

Technology Assessment Unit of the McGill University Health Centre (MUHC)

The Impact of Reports

of

The Technology Assessment Unit of the McGill University Health Centre

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by

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LIST OF ABBREVIATIONS

AS	Aortic Stenosis
BOTOX	Botulinum Toxin A
C-Diff	Clostridium Difficile
C-E	Cost Effectiveness
CHUM	Centre hospitalier de l'Université de Montréal
DBS	Deep Brain Stimulation
DES	Drug Eluting Stents
DVT	Deep Vein Thrombosis
EPO	Epotein Alfa
FISH	Flourescence In Situ Hybridization
GVH dis	Graft versus Host Disease
HER 2	Human Epidermal Growth Factor Receptor 2
HTA	Health Technology Assessment
ICD	Implantable Cardiac Defibrillator
IHC	ImmunoHistoChemistry Assay
IRB	Institutional Review Board
LMWH	Low Molecular Weight Heparin
MNH	Montreal Neurological Institute & Hospital
MS	Multiple Sclerosis
MSSS	Ministère de la Santé et des Services sociaux du
MUHC OR PCI PRCA PREM PRF RFA RGAM RVH SEP SSEP SRS TAU TAVI UFH US	Québéc McGill University Health Centre Operating Room Percutaneous Coronary Intervention Pure Red Cell Aplasia Priorité Régionale d'Effectif Médicaux (an approved medical staff position) Percutaneous Radio-Frequency Radio-Frequency Ablation Régime général d'assurance-médicaments Royal Victoria Hospital Somatosensory Evoked Potentials Surgical Resection Technology Assessment Unit Transcatheter Aortic Valve Implantation Unfractionated Heparin Ultrasound

SUMMARY

Health Technology Assessment (HTA) that fails to influence policy is wasted effort.

The Technology Assessment Unit was created in 2001 to advise the McGill University Health Centre on difficult resource allocation decisions. The present report aims to review the impact of the recommendations made in the first 55 reports.

Policy Impact. Of 63 recommendations, 45 (71%) have been accepted and incorporated into MUHC policy. The recommendations contained in six reports were not rejected by the MUHC, but due to uncertainty as to who should be responsible for carrying them out there was failure to take the necessary administrative action.

Economic Impact. Overall, 19 accepted reports have resulted in conservation of hospital resources. The extent of these savings could only be estimated in the case of 15 reports. In these the estimated overall savings have totalled \$9,840,270. Over the eight years of full functioning of the TAU (2004-11) the average annual quantifiable savings has been \$1,140,958.

RECOMMENDATIONS

It is recommended that in each report there should be clear identification of the following individuals:

- The hospital authority responsible for the initiation of the report.
- The senior administrative and clinical authorities responsible for acceptance of the report.
- The individuals responsible for carrying out its recommendations.

SOMMAIRE

L'unité d'évaluation des technologies (Technology Assessment Unit (TAU)) fut créée en 2001 pour conseiller le Centre Universitaire de Santé McGill (CUSM) en regard des décisions difficiles concernant l'allocation des ressources. Le présent rapport a pour objectif de revoir l'impact des recommandations émises lors des 55 premiers rapports d'évaluation.

Impact sur les politiques en place

Parmi les 63 recommandations émises, 45 (71%) ont été acceptées et incorporées dans les politiques du CUSM. Les recommandations mentionnées dans six rapports ne furent pas rejetées par le CUSM mais devant l'incertitude quant à la responsabilité de leur réalisation, aucune action administrative ne fut mise de l'avant.

Impact économique

Globalement, 19 rapports acceptés se sont traduits par la conservation des ressources hospitalières. L'ampleur de ces économies ne peut être estimée que pour 15 rapports, seulement, et totalisent 9 840 270 \$. Au cours des 8 années où le TAU était pleinement productif (2004-2011), les économies annuelles chiffrables ont été de 1 140 958 \$.

RECOMMANDATIONS

Il est recommandé que dans chaque rapport les individus suivants soient identifiés sans ambiguïté:

- L'autorité hospitalière responsable de l'initiation du rapport.
- Les autorités administrative et clinique responsables de l'approbation du rapport.
- Les individus responsables de la mise en place des recommandations.

The Impact of Reports of the Technology Assessment Unit of the McGill University Health Centre

BACKGROUND

In 2001 the McGill University Health Centre (MUHC) established a Health Technology Assessment Unit (TAU). Its purpose is to advise the hospital in difficult resource allocation decisions, using an approach based on sound, scientific technology assessment and a transparent, fair decision-making process.

The TAU consists of two distinct components. A professional group prepares technology *evaluations* that reflect the health benefits, risks, and costs of the technologies in question, and a Policy Committee, consisting of elected representatives of all components of the hospital, develops recommendations concerning the actions the hospital should take in the light of the evaluations. The completed report (evaluation and recommendations) is then submitted to the hospital administration and widely distributed, both in the hospital and on the web.

Objectives. The primary objective of the present review is to evaluate the extent to which the reports developed by the TAU have actually influenced hospital policy decision-making, and hospital spending. Secondary objectives are to identify the reasons that reports have influenced or failed to influence hospital policy, and to develop recommendations to improve the process.

METHODS

Definitions

Health Technology refers to the equipment, drugs and procedures used by health care professionals, and the systems within which they are used.

A Health Technology Assessment (HTA) is a synthesis of the evidence concerning the effectiveness, risks, and costs of a health technology, with, when relevant, a review of the related ethical and legal issues. Most, but not all HTAs developed by the TAU include policy recommendations.

An accepted recommendation. A recommendation is considered to have been "accepted" when there is clear evidence that MUHC policy is consistent with the recommendation in question.

Assessment of impact

Policy impact. The evidence and the recommendations contained in each report developed by TAU were first extracted. Then the clinical and/or administrative individuals responsible for the technologies in question were contacted to determine the extent to which actual MUHC policy was consistent with the recommendations of the report in question, and to the extent possible, the role played by the TAU report in establishing such policy (For the hospital position held by cited individuals, see Acknowledgments section). Recommendations were classified as "accepted" when subsequent MUHC policy was consistent with these recommendations. Whenever recommendations were not carried out due to budgetary or other reasons they were classified as "not accepted"

Economic impact. The prime objective of reports developed by the TAU has not been to save money but to achieve the maximum health gain from the money available. However, some reports clearly have resulted in the conservation of institutional resources by providing recommendations and reasons why acquisition of some technologies should be rejected or limited. Though it can never be absolutely certain what decision would have been arrived at in the absence of a TAU report, to get some idea of their economic impact we make the assumption here that in the absence of a TAU report each technology acquisition would have been approved.

