Malaysian HTA Section

# MaHTAS Newsletter

::Volume 10 ::August 2010

## NEWS

For the first time, HTAi Annual Meeting was held in Asia namely Singapore in June 2009. Malaysian Health Technology Assessment Section (MaHTAS) members participated actively in this meeting. Datin Dr. Rugayah Bakri presented a talk entitled "HTA findings as Input to Decision Making: Malaysian Experience" in one of the plenary session. She also co-chaired a Parallel Oral Session on HTA in Hepatology and Gastroenterology. Mrs Noormah Mohd Darus presented a talk on "Telehealth Malaysia The Last 10 years" in a Parallel Panel Session on behalf of Dr. Amiruddin Hisan, Director of Telehealth, Ministry of Health, Malaysia.

MaHTAS also took part in posters presentation during this 6th HTAi Annual Meeting in Singapore. Six posters were presented entitled as follows: Enzyme Replacement Therapy, Endobronchial Ultrasound (EBUS), Exhaled Nitric Oxide Measurement Using NIOX or NIOX MINO, Is Artificial Blood an Alternative to Red Blood Cells Transfusion, HTA Impact Study at Ministry of Health Malaysia and Trilogy system.

Several initiatives were introduced to improve the quality of the reports and CPG produced as well as promote the utilisation of the documents. A continuous survey using MaHTAS user feedback was started in 2009 to get the feedback on the quality of the HTA and TR reports. As for TR reports, external reviewer process was introduced to improve the quality of the reports. In addition, a consumer writing course was conducted as a strategy to increase understanding and hence, increase utilization of the HTA reports by various target users. Annual training courses on HTA, and CPG development and implementation were also continued to impart the knowledge and skills in this area to healthcare professionals.

MaHTAS continue to produce actively Health Technology Assessment (HTA) reports, Technology Review (TR) reports as well as Clinical Practice Guidelines (CPG). Four HTA reports and seven CPG were approved between June 2009 and August 2010 in two HTA and CPG Council meetings (refer to Table 1). A total of twenty-eight TR reports were also endorsed (refer to Table 2).

**Table 1. HTA REPORTS AND CPG APPROVED IN HTA AND CPG COUNCIL MEETINGS NO. 2/2009 AND NO. 1/2010**

| | |
|---|---|
| | **HTA reports** |
| 1. | Intraocular lens (IOL) implantation-hydrophilic acrylic versus hydrophobic acrylic |
| 2. | Bevacizumab for 1)Age-related Macular Degeneration 2) Diabetic Retinopathy |
| 3. | Antiseptics for Skin Preparations Prior to Procedures |
| | **CPG** |
| 1. | Management of Transfusion Dependent Thalassaemia |
| 2. | Management of Dementia (2nd Edition) |
| 3. | Management of Chronic Obstructive Pulmonary Disease (2nd Edition) |
| 4. | Hormone Therapy during Menopause in Malaysian Women |
| 5. | Management of Cancer Pain |
| 6. | Management of Stable Angina Pectoris |
| 7. | Management of Dengue Infection in Adults (Revised 2nd Edition) |

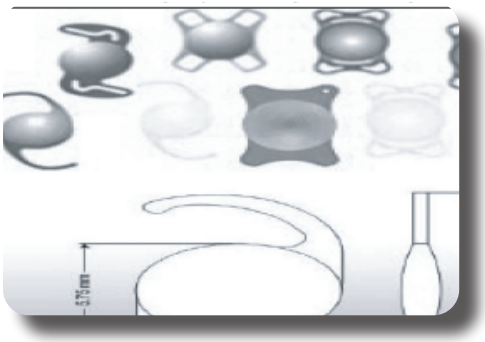
**Table 2. TECHNOLOGY REVIEW REPORTS PRODUCED IN 2009**

