Centre universitaire de santé McGill | McGill University Health Centre

Technology Assessment Unit of the McGill University Health Centre

TAU Annual Report

April 2012-2013

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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

Dr. Nandini Dendukuri	**Director**
Dr. Maurice McGregor	**Chairperson (April 2012 - December 2012)**
Dr. James Brophy	**Chairperson (January 2013 - present)**

Committee Members	Discipline
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Sandra Dial	Clinical Epidemiology
Christian Janicki	Quality Management
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Hugh Scott	Consultant (Invited Member)
Gary Stoopler	Administration

STAFF

Alison Sinclair	Research Scientist
Xuanqian (Shawn) Xie	Research Assistant/Biostatistician
Ioana Nicolau	Research Assistant
Lorraine Mines	Administrative Technician
James Brophy	Consultant (April 2012-December 2012)
Alain Lapointe	Consultant
Benjamin Rich	Postdoctoral student

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

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 become “the authors” of the final report.

The following reports have been completed during the year.

KTP

Title:	**532 nm KTP Laser for vocal fold.**
Requestor:	Gary Stoopler, Administrative Director, , MUHC
Publication date:	April 24, 2012
Authors:	Xie X., McGregor M.
Background:	The KTP 532 nm Aura XP is a laser in the green visible light spectrum. In recent years, it has been used for laryngeal surgery. The Technology Assessment Unit (TAU) was requested to evaluate the clinical effectiveness and budget impact of using this technology for vocal fold surgery at the MUHC
Conclusions:	Use of KTP for laryngeal surgery is still innovative. Approved in Canada in 2011, there is still only one Canadian centre using this technology. ▪ There are seven publications describing the use of KTP, five of which derive from the same group of authors. These indicate that it is a safe, effective technology for the treatment of several laryngeal pathologies.

- However, there are presently no published data to indicate that the KTP laser produces clinically better outcomes or is safer than the presently available CO2 laser.
- Unlike the CO2 laser, the KTP laser can be used in an office setting for a certain number of cases. Assuming a total of 60 procedures per year, and assuming that with the use of KTP 30 of these could be carried out in the outpatient clinic, the cost per procedure using the CO2 and KTP instruments would be $1,865 and $1,652, respectively. This would diminish pressure on the OR and reduce wait times for this procedure

Recommendations:

- While it may be appropriate that a University Hospital such as the MUHC should take part in the evaluation of a new technology, it would not be appropriate to acquire this technology from the operating budget without further evidence of superiority. Consideration to purchase this technology should be deferred until the following steps have been completed.
- The instrument should first be acquired on a temporary basis (rental or loan) during which time it could be used and evaluated by members of the department with particular focus on the following issues:

1) The percentage of patients that can be treated in the outpatient clinic

2) The clinical outcomes (sound/voice assessment, and complications) following use of the KTP laser.

3) The possibility of reusing the glass fiber and the cost of recycling

4) The effect of KTP use on wait times.

- With information on these issues and with the benefit of any new evidence that may be available at the time,

permanent acquisition of this technology could then be reconsidered.

Video Capsule Endoscopy

Title:	**Video capsule endoscopy for obscure GI bleeding and Crohn's Disease (Update of Report 7)**
Requestor:	Gary Stoopler, Administrative Director, Surgery, Medicine, Cancer Care, Mental Health & Women's Health, MUHC Joyce Pickering, McGill University Interim MUHC Physician-in-Chief.
Publication date:	June 13, 2012
Authors:	Xie X., McGregor M.
Background:	In 2003 the Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC) recommended that Video Capsule Endoscopy (VCE) should not be approved for routine clinical practice at the MUHC. Subsequently, after an interval of 2-3 years its use at the MUHC has progressively increased. This update was requested by Mr Gary Stoopler (Administrative Director, Surgical Mission, MUHC).
Conclusions:	The present evidence is consistent that for the diagnosis of patients with small bowel disease VCE provides a comparable and sometimes higher diagnostic yield than alternative diagnostic approaches. • For patients with OGIB, the diagnostic yield of VCE is significantly higher than that of push enteroscopy, and small bowel barium radiography, and not significantly different from that of double balloon enteroscopy. • For patients with suspected and established small-bowel Crohn's Disease, the diagnostic yield of VCE is significantly higher than that of small bowel barium radiography, CT enterography/enteroclysis, colonoscopy with ileoscopy and

push enteroscopy. There is no statistically significant difference in yield between VCE and MRE enterography.

• In spite of the absence of data it must be noted that VCE may be associated with overdiagnosis. Two RCTs have demonstrated that compared with other diagnostic tests, VCE did not significantly improve the clinical outcomes in 1 year follow-up.

