Centre universitaire de santé McGill

McGill University Health Centre

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

Recommendation checklist for:

Report number 91: The CardioMEMS™ pulmonary artery pressure monitor for preventing heart failure-related hospitalisations in patients with heart failure

DATE: September 8, 2022

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RECOMMENDATION PROCESS

TAU has developed a framework to facilitate the translation of evidence into recommendations using a structured, transparent process.

STEP 1:

- The decision-aid checklist incorporates 23 decision criteria relevant to the decision-making process (Appendix A).
- TAU research staff complete the health technology assessment and record their findings for each decision criterion in the tool.
- They also rate whether the findings were favourable for each decision criterion (see illustration). Options include Yes, No, Maybe, and Need more information.

Criterion	Findings of the Health Technology Assessment Report	Do these findings favour the approval of VA-ECMO for cardiac arrest at the MUHC? [Completed by TAU]
Quality of the evidence	The quality of the evidence is low. A number of propensity score adjusted studies have been published, but these have several limitations.	No
Safety of the technology	No comparative studies. A meta-analysis of case series found a high rate of complications with VA-ECMO.	No

GOAL: To ensure a systematic approach to considering different factors relevant to the decision-making process.

STEP 2:

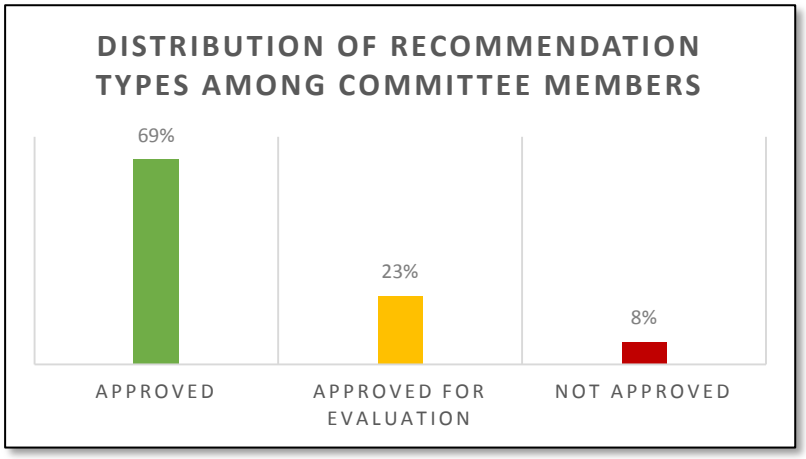
- Each committee member is sent the technology assessment report and a link to the decision-aid tool, to be completed online.
- After reading the report, each committee member rates how important they consider each criterion in shaping the final recommendation, within the context of the policy question (see illustration). Options include Very important, Somewhat important, and Not at all important.
- Committee members will then be asked to provide a recommendation and their reasons for it. **This is a tentative recommendation**; the final recommendation will be issued at the TAU Policy Committee meeting through consensus after discussion of the principal issues.

Criterion	Findings of the Health Technology Assessment Report	Do these findings favour the approval of VA-ECMO for cardiac arrest at the MUHC? [Completed by TAU]	How important is this criterion in shaping the final recommendation? [Completed by each committee member]
Quality of the evidence	The quality of the evidence is low. A number of propensity score adjusted studies have been published, but these have several limitations.	No	Very important
Safety of the technology	No comparative studies. A meta-analysis of case series found a high rate of complications with VA-ECMO.	No	Very important

GOAL: To provide a visual means for arriving at a final recommendation, by juxtaposing the importance rating for each criterion against the results of the health technology assessment. For a technology to be approved, a majority of criteria considered important should also have received favourable findings.

STEP 3:

