Centre universitaire de santé McGill
McGill University Health Centre

Technology Assessment Unit of the McGill University Health Centre

TAU Annual Report

April 1, 2009-March 31, 2010

For information on this publication or on any other report of the MUHC TAU, please address your inquiries to the:

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Mission Statement

- To advise the hospital in difficult resource allocation decisions, using an approach based on sound, scientific technology assessments, and a transparent, fair decision-making process.

- To publish its research in peer-reviewed journals when appropriate, and contribute to the training of personnel in the field of health technology assessment.

MUHC TAU Executive Committee

Nandini Dendukuri – Director **Dr. Maurice McGregor - Chairperson**

Committee Members	Discipline
André Bonnici	P & T Committee
Sandra Dial	Clinical Epidemiology
Christian Janicki	Quality Management
Brenda MacGibbon-Taylor	Patients' Committee
Gary Pekeles	Council of Physicians & Dentists
Guylaine Potvin	Multidisciplinary Council
Judith Ritchie	Council of Nurses
Hugh Scott	Consultant (Invited Member)
Gary Stoopler	Administration

Administrative Changes

Dr. Sandra Dial has kindly accepted to be the representative on our committee for Clinical Epidemiology and Dr. Hugh Scott has joined our committee in a consultant role.

This publication was written by Lorraine Mines of the Technology Assessment Unit of the McGill University Health Centre (MUHC TAU). This document is available in PDF format on our website: http://www.mcgill.ca/tau/publications/annual

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TAU Reports

NOTE: Projects are researched and drafts prepared by members of the MUHC TAU, referred below as "the authors". They are assisted by expert consultants appointed for each project. Draft reports are then circulated, reviewed, amended and finally approved by the full Executive Committee who thereby become “the authors” of the final report. From April 1, 2009 through March 31, 2010 the following 11 reports were approved:

Carmustine Wafers (Update)

Requestor:	TAU Initiative
Title:	L'utilisation des implants Carmustine (Gliadel wafer) chez les patients attients de gliome malin.
Publication date:	April 2009
Author(s):	Mouhcine Nassef Nandini Dendukuri Maurice McGregor
Background:	In January 2004 it was the subject of a review by the Technology Assessment Unit (TAU) of the MUHC. At that time it was recommended that its use should be limited to 10 patients per year, who were undergoing recurrent glioma resection, and who had had an unsuccessful response to standard chemotherapy. This report is an update, to determine whether new evidence suggests this recommendation should be changed
Recommendation(s):	It was recommended that there should be no change of the recommendations of the previous report, i.e. that use of Gliadel

wafers should be restricted to no more than 10 highly selected cases per year and that a registry should be maintained on all use of this technology.

Opportunity Costs

Requestor:	TAU Initiative
Title:	Opportunity Costs Associated with Technology Expansion in the MUHC.
Publication date:	May 5, 2009
Author(s):	Maurice McGregor
Consultants:	Christiane Bérubé, René Carignan, Benoit De Varennes, Peter Goldberg, Nicolas Robert, Larry Stein, Gary Stoopler, Carole Tétreault, James Brophy , Robert Jacob, Allan Sniderman, Lee Soderstrom, and Nandini Dendukuri
Background:	This report is not a Health Technology Assessment (HTA). Its purpose is to identify a largely unrecognized phenomenon. Each new technology acquired by the MUHC that increases net costs without reimbursement by government pushes the budget into greater deficit. In 2007-08 the net cost to the MUHC of new technologies that were not reimbursed by government was $6,552,496
Recommendation(s):	The MUHC should initiate a process whereby the rigor of evaluation of each contemplated technology acquisition is assured. The hospital should also consider more closely tracking the costs of unreimbursed technologies over time in order to increase the number appeals for reimbursement.

Impella® Ventricular Assist Device

Requestor:	Mr. Gary Stoopler, Administrative Director, Surgery, Medicine, Cancer Care, Mental Health & Women's Health
Title:	The Impella® Percutaneous Ventricular Assist Device

Publication date:	June 16, 2009
Author(s):	Shahrokh Esfandiari, Lonny Erickson, Maurice McGregor
Consultants:	Dr. Renzo Cecere and Dr. Gordon Samoukovic, Department of Cardiovascular Surgery Mr. Nicolas Robert, Department of Finance Mme. Christiane Bérubé, Vascular Laboratory
Background:	In early 2008 the Department of Cardiovascular Surgery received authority to use the Impella® percutaneous ventricular assist device for the temporary support of up to 10 cases of actual or threatened left ventricular failure after which there should be a complete evaluation of the use of this device based on the available literature and on this experience. On February 3, 2009 the TAU was requested by Mr. Gary Stoopler to undertake such an evaluation.
Recommendation(s):	This technology should be supported by the MUHC. However it is an expensive technology and its use should be monitored. Should the annual use of Impella® exceed the currently estimated 10 units per year, the appropriateness of selection of cases, should be reviewed.

