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

**The Hybrid Operating Room. Should  
one be available for Cardiovascular-Thoracic  
procedures in the MUHC?**

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of the McGill University Health Centre (MUHC)

by

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- Dr O Steinmetz. Head, Vascular Surgery.
- Ms Donna Stanbridge. Associate Director of Nursing – Perioperative Mission.
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### External Consultants

- Dr R Cartier. Chief, Dept of Cardiac Surgery, Montréal Heart Institute (MHI).
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## SUMMARY

**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.

**Objective:** To assemble the technological and cost data pertinent to this decision.

**Method:** Literature review and consultation with experts to find evidence of health benefits and costs of such facilities.

**Conclusions:**

- 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.

## SOMMAIRE

### Contexte

Le département de chirurgie cardiovasculaire et thoracique (CVT) a demandé l'aménagement d'une salle d'opération hybride de façon à répondre à leurs besoins dans le prochain hôpital présentement en construction au site Glen.

### Objectif

Colliger les données technologiques et les coûts pertinents en regard de la prise de cette décision.

### Méthodologie

Une revue de la littérature et des consultations avec des experts furent menées pour identifier les avantages pour la santé ainsi que les coûts découlant de tels aménagements.

### Conclusion

- Nos chirurgiens cardiovasculaires et thoraciques croient qu'ils auront de plus en plus de difficultés à donner des soins optimaux aux patients dans l'avenir, sans avoir accès à une salle d'opération hybride.
- Il n'y a pas de preuve scientifique objective reposant sur les avantages pour la santé attendus de l'utilisation d'une salle d'opération hybride pour les chirurgies cardiovasculaires et thoraciques (Note: l'absence de telles preuves n'indique absolument pas qu'une telle facilité n'entraînerait pas de meilleurs soins).
- Les coûts d'une salle d'opération hybride pour les chirurgies cardiovasculaires et thoraciques (incluant le coût d'immobilisation annualisé, les coûts d'entretien et de fonctionnement) seraient environ 410 000\$ par année. En termes de coûts d'opportunité, ceci équivaut au coût annuel de 3,1 lits de soins chirurgicaux aigus (en supposant un coût de 360\$ par jour).
- Actuellement, le besoin d'une salle d'opération hybride ne s'impose pas pour faire face au surplus de patients de la cardiologie. Les laboratoires de cathétérisme actuels et prévus ont une capacité qui peut répondre aux demandes actuelles et maximales estimées pour les implantations percutanées de valves aortiques et de procédures mitrales.
- La nouvelle salle d'opération hybride allouée à la chirurgie vasculaire sera occupée à 65% par des procédures vasculaires (O Steinmetz). La possibilité de négocier une entente de partage pourrait être discutée pour permettre les chirurgies cardiovasculaires et thoraciques.
- À moins d'une révision de l'entente avec les infirmières, il sera impossible d'effectuer des interventions chirurgicales dans le laboratoire de cathétérisme du nouvel hôpital.

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## LIST OF ABBREVIATIONS

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A-C	Aorto-coronary
CADTH	Canadian Agency for Drugs and Technologies in Health
CHUM	Centre hospitalier de l'Université de Montréal
CVT	Cardiovascular Thoracic Surgery
DARE	Database of Abstracts of Reviews of Effects, Centre for Reviews and Dissemination
ECMO	Extracorporeal membrane oxidation
EMBASE	Excerpta Medica Database
HTA	Health Technology Assessment
INAHTA	International Network of Agencies for Health Technology Assessment
JGH	Jewish General Hospital, McGill
MHI	Montreal Heart Institute
MUHC	McGill University Health Centre
OR	Operating room
PCI	Percutaneous coronary intervention
RVH	Royal Victoria Hospital
TAU	Technology Assessment Unit, MUHC
TAVI	Transcatheter aortic valve implantation

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# The Hybrid Operating Room.

