Trillium Gift of Life Network

Ontario Clinical Guidelines

Ventricular Assist Devices

December 22, 2015

Ontario
Trillium Gift of Life Network

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Table of Contents

I. Purpose

This document provides clinical guidelines for all Ventricular Assist Device (VAD) practices along the patient care continuum. It includes a set of evidence-based and clinical consensus recommendations that can be used to advance best practices and quality of care for VAD patients.

The guideline applies to all VAD therapies and offers recommendation on indications, patient evaluation, patient management, and follow up care. The recommendations are not intended to take the place of the professional skill and judgement of health care providers, but rather ensure minimum standards of care are met for all patients regardless of where it is being provided.

II. Introduction to Clinical Guidelines

Health Canada aims to achieve excellence by prioritizing quality health care for all Canadians. Quality health care aims to deliver the best possible care and achieve the best possible outcomes for every patient that encounters the health care system or use its services (Health Canada). In Ontario, the *Excellent Care for All Act* (*ECFAA*) supports this by strengthening the health care sector's organizational focus and accountability to high quality patient care. ECFAA works towards defining quality, reinforcing shared responsibility, building and supporting boards' capability to oversee delivery, and ensuring health care organizations make information on their commitment to quality publicly available.

A facet of increasing quality health care in line with Health Canada and the *Excellent Care for All Act* is to enhance the link between evidence based knowledge and day to day clinical practice. As a knowledge transfer tool, clinical guidelines are evidence informed statements that assist practitioners in making decisions that will optimize patient care. Guidelines work to diminish variations between knowledge and practice by incorporating systematically examined clinical research, evidence-based practices, and clinical expertise into an accessible tool for health care providers.

The objective of developing clinical best practice guidelines is to optimize knowledge transfer amongst clinical providers to provide the highest quality care to patients. The key functions of clinical guidelines are to (CMA, 2007):

- Improve the quality of patient care and health care outcomes
- Summarize research findings and make clinical decisions more transparent
- Reduce inappropriate variation in practice
- Promote efficient use of resources and system capacity
- Provide guidance for consumers and inform and empower patients
- Inform public policy
- Support quality control.

Clinical guidelines are not intended to limit innovation or physician discretion. They cannot provide guidance in all circumstances for all patients and cannot be used as a legal resource. Ultimately, guidelines should be used to help clinicians weigh the benefits and risks of a particular diagnostic or therapeutic procedure in everyday clinical decision-making.

Why is a Clinical Guideline on Ventricular Assist Devices (VAD) necessary?

Clinical guidelines have the potential to play an important role in improving best practices when (CMA, 2007):

1. Scientific knowledge and expertise on a subject is made available
2. Mortality can be reduced
3. Interventions carry significant risks and costs.

Given the potential impact of VAD care, clinical guidelines will have a significant role in disseminating scientific knowledge and promoting its appropriate use to reduce mortality and decrease risks.

1. Availability of High Quality Evidence

As a relatively new and ever evolving treatment, there is a need to disseminate scientific knowledge and expertise on VAD use to ensure all patients receive the best care available. Increasing VAD use and data collection over the last decade has enabled the development of high quality clinical based research. In addition to independent single centre studies, the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) has been collecting data on patients from the USA and Canada who received mechanical circulatory support since 2006. As of August 2015, INTERMACS had 164 participating hospitals and over 16,000 patients entered into a database, producing a wealth of information on patient characteristics, outcomes and risk factors.

The availability of such research and clinical consensus can be used to inform practical recommendations to ensure that health care providers at every VAD centre can access the same high quality of evidence based practices.

2. Reducing Mortality

As an evolving technology, VADs continue to improve and decrease mortality for heart failure patients. Whether indicated for bridge to transplant or destination therapy, the ability of a VAD in prolonging survival is undeniable. A 2005-2012 study of 9,000 patients compared 1,600 patients who received left ventricular assist devices (LVAD) to those who did not. Patients who received LVADs (N=1,600) had a 1 year survival-to-transplant rate of 91% compared to 77% for non-LVAD patients. At 2 years, rates of survival were 85% for LVAD patients and 68% for non-LVAD patients (Trivedi et al., 2014).

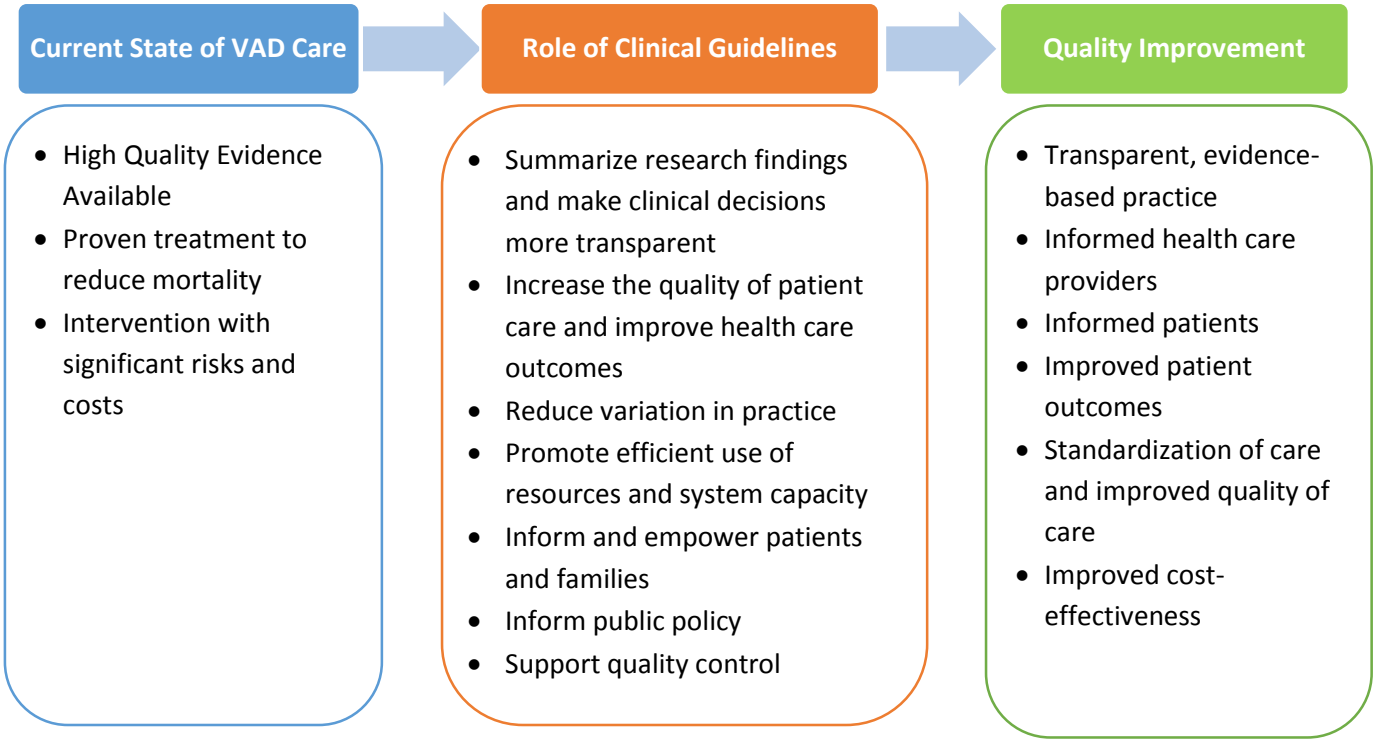
Over the last five years, survival rates for continuous-flow VAD patients continue to improve for all indications, with 80% survival at 1 year and 70% at 2 years (Kirklin et al., 2014). It is anticipated that the increasing use and technological advancements in VAD therapy for heart failure patients will continue to improve and reduce mortality.

3. Significant Risks and Costs

As of 2013, the Ontario Ministry of Health and Long-Term Care (MOHLTC) provides funding to the value of $182,600 for each adult VAD patient and $223,400 for paediatric VAD patients. In the 2014-2015 fiscal year, the MOHLTC funded over 50 VADs to Ontario heart transplant programs. Given the significant economic costs of VADs, it is imperative that every effort is taken to maximize their effectiveness.

Intensive research with continuous flow LVADs over the past decades has helped to reveal the critical variables in determining outcomes. Factors such as patient selection, post-operative management, prevention of adverse events, and identification of postoperative complications aid in determining the effectiveness of VAD therapy (Kirklin, 2014). Given the vast resources required for VAD care, improved economic and patient outcomes can be achieved by identifying and optimizing factors affecting VAD therapy for cardiac failure patients.

Well-developed VAD guidelines have the potential to improve the quality of cardiovascular care, lead to better patient outcomes, and improve cost- effectiveness. Overall, the development of clinical guidelines for VAD aims to provide quality improvement and ensure that patients receive **the right care, at the right place, at the right time**.



Currently, all heart transplant centres in Ontario provide VAD support to eligible patients as part of transplant management (University Health Network, Ottawa Heart Institute, The Hospital for Sick Children, London Health Sciences Centre). All centres are committed to collaborating, developing standardized care maps, and monitoring performance across Ontario.

III. Introduction to Ventricular Assist Devices

Heart failure is a growing worldwide health problem for which there is no one definitive therapy. In Canada, approximately one percent of the population is living with heart failure (CCN, 2014). Medical and surgical therapies are effective at alleviating symptoms and improving functional status in the early stages of heart failure, but treatment options become limited as the disease progresses to advanced stages (Slaughter et al., 2011).

For end-stage heart failure, heart transplantation is the preferred treatment, providing significant survival and quality of life benefits (Elhenawyet al., 2011; Meyer et al., 2005). Despite its efficacy, the lack of suitable donor hearts and patient contraindications to transplantation continue to severely restrict its application. Coupled with rising chronic heart failure prevalence, heart transplantation poses a significant waitlist challenge for Canadian healthcare providers.

In response to increasing heart failure rates and lengthy transplant wait times, implantable mechanical circulatory support (MCS) devices that assist the circulation of blood by one or both ventricles of the heart, have progressed over the last two decades. MCS encompasses all ventricular assistive devices (VADs) and can remain temporarily or permanently in patients' bodies. Left ventricular assist devices (LVAD) aid the left ventricle and are the most common type of VAD. LVADs work as blood from the native left ventricle of the heart flows into the surgically implanted assist device and is pumped out into the aorta via an implanted conduit. Right ventricular assist devices (RVAD) aid the right ventricle to pump blood to the pulmonary artery and are typically used for short term support. Biventricular assist devices (BIVAD) are a combination of both the LVAD and RVAD, used to support both ventricles in rare circumstances (Rector et al., 2012).

The first generations of modern MCS devices were pulsatile LVADs used as bridge to transplant therapy in the 1990s. Due to frequent device complications and size, the devices were associated with numerous infections and were limited to patients with a body surface area of $1.5m^2$ or greater (Shreenivas et al., 2010). Initial survival outcomes for patients on VAD were favourable to alternative medical therapies. In one of the first randomized studies of 129 patients with New York Heart Association class IV heart failure, the patients who received an LVAD had a 48% reduction in the risk of death from any cause. The device group had an estimated 1 year survival of 52% compared to 25% in the medical therapy group (Rose et al., 2001). However, studies also showed that device failure played a major role in outcomes. The New York Heart Association found that although patients on MCS survived for an average of 258 days longer, they also spent more than two months longer in the hospital and were more likely to experience fatal outcomes such as sepsis, bleeding, and device failure (Rose et al., 2001). A follow up study on a group of 280 patients from 2001 to 2005 showed that the same risks persisted as device failure still posed a serious threat to 73% of patients who required device replacement or experienced a fatal event secondary to device failure (Leitz eta al., 2007). Despite the survival benefits, first generation VADs were not widely implanted outside transplant centres due to their large size, the specialized care that VADs require, and frequent device failure after 18 months of continued use.

Technological advancements since the first pulsatile VADs have led to considerable device improvements. Second-generation LVADs are continuous-flow devices that work with an axial flow mechanism. Continuous-flow devices include the HeartMate II®, Jarvik 2000®, and HeartAssist 5® (Shreenivas et al., 2010). Due to the single moving rotor, device wear and tear is less problematic in continuous flow VADs. In addition, their smaller size makes them less invasive, less likely to become infected, and can be used more frequently in patients with smaller body surface areas (Shreenivas et al., 2010). Early studies showed promising results; a study that followed 281 bridge-to-transplant patients for 18 months found that 79% of patients survived, 55.8% successfully underwent transplantation, 2.5% achieved cardiac recovery and had the device explanted, and 20.6% were still dependent on mechanical support and were on the wait list (Pagani et al., 2009).

The overwhelming success of LVADs as a temporary support device for bridge to transplant has led to a growing interest in the use of MCS as destination therapy, a permanent therapy for long-term support as an alternative for patients who are ineligible for transplant (Shreenivas et al., 2010). This is enabled by newer continuous flow LVADs which, amongst other things, are less traumatic to blood components, and capable of providing sufficient circulatory support for extended end-organ function (Slaughter 2010; Slaughter et al., 2011; Kirklin et al., 2013).

As outcomes of second-generation LVADs continue to improve, trials evaluating third-generation LVADs such as HeartWare HVAD®, HeartMate III®, and Synergy® are underway. Continued innovation aims to provide continuous blood flow but have a "bearing-less" mechanism for moving blood, usually through a magnetically levitated impeller (Shreenivas et al., 2010). It is evident by the improving technology, survival rates, and increased indications, that VAD technology will play an important role in managing heart failure patients. In response, numerous published studies and guidelines have been developed to recommend indications, patient selection, and management strategies to reduce risks and mortality (see section V for a summary).

Indications

There are four broad indications for the use of LVADs; 1) bridge to transplant; 2) destination therapy; 3) bridge to candidacy; and 4) bridge to recovery:

1. Bridge to Transplant Therapy (BTT)

Long wait times and high mortality have led to the use of mechanical circulatory support (MCS) as standard bridge to transplant (BTT) therapy to support patients on the wait list until a donor heart becomes available (Elhanawy et al., 2011; Uriel et al., 2013). Despite increasing heart transplant volumes, data from Trillium Gift of Life Network (TGLN) show that wait list numbers for heart transplantation over the last five years remain stable at approximately 60-70 patients. Table 1 shows the total number of heart transplants in each year between 2009 and 2014, together with the number of patients on the wait list as of December 31st of that year.

Table 1: Ontario Heart Transplants and Heart Wait List

Year	2014	2013	2012	2011	2010	2009
Heart Transplants (January 1 – December 31)	69	83	74	61	68	62
Patients remaining on the Heart Wait List (as of December 31)	65	60	61	68	57	59

Source: TGLN TOTAL Database 2015

Overall, the use of LVAD for bridge-to-transplant is well supported in both clinical evidence, as well as in practice. The devices have demonstrated improved survival and quality of life for waitlisted patients, including older patients with multiple co-morbidities (Trivedi et al. 2014). A study from 2005 to 2012 analyzing 9,000 patients compared 1,600 LVAD patients to the remaining non-LVAD patients. At 1 year, survival-to-transplant was 91% for LVAD patients compared to 77% for non-LVAD patients. At 2 years, rates of survival were 85% compared to 68% for LVAD and non-LVAD patients, respectively (Trivedi et al. 2014).