Deep Brain Stimulation for Parkinson's Disease

Requestor:	Françoise Chagnon, Director of Professional services, MUHC
Title:	Subthalamic Deep Brain Stimulation (DBS): Clinical efficacy, safety and cost compared to medical therapy for the treatment of Parkinson's Disease
Publication date:	November 27, 2009
Author(s):	Irene Pan, Nandini Dendukuri, Maurice McGregor
Consultants:	Dr. Abbas Sadikot, Department of Neurosurgery, MUHC Ms. Elizabeth Coté, Department of Neurosurgery, MUHC Mr. Nicolas Robert, Department of Finance, MUHC
Background:	The objective of this health technology assessment (HTA) is, 1) to systematically review the literature since 2005 on efficacy and safety of bilateral subthalamic deep brain stimulation (DBS) compared to best medical therapy for the treatment of Parkinson's disease (PD),

	and, 2) to estimate the cost of this procedure from the point of view of the MUHC.
Recommendation(s):	The committee recommends that Deep Brain Stimulation of the Subthalamic Nucleus is a procedure that should be maintained and expanded at the MNH to the extent possible.

Radiofrequency Ablation of Hepatocellular Carcinoma

Requestor:	Dr. L. Stein (Radiologist-in-charge, Royal Victoria Hospital), Dr. R. Lisbona (Chairman, Department of Radiology, McGill University Health Centre (MUHC)) and Ms. P. Rozanski (Director, Therapeutic & Diagnostic Services-MUHC)
Title:	Percutaneous Radiofrequency Ablation for treatment of hepatocellular carcinoma
Publication date:	July 30, 2009
Author(s):	Xuanqian Xie, Nandini Dendukuri and Maurice McGregor
Consultants:	Dr. Lawrence Stein, Chief Radiologist, Royal Victoria Hospital; Nicolas Robert, Department of Finance, MUHC; Dr. David Valenti, Department of Radiology, Royal Victoria Hospital Alain Lapointe, La direction de l'évaluation des technologies et des modes d'intervention en santé, du CHUM.
Background:	Surgical resection (SRS) is regarded as the gold standard therapy for early stage Hepatocellular Carcinoma (HCC). There is an increasing interest in percutaneous radiofrequency ablation (PRFA) for early stage HCC patients because it is not as invasive as surgery and also less costly. At the MUHC in 2008 there were 40 such procedures for liver cancer. However, for budgetary reasons, this number was less than the demand.
Recommendation(s):	On the basis of the evidence currently available, the MUHC should fully fund the use of PRFA for the treatment of appropriate liver cancers. However, the evidence should be frequently reviewed, and this recommendation should be reconsidered, should any new evidence that confirms higher recurrence rates and shorter disease free survival following PRFA, become available.

Acellular Dermal Matrix for Breast Reconstruction

Requestor:	Lucie Thomas, Associate Director of Nursing, Perioperative Service, Surgical Mission
Title:	Clinical efficacy and cost of Allogenic Acellular Dermal Matrix (AADM) in implant-based breast reconstruction of post mastectomy cancer patients
Publication date:	May 5, 2010
Author(s):	Shahrokh Esfandiari, Nandini Dendukuri, Maurice McGregor
Consultants:	Dr. Karl Schwarz, Department of Plastic Surgery, MUHC. Dr. Alain Danino, Department of Plastic Surgery, CHUM. Jane Chambers-Evans, Clinical Ethicist, MUHC. Dr Lucie Lessard, Chair. Department of Plastic Surgery, MUHC.
Background:	Restoration of the breast following mastectomy can be performed using either implants or autogenous tissue. This report is concerned only with the former procedure. Implantation of an expander or prosthesis is frequently complicated by lack of a sufficiently large skin-muscle envelope resulting in complications and poor aesthetic outcomes. Use of an Allogenic Acellular Dermal Matrix (AADM) has been suggested as a means to avoid these complications and possibly shorten the reconstructive process. The purpose of this report is to carry out a systematic review of the use of AADM (brand names AlloDerm or DermaMatrix) for breast reconstruction following mastectomy with the objective of estimating the safety, health benefit and cost impact of this intervention
Recommendation(s):	It is recommended that this technology receive temporary approval for 60 cases on the following conditions**.** • To assist the MUHC in establishing a permanent policy, the surgeon concerned should be requested to maintain a record of all breast reconstructions in which AADM is used, with documentation of risk factors for poor outcomes, perioperative and post-operative complications, and all other relevant details including subsequent revision procedures.

