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Centre universitaire de santé McGill
McGill University Health Centre

TAU
Annual Report

April 2003 - April 2004

Technology Assessment Unit (TAU)
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"It 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]

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

Dr. Raghu Rajan and Mr. William Brodie left our committee in the Spring of 2003. We would like to gratefully acknowledge their expert assistance and generous support during their involvement in the TAU Committee. Mr. André Bonnici of the Pharmacy and Therapeutics Committee and Ms. Juliana Arnoldo of the Multidisciplinary Council have kindly accepted to join our committee. Welcome.

Staff

The TAU currently has two full-time research assistant/epidemiologists, one part-time research scientist, one part-time health economist and one administrative/research assistant on staff.

Name	Position
Dr James Brophy	Director
Jun Chen	Research Assistant
Vania Costa	Research Assistant
Dr Nandini Dendukuri	Research Scientist
Lorraine Mines	Administrative Assistant
Dr John Penrod	Health economist

TAU Reports ***(April 2003-April 2004)***

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:

COATED STENTS in PCI:

Requestor: Mr. Victor Simon

Title: **An evaluation of drug eluting (coated) stents for percutaneous coronary interventions; What should their role be at the McGill University Health Centre (MUHC)?**

Publication date: July 2003

Author(s): James Brophy MD PhD, Director - TAU

Added members: Pierre Beaudry MD, Christian Constance MD

Consultants: Pierre Beaudry MD, Christian Constance MD

Background: This technology assessment was carried out to provide guidance on the future use of drug eluting (coated) stents for percutancous coronary interventions at the MUHC. These new devices are expected to cost approximately five times the price of regular stents and it is imperative to fully assess their safety, efficacy and cost-effectiveness.

Recommendation(s): **1.That despite good evidence supporting the efficacy of coated stents to reduce the rate of restenosis, the current budget of the hospital should not be redistributed to permit the routine acquisition of drug eluting stents. Thus in the absence of a specially dedicated provincial budget for this technology, coated stents should not be provided by the MUHC except for special circumstances. 2. The special cases requiring a coated stent should be approved by two members of the Division of Cardiology, ideally two interventional cardiologists. 3. The evidence on which this policy recommendation is based is likely to be very time sensitive. The decision should be frequently reviewed and modified if necessary in the light of such evidence. The responsibility for requesting review can be initiated by either the Division of Cardiology or the Technology Assessment Unit.**

IMPLANTABLE CARDIAC DEFIBRILLATORS (ICD)

Requestor: Mr. Victor Simon
Title: **Use of the Implantable Cardiac Defibrillator (ICD) at the McGill University Health Centre (MUHC)**
Publication date: September 2003
Author(s): Maurice McGregor MD, Chair – TAU, Jun Chen MB MSc
Added members: Magdi Sami MD
Consultants: Solly Benatar MbBCh, Jane Chambers-Evans MSc(A), James Hanley PhD, John Penrod PhD, David Roy MD, Mario Talajic MD
Background: The effectiveness of ICDs in the secondary prevention of sudden death in certain defined patient groups has been well demonstrated. However, in March 2002 the Multicenter Automatric Defibrillator Implantation Trial II (MADIT II) published the results of a study which indicated that the ICD could effectively prevent sudden death in a much larger group of patients than those previously identified. These instruments are relatively expensive and the economic impact of accepting the expanded indications for ICD use would be considerable
Recommendation(s): **1. That the MUHC if possible with other institutions, urgently present this problem to government with a request that they consider the provision of specials funds to finance ICD acquisition. 2. Until special funding becomes available, the committee feels that ICD use at the MUHC should not be unlimited. Implantation of no more than an additional 25 ICDs should be approved for the coming year. 3. Patients should not be permitted to purchase their ICD or to pay for an upgrade of their ICD through private resources. 4. ICD policy must be formally adopted by the MUHC. 5. These recommendations should be considered temporary and should be subject to review and amendment when necessary.**

