Centre universitaire de santé McGill
McGill University Health Centre

TAU
Annual Report

April 2005 - April 2006

Technology Assessment Unit (TAU)
McGill University Health Centre – Royal Victoria Hospital
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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. Consistent with its role within a University Health Centre, it will publish its research when appropriate, and contribute to the training of personnel in the field of health technology assessment.

TAU Committee

Juliana Arnoldo
Multidisciplinary Council

André Bonnici
P&T Committee

Pierre Ernst MD
Clinical Epidemiology

Marilyn Kaplow
Quality Management

Gary Pekeles MD
Paediatrics

Gary Stoopler
Administration

Jeffrey Barkun MD
Surgery

James Brophy MD PhD
Director - TAU

John Johnston
Patients' Committee

Maurice McGregor MD
Chair - TAU

Judith Ritchie PhD
Council of Nurses

Donatella Tampieri MD
Council of Physicians, Dentists & Pharmacists

Staff

The TAU currently has two full-time research assistants, two part-time research scientists, one health economist (consultant) and one administrative/research assistant on staff.

Name	Position
Dr James Brophy	Director
Vania Costa MSc	Research Assistant
Dr Nandini Dendukuri	Research Scientist
Dr Lonny Erickson	Research Scientist
Dr Maurice McGregor	Consultant
Michelle McIsaac MSc	Research Assistant
Lorraine Mines	Administrative Assistant
Dr John Penrod	Health economist (consultant)

TAU Reports ***(April 2005-April 2006)***

NOTE: Projects are researched and drafts prepared by members of TAU, referred to 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 Committee who become the authors of the final report. In the past year of the following six reports have been approved:

NEEDLESTICK

Requestor:
Title: Should the McGill University Health Centre use safety devices to reduce needlestick injuries associated with intravascular infusions? An update to July 2002 report.
Publication date: **March 2006**
Author(s): Vania Costa, MSc – Research Assistant/Epidemiologist – TAU
Maurice McGregor MD - Cardiology
Consultants: Marc Deschênes, Director, Hepatology Unit. MUHC
Katherine DeFalco, Standardization Officer, Materials Management, MUHC
Richard Lalonde, Director, Infectious Diseases Unit. MUHC
Filomena Pietrangelo. Division of Occupational Health and Safety. MUHC
AdditionalMembers: Jane Chambers-Evans
Background: In this update to the original Needlestick report, we revisit the issue with the objective of identifying any new information that has become available since the original report, and estimating its influence on the effectiveness and costs of a contemporary policy to introduce such safety devices.
Recommendation(s): **1)** Some fraction of the approximately $170,000 expenditure envisaged would be better used on education directed to the reduction of *all* needlestick injuries. The fact that injuries still occur through inadequate disposal of sharps and that only 93% of health workers are at present

immunized against HB suggests that there is a need for increased health information for all healthcare workers.
2) The greatest negative effect of needlestick injuries under conditions currently pertaining at the MUHC is the fear of infection. Widespread understanding of how small this risk really is would go far to diminish the fear experienced by healthcare workers who are injured.
3) Such safety devices should be considered in all areas where there is a high incidence of patients with these infections, such as the HIV clinic (where they are already in use).
4) This is the type of issue that should be decided at a provincial level rather than each hospital making its own deciding in isolation. Accordingly, it is recommended that the MUHC refer this problem to the appropriate authorities.
5) However, until such time as the Ministry undertakes to fund their use, the opportunity costs of introducing these safety devices are too great to justify the benefits achieved.
Accordingly, a general conversion to these safety devices throughout the institution is not recommended at this time.