• While the optimal sequence of diagnostic tests must be determined for each case, there is agreement that VCE should not be a first line test.

• The unit cost to the MUHC of each VCE study is estimated to be $984.55. The budget impact of the projected 100 tests per year would therefore be $98,455. Its use will reduce demand on alternative test procedures, thus diminishing wait times.

Recommendations:

VCE is now a fully established test for the diagnosis of patients with small bowel disease. It should be available for judicious use at the MUHC. The present practice of using it should be maintained.

• Due to the substantial budget impact and consequent opportunity costs of a technology which cannot in many cases be justifiably refused, government should be approached with a special request to provide budgetary compensation.

Procalcitonin

Title: **Use of serum procalcitonin levels in treatment decisions for adult patients in the Intensive Care Unit**

Requestor: Dr. Peter Goldberg, Director of Adult ICU, Royal Victoria Hospital

Publication date:	July 17, 2012
Authors:	Sinclair A., Dendukuri N., McGregor M.
Background:	Serum procalcitonin (PCT) level is a biomarker for the presence and persistence of infection, and has been used to guide decisions around the initiation of, continuation of, and termination of antibiotic treatment. The Technology Assessment Unit (TAU) was asked by Dr. Peter Goldberg (Director of Adult ICU, Royal Victoria Hospital) to evaluate the use of PCT in the diagnosis of infection and/or sepsis and in antibiotic treatment decision-making for patients with infection/sepsis in the ICU.
Conclusions:	Single PCT levels are only moderately sensitive and accurate in the diagnosis of infection, using infection confirmed by culture as a comparator. Such a test would not have the sensitivity required to inform a decision to withhold antibiotic therapy in a critically ill patient. • Measurement of single or serial PCT levels as a part of a treatment algorithm do not appear to be useful in determining when to start or escalate antibiotics, although only a limited number of studies have tested it. • Measurement of serial PCT levels as part of a treatment algorithm may have some usefulness in determining when to discontinue antibiotics. Studies have not compared PCT algorithms to best practice intended to reduce antibiotic use, and studies to date have not been large enough to detect small differences in clinical outcomes, especially mortality. Three large studies are ongoing.
Recommendations:	• The use of single PCT measurements in the detection of infection in ICU patients or to guide in the decision to initiate or escalate antibiotics is not recommended.

	• The available evidence does not support routine use of PCT-guided algorithms in the decision to terminate antibiotics. We recommend the question be reviewed when the results of three large ongoing studies become available.

Drotrecogin Alfa

Title:	**Drotrecogin Alfa (Activated) in Severe Sepsis: a systematic review of observational studies (Update of Report 29)**
Requestor:	Internal Review
Publication date:	July 25, 2012
Authors:	Nicolau I., Pan I., Xie X., McGregor M., Dendukuri N.
Background:	In April 2003 and March 2007 reports were developed by the Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC) on the use of drotrecogin alfa (activated) (DrotAA) for the treatment of severe sepsis. Both concluded that there was no good evidence of a significant reduction in 28-day mortality with DrotAA treatment, even in high-risk patients, and recommended that DrotAA be used only in severe sepsis patients at highest risk of mortality.
Conclusions:	• The mortality rates reported in the observational studies we reviewed, were higher than the rates previously reported in RCTs (PROGRESS and ADDRESS). • Studies that included a comparison group of patients not treated with DrotAA, generally concluded that there was a beneficial effect of DrotAA treatment. • The majority of studies reported being supported by the manufacturer
Recommendations:	On October 25, 2011, the US Food and Drug Administration notified healthcare professionals and the public that Eli Lilly and Company had announced a worldwide voluntary market

withdrawal of Xigris [drotrecogin alfa (activated)] (See announcement on FDA website) This decision had been taken in the light of the results of a new clinical trial (subsequently published, May 31, 2012, (1)) in which Xigris failed to show a survival benefit for patients with severe sepsis and septic shock. In this study 1696 patients were randomly selected into two groups. The 28 day all cause mortality rates were 26.4% and 24.2% for the treatment and placebo groups, respectively. Thus, the present report is no longer necessary for the purpose of guiding MUHC policy on this issue. However, since it constitutes a significant contribution to knowledge the report is published and available on our website.