Estimation of the extent of resource savings was based on the difference between the observed net annual expenditure following a report, and an estimate of what that expenditure would have been if the recommendations in question had not been accepted . The economic impact of a report was considered to end when government started to fund the technology in question, or when changes in pricing or changes in utilisation eliminated further economic benefit (For examples see Table 2).

Estimation of how great expenditure would have been if the recommendations of any particular report had not been adopted also requires some assumptions. The information and assumptions used in these estimates are, unless otherwise stated, obtainable from the original reports, obtainable at <u>www.mcgill.ca/tau</u>. The estimation of savings was carried out by the author, and verified independently by two colleagues (X. Xie, N. Dendukuri), and a hospital administrator (G. Stoopler). Differences were resolved by discussion.

RESULTS

The topics addressed in each report, the principal recommendations, and their impact on policy are summarised in Table 1 and in the accompanying Explanatory Notes. In the last 10 years (January 2002 - December 2011) TAU has produced 57 reports. The last two reports are too recent for their impact to be estimated. Six reports do not include policy recommendations. Although some of these may well have influenced policy by defining defects in service and suggesting remedies, this would be difficult to quantify. We are, therefore, concerned here only with the impact of 63 policy recommendations contained in 49 reports.

Policy impact

Of 63 recommendations, 45 (71%) have been accepted and incorporated into MUHC policy, one has been partially incorporated, and 17 (29%) have not been incorporated into policy (see Table 1). The identified reasons for failure of recommendations to be incorporated into hospital policy (absence of impact) were as follows:

- Not accepted for "administrative reasons" (No. 31a, b, c). Acceptance, of recommendation No. 31d eventually achieved the objective in question, a reduction in wait times.
- Not accepted on legal advice because of a potential for legal action (No. 25).
- Not accepted because of lack of funds (No. 47).
- Recommendations not carried out due to failure to identify administrative responsibility to carry them out (No. 7, 11a,b,c, 13, 19, 40b).
- Unknown (No. 20, 32b,c,e).

Economic impact.

We have attempted to identify the economic impact of those recommendations which have been accepted and have resulted in conservation of hospital resources. Some recommendations that have clearly resulted in budgetary savings could not be quantified (2,7, 18, 23). Overall, 15 *accepted* reports have resulted in quantifiable conservation of hospital resources (see Table 2). Most of these have been the result of reduced budgetary demand due to limitation of technology acquisition. Others (Nos 5, 39) have not caused any reduction in budgetary demand but have increased efficiency by allowing increased productivity without increase in expenditure. We have estimated the economic impact of these reports by comparing the cost of the increase in services with what their cost would have been if there had been no report.

The assumptions involved in estimating economic impact are set out in the original reports and in the Explanatory Notes to Tables 1 and 2. Over the 10 year period the estimated overall savings associated with these 15 reports either through limitation

of technology acquisition or through increased efficiency have totalled \$9,840,270. Excluding the first two start up years (2002-03) the average annual quantifiable saving has been \$1,140,958.

TABLES

Table 1 The year, Subjects addressed, Recommendations, and Impact on Policy (Acceptance)

Report No.(Yr)	Subject	Recommendations	Accepted
1 (02)	Device to prevent needlestick injury	Not cost effective. Not recommended for general use	Yes
25 (06)	Update	Not cost effective. Not recommended for general use	No
2 (02)	Anti-viral treatment for chronic Hepatitis C	Well proven benefit. Cost-effective. Program recommended	Yes
3 (02)	Mitoxantrone treatment for MS	Benefits small and duration unproven. Limit to 20 new pts/yr.	Yes
24 (06)	Update.	Limit use to 20 new patients per year. Use only in context of an observational phase IV trial.	Yes Yes
4 (02)	Glycoprotein 11b/111a inhibitors during PCI	a)Routine use not recommended. Use for high risk patients only. b)Use tirofiban or eptifibatide in preference to abciximab	Yes Yes
5 (03)	Use of low-molecular-weight heparin for DVT	Use LMW Heparin wherever clinically indicated	Yes
6 (03)	Colorectal stents	Continued use approved. Cost neutral	Yes
7 (03)	Video-capsule Endoscopy	Insufficient evidence of benefit . General use not recommended	Yes
8 (03)	Eprex for haemodialysis patients	Both Eprex and Aranesp should be available for use at MUHC.	Yes
9 (03)	Drotrecogin alfa for severe sepsis	Proof of benefit unsatisfactory. Poor C-E. Not for general use.	Yes
29(07)	Update	Restrict use to patients at highest risk	Yes
10 (03)	Drug eluting stents	Use only for patients at increased risk of restenosis on approval of two cardiologists.	Yes
11 (03)	ICD for primary prevention of sudden death	 a) Efficacy proven. Recommend urgent request for special funding. b) Until funded, restrict to additional 25/yr for primary prevention. c) Responsibility for rationing must be clearly accepted by MUHC 	No No No
12 (03)	Oesophageal stents for malignant strictures	Clinically effective. Minor budget impact. Use recommended.	Yes
13 (04)	Bi-ventricular pacing for severe heart failure	Mortality benefit unproven. Routine use not recommended.	No
14 (04)	Carmustine implants for malignant glioma	Benefits marginal. Poorly proven. Limit use to 10 special cases/yr.	Yes
35(09)	Update	Unchanged	Yes
15 (04)	Gastric Banding Procedure for morbid obesity.	Unproven. Until funded use only when R-en-Y carries >risk.	Yes
16 (04)	Matrix Coils for cerebro-vascular Aneurysms	Benefit unproven. Use for routine patient care not recommended.	Yes
42(09)	Update	Unchanged	Yes
17 (05)	Expansion of stem cells transplant programme .	 a) Opportunity costs too great. Seek designated funding. b) No expansion without designated funding. c) Adult transplant activity should be concentrated into one centre 	Yes Yes Yes

