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McGill University  
Health Centre

**Technology Assessment Unit of  
the McGill University Health Centre**

# **TAU Annual Report**

**April 2014-2015**



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## **Mission Statement**

- To advise the hospital in difficult resource allocation decisions, using an approach based on sound, scientific technology assessments, and a transparent, fair decision-making process.
- To publish its research in peer-reviewed journals when appropriate, and contribute to the training of personnel in the field of health technology assessment.

## **MUHC TAU Executive Committee**

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**Dr. Nandini Dendukuri**  
**Dr. James Brophy**

**Director**  
**Chairperson**

### **Committee Members**

### **Discipline**

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P & T Committee

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### **STAFF**

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Consultant

Ioana Nicolau

Research Assistant

This publication was compiled and edited by Lorraine Mines of the Technology Assessment Unit of the McGill University Health Centre (MUHC TAU). This document is available in PDF format on our website:

<http://www.mcgill.ca/tau/publications/annual>

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## **TAU Reports**

**NOTE:** Projects are researched and drafts prepared by members of the MUHC TAU, referred below as "the authors". They are assisted by expert consultants appointed for each project. Draft reports are then circulated, reviewed, amended and finally approved by the full TAU Policy Committee who thereby take ownership of the recommendations made.

**The following reports have been completed during the year.**

### **ISLET TRANSPLANTATION**

**Title:** **Islet transplantation in patients with Type 1 Diabetes Mellitus**

**Requestor:** Dr. Ewa Sidorowicz, Associate Director of Professional Services, MUHC

**Publication Date:** April 18, 2015

**Authors:** Xuanqian Xie, Benjamin Rich, Nandini Dendukuri.

**Background:** The McGill University Health Centre (MUHC) has been supporting research related to IT (Islet Transplantation) for a number of years. The Technology Assessment Unit (TAU) received a request to review IT from Dr. Ewa Sidorowicz, Associate Director of Professional Services, (MUHC)

to determine whether it can be routinely considered as an alternative to whole organ transplantation in the subgroup patients who have previously had a kidney transplant. The rationale for focusing on this subgroup of patients is that they are already undergoing immunosuppression therapy and present with stable renal function; extending IT to a broader group of patients could potentially be considered at a future time, but such indications will not be considered in this report.

**Conclusions:**

**Effectiveness** For type 1 diabetes patients with unstable metabolic control who have previously undergone a kidney transplant, islet transplantation (IT) therapy can improve glycemic control and reduce the risk of hypoglycaemia. The rate of insulin independence following IT appears to be lower than that achievable with the standard procedure of whole pancreas transplant (PT). However, the rate of graft survival (i.e. when the patient has either full or partial graft function) following the two procedures is similar.

**Safety** PT is associated with a risk of procedural mortality and of serious post procedural complications. By contrast IT is associated with a negligible risk of procedural mortality or complications. Both procedures carry a high risk of severe adverse events that are associated primarily with the immunosuppression therapy.

**Cost** Compared to PT, IT is a more expensive procedure. It costs an estimated \$29,575 per procedure. Using a six-month time horizon, our cost analysis shows that after adjusting for the cost of treating procedure-related adverse events, the IT procedure has a higher net cost of \$4,508 per patient compared to PT.

**Budget impact** The budget impact of a single IT procedure will depend on whether it replaces PT or is offered to a patient who is not a candidate for PT. For example, the budget impact of using IT instead of PT for 10 patients per year, would be approximately \$45,079. If IT were to be used instead of PT for 8 patients, and for 2 patients who were not candidates for PT, the budget impact would be approximately \$95,212.

**Cost-effectiveness** Compared with PT, IT leads 0.092 life-years or approximately one month gained in 5 years follow up. This translates into a relatively high incremental cost-effectiveness ratio of IT vs PT of \$66,552 per life-year gained at 5- years post-transplant. Compared with IIT, IT is associated with a significantly higher cost, but, also with a significantly reduced risk of diabetes-related complications. After adjusting for the cost of diabetes-related complications but not considering costs of maintenance of immunosuppression therapy, we estimated the incremental cost to be \$23,023 at 5 years follow up.

**Recommendations:**

- There is as yet insufficient evidence that IT is equal or superior to PT to justify its routine use when PT is

the contemplated procedure. This decision should be reviewed in approximately 2 years. Islet transplantation for treatment of Type 1 diabetes

- The evidence of effectiveness and safety is adequate to justify IT being offered as an alternative to carefully selected patients. The interdisciplinary pancreas and kidney transplant groups (within the MUHC multi-organ transplant program and Transplant Quebec) should develop a list of inclusion and exclusion criteria for IT and define a protocol for its appropriate use.

- Because confident evidence of effectiveness is lacking, and the somewhat higher costs, the use of IT should be limited to not more than seven patients per year.

- As an innovative and not yet routine procedure, detailed, regularly updated patient records, including details of patient selection, should be kept available for review by the Director of Professional Services or her nominee at any time.