While lowering the risk of death on the wait list, LVADs also function to improve circulation resulting in preserved organ function. In ideal circumstances, VAD therapy can aid in the recovery of other organs affected by the weakened heart's poor blood flow (such as the kidneys and liver). Increased blood circulation enables rehabilitation and improved nutrition, making patients stronger and better transplant candidates. This is evidenced in a Toronto General Hospital (TGH) study which found that LVAD patients who are discharged back to their homes experience better pre-and post-transplant outcomes (MacIver et al. 2009).

LVADs also offer benefits to quality of life and functional ability during the bridging period. Typically, patients with advanced heart failure requiring a transplant are dependent on intravenous pumps providing life-saving medication and must remain in the hospital while awaiting a donor organ. Technological advances in miniaturization have resulted in highly portable, wearable LVADs which allow patients to leave the hospital and return to work or school while awaiting transplantation. However, there are some patients that receive a VAD as bridge to transplant for increasingly prolonged periods and become ineligible for transplant while waiting for a donor heart (Rector et al., 2014).

2. Destination Therapy

With the advent of continuous flow LVADs, safe and effective long-term circulatory support is available for properly identified candidates (Slaughter et al., 2011; Kirklin et al., 2013). Data from Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) show increasing use of destination therapy as LVAD implantations have increased despite stable heart transplant volumes. In 2006, 206 LVADs were implanted while 2,193 heart transplantations were performed. By 2010, there were 1,451 LVAD placements and 2,333 heart transplants (Birks, 2011).

For destination therapy patients, survival exceeds 75% at 1 year and 50% at 3 years (Kirklin et al., 2014). Destination therapy continues to carry a slightly higher risk than bridge to transplant therapy as outcomes of destination therapy are most frequently affected by post implant bleeding, infection, and stroke (Slaughter et al., 2011). After adjusting for risk factor prevalence in each group, the

difference in predicted 1 year survival between destination therapy and BTT is approximately 5% (Kirklin et al., 2013).

Although survival rates with a newer generation of continuous flow VADs is becoming similar to that of a heart transplant, long term use of the device by patients who are eligible for a heart transplant is not currently accepted practice. Transplantation remains the preferred therapy for eligible patients (Rector et al., 2014).

3. Bridge to Candidacy

Though destination therapy is generally considered for patients who are ineligible for transplant, some of these patients improve to a degree that they recover or become transplant eligible. Bridge to candidacy is indicated for patients that require immediate mechanical support, but implantation occurs without any definitive decision regarding transplant eligibility (Mountis and Starling, 2009). Acute cardiogenic shock often presents in patients who are unable to undergo a complete transplant evaluation or consideration of an implantable LVAD. These patients are often candidates for paracorporeal support either in the form of extracorporeal life support (ECLS or ECMO) incorporating an oxygenator to provide full cardiopulmonary support, or with an external short term/temporary VAD that can stabilize hemodynamics and allow for a more detailed evaluation of transplant/durable VAD candidacy.

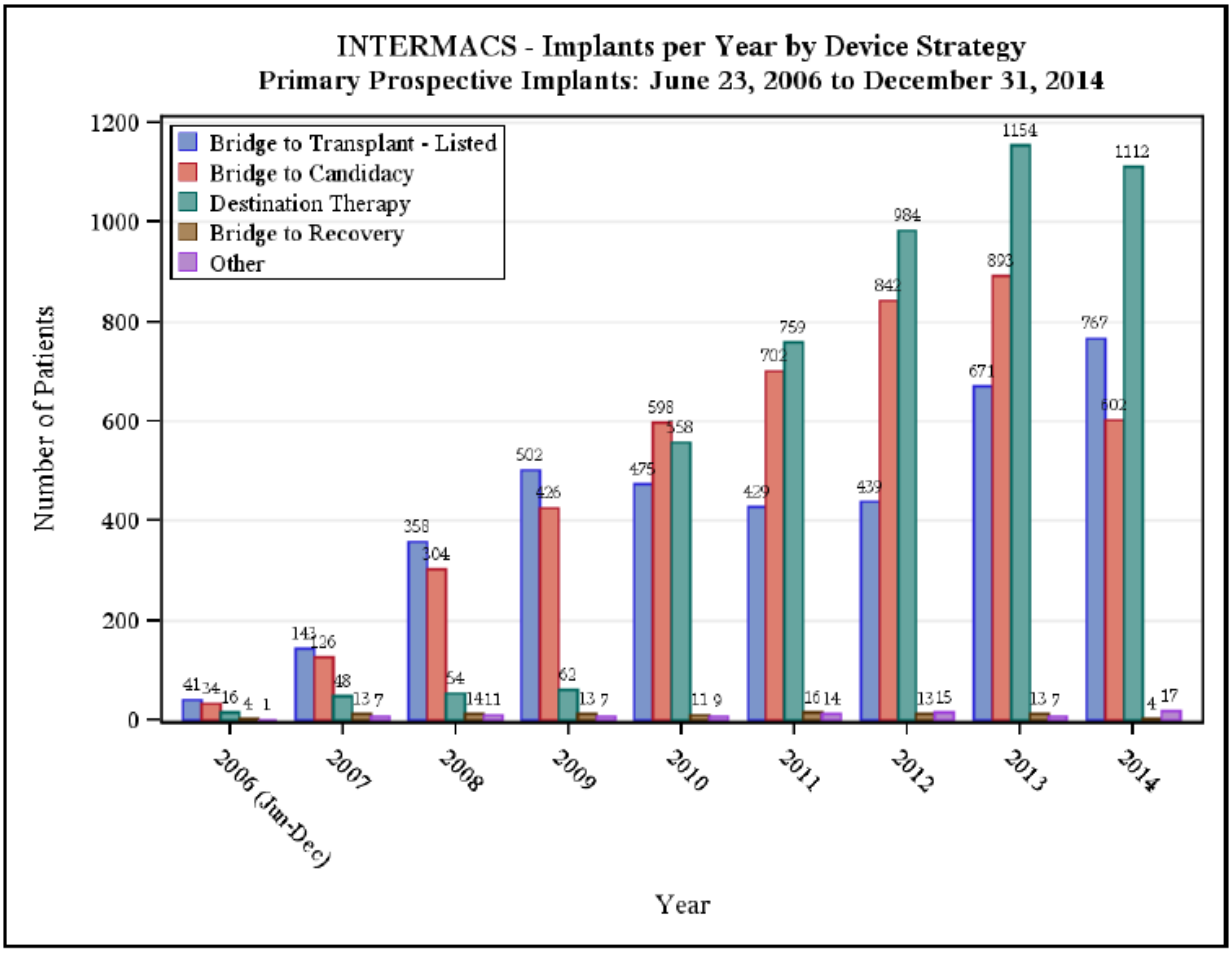
The increasing number of destination therapy as the primary indication signals that some institutions are approaching VAD patients differently; considering destination therapy first and then considering bridge-to-transplant as the patient status improves to optimize transplantation success (Birks, 2011).

4. Bridge to Recovery

Bridge to recovery refers to a limited number of patients who are supported by LVADs and demonstrate adequate cardiac recovery to allow device explantation. LVADs are used in patients requiring the application of active mechanical unloading of the systemic ventricle, exclusively in non-ischemic heart failure, to restore myocardial function to a level that can sustain the individual with minimal or no heart failure symptoms after the explantation of the LVAD (Shreenivas et al., 2010). The number of patients in North America who recover left ventricular function and have the device removed is minimal.

Historically, LVADs were predominately used as bridge to transplant. However, destination therapy and bridge to candidacy has been increasingly prevalent since the advent of better technology and continuous flow devices. The data in Figure 1 shows that since 2010, destination therapy and bridge to candidacy has surpassed bridge to transplant as the primary device strategy. The proportion of patients receiving MCS for destination therapy increased from 14.7% in 2006-2007 to 41.6% in 2011-2013. Conversely, the proportion of patients actually listed for cardiac transplant at the time of implant decreased from 42.4% in 2006-2007 to 21.7% in 2011-2013 (Kirklin et al., 2014).

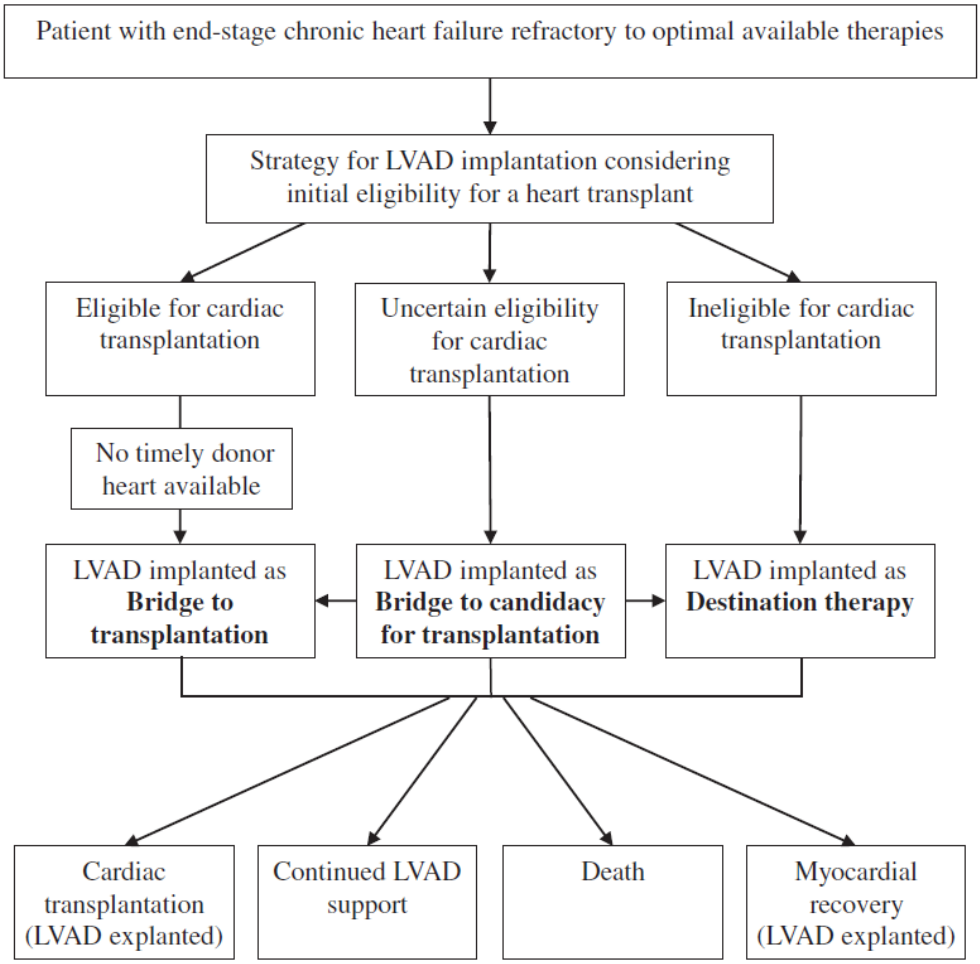
Figure 1: INTERMACS – Implants per Year by Device Strategy



Source: INTERMACS website

As a result of increasing VAD use, heart failure patients have several therapy options. Figure 2 provides a general process map for determining which patients are applicable for VAD implantation.

Figure 2: Care pathways and outcomes for LVAD treatment



Source: Boothroyd et al., 2013

Although bridge to transplant and destination therapy were initially comprised of two completely separate populations, it has become apparent that a significant number of patients could qualify for either transplant or destination therapy. Movement between the indications can occur with patient improvement or deterioration. For example, patients who are deemed unsuitable for transplant may initially receive destination therapy, but their comorbidities may eventually improve to the point that they are eligible for a transplant. Conversely, bridge to transplant patients may suffer a complication while on LVAD support, making them unsuitable for a transplant (Shreenivas et al., 2010).

Patient Selection

Patient selection for LVAD implantation plays a major role in influencing the development of post implant complications and ultimately, the success of the therapy (Slaughter et al., 2011). The main dilemma for patient selection is identifying between patients who are "too sick" and those who are "too well". To analyze

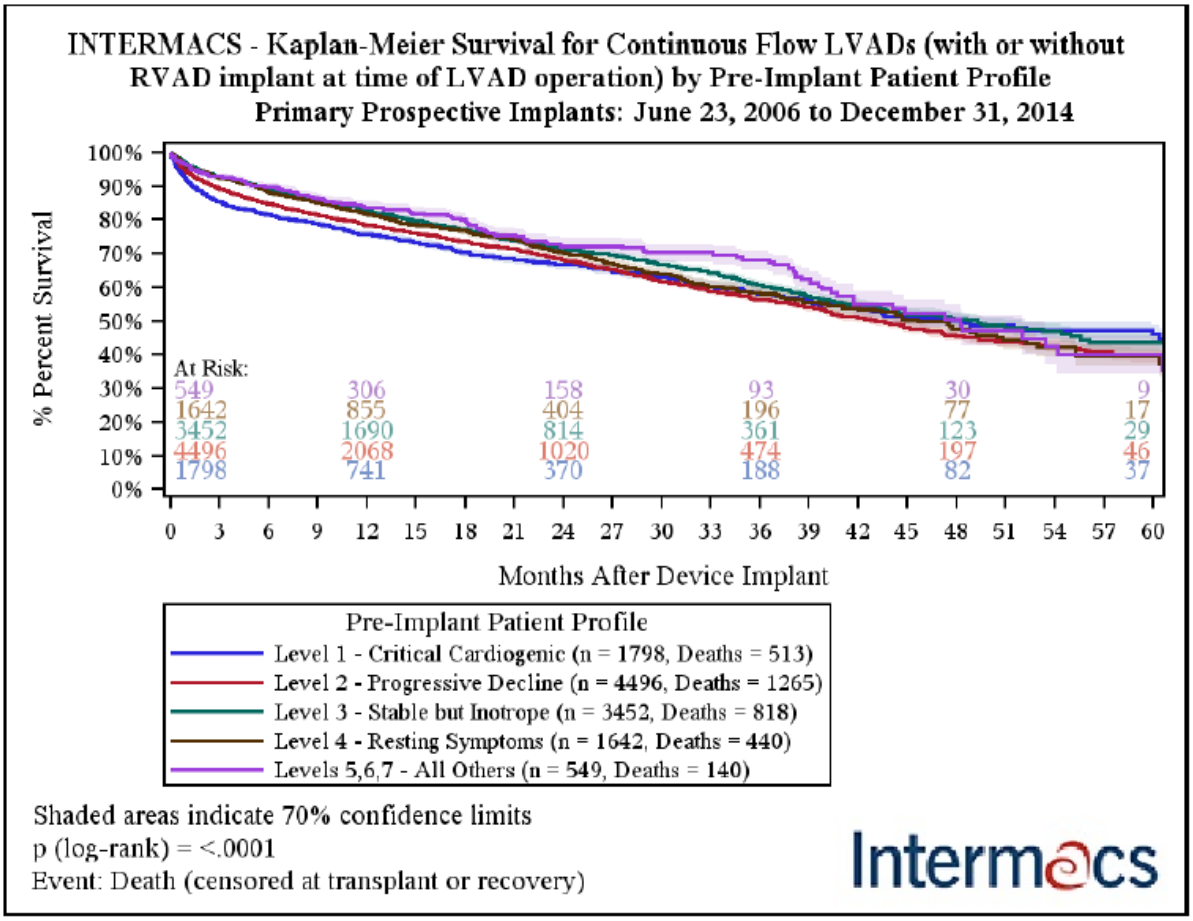
outcomes in patients with different profiles of end-stage heart failure, INTERMACS has defined seven profiles. The profiles range from patients in cardiogenic shock to patients with advanced NYHA class III symptoms:

Profile	INTERMACS Profile Description	Time Frame for Intervention
PROFILE 1: Critical cardiogenic shock	A patient with life-threatening hypotension despite rapidly escalating inotropic support and critical organ hypo perfusion.	Definitive intervention needed within hours
PROFILE 2: Progressive decline	A patient who has been demonstrated 'dependent' on inotropic support but nonetheless shows signs of continuing deterioration.	Definitive intervention needed within few days
PROFILE 3: Stable but inotrope dependent	A patient who is clinically stable on mild-moderate doses of intravenous inotropes.	Definitive intervention elective over period of weeks to few months.
PROFILE 4: Resting symptoms	A patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with ADL.	Definitive intervention elective over period of weeks to few months.
PROFILE 5: Exertion intolerant	A patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or household.	Variable urgency, depends upon maintenance of nutrition, organ function, and activity
PROFILE 6: Exertion limited	A patient who is comfortable at rest without evidence of fluid overload, but who is able to do some mild activity.	Variable, depends upon maintenance of nutrition, organ function, and activity
Profile 7: Advanced NYHA III	A patient who is clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent.	Transplantation or circulatory support may not currently be indicated

Overall, the percentage of the sickest patients (profile 1) receiving mechanical circulatory support has declined from 35% in 2006-2008 to 17% in 2009-2010, (Kirklin et al., 2011). By 2013, even fewer patients in profile 1 or 2 had received VADs, whereas the proportion of patients implanted in a stable, inotrope-dependent state (profile 3) had increased.