- A retrospective evaluation of all procedures in which AADM has been used, should also be undertaken, based on the same criteria.
- In addition, the aesthetic outcome of each procedure involving the use of AADM should be formally evaluated by at least three individuals who are not members of the Department of Plastic Surgery.
- This record of procedures and aesthetic evaluations should be submitted to the Hospital (the Head of Surgery and the Administrative Director responsible for the Department of Surgery) within 18 months, at which time the decision concerning the continued use of AADM should be made.

Matrix Coils for C-V Aneurysms (Update)

Requestor:	TAU Initiative
Title:	Use of Matrix Coils in the Treatment of Cerebro-vascular Aneurysms: An Update
Publication date:	July 9, 2009
Author(s):	Mouhcine Nassef, Maurice McGregor
Background:	In June 2004 at the request of Mr Victor Simon, Chief Operating Officer of the MUHC, the TAU carried out an evaluation of the use of Matrix Coils in the treatment of cerebro-vascular aneurysms. It was concluded that evidence of additional health benefits had not been identified, and it was recommended that despite the relatively low budget impact, the purchase of matrix coils for routine management of cerebral aneurysms could not be recommended [1].The objective of the present report is to identify and evaluate any new evidence on this topic that might have become available since the original publication, and to reconsider whether its recommendations should be modified.

Conclusion(s):	A review of the literature published since our previous report contains no evidence that suggests the use of Matrix coils will have superior clinical outcomes to GDC. There is therefore no reason to change the previous recommendation that the purchase of matrix coils for routine management of cerebral aneurysms is not recommended.

A gentamicin-collagen sponge for prevention of sterna wound infections

Requestor:	Mr. Gary Stoopler, Administrative Director, Surgical Mission (MUHC)
Title:	Efficacy and cost-effectiveness of Collatamp-G for infection prophylaxis in cardiac surgery
Publication date:	November 30, 2009
Author(s):	Irene Pan, Nandini Dendukuri and Maurice McGregor with the assistance of Xuanqian Xie
Consultants:	Dr. Benoit de Varennes, Department of Cardiac Surgery MUHC Ms. Christine Page, Department of Cardiac Surgery MUHC Ms. Connie Patterson, Department of Infection Control MUHC Mr. Nicolas Robert, Department of Finance MUHC
Background:	Sternal wound infections (SWI) are associated with serious morbidity and increased healthcare costs. There have been reports that the risk of SWI can be reduced by insertion of a Gentamicin-loaded collagen sponge (GCS) in the wound at the time of surgery. The aims of this technology assessment report are: i) to systematically review the literature on the efficacy of GCS in preventing infections following cardiac surgery, ii) to review the literature on risk factors for SWI after cardiac surgery, iii) to estimate the frequency of SWI following cardiac surgery at the MUHC and to estimate the influence of putative risk factors and iv) to determine cost-effectiveness and budget impact of GCS in the MUHC setting.

Recommendation(s):	1) Though promising, evidence of the benefit of GCS is insufficiently strong to justify a recommendation that it should be used on a permanent ongoing basis. 2) However, the evidence of possible benefit and the likelihood that it may lower hospital costs enough to largely offset the costs of its use strongly suggests that an effort to procure better evidence would be justified. 3) The Department of cardiac surgery should be encouraged to conduct research with two objectives: 1) To determine the risk factors predictive of SWI at the MUHC and their frequency, and 2) To determine the effectiveness of GCS in lowering the incidence of SWI through an RCT. 4) Every support should be given to the Department to find the necessary funding for these projects.

Probiotics for prevention of *Clostridium difficile* diarrhea (Update)

Requestor:	TAU Initiative
Title:	The use of probiotics in the prevention and treatment of *Clostridium Difficile* diarrhea: An Update
Publication date:	November 25, 2009
Author(s):	Xuanqian Xie, Maurice McGregor and Nandini Dendukuri
Background:	In 2005, the use of probiotics for the prevention and treatment of CDAD in adults was evaluated by the Technology Assessment Unit (TAU) of McGill University Health Centre (MUHC). It was concluded at that time that there was insufficient evidence of benefit for either prevention or treatment of CDAD, and the use of probiotics for this purpose at the MUHC was not recommended. The present document is an update of that report.
Recommendation(s):	Use of probiotics for the prevention or treatment of CDAD at the MUHC is not recommended.

