



Unité Conjointe d'évaluation des technologies de la santé
Joint Technology Assessment Unit (TAU)



Centre Hospitalier de l'Université de Montréal (CHUM)
McGill University Health Centre (MUHC)

FINAL VERSION

JOINT TAU

Annual Report

April 2006 - April 2007

Unité Conjointe d'évaluation des technologies de la santé - CUSM/CHUM
Joint Technology Assessment Unit - MUHC/CHUM
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IMPORTANT FOREWORD

**In November 2006 the McGill University Health Centre (MUHC)
and the
Centre Hospitalier de l'Université de Montréal (CHUM)
concluded an agreement to create a new organization,
The Joint TAU.**

In addition to this new unit the original TAU of the MUHC has continued to exist in order to complete projects already undertaken.

The following report covers the activity of both units from April 2006 to April 2007

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- MUHC (April 2006 - November 2006)

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

Joint MUHC/CHUM TAU Committee

James Brophy MD PhD
Director - Joint TAU

Maurice McGregor MD
Chair -Joint TAU

(MUHC members)
Juliana Arnoldo
Multidisciplinary Council

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Gary Pekeles MD
Paediatrics

Judith Ritchie PhD
Council of Nurses

Gary Stoopler
Administration

(CHUM members)
Luc Amendola
CMDP Pharmacy Representative

Marie-Dominique Beaulieu MD
Director General Representative

Jean-Sébastien Billiard MD
CMDP Medical Representative

Sylvie Décarie
Nursing Representative

Jean-Marie Dumesnil
Patients Representative

Pierrette Gervais
Administration

Georges Kasparian
Multidisciplinary Council

Staff

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

| Name | Position |
|-------------------------|---------------------------|
| Carmen Victoria Atwood | Research Assistant (MUHC) |
| Dr James Brophy | Director |
| Dr Nandini Dendukuri | Research Scientist (MUHC) |
| Dr Lonny James Erickson | Research Scientist (MUHC) |
| Dr Alain Lapointe | Consultant (CHUM) |
| Dr Maurice McGregor | Consultant (Chair) |
| Lorraine Mines | Administrative Officer |
| Dr. Mouhcine Nassef | Research Assistant (CHUM) |

Vania Costa.

We would like to acknowledge the enormous contribution of our staff member Ms. Vania Costa. Vania was with our Unit almost since its inception and produced work of the highest calibre throughout the past five years. Vania left our group in April 2007 to take on a new challenge at a hospital-based research group in Toronto, Canada. Good Luck, Vania!.

TAU Reports (April 2006-April 2007)

NOTE: Projects are researched and drafts prepared by members of the Joint 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 Executive Committee who become the authors of the final report. In the past year the following seven reports have been approved:

NEEDLESTICK

Requestor: Update of previous report initiated by TAU
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: **May 23, 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 (Chair MUHC ethics committee).

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 \$137,000 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 decision 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: Update of previous report initiated by TAU.
Title: The Use of Mitoxantrone in the Treatment of Patients with Multiple Sclerosis. An update to November 2002 report.

Publication date: **May 23, 2006**
Author(s): Vania Costa, MSc - Research Assistant/Epidemiologist - TAU
James Brophy, MD PhD - Cardiology and Clinical Epidemiology

Consultants: Maurice McGregor MD - Cardiology
Yves Lapierre MD. Head, Multiple Sclerosis Clinic

Background: Mr. Stanley Hum (Montreal Neurological Institute Clinical Research Unit and MS Clinic)
It was necessary to consider whether there was new evidence of efficacy and safety that should alter previous recommendations.

Recommendation(s): Since the last report no new evidence of therapeutic benefit in a general MS population has been identified There is new evidence of cardiotoxicity even at relatively low doses. Reports of treatment benefits in aggressive forms of RRMS or SPMS are sufficiently promising to justify its continued study at the MUHC in the context of an observational phase IV data collection .
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.
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: **May 15, 2006**

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

Consultants: Dr. Karim Khetani - Department of Pathology (MUHC)

Background: New breast cancer chemotherapy eligibility protocols require tumor markers re: HER and FISH and others. There is a need to know the sensitivity and specificity of tumor markers. Help in making recommendations on the tumor marker testing which needs to be provided at the MUHC was requested.