Clinical practice is supported by outcome data from over 13,000 patients, which consistently show that the sickest patients have the worst mortality rate regardless of indication or type of device use (Kirklin et al., 2014). This is shown in Figure 3 below, which provides survival data by patient profile:

Figure 3: INTERMACS – Survival by Pre-Implant Patient Profile



Source: INTERMACS website, 2015

Patients in profile 4 or higher have historically been considered "too well" and are less than 20% of all implants (Kirklin et al., 2014). Though a less sick patient cohort might tolerate surgery much better than a patient in cardiogenic shock, the immediate survival advantage from mechanical support may not be as obvious. Nevertheless, significant improvement in functional capacity could be achieved if a detailed evaluation is performed to identify patients who might derive symptomatic and survival benefit without prohibitive risk (Shreenivas et al., 2010).

Using all available data and clinical expertise, specific recommendations for MCS candidacy have been published by The Canadian Cardiovascular Society (McKelvie, et al., 2011). They recommend mechanical circulatory support for patients with advanced heart failure that continue to exhibit New York Heart Association (NYHA) functional class IIIb (limited even with low-level activity; comfortable only at rest) or IV (severe symptoms even at rest) heart failure symptoms, with one of the following:

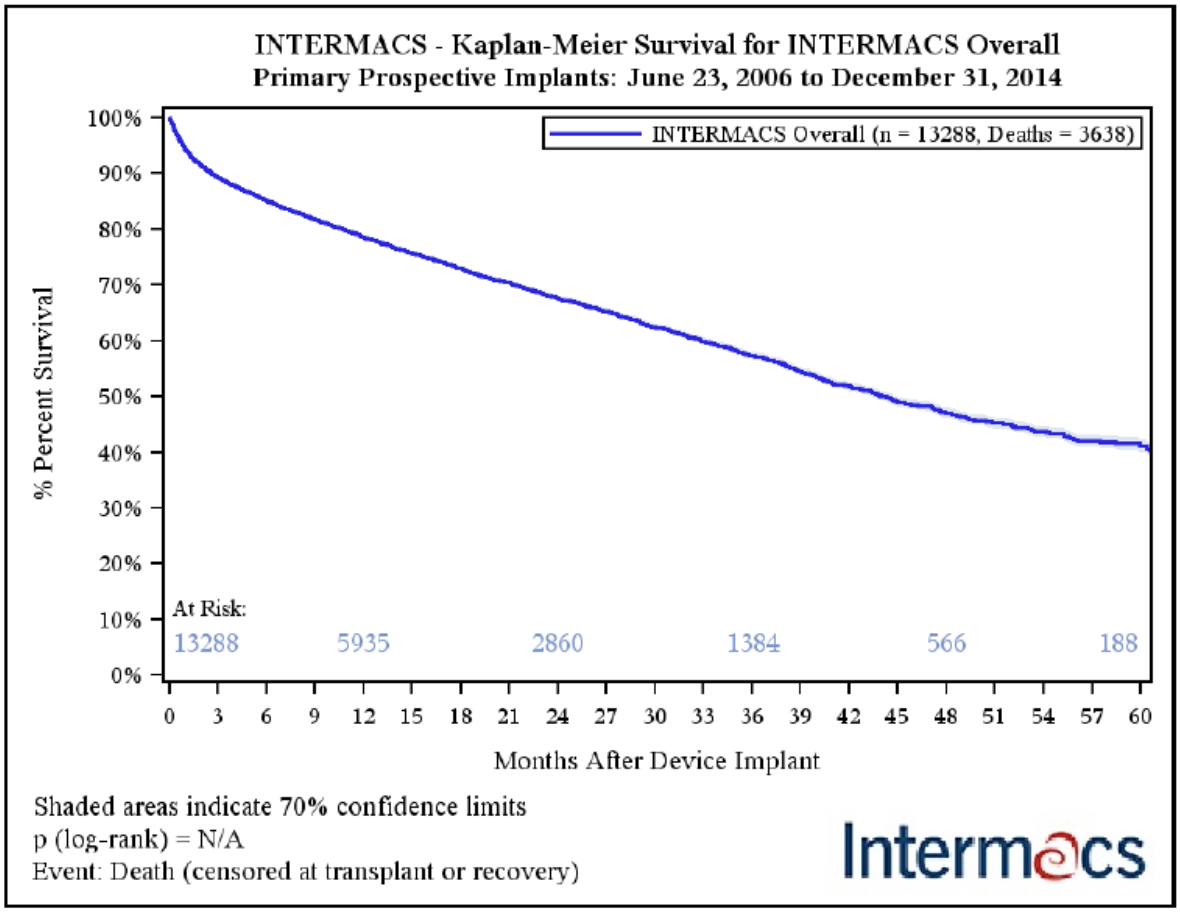
- Left ventricle ejection fraction < 25% and peak exercise oxygen consumption < 14mL/kg/min
- Evidence of progressive end-organ dysfunction due to reduced perfusion, which is not due to inadequate ventricular filling pressures
- Recurrent heart failure hospitalizations (>3 in 1 year), not due to a clearly reversible cause

- Need to progressively reduce or eliminate evidence-based heart failure therapies such as angiotensin-converting-enzyme inhibitor (ACE) inhibitors or beta-adrenergic blocking agents (β-blockers), due to symptomatic hypotension or worsening renal function
- Requirement for inotropic support (medical therapy).

Outcomes and Comorbidities

Survival rates for continuous-flow VADs have remained positive over the last five years, with 80% survival at 1 year and 70% at 2 years (Kirklin et al., 2014). The figure below depicts that Kaplan-Meier Survival rates for over 13,000 patients implanted with VAD since 2006.

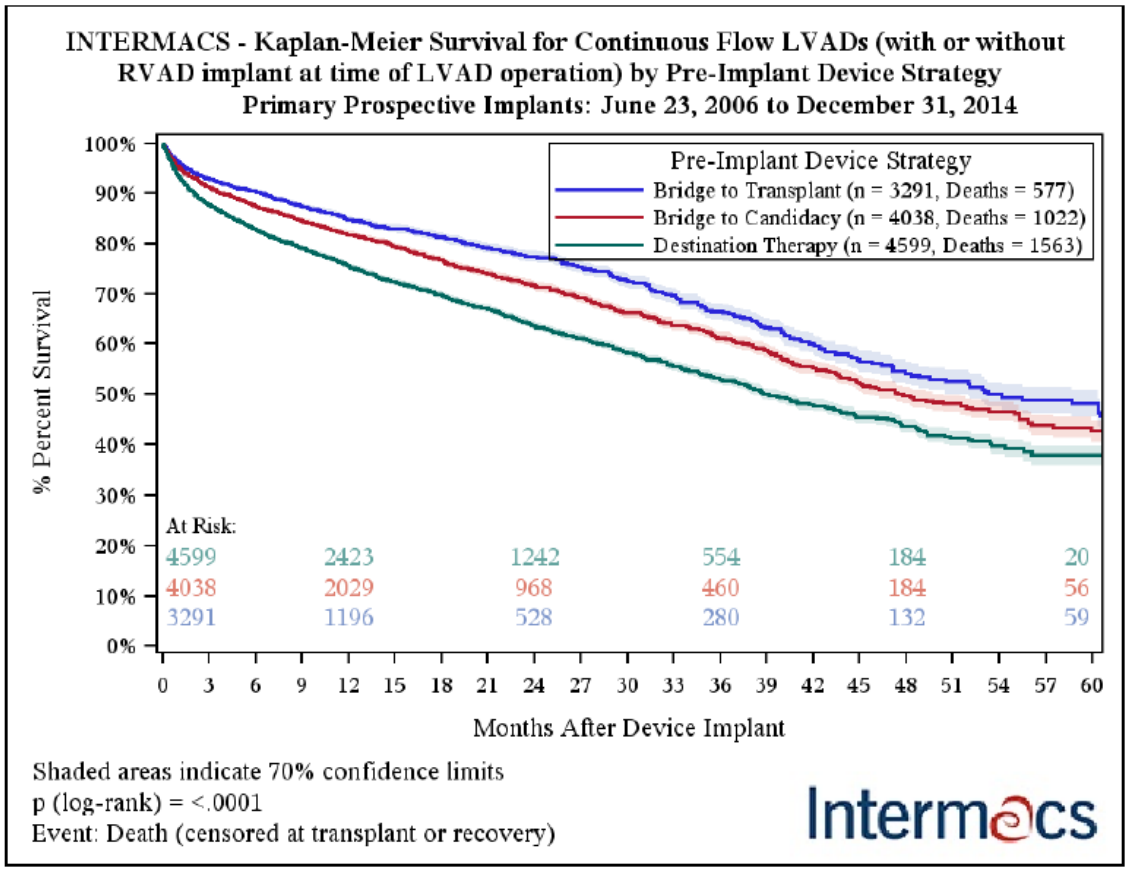
Figure 4: INTERMACS – Survival for Overall Implants



Source: INTERMACS website, 2015

In comparing survival rates by indication, Figure 5 below shows that survival rates are best for bridge to transplant patients, followed by bridge to candidacy, and then destination therapy. This is expected as patients who receive bridge to transplant therapy remain on the heart transplant wait list and are likely to receive a donor heart. Among the bridge to transplant patients, the likelihood of transplant within 1 year was 37%. For bridge to candidacy patients who are not listed at implant, the likelihood of transplant within 1 year is 20% (Kirklin et al., 2014).

Figure 5: INTERMACS – Survival by Pre-Implant Device Strategy



Source: INTERMACS website, 2015

The severity of heart failure alone is not predictive of mortality. Adverse events leading to death post implantation include bleeding, infection, and stroke (Wiwanitkit 2010; Wang et al., 2010; Slaughter et al., 2011). During the early post implant phase, the risk of multi-organ system failure mortality persists until approximately four months. After the first three months, neurologic causes of death have the greatest risk during the remainder of the first year. By 4 to 5 years post transplant, the gradually increasing late hazard for death from infection and multi-system organ failure is apparent (Kirklin et al., 2014).

The presence of comorbidities such as renal and hepatic dysfunction, and right ventricle dysfunction are observed risk factors that greatly increase mortality (Leitz et al., 2009, Kirklin et al., 2013). A study of 6,000 VAD patients found that severe renal dysfunction, defined as patients requiring dialysis near the time of transplant, was associated with a major reduction in early survival for patients (Kirklin et al., 2013). For patients with frequent hepatic dysfunction and high perioperative bleeding risk, the Model for End-Stage Liver Disease (MELD) score significantly predicted perioperative and six month mortality with LVAD placement; Patients with a MELD score greater than 17 had a six month mortality that was 2.5 times higher than those with a MELD score less than 17 (Matthews et al., 2010). The requirement for a right VAD indicates severe right ventricular failure, which has a detrimental impact in mortality within one to two months. An RVAD implant during the same operation has an early hazard ratio of 3.73 ($p<0.0001$) (Kirklin et al., 2013).

IV. Ontario VAD Programs

In Canada, the use of an LVAD is indicated for bridge to transplant therapy in cardiac transplant candidates that are at imminent risk of death from non-reversible left ventricle failure (Health Canada, 2009). In patients suffering from post-cardiotomy shock there is a spectrum of management strategies ranging from high dose inotropic support, intra-aortic balloon pump (IABP) support, to short term paracorporeal VAD or ECLS. All cardiac surgical centres in the Province of Ontario should be equipped to offer patients this entire spectrum of short-term support with appropriate referral to a transplant centre for ongoing management.

The Ontario Ministry of Health and Long Term Care (MOHLTC) provide transplant hospitals with funding to support VAD/LVAD procedures as a bridge-to-transplant. Currently, LVAD therapy is restricted to heart transplant centres; University Health Network (UHN), Ottawa Heart Institute (OHI), London Health Sciences Centre (LHSC), and The Hospital for Sick Children (SickKids).

Multiple generations of LVAD technology are available to Ontario patients, including HeartMate II®, HeartWare®, Centrimag®, and Berlin Heart EXCOR®. Ontario hospitals currently utilize LVADs to ensure that scarce donor hearts are allocated to those patients who are most likely to have long-term survival following transplant. The Ontario experience finds that a critically ill heart transplant patient who is supported by an LVAD is at lower risk for multi organ failure while awaiting transplant compared to prolonged inotropic support. Patients on LVAD have improved mobility and physical conditioning, nutrition, renal and hepatic recovery, and normalization of the pulmonary vascular abnormalities of advanced heart failure. In adult centres, patients on LVAD are discharged from hospital to be managed as outpatients while awaiting heart transplant. Due to the paediatric patient profiles that require LVADs, most paediatric patients have remained in the Hospital for Sick Children while waiting for heart transplantation.

Volumes

Canadian guidelines identify that expertise in adult MCS implantation, follow up, and explantation includes a minimum combined (short term and long term) yearly device volume of 10 per year. INTERMACS data concludes that the worst outcomes result at centres when adult VAD volumes are greater than 5 per year. For paediatric patients, data is limited due to shall numbers. The number of LVAD insertions by Ontario programs over the last three fiscal years is provided in the Table 2 below.

Table 2: Ontario LVAD Volumes by Hospital

	2012-2013	2013-2014	2014-2015
University Health Network	20	21	27
Ottawa Heart Institute	12	9	15
London Health Sciences Centre	3	3	5
The Hospital for Sick Children	7	3	5

Data submitted from hospitals show that from April 1, 2014 to March 31, 2015, UHN implanted 27 devices, 10 of whom were transplanted within the same time period; London Health Sciences centre implanted 5 LVADs and transplanted 3; The Ottawa Heart Institute performed 15 implants and transplanted 4; SickKids implanted 5 patients and transplanted 2. Note that the number of transplants includes only patients who were transplanted within that time period. LVAD patients who were transplanted after March 31st, 2015 are not captured.

