sensitivity which resolve without further treatment

Use of 5-ALA as an **intraoperative optical adjunct in high grade glioma surgery** is better than conventional white light surgery



Compared to conventional method, 5-ALA improves:

- Progression Free Survival (PFS)
- Gross Total Resection (GTR)
- Overall Survival (OS)

From the included studies, 5-ALA showed a **potential of cost-effective** compared to white light microscopy for high grade glioma surgery

Sublingual Immunotherapy (SLIT) for Atopy (Allergic, Rhinitis, Eczema and Asthma)

By Dr. Ana Fizalinda Abdullah Sani



EFFICACY

Allergy Rhinitis: Significant reduction in symptoms when compared with placebo

Asthma: May reduce exacerbations compared with placebo or usual care

Atopic eczema: Inconclusive results



SAFETY

Proven to be a safe route of administration



ORGANISATIONAL ISSUE

SLIT represents a viable alternative to subcutaneous immunotherapy (SCIT); an alternate mode of immunotherapy



ECONOMIC

- Both SCIT and SLIT are cost-effective
- Estimated cost of 3 years between MYR13,729.00 to MYR17,014.00 per patient
- Expected total expenditure is based on the prevalence of this population

Horizon Scanning: TechBrief Summary

Promising results phase III, hence awaiting for publication of study in peer-reviewed journal

Lecanemab (BAN2401) for Alzheimer's Disease

By Pn. Nurfarah Aqilah Mohd Nizam

About Lecanemab

Humanised IgG1 monoclonal antibody that selectively binds to neutralise and eliminate soluble, toxic amyloid-beta (Aβ) aggregates (protofibrils) that contribute to the neurodegenerative process in Alzheimer's disease.

Route of Administration

Intravenous infusion biweekly or monthly.

Developer

Eisai in collaboration with Biogen.



Clinical Impact

Phase 2b CORE clinical trial

At 12 months, 10mg/kg biweekly ED90 dose showed **64% probability to be better than placebo on ADCOMS***, which miss the 80% threshold for the 12-month primary outcome.

At 18 months, 10-mg/kg biweekly Lecanemab had **76% probability of being better than placebo** by a consistent clinical decline across several clinical and biomarker endpoints.

Safety

Lecanemab was **generally well-tolerated, with the key adverse event** being ARIA-E with an incidence rate of less than 10% at the two highest doses for overall population and 14.3% for ApoE4-positive subjects.

Cost**

The potential annual value-based price of Lecanemab was estimated at: \$9,249 (MYR40,746.47) to \$35,605 (MYR156,857.83)

Societal perspective: \$10,400 (MYR45,817.20) to \$38,053 (MYR167,642.49)

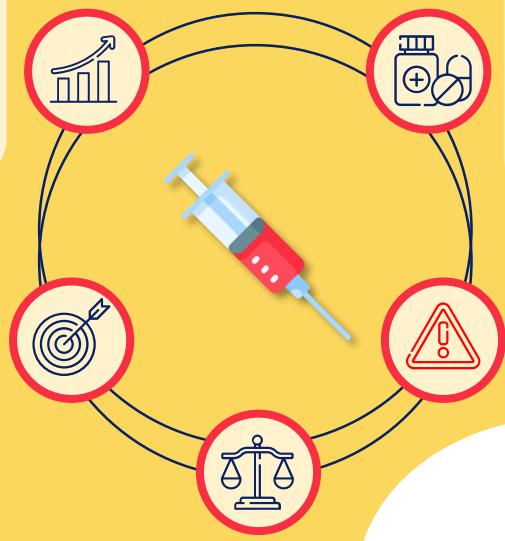
*Alzheimer's Disease Composite Score
**1USD = MYR4.41

Abelacimab for Venous Thrombo-Embolism (VTE) Prophylaxis

By Dr. Asliza Ayub

Venous thrombo-embolism is a **preventable disease**; however, it has high morbidity and mortality.

Abelacimab is a novel, investigational, single-dose anti-coagulant made from human monoclonal antibody against factor XI and its activated form, factor XIa.



It has been shown that **Abelacimab reduced risk of thrombo-embolism in a phase two study** among patient post-total knee arthroplasty.

Clinically relevant bleeding occurred more common among Abelacimab group, however there **was no serious adverse events reported**.

Limited evidence showed that single dose of Abelacimab prevent the occurrence of venous thrombo-embolism post-operatively with low-risk of bleeding. Further usage in other high-risk group and other aspects such as data on duration of protection, cost and its cost-effectiveness studies needs to be determined.