## Should one be available for Cardiovascular-Thoracic procedures in the MUHC?

### BACKGROUND

- A Hybrid OR consists of a large operating room equipped with the same sophisticated imaging apparatus that is used in a cardiac catheterization laboratory.
- The MUHC is in the process of constructing a new hospital complex at the Glen site. An OR of appropriate dimensions to accommodate the necessary imaging equipment is already planned for CVT.
- Dr Benoit de Varennes, Head of the Department of Cardiovascular Thoracic Surgery (CVT), has requested the hospital administration to equip this OR with imaging equipment to create a Hybrid OR for the use of CVT at the Glen site.
- The cost of the imaging equipment in question is approximately \$2 million. [I. Franco]
- A hybrid OR is planned for Vascular Surgery, and a Catheterization laboratory of appropriate size with appropriate ventilation for aseptic surgical procedures is planned for Cardiology.
- Dr T Meagher, ADG Medical Affairs, has requested the Technology Assessment Unit (TAU) to develop an HTA to evaluate this proposal.

### OBJECTIVE

To assemble the technological and cost data pertinent to this decision

### METHODS

We carried out a non-systematic literature review with the objective of finding evidence for or against the use of the Hybrid OR for cardiovascular surgery, searching the following sources:

The Cochrane Collaboration, INAHTA, and DARE using “hybrid” as a keyword for HTAs and SRs, (adding “operating”, “suite” or “procedure”), PubMed and EMBASE using “hybrid” in combination with “room”, “suite”, and “procedure”, without restriction as to type of document. We then scanned and selected from the findings. We reviewed the citation lists of commentaries and reviews that dealt specifically with



the experience of hybrid operating rooms, and expanded the list of citations of interest from there.

In addition, we consulted the experts from within and outside the institution, who are listed in the Acknowledgements.

## RESULTS

### Literature Review

We found no objective evidence bearing on the efficacy, or cost, of the hybrid OR for cardiovascular thoracic procedures. Considered opinion indicates that transcatheter valve repair and replacement can be carried out successfully in a hybrid OR or in a suitably modified catheterisation laboratory.

Thus, an Overview on Transcatheter Valve Therapy published in 2011 by the American College of Cardiology Foundation and the Society of Thoracic Surgeons<sup>1</sup> observes that these procedures can be carried out in modified catheterisation laboratories or in hybrid operating rooms so long as both have superior imaging and high sterility. “An important, yet unresolved issue is the location of these new-generation hybrid rooms”. They observe that no matter where the procedural room is located—catheterisation laboratory or operating suite—*equal access by both cardiologists and cardiac surgeons is essential.*

An expert Consensus Statement on the “Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement”<sup>2</sup> was published in 2012 by The Society for Cardiovascular Angiography and Interventions, the American Association for Thoracic Surgery, the American College of Cardiology Foundation, and the Society of Thoracic Surgeons 2012. In listing the essential requirements of institutions that carry out such procedures, whether in cardiac catheterisation laboratories or hybrid operating rooms, they stress the importance of collaboration between cardiologist and surgeon in an interdisciplinary team.

A Health Technology Assessment (HTA) prepared for the Centre hospitalier de l'Université de Montréal (CHUM) in 2010 concluded that “there is no strong evidence supporting the claim that hybrid procedures are better than the standard approach.”<sup>3</sup> Experts at the CHUM maintained “that a single hybrid operating room can support the present combined needs of cardiology, cardiac surgery and vascular surgery”. The report recommended that following the construction of a hybrid operating room at the CHUM, field evaluations should be planned to assess the clinical effectiveness and cost-effectiveness of this approach, and to confirm assumptions of enhanced patient care.

## **Consultations**

Consultations with experts both in and outside the MUHC have led to the following observations:

### **Current status of percutaneous valve procedures at the MUHC**

Elective procedures. At the present time approximately 25 percutaneous aortic valve placements are carried out each year. Approximately half of these are carried out via the trans-femoral route, and the remainder via the trans-subclavian, trans-aortic, or trans-apical routes [J Martucci].

These procedures are all performed under general anaesthesia in the cardiac catheterisation laboratory. For trans-subclavian, trans-aortic, and trans-apical procedures the surgical approach to the heart is carried out by the CVT surgeons, and the cardiologists implant the valves. Trans-femoral procedures are carried out by the cardiologists, usually with the surgeons present, or sometimes on call [J Martucci]. Current miniaturisation makes it likely that in the future 90% of procedures will be trans-femoral [J Martucci].