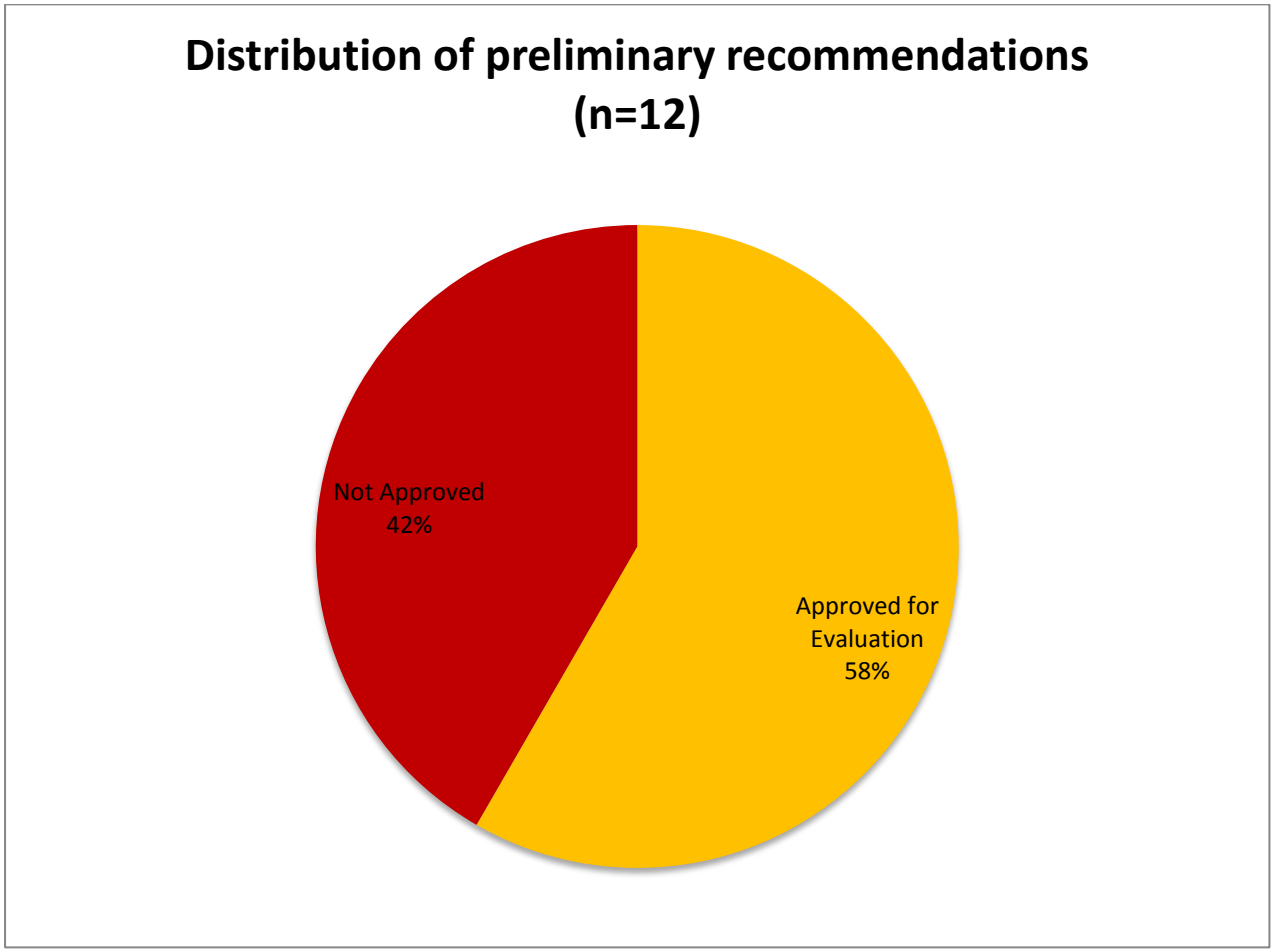
- At the meeting, the distribution of importance ratings and recommendations across the committee will be presented (see illustration).
- Committee members will have the opportunity to express their views and justify extenuating reasons, until a consensus on the final recommendation is reached.
- All reasons will be explicitly documented.



GOAL: To create a structured and transparent decision-making process.

1. PRELIMINARY RECOMMENDATION FROM CHECKLIST FOR CARDIOMEMS

- The checklist used by the committee is available here: https://survey.alchemer.com/s3/6972822/Decision-aid-Tool-CardioMEMS
- 10 committee members and 2 invited guests completed the decision-aid checklist. The figure below shows the distribution of preliminary recommendations.



2. DISCUSSION AT THE TAU POLICY COMMITTEE MEETING

- The meeting was attended by 9 Policy Committee members (Appendix C) and 3 invited members:
    - Dr. Nadia Gianetti, Associate Physician-in-Chief, Department of Medicine, MUHC
    - Mr. Steeve Gaudreault, Nurse advisor specialized products, MUHC
    - Mr. Nicolas Robert, Associate Director of Finance, MUHC
- The main issues discussed were:
    - Low quality of evidence for effectiveness of CardioMEMS in reducing heart failure hospitalizations, leading to a consensus that the evidence for clinical benefit is weak;
    - High device costs that are not offset by the costs avoided through reducing hospitalizations in NYHA class III patients;
    - Uncertain patient compliance:
        - Further information is needed on whether patients adhere to using this technology regularly;
        - "A very costly and useless intervention if patients are non-adherent";
    - Uncertainty of resource utilization to monitor patient readings issued through CardioMEMS.

3. FINAL RECOMMENDATION FOR CARDIOMEMS

RECOMMENDATIONS

- The TAU Policy Committee, made up of stakeholders from across the McGill University Health Centre (Appendix C), reviewed the evidence and issued the following recommendation: Not Approved
- This recommendation was reached based on the following:

  - Evidence for the effectiveness of CardioMEMS in reducing hospitalizations is weak, and it is difficult to ascertain whether reductions in hospitalizations can be attributed to the use of CardioMEMS.
  - Device costs are high and are not justifiable given the uncertainty in clinical benefit and patient compliance.

