

# Health Quality Ontario

*Let's make our health system healthier*

## Portable Normothermic Cardiac Perfusion System in Donation After Cardiocirculatory Death: Health Quality Ontario Recommendation

### DRAFT RECOMMENDATION

- Health Quality Ontario, under the guidance of the Ontario Health Technology Advisory Committee, recommends publicly funding portable normothermic cardiac perfusion systems for use in heart transplant following donation after cardiocirculatory death, conditional on Health Canada approval

### RATIONALE FOR THE RECOMMENDATION

The Ontario Health Technology Advisory Committee has reviewed the findings of the health technology assessment<sup>1</sup> and concluded that the use of portable normothermic cardiac perfusion systems for the preservation and transportation of donor hearts following cardiocirculatory death (DCD hearts) will likely allow for more donor hearts to become available for heart transplant.

Committee members noted that, based on the available evidence, the outcomes of recipients of DCD hearts preserved with a portable normothermic cardiac perfusion system were reasonably similar to those of recipients of hearts donated after neurological determination of death (NDD) that were preserved with cold storage (standard practice). Committee members also noted another conceivable comparison to patients who would not receive a transplant at all. Although the health technology assessment did not address this comparison directly, it seemed obvious that survival after receiving a DCD heart preserved with a perfusion system would be substantially better than survival without a transplant.

The committee felt that the cost of using the normothermic cardiac perfusion system to preserve DCD hearts was acceptable. In making this recommendation, the committee also considered the lived experience of people awaiting heart transplant, transplant recipients, and family members of organ donors. The committee recognized the importance of Health Canada regulations for medical devices. Therefore, the recommendation to publicly fund this technology was made conditional on the technology receiving approval for use in Canada by Health Canada.

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Public Comment: TBA

## Decision Determinants for Portable Normothermic Cardiac Perfusion System in Donation After Cardiocirculatory Death

Decision Criteria	Subcriteria	Decision Determinants Considerations
<b>Overall clinical benefit</b> How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	<b>Effectiveness</b> How effective is the health technology/intervention likely to be (taking into account any variability)?	Based on evidence of very low quality, DCD heart transplantation using the portable normothermic cardiac perfusion system resulted in similar recipient survival at 30 and 90 days, and at 1 year after transplant. DCD hearts required similar levels of mechanical or inotropic support in the early post-operative period, had similar ICU length of stay, and hospital length of stay and, may result in better cardiac output in the early post-operative period compared with donation after neurological determination of death (NDD) hearts.  There is a chronic shortage of donor hearts. In Ontario in 2017, 93 adult heart transplants were performed, with an additional 159 people waitlisted for heart transplant.  Over the past decade, the number of people listed for cardiac transplant has increased by about one-quarter with no change to the supply of donor hearts. An estimated 50% of Canadians on the active waitlist for a heart transplant will never receive a heart, and 20% to 30% will die while waiting or deteriorate to the point of being ineligible for transplant.
	<b>Safety</b> How safe is the health technology/intervention likely to be?	
	<b>Burden of illness</b> What is the likely size of the burden of illness pertaining to this health technology/intervention?	
<b>Consistency with expected societal and ethical values<sup>a</sup></b> How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	<b>Need</b> How large is the need for this health technology/intervention?	The core societal values and ethics that provide the framework for existing DCD organ donation in Canada are also expected to apply to a DCD heart donation program.  The 2006 Canadian guiding principles for the ethical implementation of DCD organ donation include respect for the lives and dignity of all individuals, optimal end-of-life care that respects the holistic well-being of the dying person, respect for individual autonomy with regard to known values and preferences for a meaningful life and death, support for the grieving family and loved ones through all phases of dying, public trust and avoidance of actual or perceived conflicts of interest in care provision, and respect for professional integrity. <sup>b</sup> DCD heart transplantation is expected to be congruent with these ethical values.
	<b>Societal values</b> How likely is adoption of the health technology/intervention to be congruent with expected societal values?	
<b>Ethical values</b> How likely is adoption of the health technology/intervention to be congruent with expected ethical values?	<b>Economic evaluation</b> How efficient is the health technology/intervention likely to be?	Owing to the limited and low-quality evidence related to short- and long-term outcomes after DCD heart transplantation using the portable normothermic cardiac perfusion system, we did not conduct a cost-effectiveness analysis.
	<b>Cost-effectiveness</b> How efficient is the health technology/intervention likely to be?	

Decision Criteria	Subcriteria	Decision Determinants Considerations
<p><b>Feasibility of adoption into health system</b> How feasible is it to adopt the health technology/intervention into the Ontario health care system?</p>	<p><b>Economic feasibility</b> How economically feasible is the health technology/intervention?</p> <p><b>Organizational feasibility</b> How organizationally feasible is it to implement the health technology/intervention?</p>	<p>Based on the number of DCD donors in the last 5 years who were under 40, we estimated that the increased availability of donor hearts made possible by the technology would result in an additional seven transplants in year 1, increasing to 12 in year 5. The cost of the normothermic cardiac perfusion system, including maintenance, is about \$382,000. We estimated that the net budget impact of publicly funding the normothermic cardiac perfusion system for transplantation of DCD hearts in Ontario is about \$2.0 million in the first year of funding. Over the next 4 years, the net budget impact is on average \$0.9 million per year. The total 5-year net budget impact is expected to be about \$5.6 million.</p> <p>The Trillium Gift of Life Network will be undertaking a pilot program in 2019 at an Ontario academic hospital using the portable normothermic cardiac perfusion system, funding of which is not contingent upon Health Quality Ontario's recommendation.</p>

Abbreviations: DCD, donation after cardiocirculatory death; ICU, intensive care unit; NDD, donation after neurological determination of death.

<sup>a</sup>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.

<sup>b</sup>Shemie SD, Baker AJ, Knoll G, Wall W, Rocker G, Howes D, et al. National recommendations for donation after cardiocirculatory death in Canada: donation after cardiocirculatory death in Canada. CMAJ. 2006;175(8):S1.

## REFERENCE

(1) TBA

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