1

Acne vulgaris is a **chronic inflammatory skin disease** of the pilosebaceous units, commonly affecting adolescents and young adults

10

- Patients with moderate to severe acne vulgaris (e.g. nodulocystic acne) should be referred early to a dermatologist
- Those who exhibit suicidal behaviour should be referred urgently to a psychiatrist

Isotretinoin is indicated for severe nodulocystic acne and should only be prescribed by a dermatologist

9

Oral antibiotics may be used in moderate to severe disease but should not be used for more than 4 months

8

Topical therapy is the mainstay of treatment in mild to moderate disease

7

2

- Affects the face and trunk
- **Characterised by:**
 - Non-inflammatory lesions (open and closed comedones)
 - Inflammatory lesions (papules, pustules, nodules and cysts)

3

4 pathogenic factors:

- Increased sebum production
- Altered follicular keratinisation
- *Cutibacterium acnes* colonisation
- Inflammation of the pilosebaceous unit

4

Risk and aggravating factors:

- Adolescence
- Positive family history in first degree relatives
- High glycaemic load diet
- Dairy products
- Sweetened beverages and food
- Unhealthy fat intake

5

Acne vulgaris is **diagnosed clinically** but **laboratory investigations** may be indicated in some cases

6

Comprehensive Acne Severity Scale (CASS) may be used for grading of acne severity in clinical practice



International Activities

Malaysia's Capacity Building Workshop on Autumn/Summer Package (13 May 2022)

By Dr. Tengku Noor Farhana Tengku Khalid

MaHTAS collaborated with World Health Organization, Monash University and National Institute of Health in conducting a series of infectious disease modelling workshop using Autumn/Summer package in Python software. The main objective was to develop capacity building in conducting infectious disease models in Malaysia using real-time and real-life applicable scenarios to model the impact of health technology on infectious disease. Eight officers from MaHTAS were selected to join the sessions via online platform and it was proposed to be conducted every two weeks until the end of the year. Throughout the sessions, the participants learned to use Python as well as write the codes to create the model themselves.



World Health Organization



MONASH University



APACMED: The Future of Patient Care Symposium 2022 (9 June 2022)

By Dr. Aidatul Azura Abdul Rani

The theme of this symposium was Remote Care Management (RCM) and it focused on user experience from the perspective of healthcare professionals, patients/caregivers, and society. The RCM encompassed patient-facing digital technologies and services as a means to facilitate clinically driven remote monitoring, care and education of patients. The COVID-19 pandemic had highlighted the need for RCM to implement an effective population health management strategy.

Fourteen renowned speakers assembled to outline the gaps, share best practices, and exchange real life stories on topics ranging from RCM use, value demonstration to reimbursement and economic sustainability. As this was a virtual event, more than 700 attendees from 26 countries participated. The Head of MaHTAS, Dr. Izzuna Mudla Mohamed Ghazali, shared the delivery, achievement and challenges of digital health in Malaysia ecosystem in addressing "RCM for Better Access".

APACMed

THE FUTURE OF
PATIENT CARE

SYMPOSIUM 2022

9 June | 3:00pm - 6:30pm SGT

Remote Care Management





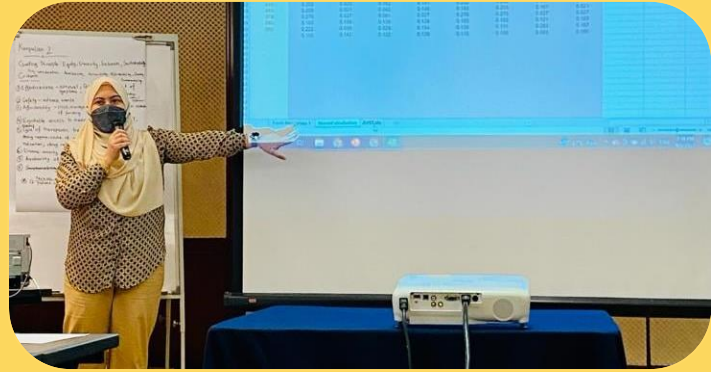
Four officers from MaHTAS attended the biannually INAHTA Congress 2022 held on 29 to 30 June 2022 with the theme “Exchanging Solutions in a Changing Environment”. The congress was conducted in a hybrid style (virtually and in-person) in Utrecht, Netherlands.