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.

Wait Times No.1

Requestor: Dr. Arthur Porter - Executive Director of the MUHC.

Title: Wait times at the MUHC. I. Diagnostic imaging, Joint replacement, Cancer care, Sight restoration, and Cardiac care

Publication date: **September 22, 2006**

Author(s): Lonny Erickson, Research Scientist - Joint TAU
Maurice McGregor MD - Cardiology

Background: This report is the first of a series undertaken in response to a request of the Director General of the MUHC to determine the wait times experienced by patients in the MUHC in undergoing tests and procedures, and to identify the measures necessary to correct them where excessive. This report identifies the wait times experienced in the five problem areas identified by the Canadian provincial First Ministers

Recommendation(s): The wait times benchmarks for emergency and urgent care were satisfactorily met in all disciplines investigated. For elective procedures, the wait times for cataract surgery are now <7 days. However, access to this procedure is blocked by the approximately 24 weeks

wait time to see an ophthalmologist. Similarly, elective coronary angiography or coronary bypass surgery is carried out within six weeks of request. However, the time taken to achieve an appointment with a cardiologist necessary to initiate these procedures varies from 7-32 weeks, while the time taken for Holter, stress ECG, or stress ultrasound, may range from 7-58 weeks. Wait times for arthroplasty vary from 1-2 years. While these bottlenecks can clearly not be solved by the hospitals alone, these institutions can play their part by identifying the causes for each obstruction to patient flow, by defining the solutions that will be most effective, and by estimating their cost. These issues will be addressed in subsequent reports

Wait Times No:2

Requestor: Dr. Arthur Porter - Executive Director of the MUHC.
Title: Wait times at the MUHC. 2. Selected divisions of the departments of medicine and surgery. Supplement to Report No 26 Wait times at the MUHC. I.
Publication date: **September 20, 2006**
Author(s): Lonny Erickson, Research Scientist - Joint TAU
Maurice McGregor MD - Cardiology
Background: The present document is an extension of the previous report. We review the wait times experienced by adult patients for consultations and procedures in various specialty areas within the Departments of Medicine and Surgery of the MUHC.
Conclusions): Wait times that reflect bottlenecks to patient flow and result in significant limitation of patient access to health care have been identified in five Divisions of the Department of Medicine. Borderline wait times were found in the Department of General Surgery. Accordingly, TAU will now engage with these departments in an endeavour to identify the specific components that are causing the excessive wait times

SEPSIS (Drotrecogin Alfa)

Requestor: Update to informal report (April 2003) initiated by TAU.
Title: Drotrecogin Alfa (Activated) in Severe Sepsis.
Publication date: **March 19, 2007**
Author(s): James Brophy, MD PhD - Cardiology and Clinical Epidemiology
Vania Costa, MSc - Research Assistant/Epidemiologist - TAU
Consultants: Dr. Peter Goldberg - Director - Intensive Care Unit (ICU) MUHC
Dr. Jean-Gilles Guimond - Intensive Care Unit (ICU) CHUM
Background: In April 2003, the Technology Assessment Unit (TAU) of the MUHC prepared an informal report on the use of drotrecogin alfa (activated), in patients with severe sepsis in which its use was not recommended. In view of recent publications and progressive increase in the use of drotrecogin alfa at the MUHC, the TAU has updated its evaluation by incorporating all recent evidence.
Recommendation(s): In view of the uncertain clinical benefit, the evidence of increased risk of serious bleeding, and its high acquisition costs, the TAU recommends that drotrecogin alfa should not be used routinely in adult patients with severe sepsis at the MUHC and CHUM. The totality of the evidence suggests that the current MUHC/CHUM policies of restricting use of this medication to those severe sepsis patients at the highest risk is most appropriate. The current clinical measures to assure optimum drug utilization should be continued. TAU also concluded that there are no current pediatric indications for drotrecogin alfa. .

Computer System for Knee Replacement Surgery

Requestor: Mr. Gary Stoopler, Administrative director of the MUHC
Title: The use of image-free computer assisted systems in total knee replacement surgeries.
Publication date: **March 19, 2007**

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

Consultants: Dr. Eric Lenczner , Orthopaedic Surgery, MUHC

Background: In July 2006 the administrative director of the MUHC, Mr. Gary Stoopler requested an evaluation of the Navitrack® computer assisted system in total knee replacement.