Emergency procedures. Patients undergoing a TAVI procedure sometimes require urgent surgical intervention. Over the last three years there have been approximately 4 such patients of which 2 have had to be transported to the operating room [J Martucci]. Up to the present these events have been successfully managed without loss of life [J Martucci]. Nevertheless, they would be easier to manage if the procedure were already being carried out in an operating room. Note, that at the Glen site the catheterisation laboratory and operating rooms will be on the same level at a distance of 62m. It has been estimated that the likely rate of aortic valve placement in the future will not exceed 46 /yr.<sup>4</sup> In the near future the percutaneous Mitral-clip procedure will also be introduced [J Martucci].

### **The intended use of the proposed new CVT hybrid OR**

CVT anticipates carrying out the following procedures in approximately the numbers indicated [B de Varennes, K Lachapelle]:

1. Trans-catheter aortic and eventually mitral valve implantations, via trans-apical, trans-subclavian, trans-aortic and probably trans-femoral approaches. Currently in cath lab.....50-75/yr\*  
(\* This estimate is over and above the 24 annual procedures currently carried out in the catheterisation laboratories)
2. Impella assist device implantation for post-cardiotomy shock. Currently not met ..... 2-5/yr
3. Open Aortic Valve placement or Minimally invasive aortic or mitral valve replacements (surgical) + Percutaneous Coronary dilatation. Currently not met .....25-40/yr
4. A-C Bypass + TAVI. Currently consecutive procedures .....50/yr

5. Percutaneous ECMO implantation. Currently not met .....5/yr
6. Aortic dissection. Currently requiring open surgery .....10/yr
7. Coronary angio post A-C bypass (10% of 400 bypass cases have poor flow on direct measurement). Currently not met .....40/yr

The Arrhythmia Service has no intended use for a hybrid OR. [V Essebag]

### **Additional issues to consider**

**Why have other institutions adopted this technology?** To judge from the literature the principal use of cardiovascular hybrid ORs is to allow open surgical aortic valve replacement and PCI to be carried out, when necessary, as a single operative procedure (see item 3 in the preceding paragraph on Uses) (eg. Shannon 2012<sup>5</sup>, Leacce 2012<sup>6</sup>). This is also the principal procedure that will be carried out at the Jewish General Hospital [J-F Morin]. At the Montreal Heart Institute, and as planned at the CHUM, the hybrid OR is shared by CVT, Cardiology, and vascular surgery, and the facility is used for TAVI's, aortic aneurysm and aortic stent graft placement. [N Racine].

**Asepsis.** It is believed that the level of asepsis in an operating room is superior to that in a catheterisation laboratory [B de Varennes, R Cartier]. This was one reason for the creation of a hybrid OR in the MHI [N Racine]. However, the multi-Society reviewers cited above<sup>1,2</sup> clearly believe that adequate levels of asepsis can be maintained in either type of facility. At the MUHC both the present catheterisation laboratory, and the new laboratory presently under construction have operating room standard ventilation and maintain equivalent levels of asepsis.[J Martucci] To date there has been no case of sepsis following interventions in the catheterisation laboratory [L Bilodeau].

**Nurse availability.** Presently at the RVH site OR nurses are scrubbing for procedures such as TAVIs in the catheterisation lab. As a result of complaints to the union the MUHC has negotiated an agreement to permit this to continue until the move to the Glen. Thereafter, unless the present collective agreement is amended, we will not be able to place nursing staff in the catheterisation laboratory. [D Stanbridge].

**Cost Factors.** The capital cost of the imaging equipment for a hybrid OR is approximately \$2 million [I Franco]. In the planned (non-hybrid) OR, a C Arm would normally be installed, costing approximately \$200,000. Thus the net-capital cost of the imaging equipment would be approximately \$1.8 million. (The room in question is shielded, irrespective of the installation of imaging equipment). [I Franco]. Assuming a replacement life of eight years, and an annual discount rate of 0.05, the equivalent annualized capital cost would be \$265,237 [X Xie], Assuming a service contract of approximately \$85,000 per year [Marie-Claude Trudel], and the cost of a radiation

technologist of \$60,000, the total cost of the imaging equipment for the hybrid OR would be approximately \$410,237 per year.

Note: These estimates apply to the installation of the hybrid OR at this time, while the construction of the new hospital is in progress. The cost of carrying out this installation after the move to the Glen would “be relatively high given the disruption to the functioning of the OR. In fact, we would have to close a large portion of the block for these renovations to occur.” [I Franco]

## 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.

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