With the demand for donor hearts continuing to outstrip the supply, innovative ways are necessitated to manage patients on transplant waiting lists, including advances in MCS therapy and best practice implementation.

Standardization Model

Beyond the clinical best practices outlined in these guidelines, there is a commitment to collaboration from the four Ontario programs, which will provide potential opportunities for educational rounds, development of standardized care maps and monitoring performance across Ontario.

The Ontario programs have outlined several necessary staff requirements for success:

- LVAD programs must have a designated medical lead trained in transplantation and heart failure surgery.
- Each program must have sufficient surgical implant physicians to ensure competency while still able to adequately manage call and emergency care requirements.
- Members of the surgical implant team must receive dedicated training in VAD surgery. This can be provided by fellowships in LVAD and by industry partners as new models of LVAD are introduced.
- The surgical implant team will maintain competence through continued use of the VAD implant skills, clinical in-services, debriefing sessions when difficult situations have occurred and attendance at national and international conferences.
- Cardiac operating room nurses and perfusionists are trained as part of the surgical implant team.

Many of the multidisciplinary staff of the heart failure program will work in close collaboration with the staff of VAD programs. This includes LVAD coordinators who are an integral part of the team, for both the inpatient and outpatient care. VAD programs also include clinical educators, who, as part of their scope have the ability to train staff and support them in troubleshooting issues. Additional strategies for ongoing maintenance of skills include: developing a manual with pertinent information, troubleshooting guidelines, and protocols for all staff; a mechanism for skills review and updating established by each program; and a mentorship approach for staff as needed.

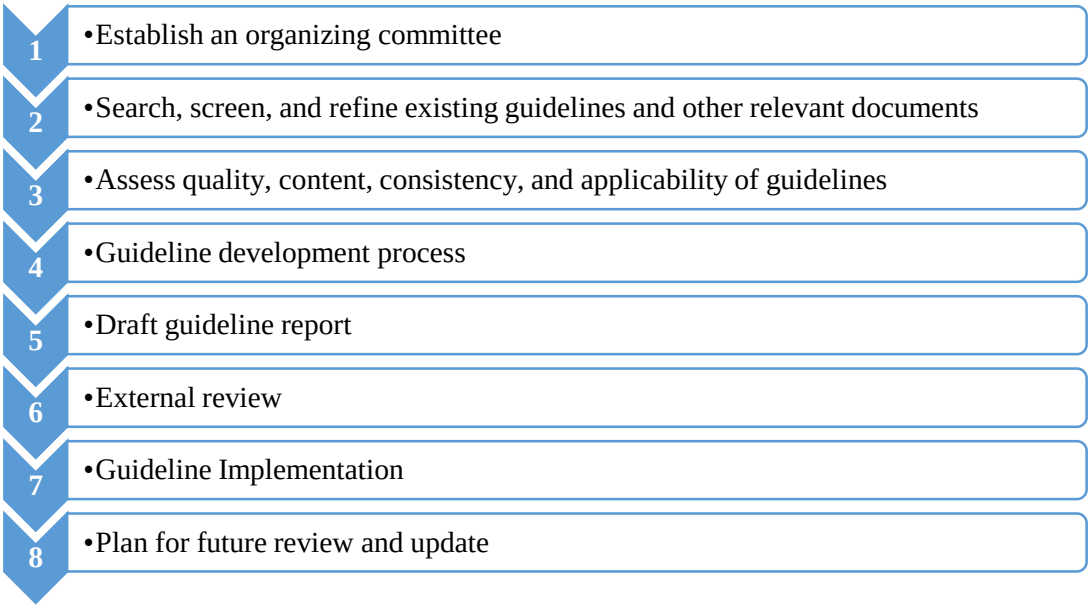
V. Methodology

The systemic process of developing clinical guidelines ensures that they are based on the best available evidence, supplemented by clinical expertise and patient preferences. Many organizations and collaborations have produced documents detailing steps for modifying clinical guidelines for local purposes. Such resources provide strategies to promote a consistent, evidence-based transparent process and are critical for the production of methodologically sounds clinical guidelines.

The ADAPTE framework was chosen as the method of developing Ontario consensus guidelines. The ADAPTE group, an international collaboration of researchers, guideline developers, and guideline implementers, have worked to develop and validate a generic adaptation process to foster valid and high-quality adapted guidelines for different user groups. The core principles of the ADAPTE include:

- Respect for the evidence-based principles of guideline development
- Reliable and consistent methods to ensure the quality of the adapted guideline
- Participative approach, involving all key stakeholders, to foster acceptance and ownership of the adapted guideline
- Explicit consideration of context during adaptation to ensure relevance for local practice
- Transparent reporting to promote confidence in the recommendations of the adapted guideline
- Flexible format to accommodate specific needs and circumstances
- Accountability to the primary guideline sources.

Using the ADAPTE process, the following steps were outlined for the development of LVAD/VAD guidelines for Ontario:



Establish an organizing committee

A VAD guideline development committee requires experts in the field of vascular devices and heart failure in general. As an organ donation and transplantation network organization, TGLN utilized the Heart and Lung Working Group membership. The provincial Heart and Lung Working Group includes one administrative and one clinical lead from each Ontario transplant centre. Working Group members are experts in LVAD care and several members were involved in developing national MCS guidelines.

Additional experts were consulted as necessary. For the writing workshop, members of the group were asked to refer clinicians at their centre who are leaders in VAD management. The resulting recommendations have been developed by active clinicians and leading heart failure experts.

Search, screen, and refine existing guidelines and other relevant documents

TGLN performed a systemic search of the scientific literature published using PubMED, MEDLINE, Cochrane Reports, and Google Scholar to understand VAD indications, usage, and best practices across the patient continuum. A jurisdictional scan reviewing LVAD guidelines of Canadian, American and International cardiovascular societies and a literature review on clinical evidence was completed. The organizations searched include:

- Canadian Cardiovascular Society (CCS)
- American College of Cardiology Foundation (ACCF)
- American Heart Association (AHA)
- Heart Failure Society of America (HFSA)
- Centers for Medicare and Medicaid Services (CMS)
- INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support)
- European Society of Cardiology (ESC)
- International Society for Heart and Lung Transplantation (ISHLT)
- National Institute of Clinical Excellence (NICE)
- National Heart Foundation of Australia, Cardiac Society of Australia and New Zealand (NHFA/CSANZ)

The literature review revealed ample existing guidelines on VAD use which could be adopted for Ontario. Two reputable organizations that have developed guidelines for MCS were identified to be relevant and of high quality, the *Canadian Cardiovascular Society* and the *International Society for Heart and Lung Transplantation*.

Canadian Cardiovascular Society (CCS)

The Canadian Cardiovascular Society has over 2,000 members and is known nationally and internationally by cardiovascular healthcare professionals. The development of guidelines has been a key activity of the CCS for over a decade and the presentation of guidelines has become an anticipated event at the annual Canadian Cardiovascular Congress. Guidelines serve an important role in supporting the mission of the

CCS "to advance the cardiovascular health and care of Canadians through advocacy, continuing professional education and the promotion and dissemination of research."

CCS Guidelines deal with topics of clinical relevance where there is sufficient literature, but where clinical practice patterns are contentious, literature is conflicting, or evidence is rapidly accumulating. They represent the consensus of a multidisciplinary panel of topic experts with a mandate to formulate disease-specific recommendations. Their purpose is to synthesize and analyze the literature to provide evidence-based guidelines for Canadian practitioners.

To ensure high quality and transparency, the CCS uses the international AGREE II Instrument as a tool for guiding development and assessing the quality and methodological transparency of guidelines. The CCS has also adopted the GRADE Scale for rating the strength of recommendations and the quality of evidence.

The following CCS guidelines were identified as relevant for the development of Ontario VAD guidelines:

- *2001 Canadian Cardiovascular Society Consensus Conference on Cardiac Transplantation*

  In 2003, the Canadian Cardiovascular Society (CCS) published its 2001 guidelines on cardiac transplantation. The purpose of this document was to outline the indications and contraindications for transplant, to review the surgical management of the recipient and donor, and to review post-transplant management.

- *2009 Canadian Cardiovascular Society Consensus Conference Update on Cardiac Transplantation*

  An update to the 2001 consensus document was published in 2009 and focused on new evidence and changes in the management of issues surrounding cardiac transplantation, including in the use of mechanical circulatory supports.

- *2011 Canadian Cardiovascular Society Heart Failure Management Guidelines Update: Focus on Sleep Apnea, Renal Dysfunction, Mechanical Circulatory Support, and Palliative Care*

  The CCS published Heart Failure (HF) Guidelines as part of their initiative to provide support for the best practice of HF management. The 2011 version of these guidelines contains recommendations on the use of mechanical circulatory support.

International Society for Heart and Lung Transplantation (ISHLT)

The International Society for Heart and Lung Transplantation is a multidisciplinary, professional organization dedicated to improving the care of patients with advanced heart or lung disease through transplantation, mechanical support and innovative therapies via research, education, and advocacy. It is comprised of over 2500 members from over 45 countries, representing over 14 different disciplines involved in the management and treatment of end-state heart and lung disease.

As part of its mission, ISHLT engages in the regular development of guidelines, consensus documents, standards statements, and policy statements regarding end-stage heart disease, end-stage lung disease, heart

transplantation, and lung transplantation. ISHLT Guidelines provides strategies, information, and specific recommendations that assist physicians and other healthcare practitioners in making decisions about appropriate measures of care for specific clinical circumstances. All ISHLT guidelines include the following components:

1. A multidisciplinary development process that includes broad geographic representation within ISHLT.
2. A comprehensive literature search and expert opinion which provide the evidence for recommendations
3. Specific recommendations which include a formal grading based on the quality of available evidence
4. Each recommendation formally graded by an evaluation of benefits, harms, burdens, and costs.

In 2013, the ISHLT convened a multidisciplinary panel of experts in mechanical circulatory support care in order to develop recommendations on patient selection and care of patients with MCS. The focus of this 2013 practice guideline is long-term device therapy with the goal of patient discharge from the hospital. The document results from the work of five Task Forces that cover the areas of patient selection and comorbidity management, patient optimization, consent and timing of MCS implantation, intraoperative and immediate post-operative management, inpatient management of patients with MCS and outpatient management of MCS recipient.

Assess quality, content, consistency, and applicability of guidelines

Upon review of all available guidelines, the Working Group chose to adopt recommendations from the following sources:

- ISHLT: The 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support.
- CCS: The 2011 Canadian Cardiovascular Society Heart Failure Management Guidelines Update: Focus on Sleep Apnea, Renal Dysfunction, Mechanical Circulatory Support, and Palliative Care.

These guidelines were chosen as they include the most up to date VAD research and evidence. Both sets of guidelines are produced by well known, reputable leaders in heart failure management.

The prerequisite for data to be considered for inclusion and integration into guidelines is their credibility, and an important undertaking of the Writing Group was to gather and weigh the available evidence. The Working Group was asked to assess the quality, content, and applicability of the recommendations for Ontario. In assessing the quality of the evidence in the ISHLT guidelines, the group chose to exclude low evidenced recommendations. The ISHLT grades their recommendations based on the following criteria:

Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses
Level of Evidence B	Data derived from a single randomized clinical trial or large non-randomized studies
Level of Evidence C	Consensus of opinion of the experts and/or small studies, retrospective

Given the intent of the guidelines as a practical tool, any recommendations that are not Level A or B were deemed too precarious to be included in Ontario's consensus document. There should be no recommendations on controversial practices or various schema that only specific institutions use where no definitive evidence exists. The availability of high quality evidenced based recommendations did not warrant the inclusion of debatable recommendations.

The specificity of the low evidenced recommendations also contributed to their exclusion. The Working Group agreed that effective Ontario guidelines should not be so prescriptive that it outweighs clinical expertise and becomes ineffective. The excluded ISHLT guidelines provided many recommendations in a vast number of specific topics including:

1. Patient Selection and Risk Management
    - Clinical Classification of MCS Candidates
    - Risk-Stratification for Consideration of MCS
    - Coronary Artery Disease
    - Acute Myocardial Infarction
    - Evaluation of MCS Candidates with Congenital Heart Disease
    - Aortic Valve Disease
    - Aortic Regurgitation
    - Aortic Stenosis
    - Aortic Root Disease
    - Mitral Valve
    - Mitral Valve Stenosis
    - Mechanical Mitral Valves
    - Tricuspid Valve Regurgitation
    - Infective Endocarditis
    - Intracardiac Shunts
    - Intracardiac Thrombus
    - Atrial Arrhythmias
    - Arrhythmia Therapy
    - Peripheral Vascular Disease
    - Life-Limiting Co-Morbidities and Multiorgan Failure
    - Pulmonary Hypertension
    - Neurologic Function
    - Coagulation and Hematologic Disorders
    - Malignancy
    - Diabetes
    - Pregnancy
    - Age
    - Psychologic and Psychiatric Evaluation
    - Adherence to Medical Therapy and Social Network
    - Tobacco Use
    - Alcohol and Substance Abuse
    - Caregiver Burden

2. Evaluation of Patient's Financial Situation and Insurance Coverage
    - Managing Patient Expectations
    - Palliative Care

- Managing Renal Function
- Nutritional Assessment
- Managing Infection Risk
- Managing Active Infection
- Antibiotic Prophylaxis
- Hepatic Dysfunction
- Pulmonary and Thoracic Assessment
- Management of Patients with Decompensated Heart Failure
- Temporary Mechanical Support
- Assessing RV Function
- Management of RV Dysfunction
- Patient Optimization and Risk Modification

3. Intraoperative and Immediate Post-Operative Management
    - Right-Heart Dysfunction in the non-ICU Post-Operative Period
    - Managing Hypotension in the non-ICU Post-Operative Period
    - Neurohormonal Blockade and the Treatment of Hypertension post-MCS Implant
    - Echocardiography in the non-ICU Post-Operative Period
    - Anti-Coagulation and Anti-Platelet Therapy Post-MCS Therapy
    - Infection Prevention Post-MCS Therapy
    - Optimization of Nutritional Status
    - Healthcare Provider and Patient Education
    - Documentation of Device Parameters
    - Device Monitoring
    - Psychosocial Support While in Hospital
    - Discharge
    - Anti-Coagulation and Anti-Platelet Therapy for Patients who Present with Gastrointestinal Bleeding
    - Evaluation and Management of Patients who Present with First Episode of Gastrointestinal Bleeding
    - Evaluation and Management of Patients who Present with Recurrent Gastrointestinal Bleeding
    - Acute Management of Patients who Present with New Neurologic Deficit
    - Chronic Management of Patients After Presentation with New Neurologic Deficit
    - Assessment of Neurocognitive Deficits
    - Evaluation of MCS Patient with Suspected Infection
    - Inpatient Treatment of Ventricular Arrhythmias
    - RV Function
    - Device Failure and Malfunction
    - Management of MCS Patient During Non-Cardiac Procedures

4. Outpatient, Management
    - Evaluation of Safety of Home Environment
    - Community Outreach by MCS Team
    - Assessment of Social Network
    - Operation of Motor Vehicle
    - Multidisciplinary Approach to Follow-Up Care
    - Right-Heart Catheterization
    - Functional Capacity Testing

- Laboratory Studies
- Assessment of the MCSD
- Exercise and Cardiac Rehabilitation
- Anti-Platelet Therapy
- Heart Failure Therapy
- Hypertension Management
- Diabetes Management
- Treatment of Renal Disease
- Evaluation and Management of Hemolysis
- Dietary Management
- Smoking and Substance Abuse
- ICD Placement
- Management of Atrial Fibrillation and Flutter
- Management of Ventricular Arrhythmias
- Psychologic and Psychiatric Issues
- Emergency Procedures for Device Failure or Malfunction
- End of Life Issues

The details of the low evidence recommendations were excluded so that resulting guidelines apply to VAD care rather than a wide range of potential activities that *could occur* surrounding VAD care. As centres of excellence, Ontario VAD programs have existing guidelines and protocols that address standard medical issues that may arise.