| | Technology Review | Recommendation |
|---|---|---|
| **A** | **Neoplasms** | |
| 1. | High Focused Ultrasound (HIFU)-Albatherm® for prostate cancer | Recommended for research purpose |
| 2. | Onco VAX | Recommended for research purpose |
| 3. | DENVAX – Dendritic Cell Therapy | Recommended for research purpose |
| 4. | Electrical Impedance Tomography (EIT) in breast cancer screening | Not recommended |
| **B** | **Musculoskeletal diseases** | |
| 5. | Isokinetic Exercise Machine | Recommended |
| 6. | Shockwave therapy for musculoskeletal disorders | Recommended only for specific condition namely calcific tendinitis of the shoulder |
| 7. | Axiom DRX-9000 True Non-Surgical Spinal Decompression System | Recommended for research purpose |
| 8. | Splinting Material (Aquaplast) – Reveals version of Aquaplast | Not recommended |
| 9. | Computerized Upper and Lower Extremity Evaluation and Exercise System Complete with Computer (E-Link) | Not recommended |
| **C** | **Hemic and Lymphatic Diseases** | |
| 10. | Stopbleed M.Doc | Recommended for research purpose |
| 11. | Recombinant Activated Factor VII for off-label use | Recommended for research purpose |
| **D** | **Otorhinolaryngologic Diseases** | |
| 12. | Mediclaser + Tinnitool® | Recommended for research purpose |
| 13. | Sinomarin® | Recommended for research purpose |
| **E** | **Diagnostic Procedures/Screening** | |
| 14. | Dry test versus wet test for drug testing/ screening | Recommended |
| 15. | Non-invasive Handheld Transcutaneous Bilirubinometer | Recommended |
| 16. | Ceretom Portable CT Scanner – An Update | Recommended for research purpose |
| 17. | Parting Laser Perforator | Not recommended |
| **F** | **Digestive System Diseases** | |
| 18. | Videofluroscopy swallowing study(VFSS) | Recommended for research purpose |
| **G** | **Disorders Of Environmental Origin** | |
| 19. | Bio-oxygen (An update) | Not recommended |
| 20. | OS 1000 | Not recommended |
| **H** | **Infectious Diseases** | |
| 21. | AGT-1 Liquid Gloves (AGT) | Recommended for research purpose |
| **I** | **Organizational Issues** | |
| 22. | Routine Medical Examination – An Update | Recommended for specific purpose |
| **J** | **Transplantation/Eye Disease** | |
| 23. | Corneal Endothelial Stem Cell | Not recommended |
| **K** | **Miscellaneous** | |
| 24. | Low Temperature Steam and Formaldehyde (LTSF) Sterilizer | Recommended for research purpose |
| 25. | E-membrane | Not recommended |
| 26. | Colon Hydrotherapy An Update | Not recommended |
| 27. | Changing to theatre clothes among parents accompanying children undergoing surgery | Not recommended |
| 28. | High Definition Light Emitting Diode (LED) Medical Lighting | Not recommended |

Volume 10 : August 2010

HTA REPORTS IN BRIEF

# Intraocular Lens (IOL) Implantation – Hydrophilic Acrylic versus Hydrophobic Acrylic



Cataract is the most prevalent ophthalmic disease and cataract surgery is a commonly performed surgery in all ophthalmology centres. Late postoperative opacification of IOL caused by dystrophic calcification requiring explantation has been reported with some hydrophilic IOL designs. This has also been encountered in a few government hospitals in Malaysia. We conducted a systemic review to assess the safety of commonly used foldable IOLs (hydrophilic and hydrophobic acrylic implants). Systemic search of electronic databases were conducted and based on inclusion and exclusion criteria and appraisal of the full text articles, 19 relevant articles were included in this review