ESOPHAGEAL STENTS at the MUHC

Requestor: Dr. Ewa Sidorowicz, Assistant Director , Professional Services
Title: **The use of self-expanding metallic stents in the palliation of dysphagia in patients with malignant esophageal strictures.**
Publication date: September 2003
Author(s): Vania Costa MSc - Research Assistant/Epidemiologist - TAU
James Brophy MD PhD, Director - TAU
Added members: Peter Szego MD, John Penrod PhD
Consultants: Peter Szego MD, John Penrod PhD
Background: This Technology Assessment was carried out to evaluate the current available literature regarding esophageal stents and to make recommendations regarding their use.
Recommendation(s): **Despite the variation in results observed in the literature, it appears that the use of SEMS for the palliative treatment of malignant dysphagias and esophagorespiratory fistulas represents an improvement for the patients status and quality of life, with an additional cost of only CDN$ 13,524 to the MUHC (based on 6 treated patients/year). The TAU recommends the use of esophageal self-expanding metallic stents in patients with malignant dysphagia and esophagorespiratory fistulas.**

GLIADEL WAFERS

Requestor: Mr. André Bonnici, Coordinator of the Pharmacy & Therapeutics Committee
Title: **Use of carmustine implants (GLIADEL wafers) in patients with malignant glioma at the McGill University Health Centre.**
Publication date: January 2004
Author(s): James Brophy MD PhD, Director - TAU
Jun Chen MB MSc, Research Assistant/Epidemiologist - TAU
Added members: Rolando Del Maestro MD
Consultants: Rolando Del Maestro MD

Background: This Technology Assessment was carried out to review the effect of GLIADEL wafer on survival and quality of life of patients following primary or recurrent resection of malignant gliomas, to assess the complications of this technology, and to estimate the cost effectiveness and potential budgetary impact of the use of GLIADEL at the MUHC.

Recommendation(s): **The TAU recommends that the use of carmustine implantable wafers at the MUHC, be restricted to a limited number of selected Quebec patients undergoing recurrent resection for malignant glioma and who have had an unsuccessful response to previous standard chemotherapy. The number so supported should not exceed 10 cases per year. Recognizing that the evidence for this therapy is less than ideal, it is recommended that a registry be kept of all patients receiving this therapy so this assessment may be revised in light of accumulating data.**

BIVENTRICULAR PACING

Requestor: Mr. Victor Simon , Chief Operating Officer (MUHC)

Title: **The use of biventricular pacemakers at the McGill University Health Centre.**

Publication date: January 2004, updated version March 2004

Author(s): James Brophy MD PhD, Director – TAU
Vania Costa MSc - Research Assistant/Epidemiologist - TAU

Added members: Jacques Genest MD, Tom Hadjis MD, John Penrod PhD

Consultants: Jacques Genest MD, Tom Hadjis MD, John Penrod PhD

Background: The TAU was requested to "give its opinion" concerning the use of biventricular pacemakers at the MUHC.

Recommendation(s): **Based on the lack of mortality benefits, the marginal impact on quality of life, the lack of long term results at this time, the presence of ongoing research designed to establish the benefit of this therapy, and the considerable opportunity costs, the TAU does not recommend routine use of biventricular pacemakers with ICD at the MUHC. TAU encourages the active participation of the MUHC in the CIHR funded trial that is further examining this technology. At present, TAU does not expect that more than a maximum of 5 or 6 exceptional cases annually would require biventricular pacing outside the context of the funded research trial.**

TAU Current Projects

1. Laparoscopic surgery for obesity
2. Endovascular coils for cerebral aneurysms

Independent evaluation of previous TAU reports

During the past year, we requested an independent evaluation of the impact of the first 11 TAU reports. This work was performed by the Quality Management Team of the MUHC and the details are to be found in Appendix 1. Three recommendations (establishment of a hepatitis C clinic, increase purchase of implantable cardiac defibrillators and self expanding esophageal stents) involved increased annual spending of approximately $625,000 accompanied by the purchase of meaningful health benefits to our patient population. Two evaluations were seen to be budget neutral. Seven reports have lead to projected budget savings of 2.9 million dollars annually.