A full list of evidence level B and C recommendations that were excluded for further assessment is provided in Appendix B.

Guideline Development Process

Following the removal of all low evidence ISHLT recommendations, the Working Group was asked to assess the content of the remaining guidelines. A summary document identifying the following recommendations was circulated to all hospitals that perform VAD implantation in Ontario:

- All recommendations on mechanical circulatory support (MCS) devices from CCS;
- Any ISHLT recommendations that correspond to the CCS recommendations and;
- ISHLT recommendations with an evidence level of A (data derived from multiple randomized clinical trials or meta-analyses) or B (Data derived from a single randomized clinical trial or large nonrandomized studies).

All hospital groups responded with a general consensus to use the proposed CCS and ISHLT recommendations. Working Group members were asked to refer colleagues specializing in heart failure who would be able to conduct an in depth analysis of the proposed guidelines and provide Ontario specific recommendations. The Working Group, including additional expertise and the Cardiac Care Network, attended a one day workshop to assess and provide revisions on each recommendation. Each recommendation was discussed, analyzed, and evaluated by the group as a whole. Omissions and modifications to the recommendations were made as a group and finalized through consensus.

The Working Group identified recommendations that could be adopted generally rather than prescriptively. The group did not want to limit physician discretion by including specific thresholds or actions that programs would have to adhere to without consideration to context. The following considerations were discussed in each area:

1. *Patient Selection and Risk Management*

   For all indications, the group recommended that patients should have severely impaired function rather than specifying the degree of dysfunction, number of hospitalizations, and other limiting conditions.

   When recommending patient indications, the ISHLT specifies LVEF < 25%. However, the specific threshold does not account for the evolution of technology and indications. Rather than including a threshold in the guidelines that would be adopted by all programs, the group decided to rephrase the recommendation to "impaired LVEF." Such wording allows physicians to determine their patient's threshold based on each patient's circumstances.

   In providing destination therapy recommendations, the group agreed that it is not advisable for patients to be in acute cardiogenic shock before being eligible for VAD placement. Patients that are not candidates for transplantation and not in cardiogenic shock, but have an irreversible problem that will get worse over time should be candidates for destination therapy.

   The group agreed to support the continued use of mechanical support for transplant eligible patients in order to allow room for different treatment options. Individual institutions are responsible for developing policies surrounding the use of destination therapy.

2. *Patient Evaluation*

   The group agreed to omit detailed ISHLT recommendations surrounding echocardiography, MELD, and obesity as these factors are recognized and accepted health care evaluation practices. Instead, a more general cardiac assessment from CCS guidelines on patient evaluation was included.

3. *Patient Management*

   Since VAD programs in Ontario are only available in advanced heart failure and transplant centres with access to a team of multi-disciplinary experts, the workshop members opted to omit all general care recommendations that apply to all patient populations. This includes prescriptive recommendations on the management of comorbidities and complications that are not specific to VAD patients. For example, recommendations on obesity, managing anesthesia, hepatic dysfunction, infections, neurological deficits, and intra-operative and post-operative patient management were excluded. Though specific recommendations on anti-coagulation and anti-platelet therapy have been omitted, each VAD centre is encouraged to work with their specialists to establish a policy on anti-coagulation and anti-platelet therapy for patients with MCS.

The decision to exclude a large number of patient management recommendations is based on the fact that all Ontario VAD programs have access to the necessary experts for consultation should complications in these areas arise. All Ontario VAD programs are within heart failure centres that have the expertise to manage complex patients. Rather than outline every possible complication and patient management strategy, the Working Group opted for a general recommendation to using a multi-disciplinary approach to VAD care. This is because specifying certain complications may emphasize and prioritize them over more severe complications that are not outlined in the recommendations, such as thromboembolic complications, gastrointestinal bleeding and stroke. The group did not think it would be consistent to include some, but not all possible complications. Instead, there is a recommendation to consult a multi-disciplinary team including nutritional, psychosocial, infectious disease, and other specialists as necessary.

Recommendations on specific assessments were replaced with a general statement for using appropriate lab imaging and diagnostic testing. The implanting centre will have a relationship with non-program VAD patient care providers, determining follow up intervals and communicating frequently.

4. *Data Collection*

   The group agreed that data collection is vital for measuring success. The working group recommended that a currently established registry be used, noting that several databases are available. The relevant clinical parameters and method of data collection will be determined in collaboration with the Ministry of Health and Long Term Care at a later date.

The final recommendations were the result of multiple debates and lengthy considerations. All recommendations were agreed upon unanimously.

Draft guideline

TGLN used the available information from a jurisdictional scan, clinical experts, and the development workshop to draft clinical guidelines for Ontario VAD programs. A draft of the document was circulated to the Working Group chairs for initial comments and review. The guidelines were then distributed to the rest of the Working Group to ensure that the document reflects the expert discussions and intended guidelines.

External review

When a draft guideline was approved by the Working Group co-chairs, broader stakeholder engagement was conducted with the following groups:

- VAD clinicians and care providers
- Cardiac Care Network (CCN)
- Hospital administrators from centres that provide VAD care

TGLN distributed the document to all Ontario transplant programs via the Heart and Lung Working Group to obtain consensus on the clinical accuracy and efficacy of the guidelines. The document was also distributed to heart failure specialists for comment through the CCN. This ensured that consensus was not limited to VAD and transplant specialists but rather all heart failure experts.

Hospital administrators were asked to comment on the feasibility of adherence to the guidelines. Given the varied resources allocated to VAD procedures throughout different centres in Ontario, hospital administrators need to ensure that the standards of care recommended can be met.

Feedback from each group was assessed and incorporated into the guidelines where appropriate. A clinical representative from each VAD insertion hospital approved the recommendations as an act of endorsement.

Guideline Implementation

The recommendations are to be adopted and adhered to by all Ontario VAD implant centres as part of their commitment to quality care. TGLN will provide the necessary educational tools to transplant hospital partners in order to aid with the dissemination of the guidelines.

The Cardiac Care Network will support guideline development and implementation by distributing and implementing VAD consensus guidelines beyond transplant centres.

Data and Reporting

Monitoring and reporting of care measures is central to the efficacy and impact of the recommendations. Several data points have been identified as necessary to assess quality VAD care. This includes:

- Patient Characteristics
- VAD implant information
- Date of hospital discharge
- Date and number of hospital readmissions
- Date of heart transplant listing
- Date of transplant
- Patient survival

As the capacity to collect data increases, more indicators will be gathered to assess the efficacy of VADs on patient outcome. TGLN will continue to work in partnership with transplant centres to ensure that all reporting requirements and quality of care measures are collected on a regular basis.

Future review and update

The guidelines will be updated on a regular basis to reflect the evolving nature of VAD technology. The adopted guidelines will be reviewed when CCS or ISHLT releases new updates to their guidelines on MCS.

TGLN will conduct an annual review of VAD guidelines to determine whether any revisions to the Ontario guidelines are warranted.

If no guidelines are published during the annual review, the guidelines will be reviewed every 2 years by the Heart and Lung Working Group members. Comments received will be collated and presented to the Working Group as necessary.

VI. Recommendations

Due to the expertise required, implantable VADs should only be performed in heart transplant centres with an identified and adequately trained multidisciplinary VAD team. The recommendations provided are best practices that should be adopted by all Ontario programs that provide VAD care. They are evidence based guidelines that will benefit quality and patient outcomes. In addition to the recommendations below, all VAD hospitals are expected to have their own protocols on how to treat complications common to all heart failure patients. VAD programs have expertise in advanced heart failure management and the flexibility to consult with multidisciplinary teams to inform complex care practices beyond the scope of existing recommendations.

All recommendations were adapted either from *The 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support* or *The 2011 Canadian Cardiovascular Society Heart Failure Management Guidelines Update*. Some of the recommendations have been rewritten to reflect best practices in the Ontario centres while others remain unchanged.

For each recommendation, the document it was adapted from and the evidence level it was assigned are provided. Readers can refer to the original documents for information on the evidence cited. The table below describes how each organization assigns their recommendation and evidence levels:

Organization	Type	Level	Description
Canadian Cardiovascular Society	Evidence	High	Further research very unlikely to change confidence in the estimate of effect
	Evidence	Moderate	Further research likely to have an important impact on confidence in the estimate of effect and may change the estimate
	Evidence	Low	Further research very likely to have an important impact on confidence in the estimate of effect and likely to change the estimate
	Evidence	Very Low	Estimate of effect very uncertain
International Society for Heart and Lung Transplantation	Evidence	A	Data derived from multiple randomized clinical trials or meta analyses
	Evidence	B	Data derived from a single randomized clinical trial or large nonrandomized studies
	Evidence	C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries

Recommendations are categorized into the following sections: indications, patient evaluation, patient management, and data collection.

Indications

1. ***Heart Failure (HF)***
   a. Patients with advanced heart failure, including those, despite optimal treatment, continuing to exhibit NYHA IIIb or IV HF symptoms AND accompanied by MORE THAN ONE OF the follow:
      - Evidence of progressive end organ dysfunction due to reduced perfusion not due to inadequate ventricular filling pressures,
      - Recurrent HF hospitalizations not due to a clearly reversible cause,
      - Need to progressively reduce or eliminate evidence-based HF therapies such as ACE inhibitors or beta-blockers, due to symptomatic hypotension or worsening renal function,
      - Requirement for inotropic support.

CCS: Practical Tip

2. ***Temporary Support/ Bridge-to-Transplant/ Bridge-to-Candidacy (adapted from CCS)***
   a. MCS should be considered for patients who are listed for cardiac transplantation and who deteriorate or are otherwise not likely to survive until a suitable donor organ is found.

   b. Patients with fulminant HF should be considered for temporary MCS to afford an opportunity for evaluation for long-term options.

   c. MCS should be considered for patients for whom there is a contraindication for cardiac transplantation but may, via MCS, be rendered transplant eligible.

a-b. CCS: Moderate Evidence
c. CCS: Low Evidence

3. ***Long-Term Support/ Destination Therapy***

   a. Permanent MCS should be considered for highly selected transplant ineligible patients, including:
      - Patients whose ventricular function is deemed unrecoverable or unlikely to recover without long-term device support,
      - Patients who cannot be weaned from temporary MCSDs or inotropic support,
      - Patients with the capacity for meaningful recovery of end-organ function and quality of life,
      - Patients without irreversible end-organ damage.

   b. The continued use of MCS for carefully selected transplant eligible patients is supported.

   c. Institutions providing MCS therapy should develop a policy regarding destination therapy within the conventions, resources, and philosophy of care of their organization, including indications for destination therapy for transplant eligible patients.

a. ISHLT: Level of Evidence, C
b-c. Workshop group consensus

Patient Evaluation

1. ***Cardiac Assessment/Clinical Classification***
   a. Patients with either acute severe or chronic advanced HF and with an otherwise good life expectancy should be referred to a fully equipped cardiac centre for assessment and management by a team with expertise in the treatment of severe HF, including MCS, in collaboration with an established transplant team.

CCS: Moderate Evidence

2. ***Transplant Assessment***
   a. All patients referred for MCS should have their transplant candidacy assessed prior to implant.

ISHLT: Level of Evidence A

3. ***Echocardiography***
   a. Echocardiography should be performed as part of the pre-operative assessment.

ISHLT: Level of Evidence A

Patient Management

The management of patients who undergo VAD placement should be completed with a broad multidisciplinary team across the care paradigm. Specialists in nutrition, psychosocial care, infectious disease, neurology, anesthesiology, and other appropriate disciplines should be available as part of routine patient care.

1. ***Nutritional Assessment***
   a. All patients should have assessment of their nutritional status prior to MCSD implantation with at least a measurement of albumin and pre-albumin.

ISHLT: Level of Evidence B

2. ***Quality of Life Assessment***
   a. Quality of life should be measured before MCSD implantation and at regular intervals longitudinally for the duration of MCSD support using an established quality of life tool.

ISHLT: Level of Evidence B

3. ***Anti-Coagulation and Anti-Platelet Therapy***
   a. All MCS centres must have routines and protocols on anti-coagulation and anti-platelet therapy on initiation, cessation and bridging.

ISHLT: Level of Evidence B

4. ***Assistive Devices***

a. Ambulatory patients with MCS therapy who are discharged from hospital and who have had minimal HF symptoms or ventricular arrhythmias for a period of at least 1 month should be considered candidates for operation of a personal motor vehicle for a period not exceeding two thirds of the known battery charge time.

CCS: Low Evidence

5. ***Frequency of Visits***
   a. MCS patients should be seen in clinic regularly, the frequency of which is dictated by their clinical stability with appropriate laboratory testing and diagnostic imaging based on clinical indications.

ISHLT: Level of Evidence B

6. ***Health Maintenance***
   a. Patients with MCSD therapy should continue to follow a general health maintenance schedule, including gender-related and age-specific recommendations, routine vaccinations, and dental care.

ISHLT: Level of Evidence A

7. ***ICD Placement***
   a. Routine placement of an ICD should be considered for patients who did not have an ICD prior to MCS.

ISHLT: Level of Evidence B

Data Collection

1. ***Data Collection/Registry***
   a. All relevant clinical parameters should be collected in a currently established registry for outcomes to be monitored.

ISHLT: Level of Evidence C

VII. Appendix A

All recommendations provided to heart transplant hospitals for review, including those considered, but not contained in the final guidelines. Recommendations highlighted in gray may have been modified, but are included in the Ontario guidelines.