A MaHTAS officer was invited as a speaker in a plenary session entitled “The continual evaluation of health technologies” as well as a moderator and rapporteur to two roundtable sessions “Interactions between Guideline and HTA communities - What can we learn from guidelines and vice versa?” and “Moving towards an INAHTA position statement on real world evidence”

Multiple Criteria Decision Analysis for Rare Disease (8 - 10 February 2022)

By Pn. Ku Nurhasni Ku Abdul Rahim

An evidence informed stakeholder engagement was successfully held which aimed for an interactive engagement of multi-stakeholders in the development of MCDA process for rare disease and to explore the feasibility of its implementation. The attendees of this workshop were the rare disease committee members, including healthcare professionals from Ministry of Health and Ministry of Education, government officers and patients or their representative from patient's organisations. Several representatives from industry were also invited to this workshop. A set of prioritisation criteria and its weightage for prioritisation were proposed and discussed in depth to obtain a collective decision.



Systematic Review on Evidence-based Clinical Practice Guidelines Development and Implementation Workshop (14 - 16 March 2022)

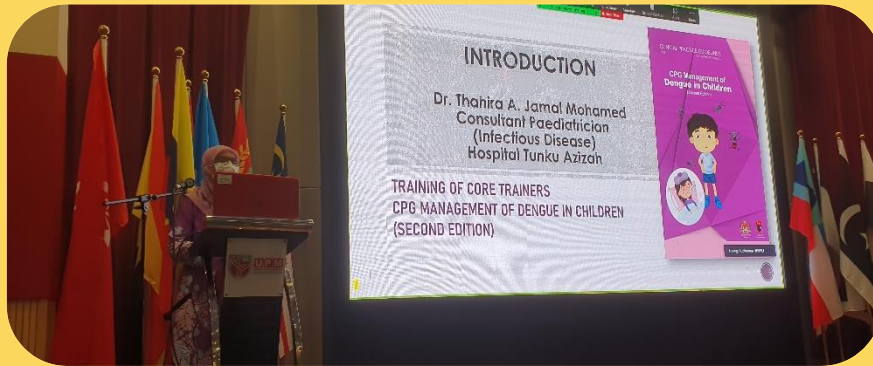
By Dr. Karen Sharmini a/p Sandanasamy

CPG Unit of MaHTAS had successfully conducted a training on CPG development using the systematic review approach. It contained lecture/group work on literature search, literature/guidelines appraisal and, analysis, synthesis and formulation of recommendations based on the evidence. The 36 participants were mainly Development Group members of CPG Management of Bipolar Disorder (Second Edition) and Management of Erectile Dysfunction.



Training of the Core Trainers (ToT) on CPG Management of Dengue in Children (Second Edition) (22 March 2022)

By Pn. Siti Aisah Fadzilah



The above-titled was the first physical ToT organised by MaHTAS during COVID-19 pandemic. It was also the first ToT conducted at Hospital Pengajar Universiti Putra Malaysia. Its objectives were to actively disseminate the contents of the clinical practice guidelines and train healthcare providers in the management of dengue in children in various healthcare settings. A total of 85 multidisciplinary participants (paediatricians, emergency physicians, microbiologists, family medicine specialists and public health officers) from the Ministry of Health and local universities attended the training of interactive lectures and case discussions.



MaHTAS Business Canvas Model Workshop (11 - 12 April 2022)

By Dr. Roza Sarimin

MaHTAS successfully conducted a workshop to brainstorm and prepare for the role of HTA in line with the proposal of white paper reformation of the country's health system. The session consisted of presentations on an overview of health systems, role of HTA agencies scope of work, funding and legal requirement in several countries including Canada, United Kingdom, Spain, Australia, Thailand, Taiwan, Japan, Korea and the Phillipines. Subsequent session involved deliberation and active group discussion by all MaHTAS officials on pertinent areas such as current set-up, exploration on MaHTAS scope and function from the current practice to the expected as well as expanded roles for the next 5 to 15 years. It's hoped that the session provided insightful direction for MaHTAS to keep delivering excellent services, be adaptive and resilient in changing times and continue growing for a better future.



Local Activities

Systematic Review on Evidence-based Clinical Practice Guidelines Development and Implementation Workshop bagi Pakar dan Pegawai Pergigian bagi tahun 2022 (17 - 18 May 2022)

By Dr. Tengku Noor Farhana Tengku Khalid

Staff from MaHTAS had been invited as speakers and facilitators for the above-named workshop which was held at Dorsett Hartamas, Kuala Lumpur. The participants consisted of development group members of two CPGs to be developed by Oral Health Programme. Lectures and group works on literature search, critical appraisal of different study designs and AGREE II instrument were delivered to the participants for their understanding and work on CPG projects.