In addition, TAU has produced one informal report on the use of activated protein C in sepsis. According to André Bonnici pharmacist, projections for the use of this medication by the ICU staff was for 70 cases or $700,000 annually[1]. Clinicians were subsequently supplied the TAU report on this medication and use of this drug over the last year has been limited to 7 cases. At least part of these savings are undoubtedly related to the TAU report.
Finally, it is also known that several TAU reports have had a significant impact on provincial health decisions (Claude Dussault, MSSS).

[1]This calculation has assumed that the use of DES would have been 20%, as in our Quebec University Centers instead of the 5% currently used. This 15% reduction equals 210 less coated stents at a price differential of $1800.

Additional Activities

Communications.
McGregor M., Scott H. M. Bottom up or top down? How to get Technology Assessments to influence Policy. Fifth International Conference on the Scientific Basis of Health Services. September 20, 2003. Washington DC USA.

Publications.
McGregor M., Jun Chen. Should the Implantable Cardiac Defibrillator be used for primary prevention of sudden death? A review of issues relevant to hospital decisionmaking. Canadian Journal of Cardiology. *In Press*

ACKNOWLEDGMENT

It has been a privilege to take part in this second year of full functioning of the Technology Assessment Unit.. 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", most have supported new developments because they have identified the benefits, both clinical and financial, 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.*

Appendix 1 Details of the independent evaluation of previous TAU reports

TAU - IMPACT REPORT

TA report title:	Should the McGill University Health Centre replace the Jelco/Cathlon catheter by the Protect IVPlus catheter for intervenous infusions?
Date submitted:	***February 26, 2002***
Requestor name:	Ms. Valerie Shannon
Requestor department:	Director of Nursing - MUHC
Recommendations:	The principal benefit that would result from the introduction of the ProtectIVPlus (J&J) safety device for all intravenous infusions carried out at the McGill University Health Center (MUHC) would be relief from fear of infection for approximately 20 individuals per year, and protection of 7 individuals from the need to undergo 28 days prophylactic triple therapy. It would have no easily measurable effect on the risk of infection of health workers. The estimated direct net cost of obtaining these benefits would be approximately $244,000 per year to the Québec health-care system or $193,000 to the MUHC.
Impact	The recommendation was followed in that it was felt it was an unreasonable amount of money for the benefit provided, so the technology was not introduced. **Budget Impact** Estimated saving $193,000 annually.

TA report title:	Should the McGill University Health Centre initiate an antiviral treatment program for patients with Chronic Hepatitis C?
Date submitted:	***October 8, 2002***
Requestor name:	Dr. Michel Marcil
Requestor department:	Associate Director – Professional Services
Recommendations:	An MUHC program for the antiviral treatment of 70 patients per year should prevent the development of cirrhosis, with subsequent hepatic failure or hepatoma followed by death of 16, and possibly as many as 25 individuals per year, and cost the MUHC approximately $111,782. After an uncertain interval of possibly 12 years, the money saved would considerably exceed the costs of the program. The TAU committee recommends that the MUHC should initiate a program for the antiviral treatment of chronic HCV.
Impact	According to Dr Deschenes, the program has been initiated but is hampered by a lack of nursing resources. There is a waiting list of 4-5 months to begin treatment. **Budget Impact** Initially there will be increased expenditure of approximately $111, 782 per year. After approximately 12 years there will be major savings.

