Malaysian HTA Section

MaHTAS

Newsletter

:: Volume 11

:: December 2011

NEWS

Newly Approved HTA and CPGs

The Health Technology Assessment and Clinical Practice Guidelines Council is the highest body overseeing the Health Technology Assessment (HTA) and Clinical Practice Guidelines (CPG) programs. It gives the final approval of the health technologies and CPGs to be adopted as national evidence-based policies related to health technologies. Three HTA reports and eight CPGs were approved in the two recent HTA and CPG Council meeting held on 15 October 2010 and 6 June 2011 respectively (see Table 1). A total of 25 Technology Review (TR) reports were also endorsed in the meetings (see Table 2).

Table 1. Health Technology Assessment reports and Clinical Practice Guidelines approved in HTA and CPG Council Meeting 2/2010 and 1/2011

	Clinical Practice Guidelines(CPG)
1	Management of Unstable Angina/Non ST Elevation Myocardial Infarction
2	Management of Dyslipidemia (4th Edition)
3	Screening of Diabetic Retinopathy
4	Management of Chronic Kidney Disease in Adults
5	Management of Pulmonary Arterial Hypertension
6	Management Of Breast Cancer (2nd Edition)
7	The Use of Growth Hormone in Children and Adults
8	Management of Avulsed Permanent Anterior Teeth in Children (2nd-Edition)
	Health Technology Assessment (HTA) Reports
1	HPV DNA-Based Screening Test for Cervical Cancer
2	Prostate Cancer Screening
3	Nasopharyngeal Carcinoma Screening

Table 2. Technology Review Reports Produced in 2010

	Technology Review	Recommendation
A	***Hemic and Lymphatic Disease***	
1	Nucleic Acid Testing for Blood Banking – An Update	Recommended
2	Pathogen Inactivation in Donated Blood	Recommended
B	***Musculoskeletal disease***	
3	Prolotherapy	Recommended
4	Autologous Conditioned Plasma for Achilles Tendinitis	Recommended for research purpose
5	Extracorporeal Shockwave Therapy for Chronic Plantar Fasciitis	Recommended for research purpose
6	Spine MED Decompression System	Recommended for research purpose
C	***Nervous System Disease***	
7	Deep Brain Stimulation	Not recommended
8	Stem Cell Therapeutic Centre	Not recommended
D	**Miscellaneous**	
9	PRO NATURE Electrostatic Field Therapy	Not recommended
E	***Neoplasms***	
10	Mobetron ® 1000	Recommended for research purpose
11	Folic Acid Supplementation and Cancer	Recommended for research purpose
F	***Skin and Connective Tissue Diseases***	
12	Versajet™ Hydrosurgery	Recommended for research purpose
G	***Eye Diseases***	
13	Buccal Mucosal Epithelium for Treatment of Ocular surface and Corneal Reconstruction	Recommended for research purpose
H	***Cardiovascular***	
14	Zazen Far Infrared Ray (FIR) Thermal System	Not Recommended
I	***Enviromental Related Issues***	
15	Photo Catalytic PURE AIR	Recommended for research purpose
16	Cyrus Infection Control Unit	Recommended for research purpose
17	Environmental Friendly Chemical (Emulgen)	Not Recommended
18	Bionano Clean and Bionano Care (Sanitiser and Disinfectant Spray)	Not Recommended
19	RydAir Electrostatic Air Cleaner and UV-C Lamps	Not Recommended
20	Filterqueen Indoor Air Quality System (Majestic 360° and Defender 360°)	Not Recommended
21	Complete Systematic Decontamination and Treatment on HVAC System	Not Recommended
22	GUAA disinfection agent	Not Recommended
23	Osprey Deep Clean Dry Steam Vapour (VSD) Cleaning Technology	Not Recommended
24	Nocospray Nocolyse	Recommended for research purpose
J	***Infectious Diseases***	
25	Routine used of Acetominophen Following Childhood Immunization	Not Recommended
26	Antiviral Biomask	Not Recommended
27	OSMOS Mosquito Repellant Wristband	Not Recommended
K	***Otorhinolaryngologic Diseases***	
28	G. TEC System (G. USBAmp, G. TRIGbox, G. PAH)	Recommended for research purpose
L	***Psychology and Psychiatric***	
29	Haemoperfusion Rapid Drug Detoxification with Single Use Haemoperfusor	Not recommended
M	***Surgical procedure***	
30	Syrijet Mark-II Needless Injector	Recommended for research purpose

All the HTA and TR reports, and CPG are accessible online at www.moh.gov.my.