MITOXANTRONE

Requestor:
Title: The Use of Mitoxantrone in the Treatment of Patients with Multiple Sclerosis. An update to November 2002 report.
Publication date: **March 2006**
Author(s): Vania Costa, MSc – Research Assistant/Epidemiologist – TAU
James Brophy, MD PhD – Cardiology and Clinical Epidemiology
Maurice McGregor MD - Cardiology
Consultants: Yves Lapierre MD. Head, Multiple Sclerosis Clinic
Mr. Stanley Hum (Montreal Neurological Institute Clinical Research Unit and MS Clinic)
AdditionalMembers:
Background: In April 2005, due to drug safety concerns, the FDA and the manufacturer of Novantrone ® (Mitoxantrone) sent a letter to healthcare professionals issuing a box warning for both cardiac toxicity and secondary acute myeloid leukemia (AML).
Recommendation(s): The increasing evidence of cardiotoxicity even at relatively low doses, and the absence of any new evidence indicating more substantial or more permanent benefit of mitoxantrone treatment is cause to reconsider the present indications for its use.
Whenever its use is decided on, treatment should only be initiated after full discussion with patients of the limited benefits to be expected, the absence of knowledge of the duration of these effects, and the incidence of serious side effects. In view of the recent FDA warning, it is recommended that signed informed consent be obtained.
It is suggested that follow-up of each patient be continued as long as possible after treatment completion in order to better determine the frequency of delayed complications. The subsequent use of other cardiotoxic drugs such as cyclophosphamide should also be accompanied by cardiac monitoring.
It is suggested that the contents of this report be shared with referring physicians with the objective of discouraging mitoxantrone therapy except for those cases most likely to benefit. The MUHC should not authorize any increase in patients above the present threshold of 20 per year.

HER2

Requestor: Dr. Françoise Chagnon, Director of Professional Services (MUHC)
Title: Testing for HER2 Positive Breast Cancer: A Cost-effectiveness analysis.
Publication date: **December 2005**
Author(s): Nandini Dendukuri, Research Scientist (TAU)
James Brophy, MD PhD – Cardiology and Clinical Epidemiology
Consultants: Dr. Karim Khetani – Department of Pathology (MUHC)

AdditionalMembers:

Background: This report has been prepared in response to a request from Dr. Françoise Chagnon. New breast cancer chemotherapy protocols eligibility require tumor markers re: HER and FISH and others. There is a need to know the sensitivity and specificity of tumor markers. Dr. Chagnon requested the TAU's help in making recommendations on the tumor marker testing which needs to be provided at the MUHC. Help is needed to define the problem and formulate the question surrounding the impact of these requirements on our laboratory services. MUHC needs to make a business plan for acquisition of this technology.

Recommendation(s): **It is recommended that all breast cancer cases be screened with IHC and those who have scores of 2+ and 3+ be tested by FISH to confirm their HER2 positive status.**

BOTOX

Requestor: Jean-François Guévin, Associate Director of Pharmacy (MCH)

Title: Botulinum Toxin A for the Treatment of Refractory Chronic Anal Fissures and Internal Anal Sphincter Achalasia in Pediatric Patients.

Publication date: **December 2005**

Author(s): Vania Costa, MSc – Research Assistant/Epidemiologist – TAU
James Brophy, MD PhD – Cardiology and Clinical Epidemiology

Consultants: Dr. Hélène Flagéole

Additional Members:

Background: This report was prepared in response to a request from the pharmacy of the Montréal Children's Hospital to review the use of botulinum toxin A for the treatment of pediatric patients with chronic anal fissure refractory to other treatments, and for persistent obstructive symptoms (internal anal sphincter achalasia) in children who underwent treatment for Hirschsprung's disease.

Recommendation(s): 1 - Botulinum toxin A could be used in the following exceptional circumstances (approximately 4 patients per year), and only after consultations with at least two specialists:

- In pediatric patients with chronic anal fissures refractory to conservative treatment and who are not eligible for surgery.
- In pediatric patients with internal anal sphincter achalasia refractory to conservative treatment, botulinum toxin A could be used as a means of identifying those patients who would benefit from surgical treatment, thus avoiding operating on patients who would likely not benefit from surgery and who might nonetheless be at risk of developing permanent complications.

2 - The patients' families should be informed that these are off-label treatment indications for botulinum toxin A that have not been approved by Health Canada.
3 - The efficacy and safety outcomes of these patients should be recorded and reviewed in a systematic fashion.