Report No.(Yr)	Subject	Recommendations	Accepted
18 (05)	Probiotics for prevention of C Diff diarrhoea	Evidence insufficient to support routine use. Not recommended.	Yes
44(09)	Update. Probiotics for C Diff diarrhoea	Unchanged. Not recommended.	Yes
54 (11)	Update. Lactobacillus probiotics For C Diff	Evidence insufficient to support routine use.	Yes
19 (05)	Negative pressure wound therapy	Proof inadequate to support routine use. Not recommended	No
48 (10)	Update.	Proof of efficacy sufficient for diabetes-associated leg wounds	Yes
20 (05)	Neuro- monitoring during spinal surgery.	SEP, SSEP should be available for all cases at risk of injury	Partly
21 (05)	Microdialysis to monitor traumatic brain injury	Not recommended except in the context of a research project.	Yes
22 (05)	Botox for anal fissures & sphincter achalasia.	Approve for special cases only after 2 consultations. Limit to 4/yr,	Yes
23 (06)	Testing for HER2 breast Cancer.	First screen with IHC. Then test scores of 2+ and 3+ by FISH	Yes
26 (06)	Wait times at MUHC 1	A descriptive report. No explicit recommendations.	N/A
27 (06)	Wait times at MUHC 2	A descriptive report. No explicit recommendations.	N/A
30 (07)	Pulsatile perfusion for kidney preservation	Probably effective and cost saving. Acquisition recommended.	Yes
31 (07)	Wait times at MUHC 3. Fracture management	a) Urgently inform health authorities of egregious situation	No
()	5	b) Request urgent authority to open additional operating room	No
		c) Request one additional anaesthetist and one orthopaedic PREM	No
		d) Interim solution recommended	Yes
32 (08)	Wait times at MUHC. 4. Diagnostic imaging.	a) MUHC should urgently request more radiologist PREMs	Yes
		b) Create an Imaging-dedicated transportation unit.	No
		c) When technologists not available consider using tech. assistants.d) Acquire voice recognition technology for inscription of reports	No Yes
		e) Temporarily divert general radiological patients to private labs	No
33(08)	Impact of TAU reports	No recommendations	N/A
34 (08)	Coblation Tonsillectomy	Cost excessive for uncertain pain reduction. Not recommended	Yes
36 (09)	Opportunity costs of technology expansion.	No recommendations	N/A
37 (09)	The Impella ventricular assist device	More effective and less costly than alternatives. Recommended.	Yes
38 (09)	Subthalamic DBS for Parkinsons disease.	This technology should be maintained and expanded at the MNH	Yes
39 (09)	Percutaneous RF ablation for hepatic carcinoma	PRF should be funded.	Yes
40 (09)	Allogenic Acellular Dermal Matrix for breast	a) Recommend temporary approval for 60 cases. Maintain registry. b)	Yes
- (/	reconstruction	Reconsider 18 months after review of registry.	Yes
41 (10)	Collatamp-G for infection prophylaxis in	Do not use until infection rate has been determined while using	Yes
	colorectal surgery.	standard antibiotic protocol	
43 (09)	Collatamp-G for infection prophylaxis in cardiac surgery	Evidence promising but insufficient. Use not recommended.	Yes
45 (09)	Transcatheter Aortic Valve Implantation	a) An effective technology that should be funded provisionally.	Yes

Report No.(Yr)	Subject	Recommendations	Accepted
		 b) A registry of all cases, with follow-up should be maintained c) At 1 year this registry should be examined by MUHC and funding reviewed. 	Yes No
46 (09)	RFA for Barrett's oesophagus.	Effective and less costly than esophagectomy. Limit to 10 per yr	Yes
47 (10)	Ultrafiltration for decompensated Heart Failure	Recommended for diuretic resistant heart failure.	No
49 (10)	Argon beam coagulation	A brief report, reviewing uses and costs. No recommendations.	NA
50 (11)	Apico-aortic conduit for degenerative AS	Use only on unanimous recommendation of joint committee*.	Yes
51 (11)	Blood irradiation for prevention of GvH dis.	A brief report without recommendations.	NA
52 (11)	Fiducial markers in radiotherapy for prostate ca.	A mini-HTA. Use only when prostate hard to visualise by US.	Yes
53 (11)	Verify NOW. To detect clopidogrel resistance	A mini-HTA. Recommend funding only in context of research	Yes
55 (11)	Drug eluting stents. Current indications for use	Recommend DES be used only for certain defined indications.	Yes
56 (11)	Subglottic drainage enabled endotracheal tubes	Recommended.	
57 (11)	Binax Now.	Not recommended for routine use.	

MS=Multiple Sclerosis. C-E= Cost Effectiveness. ICD=Implantable Cardiac Defibrillator. C Diff= Clostridium Difficile. SEP SSEP=Somatosensory Evoked Potentials. HER 2=Human Epidermal Growth Factor Receptor 2. IHC=ImmunoHistoChemistry assay. FISH=Flourescence In Situ Hybridization. PREM=Priorite Regionale d'Effectif Medicaux.(An approved medical staff position). TAU=Technology Assessment Unit of the MUHC. DBS= Deep Brain Stimulation. PRF= Percutaneous Radio-Frequency Ablation. RFA= Radio-Frequency Ablation. GvH dis = Graft versus host disease. US = Ultrasound

* Joint Committee = a multidisciplinary team consisting of 2 interventional cardiologists, 2 cardiac surgeons, 2 general cardiologists, and a critical care specialist.

Report No.(yr)	Realized Savings										
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Total
1,25	160,693	179,516	166,200	152,884	137,699						796,992
3,24		100,000	75,000	50,000	25,000						250,000
4		115,240	240,250	171,570	178,450						705,510
5*		57,150	57,150								114,300
9		100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	900,000
16			50,000	40,000	30,000	20,000	10,000				150,000
17				950,000	1,900,000						2,850,000
21				32,500	65,000	65,000	65,000	65,000	65,000	65,000	422,500
30						25,230	25,230	25,230	25,230	25,230	126,150
34							135,235	135,235	135,235	135,235	540,940
37								227,587	284,484	227,587	739,658
39*									325,980	181,100	507,080
41									120,000	180,000	300,000
43									716,470	716,470	1,432,940
53										4,200	4,200
Total	160,693	551,906	688,600	1,496,954	2,436,149	210,230	335,465	553,052	1,772,399	1,634,822	9,840,270

* These reports (Nos 5, 39,) have increased efficiency by allowing increased productivity without increase in expenditure. We have estimated their economic impact by comparing the cost of the increase in services with what their cost would have been if there had been no report.