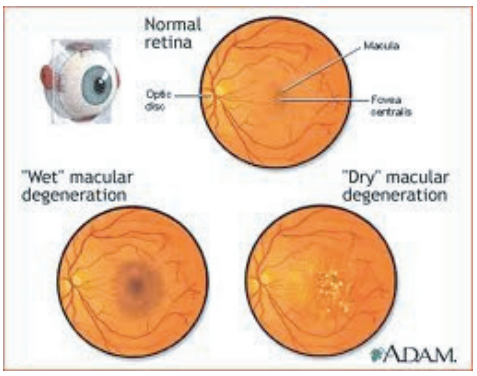
This review found that there was poor to fair level of evidence to suggest that the incidence of IOL opacification affecting vision was only reported in hydrophilic acrylic IOL and not with hydrophobic acrylic IOL. IOL opacification of hydrophilic acrylic IOL was caused by deposition of calcium and phosphate on the IOL surface, or within the optic material or both (on the surface and within the IOL material) depending on the designs of the hydrophilic acrylic IOL. However, the pathophysiology of the causes of such complications have not yet been fully elucidated. Diabetic patients appeared to be more often and more severely affected by IOL opacification. Based on the above review, we recommend the use of hydrophobic acrylic IOLs. Patients who had hydrophilic acrylic IOLs implantation need longer and more frequent follow-up, particularly in the presence of predisposing factors such as diabetes. In view of the absence of Medical Device Act in Malaysia, an incident reporting mechanism for IOL opacification irrespective of materials and designs need to be established to provide more information regarding IOL opacification locally.

## Bevacizumab for Age-related Macular Degeneration and Diabetic Retinopathy

Age-related macular degeneration (AMD) is a disease associated with aging that gradually destroys sharp, central vision. It is the leading cause of vision loss for people over the age of 50 in the western world, affecting approximately 25-30 million people.

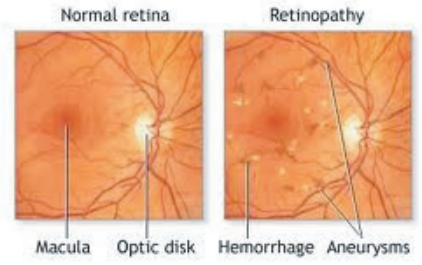
Diabetic retinopathy (DR) is the major blinding ocular complication of diabetes mellitus (DM). Among Malaysians diagnosed to have DM before the age of 40 years, the prevalence of DR was 12.3% in type 1 and 22.3% in type 2 DM, while the prevalence of proliferative DR was 4.0% in type 1 and 9.3% in type 2 DM.

The prevalence of AMD and DR is expected to increase with the increasing aging population and prevalence of diabetes in Malaysia.




Bevacizumab (Avastin®, Genentech) is a monoclonal antibody that binds and inhibits all isoforms of Vascular Endothelial Growth Factor (VEGF). It was approved by US Food and Drug Administration (FDA) in 2004 for metastatic colorectal cancer and later approved for non-squamous non-small cell lung cancer and advanced HER-2 negative breast cancer. It is not yet approved for intraocular use. However, as cost is a factor, bevacizumab has been used off-label for intraocular diseases by many ophthalmologists worldwide.

Twenty full text articles were included in this systematic review. The review suggested that bevacizumab was effective for AMD but the evidence was only of poor to fair quality and the studies were of short duration. Fair evidence showed that bevacizumab was more effective compared to verteporfin photodynamic therapy for patients with minimally classic or occult choroidal neovascularization due to AMD. As for DR, bevacizumab was shown to be more effective in patients with clinically significant diabetic macular edema when compared to macular photocoagulation or combined therapy with intravitreal triamcinolone. There was good evidence to show that bevacizumab treatment given after phacoemulsification and intraocular lens implantation reduced DR progression. There was evidence to support the safety of bevacizumab for management of AMD and DR.