- A proposal for provincial funding of this technology should be submitted to the Ministry

## **EXCIMER LASER**

**Title:**

**Excimer laser atherectomy for uncrossable coronary lesions and improperly deployed coronary stents.**

**Requestor:**

Mr. Gary Stoopler, Administrative Director,  
Medical Mission, MUHC.

**Publication date:**

June 9, 2014

**Authors:** Sinclair A., Dendukuri N.

**Background:** The Technology Assessment Unit was requested by : Gary Stoopler, Administrative Director, Medical Mission, McGill University Health Centre and to review the evidence for excimer laser use in selected patients undergoing percutaneous coronary intervention for complicated lesions, specifically i) patients with balloon uncrossable lesions (<1% of lesions)<sup>6</sup> , and ii) those with improperly deployed coronary stents (<5% of lesions)<sup>7</sup> . The former are generally found at the time of the initial procedure, while the latter may be observed either at the time of the initial procedure, or when symptoms recur. The request considers the cost of the catheters only (ELCA Coronary Laser Atherectomy Catheter), as the laser generator itself is available by previous arrangement between the MUHC and the manufacturers

**Conclusions:**

- The overall benefit of angioplasty with stent implantation is established, However, failure may result in two small sub-groups of patients; those with uncrossable lesions and those with underexpanded stents.
- Evidence for the use of excimer laser atherectomy using current technology for these two indications is restricted to case series. Most of these report a fairly high rate of procedural success, but information on outcomes during follow-up is limited to one observational study (6 months).

- There is no evidence to support a conclusion that a successful procedure leads to symptomatic improvement or increased longevity.
- Reported serious adverse events are not infrequent. In a total of 261 procedures, one patient died as a result of perforation. Per-study rates of coronary artery dissection were 0-9.3%, myocardial infarction, 0-10.4%, and major bleeding, 0-6.2%.
- The additional cost to the hospital for 10 patients per year would be between \$15,000 (assuming no additional procedures) and \$80,000 (assuming all are additional procedures).

**Recommendations:**

The present evidence of benefit of this procedure is insufficient to justify the associated opportunity cost. It could be considered only as a fully funded research activity.

## **Diffusion**

- Our reports are indexed in the international database for the Center for Reviews and Dissemination, York University, UK.  
<http://www.crd.york.ac.uk/CRDWeb/>
- Our reports are diffused from our website ([www.mcgill.ca/tau](http://www.mcgill.ca/tau)) .

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## **TAU Related Activities**



TAU staff members represent TAU at quarterly meetings of hospital-based technology assessment units in Quebec that are organized at INESSS.

Dr. Nandini Dendukuri and Dr. James Brophy developed a 2-credit course EPIB 670: Introduction to Health Technology Assessment, that was taught at, Department of Epidemiology, Biostatistics and Occupational Health, McGill University

Dr. James Brophy selected to join the board of governors of Institut national d'excellence en santé et en services sociaux (INESSS) 2010-

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## **Presentations**

### **Oral**

Dendukuri, N. "Technology Assessment Unit (TAU) of the MUHC". McGill University Health Centre - Medical Grand Rounds, March 2015.

Brophy, J. Health technology assessment in the hospital setting. Health technology Assessment for Decision Makers. Dalhousie University. Nova Scotia. July 15 2014.

Dendukuri, N. "The importance of recognizing heterogeneity in a meta-analysis: The case of evaluating probiotics for prevention of C. difficile diarrhea". Biostatistics Seminar Series. Department of Epidemiology, Biostatistics and Occupational Health. September 2014.

Brophy, J. The role of local health technology assessment units. INESSS provincial HTA meeting. Montreal QC. Oct 21 2014

### **Poster**

Dendukuri, N. "Predictors of asymptomatic Clostridium difficile colonization on Hospital admission". Association of Medical Microbiology and Infectious Disease Canada, Victoria, Canada. April 2014. (Presented by \*Ling Y. Kong)  
Poster

## **Selected Peer-Reviewed Publications Related to Technology Assessment Activities (\* denotes students and staff)**

Kong LY, Dendukuri N, Schiller I, Bourgault AM, Brassard P, Poirier L, Lamothe F, Béliveau C, Michaud S, Turgeon N, Toye B, Frost EH, Gilca R, Dascal A, Loo VG. Predictors of asymptomatic Clostridium difficile colonization on hospital admission. Am J Infect Control. 2015 Mar 1;43(3):248-53.

## **Awards**

### **Grants**

**Principal Investigator: Dr Nandini Dendukuri ,**

**INESSSS (Institut national d'excellence en santé et en services sociaux)**

**New competition (PSI-ETMI) Programme de soutien aux initiatives en évaluation des technologies et des modes d'intervention**

**TAU Project Funded** (2014-2016)

**Title:** Thérapie de resynchronisation cardiovasculaire en cas d'insuffisance ou de bloc cardiaque au Québec/Cardiovascular resynchronization therapy for patients with heart failure or heart block in Quebec

## **Postscript**

The TAU attempts to adjust the services we offer to conform to the resources available in a transparent, logical, fair, and consistent fashion. While some of our recommendations 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.*