Explanatory notes for Tables 1,2

Sources not specifically referenced are derived from the original reports. </www.mcgill.ca/tau/forms>

Report No. 1. Device to prevent needlestick injury (Also Update. Report No. 25)

A special ad hoc committee had recommended that anti-needlestick devices should be used routinely for the insertion of intravascular catheters. In contrast to this advice, report No. 1 of the TAU concluded that for general use this device was not cost-effective, and from 2002 to 2007 the device was not used except in special high risk areas. The recommendation was reaffirmed in a follow-up report in 2007 but on this occasion the recommendation was rejected because the current extensive acceptance of these devices might result in their being considered standard of care [A Lynch].

<u>Cost Estimates</u>. In Feb 2002 and May 2006 the net annual cost of introducing the device was estimated to be \$192,832 and \$137,699 respectively [Reports No. 1, 25]. The fall in cost over this time was due to changes in purchase price and to a small extent, changes in demand. In estimating costs in intervening years it is *assumed* that these changes are linear. The costs in 2002 are estimated over 10 months.

Report No. 2. Anti-viral treatment for chronic Hepatitis C.

This report concluded that the benefits of treatment of chronic hepatitis C were well proven and that after approximately 12 years such a policy would be cost effective.

<u>Cost Estimates</u>. The estimated demand was 70 patients per year for whom an antiviral program would cost the MUHC \$111,782 per year. In the absence of treatment, after a latent period of approximately 12 years, these individuals would develop liver failure and hepatomas. The cost of managing such complications would substantially exceed the costs of the proposed anti-viral treatment program [Report No. 2]. However, because savings would be deferred and hard to quantify the *extent of savings has not been estimated*.

Report No. 3. Mitoxantrone treatment for MS (Also Update Report No. 24.).

This report concluded that the benefits of mitoxantrone treatment were small and the duration unproven, and that new cases should only be accepted in the context of an observational phase IV trial and limited to 20 per year. These recommendations have been strictly followed [Y LaPierre].

<u>Cost estimates</u>. It was recommended that cases be limited to 20 per year. At the time of the first report [Report No. 3] in 2002, the demand was approximately 40 per year and the estimated average cost of treatment to the MUHC approximately \$5,000 per case per year. By 2006 demand had diminished to approximately 20 per year. [Y LaPierre]. If it is assumed that the fall in demand over this time was linear the savings over four years would have been approximately \$250,000.

Report No. 4. Glycoprotein 11b/111a inhibitors during PCI

This report (November 2002) recommended routine use of Eptifibatide (13% the cost of Abciximab). The report was accepted.

<u>Cost estimates</u>. The data on which the estimation of savings is based are shown in the Appendix 2.

Report No. 5. Use of low-molecular-weight heparin(LMWH) for DVT

Although now standard of care throughout Quebec, I-m-w heparin was little used at the time of this report (2003). The report resulted in it being introduced at the MUHC earlier than would have otherwise happened. [A Bonnici].

<u>Cost Estimates</u>. If it is assumed that the report caused the use of LMW rather than UF(unfractionated) heparin for 450 patients in 2003 and 2004 and that by 2005, even in the absence of the report its use would have become routine, the estimated saving would be \$57,150 per year for each of these two years [Report No. 5]. However, this would be the result of reduced nursing hours, which in practice would not be recovered, but would be devoted to other activities. Thus, the gain would be in efficiency.

Report No. 6. Colorectal Stents

This report concluded that the use of colorectal stents and the alternative management strategy, colostomy, would each cost approximately \$3,000. Thus, the decision was budget neutral and the purchase of stents was recommended.

Report No. 7. Video capsule Endoscopy

This technology was in use at the time of this report (2003), which concluded that there was insufficient evidence to recommend its continued routine use. Although "accepted" by the MUHC, this recommendation probably only limited utilisation for 1-2 years. No clear documentation of the early use of this technology can be found. (A follow-up report, number 60, concludes there is now sufficient evidence of benefit to justify use of this technology).

Report No. 8. Eprex for haemodialysis patients

This Report had a significant effect on MUHC policy (See Appendix 3), but no economic impact since the selection of available preparations was budget neutral.

Report No. 9. Drotrecogin alfa for severe sepsis (Also Update. Report No. 29.)

Both these reports recommended restriction of use to patients at highest risk. This recommendation was accepted [P Goldberg].

<u>Cost Estimates</u>. Budget savings due to these two reports can not be estimated with accuracy. In the year following Report No. 9 strict protocols consistent with its recommendations were adopted in the ICU. Thereafter use of the drug was highly restricted. Compared to a potential 120 candidates [Report No. 9], the number of patients treated in 2004, 05,and 06, numbered 11, 18, and 7 respectively [P Goldberg]. For comparison, the rate at the CHUM (an institution of comparable size and function) in 2006 was 27 [Report No. 29]. The approximate cost per patient treated was \$10,000 . If 10 or 20 fewer patients were treated each year due to this report, the budgetary savings would have been \$100,000 or \$200,000 per year, respectively. The lower figure is included in Table 2.]

Report No. 10. Drug eluting stents.

This report (2003) recommended that drug eluting stents (DES) not be routinely used following angioplasty at the MUHC, but should be reserved for cases at high risk of restenosis. As a result use of DES at the MUHC has been considerably lower than in the rest of Canada and lower than in other Quebec University hospitals. However, from 2003 onwards Quebec has reimbursed hospitals for DES used [C Berubé]. Thus, the estimated annual saving of approximately \$400,000 (see Report No. 10) was a saving to the Quebec health care system but was without economic impact on the MUHC.