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HTA REPORTS IN BRIEF

ANTISEPTICS

FOR SKIN PREPARATION PRIOR TO PROCEDURE

Antiseptics are germicides applied to living tissue & skin, used only on the skin and not for surface disinfection. An antiseptic is a substance which inhibits the growth and development of microorganisms. It may be either bacteriocidal or bacteriostatic.

In view of the new development in the area of antiseptic, there is a need to update the evidence available to support the use of these antiseptics in the Malaysian Ministry of Health. Thus, this Health Technology Assessment was undertaken to review the antiseptics currently used for skin preparations especially prior to procedures such as surgery, central venous catheterization, epidural catheterization, urinary catheterization, intradermal, subcutaneous, and intramuscular injection which will help healthcare providers to identify the best intervention strategies in preventing and controlling infections in clinical settings. Based on the above review, the following antiseptics are recommended for use prior to the following procedures:

i) **Central venous catheterization**
Two percent (2%) chlorhexidine gluconate in 70% alcohol is the antiseptic of choice prior to central venous catheterization but 0.1% Octenidine in alcoholic solution is potentially beneficial. However, the retrieved evidence shows that 0.1% Octenidine in alcoholic solution was superior to alcohol. More clinical research is warranted.

ii) **Epidural catheterization**
Zero point five percent (0.5%) chlorhexidine in 70% alcohol is the antiseptic of choice for skin preparation prior to epidural catheterization.

iii) **Surgery**
Two percent (2%) chlorhexidine gluconate in 70% alcohol is potentially superior to 4% chlorhexidine and povidone iodine solution and may be the antiseptic of choice for skin preparation prior to surgery

iv) **Urethral catheterization**
The use of either sterile water or antiseptic for skin preparation prior to urethral catheterization is an acceptable practice.

v) **Intradermal, subcutaneous, and intramuscular injection**
For unsoiled skin, the use or not use of 70% alcohol swab prior to the above procedures can be practised.

NASOPHARYNGEAL CARCINOMA SCREENING

Although cancer is a leading cause of death worldwide and projected to rise, more than 30% of the deaths are believed to be preventable. This can be done through education and screening programme. Nasopharyngeal Carcinoma (NPC) is a cancer arising from the epithelial cells that line the nasopharynx. It is more common in certain regions of Asia and Africa than elsewhere in the world in which certain factors are thought to predispose to its occurrence. Screening methods for NPC includes Epstein-Barr virus (EBV) serology and nasopharyngoscopy. In the former, EBV antibodies detection is done on antibodies against Viral Capsid Antigen, Nuclear Antigen and Early D Antigen.

Despite improvements in treatment and its outcomes, only less than 10% of NPC unscreened patients presented with early stage of the disease. With the significant burden of disease of NPC in Malaysia and possible significant role of screening of the malignant condition, one of the strategies for screening and early detection in National Cancer Control Blueprint 2008-2010 is to provide NPC screening service. Thus, a health technology assessment was conducted to assess the effectiveness and cost-effectiveness of NPC screening programme and to assess the diagnostic accuracy of the screening tests used in the NPC screening programme. Based on the assessment, the following are recommended:-

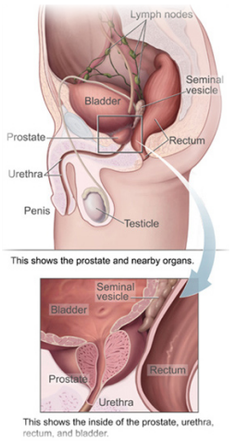
i) There is insufficient evidence to recommend a population-based NPC screening programme as a public health policy. EBV infection is a risk to NPC in individuals with a family history of the disease. In view of the acceptable diagnostic accuracy that it has, the EBV serology test is a promising tool for selective screening in those with a family history of NPC. However, standard guidelines should be developed in its application including follow up of those who are seropositive to EBV infection. Interpretation of such tests is complex and trained physician in EBV testing is necessary.

ii) Evidence of high and good quality assessing the effect of such population-based screening, in terms of the reduction in mortality of NPC in the screened population, the risk-benefit ratio and cost-effectiveness is warranted to recommend a NPC Screening Programme.