Recommendations from the *2011 Canadian Cardiovascular Society Heart Failure Management Guidelines Update.*

Recommendation	Evidence Level	Decision
We recommend that patients with either acute severe or chronic advanced HF and with an otherwise good life expectancy be referred to a fully equipped cardiac centre for assessment and management by a team with expertise in the treatment of severe HF, including MCS	Strong Recommendation, Moderate Quality Evidence	Included
We recommend MCS be considered for patients who are listed for cardiac transplantation and who deteriorate or are otherwise not likely to survive until a suitable donor organ is found	Strong Recommendation, Moderate Quality Evidence	Included
We recommend that MCS be considered for patients for whom there is a contraindication for cardiac transplantation but may, via MCS, be rendered transplant eligible	Strong Recommendation, Low-Quality Evidence	Included
We recommend that patients with fulminant HF be considered for temporary MCS to afford an opportunity for evaluation for long-term options.	Strong Recommendation, Moderate-Quality Evidence	Included
We recommend permanent MCS be considered for highly selected transplant ineligible patients.	Weak Recommendation, Moderate-Quality Evidence	Included (with modification)
We recommend that institutions providing MCS therapy develop a policy regarding DT within the conventions, resources, and philosophy of care of their organization.	Weak Recommendation, Low-Quality Evidence	Included
We recommend that ambulatory patients with MCS therapy who are discharged from hospital and who have had minimal HF symptoms or ventricular arrhythmias for a period of at least 1 month be considered candidates for operation of a personal motor vehicle for a period not exceeding two thirds of the known battery charge time.	Weak Recommendation, Low-Quality Evidence	Included
Patients with advanced heart failure, including those, despite optimal treatment, continuing to exhibit NYHA IIIb or IV HF symptoms AND accompanied by MORE THAN ONE OF the following: • LVEF < 25% and, if measured, peak exercise oxygen consumption <14mL/kg/min • Evidence of progressive end organ dysfunction due to reduced perfusion not due to inadequate ventricular filling pressures. • Recurrent HF hospitalizations (>3 in 1 year) not due to a clearly reversible cause. • Need to progressively reduce or eliminate evidence-based HF therapies such as ACE inhibitors or beta-blockers, due to symptomatic hypotension or worsening renal function • Requirement for inotropic support.	Practical Tip	Included (with modification)
Cardiac centres that perform MCS should have adequate manpower and resources for support of patients requiring MCS support. These include: • An identified and adequately trained multidisciplinary MCS team • Access to the full array of medical and surgical consultative support, and institutional administrative and financial support • Expertise in MCS implantation, follow up, and explantation	Practical Tip	Included (with modification in introduction)

Recommendations from the *2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support.*

Topic	Recommendation	Evidence Level	Decision
Patient Selection and Risk Management			
Evaluation Process of MCS Candidates	All patients should have any reversible causes of heart failure addressed prior to consideration for MCS	I-A	Not Included
	All patients referred for MCS should have their transplant candidacy assessed prior to implant	I-A	Included
	All patients being assessed for MCS should have their Interagency Registry for Mechanically Assisted Support (INTERMACS) profile determined	I-C	Included (with modification to not specify registry)
	Long-term MCS for patients who are in acute cardiogenic shock should be reserved for the following: a. Patients whose ventricular function is deemed unrecoverable or unlikely to recover without long-term device support. b. Patients who are deemed too ill to maintain normal hemodynamics and vital organ function with temporary MCSDs, or who cannot be weaned from temporary MCSDs or inotropic support. c. Patients with the capacity for meaningful recovery of end-organ function and quality of life. d. Patients without irreversible end-organ damage.	II-C	Included (with Modifications)
Risk-Stratification for Consideration of MCS	Patients who are inotrope-dependent should be considered for MCS because they represent a group with high mortality with ongoing medical management	IIa-B	Not Included
Patient Optimization and Risk Modification			
Obesity	Obesity (body mass index 30–35kg/m2), in and of itself, is not a contraindication to MCS, but surgical risk and attendant comorbidities must be carefully considered prior to MCS in the morbidly obese patient (body mass index > 35 kg/m2)	I-B	Not Included
Nutritional Assessment	All patients should have assessment of their nutritional status prior to MCSD implantation with at least a measurement of albumin and pre-albumin	I-B	Included
Hepatic Dysfunction	Patients with confirmed cirrhosis or an increased Model for End Stage Liver Disease (MELD) score are poor candidates for MCSD therapy	III-B	Not Included
Intraoperative and Immediate Post-Operative Management			
Managing Anesthaesia Issues	Patients undergoing MCSD placement should have insertion of a large-bore intravenous line, arterial line, and pulmonary artery catheter to allow for continuous monitoring and intravascular access	I-B	Not Included
	Cardiac anesthesia should be performed by those familiar with the clinical issues associated with MCSD placement, including considerations at the time of induction, during surgery, during separation from cardiopulmonary bypass, and at the time the MCSD is actuated	I-B	Not Included
	Intraoperative trans esophageal echocardiography should be performed by physicians with advanced training in the intraoperative assessment of cardiac structure and function	I-B	Not Included

Topic	Recommendation	Evidence Level	Decision
Echocardiography in the non-ICU Post-Operative Period	Post-operatively, the revolutions per minute of continuous-flow pumps should be set low enough to allow for intermittent aortic valve opening	IIb-B	Not Included
	Long-term, maintaining intermittent aortic valve opening may reduce the risk of aortic valve fusion and the risk of late aortic valve insufficiency	IIb-B	Not Included
Anti-Coagulation and Anti-Platelet Therapy Post-MCS Therapy	Anti-coagulation and anti-platelet therapy initiated post-operatively in the ICU setting should be continued with the aim of achieving device-specific recommended INR for warfarin and desired anti-platelet effects	I-B	Included (with modification to remove specifics)
Psychosocial Support While in Hospital	Routine surveillance for psychiatric symptoms should be performed. If symptoms develop, consultation with specialists (including social work, psychology, and/or psychiatry) for diagnosis, treatment, and follow-up is recommended	I-B	Included (without specifics, in introduction)
Multidisciplinary Inpatient Care	A multidisciplinary team led cooperatively by cardiac surgeons and cardiologists and composed of sub-specialists (ie, palliative care, psychiatry, and others as needed), MCS coordinators, and other ancillary specialties (ie, social worker, psychologist, pharmacist, dietitian, physical therapist, occupational therapist, and rehabilitation services) is indicated for the in-hospital management of MCS patients	I-C	Included (without specifics, in introduction)
Routine Assessment of Health-Related Quality of Life post-MCSD in Hospital	Routine assessment of health-related quality of life (HRQOL) while hospitalized after MCS implantation may be reasonable. Hospitalized patients are beginning to adjust to living with MCS and thus require MCS team support as they recover from surgery and rehabilitate. Assessment of specific problems that are related to domains of HRQOL (eg, depression, anxiety, or pain) based on symptoms should help guide an action plan for these patients	IIb-B	Included (with modification to remove specifics)
Acute Management of Patients who Present with New Neurologic Deficit	Assessment of current INR and review of recent INR is recommended	I-B	Not Included
	Prompt consultation with neurology is recommended	I-B	Not Included
	CT and angiography of the head and neck is recommended	I-B	Not Included
	Discontinuation or reversal of anti-coagulation in the setting of hemorrhagic stroke is recommended	I-B	Not Included
	Assessing for the source of thrombus in the setting of an embolic stroke should be considered	IIa-B	Not Included
Chronic Management of Patients After Presentation with New Neurologic Deficit	Formal stroke rehabilitation in consultation with neurology is recommended	I-B	Not Included
	Long-term control of blood pressure is recommended	I-B	Not Included
Evaluation of MCS Patient with Suspected Infection	In all patients, a complete blood count, chest radiographic imaging, and blood cultures is recommended	I-A	Not Included
	At least 3 sets of blood cultures over 24 hours should be drawn, with at least 1 culture from any indwelling central venous catheters	I-A	Not Included
	For those with a suspected cannula or driveline infection, obtaining a sample for Gram stain, KOH, and routine bacterial and fungal cultures is recommended	I-A	Not Included
	When clinically indicated, aspirate from other potential sources, as dictated by presenting symptoms and examination, is recommended	I-A	Not Included
	Directed radiographic studies based on presenting symptoms and examination are recommended	I-A	Not Included

Topic	Recommendation	Evidence Level	Decision
Determination of MCSD-Suspected Infection	A proven MCSD-specific infection is defined as definitive microbiologic, histologic confirmation at MCS explant or 2 major clinical criteria	I-B	Not Included
	A probable MCSD-specific infection is defined as 1 major and 3 minor criteria or 4 minor criteria	I-B	Not Included
	A possible MCSD-specific infection is defined as 1 major and 1 minor or 3 minor criteria	I-B	Not Included
Determination of MCSD Pocket Infection	A proven MCSD pocket infection is defined as organisms cultured from fluid, abscess, or other infection seen during surgical exploration, or 2major criteria	I-B	Not Included
	A probable MCSD pocket infection is defined as 1 major and 3 minor or 4 minor criteria	I-B	Not Included
	A possible MCSD pocket infection is defined as 1 major and 1 minor or 3 minor criteria	I-B	Not Included
Device Failure and Malfunction	For patients who are unable to undergo surgery, the outflow cannula may be occluded percutaneously to halt the backflow of blood through the valveless outflow cannula as a stabilizing maneuver	IIb-B	Not Included
Management of MCS Patient During Non-Cardiac Procedures	For emergency procedures, warfarin may need to be rapidly reversed with fresh frozen plasma or prothrombin protein concentrate. Vitamin K can be administered with caution, but has slower onset of action	I-B	Not Included
	Post-procedure, warfarin and anti-platelet therapy may be resumed when risk of surgical bleeding is deemed acceptable. Patients may be bridged with heparin or a heparin alternative while waiting for the INR to reach the target range	I-B	Not Included
	A central venous catheter may be placed for monitoring of central venous pressure and to administer drug sin the case of hemodynamic instability during surgical procedures of moderate or high risk	I-B	Not Included
Outpatient Management: Follow-up Care			
Frequency of Visits	MCS patients should be seen in clinic regularly, the frequency of which is dictated by their clinical stability.	I-B	Included
	MCS patients should have a routine schedule of testing to survey for patient-related or device-related issues that may adversely affect outcomes	I-B	Included
	Between routinely scheduled visits, monitoring phone calls from the MCS coordinator to the patient or caregiver may help proactively identify issues that may adversely affect patient outcomes	IIa-B	Not Included
Echocardiography	Echocardiography should be performed as part of the pre-operative assessment and routinely at regular intervals post-operatively to evaluate for signs of myocardial recovery and optimal MCSD function. Echocardiography can be used for setting optimal pump parameters	I-B	Included
	In addition to routine studies, echocardiography should be performed as part of the evaluation of sub-optimal MCSD function or in the presence of clinical signs of circulatory dysfunction, including congestive or low output symptoms	I-B	Not Included
Right-Heart Catheterization	Right heart catheterization is useful in the assessment of persistent or recurrent heart failure symptoms after MCSD placement and to evaluate for evidence of RV failure or device malfunction	I-B	Not Included

Topic	Recommendation	Evidence Level	Decision
	Right heart catheterization should be performed at regular intervals in patients being evaluated for or listed for heart transplant to document pulmonary artery pressures because irreversible pulmonary hypertension is associated with early allograft dysfunction/failure after heart transplantation	I-A	Not Included
CT Angiography	CT angiography allows visualization of the native heart and MCSD components and may be valuable when other imaging modalities have not been revealing	I-B	Not Included
Functional Capacity Testing	Measurement of exercise capacity should be undertaken after MCSD placement to allow for appropriate exercise prescription, which may be part of a formal cardiac rehabilitation program	I-B	Not Included
Health-Related Quality of Life	HRQOL should be measured before MCSD implantation and at regular intervals longitudinally for the duration of MCSD support. Generic measures and those specific to heart failure can both be used. Suggested intervals are 3 months, 6 months, at 6-month intervals through 2 years after implant, then yearly thereafter	IIa-B	Included (with modification to remove specifics)
Health Maintenance	Patients with MCSD therapy should continue to follow a general health maintenance schedule, including gender- related and age-specific recommendations, routine vaccinations, and dental care	I-A	Included
Outpatient Management			
Anti-Coagulation	Patients with MCSD should receive anti-coagulation with warfarin to maintain an INR within a range as specified by each device manufacturer	I-B	Not Included
Evaluation and Management of Hemolysis	Hemolysis in the presence of altered pump function should prompt admission for optimization of anti- coagulation and anti-platelet management and possible pump exchange	I-B	Not Included
ICD Placement	For patients who have an ICD prior to MCS, the ICD should be reactivated in the post-operative setting	I-A	Not Included
	Routine placement of an ICD should be considered for patients who did not have an ICD prior to MCS	IIa-B	Included

VIII. Appendix B

Recommendations excluded due to low levels of evidence.

Topic	Recommendation	Evidence Level
Patient Selection and Risk Management		
Clinical Classification of MCS Candidates	All patients being considered for MCS should have their New York Heart Association functional class assessed	I-C
Risk-Stratification for Consideration of MCS	Patients with end-stage systolic heart failure who do not fall into recommendations 1 and 2 above should undergo routine risk stratification at regular intervals to determine the need for and optimal timing of MCS. This determination maybe aided by risk assessment calculators and cardiopulmonary stress testing	IIa-C
	Heart failure patients who are at high-risk for 1-year mortality using prognostic models should be referred for advanced therapy including heart transplant, or MCS (bridge to transplantation [BTT] or destination therapy as appropriate.	IIa-C
Coronary Artery Disease	Patients being considered for MCS who have a history of coronary artery bypass grafting should have a chest computed tomography (CT) scan to provide the location and course of the bypass grafts to guide the surgical approach	IIa-C
Acute Myocardial Infarction	If possible, permanent MCS should be delayed in the setting of an acute infarct involving the left ventricular (LV) apex	IIb-C
Evaluation of MCS Candidates with Congenital Heart Disease	All patients with congenital heart disease should have recent imaging to fully document cardiac morphology, assess for the presence of shunts or collateral vessels, and the location and course of their great vessels	I-C
	Patients with complex congenital heart disease, atypical situs, or residual intraventricular shunts who are not candidates for LV support should be considered for a total artificial heart	IIa-C
Aortic Valve Disease	Functioning bio prosthetic valves do not require removal or replacement at the time of implant	I-C
	Replacement of a pre-existing aortic mechanical valve with a bio prosthetic valve or over sewing the aortic valve at the time of implantation is recommended	I-C
Aortic Regurgitation	More than mild aortic insufficiency should prompt consideration for surgical intervention during device implantation	I-C
Aortic Stenosis	Patients with aortic stenosis of any degree that is accompanied by more than mild aortic insufficiency should prompt consideration for a bio prosthetic aortic valve replacement during MCS implant	I-C
	Patients with severe aortic stenosis may be considered for aortic valve replacement, regardless of the degree of concomitant aortic insufficiency	I-C
Aortic Root Disease	Patients with a history of vascular disease and/or coronary artery disease should have a pre-operative assessment of their ascending aorta for aneurysmal dilation and atherosclerotic burden with a CT scan prior to implant	IIa-C
Mitral Valve	Severe mitral insufficiency is not a contraindication to MCS and does not routinely require surgical repair or valve replacement, unless there is expectation of ventricular recovery	IIb-C
	Routine mitral valve repair or replacement for severe mitral regurgitation is not recommended	III-C
Mitral Valve Stenosis	Valve replacement with a tissue valve should be considered if there is moderate or worse mitral valve stenosis at the time of left ventricular assist device (LVAD) implantation	I-C
Mechanical Mitral Valves	Routine replacement of properly functioning mechanical mitral valve is not recommended	III-C
Tricuspid Valve Regurgitation	Moderate or greater tricuspid regurgitation should prompt consideration of surgical repair at the time of implant	IIa-C