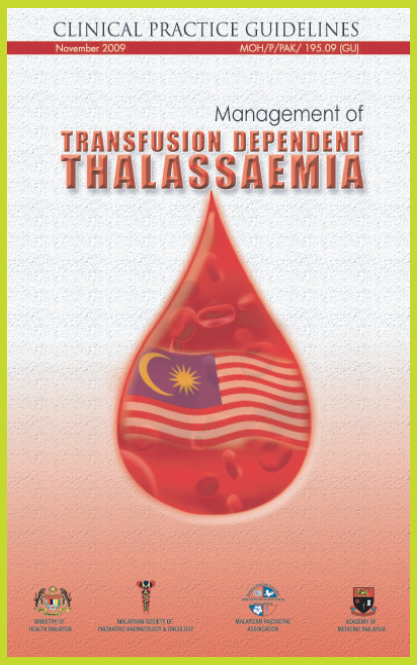



Based on this review, intraocular bevacizumab can be used selectively in patients with predominantly classic, minimally classic or occult choroidal neovascularisation due to AMD and patients with diabetic macular edema. However, caution needs to be taken for high risk patients with history of ischaemic heart disease or thrombo-embolic events. For other indications such as proliferative DR, more clinical research is warranted.

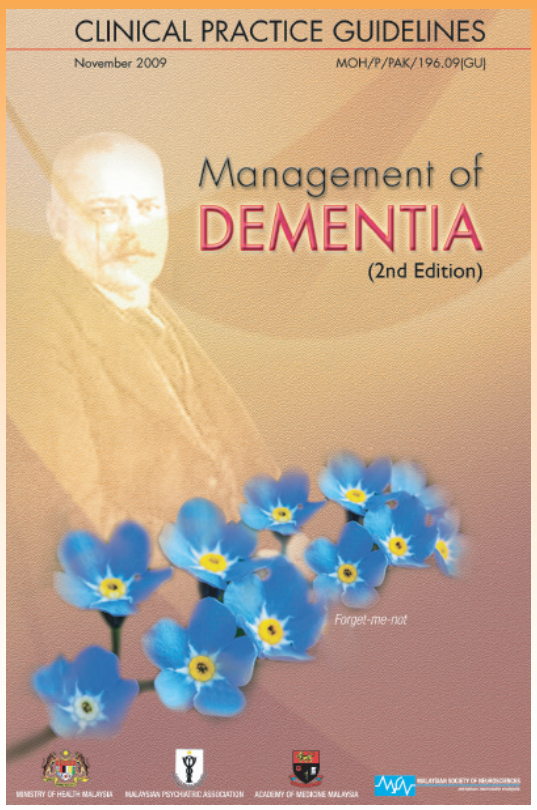
CPG KEY MESSAGES

# MANAGEMENT OF TRANSFUSION DEPENDENT THALASSAEMIA

1. Thalassaemia is an inherited blood disorder affecting all major ethnicities in Malaysia.
2. All patients with Mean Corpuscular Haemoglobin (MCH) < 27 pg should be screened for **thalassaemia**.
3. Cascade screening and appropriate genetic counselling should be provided to the immediate and extended family members of an index patient.
4. All thalassaemia major patients should receive safe and optimal blood transfusions.
5. Monitoring and treatment of iron overload must be optimised to improve survival.
6. Monitoring and treatment of cardiac, infective and endocrine complications will ensure better quality of life and survival.
7. Effective patient management requires good collaboration between transfusion medicine, laboratory and clinical services.
8. Bone marrow transplantation from a matched sibling donor is an established curative treatment option.