Report No. 11. The Implantable Cardiac Defibrillator (ICD) for primary prevention of sudden death

While this technology was judged to be effective and life-saving, in the absence of special funding the opportunity costs that would result from its free application would be excessive, with adverse effects on hospital function. Thus, it was recommended that its use should be restricted. The report was never formally accepted or rejected. It may have initially restrained the rate of increase of ICD use. However, usage increased annually from 23 in 2003 (year of the report), to 34 in '04, 83 in '05,, 100 in '06, 166 in '07, 175 in '08, 198 in '09, 210 in 2010 and 245 in 2011 [G Stoopler].

Report No. 12. Oesophageal stents for malignant strictures.

This report concluded that this technology significantly improved quality of life at modest cost, and was less expensive than laser surgery. Its recommendation that the MUHC acquire it without restriction was accepted.

Report No. 13. Bi-ventricular pacing for severe heart failure

At the time of this report there was insufficient evidence that use of this technology would result in reduced mortality, and its use was not recommended. However, enforcement of this recommendation was limited and ineffective. Thus, implants increased steadily from 10 per year in '04-'05 to 67 per year in '06-'07, and 97 per year in 2010-'11. [M Black]. The later increase was probably in response to publication of new evidence of clinical benefit.

<u>Report No14.</u> Carmustine implants for malignant glioma . (Also Update . Report No. 35)

The recommendation of these two reports that implants be used only for special cases, and their number limited to 10 per year was accepted. No implants have been carried out to date . Cost savings have not been estimated because it is reported that this decision would probably have been made regardless of the report. [R Del Maestro].

Report No15. Gastric Banding Procedure for morbid obesity

This report concluded that since this procedure was not yet recognised by the Ministry, and its superiority over a recognised alternative (Roux-en-Y) was unproven, it should not be routinely carried out at the MUHC. This recommendation was accepted by MUHC. However, the devices were not funded by government (until 2010), and they were not used because of the cost to the patient and not because of the TAU recommendation. Although approved in 2010 they were still not used because of wide recognition of high complication rates. Thus, in effect the recommendations of this report were without impact.

<u>Report No16. Matrix Coils for cerebro-vascular Aneurysms (Also Update .</u> Report No. 42.)

As recommended in these two reports no coils have been used. By 2009 the initial demand of 40 per year [Report No16] had fallen to 0.

<u>Cost Estimates</u>. In estimating savings we assume that the additional cost per procedure of using the coil would be \$1,252, with demand falling linearly from an initial 40/yr in 2004 [Report No. 16] to 0 in 2009[M Angle].

Report No. 17. Expansion of stem cells transplant programme

At the time of this report there was a very limited stem cell programme at the MUHC. There was a request to increase this by 20 per year. The report found that this was an effective, and reasonably cost-effective technology, but that because of the high opportunity cost it should not be expanded until government funding was provided. At such time all adult transplant activity should be concentrated at the Royal Victoria Hospital (RVH). Acceptance of these recommendations blocked the requested

expansion for half of 2005 and all of 2006. Thereafter additional funding was received, and by 2011 the transplant rate had increased to 60 per year. [P Laneuville].

<u>Cost Estimates</u>. Estimated savings assume a demand for an additional 20 allogeneic stem cell transplantations per year, at an additional cost of \$1,900,000 [Report No17].

<u>Report No. 18. Probiotics for prevention of C Diff diarrhoea.</u> (Also Follow Up Reports. No. 44, 54.)

These reports, including the most recent (No. 54 in 2011) found that evidence of efficacy was not yet sufficiently convincing to cause the MUHC to initiate probiotic prophylaxis. Acceptance of these recommendations has resulted in some saving of pharmacy and nursing hours in addition to the cost of probiotics (not calculated).

Report No. 19. Negative Pressure Wound Therapy.(Also Update. Report No. 48.).

By the time the first report came out in 2005 negative pressure wound therapy was already widely used in the MUHC. The report recommended that use of this therapy should not be expanded. However, no executive actions were taken to limit its expansion which took place progressively [L D'Souza]. An Update in 2010 (Report No. 48) found that there was now sufficient evidence to support expanded use of this therapy at the MUHC.

Report No. 20. Neuro- monitoring during spinal surgery

This report recommended that appropriate neuro-monitoring should be available for use during spinal surgery. This report was neither formally accepted nor rejected. The executive actions necessary to carry out this recommendation was slowly implemented over the following three years [J Ouellet].

Report No. 21. Microdialysis to monitor traumatic brain injury

This report concluded that there was not yet sufficient proof of the efficacy of this technology to justify its introduction except in the context of a research procedure. As recommended this technology was not acquired on operating budget, but was purchased using research funds and is currently the object of a research study [M Angle].

<u>Cost Estimates</u>. The cost of expendable equipment for the anticipated 60 patients per year would have been \$65,000 [Report No. 21]. It is assumed that use of this technology would have commenced in mid-2005 and that demand and costs would have remained unchanged for six years.

Report No. 22. Botox for anal fissures and sphincter achalasia

This report concluded that the evidence of efficacy and safety of this technology was sparse and that it should not be considered an accepted technology at this time. It recommended that it might be used in defined exceptional circumstances and that use should should be limited to 4 per year. These recommendations have been strictly followed [M ste-Marie].

Cost Estimates. Since the demand has not exceeded the limit no savings can be assumed.

Report No. 23 Testing for HER2+ breast Ca. A C-E analysis

This report identified the most cost-effective process for testing breast cancer cases who are to be offered trastuzumab therapy. Current practice is identical with the report's recommendations. Although undoubtedly cost-saving the amount of saving cannot be quantitated.

Report No. 26, 27 Wait times at MUHC 1. 2.

These two reports identified the wait times experienced by patients in the fields of diagnostic imaging, joint replacement, cancer care, sight restoration, cardiac care and in selected divisions of the Departments of Medicine and Surgery. The objective was to increase awareness and identify the extent of this problem. There were no specific recommendations.

Report No. 30. Pulsatile perfusion for kidney preservation.

Acquisition of this technology was recommended and accepted.

<u>Cost Estimates</u>. It was estimated that at a level of usage of 20 per year there would be an annual net saving to the MUHC of approximately \$25,230 [See Report No. 30].