Recommendation(s): There is no convincing evidence that demonstrates improved clinical outcomes with the computer assisted navigation systems in total knee replacement surgery. However, expert opinion believes that this technology is likely to decrease malalignment in some patients. For this reason it is recommended that funding for a limited number of cases (Max. 40) annually should be approved for use in patients at the highest risk of malalignment. This will also allow the MUHC and the CHUM to fulfill their role as educational institutions.

TAU Current Projects

NEW PROJECTS (in progress) and potential projects

1. Examining waiting times in university hospitals (MUHC/CHUM)
2. Machine perfusion for kidney transplantation
3. Meta-analysis of predictive value of Electron Beam Computed Tomography CADTH (formerly CCOHTA) funded project.
4. Percutaneous cardiac valve replacement (potential project)
5. Brain natriuretic peptide (BNP) testing of dyspneic patients in the emergency department. (potential project)
6. Sacral neuromodulation for fecal incontinence.
7. Sacral neuromodulation for urinary incontinence.
8. A meta-analysis and decision analysis of T wave alternans to predict the need for implantable cardiac defibrillators (internship student project - Radboud University Netherlands)

The extramural role of TAU in Québec

TAU has continued to forge 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 (CHUQ) 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 international master's student completed a 6 month training program (October 2006 - April 2007) and a newly arrived master's student will complete the training program this summer.
5. Reception of medical student from Leicester Warwick medical school in the United Kingdom
6. Reception of two medical doctors for research projects 2006-2007. One from Lebanon and one from Canada.
7. 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)
8. The TAU experience is the subject of detailed review by Dr. McGregor at the Canadian EXTRA Health Executives annual meeting in Calgary
9. 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. McGregor M, Brophy JM. Needlestick injury in the hospital. Should we always choose zero risk? American Congress of the Union of Risk Management for Preventive Medicine. Montreal June 2007.
2. Nassef M, Erickson L, McGregor M, Brophy JM. Evaluating wait times in a university hospital. Health Technology Assessment International 2007. Barcelona Spain. June 2007
3. Nassef M, Erickson L, Brophy JM. Wait times at Montreal University Hospitals. Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). Montreal March 15 2007
4. Lapointe A, Brophy JM. Sacral nerve stimulation in fecal incontinence. Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). Montreal March 15, 2007
5. Chiu K, Dendukuri N, Brophy JM. Systematic review and meta-analysis of studies evaluating Electron Beam Computed Tomography (EBCT) for predicting hard outcomes and coronary artery disease. Asia Pacific EBM Network Conference. Hong Kong Dec 2006
6. Ligthart S, Vlemmix F, Dendukuri N, Brophy JM. The cost effectiveness of sirolimus eluting stents – evaluating the evaluations. Asia Pacific EBM Network Conference. Hong Kong Dec 2006
7. Dendukuri N, Brophy JM. Testing for HER2 positive breast cancer: A cost-effectiveness analysis CCOHTA. Ottawa Ont. April 2006
8. Ligthart S, Vlemmix F, Dendukuri N, Brophy JM. The cost effectiveness of sirolimus eluting stents – evaluating the evaluations. CCOHTA. Ottawa Ont. April 2006