# MANAGEMENT OF DEMENTIA (2ND EDITION)




1. Alzheimers disease (AD) is the most common type of primary degenerative dementia.
2. Routine screening of elder population for dementia at the primary care level is not recommended except in patients with subjective memory complaints or if requested by an informant.
3. All patients with suspected dementia at primary care should be referred to a secondary specialist service, and where available a memory clinic.
4. History, physical neurological and mental state examination remains important components of assessment for dementia. Brief cognitive tests can be used to assist diagnosis.
5. Behavioural problem and depression should be enquired on a routine basis. All patients with dementia will need to be assessed mainly on basic activities of daily living and instrumental activities.
6. Acetylcholinesterase inhibitors and/or memantine may be beneficial in improving cognitive function and behavioural problem.
7. Depression in dementia should be treated with antidepressants.
8. Antipsychotic should not be used routinely to treat aggression and psychosis. Antipsychotic if prescribed should be specifically targeted, slowly titrated and time limited.
9. An evaluation of the caregiver needs should be carried out on a routine basis. A multi-component caregiver intervention (e.g. psychoeducation, problem solving abilities, etc) should be offered.

# Consumer Summary Writing Course

A consumer summary writing course was held from 1st to 3rd December 2009 to train MaHTAS staffs and the relevant agencies involve in educating consumers regarding health technologies and clinical practice guidelines. Consumer summary is a strategy to increase understanding and hence, increase utilisation of the reports and guidelines by target users. Miss Eleanor Ahern, a Senior Project Officer for Consumer from Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S) was invited to conduct the course. Thirty three participants comprising of clinical specialists, medical officers, pharmacists, nurses, health education officers and journalists attended the course. We planned to produce consumer summary for selected HTA and TR report starting from 2011, in order to increase utilisation of the reports.

Miss Eleanor Ahern from ASERNIP_S conducting the course

# HTA Courses

Participants of the HTA course for Northern zone

Three HTA courses were conducted within July 2009 till July 2010 period. The first workshop was aim at increasing awareness, promoting utilization and conducting of HTA for healthcare providers in the government sector in the Northern Zone. It was held from 4th until 6th August 2009 at Langkawi.

Another training course on Health Technology Assessment was conducted on 17th August 2009 for the expert committee members who were involved in the preparation of Health Technology Assessment Reports.

HTA Course for Eastern region was conducted from 6th July until 8th July 2010. The participants were expert committee members for the new HTA topics and healthcare providers working in the Eastern region.

Participants of the HTA course for Expert committee listening to the lectures

Group work during HTA course for Eastern region

CPG ACTIVITIES

# Training of Trainers
## on CPG Management of Schizophrenia in Adults

Active participation in discussion of case study

Training of the core trainers using the training module developed from CPG Management of Schizophrenia in Adults was conducted at the Institute for Heath Management on 29 March 2010. The trainers were members of the Development Group. A total of 40 participants comprising of psychiatrists, family medicine specialists and state health officers from all states attended the workshop. They were expected to conduct echo-training in their respective states subsequently. It is envisaged that the CPG utilisation will be enhanced which ultimately will improve the quality of the delivery of health care to the patients.

## Systematic Review on Evidence-based Clinical Practice Guidelines (CPG)
# Development & Implementation Workshop 2010

An annual Systematic Review on Evidence-based CPG Development & Implementation Workshop had been held at Felda Residence Hotel, Kuala Terengganu on 22 – 24 June 2010. A total of 22 participants attended consisting mainly Development Group members of CPG on Management of Otitis Media with Effusion in Children (OME). They were multidisciplinary healthcare professionals such as otorhinolaryngologist, pediatrician, family medicine specialist, audiologist and pharmacist.

The objectives of the workshop were to create awareness and provide knowledge on development of evidenced-based CPG, and to encourage the implementation of such documents. The trainers were staff from MaHTAS who emphasised the importance of proper methodology in CPG development. The workshop was conducted successfully for three days with presentation of relevant topics followed by various group works including hands on session on evidence search and critical appraisal. An evaluation of the workshop showed that the objectives were successfully achieved.