CEREBRAL MICRODIALYSIS

Requestor: Mr. Gary Stoopler

Title: Cerebral Microdialysis as a Tool for Neuromonitoring Following Traumatic Brain Injury.

Publication date: **August 2005**

Author(s): Nandini Dendukuri, Research Scientist (TAU)
James Brophy, MD PhD – Cardiology and Clinical Epidemiology

Consultants: Dr. Judith Marcoux (Department of Neurology MUHC)
Dr. Mark Angle (Department of Anaesthesia MUHC)

AdditionalMembers:

Background: Cerebral microdialysis (CMD) is a method of sampling biochemical markers of secondary brain damage from cerebral interstitial tissue fluid. Dr. Judith Marcoux identified some requirements that she had for the treatment of brain injured patients. The purpose of this report is to

summarize current literature on the efficacy and safety of this method among traumatic brain injury (TBI) patients.

Recommendation(s): It is recommended that the MUHC not purchase this equipment at this time. Any application of this technology at the MUHC should be considered to be in the category of research, and supported by research funds.

SPINAL MONITORING

Requestor: Dr. Françoise Chagnon, Director of Professional Services (MUHC)

Title: Use of intraoperative neurophysiological monitoring during spinal surgery

Publication date: **July 2005**

Author(s): Lonny Erickson, PhD – Research Scientist - TAU
Vania Costa, MSc – Research Assistant/Epidemiologist – TAU
Maurice McGregor MD - Cardiology

Consultants: Mme. Diane Bouchard, Montréal Children's Hospital, MUHC
Dr. Paola Diadori, Hôpital Ste Justine
Dr. Jean Ouellet, Montreal Children's Hospital, MUHC
Dr. Gilles Plourde, Montreal Neurological Institue, MUHC
Dr. Bernard Rosenblatt, Montreal Children's Hospital, MUHC

AdditionalMembers:

Background: In the Fall 2004, Dr. Françoise Chagnon, DPS of the MUHC, requested that the TAU evaluate electrophysiological monitoring with particular attention to identifying the standard of care, to determining the indications for monitoring , the costs involved, and future trends in this field.

Recommendation(s): It is recommended that the MUHC make available combined SSEP / MEP monitoring for all cases of spinal surgery for which there is a risk of spinal cord injury.
Although professional remuneration is outside the hospitals responsibility, it is suggested that the MUHC, together with other institutions that undertake this form of monitoring, should consider drawing this problem to the attention of the FMSQ.

V.A.C.® (Vacuum-Assisted Closures)

Requestor: Ms. Marie-France Noel, Chair – MUHC Nursing Equipment Committee

Title: Vacuum-Assisted Wound Closure Therapy (V.A.C.®)

Publication date: **July 2005**

Author(s): Vania Costa, MSc – Research Assistant/Epidemiologist – TAU
James Brophy, MD PhD – Cardiology and Clinical Epidemiology
Maurice McGregor MD - Cardiology

Consultants: Mr. Tarik Alam, Ms. Nevart Hotakorzian, Dr. Teanoosh Zadeh, Dr. Benoit de Varennes

AdditionalMembers:

Background: In December 2004, the TAU received a request from Ms. Marie-France Noel, Chair, MUHC Nursing Equipment Committee to evaluate the current clinical evidence for the use of vacuum-assisted closure (V.A.C.®) therapy in wound closure.

Recommendation(s): **1)** No additional (V.A.C.®) pumps should be purchased or rented until clear evidence of efficacy becomes available.
2) In view of the conviction of users of (V.A.C.®) therapy at the MUHC that this therapy is effective, the recent purchase of (V.A.C.®) equipment by the institution, and the absence of compelling published evidence of efficacy of (V.A.C.®), the MUHC should urgently consider undertaking studies designed to establish the value of this treatment in the different clinical situations in which it is employed.