Training of the Core Trainers on CPG Management of Attention-Deficit/Hyperactivity Disorder in Children and Adolescent (Second Edition) (8 June 2022)

By Dr. Noor Ayuni Bazura Muhamad



This TOT aimed to disseminate CPG content and train healthcare providers in the management of ADHD. It was successfully organised at National Institute of Health, Shah Alam, and attended by 95 multidisciplinary participants of psychiatrists, paediatricians, family medicine specialists, paediatricians, clinical psychologists and occupational therapists from Ministry of Health and local universities. The attendees actively participated in the interactive lectures and case discussions. They were expected to conduct at least a state level echo training in 2023.

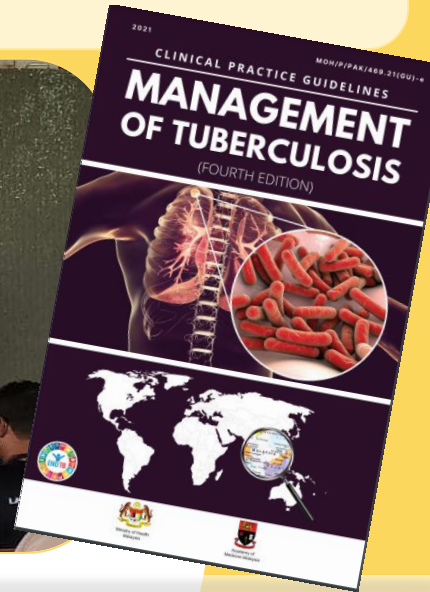


Local Activities

Launching of CPG Management of Tuberculosis in Adults (Fourth Edition) (11 June 2022)

By Pn. Subhiyah Ariffin

World Tuberculosis Day, celebrated on 24 March each year, aims to build public awareness on the global epidemic of TB and efforts to eliminate the disease. The fourth edition of CPG on Management of Tuberculosis was published in 2021. It updated issues on diagnosis and treatment of the disease which were in line with World Health Organization's End of TB Strategy. The CPG was officially launched by YB Dato' Dr. Noor Azmi Ghazali, Deputy Minister of Health I, at Telaga Walk, Langkawi during World TB Day celebration at national level.



Training of the Core Trainers on CPG Management of Dementia (Third Edition) (15 June 2022)

By Dr. Noor Ayuni Bazura Muhamad

The above-titled training of core trainer (TOT) was conducted at Bangi Resort Hotel. It was organised in collaboration with the Malaysian Psychiatric Association (MPA) and Malaysian Society of Geriatric Medicine. MPA was particularly very supportive on mental health-related CPGs. A total of 112 participants attended the training comprising of psychiatrists, physicians, geriatricians, family medicine specialists and occupational therapists from MoH and local universities. The training consisted of lectures and case discussions on evidence-based management of dementia. The participants were expected to conduct echo training at their respective states led by nominated state champions in 2023.



Hospital Directors Conference: Value-based Workshop (20 - 21 June 2022)

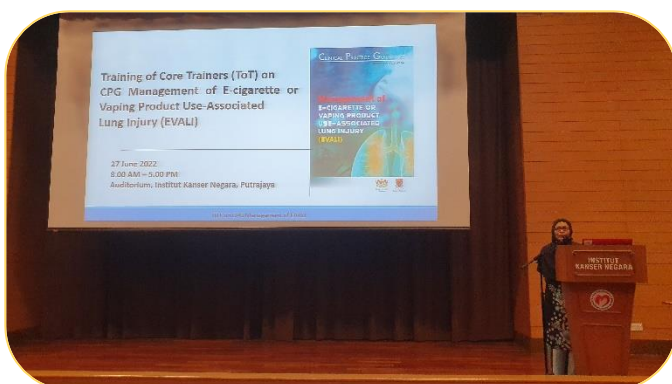
By Pn. Ku Nurhasni Ku Abdul Rahim

A Hospital Directors Conference was held in Eastin Hotel Kuala Lumpur. It was attended by the Hospital Directors of Ministry of Health in Malaysia. The theme was Value based healthcare: Role of Hospital Leaders and MaHTAS was being invited to lead a concurrently held workshop on "Value based healthcare from provider perspective: Decision making in resource allocation". The overall objective of the workshop was to introduce a systematic and explicit value assessments in hospital-based decision making for resource allocation. Fifty hospital directors participated in the scenario-based resource allocation exercise. Participants were divided into five groups and each group was given a set of materials including a description of scenario, wish list and shift list. The prioritisation criteria and its applicability in the decision making were identified. At the end of the workshop, the participants provided positive feedbacks and valued the exercise.