PROSTATE CANCER SCREENING

HTA REPORTS IN BRIEF

In Peninsular Malaysia, from 2003 to 2005, prostate cancer was the fourth most frequent cancers among males with ASR of 12 per 100,000 population. The risk factors for prostate cancers are age, family history and race. The natural history of prostate cancer range from indolent to strikingly aggressive with long preclinical phase. Prostate Specific Antigen (PSA) test and the digital rectal examination (DRE) has been used as primary screening tools in the early detection of prostate cancer. While the intention of screening for prostate cancer is to decrease mortality and increase patient's quality of life, the true benefit of screening remains uncertain.



Thirty four full text articles were included in this review. The review showed that there was evidence to suggest that prostate cancer screening may reduce the likelihood of men dying from prostate cancer. However, current published data are insufficient to recommend the adoption of population screening for prostate cancer as a public health policy because of the significant overdetection and overtreatment that would result from the screening. Since men with family history of prostate cancer have a significantly higher risk of developing prostate cancer, we therefore recommend selective screening of asymptomatic men with a family history of prostate cancer from the age of 40 years and above. PSA test may be used for prostate cancer screening. Men who expressed an interest in prostate cancer screening need to be properly informed on the potential benefits and harms associated with prostate cancer screening. A standard guideline for prostate cancer screening needs to be established. Organizational issues such as training, manpower, good referral system, treatment and funding need to be addressed at all levels.

OTHER ACTIVITIES/ NEWS

PUBLICATIONS IN PEER-REVIEWED JOURNAL

Recently MaHTAS has published three articles in peer-reviewed journals. Two of the articles were based on CPG on Management of Hypertension and CPG on Management of Major Depressive Disorder (MDD) respectively. Another article was based on a Health Technology Assessment report entitled School Scoliosis Screening Programme. The articles were as follows:-

1. Management of Hypertension. Malaysian Family Physician. 2011;6(1): 40-43.
2. Management of Major Depressive Disorder (MDD). Malaysian Family Physician. 2011;6(1):44-48.
3. School Scoliosis Screening Programme - A Systematic Review. Med J Malaysia. 2010;65(4):261-267.

RESEARCH ACTIVITIES

At MaHTAS, we conduct primary researches related to HTA and CPG program. In order to evaluate the utilization of Health Technology Assessment (HTA) and Technology Review reports, a continuous survey was conducted through MaHTAS user feedback. The analysis of the feedback received for two HTA reports revealed that 87.1% of the respondents used the report and 93.9% of the respondents felt that the quality of the reports were excellent or good.

Survey on utilization of Quick Reference (QR) on CPGs was conducted to assess their utilization rate. The survey on QR on Management of Major Depressive Disorder was conducted on selected hospitals and health clinics. The results showed that the overall percentage of QR utilisation was 38.3%. Few strategies have been proposed to increase the utilisation such as improving the mechanism of QR dissemination.

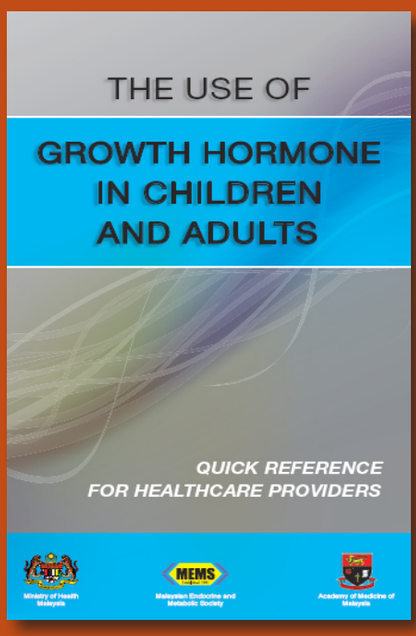
MaHTAS in collaboration with researchers from Universiti Utara Malaysia conducted a study to determine the impact of HTA products' on health policy makers, health providers, specialists, decision makers, and researchers. Mixed method approach was employed where the study has quantitative as well as qualitative components. Although the response rate was 35%, and only 56% of the survey form received could be used for further analysis, the study showed that HTA products had positive impact in influencing decision of public health providers, policy makers and researchers. The HTA products were used by specialists to update their clinical practices and help them in deciding for treatment option. The impact was highly observed for those who used the products in assisting them in policy making. For researchers, the products were to have impact, if they were related to their tasks.