TAU Current Projects

1. Examining waiting times in university hospitals
2. Cost-effectiveness of herceptin
3. Cost-effectiveness of LVADs as destination therapy
4. Role of registries in HTA
5. An evaluation EBCT in cardiology

Establishing a Joint CHUM / MUHC TAU

TAU has negotiated throughout the past year with the designated representatives of the CEO from the Centre Hospitalier du Montréal (CHUM) and the McGill University Health Centre (MUHC) to arrive at an agreement in principle for a joint TAU. This joint unit will respect the goals of "complémentarité" that the Quebec government desires between the two university hospital centers. A protocol of agreement has been signed and Dr. Brophy's position has been approved by the Conseil d'Administration of the CHUM. Hiring for the expanded unit is in progress. In principle, this joint unit with fully integrated offices will be maintained at both the MUHC and the CHUM. It is felt that this will best serve the advancement of the culture of health technology assessment in both institutions.

The extramural role of TAU in Québec

TAU has continued to forged links with the provincial technology assessment group, Agence d'Évaluation des technologies et des modes d'intervention en santé. (*AETMIS*). Both Drs Brophy and McGregor gave presentations to the initial conference organized by *AETMIS* to further hospital-based health technology assessment.
Dr. Brophy serves on the provincial *Table Sectorielle des RUIS en ETMIS* which seeks to advance and coordinate health technology evaluation throughout the province.
Dr. Brophy has also served as a consultant to the Centre hospitalier universitaire de Québec in establishing their local technology assessment unit.

TAU Scientific Activities

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 now indexed in the international database for the Center for Reviews and Dissemination managed by York University, UK (http://www.york.ac.uk/inst/crd/crddatabases.htm)
2. Our reports are widely diffused from our website (www.mcgill.ca/tau) with several thousand "hits" annually
3. Reception of British Columbia ministry of health personnel for discussions on hospital based health technology assessment
4. Collaboration with the Nijmegen Center for Evidence Based Practice, Nijmegen, The Netherlands to train students in technology assessment; two international doctoral students completed a 6 month training program (August-December 2005)and another is scheduled for Spring 2007.
5. Reception of medical student from Leicester Warwick medical school in the United Kingdom.
6. Two recent successes in obtaining peer review funding from the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) for research in health technology assessment (see next section for details)
7. Numerous scientific publications (see next section for details)

TAU Scientific Publications

Peer Review Grants

1. Brophy JM, Dendukuri N. Bayesian methods for evaluating diagnostic technologies: An application in the health technology assessment of electron beam computed tomography for the screening of coronary artery disease. CCOHTA's 2005 Health Technology Assessment Capacity Building Grants program. $84,000 Feb 2005 – March 2006.
2. Brophy JM, Dendukuri N, McGregor M, Erickson L. Collaborative Development and Implementation of a Joint HTA Unit by two University Hospital Networks in Montreal, Quebec. CCOHTA's 2005 Health Technology Assessment Capacity Building Grants program. $197,000 Feb 2005 – March 2007.

Abstracts

1. Dendukuri N, Brophy JM. Testing for HER2 positive breast cancer: A cost-effectiveness analysis CCOHTA. Ottawa Ont. April 2006
2. Ligthart S, Vlemmix F, Dendukuri N, Brophy JM. The cost effectiveness of sirolimus eluting stents – evaluating the evaluations. CCOHTA. Ottawa Ont. April 2006
3. Filion K, Delaney JAC, Brophy JM, Ernst P, Suissa S The impact of over-the-counter simvastatin on the number of statin prescriptions in the United Kingdom: A View from the General Practice Research Database. ACC New Orleans March 2006.
4. McGregor M. HTA use in a Canadian Hospital System. Panel on "bringing HTA into Practice. Annual Meeting Health Technology Assessment International, Rome, June 21, 2005.

Invited Presentations

1. McGregor M. Priority Setting. Whose Priorities? In: An Invitational Symposium for HTA Researchers and Policy Makers, on "Current Issues for Health Technology Assessment in Canada. The Canadian Coordinating Office for Health Technology Assessment. Ottawa. April 26, 2005

2. McGregor M. On increasing the impact of HTAs. Invited Plenary address, 10th annual meeting of the International Society for Pharmacoeconomic and Outcomes Research. Washington DC. May 18, 2005.