Topic	Recommendation	Evidence Level
Infective Endocarditis	Device implantation in patients who have been bacteremia should have documented clearance of the bacteremia for at least 5 days on appropriate anti-microbial therapy. This anti-microbial therapy should include a total duration of at least 7 total days prior to MCSD implantation	I-C
	Acute valvular infectious endocarditis with active bacteremia is an absolute contraindication to MCS implantation	III-C
	Active infection of an implantable cardioverter defibrillator (ICD) or pacemaker with bacteremia is an absolute contraindication to MCS implantation	III-C
Intracardiac Shunts	Atrial septal defects and patent for amenovale should be closed at the time of MCS implantation	I-C
	An LVAD alone in the setting of an unrepairable ventricular septal defect or free wall rupture is not recommended	III-C
Intracardiac Thrombus	Echocardiography or CT, with contrast when necessary, should be used pre-operatively to screen for intra cardiac thrombus	IIa-C
Atrial Arrhythmias	Atrial flutter or fibrillation is not a contraindication to MCS	I-C
	Patients with medically refractory atrial tachy arrhythmias may benefit from ablation of the arrhythmia or atrioventricular node (with subsequent ICD/pacemaker placement) prior to LVAD implantation	IIa-C
Arrhythmia Therapy	Patients with treatment-refractory recurrent sustained ventricular tachycardia (VT)or ventricular fibrillation (VF) in the presence of untreatable arrhythmogenic pathologic substrate (eg, giant cell myocarditis, scar, sarcoidosis), should not be considered for LV support alone, but rather biventricular support or a total artificial heart	IIa-C
Peripheral Vascular Disease	All patients with known atherosclerotic vascular disease or significant risk factors for its development should be screened for peripheral vascular disease prior to MCS	IIa-C
	Peripheral vascular disease may be a relative contraindication to MCS based on its extent and severity	IIb-C
Life-Limiting Co-Morbidities and Multiorgan Failure	Consideration of MCS in the setting of irreversible multi-organ failure is not recommended	III-C
Pulmonary Hypertension	All patients being considered for MCS should have an invasive hemodynamic assessment of pulmonary vascular resistance	I-C
Neurologic Function	A thorough neurologic examination should be performed on every patient being considered for MCS. Neurologic consultation should be obtained for patients with significant neurologic disease or dementia, or significant atherosclerotic vascular disease of their carotid or vertebral systems	I-C
	All patients being considered for MCS should have a carotid and vertebral Doppler examination as a screen for occult vascular disease	I-C
	CT scan or magnetic resonance imaging is warranted in patients with previous stroke to establish a pre-operative baseline study	I-C
	MCS is not recommended inpatients with neuromuscular disease that severely compromises their ability to use and care for external system components or to ambulate and exercise	III-C
Coagulation and Hematologic Disorders	All patients evaluated for MCS therapy should have a prothrombin time/international normalized ratio (INR), partial thromboplastin time, and platelet assessed pre-operatively	I-C
	Baseline abnormalities in coagulation parameters not due to pharmacologic therapy should prompt an evaluation to determine the etiology prior to implant	I-C
	Patients with a history of thrombophilia prior to MCS should have a hypercoagulable assessment before implant	I-C
	Patients with a clinical syndrome of heparin-induced thrombocytopenia should have confirmatory testing performed	IIa-C
	Thienopyridine anti-platelet agents should be stopped at least 5 days prior to surgery unless there is a compelling indication for continued use	IIa-C

Topic	Recommendation	Evidence Level
Malignancy	Patients with a history of a treated cancer who are in long-term remission or who are considered free of disease may be candidates for MCS as BTT, with the involvement of an oncologist to determine risk of recurrence or progression	I-C
	Patients with a history of recently treated or active cancer who have a reasonable life-expectancy (42 years) may be candidates for destination therapy if evaluated in conjunction with an oncologist to determine risk	IIa-C
	MCS as BTT or destination therapy is not recommended for patients with an active malignancy and a life expectancy of < 2 years	III-C
Diabetes	All patients should be screened for diabetes with a fasting glucose prior to MCS	I-C
	All patients with an abnormal fasting glucose or established diabetes should have a hemoglobin A1c assessed and be evaluated for the degree of end-organ damage (retinopathy, neuropathy, nephropathy, and vascular disease).	I-C
	Patients with poorly controlled diabetes should have a consultation with an endocrinologist prior to implantation	I-C
	Diabetes-related proliferative retinopathy, very poor glycemic control, or severe nephropathy, vasculopathy, or peripheral neuropathy	IIb-C
Pregnancy	Use of contraception in women of child bearing age after MCS is recommended	I-C
	MCS in the setting of active pregnancy is not recommended	III-C
Age	Patients aged > 60 years should undergo thorough evaluation for the presence of other clinical risk factors that may decrease survival or quality of life after MCS	IIb-C
Psychologic and Psychiatric Evaluation	All patients should have a screen for psychosocial risk factors prior to MCS	I-C
	All patients should have a screen for cognitive dysfunction prior to MCS	I-C
	Family, social, and emotional support must be assessed prior to MCS	I-C
	Patients with a history of a significant psychiatric illness who are considered for MCS should undergo a thorough psychiatric and psychologic evaluation to identify potential risk factors	I-C
	MCS should not be performed in patients who are unable to physically operate their pump or respond to device alarms. In addition, an inability to report signs and symptoms of device malfunction or other healthcare needs to the MCS team, or patients who live in an unsafe environment are all contraindications to implantation	III-C
	MCS is not recommended in patients with active psychiatric illness that requires long-term institutionalization or who have the inability to care for or maintain their device	III-C
Adherence to Medical Therapy and Social Network	Assessment of medical compliance, social support, and coping skills should be performed in all candidates for MCS device implantation	I-C
	Lack of sufficient social support and limited coping skills are relative contraindications to MCS in patients with a history of non-adherent behavior	IIa-C
	Poor compliance with medical regimens is a risk factor for poor outcomes related to MCS and death after heart transplantation. Patients who demonstrate an inability to comply with medical recommendations on multiple occasions should not receive MCS	III-C
Tobacco Use	Patients considered for MCS implantation should receive education on the importance of tobacco cessation and reduction in environmental and second-hand exposure before device implantation and throughout the duration of device support	I-C
	Previous tobacco use should not preclude emergent pump implantation as a potential BTT. However, patients should not be made active on the transplant waiting list until 6 months of nicotine abstinence has been proven	IIa-C
Alcohol and Substance Abuse	The patient should be abstinent for a period of time as determined a priori by the program in order to be considered for MCS therapy	IIb-C
	Active substance abusers (including alcohol) should not receive MCS therapy	III-C
Caregiver Burden	Caregiver burden should be assessed prior to MCS implantation to assure that support will be available. Agreement on behalf of the patient is not sufficient	I-C
	Significant caregiver burden or lack of any caregiver is a relative contraindication to the patient's MCS implantation	IIb-C

Topic	Recommendation	Evidence Level
Evaluation of Patient's Financial Situation and Insurance Coverage	A mechanism must be in place to provide financial aid or support for post-operative care for those who have limitations to medical coverage. Depending on the country, this may be provided by the government, an insurance agent, or an individual's family	IIa-C
Patient Optimization and Risk Modification		
Managing Patient Expectations	A detailed informed consent should discuss the salient aspects of the MCSD placement, common expectations, and possible complications in the peri-operative and post-operative period	I-C
	Quality of life should be assessed before and after MCSD implantation to help guide patient decisions. Assessment tools, including Minnesota Living with Heart Failure questionnaire, Sickness Impact Profile, Euro Qol, and others should be considered to help guide patient care	IIb-C
Palliative Care	Palliative care consultation should be a component of the treatment of end-stage heart failure during the evaluation phase for MCS. In addition to symptom management, goals and preferences for end of life should be discussed with patients receiving MCS as destination therapy	IIa-C
Managing Renal Function	All patients should have their renal function monitored closely prior to MCSD implantation	I-C
	Patients with volume overload and/or poor output in the setting of renal dysfunction should have a period of hemodynamic optimization (with inotropic support if clinically indicated) combined with aggressive diuresis or mechanical volume removal	I-C
	Assessment of serum creatinine, blood urea nitrogen, and a 24-hour urine collection for creatinine clearance and proteinuria after patients are hemodynamically optimized should be performed in all patients being considered for MCS	I-C
	Permanent dialysis should be a contraindication for destination therapy	III-C
Nutritional Assessment	Patients who have indices of malnutrition prior to MCSD implantation should have an evaluation by a nutritional consultation service	I-C
	Patients who have evidence of malnutrition prior to MCSD implantation should be considered for nutritional interventions prior to implantation if the patient's clinical status allows	IIa-C
	Patients who have evidence of severe malnutrition prior to MCSD implantation should consider having implantation delayed to maximize the nutritional status, if the patient's clinical status allows	IIb-C
Managing Infection Risk	All patients should have all unnecessary lines and catheters removed prior to MCSD implantation	I-C
	All patients should have a dental assessment and any remedial treatment, if time and clinical status permits, prior to MCSD implantation	I-C
Managing Active Infection	Patients with active infections should receive an appropriate course of antibiotic therapy, as directed by an infectious disease specialist, prior to MCSD implantation	I-C
Antibiotic Prophylaxis	Patients should receive pre-operative antibiotics with broad-spectrum gram-positive and gram-negative coverage, as appropriate, prior to MCSD implantation	I-C
	Routine antibiotic prophylaxis should include at least 1 dose prior to surgery administered within 60 minutes of the first incision, remain in the therapeutic range throughout the duration of their use, and not extend beyond 24 to 48 hours	I-C
	Patients should have a nasal swab to screen for methicillin-resistant Staphylococcus aureus and receive topical treatment if positive prior to MCSD implantation	I-C
Hepatic Dysfunction	Patients with a history of liver disease, abnormalities of liver function tests, chronic right heart failure, or Fontan physiology should have an ultrasound assessment of their liver to screen for cirrhosis prior to MCSD implantation	I-C
	Patients who have suspected cirrhosis should receive further radiologic and tissue confirmation in conjunction with a hepatology consultation	I-C

Topic	Recommendation	Evidence Level
	Patients with abnormal liver function and decompensated hemodynamics should receive aggressive therapy aimed at the restoration of hepatic blood flow and reduction of hepatic congestion	I-C
	Patients with an elevated INR not due to warfarin therapy should be considered for treatment prior to MCSD implantation, and efforts should be made to optimize nutrition and right-sided intra cardiac filling pressures	II-C
Pulmonary and Thoracic Assessment	Patients should have a chest X-ray and an arterial blood gas assessment prior to MCSD implantation	I-C
	Patients should have some assessment of thoracic anatomy prior to MCSD implantation or in the setting of prior surgery or suspected thoracic abnormalities. These may include a radiologic examination with CT or magnetic resonance imaging	I-C
	Positive airway pressure, early ambulation, induced cough, incentive spirometry, and effective pain control subsequent to surgery may all decrease post-operative complications	I-C
Management of Patients with Decompensated Heart Failure	Short-term mechanical support, including extracorporeal membrane oxygenation, should be used in acutely decompensated patients who are failing maximal medical therapy	I-C
Temporary Mechanical Support	The use of temporary mechanical support should be strongly considered in patients with multi-organ failure, sepsis, or on mechanical ventilation to allow successful optimization of clinical status and neurologic assessment prior to placement of a long-term MCSD	I-C
Assessing RV Function	All patients should have an echocardiographic assessment of RV function prior to MCSD implantation	I-C
	All patients should have invasive assessment of intra cardiac filling pressures prior to MCSD implantation, with a particular emphasis on RV hemodynamics	I-C
Management of RV Dysfunction	Pre-operatively, patients with evidence of RV dysfunction should be admitted to the hospital for aggressive management, which may include diuresis, ultrafiltration, inotropes, intra-aortic balloon pump, or other short-term mechanical support. Once optimized, RV function should be reassessed	I-C
	RV dysfunction post-MCS should be managed with diuresis, inotropes, and pulmonary vasodilators, including nitric oxide or inhaled prostacyclin. RV dysfunction refractory to medical management may require placement of a short-term or long-term mechanical RV support device	I-C
	Phosphodiesterase 5 inhibitors may be considered for management of RV dysfunction in the setting of pulmonary hypertension after MCS	IIb-C
Intraoperative and Immediate Post-Operative Management		
Right-Heart Dysfunction in the non-ICU Post-Operative Period	Inotropic support may need to be continued into the remote post-operative period (> 2 weeks) when there is evidence for right heart dysfunction such as elevated jugular venous pressure, signs of venous congestion, decreased VAD flows (or low pulsatility in continuous-flow MCSD), or end-organ dysfunction. Once euvolemic, inotrope wean should be done cautiously, with ongoing examination for recurrent signs and symptoms of RV dysfunction	I-C
	Diuretics and renal replacement therapy, such as continuous veno venous hemofiltration, should be used early and continued as needed to maintain optimal volume status	I-C
	Cardiac glycosides may be used to support RV function	IIb-C
	For patients with persistent pulmonary hypertension who exhibit signs of RV dysfunction, pulmonary hypertension-specific therapies, such as phosphodiesterase-5 inhibitors, should be considered	IIb-C
	Pacemaker therapy can be used if the heart rate is not optimal to support hemodynamics	IIb-C
Managing Hypotension in the non-ICU Post-Operative Period	A systematic approach to hypotension should be used	I-C

Topic	Recommendation	Evidence Level
Neurohormonal Blockade and the Treatment of Hypertension post-MCS Implant	Pharmacotherapy with heart failure medications (angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, b-blocker, hydralazine, nitrates) is preferred for blood pressure management	I-C
Echocardiography in the non-ICU Post-Operative Period	Echocardiography is an integral part of determining the revolutions per minute of continuous-flow pumps. Common goals include adequate LV unloading while maintaining the LV septum in the midline and minimizing mitral regurgitation	I-C
Anti-Coagulation and Anti-Platelet Therapy Post-MCS Therapy	Bleeding in the early post-operative period during the index hospitalization should be urgently evaluated with lowering, discontinuation and/or reversal of anti-coagulation and anti-platelet medications	I-C
Infection Prevention Post-MCS Therapy	The driveline should be stabilized immediately after the device is placed and throughout the duration of support	I-C
	A dressing change protocol should be immediately initiated post-operatively	I-C
	Secondary antibiotic prophylaxis for prevention of endocarditis has not been studied in the MCS population but would be considered reasonable due to the risk of bacteremia in this group	I-C
Optimization of Nutritional Status	Consultation with nutritional services should be obtained at the time of implantation with ongoing follow-up post-operatively to ensure nutrition goals are being met	I-C
	Post-operatively for those unable to meet nutritional goals orally, feeding should be started early and preferably through an enteral feeding tube. Parenteral nutrition should only be started if enteral nutrition is not possible and under the guidance of nutritional consultation	I-C
	Pre-albumin and C-reactive protein levels can be monitored weekly to track the nutritional status of the post-operative patient. As nutrition improves, pre-albumin should rise and C-reactive protein should decrease	I-C
Healthcare Provider and Patient Education	Healthcare providers should be trained in MCSD therapy with opportunity to attend refresher classes and ongoing assessment of competency	I-C
	Patient and caregiver education should be initiated shortly after surgery and reinforced by the nursing staff. Educational strategies should use written, verbal, and practical methods	I-C
Documentation of Device Parameters	MCS parameters should be recorded in the medical record at regular intervals with established criteria for parameters which require physician notification	I-C
Device Monitoring	Normal values for device parameters should be established and recorded in the medical record with triggers for physician notification	I-C
	The patient and family members should be taught to track their device parameters and alert staff when changes are observed	I-C
	Changes in parameters outside of normal ranges should be thoroughly evaluated and treated appropriately	I-C
Psychosocial Support While in Hospital	Routine support should be available from social workers, psychologists, or psychiatrists as patients and families adjust to life changes after MCS	I-B
Discharge	Caregiver and community provider education with written discharge instructions and pre-emptive home preparation regarding the safe management of the device and the MCS patient is recommended	I-C
Anti-Coagulation and Anti-Platelet Therapy for Patients who Present with Gastrointestinal Bleeding	Anti-coagulation and anti-platelet therapy should be held in the setting of clinically significant bleeding	I-C
	Anti-coagulation should be reversed in the setting of an elevated INR and clinically significant bleeding	I-C
	Anti-coagulation and anti-platelet therapy should continue to be held until clinically significant bleeding resolves in the absence of evidence of pump dysfunction	I-C
	The patient device parameters, and the pump housing (if applicable) should be carefully monitored while anti-coagulation and anti-platelet therapy is being withheld or the dose reduced	I-C
Evaluation and Management of Patients	Patients should be managed in consultation with gastroenterology	I-C
	Patients should at least have a colonoscopy and/or upper endoscopic evaluation	I-C