Report No. 31 Wait times at MUHC 3. Fracture management

This report found serious prolongation of wait times and made four recommendations for their correction. Partly as a result of the report, increased fracture operating room resources were made available [A Lynch], and as a result wait times have been largely eliminated.[G Berry].

Report No. 32 Wait times at MUHC. 4. Diagnostic imaging

This report identified sources of wait times in the department of diagnostic imaging and made recommendations for their correction.

The impact of this report was negligible. Only two of the five recommendations were recorded as "accepted". One, the addition of more radiology staff positions (PREM's) had already been requested when the report was delivered. The other, voice recognition technology for reporting was requested from the administration. Although not refused, it has yet to be delivered.

Report No. 34 Coblation Tonsillectomy

It was concluded that the evidence for pain reduction claimed for this technology was uncertain and the cost considerable. Acquisition was not recommended. As a result this technology has not been acquired. [M Schloss].

<u>Cost Estimates</u>. It was projected that if it had been acquired it would have been used for 490 procedures in 2008, and that it would have cost \$210 per child more than the alternative procedure, electrocautery [Report No. 34]. For the estimation of savings it is *assumed* that these costs would have remained constant up to the present.

Report No. 36. Opportunity costs of technology in expansion.

This report quantified the extent to which the purchase of new technologies that were not reimbursed by government could impact the hospital operating budget. There were no recommendations.

Report No. 37. The Impella ventricular assist device.

This report concluded that this technology was more effective and less costly than the available alternatives and recommended acquisition. Report accepted.

<u>Cost Estimates.</u> The budget impact of the use of Impella will vary from case to case, depending on the alternative management that would be used. In 8 cases managed at the MUHC there was an estimated net saving of \$227,587.[Report No.37]. Assuming the same rate is applicable to the 8,10,and 8 Impella procedures in 2008-09, 2009-10, and 2010-11, respectively, there would be an estimated \$739, 648 saving over the three years.

Report No. 38 Subthalamic Deep Brain Stimulation for Parkinsons disease

This report concluded that deep brain stimulation improves motor function in patients with medically resistant disease for up to 5 years. It was recommended that the programme should be expanded. The report also made specific recommendations concerning applications for funding. The report was accepted, the recommended approach to government was made, and although increased government funding was not secured some limited increase in the programme was authorized by the MUHC [A Sadikot]. For details see Appendix 4.

Report No. 39 Percutaneous Radio Frequency Ablation (RFA) for hepatic carcinoma

It was concluded that survival rates for this technology (RFA) and surgical resection (SRS) were comparable when both options were available, and the cost of RFA was lower. Funding of this technology was recommended, and accepted.

<u>Cost Estimates</u>.On average use of RFA costs the MUHC \$7,244 less than SRS.[Report 39]. Use of RFA was already beginning to increase when this report was published in mid-2009 [L Stein]. It is conservatively assumed that adoption of the report resulted in 45 and 25 cases per year being carried out by RFA in the subsequent two years [L Stein]. Note also that the lower cost of RFA technology was the result of surgical procedures avoided. In practice, the result would not be realised as reduced demand on budget but would result in increased patient service without increased expense, ie. increased efficiency.

Report No. 40 Allogenic Acellular Dermal Matrix for breast reconstruction

The estimated cost of using Allogenic Acellular Dermal Matrix was \$1, 920 per procedure and the estimated demand 60 women per year (20 with bilateral procedures), with an estimated budget impact of \$138,240 per year. Since the principal benefit claimed was improved aesthetic outcome and good evidence of this was not available, it was recommended that the application be given temporary approval for 60 cases on the following conditions: a detailed record of all reconstructions be maintained and the aesthetic outcome of each procedure be formally evaluated, records to be submitted to the head of surgery and the administrative director of the surgical mission within 18 months at which time the decision as to continuing use should be made. This recommendation was accepted and the technology is currently under review.

Report No. 41 Collatamp-G for infection prophylaxis in colorectal surgery.

It was concluded that the efficacy of this intervention appears to be dependent on the post-operative site infection rate, which in the MUHC at the time of the report was high (15%). Furthermore, routine antibiotic prophylaxis was not routinely being practiced. Acquisition of this technology was not recommended until prophylaxis measures were routinely carried out. The recommendation was accepted and the technology has not been put in use [B Stein].

<u>Cost Estimates</u>. The estimated gross cost is \$600 per procedure with an estimated 300 procedures per year = \$180,000 per year [Report No. 41]. It is assumed that this report, delivered in April 2010 was operative for eight months only in that year.

Report No. 43 Collatamp-G for infection prophylaxis in cardiac surgery

This report concluded that the evidence of efficacy was not sufficiently substantial and that the technology should not be funded except in the context of a research study. Collatamp has not been used following the report. A research protocol was submitted but was turned down by the IRB because it coincided with the adoption of antibiotic-coated sutures throughout the OR. [B deVarennes].

<u>Cost estimates</u>. The assumptions and method used to calculate the potential savings are detailed in Report No. 43.

Report No. 45. Transcatheter aortic valve implantation (TAVI)

It was concluded that preliminary evidence showed this to be an effective technology that should be funded conditional on maintenance of a registry that should be examined by the MUHC within one year. This recommendation was accepted and carried out.

Report No. 46 Radio-frequency Ablation for Barrett's oesophagus

It was concluded that this was an effective procedure. However, the high opportunity costs led to a recommendation to limit use to 10 patients per year until additional funding could be obtained. Recommendation accepted.

<u>Cost Estimates</u>. Estimated demand was 20 and the average unit cost \$11,000. Thus, there is a potential saving of \$110,000 per year. In effect, 3 cases completed treatment in 2011 [S. Mayrand]. Savings will only result from this report when demand exceeds 10 per year, probably in 2013.

Report No. 47 Ultrafiltration for decompensated Heart Failure

The report's recommendation that this technology be available for treatment of diuretic resistant heart failure was not rejected , however since it has not yet been implemented because of shortage of funds[V.Nguyen] this is considered a rejected recommendation (Table 1).

Report No. 49. Argon beam coagulation.

A short report on reviewing the uses and costs of this technology no recommendations were made.