TA report title:	An evaluation of glycoprotein IIb/IIIa inhibitors during percutaneous coronary interventions at the MUHC: Is there a difference between the drugs?
Date submitted:	***November 21, 2002***
Requestor name:	Dr. Denis Roy
Requestor department:	Director of Professional Services (MUHC)
Recommendations:	Routine use of GP 2b3a inhibitors during PCI at the MUHC catheterization laboratories is not recommended; rather treatment should be reserved for high-risk patients as defined by clinical and angiographic assessments. Since there are no clinically meaningful differences in outcomes between the different agents, in most cases the lower priced agents, tirofiban or eptifibatide, should be favored. It is nevertheless recognized that the more expensive agent, abciximab, may be the preferred drug for certain specific clinical indications.
Impact	Recommendations have been followed. The result is that last year 563 patients at $1674 (abciximab)=942,462$ and 32 patients at 450$ (eptifibatide)=14,400$ Total 595 patients for total **$**956862 This year, the projections are for 283 patients at $1674 (abciximab)=473,742$ and 542 patients at 450$ (eptifibatide)=243,900$ Total 825 patients for total $717,642 **So 230 more patients for 239,220$ less** **Budget Impact** Without this report costs for these drugs would be $956,862x825/595 = $1,326,741 in current year. Savings= $1,326,741-$717, 624= $609,117. Recurring.

TA report title:	Should the MUHC use Mitoxantrone in the Treatment of Multiple Sclerosis?
Date submitted:	***December 2, 2002***
Requestor name:	Mr. James Gates
Requestor department:	Associate Director – MNH
Recommendations:	There is relatively good evidence that treatment with mitoxantrone can be expected to reduce the relapse rate and the rate of clinical deterioration, as well as MRI evidence of diminished CNS activity, at least during the course of the treatment. The clinical benefits to be expected, although not very substantial and not yet shown to be permanent, are still sufficient to justify offering patients with very active forms of MS, similar to those in reported studies, the possibility of treatment. The TAU committee recommends that a programme limited to 20 new enrollments per year should be approved at this time. This decision should be reviewed in one year in light of the experience accumulated and any new evidence concerning benefits and side effects of mitoxantrone.
Impact	As recommended, 20 patients per year are being enlisted. A follow up report is expected in December 2003. **Budget Impact** Estimated cost of 20 patients per year = $100,000 . Estimated result of unrestricted approval would be 40 patients per year costing $200,000. Thus estimated budget saving= $100,000. Recurring

TA report title:	Should the MUHC approve the use of colorectal stents?
Date submitted:	***February 3, 2003***
Requestor name:	Dr. Ewa Sidorowicz
Requestor department:	Associate Director of Professional Services (MUHC)
Recommendations:	Because of the increased efficiency and productivity that would result from increased stent use, and because of the associated improvement in quality of life when used for palliation, the TAU committee recommends that the MUHC approve the use of colorectal stents for the relief of large bowel obstruction, both for palliation, and whenever clinically indicated, as a bridge to ultimate surgical resection.
Impact	Even before the TAU approval GI used these stents to improve the quality of life of these patients. Since the approval, the financing of the stents has become easier. The TAU also approved the use of oesophageal stents more recently. According to P. Szego, GI has been using these stents with good results. **Budget Impact** Current stent use is 15 per year. Each use will cost $854 less than the cost of colostomy. Thus, savings = 15x $854 = **$12,810** per year. Recurring.

TA report title:	Should the MUHC use low-molecular-weight heparin in inpatient treatment of deep vein thrombosis with or without pulmonary embolism?
Date submitted:	***February 6, 2003***
Requestor name:	Mr. André Bonnici
Requestor department:	Coordinator – P&T Committee
Recommendations:	The TAU Committee recommends that the MUHC approve the replacement, when clinically indicated, of unfractionated heparin by low-molecular-weight heparin for the inpatient treatment of deep vein thrombosis, with or without pulmonary embolism.
Impact	P&T has approved the recommendation, but this has **not** been implemented yet for the following reasons: 1) Pharmacy Technical assistant shortage currently does not permit additional workload that would be added for preparing syringes. 2) Pharmacy is in the process of reviewing the LMWH class to choose the most cost-effective agent to implement the recommendation. (Review will be presented in November to P&T) 3) A protocol is being written to implement this new practice safely as it implies a major change in practice, which affects almost all areas of the hospital. The MUHC is looking at the experience in some other Canadian hospitals and considering pre-filled syringes which would probably resolve the staffing issue described above. 4) The extra 9,000$ required to cover the additional drug acquisition costs has not been completely worked out yet **Budget Impact** Additional drug acquisition and preparation costs would be $9,000 There would be estimated savings of $ 58,000 in nursing and lab costs. Since only the supplies portion of the lab costs would be recoverable, the consequences of this report are virtually budget neutral