Participants listening to lecture

Group discussion

Volume 10 : August 2010

TR REPORTS IN BRIEF

# NEW TECHNOLOGIES FOR MUSCULOSKELETAL DISEASES

**Introduction**

Musculoskeletal disorders is also called ergonomic injuries and illnesses. The Federal Bureau of Labor Statistics (BLS) defined musculoskeletal disorders (MSDs) as injuries and disorders to muscles, nerves, tendons, ligaments, joints, cartilage, and spinal discs and do not include injuries resulting from slips, trips, falls, or similar accidents. It may include many kinds of sprain and strain, carpal tunnel syndrome, tendinitis, sciatica, and low back pain.

It is the most common and disabling of medical disorders and the leading cause of work related disability among men and women age between 16 to 72 years old. Musculoskeletal disorders have substantial impact on quality of life, use of healthcare resources and economy of the affected person as well as the country.

According to the Malaysian Burden of Disease and Injury Study, 2000, musculoskeletal disorders contributed 6% of Years Live with Disability (YLD) among males and 9% YLD among females. As a group, they contributed 2% of the total Disability Adjusted Life Years (DALYs). Osteoarthritis is the single most important contributor which contributed more than 50% of the cases.

Various methods have been introduced to treat musculoskeletal disorders which include exercise, ultrasound, heat therapy, extracorporeal shock wave therapy and various other methods.

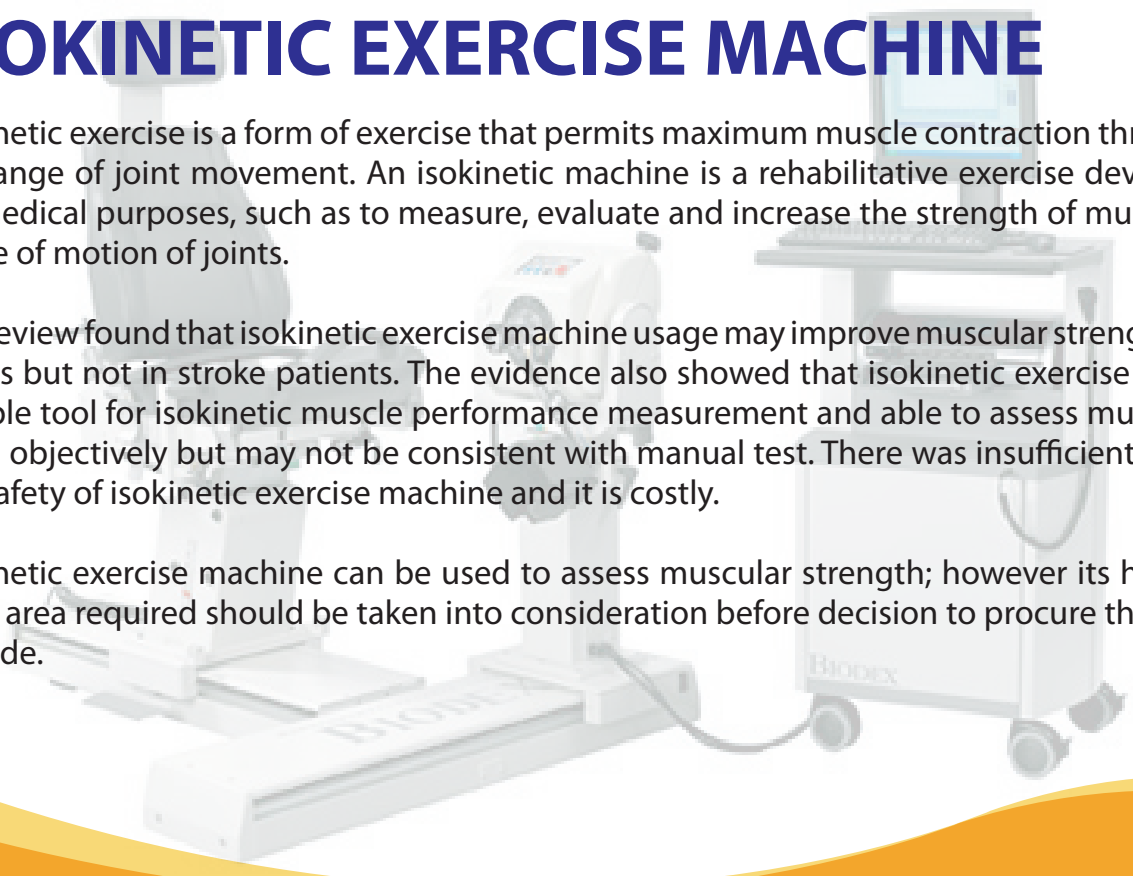
Recently MaHTAS reviewed 5 technologies related to musculoskeletal diseases namely Isokinetic Exercise Machine, Shockwave therapy, Axiom DRX-9000 True Non-Surgical Spinal Decompression System, Splinting Material (Aquaplast), Computerized Upper and Lower Extremity Evaluation and Exercise System Complete with Computer (E-Link).