Topic	Recommendation	Evidence Level
who Present with First Episode of Gastrointestinal Bleeding	If the result of the colonoscopy and/or upper endoscopic evaluation is negative, evaluation of the small bowel, particularly in those with continuous-flow devices, should be considered	I-C
	In the setting of persistent bleeding and a negative endoscopic evaluation, a tagged red blood scan or angiography should be considered	I-C
	Once the gastrointestinal bleeding has resolved, anti-coagulation and anti-platelet therapy can be reintroduced with careful monitoring	I-C
Evaluation and Management of Patients who Present with Recurrent Gastrointestinal Bleeding	Repeated endoscopic evaluation should take place in conjunction with gastroenterology consultation	I-C
	In the setting of recurrent gastrointestinal bleeding with no source or a source that is not amenable to therapy, the type and intensity or even the use of anti-platelet therapy should be re-evaluated in the context of the bleeding severity and pump type	I-C
	In the setting of recurrent gastrointestinal bleeding with no source or a source that is not amenable to therapy, the goal INR or even the continued use of warfarin should be re-evaluated in the context of the bleeding severity and pump type	I-C
	The patient and device parameters should be carefully monitored when anti-coagulation and anti-platelet therapy have been reduced or discontinued due to recurrent gastrointestinal bleeding	I-C
	Reducing the pump speed for continuous-flow pumps in the setting of recurrent gastrointestinal bleeding due to arteriovenous malformations may be considered	IIb-C
Acute Management of Patients who Present with New Neurologic Deficit	Review of pump parameters for signs of device thrombosis or malfunction is recommended	I-C
	Inspection of pump housing for clots in extracorporeal pumps is recommended	I-C
	Selective use of an interventional radiologic approach to thrombotic strokes may be considered	IIb-C
	Selective use of thrombolytic agents in the setting of thrombotic stroke without CT scan evidence of hemorrhage may be considered	IIb-C
	Routine use of an interventional radiologic approach to thrombotic strokes is not recommended	III-C
	Routine use of thrombolytics in the setting of thrombotic stroke without head CT scan evidence of hemorrhage is not recommended	III-C
Chronic Management of Patients After Presentation with New Neurologic Deficit	Close monitoring of anti-coagulation in the setting of an embolic event to assure adequate levels of anti-coagulation is recommended	I-C
	Administration of National Institutes of Health (NIH) stroke scale at 30 and 60 days after a neurologic event is recommended	I-C
	Resumption of anti-coagulation in consultation with neurology or neurosurgery in the setting of hemorrhagic stroke is recommended	I-C
Assessment of Neurocognitive Deficits	Routine neurocognitive assessment at 3, 6, 12, and 18 months after implant is recommended	I-C
Evaluation of MCS Patient with Suspected Infection	Erythrocyte sedimentation rate or serial C-reactive protein should be considered	IIa-C
	Routine CT of the chest, abdomen, and pelvis is not recommended	III-C
Inpatient Treatment of Ventricular Arrhythmias	MCS patients with incessant ventricular arrhythmias require prompt admission for further management because hemodynamic compromise may occur	I-C
	Patients with ongoing VT refractory to medical therapy may require catheter ablation, which should be performed by an electro physiologist with the requisite knowledge and expertise in treating patients with MCS	I-C
RV Function	RV dysfunction after LVAD placement may occur as a late manifestation with symptoms and signs of right heart failure and changes in LVAD parameters, including a decrease in flows and pulsatility. Further evaluation should include an echocardiogram and right heart catheterization	I-C
	When evidence of RV dysfunction exists, MCS patients may need to be admitted to the hospital for optimization, which may include initiation of inotropic support	I-C

Topic	Recommendation	Evidence Level
Device Failure and Malfunction	Pump stoppage of a continuous-flow MCSD constitutes a medical emergency, and the patient should be rapidly transported back to the implanting center or another expert MCSD center for treatment	I-C
	Definitive therapy for pump stoppage is surgical pump exchange if the patient is stable enough to undergo reoperation	I-C
	Patients with a functioning pump, but with alarms or changes in parameters that cannot be resolved as an outpatient, may need to be admitted to the hospital for observation and close monitoring	I-C
Management of MCS Patient During Non-Cardiac Procedures	The MCS team should be made aware when an MCS patient is undergoing a non-cardiac procedure so that collaboration between the MCS and surgical teams can take place	I-C
	For non-emergency procedures, warfarin and anti-platelet therapy may be continued if the risk of bleeding associated with the procedure is low. If therapy needs to be stopped, warfarin and anti-platelet therapy should be held for an appropriate period of time as determined by the type of procedure being undertaken and risk of bleeding. Bridging with heparin or a heparin alternative while a patient is off warfarin may be considered	I-C
	During minor procedures, blood pressure monitoring with Doppler is appropriate	I-C
	During procedures with risk of hemodynamic instability, an arterial catheter should be placed for blood pressure monitoring	I-C
	During non-cardiac procedures, MCSD parameters should be continuously monitored by expert personnel such as MCS nurses or perfusionists	I-C
	A cardiovascular surgeon should be in the operating room or immediately available, especially in situations when the non-cardiac procedure is occurring close to the MCSD	I-C
	Whenever possible, the surgeon performing the non-cardiac procedure should have experience in operating on patients with MCSD	II-C
Outpatient Management		
Evaluation of Safety of Home Environment	An uninterrupted supply of electricity to continuously power the MCSD must be ensured. Outlets must be grounded, and the use of electrical extension cords or outlets with a switch should be avoided. The local electrical company must be notified of the customer's need for electricity to power life-sustaining equipment in the home. Patients are advised to develop an emergency plan in the event electricity becomes unavailable in the home	I-C
	Patients should have a working telephone to allow outgoing calls in the event of an emergency and to allow the implanting center to contact the patient. The patient should familiarize himself or herself with paging the MCS team should an actual emergency arise	I-C
	Equipment at home should be placed in a configuration that minimizes the risk of falls, allows easy access to living and sleeping areas, and allows family members to hear alarms. Lighting should be adequate. The bathroom should be safe for showering with a shower chair, and have the appropriate toilet seat or any other necessary physical aids	IIa-C
	A discharge checklist may be developed to facilitate communication regarding the specific necessary home modifications and to document progress in meeting these requirements prior to discharge	IIa-C
Community Outreach by MCS Team	Community outreach should be performed by the implanting center's MCS team to inform the local health care providers, including emergency medical services personnel, emergency department staff, and referring physicians, of the reintegration of the MCSD patient to his or her local environment. Education should be delivered so providers have knowledge of the concepts involving MCS and the associated physiologic changes	I-C
	Appropriate emergency maneuvers should be reviewed with local health care providers. Consideration may be given to developing a field guide for emergency medical services personnel to aid in emergency responses	IIa-C

Topic	Recommendation	Evidence Level
Assessment of Social Network	The primary designated caregiver should demonstrate competency in functioning of the MCSD and the appropriate response to alarms	I-C
	The MCS team designee must interview patients and family members regarding the strength and depth of their social support. The social worker or other MCS staff member may need to develop a formal ''social contract'' with the patient's social network and/or caregiver(s) that outlines their commitment and responsibilities to ensure they are prepared to assist patients with device and/or driving needs until the patient is able	I-C
	A survey tool should be developed that allows patients to provide feedback to the MCS program on their preparedness for the transition to the home environment. The multidisciplinary MCS team should review survey results at regular intervals to help facilitate programmatic improvements	IIb-C
Operation of Motor Vehicle	Clearance to drive a motor vehicle is a center-specific decision and should be guided by local laws	IIb-C
Multidisciplinary Approach to Follow-Up Care	Management of the patient with an MCSD should be performed by a multidisciplinary team that includes cardiovascular surgeons, advanced heart failure cardio- gist's, and specialized MCS coordinators. Other health care providers may collaborate with the primary MCS team when additional expertise is required	I-C
Right-Heart Catheterization	Right heart catheterization should be performed to help corroborate evidence of myocardial recovery. The pulmonary artery catheter may be left in place with serial lowering of the pump speed to confirm acceptable hemodynamics with decreasing VAD support prior to pump explanation	IIa-C
Functional Capacity Testing	Cardiopulmonary stress testing and/or 6-minute walk testing performed at regular intervals may be helpful in objectively assessing functional capacity in patients with MCSD. Suggested intervals are 3 months, 6 months, at 6-month intervals through 2 years after implant, and then yearly thereafter	IIa-C
Laboratory Studies	Laboratory studies should be obtained at regular intervals to assess end-organ function, monitor device-specific issues, and diagnose or monitor the status of comorbid conditions	I-C
Assessment of the MCSD	The driveline, exit site, and MCSD components should be examined at each clinic visit to ensure their integrity. Alarm history and downloads should be obtained at regular intervals. Pump parameters should be reviewed regularly and adjusted accordingly to optimize pump functioning for the duration of time the patient is on support	I-C
	The driveline should be assessed for proper position and use of binder or driveline immobilization at each clinic visit	I-C
	The patient should be trained in proper self-care, including showering technique and dressing changes, prior to hospital discharge. These skills may need reinforcement over the patient's lifetime, depending on the clinical course	I-C
Exercise and Cardiac Rehabilitation	All patients who are able should be enrolled in cardiac rehabilitation after surgical placement of an MCSD	I-C
Anti-Platelet Therapy	Chronic anti-platelet therapy with aspirin (81–325 mg daily) may be used in addition to warfarin in patients with MCSD	I-C
	Anti-platelet therapy beyond aspirin may be added to warfarin according to the recommendations of specific device manufacturers	I-C
	Assessment of platelet function may be used to direct the dosing and number of anti-platelet drugs	IIb-C
Heart Failure Therapy	Diuretic agents are useful for the management of volume overload during MCS	I-C
	An angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker may be used for hypertension or for risk reduction in patients with vascular disease and diabetes	I-C
	b-Blockers may be used for hypertension or for rate control in patients with tachy arrhythmias	I-C
	Mineralocorticoid receptor antagonists may be used to limit the need for potassium repletion in patients with adequate renal function and for potential beneficial anti-fibrotic effects on the myocardium	I-C

Topic	Recommendation	Evidence Level
	Digoxin may be useful in the setting of atrial fibrillation with rapid ventricular response	II-C
Hypertension Management	Patients with pulsatile MCSDs should have a blood pressure goal of systolic blood pressure of o 130 mm Hg and a diastolic blood pressure of o 85 mm Hg	IIb-C
	Patients with non-pulsatile MCSDs should have a mean blood pressure goal of r 80 mm Hg	IIb-C
Diabetes Management	Patients with diabetes should have continued therapy and close follow-up for their diabetes while receiving MCS	IIa-C
Treatment of Renal Disease	Renal function should be monitored on an ongoing basis after MCSD placement	IIb-C
	Persistent renal insufficiency after MCS should prompt further evaluation and management in collaboration with nephrology	IIb-C
Evaluation and Management of Hemolysis	Screening for hemolysis should occur in the setting of an unexpected drop in the hemoglobin or hematocrit level or with other clinical signs of hemolysis (eg, hemoglobinuria)	I-C
	Routine screening for hemolysis with lactate dehydrogenase and plasma-free hemoglobin assessment in addition to hemoglobin or hematocrit should occur periodically throughout the duration of MCS	IIa-C
Dietary Management	Weight loss should be encouraged for all patients with a body mass index 430 kg/m2	IIa-C
Smoking and Substance Abuse	Smoking cessation should be encouraged in all patients on MCS who continue to use tobacco	I-C
	Alcohol and drug treatment programs should be required for patients with a history of substance abuse	IIa-C
ICD Placement	Inactivation of the ICD should be considered in patients with biventricular assist devices who are in persistent VT/VF or who have frequent sustained runs of VT despite optimal anti-arrhythmic therapy	IIa-C
Management of Atrial Fibrillation and Flutter	Cardioversion of atrial fibrillation is recommended in patients with rapid ventricular rates that compromise device performance	I-C
	When atrial fibrillation is present and does not interfere with device functioning, management following the most recent American College of Cardiology/American Heart Association atrial fibrillation guidelines (2011) is recommended	IIa-C
Management of Ventricular Arrhythmias	Cardioversion is recommended for VT that results in poor device flows and/or hemodynamic compromise	I-C
	The occurrence of VT on MCS should prompt a search for reversible causes such as electrolyte abnormalities or drug toxicities	I-C
	Amiodarone is a reasonable chronic outpatient treatment to prevent recurrence of VT in patients with MCS	IIa-C
	Therapy with b-blockade may be a useful in the setting of recurrent VT	IIa-C
	Recurrent VT in the setting of a continuous-flow pump should prompt consideration of a suction event	IIa-C
	In patients with biventricular support with VF who are refractory to therapy, but have stable flows, the patient may be left in VF with the defibrillator function of the ICD turned off	IIb-C
Psychologic and Psychiatric Issues	Patients being considered for MCSD should have a detailed psychosocial evaluation	I-C
	A formal consultation with a psychiatrist should be obtained for those with concerns for psychiatric illness. Appropriate pharmacologic and psychologic therapy should be initiated as needed. Counseling may need to be extended to include family members as well	I-C
Emergency Procedures for Device Failure or Malfunction	The patient and their caregivers should be trained to recognize MCSD alarms and troubleshoot emergencies prior to hospital discharge. This training should be delivered using both written materials and visual demonstrations, and emergency response skills should be tested before the patient and caregiver leave the hospital	I-C
	Ongoing refreshers should be provided to patients and caregivers at outpatient visits to ensure they remain competent in emergency procedures	I-C

Topic	Recommendation	Evidence Level
	An emergency on-call algorithm should be established that patients and caregivers are familiar with so they may quickly contact the implanting center in the event of emergencies	I-C
	An emergency transport system should be established to expedite transfer to the implanting center in the case of emergency	I-C
End of Life Issues	Consultation with palliative medicine should be considered prior to MCSD implantation to facilitate discussion of end of life issues and establish an advance directive or living will, particularly when implanted as destination therapy	I-C
	In situations when there is no consensus about discontinuing MCSD support, consideration may be given to consulting with the hospital ethicist or ethics board	I-C

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