ON LINE HTA REQUEST FORM

In collaboration with Information Management Division, MaHTAS has developed an online request form for Health Technology Assesment. Starting from 2011, request for assesment on health technologies can be submitted using this form which is available from Ministry of Health Malaysia website **http://eservices.moh.gov.my/ubt/Apl/PermohonanPenilaian.php**

CPG KEY MESSAGES

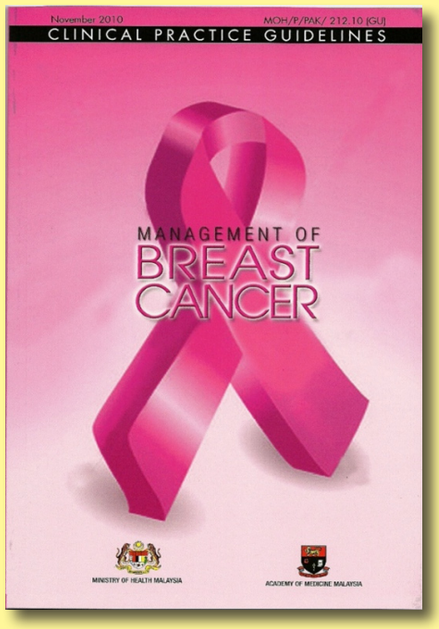
The Use of Growth Hormone in Children and Adults



1. All growth hormone deficient (GHD) children should be treated using the recommended dose of recombinant human growth hormone (rhGH).
2. rhGH therapy can also be used in non-GHD children such as in Turner syndrome and small for gestational age (SGA).
3. Early recognition and early referral is important for optimal outcome.
4. rhGH therapy should not be taken lightly in view of its high cost, the need of prolonged therapy with close follow up by practicing clinicians familiar with rhGH therapy, potential adverse effects and the negative psychological impact from unsuccessful therapy.
5. All rhGH-treated patients should be re-evaluated during transition period.
6. In adults, rhGH should only be given to patients with GHD symptoms with proven adverse quality of life (QoL) and confirmed growth hormone (GH) deficiency.
7. Adults with normal GH status (burns, critically ill patients, ageing, sports, infertility and obesity) should not be offered rhGH.

Management of Breast Cancer

1. Breast cancer is the commonest cancer in all ethnic groups and in all age groups in females from the age of 15 years onwards. The overall Age-Standardised Incidence Rate (ASR) was 39.3 per 100,000 populations in 2006 in Malaysia.
2. Of the cases diagnosed in 2003, 33.6% were women aged between 40 and 49 years.
3. All Chinese women had the highest incidence with an ASR of 46.4 per 100,000 population.
4. Triple assessment which consists of clinical assessment, imaging (ultrasound and/or mammography) and pathology (cytology and/or histology) is an established method for the diagnosis of breast cancer.
5. The American Joint Committee on Cancer (AJCC) Cancer Staging Manual (7th Edition) has been used for staging of cancers in these guidelines.
6. Surgery is the mainstay of treatment of early breast cancer and consists of either breast conserving surgery (BCS) or mastectomy, and assessment of axillary lymph nodes.
7. Breast cancer is recognised as a systemic condition even in early stage of the disease, with a significant risk of distant micro-metastases. As a result, adjuvant chemotherapy has an established role in eradicating these micro-metastases, thus improving survival.
8. The diagnosis of breast cancer is undeniably distressing. In addition to the normal reactions to such a diagnosis, many women experience elevated levels of distress as the illness progresses.
9. Palliative care aims to maximise the quality of life in the time remaining for the patient with breast cancer.