3. McGregor M. What decision makers want and what they have been getting. Invited Noon lecture. The Ulysses International Masters Program in Health Technology Assessment and Management. Ottawa. May 25, 2005.

4. McGregor M. Health Technology Assessment. A great idea not fully realized. University of British Columbia and Vancouver Coastal Health Research Institute June 6, 2005.

5. McGregor, M. Promoting the use of research-based evidence in health-care organizations. Executive Training for Research Application. EXTRA. Program. Banff. August 18, 2005.

6. Brophy, JM. Agence d'évaluation des technologies. Symposium of hospital health technology evaluation. "The McGill MUHC experience". Montreal Quebec October 28, 2005.

7. McGregor, M. Évaluation des technologies. L'avenir ? Opening address. FORUM. Vers une vision commune de la production en evaluation des technologies. Agence d'évaluation des technologies et des modes d'intervention en santé. Montréal. October 28, 2005.

8. Brophy, JM. CHUQ. Symposium on Health Technology Assessment. "Building a hospital-based health technology unit". November 29, 2005 Quebec City.

9. Brophy, JM. Centre Hospitalier Université de Montréal. (St. Luc). "Reading the clinical trials – the case of GP2b3a inhibitors in cardiology". December 14, 2005. Montreal, Quebec.

10. McGregor M. Les aigiuilles sécuritaire: Les employer ou non ? Colloque. L'évaluation des technologies et des modes d'intervention dans les établissements universitaire: répondre aux defies de la decision en santé. Montréal. 17 mars 2006.

Peer Review Publications

1. Brophy, J. M. The dollars and sense of drug-eluting stents. CMAJ. 2005 Feb 1; 172(3):361-2.

2. Brophy, J. M. and Erickson, L. J. Cost-effectiveness of drug-eluting coronary stents in Quebec, Canada. Int J Technol Assess Health Care. 2005 Summer; 21(3):326-33.

3. Brophy, J. M. and Joseph, L. Medical decision making with incomplete evidence--choosing a platelet glycoprotein IIbIIIa receptor inhibitor for percutaneous coronary interventions. Med Decis Making. 2005 Mar-2005 Apr 30; 25(2):222-8.

4. Dendukuri, N.; Costa, V.; McGregor, M., and Brophy, J. M. Probiotic therapy for the prevention and treatment of Clostridium difficile-associated diarrhea: a systematic review. CMAJ. 2005 Jul 19; 173(2):167-70.

5. McGregor, M. and Brophy, J. M. End-user involvement in health technology assessment (HTA) development: a way to increase impact. Int J Technol Assess Health Care. 2005 Spring; 21(2):263-7.

6. Simpson, C. S.; O'Neill, B. J.; Sholdice, M. M.; Dorian, P.; Kerr, C. R.; Ross, D. B.; Ross, H., and Brophy, J. M. Canadian Cardiovascular Society commentary on implantable cardioverter defibrillators in Canada: Waiting times and access to care issues. Can J Cardiol. 2005 May; 21 Suppl A:19-24.

7. McGregor M. What decision makers want and what they have been getting. Value in Health. In Press.

8. Brophy JM. Selling safety – lessons learned from muraglitizar. (invited editorial) JAMA 2005;294: 2633-5. Early online release Oct 20 2005.

9. Ligthart S, Vlemmix F, Dendukuri N, Brophy JM. The cost effectiveness of sirolimus eluting stents – evaluating the evaluations. CCOHTA. Submitted for publication April 2006

ACKNOWLEDGMENT

"(I)t does not make sense to ask whether a particular rationing decision is right… … …., one asks whether the decision was made in the right way". A good process "promotes the consistency, and thus the fairness, of treatment; it makes rationing more visible; it reduces the burden on individual physicians; and it enhances the accountability of doctors and the medical profession" [Hoffmaster. Can J Cardiol 2000;16:1313]

The TAU is a unique example of an attempt to adjust the services we offer to conform to the resources available in a 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.