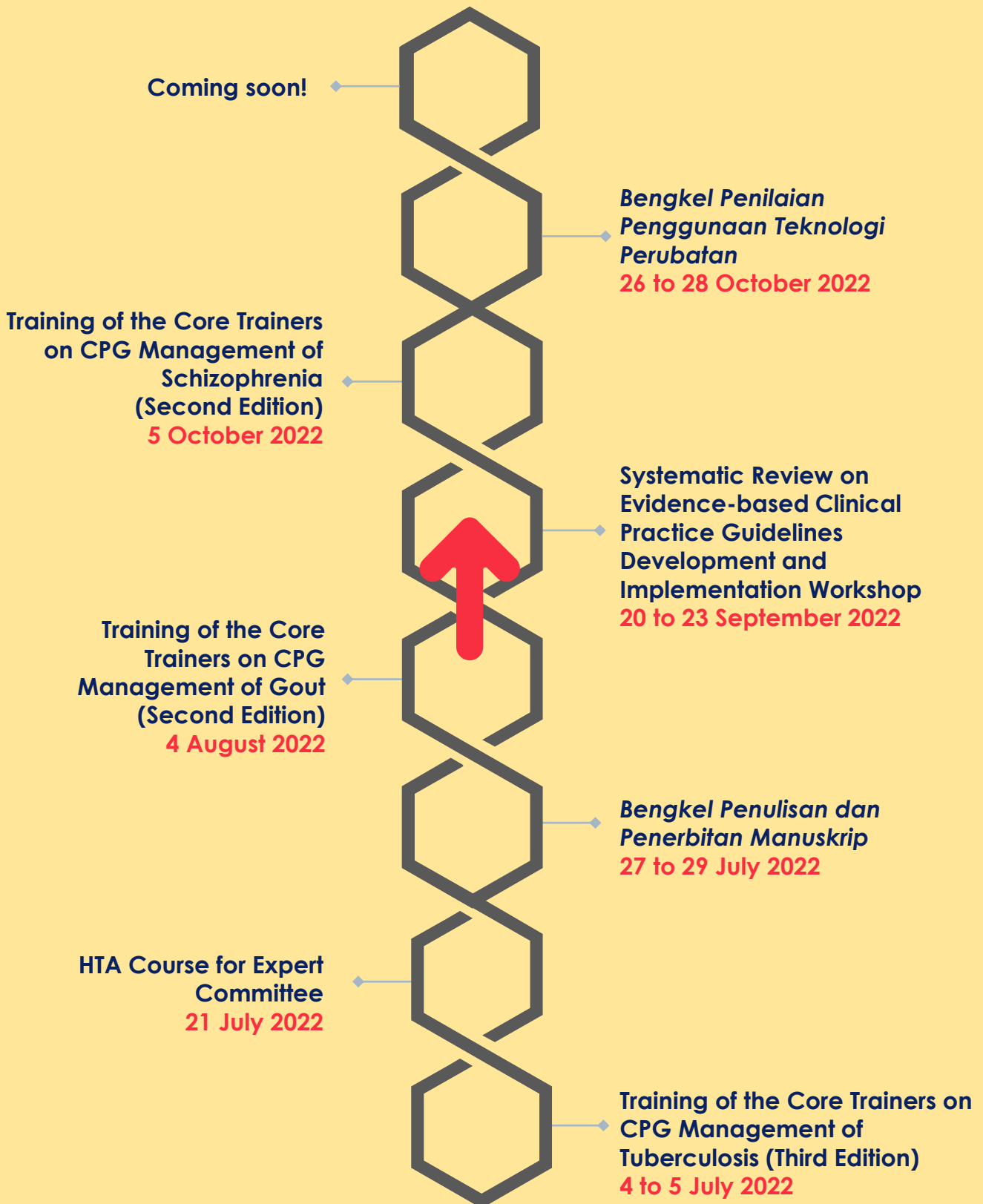


Training of the Core Trainers on CPG Management of E-cigarette or Vaping Product Use-Associated Lung Injury (EVALI) (27 June 2022)

By Dr. Nur Hanani Mat Daud



The CPG Unit of MaHTAS had again successfully conducted a ToT on CPG Management of EVALI as part of its implementation strategy at the Auditorium of National Cancer Institute, Putrajaya. The 104 multidisciplinary attendees comprised of respiratory medicine physicians, general physicians, family medicine specialists, emergency physicians and radiologists from the Ministry of Health and main public universities. The ToT aimed to disseminate the CPG contents comprehensively. It's hope that this ToT will enhance utilisation of the CPG among various relevant stakeholders in the country.



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