TA report title:	Should the MUHC Approve the Video Capsule Endoscopy System in the Diagnosis of Small bowel Abnormalities?
Date submitted:	***March 24, 2003***
Requestor name:	Dr. Ewa Sidorowicz
Requestor department:	Associate Director of Professional Services (MUHC)
Recommendations:	The TAU, while recognizing the innovative characteristics of the capsule endoscopy does not feel that there is sufficient evidence to recommend either the purchase of this technology or its incorporation into routine clinical practice.
Impact	It is being used a basis of a research project. The GI division will soon purchase the technology with research private funds, and have submitted protocols to the MUHC Research Institute and US (and soon Canadian) peer-review funding agencies. Follow Up: They have received MUHC-RI funding and will proceed with a pilot trial. **Budget Impact** Equipment acquisition costs ($62,000) saved in year one, and $900 per capsule (for an estimated 7 patients) there after. Thus savings equals $63,000 recurring.

TA report title:	Eprex and pure red cell aplasia. What should be MUHC policy for hemodialysis patients?
Date submitted:	***April 25, 2003 update June 18, 2003***
Requestor name:	Mr. Victor Simon
Requestor department:	Chief Operating Officer - MUHC
Recommendations:	**1**. It is recommended that both Aranesp and Eprex iv should be available at the MUHC. The costs to the MUHC are very similar. However, while both medications have a good safety record, the evidence supporting the safety of eprex iv is at present more extensive and of longer duration. Many patients are used to, and strongly prefer, receiving their medication at the time of hemodialysis rather than subcutaneously at home. It would seem to be completely inappropriate for this choice to be determined by a purely administrative directive. Accordingly, the ministry should be requested to resolve the issue as rapidly as possible by exempting this medication from its directive. **2.** In addition, the ministry should also be urgently requested to refund the cost of these medications directly to the hospitals as elsewhere in Canada, or alternatively to authorize the budget overrun that will result from application of present policy. **3.** The conclusions arrived at in the present document should be repeatedly reviewed to make sure that they are consistent with contemporary information.
Impact	The TAU recommendation was accepted, but represented pretty much present practice: i.e. Most patients were receiving Eprex IV in the dialysis facility already, others were on Aranesp. Meanwhile letters were sent by Dr Chagnon to the Ministry, the Conseil du Medicament Update: At a meeting in December there will be a review of all the latest administrative and clinical information with the experts. There is a possibility that if the Ministry does not agree to change its policy on Eprex (i.e. that hospital should cover the costs), the MUHC may have no choice but to propose that all patients be switched to Aranesp SC. **Budget Impact** Recommendations are budget neutral