Report No. 50 Apico-aortic bypass (AVB) for degenerative aortic stenosis

It was concluded that there was evidence that this procedure might relieve symptoms and increase life expectancy, but no evidence of superiority to the TAVI procedure already established at the MUHC.

It was recommended that the equipment be purchased but the decision to use the conduit only be made on the unanimous recommendation of the existing joint committee. This has been carried out, and no interventions have yet been recommended. [B. de Varennes].

<u>Cost Estimates</u>. The alternative technology,TAVI, costs approximately the same as the conduit [Report No. 50].

Report No. 51 Blood irradiation for prevention of GvH disease.

This was a brief report which supplied information necessary for decision-making. It made no recommendations. The report did not influence the final decision [D. Lamy].

Report No. 52 Fiducial markers in radiotherapy for prostate cancer

This mini HTA recommended use of the markers when the prostate gland was difficult to visualise by ultrasound. Accepted. However, by 1/2/12 no markers have been used [F. Cury].

Report No. 53 . Verify NOW to detect clopidogrel resistance

This mini-HTA found that the VerifyNow test could detect clopidogrel resistance (sensitivity and specificity uncertain) and that it was likely that treatment of such patients would be therapeutically beneficial. However this was as yet unproven. It was recommended that this intervention should only be funded in the context of a data gathering research project. This policy has been adopted [G Stoopler] and to date (Aug 2012) the test has not been used [L Bilodeau]

<u>Cost Estimates</u>. The cost of testing an anticipated 100 patients per year has been estimated to cost \$8,400 [Report No. 53]. This anticipated saving it is applied to only six months of 2011. There will be an annual saving of \$8,400 each subsequent year.

Report No. 55 Drug eluting stents. Indications for the use of.

To minimise wastage of expensive DES, this report identified the clinical indications for their use. It found also that the present level of usage in MUHC was largely consistent with these indications. In this way this report supported a policy already established in the haemodynamics laboratory but was under pressure. Currently of 34% stents used at MUHC are DES compared to a rate of 47% (Range 45%-50% in the other Quebec University Hospitals [C Bérubé] If at the MUHC the percentage of DES used in 2011 had also been 47% rather than the actual 34%, the number of DES used would have been 947 rather than 694. The 253 additional DES would have cost an additional \$646 per stent = \$163,438. Because this policy was already being observed, this saving is not attributed to Report No. 55, and is not included in Table 2.

DISCUSSION

To actually document the influence of an HTA on the policy decisions of an institution is an extremely difficult process that requires review of the minutes of policy meetings to establish evidence that the report was cited and actually used as evidence in arriving at a decision. For this reason we have merely attempted to determine whether institutional policy is consistent with the recommendations of reports.

Likewise, in attempting to define the reasons for high or low impact, it is not possible to establish proof. However, our experience suggests that the following factors have probably influenced the impact of reports.

Reasons for high impact.

- <u>Relevance</u>. Recommendations that are developed in response to a request are more likely to be accepted than unsolicited policy advice. In this review 85% of TAU reports have been developed in response to requests from the hospital administration or clinical leadership[N Dendukuri]. The principles that guide the selection of projects are summarised in Appendix 1).
- <u>Timeliness</u>. To be useful, an HTA must be available at the time decisions must be made. A recent review establishes that 64% of TAU Reports have been delivered within six months of being requested [N Dendukuri]. However, in some cases much of this time reflects waiting due to high demand. In practice the urgency of requests is evaluated and prioritisation accelerated when necessary.
- <u>Stakeholder involvement</u>. Senior representatives of the health-care professionals most affected by decisions have been involved from the beginning of the development of each report. This has resulted not only in increased relevance, but better "buy-in" of the finished product.
- <u>Acceptability</u>. There is likely to be acceptance of recommendations in an institution such as an academic Hospital when they reflect the values of institutional members. The Policy Committee, who develop the recommendations contained in each TAU report includes elected or appointed representatives of nurses, doctors, allied health professionals, patients and administrators. Recommendations developed by such a representative body are probably more likely to be accepted then decisions developed within a bureaucratic structure.
- <u>Transparency.</u> TAU reports which reflect both the evidence and the reasoning underlying recommendations, are made public both locally and internationally on the web. It is probable that in this way they gain greater traction than would similar recommendations delivered to the administration without wider distribution.

Reasons for low impact

The reasons for absence of impact of some recommendations could be established with certainty in some cases.

- One report (No. 25 was rejected because adoption of the technology in question by most North American hospitals has made it arguably standard of care and failure to use it might render the MUHC vulnerable to legal action .
- Another report was agreed to, but action was deferred because of lack of funds (No. 47).
- In two reports (No. 31a,b.c. No. 32, b,c,d.) the relatively complex administrative changes recommended for the reduction of wait times, were not found to be feasible by the responsible administration.
- Failure to act on the recommendations of one report (No19) was chiefly because the technology in question had already become implanted in hospital practice before the evaluation took place. It is easier to block a technology before its introduction then to eliminate one that is already implanted. Another reason for lack of impact of this report was that key players (Chief of Surgery, Divisional Heads) were unaware of the report's existence.
- The commonest reason that recommendations were not promptly incorporated into practice was failure to identify administrative responsibility for carrying this out. This was the cause of delayed execution or sometimes failure to execute the recommendations contained in six reports (Nos.7,11a,b,c.,13,19, 40b, 45b).

Cost and Effectiveness of TAU

The effectiveness of this Unit should be measured, not in terms of conservation of resources but by the extent to which its recommendations have resulted in optimization of resource use. This can only be estimated by detailed and somewhat subjective evaluation of each decision which we have not attempted to carry out. The overall impact of recommendations can be gained from the present report and some idea of their value to users from a recent external evaluation of the TAU [Pickering 2012]

The cost of the development of these reports has not been estimated. Over the tenyear period (Dec 2001-Dec 2011) the annual budget of the TAU has averaged \$299,342. If all expenditure were to be attributed to the production of the 57 reports (six without recommendations) completed during this period, the average cost per report would be \$52,516. However, there have been other activities supported by this budget. These include the preparation of nine short reports, the shared preparation of six full reports developed in collaboration with the Hospital Centre of the University of Montréal (CHUM), the publication of 31 articles in refereed medical journals, and 72 presentations at national and international meetings. (See <u>www.mcgill.ca/tau</u>.)