Invited Presentations

1. Testing for HER-2 positive breast cancer: A systematic review and cost-effectiveness analysis. Division of Clinical Epidemiology and Community studies. St. Mary's Hospital Centre. Montreal. November 2006 Dendukuri, N.
2. Testing for HER-2 positive breast cancer: A systematic review and cost-effectiveness analysis. Division of Clinical Epidemiology. McGill University Health Centre Montreal October 2006 Dendukuri, N.
3. Division of Critical Medicine. MUHC. Activated protein C in sepsis - A health technology assessment. October 4, 2006. Brophy JM
4. Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). Symposium of hospital health technology evaluation. "Hospital health technology assessment". Montreal October 6 2006. Brophy JM
5. McGill University Faculty of Medicine. "The challenge of evidence-based practice". Jan 8 2007 Brophy JM
6. University of Montreal. "Evidence-based medicine; clinical & legal implications". Jan 10 2007. Brophy JM
7. Division of Clinical Epidemiology. MUHC. "Drug eluting stents and the biases of cost-effectiveness studies". February 1 2007. Brophy JM
8. Canadian Chief Medical Resident Conference. "New medical technologies: Looking beyond the gloss". Montreal. March 2 2007. McGregor, M.
9. Needlestick injury in the hospital. Should we always choose zero risk? Union of Risk Management for Preventive Medicine. Second American Congress. Montréal, June 14-15, 2007. McGregor M., Brophy JM
10. Les aiguilles sécuritaire: Les employer ou non ? Colloque. L'évaluation des technologies et des modes d'intervention dans les établissements universitaires: répondre aux défis de la decision en santé. Montréal. 17 mars 2006. McGregor M.
11. Context for decisions: how one organization promotes the use of research-based evidence. Executive Training for Research Application. (EXTRA). Banff, Alta. August 24, 2006. McGregor M.
12. L'unité d'évaluation des technologies, CHUM/CUSM. Conférence des CHU du Québec. Mission des CHU de France. Montréal. 11 décembre 2006. McGregor M.
13. Electron Beam Computed Tomography for screening and detection of coronary artery disease: a systematic review and meta-analysis." Centre for Clinical Epidemiology and Community Studies. Jewish General Hospital. Montreal Jan 2007 Dendukuri N.
14. Health Technology Evaluation Before Technology Acquisition: A new Approach to Hospital Decision Making. Plenary Session, Annual Meeting of the Ontario Thoracic Society and the Ontario Lung Association. Toronto. 2007 McGregor M.
15. Health technology evaluation before acquisition. Decision making at the local level. Evidence, Economics, and Ethics for Tough Decision Making. And Invitational Conference convened by Canadian Agency for Drugs and Technologies in Health and Dalhousie University. Moncton, New Brunswick, May 4, 2007 McGregor M.

16. La direction de l'évaluation des technologies et des modes d'intervention en santé. Executive Committee, Conseil Multidisciplinaire, CHUM, January 17, 2007. Lapointe A.
17. La direction de l'évaluation des technologies et des modes d'intervention en santé. Nursing Department, CHUM, November 20, 2006. Lapointe A.

Peer Reviewed Publications

1. Dendukuri N, Brophy JM. Inappropriate use of meta-analysis to estimate efficacy of probiotics. *American Journal of Gastroenterology Am J Gastroenterol*. 2007;102(1):201
2. Dendukuri N, Brophy JM, Khetani K, McIsaac M. Testing for HER2 positive breast cancer: A cost-effectiveness analysis. Accepted CMAJ.
3. McIsaac ML, Goeree R, Brophy JM. Primary Data Collection in Health Technology Assessment. *Int J Technol Assess Health Care*. 2007;23(1):24-9.
4. Ligthart, S Vlemmix F, Dendukuri N, Brophy JM. The cost effectiveness of sirolimus eluting stents: A systematic review. *CMAJ* 2007;176:199-205. [Epub ahead of print Dec 17 2006].
5. Filion KB, 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. *Pharmacoepidemiol Drug Saf*. 2007 Jan;16(1):1-4. [Epub ahead of print Sept 5 2006].
6. Costa V, Brophy JM, McGregor M, Laneuville P. The cost-effectiveness of stem cell transplantation from unrelated donors in adult patients with leukemia. Accepted *Value in health* .2007;10(4):1-9.
7. Brophy JM, Babapulle M, Costa V, Rinfret S. Interaction Between Atorvastatin and Clopidogrel Following Percutaneous Coronary Intervention. *Am Heart J*. 2006. 152(2):263-9.
8. McGregor M. What decision makers want and what they have been getting. *Value in Health*. 2006;9(3):181-5.
9. McGregor M. Caro JJ. QALYs. Are They Helpful to Decision Makers? *Pharmacoeconomics*. 2006; 24 (10): 947-52.
10. Zanke B, Spencer PC, Culyer T, Longo C, McGregor M. Facing cancer costs. How will we afford hi-cost cancer therapies? *Oncology Exchange*. 2007; 6(1): 42-48.
11. McGregor M. Evaluation *Before* Acquisition: a hospital approach to decision-making. *Ontario Thoracic Revues*. 2007;19(2):1-4.

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.*