Transcatheter Aortic Valve Implantation

Requestor:	Mr. Gary Stoopler, Administrative Director of the Surgical and Medical Missions of the MUHC
Title:	Transcatheter Aortic Valve Implantation (TAVI) at the MUHC:
Publication date:	December 7, 2009
Author(s):	Maurice McGregor and Shahrokh Esfandiari
Consultants:	Dr. Giuseppi Martucci, Cardiovascular Division for clinical advice and provision of clinical data. Mme Doris Dubé, Department Quality Management, for provision of hospital stay data. Mr. Nicolas Robert, Department of Finance, for provision of MUHC cost data.
Background:	Severe aortic stenosis is a disabling disease with a high mortality. The only effective treatment is surgical replacement of the aortic valve. However, advanced age or serious comorbidities may render this impossible. Recently a procedure has been developed whereby a valve prosthesis can be inserted either via retrograde arterial catheterization or by trans-apical insertion through the chest wall. This procedure was given preliminary approval at the MUHC in 2007 on the understanding that it would be the subject of a formal review within approximately one year. This report is based on a systematic review of the literature and examination of the records of the first 12 cases undertaken at the MUHC.
Recommendation(s):	1) This is an effective technology that should continue to be funded by the MUHC. 2) Since this is a relatively new procedure, and one in which both the selection of patients and its execution are crucial for success, the Cardiovascular Division should maintain a registry, including follow-up, of all cases. 3) The register should be examined by the MUHC in approximately one year at which time the decision to continue funding should be reviewed.

BAÂRX (Radio Frequency Ablation treatment for Barrett's Esophagus

Requestor:	Dr. Baffis V., Interim Chief of Division of Gastroenterology, MUHC
Title:	Radiofrequency ablation for treatment of Barrett's esophagus: A systematic review and cost analysis
Publication date:	November 12, 2009
Author(s):	Xuanqian Xie, Maurice McGregor, Nandini Dendukuri
Consultants:	Dr. Serge Mayrand, Gastroenterologist, MUHC Dr. Lorenzo Ferri, Surgeon, MUHC
Background:	Barrett's esophagus (BE) patients with high-grade dysplasia have a high risk of esophageal cancer (59% in five years). The standard treatment for high-grade dysplasia is esophagectomy. However, it is associated with an operative mortality of 3-5%, and a rate of serious operative complications of 30 to 50%. Therefore there has been a keen interest in alternative therapies. A radiofrequency ablation (RFA) technology recently developed by BÂRRX Medical Inc., has shown promise. Roughly 7 high-grade dysplasia patients would be eligible for RFA treatment each year at the McGill University Health Centre (MUHC). The aims of this report are to systematically review the literature on the effectiveness of RFA for BE patients with high-grade dysplasia, and to compare the cost of RFA and esophagectomy from the point of view of the MUHC.
Recommendation(s):	1) The TAU committee strongly recommends that RFA treatment for high grade oesophageal dysplasia be funded by the MUHC. 2) In the absence of increased funding for this procedure from government, an annual turnover above 10 procedures per year should not be permitted without review of this decision. 3) Because of the paucity of follow-up data, this report should be considered for update within approximately 2 years.

Diffusion

As TAU gains maturity, it is being increasingly recognized as an innovative and effective model for health technology assessment. This recognition has taken several avenues:

1. Our reports are indexed in the international database for the Center for Reviews and Dissemination, York University, UK. http://www.york.ac.uk/inst/crd/crddatabases.htm)

2. Our reports are diffused from our website (www.mcgill.ca/tau) . Between April 1, 2009 and March 31, 2010 our website received 251,156 hits a large increase from the 2008-2009 level of 120,138.

3. Our reports are also now circulated to all members of the McGill RUIS.

Work in Progress

1. Efficacy and cost-effectiveness of a gentamicin-loaded collagen sponge as an adjuvant antibiotic prophylaxis for colorectal surgery.

2. Negative Pressure Wound Therapy (NPWT) Update of Report 19

3. Efficacy, safety and cost of ultrafiltration for the management of acute decompensated heart failure.

4. Estimating the cost of central line infections at the MUHC.

5. Argon Beam

TAU Related Activities

Dr. McGregor is a member of the International Expert Committee advising the Institut fur Qualitat und Wirtschaftlicheid im Gesundheitswesen (IQWiG) of Germany on Methods for Economic Evaluation of Health Care Interventions.