RECOMMENDATIONS

The recommendations contained in six reports were not rejected by the MUHC, but due to uncertainty as to who should be responsible for carrying them out there was failure to take the necessary administrative action.

It is recommended that in each report there should be clear identification of the following individuals:

- The hospital authority responsible for the initiation of the report.
- The senior administrative and clinical authorities responsible for acceptance of the report.
- The individuals responsible for carrying out its recommendations.

REFERENCES

Pickering J, Brophy J, Léfebvre P, Schubert F, Stoopler G. Report of the Review Committee of the Technology Assessment Unit (TAU) .McGill University Health Centre (MUHC), April 2012.

APPENDICES

Appendix 1 On the selection of projects for assessment

A necessary prelude to making a decision to carry out an HTA on any particular project is the receipt of a satisfactorily completed standardised application form (www//mcgill.ca/tau/forms)

Acceptance and priorization of topics for study are carried out according to the following principles :

Underlying principle. Since the resources of TAU are limited, each report must produce the greatest possible benefit to the institution (MUHC) with the lowest possible use of available resources.

Accordingly, the following questions must be considered before accepting a request to undertake an assessment,

- 1. Is there an important question, i.e. a question whose answer will significantly influence healthcare delivery, institutional function, or budget?
- 2. Are we likely to be able to develop a valid, robust, well supported answer to this question?
- 3. What resources will be necessary? How long will this report take to develop?
- 4. How urgent is this question? Can we produce it in time?
- 5. What are the competing requests for technology assessments at this time, and what is their urgency?

Appendix 2 Report No. 4 – Glycoprotein 11b/111a inhibitors during PCI

The annual use of 2B-3A is shown in the following table [C Bérubé]. The full effect of Report No. 4, published in November 2002, was not realised until 2004-05. Following 2006-07 there was a clinically determined and progressive fall off in the use of 2b-3A. Thus the apparent cost savings from this time on are not due to the selective use of the low cost preparations and are not considered to be savings resulting from this report .

Row		2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
1	N, PCI	1477	1556	1322	1310	1194	1086	1185	1269	1344	1304
2	%,2B-3A	41%	57%	40%	45%	42%	36%	29%	28%	11%	8%
3	N, 2B-3A	606	887	529	590	501	391	344	355	148	104
4	% reo-pro	94%	34%	18%	29%	31%	28%	43%	52%	75%	58%
5	N, reo-pro	570	302	95	171	155	109	148	185	111	60
6	Change *		268	475	399	415	461	422	385	459	510
7	Row 6 x \$		115,240	204,250	171,570	178,450					

*Change in the use of reo- pro following publication of the report in November 2003. Change reflects the difference between usage in 2002-03 (570) and usage in the year in question. \$ = Unit cost of treatment with reo-pro less cost of treatment with Eptifibatide = approximately \$430

Appendix 3 Report No. 8 – Eprex for haemodialysis patients

Report No. 8. Eprex for haemodialysis patients

Comment of Dr Paul Barré : "In re-reading the assessment of " Eprex and pure red cell aplasia-What should be MUHC policy for hemodialysis patients", I am impressed with the thoroughness and clarity of the report and its recommendations. There is no question that it had an impact on hospital policy and I suspect its impact was probably broader than that.

Prior to the report there was considerable anxiety on the part of various sectors in the hospital as to the management of the administration of Eprex and Aranesp. The report clearly outlined the known risks at the time of iv and sc administration of both products and also their track record since being available on the market. The dialysis units were allowed to continue the practice of iv administration of both products which at the time was demonstrated to be the safest alternative in preventing pure red cell aplasia.

It ultimately turned out that the cause of PRCA in our patients was the introduction of a new syringe by BD and marketed by Ortho Biotec with an unprotected rubber plunger and the rubber on the plunger came in direct contact with the EPO causing in a small number of cases alteration of the protein.

The suggestion that the hospital purchase EPO and be reimbursed by the RGAM was never carried out and I'm not sure whether this was turned down by the ministry or the MUHC. It made a lot of sense and would have facilitated the use of EPO in the dialysis population.

We were very grateful to you and your committee in clarifying a difficult medical administrative problem and providing solutions and alternatives some of which were accepted by the MUHC allowing us to provide safe administration of EPO to our patients.

Paul Barré, MD, Medical Director of Hemodialysis, RVH "

Appendix 4 Report No. 38 – Subthalamic Deep Brain Stimulation for Parkinson's disease

Report No. 38 Subthalamic Deep Brain Stimulation for Parkinsons disease

Extracts from Comments by Dr A Sadikot : "The TAU report stood out as a very useful exercise which highlighted the importance of a well-validated procedure which is accepted world-wide. We used the report in asking the MUHC administration for support for our program beyond the 8 month mark.

Last October, an important step was taken by the MUHC administration. It was decided to continue strong sensitization at the level of the MSSS and not to artificially restrict the reasonable level of DBS implants we are providing to patients

I therefore believe that the research done by the TAU, was extremely important in clarifying the program, and emphasizing the importance of providing this type of treatment if the MUHC wants to maintain its subspecialty quaternary care mission. I believe that all intensive programs should be evaluated by the TAU committee, as an aid to patients, clinicians and administrators. I was most impressed by the TAU research group. I was somewhat disappointed that the committee itself did not support the program in stronger terms, especially in view of the clear findings based on TAU research, and since the obstacles we have to face are considerable. However, the TAU research and final recommendation clearly helped us in clarifying our program, and along with the Ontario Technology Assessment Agency report, made for a very clear case for deep brain stimulators for Parkinson's disease.

Dr Abbas Sadikot.Program Director

ACKNOWLEDGEMENTS

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The individuals listed below have graciously provided information to assist us in the preparation of this report:

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Mr. G. Stoopler	Administrative Director	Surgery, Medicine, Cancer Care, Mental Health & Women's Health	МИНС

The individuals listed below have generously given time and thoughtful consideration to the development of sound policy recommendations through their service on the Policy Committee.

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Arnoldo, J.	Multidisciplinary Council
Barkun, J.	Surgery. Council of Physicians
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