## ISOKINETIC EXERCISE MACHINE

Isokinetic exercise is a form of exercise that permits maximum muscle contraction throughout the full range of joint movement. An isokinetic machine is a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate and increase the strength of muscles and the range of motion of joints.

The review found that isokinetic exercise machine usage may improve muscular strength in healthy adults but not in stroke patients. The evidence also showed that isokinetic exercise machine is a reliable tool for isokinetic muscle performance measurement and able to assess muscle strength more objectively but may not be consistent with manual test. There was insufficient evidence on the safety of isokinetic exercise machine and it is costly.

Isokinetic exercise machine can be used to assess muscular strength; however its high cost and large area required should be taken into consideration before decision to procure the equipment is made.



# AXIOM DRX 9000

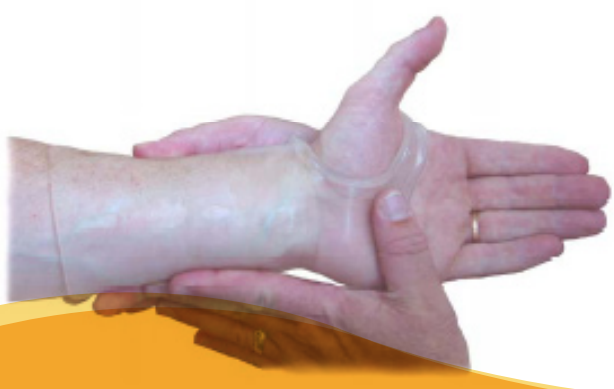
AXIOM DRX 9000 is a non-invasive, traction based therapy for the relief of back and leg pain or neck and arm pain. This spinal decompression system creates a controlled unloading of the vertebra to decrease disc pressure thus increasing blood and nutrient exchange. During spinal decompression therapy, a negative pressure is created within the disc. Because of the negative pressure, disc material that has protruded or herniated can be pulled back within the normal confines of the disc, and permit healing to occur. Non-surgical spinal decompression therapy received FDA approval in 2003.

The review revealed that there was only limited evidence to warrant the routine use of non-surgical spinal decompression system DRX9000. The retrieved evidence is inconclusive due to conflicting results of the randomized controlled trials in the systematic review and the low level of evidence from the phase II non randomized controlled trial and audit chart. This may be, in part, due to heterogeneous patient groups and the difficulties involved to properly blind patients to the mechanical pulling mechanism. Scientifically more rigorous studies with better randomization, control groups, and standardized outcome measures are needed to overcome the limitations of past studies. In view of the above, this non-surgical decompression system DRX9000 can only be recommended for research purposes.

## SPLINTING MATERIAL (AQUAPLAST)– REVEALS VERSION OF AQUAPLAST

Plaster of Paris casts have been the mainstay of early fracture management because plaster cast offers certain advantages compared to other devices, hence they maintain a commonly used method for fracture treatment. However it has poor strength to weight ratio that may render it less desirable as a cast material in some cases.