Epidisk (MINI-HTA)

Title:	**Hyaluronic Acid Fat Graft Myringoplasty or Epidisk Tympanoplasty (ET).**
Requestor:	Gary Stoopler, Administrative Director, Surgery, Medicine, Cancer Care, Mental Health & Women's Health, MUHC
Publication date:	August 29, 2012
Authors:	McGregor M., Xie, X.
Background:	This is a new procedure that has been in the peer reviewed literature and was featured as a breakthrough in the popular media. It permits doing tympanoplasties (closing perforations for the ear drum) in the clinic rather than taking patients to the operating room.
Conclusions:	• This is a promising procedure, apparently equivalent to existing surgical procedures in safety and efficacy. • As a result of the ability to carry it out in the outpatient department it would be cost saving.

	• Its use consists of case series, all deriving from one centre. Until it is more widely accepted it should be looked on as an innovative but not yet accepted procedure.
Recommendations:	• ET is an innovative procedure. The evidence of efficacy and safety is sufficient to support its approval for use at the MUHC. • However, until it becomes more widely accepted a registry of all procedures, including complications and outcomes, with follow-up for at least two years should be maintained. This registry should be reviewed annually by the surgical division.

Impact OF TAU Reports

Title:	**The Impact of Reports of The Technology Assessment Unit of the McGill University Health Centre**
Requestor*:*	Internal Review
Publication date:	September 13, 2012
Authors:	McGregor M.
Background:	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.
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.

Balloon Sinuplasty (MINI HTA)

Title:	**Balloon Catheter Dilation for Chronic Rhinosinusitis**
Requestor:	Gary Stoopler, Administrative Director, Surgery, Medicine, Cancer Care, Mental Health & Women's Health, MUHC
Publication date:	October 30, 2012
Authors:	Nicolau I., Dendukuri N.
Background:	Balloon catheter technology for dilating the sinus ostia in patients with chronic rhinosinusitis was approved by the Food and Drug Administration (FDA) in the United States in 20051. It is a minimally invasive procedure that alters the anatomy of the paranasal sinus ostia without removing tissue or bone, while preserving the mucosa2. The current standard treatment is functional endoscopic sinus surgery (FESS), a surgical approach that involves the removal of tissue and bone to dilate the sinus passages.
Conclusions:	• Balloon catheter sinuplasty (BCS) is a relatively new procedure. It has been evaluated primarily in an OR setting, using general anesthesia, by studies using an observational design. These studies have generally concluded that it is comparable to the standard surgical approach for treating chronic rhinosinusitis in terms of effectiveness and safety. However, this remains to be shown in a randomized controlled trial that is sufficiently large. • Only one small recent study has examined the feasibility of BCS in an office-setting, which is the main application of interest at the MUHC. Though the results of this study are

promising, they remain to be confirmed in other studies. A majority of the patients studied (67%, 24/36) reported experiencing only a low intensity of pain.

• The per-procedure cost of balloon sinuplasty is comparable to, and perhaps slightly more expensive than, the surgical alternative despite the savings incurred from not using the operating room or recovery room. However, use of this procedure will free up OR time, which at the present time is a critical limiting factor at the MUHC.

Recommendations: Given the acknowledged need for further research studies of BCS in an office-setting and the absence of a significant cost saving, this technology should be used only in a limited number of carefully selected cases. A registry of these cases should be maintained in order to record the effectiveness and safety of each procedure over a follow-up period of at least 1 year.

Hybrid Operating Rooms

Title: **The Hybrid Operating Room. Should one be available for Cardiovascular-Thoracic procedures in the MUHC? A brief report**.(Note: Brief reports are prepared in response to urgent requests for information. They are not submitted to the Executive Committee and contain no recommendations).

Requestor: Tim Meagher, Director of Clinical Development, MUHC

Publication date: November 6, 2012

Authors: McGregor M.

Background: The Department of CVT has requested that a hybrid OR be equipped for their use in the new hospital under construction at the Glen site.

Conclusions:

Decision-makers should take account of the following points when considering this decision:

• Our CVT surgeons believe that without access to a hybrid OR they will increasingly be unable to deliver optimal patient care in the future.

• There is no objective scientific evidence bearing on the health benefits to be expected from use of a hybrid OR for CVT procedures (Note: The absence of such evidence in no way indicates that such a facility would not result in better health care).

• The cost (annualised capital cost plus maintenance plus operation) of a hybrid OR for CVT would be approximately $410,000 per year. In terms of opportunity cost, this is equivalent to the annual cost of 3.1 acute surgical beds. (Assuming a cost of $360 per day [N Robert])

• There is at present no need for a hybrid OR to accommodate overflow from Cardiology. The present and planned cardiac catheterisation laboratories have a capacity that can cope with both the present and the anticipated maximum future demand for TAVIs and mitral procedures.

• The new hybrid OR allocated to Vascular Surgery will be approximately 65% occupied with vascular procedures [O Steinmetz]. The possibility of negotiating a sharing agreement to accommodate CVT could be explored.

