Health Quality Ontario

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Extracorporeal Membrane Oxygenation for Cardiac Indications in Adults: Health Quality Ontario Recommendation

DRAFT RECOMMENDATION

- Health Quality Ontario, under the guidance of the Ontario Health Technology Advisory Committee, recommends extracorporeal membrane oxygenation for cardiac indications be publicly funded at selected centres

RATIONALE FOR THE RECOMMENDATION

The Ontario Health Technology Advisory Committee reviewed the findings of the health technology assessment[1] of extracorporeal membrane oxygenation (ECMO) for cardiac indications. Specifically, the committee reviewed evidence for two types of ECMO for cardiac indications: venoarterial ECMO used to treat refractory cardiogenic shock and extracorporeal cardiopulmonary resuscitation (ECPR) used to treat refractory cardiac arrest.

The Ontario Health Technology Advisory Committee agreed that using ECMO to treat refractory cardiogenic shock may improve survival, but there is some uncertainty. Committee members also agreed that using ECPR to treat refractory cardiac arrest may improve long-term survival and likely improves long-term neurological outcomes.

The committee acknowledged the complexity and challenges of developing high-quality evidence from randomized controlled trials that could resolve the uncertainty about the effectiveness of ECMO for cardiac indications with respect to survival. The committee was also concerned about the cost and feasibility of making ECMO for cardiac indications available to all patients in Ontario who might be deemed to benefit and recognized the equity considerations of offering this treatment in a small number of specialized centres. However, committee members noted that patients who are potential candidates for ECMO have a very high risk of death and discussed the ethical implications of withholding a potentially lifesaving treatment.

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Based on these considerations, Health Quality Ontario decided to recommend public funding of extracorporeal membrane oxygenation for cardiac indications at selected centres and suggested that a provincial strategy be developed to promote equitable access.

Members of the committee recognized the potential use of ECMO for cardiac indications in the context of critical care and noted that current hospital funding mechanisms in Ontario incorporate complexity modifiers that result in hospitals being paid more when patients are cared for more intensively. The committee would support a closer alignment between hospital costs and hospital funding for patients requiring critical care. The committee also supports Health Quality Ontario reviewing the results of any future randomized controlled trials on ECMO for cardiac indications, should they become available.

Decision Determinants for Extracorporeal Membrane Oxygenation for Cardiac Indications

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	**Effectiveness** How effective is the health technology/ intervention likely to be (taking into account any variability)?	For adults treated for refractory cardiac arrest: • ECPR may improve 30-day survival compared with conventional CPR, but we are very uncertain (GRADE: Very Low) • ECPR may improve long-term survival compared with conventional CPR (GRADE: Low) • ECPR may improve 30-day favourable neurological outcome compared with conventional CPR, but we are very uncertain (GRADE: Very Low) • ECPR likely improves long-term favourable neurological outcome, compared with conventional CPR (GRADE: Moderate) For adults treated for refractory cardiogenic shock: • ECMO may improve 30-day survival compared with intra-aortic balloon pump, but we are very uncertain (GRADE: Very Low) • ECMO may be associated with worse 30-day and long-term survival compared with nonpercutaneous ventricular assist devices, but we are very uncertain (GRADE: Very Low)
	Safety How safe is the health technology/ intervention likely to be?	ECPR may be associated with a significant increase in treatment-related complications, such as leg ischemia/malperfusion, bleeding or hematoma with need for transfusion, compared with conventional CPR (GRADE: Low). ECMO may be associated with significant increase in systemic inflammatory response compared with ventricular assist devices in patients with postcardiotomy cardiogenic shock, but we are very uncertain (GRADE: Very Low).
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	Sudden cardiac arrest occurs in about 1 per 1,000 people aged 35 years or older per year. Acute myocardial infarction accounts for about 80% of cardiogenic shock cases. In people with ST-segment elevation myocardial infarction, cardiogenic shock occurs in about 5% to 10% of cases, and in 2% to 3% of people with a non–ST-segment elevation myocardial infarction.
	Need How large is the need for this health technology/intervention?	Although survival of patients with cardiac arrest, particularly out-of-hospital cardiac arrest, can be improved with quick administration of CPR, many patients die despite conventional CPR. Vasopressor and inotropic drugs remain first line treatment for cardiogenic shock, but frequently offer inadequate support. Short-term mechanical circulatory devices for refractory cardiogenic shock may be used as a bridge to keep a person alive until they either recover, are ready for a longer-term surgically implanted ventricular assist device, or are able to have a heart transplant.

Decision Criteria	Subcriteria	Decision Determinants Considerations
Consistency with patient values, and expected societal and ethical values[a] How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	**Patient values** How likely is adoption of the health technology/intervention to be congruent with expected patient values?	Participants reported limited input or value preference in the use of ECMO, trusting medical personnel for decision-making in acute medical circumstances. Participants reported gratitude at the availability of ECMO as a life-saving device, congruent with expected societal values of access to life-saving treatments.
	Societal values How likely is adoption of the health technology/intervention to be congruent with expected societal values?	
	Ethical values How likely is adoption of the health technology/intervention to be congruent with expected ethical values?	In life-threatening emergencies involving incapacitated patients without surrogates to provide consent to treatment, clinicians may intervene without obtaining informed consent, applying the presumption that reasonable people would consent to treatment in such circumstances. This action would be congruent with the expected ethical values of beneficence and patient autonomy. In life-threatening emergencies, the chance of preserving life may be valued more than the risk of uncertainty in treatment effect from imperfect information (e.g., having evidence from observational studies with low certainty evidence vs. randomized controlled studies of high quality). Similarly, the ethical values of beneficence in life-threatening emergencies may be valued more than the known risks of the treatment (nonmaleficence; e.g., preservation of life vs. leg ischemia as a potential complication). Consideration about access to extracorporeal membrane oxygenation across the province would be congruent with the expected ethical values of justice and equity.
Cost-effectiveness How efficient is the health technology/ intervention likely to be?	**Economic evaluation** How efficient is the health technology/ intervention likely to be?	ECPR may be cost-effective in adults with cardiac arrest. Incorporating uncertainty in various model parameters, we estimated that the probability of ECPR being cost-effective vs. CPR is 51%, 93%, and 98% for in-hospital cardiac arrest at willingness-to-pay values of $20,000, $50,000 and $100,000 per life year gained, respectively. Our model suggested that the most likely estimate of the incremental cost-effectiveness ratio is $18,722 per life year gained for in-hospital cardiac arrest.
Feasibility of adoption into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	**Economic feasibility** How economically feasible is the health technology/intervention?	The equipment cost of ECMO ranges from approximately $30,000 to $100,000. In addition, costs related to the initial operation, complications, and long-term care are expected to be incurred over time. We estimated that the annual budget impact of publicly funding ECMO for patients with cardiogenic shock and cardiac arrest in Ontario over the next 5 years will range from $0.8 million in year 1 to $2.2 million in year 5.
	Organizational feasibility How organizationally feasible is it to implement the health technology/ intervention?	An experienced multidisciplinary team is required to treat and monitor patients. There may be a shortage of ECMO-required perfusionists in Ontario to support an increase in use. Specialized training to use ECMO will be needed for centres currently not experienced with the technology.

Abbreviations: CPR, cardiopulmonary resuscitation; ECMO, extracorporeal membrane oxygenation; ECPR, extracorporeal cardiopulmonary resuscitation.
[a]The anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

REFERENCE

(1) TBA

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Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

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