- This recommendation may be reviewed in 3 years, if new data from the literature and/or the local context become available.

RECOMMANDATIONS

- Le comité consultatif de l'Unité d'évaluation des technologies de la santé, composé de parties prenantes de tout le Centre universitaire de santé McGill, a examiné les données probantes et formulé la recommandation suivante : **non approuvé.**
- Le comité est parvenu à cette recommandation sur la base des éléments suivants :
  - les preuves de l'efficacité de CardioMEMS dans la diminution des taux d'hospitalisation sont faibles, et il est difficile d'attribuer la réduction des hospitalisations pour insuffisance cardiaque à la seule utilisation du système CardioMEMS;
  - les coûts liés au système sont élevés et ne sont pas justifiables compte tenu de l'incertitude quant au bénéfice clinique et à l'observance thérapeutique.
- Cette recommandation pourra être revue dans 3 ans s'il y a de nouvelles données dans la littérature ou le contexte local.

4. AGGREGATE DISTRIBUTION OF RATINGS FROM CHECKLIST

Table 1. Distribution of importance ratings for each decision criterion across the committee members (n=12)

Decision Criterion	Criteria	FAVOURS APPROVAL?	% considering criterion		
			Very Important	Somewhat	Not at all
Magnitude of effectiveness	RCTs: • 2 clinical trials (CHAMPION and GUIDE-HF) evaluated CardioMEMS efficacy to reduce heart failure hospitalisation vs. standard care management. • The CHAMPION trial (2011) reported that CardioMEMS reduced the risk of heart failure hospitalisation in NYHA class III patients (N=550) after an average follow-up of 15 months. • The GUIDE-HF (2021) reported no statistically significant difference in the risk of heart failure hospitalisation between CardioMEMS and standard care in NYHA class II - IV patients (N=1000) after 1 year of follow-up, though the main outcome of interest was a composite of mortality and heart failure hospitalisation. • A sensitivity analysis of GUIDE-HF data suggests that Covid-19 could have modified the association between CardioMEMS and risk of heart failure hospitalisation (p=0.11), though 72% of follow-up was completed before Covid-19. Observational studies: • All 11 Subgroup analyses, before-after studies and studies with administrative claims database show a reduction heart failure hospitalisation in the CardioMEMS group.	Maybe	67%	33%	0%
Quality of evidence	2 RCTs: • Low-quality evidence from the CHAMPION trial mainly due to unauthorized medical recommendations from unblinded nurse working for the sponsor for 180/270 patients in the treatment group. • Moderate-quality evidence from the GUIDE-HF trial. Observational studies: • Low-quality evidence from these studies due to serious to critical risk of bias.	Maybe	83%	17%	0%

Decision Criterion	Criteria	FAVOURS APPROVAL?	% considering criterion		
			Very Important	Somewhat	Not at all
Safety	• Not evaluated. However, there was no major safety issue requiring the removal of the sensor during the clinical trials.	Yes	83%	17%	0%
Patient preference:	• Not evaluated	Need more info	50%	42%	8%
Impact on patient convenience	Unclear • Patients need to take daily PAP readings, which requires the patient to lie down (supine). Readings take 2-5 minutes. Long-term adherence may be an issue. •Engaging with CardioMEMS may make patients more knowledgeable about their health condition and behaviours that impact blood pressure	Maybe	33%	67%	0%
Patient-reported outcomes	• Not evaluated	Need more info	50%	50%	0%
Net cost	•A single CardioMEMS devices costs $17,500 per patient. •The additional cost of managing one NYHA class III patient with CardioMEMSTM would be $14,734. The additional cost of managing 49 patients would be $564,474 per year.	No	83%	8%	8%
Costs avoided (increased hospital efficiency):	• According to the 2020 financial analysis, the variable cost is $9,878 per NYHA class III patient. • The hospitalisation avoidance rate was obtained from a meta-analysis of the 2 RCTs and estimated to be 28% (95%CI: 5% - 45%). • Based on this avoidance rate, the potential savings would be $2,766 ($494 - $ 4,445).	No	83%	8%	8%
Impact on budget of other department:	• CardioMEMS is not expected to adversely affect the budget of other departments.	Yes	17%	67%	17%
Cost-effectiveness	• No formal cost-effectiveness studies.	Need more info	50%	40%	10%
Availability of local expertise	• Expertise is available to implant device patient. • However, resource utilization to monitor daily readings of patients has not been assessed. Nursing staff needed?	Maybe	58%	42%	0%