• Unless the nursing contract can be revised it will not be possible to carry out surgical interventions in the catheterisation laboratory at the new hospital site.

Intrabeam

Title:	**Single-dose Intraoperative Radiotherapy Using Intrabeam® for Early-stage Breast cancer: A Health Technology Assessment.**
Requestor:	Gary Stoopler, Administrative Director, Surgery, Medicine, Cancer Care, Mental Health & Women's Health, MUHC
Publication date:	November 9, 2012
Authors:	Xie X., Dendukuri N., McGregor M.
Background:	Postoperative whole-breast external beam radiotherapy, usually delivering a dose of 42.56-50 Gy in 16-25 fractions over 4-5 weeks, reduces the risk of tumour recurrence and improves survival of breast cancer patients managed with breast-sparing surgery. Using a proposed newer treatment, single dose intraoperative radiotherapy (IORT), radiation is delivered to the tumour bed at the time of surgical excision without postoperative whole-breast external beam radiotherapy and boost for the selected patients with early-stage breast cancer. The objectives of the present report are to evaluate the effectiveness and safety of Intrabeam® radiotherapy for early-stage breast cancer and to estimate the budget impact of using this technology at the MUHC.
Conclusions:	• Proof of the non-inferiority of the Intrabeam® approach compared to conventional external beam irradiation rests on a single trial which has several weaknesses, including insufficient follow-up. None the less, the rates of local recurrence of breast cancer and rates of major complications appear to be comparable in the two arms of the trial. • From the perspective of MUHC, use of single dose Intrabeam® radiotherapy would slightly reduce or increase budget expenditure depending on turnover.

• Its use would reduce the workload of the Radiation Oncology Department. From the perspective of patients, it would greatly reduce the inconvenience associated with weekly external beam radiation, and would reduce the waiting time for radiotherapy patients.
• Use of this technology would cause an increased load on the Operating Room with the potential of increasing wait times for surgery.

Recommendations:

• The currently available evidence supporting the use of Intrabeam® radiotherapy is not yet adequate to justify its permanent approval.

• Acquisition of this technology should be conditional on the department's participation in research studies designed to determine local recurrence, mortality rates, and patient satisfaction following Intrabeam® over a longer term period.
• The use of this technology should be reviewed annually in the light of evidence reported in the literature and the recurrence, mortality, and complication rates at the MUHC.
• Permanent approval of this technology for routine use should only be made when robust evidence supports this decision.

• All patients offered management by Intrabeam® should be informed in writing of the paucity of robust evidence of its long-term effectiveness, by a member of the medical team.

Dermal Matrix

Title: **Evaluation of acellular dermal matrix for breast reconstruction: An Update**

Requestor: Donna Stanbridge, Associate Director of Nursing, Perioperative Services, MUHC.

Publication date:	November 15, 2012
Authors:	Nicolau I., Xie X., McGregor M., Dendukuri N.
Background:	Acellular dermal matrix (ADM) is used in breast reconstruction surgery with the goal of increasing implant expansion and capsular reinforcement, and generally improving aesthetic outcomes. There is a concern that ADM could increase the likelihood of infection as it is a foreign body and some preparations are not sterilised. It is relatively expensive, costing $2000 per breast. A previous report by the Technology Assessment Unit (TAU) in 2009 reviewed ADM use and recommended temporary use for 60 patients on the condition that a record would be maintained of the risk factors for poor outcomes, perioperative and post-operative complications, and subsequent revision procedures and that the aesthetic outcome of each procedure be formally evaluated.
Conclusions:	• Based on observational studies, the evidence suggests that there is a higher risk of exposure of the breast implant, infection, seroma, and higher overall complication rates for two-stage breast reconstruction with ADM. However, contemporary experience at the MUHC and at one other centre that was consulted does not confirm an association between ADM use and higher complication rates. • The available evidence suggests that the risk of capsular contracture appears to be lower and aesthetic outcomes superior with the use of ADM for breast reconstruction following cancer surgery. The quality of this evidence is poor. However, objective evidence on aesthetic outcome is difficult to collect and it is possible that no better evidence will be developed.

Recommendations: There is evidence (limited in quantity and quality) to support the claim that use of ADM results in superior aesthetic outcomes, but the evidence from the literature suggests that use of ADM may be associated with a higher rate of clinically significant complications. However, limited experience at the MUHC does not support this. Accordingly, the committee recommends that this material should be temporarily approved for breast reconstruction at the MUHC, but only in the context of a continuing prospective cohort study in which risk factors (age, BMI, diabetes, radiation), and relevant outcomes (length of hospital stay, frequency of additional operations), and aesthetic results are documented. These data should be reviewed at 6 and 12 months and decisions on the permanent use of ADM decided in the light of this evidence.