TA report title:	An evaluation of drug eluting (coated) stents for percutaneous coronary interventions; What should their role be at the McGill University Health Centre (MUHC)?
Date submitted:	***July 16, 2003***
Requestor name:	Mr. Victor Simon
Requestor department:	Chief Operating Officer - MUHC
Recommendations:	**1.** That despite good evidence supporting the efficacy of coated stents to reduce the rate of restenosis, the current budget of the hospital should not be redistributed to permit the routine acquisition of drug eluting stents. Thus in the absence of a specially dedicated provincial budget for this technology coated stents should not be provided by the MUHC except for special circumstances. **2.** The special cases requiring a coated stent should be approved by two members of the Division of Cardiology, ideally two interventional cardiologists. **3.** The evidence on which this policy recommendation is based is likely to be very time sensitive. The decision should be frequently reviewed and modified if necessary in the light of such evidence. The responsibility for requesting review can be initiated by either the Division of Cardiology or the Technology Assessment Unit.
Impact	1. In April of 2003, the Medical Mission Management Committee approved the use of up to seven coated stents per month (for both sites) for compassionate grounds. Very clear guidelines for their use were developed by the cardiologists, which were in line with the recommendations made by the Reseau Quebecois pour la cardiologie tertiaire (RQCT). Two interventional cardiologists must concur prior to their use. The RQCT made a formal request to the MSSS for the use of these stents based on very clear criteria. The MSSS refused broad use of this technology and instead decided to create evaluation projects. They announced that there will be $500,000 for 200 coated stents within the McGill Network (i.e. split between the RVH, MGH and JGH) and it will be the Dean (as Chair of the McGill RUIS) who will decide the allocation between the MUHC and the JGH. The U of M received money to do 600 coated stents and this is to be split between the Institut and the other U of M centres that perform angioplasty. We are expected to submit a report to the MSSS on the outcome. 2. Done. See above. 3. This will be done through the report to the MSSS. **Budget Impact** *The MSSS read this report and was largely guided by its findings (Claude Dussault) Unrestricted use of coated stents would have cost the MUHC between $2-3 million per year*

TA report title:	Use of the implantable cardiac defibrillator (ICD) at the McGill University Health Centre (MUHC)
Date submitted:	***September 10, 2003***
Requestor name:	Mr. Victor Simon
Requestor department:	Chief Operating Officer - MUHC
Recommendations:	**1.** That the MUHC if possible with other institutions, urgently present this problem to government with a request that they consider the provision of specials funds to finance ICD acquisition. **2.** Until special funding becomes available, the committee feels that ICD use at the MUHC should not be unlimited. **3.** Patients should not be permitted to purchase their ICD or to pay for an upgrade of their ICD through private resources. **4.** ICD policy must be formally adopted by the MUHC. **5.** These recommendations should be considered temporary and should be subject to review and amendment when necessary.
Impact	1. Done. We presented our case to the Regie regionale in June. They were receptive and brought it to the attention of the MSSS. Just a few weeks ago we were informed that we would be given an additional $100,000 this year for this. This will allow us to do an additional 4 or 5. 2. The cardiologists have started using them for primary prevention based on the new guidelines. Fortunately, we have been lucky that we are so far not seeing the impact that we expected. As of Period 7, we have only implanted three more ICDs then last year at this time. 3. Agreed and approved by the Medical Mission Management Committee. 4.The policy has not been formally adopted. 5. Agreed. **Budget Impact** The demand and the cost of the instruments in the future are unknown. TAU recommended a budget increase on this item of approximately $600,000. MSSS has awarded an additional $100,000. Which figure the hospital will approve is as yet undecided

TA report title:	The use of self-expanding metallic stents in the palliation of dysphagia in patients with malignant esophageal strictures
Date submitted:	***September 17, 2003***
Requestor name:	Dr. Ewa Sidorowicz
Requestor department:	Associate Director of Professional Services (MUHC)
Recommendations:	Despite the variation in results observed in the literature, it appears that the use of SEMS for the palliative treatment of malignant dysphagias and esophagorespiratory fistulas represents an improvement for the patients status and quality of life, with an additional cost of only CDN$ 13,524 to the MUHC (based on 6 treated patients/year). The TAU recommends the use of esophageal self-expanding metallic stents in patients with malignant dysphagia and esophagorespiratory fistulas.
Impact	This is partly implemented. Dr Barkun reports that they are getting them more freely, but on the other hand, we are NOT given the liberty of spending due to budget cutbacks.i.e.: they can now order this equipment, but if the general budget is reached (which it always is too early in the year),they cannot get more of these stents.He did not know how many have been done to date **Budget Impact :** Estimated increase in budget of 2,254$ per patient for 6 patients annually =13,524$