Dr. Dendukuri represents TAU at quarterly meetings of hospital-based technology assessment units in Quebec that are organized at AETMIS.

Dr. McGregor is the Chair of the Research Committee of the Montréal based Portage Programme, and a regular contributor to the Executive Training for Research Application (EXTRA) program for health executives.

Dr. Dendukuri was invited to teach a 3-hour workshop on "*Bayesian Methods for Health Technology Assessment*" at the Canadian Agency for Drugs and Technologies in Health (CADTH) at their Annual Symposium in Ottawa, April 2009.

Dr. Dendukuri is acting as a consultant to AETMIS on a project aimed at evaluating bypass surgery in Quebec.

Dr. Dendukuri participated in the monthly meetings of the Operating Room Product Approval Committee (ORPAC) of the MUHC.

Collaboration with the Nijmegen Center for Evidence Based Practice, Nijmegen, The Netherlands to train students in technology assessment; to date six international graduate students have completed a 4-5 month training program in Health Technology Assessment as well as one student from the University of Montreal's ULYSSES program, an international master's program in Health Technology Assessment and Management (HTA&M).

Presentations

1. Xie X., Dendukuri N.Measuring cost-effectiveness: Incremental Cost Effectiveness Ratio vs. NetBenefit". Technology Assessment Unit, McGill University Health Centre, Montreal. November 2009.

2. Dendukuri, N. Clinical efficacy and cost of Allogenic Acellular Dermal Matrix (AADM) in implant-based breast reconstruction of post mastectomy cancer patients". Atelier enjeux et pratiques, Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS), Montreal. October 2009.

3. Lapointe A., McGregor M. La microchirurgie endoscopique transanale (TEM). CADTH Symposium, Halifax. April 19, 2010.

4. Xie X., Dendukuri N., McGregor M. "Comparison of Coblation Tonsillectomy and Electrocautery Tonsillectomy in Pediatric Patients". CADTH Symposium, Ottawa, April 5-7, 2009.

5. McGregor M. Budget Creep, an overlooked factor in the sustainability debate. CADTH Symposium, Ottawa. April 5-7, 2009.

6. McGregor M. How do we get the most from HTA? CADTH Symposium. Ottawa April 5- 7, 2009

Peer-reviewed Publications

1. Xie X, Dendukuri N, McGregor M. Percutaneous Radiofrequency ablation for the treatment of hepatocellular carcinoma: A Health Technology Assessment. Accepted by the International Journal of Technology Assessment in Health Care

2. Filion K, El-Khoury F, Bielinski M, Schiller I, Dendukuri N, Brophy J. Omega-3Fatty Acids In High-risk Cardiovascular Patients: A meta-analysis Of RandomizedControlled Trials. BMC Cardiovascular Disorders, 10:24. 2010

3. McGregor M. Paying for Technology: The Cost of Ignoring Opportunity Costs.. Healthcare Quarterly. 2010. 13 (2), 90-2.

4. van der Avoort C, Filion K, Dendukuri N, Brophy J. Microvolt T-Wave Alternans as a Predictor of Non-Ischemic Cardiac Events: A Systematic Review and Meta-Analysis. Biomed Central Cardiology, 9:5. 2009

5. Filion K, Xie X, van der Avoort C, Dendukuri N, Brophy J. Microvolt T-wave alternans and the selective use of implantable cardioverter defibrillators for primary prevention: A cost-effectiveness study. International Journal of Technology Assessment in Health Care, 25(2):151-60. 2009

6. Oughton M, Loo V, Dendukuri N, Fenn S, Lynch A, Libman M. Plain soap and water are superior to alcohol rub and antiseptic wipes for removal of Clostridium difficile by handwashing. Infection Control and Hospital Epidemiology, 30(10):939-44. 2009

Postscript

The TAU attempts to adjust the services we offer to conform to the resources available in a transparent, logical, fair, and consistent fashion. While some of our decisions have not supported the acquisition of a technology, and have thus "saved money", others have supported new developments because they have identified the benefits, and found them to be sufficient to justify the increased expenditure. Our sincere thanks are due to the many members of the MUHC who have assisted with data collection, to those who have served as Consultants, and to the members of the Committee who have dedicated many hours to the consideration of these problems. *Maurice McGregor*.