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) . Between April 1, 2012 and March 31, 2013 our website received approximately **56,000** hits.
- Our reports are also circulated to all members of the McGill RUIS.

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. McGregor is a regular contributor to the Executive Training for Research Application (EXTRA) program for health executives.

Dr. Nandini Dendukuri and Dr. James Brophy developed a 1-credit course EPIB 642: Introduction to Health Technology Assessment, that was taught at, Department of Epidemiology, Biostatistics and Occupational Health, McGill University, June 2012

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

Nicolau, Ioana (presentor)Evaluating allogenic acellular dermal matrix in implant based breast reconstruction of post mastectomy cancer patient. 2012 Student Conference May 13-14, 2012 University of Saskatchewan

Poster

Xie X, Nicolau I, McGregor M , Dendukuri N. "Evidence supports use of subglottic secretion drainage endotracheal tubes for prevention of ventilator-associated pneumonia". Canadian Agency for Drugs and Technologies in Health 2012 Symposium, Ottawa, 2012

Sinclair A, Xie Xuanqian, Dendukuri N. "Can a urine antigen test impact on diagnosis of community acquired pneumonia and increase use of targeted antibiotics? A systematic review of the evidence". Canadian Agency for Drugs and Technologies in Health 2012 Symposium, Ottawa, 2012

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

Sinclair A, Xie X, Teltscher M, Dendukuri N. A urine pneumococcal antigen test (BinaxNOW Streptococcus pneumoniae) for the diagnosis of community acquired

Streptococcus pneumoniae pneumonia: A systematic review and Bayesian meta-analysis. Clinical Infectious Diseases. (Epub ahead of print,)

Steingart KR, Sohn H, Schiller I, Kloda LA, Boehme CC, Pai M, Dendukuri N. Xpert MTB/RIF assay for pulmonary tuberculosis and rifampicin resistance in adults. Cochrane Database Syst Rev, 1:CD009593, 2013

Xie Xuanqian, Young Jonathan, Kost Karen, McGregor Maurice
KTP 532 nm Laser for Laryngeal Lesions. A Systematic Review
Journal of Voice, Volume 27, issue 2 (March, 2013), p. 245-249.

Rene P, Frenette CP, *Schiller I, Dendukuri N, Brassard P, Fenn S, Loo VG. Comparison of Eight Commercial Enzyme Immunoassays for the Detection of Clostridium difficile from Stool Samples. Journal of Clinical Microbiology, 73:94-96, 2012

Yansouni CP, Dendukuri N, *Liu G, Fernandez M, Frenette C, Paraskevas S, Sheppard DC. Positive Cultures of Organ Preservation Fluid Predict Post-Operative Infections in Solid Organ Transplantation Recipients. Infection Control and Hospital Epidemiology, 33 (7): 672-80, 2012

*Bally M, Dendukuri N, Sinclair A, Ahern SP, Poisson M, Brophy J A network meta-analysis of antibiotics for treatment of hospitalised patients with suspected or proven meticillin-resistant Staphylococcus aureus infection. Int. J. Antimicrob. Agents 40 (6): 479-95.

Awards

Nicolau, Ioana awarded CSEB Student Award. Evaluating allogenic acellular dermal matrix in implant based breast reconstruction of post mastectomy cancer patient. 2012 Student Conference May 13-14, 2012 University of Saskatchewan

Nandini Dendukuri awarded Statistical Science Award (Theoretical Category) from Centers for Disease Control, United States for article titled ‘Evaluating Diagnostic Tests for Chlamydia
trachomatis in the Absence of a Gold Standard: A Comparison of Three Statistical Methods’ published in Statistical Methods in Biopharmaceutical Research, 2012

Nandini Dendukuri awarded Charles C. Shepard in the Data Methods and Study Design category from Centersfor Disease Control, United States for article titled ‘Evaluation of Screening Tests for Detecting Chlamydia trachomatis: Bias Associated with the *Patient-Infected-Status Algorithm’ published in Epidemiology, 2012*

Grants

Principal Investigator: .**Dr Nandini Dendukuri ,** NSERC “Bayesian Methods for Epidemiologic Studies. Total amount: $55,000, 2013-2018

Principal Investigator: .**Dr James Brophy, Co-investigator: Dr. Nandini Dendukuri,** CIHR**, “**Comparative effectiveness research for the drug treatment of atrial fibrillation.” Total amount: $141,548, 2013-2015

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*.