ACTIVITIES

A New Implementation Strategy by CPG Unit

It is important not only to develop a CPG using a strong methodology, but also to ensure the implementation of the evidence-based recommendations stipulated in the CPG. This is especially so when there is often a gap between the development and implementation into practice of the document. The approach taken for implementation should tailor to suit target users. In 2008, MaHTAS developed Quick Reference, Training Module and Patient Information Leaflet for its implementation strategies This year, the section embarks into a new strategy i.e. publication of CPG in the Malaysian Family Physician Journal (MFPJ). The manuscripts are vetted by the Chairman and a Family Medicine Specialist in the development group of the CPG before publication.

The MFPJ is co-published by Academy of Family Physicians of Malaysia and Family Medicine Specialist Association. It has a print run of about 1,300 and goes to all members including Malaysian universities and sister organisations around the world. It is open-access at www.e-mfp.org, and is indexed by DOAJ, SCOPUS, Google Scholar, Open-J-Gate, Ebscohost, WPRIM, and MyAIS. CPG briefs on Management of Hypertension and Management of Major Depressive Disorder were published in the first publication of the journal in 2011. The articles stressed on management of the medical conditions in the primary care such as diagnosis (including screening and classification), basic management and referral. Related algorithms and medication tables were also included illustrate the facts and for better understanding of the readers.

Launching of the Clinical Practice Guidelines (CPG) on “Management of Cancer Pain”

Cancer is a common cause of mortality and morbidity worldwide. Pain occurs in more than 50% of cancer patients at all stages and at least a third of them experience moderate to severe pain. Although pain is a significant source of distress for cancer patients, 43% of cancer patients with pain were undertreated. Opioid therapy is commonly used and this can be a challenge due to the many barriers amongst patients, the public and healthcare providers. In Malaysia, less than 20% of patients with moderate to severe pain receive opioid analgesia. Thus, evidence-based Clinical Practice Guidelines on Management of Cancer Pain together with a Quick Reference, a Training Module and Patient Information Leaflet have been developed aiming to assist healthcare providers to improve the management of pain in cancer patients.

The CPG and its implementation strategies were officially launched by Datuk Dr. Noor Hisham Abdullah, Deputy Director General of Health (Medical) on 10 May 2011 at the Auditorium of Hospital Selayang. The objective of the launch was to create awareness on the CPG, increase utilisation of the document and strengthen the implementation strategies. Pre-launching talks entitled Evidence-based Management of Cancer Pain and Pain Free Hospital were delivered by Dr. Richard Lim Boon Leong and Dr. Mary Suma Cardosa respectively. A total of 200 participants attended the launching ceremony. Clinical Practice Guidelines package consisting of the CPG and the implementation documents were presented to State Health Directors, Deans of Medical Faculty and President of Malaysian Association for the Study of Pain (MASP), symbolic to “roll-out” the use of this CPG in the various public and private health care facilities.

TRAINING ACTIVITIES

Systematic Review on Evidence-Based Clinical Practice Guidelines Development & Implementation Workshop 2/2011

A Systematic Review on Evidence-based CPG Development & Implementation Workshop 2/2011 was held at Bilik Mesyuarat Ibnu Sina, Block E1, Ministry of Health Malaysia, Putrajaya on 11 – 13 July 2011. A total of 27 participants attended it which consisted of mainly Development Group members of Clinical Practice Guidelines (CPG) on Management of Osteoarthritis and CPG on Management of Psoriasis. They were multidisciplinary healthcare professionals such as rheumatologist, dermatologist, family medicine specialist, pharmacist and others.

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 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 critical appraisal on and hands-on session on evidence search. An evaluation of the workshop showed that the objectives were successfully achieved.

Training of the Trainers on Search Strategy

Training of the Trainers on Search Strategy was held from 28 - 31 March 2011 to train MaHTAS staff as well as the relevant agencies involve in scientific evidence searching. The course was conducted in Bayview Hotel, Malacca and organised by MaHTAS in collaboration with World Health Organization (WHO). Miss Sari Susanna Ormstad, an experienced research librarian from Norwegian Knowledge Centre for the Health Services, was invited exclusively to be the consultant for the course.