Decision Criterion	Criteria	FAVOURS APPROVAL?	% considering criterion		
			Very Important	Somewhat	Not at all
Disruptiveness	• Use of CardioMEMS is not expected to be disruptive to regular services	Maybe	50%	42%	8%
Need to generate local evidence	• Evidence on efficacy are based on 2 RCTs and 11 observational studies (often related to the CHAMPION trial) funded by the manufacturer with substantial participation of the sponsor. • Evidence from independent study will be useful.	Yes	42%	58%	0%
Impact on cross-institution collaboration	• Not evaluated	Need more info	8%	50%	42%
Satisfaction of personnel	• Not applicable since CardioMEMS not currently used at the MUHC	Need more info	0%	91%	9%
Impact of innovativeness of the technology	• Unclear. Will the use of such telemonitoring devices be a draw for physicians and patients?	Need more info	0%	42%	58%
Benefit of the technology to society	• According to the 2020 financial analysis, NYHA class III patients who could benefit from CardioMEMS at the MUHC represent 7% of the heart failure patients Prevention of unnecessary hospitalizations is beneficial to the patient and to the healthcare system	Maybe	42%	58%	0%
Burden on other healthcare centres/services	• Not evaluated. However, unlikely to negatively impact other healthcare services as the patients upload daily their PAP data and are monitored remotely.	Maybe	17%	58%	25%
Need for the technology	• Given that congestive heart failure is considered a major health concern, there is a need to detect health deterioration before heart failure congestion.	Yes	75%	25%	0%
Ethical considerations	• No serious ethical issue.	Yes	50%	50%	0%
Stakeholder pressure	• There is a need to reduce heart failure-related hospitalisations and admission to ER.	Yes	33%	58%	8%
Availability of external funding	• No funding	No	42%	33%	25%

Decision Criterion	Criteria	FAVOURS APPROVAL?	% considering criterion		
			Very Important	Somewhat	Not at all
Number of patients affected by technology	• According to the 2020 financial analysis, 110 patients with NYHA class III per year could potentially be implanted with CardioMEMS.	Maybe	75%	25%	0%

APPENDIX

APPENDIX A: DECISION CRITERIA USED IN CHECKLIST

Domains	Criteria
Clinical benefit	Magnitude of effectiveness
	Quality of the evidence
	Safety of the technology
Impact on Patient	Patient preference
	Impact on patient convenience
	Patient-reported outcomes
Value for money	Net cost
	Costs avoided (increased hospital efficiency)
	Impact on budget of other departments
	Cost-effectiveness
Feasibility	Availability of local expertise
	Disruptiveness
	Need to generate local evidence
	Impact on cross-institution collaboration
	Satisfaction of personnel
	Impact of innovativeness of the technology
Impact on healthcare system /society	Benefit of the technology to society
	Burden on other healthcare centres/services
	Need for the technology
Ethical considerations	Ethical considerations
Strategic considerations	Stakeholder pressure
	Availability of external funding
	Number of patients affected by technology

APPENDIX B: TYPES OF RECOMMENDATIONS ISSUED BY THE TAU POLICY COMMITTEE

Type of recommendation	Explanation
Approved	• Evidence for relevant decision criteria, including efficacy, safety, and cost, as well as context-specific factors such as feasibility, is sufficiently strong to justify a recommendation that the technology be accepted, used and funded through the institutional operating budget
Approved for evaluation	• There is a *probability* that relevant decision criteria, including efficacy, safety, and cost, as well as context-specific factors such as feasibility, are favorable but the evidence is not yet sufficiently strong to support a recommendation for permanent approval. • The evidence is sufficiently strong to recommend a *temporary* approval for the purposes of evaluation, funded through the institutional operating budget.
Not approved	• There is insufficient evidence for the relevant decision criteria, including efficacy, safety, and cost; • The costs of any use of the technology (e.g. for research purposes) should not normally be covered by the institutional budget.

APPENDIX C: TAU POLICY COMMITTEE MEMBERS

Member Name	Position	Representing
Nisha Almeida	Manager, Health Technology Assessment Unit	Health Technology Assessment Unit
James Brophy (Chair)	Professor of Medicine & Epidemiology	Medicine
Julio Flavio Fiore Jr	Assistant Professor	Clinical Epidemiology
Rona Fleming	Patient Partner	Patient Partnership Office
Chantal Guévremont	Pharmacist and Coordinator, Programme de gestion thérapeutique des medicaments (PGTM)	Pharmacy & Therapeutics Committee
André Guigui	Financial Advisor – Coûts par parcours de soins et de service (CPSS), Financing and Budgets	Finance
Claudine Lamarre	Associate Director- Adult sites, MUHC Professional Services	Upper Administration
Jesse Papenburg	Pediatric Infectious Disease Specialist and Medical Microbiologist	Council of Physicians, Dentists and Pharmacists
William Parker	Clinical Chief, Department of Medical Physics,	Multidisciplinary Council
Kit Racette	Patient Partner	Patient Partnership Office