Aquaplast-T and Original Aquaplast Splinting Material are used to create flexible, customized splints for persons with upper or lower extremity disabilities. When soft, Reveals is transparent, enabling the splint maker to see areas of pressure during fabrication of the splint and it stays soft and workable long enough to allow molding without the need to reheat the material. Setting time can be hastened with ice.



Reveals returns to its original shape when reheated. This allows for correction of errors and reshaping. Like other low temperature thermoplastics, Reveals may be molded directly against the skin. Other advantages are durability, strength and good appearance. There was no retrievable evidence to support the effectiveness, safety and cost-effectiveness of the splinting material (Reveals). Clinical research is warranted to support the effectiveness, safety and cost-effectiveness of this technology before it can be recommended for routine use in the hospital.

## COMPUTERIZED UPPER AND LOWER EXTREMITY EVALUATION AND EXERCISE SYSTEM COMPLETE WITH COMPUTER (E-LINK)

E-link is a comprehensive range of products for computerized evaluation and exercise of upper and lower extremities. It comprised of several components namely E-link database, E-link exercise which cover a spectrum of rehabilitation needs and E-link evaluation which allows greater objectivity, accuracy, and speed of data collection and calculation of upper and lower extremity disorders. There was no evidence retrieved on safety, effectiveness and cost-effectiveness of E-link. E-link is not recommended to be used for evaluation and exercise of upper and lower extremities disorder or injuries until more evidence obtained.

# Past events

Consumer Summary Course
Held on 1-3/12/2009
Institute for Health Management Kuala Lumpur

Launching of CPG on Management of Dementia (2nd edition)
Held on 20/4/2010
Institute for Health Management Kuala Lumpur

Systematic Review Course for Evidence-Based CPG Development & Implementation 1/2010
Held on 22-24/4/2010
Felda Residence Kuala Terengganu, Terengganu

Health Technology Assessment Course for Eastern Region
Held on 6-9/7/2010
New Pacific Hotel Kota Bharu Kelantan

# Upcoming events

"Pharmacoeconomics for beginner"Course
22 September 2010
Bilik Mesyuarat Ibnu Al-Razi, E1, Putrajaya

Course on Retrieval of Evidence
June 2011

Regional HTA Seminar
July 2011

## THOSE WHO LEFT

- MR BEH JOO SIN (RESEARCH OFFICER Q 41) RESIGNED: 14/10/2009
- MR SAHALUDIN SHARIF (ASSISTANT MEDICAL OFFICER U 32) FROM:4/1/2010
- MR MOHD SAID MORAD (ASSISTANT MEDICAL OFFICER U 32) FROM:18/1/2010
- LAW PHUAY FERN (PHARMACIST U 41) FROM 18/1/2010
- MR ZULKIFLI ALIAS (ASSISTANT MEDICAL OFFICER U 32) FROM:12/4/2010

## AND THOSE WHO JOINED

- MR SYFUL AZLIE FUZI (SCIENTIFIC OFFICER C 44) START: 15/10/2009
- DR ROZA SARIMIN (PRINCIPAL ASSISTANT DIRECTOR UD 52) START:3/12/2009
- MRS MAHARITA AB RAHMAN (PHARMACIST U 41) START:17/2/2010
- DR HANIN FARHANA KAMARUZAMAN (SENIOR ASSISTANT DIRECTOR UD 44) START:2/7/2010
- MR SAUDI BAHARUM (ASSISTANT MEDICAL OFFICER U 32) START: 19/7/2010

## PLEASE CONTACT US

**MALAYSIAN HEALTH TECHNOLOGY ASSESSMENT SECTION (MaHTAS)**

**MEDICAL DEVELOPMENT DIVISION, MINISTRY OF HEALTH MALAYSIA, LEVEL 4, BLOCK E1, PARCEL E, PRESINT 1, 62590 PUTRAJAYA**

Tel: +603-88831245/6
Fax: +603-88831230
Email: htamalaysia@moh. gov.my