The objectives of the course were to further improve and strengthen the quality of evidence-based HTA report and CPGs developed by MaHTAS, to impart knowledge and skills on search strategy methodology to the participants and to improve skills in organising search results and reporting search history.

Twenty five participants attended the course, comprising of MaHTAS staff, officers from Disease Control Division, Oral Health Division, Institute of Health System Research (IHSR), Ministry of Health library and Ministry of Health, Singapore. Hands-on session had been very useful session whereby all participants were guided step by step on how to do systematic search.

From the course, it was concluded that search strategy is important in developing evidence-based HTA and CPG. The search strategy has to be **systematic, comprehensive** and **transparent.** The Manual on Evidence Search Strategy will be finallised following the training for reference of MaHTAS staffs.

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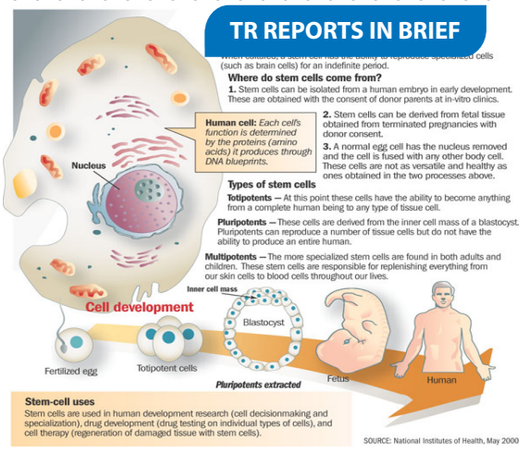
STEM CELLS

INTRODUCTION

Stem cells have the ability to build every tissue in the human body. For cells to fall under the definition of stem cells they must display two essential characteristics. First, stem cells must have the ability of unlimited self-renewal to produce progeny exactly the same as the originating cell. Second, they must be able to give rise to specialized cell type that becomes part of the healthy human.

There are major changes happening in stem cell therapies that are setting a new paradigm in medicine. These developments are building on the successes of bone marrow haematopoietic stem cell (HSCs) transplants that have more than 30 years of patient applications in blood diseases and cancer. Recently, MaHTAS conducted three reviews on stem cells therapy for various diseases.



STEM CELLS THERAPY FOR NEUROLOGICAL DISEASES

A review was conducted to determine the safety, efficacy and cost implications of stem cells transplantation for cerebral palsy, motor neuron disease, stroke, multiple sclerosis, muscular dystrophy, femoral head necrosis, diabetic foot, lower limb ischaemia, spinal cord injury and optic nerve hyperplasia.

There were eleven articles retrieved on stem cells treatment for spinal cord injury, multiple sclerosis and stroke. No published article was retrieved on other diseases in the available databases. The evidence on stem cells therapy for multiple sclerosis showed that it was still at experimental stage. Similarly, the evidence on stem cell therapy for stroke and spinal cord injury was insufficient and showed that it was still in the developmental stage. The evidence showed that adverse events were common with stem cells therapy and range from minor to severe adverse events.

CORNEAL ENDOTHELIAL STEM CELL

Endothelial cell loss due to dystrophy, trauma, or surgical intervention is usually followed by compensatory enlargement of the remaining endothelial cells; which often lead to irreversible corneal endothelial dysfunction. Penetrating keratoplasty for corneal endothelial dysfunction is not risk free, and alternative methods for replacing the endothelium without corneal trephination and sutures have been developed. Irrespective of the selected keratoplasty procedure, fresh donor corneas are necessary to treat corneal endothelial dysfunction, and because their availability is limited, the replacement of endothelial cells with cultivated corneal endothelial cells (CECs) constitutes an important alternative treatment method for corneal endothelial dysfunction. Techniques for growing human CECs in culture have been reported, and attempts have been made to develop transplantation models of cultivated human CEC sheets using carriers such as collagen sheets, amniotic membrane, or no carrier matrix.

The review was conducted to assess the effectiveness, safety and cost-effectiveness of the advanced cell based treatment technologies using corneal endothelial stem cell technology. There was no retrievable evidence to support the effectiveness, safety and cost-effectiveness of the advanced cell based treatment technologies using corneal endothelial stem cell technology. Evidence did indicate that this technology is under experimental stage. National standards for stem cell transplantation and guidelines for stem cell research and therapy developed by Ministry of Health Malaysia must be adhered by practitioners and scientists to ensure patients safety. Clinical trials are warranted to support the effectiveness, safety and cost-effectiveness of this technology before it can be recommended for use in hospitals.

BUCCAL MUCOSAL EPITHELIUM FOR TREATMENT OF OCCULAR SURFACE AND CORNEAL RECONSTRUCTION

New method of ocular surface reconstruction using autologous Cultivated Oral Mucosal Epithelial Transplantation (COMET) has been reported in the treatment of patients with bilateral Limbal Stem Cell Deficiency (LSCD). The major advantage of this new approach is that it negates the need for postoperative immunosuppressive therapy.

Evidence indicates that this technology is under experimental stage. There is a potential that autologous oral mucosal epithelium are effective for reconstructing the ocular surface and restoring vision in patients with bilateral total stem-cell deficiencies. Long-term follow-up and experience with a large series of patients are needed to assess further the benefits and risks of this method.

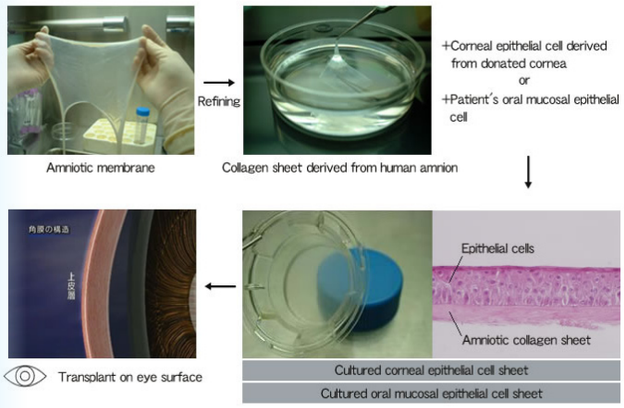


Figure 1: Cultured oral mucosal epithelial cell sheet. This sheet uses cells from the patient's oral mucosa and is designed to serve corneal epithelial functions

TRAINING ACTIVITIES FROM AUGUST 2010 TO NOVEMBER 2011

1. "Training of Trainers on Effective and Efficient Evidence Search" conducted by Sari Ormstad from Norwegien Knowledge Centre for Health Sciences from 29 - 31 March 2011.
2. Systematic Review for Development and Implementation of Evidence-Based CPG 1/2011 from 12 – 14 March 2011.
3. Training on Endnote for MaHTAS staffs on 16 June 2011.
4. Systematic Review for Development and Implementation of Evidence-based CPG 2/2011 from 11 – 13 July 2011.
5. "Meta analysis Methods in Evidence Synthesis" course from 12 – 15 September 2011.
6. Pharmaco-economic workshop from 11-13 October 2011.

TRAINING COURSES PLANNED FOR 2012

1. HTA Seminar: Maximizing Value in Conducting HTA and the Role of HTA in the New Cost-Contained World.
2. HTA Training for Southern Zone.
3. Systematic Review Workshop on Development and Implementation of Evidence-based CPG 1/2012.
4. Workshop on implementation of CPG- quick reference, patient leaflet, training the trainers.

TURNOVER OF MaHTAS STAFFS

THOSE WHO LEFT

Mrs Mariammah a/p Krishnasamy
Senior Assistant Director C 44
From: 18 April 2011

Mrs Haarathi a/p Chandriah
Principal Assistant Director U 48
From: 31 July 2011

Mr Saudi Baharom
Assistant Medical Officer U 32
From: 1 October 2011

THOSE WHO NEWLY JOINED

Mrs Khor Sok Fang
Research Officer Q 41
Start: 1 June 2011

Mrs Ku Nurhasni Ku Abd Rahim
Pharmacist U 44
Start: 8 July 2011

Mrs Norazizah Salleh
Administrative Assistant N 17
Start: 8 September 2011

Mr Mohd. Fadhlurahman Kamarudin
Assistant Medical Officer U 32
Start: 19 September 2011

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