
INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION
(ISHLT)

# MECHANICAL CIRCULATORY SUPPORT CORE COMPETENCY CURRICULUM

## (ISHLT MCS CCC)

THIRD EDITION
JULY 2015

**THE EDUCATIONAL WORKFORCE OF THE**

**ISHLT MECHANICAL CIRCULATORY SUPPORT COUNCIL**

# ISHLT MCS CCC: List of Contents

# I. INTRODUCTION AND OVERALL GOALS

The purpose of this compendium is to provide a curriculum of core competencies in mechanical circulatory support. The ISHLT Academy provides a concise synopsis of clinical *knowledge* and associated essential professional *skills* to facilitate the mastery of all surgical and medical aspects involved in the care of patients receiving mechanical circulatory support devices.

This compendium does not replace a textbook, but intends to provide an outline of essential topics and aims to assist with detailed review. This should be of benefit for both seasoned clinicians and current trainees. The former may find selective revision of complimentary areas in mechanical circulatory support useful, whereas the latter may benefit from a more complete review of all topics during fellowship or other subspecialty training in mechanical circulatory support.

Inevitably, some overlap of clinically related aspects may have occurred. Extensive referencing should assist selective review of published evidence for each topic.

The core curriculum should also serve programs providing mechanical circulatory support with a tool to review their standards of care, develop protocols and implement guidelines established in lung transplantation.

Wherever possible, specific learning objectives have been defined.

The educational workforce of the Mechanical Circulatory Support Council of ISHLT hopes that this compendium will prove to be useful. We would welcome constructive feedback to further develop its scope and accuracy.

## Overall Learning Objectives

To assist practitioners in developing improved competence and professional performance in their ability to:

1. Risk stratify patient with advanced heart failure in order to assess MCS surgical risk and optimally time mechanical circulatory support (MCS) implantation.
2. Recognize the medical and social factors which impact patient outcomes during short- and long-term MCS.
3. Recognize the various types of MCS support available for patients with advanced single or biventricular heart failure and the technological differences that may impact pump selection and patient/device management.
4. Optimize MCS implantation techniques and patient/pump management during the index admission intensive care unit and inpatient general care periods.
5. Manage patients and the MCS during outpatient long-term support with an understanding of interventions that can reduce patient- and device-related adverse events during MCS.
6. Diagnose and manage common clinical dilemmas and adverse encountered after MCS.

Learning objectives covered in this document complement the MCS portion of the curriculum of an ACGME accredited advanced heart failure and transplant fellowship in the U.S., which is required for American Board of Internal Medicine sub-specialty certification. As fellows gain experience and demonstrate growth in their ability to care for patients, they will assume roles that permit graded and progressive responsibility for patients with MCS.

## MCS Guidelines

The executive summary of the 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support was released electronically in January 2013 with publication of the Executive Summary in the February Journal of Heart and Lung Transplantation (Feldman DA, Pamboukian SV, Teuteberg JJ, et al J Heart Lung Transplant 2013; 32:157-187..

The complete Guidelines consist of 5 separate Task Forces:

Task force 1: Patient selection
Task force 2: Pre-operative optimization

Task force 3: Intra- and post-operative management
Task force 4: Inpatient management
Task force 5: Outpatient management

## II. Review of the Current State of MCS and Devices for Temporary and Permanent Circulatory Support

### Learning Objectives for the Current State of MCS

1. Understand the indications for temporary and permanent MCS and the different types of devices available for support.
2. Distinguish the basic technological differences between different temporary and permanent MCS systems and the levels of support provided by each. Review the MCS technology in development
3. Understand the differences between bridge to transplant, bridge to recovery and destination therapy
4. Understand the application and prognostication of INTERMACS Patient Profiles
5. Summarize outcomes and adverse events for current devices among the various implant strategies
6. Understand the mortality associated with cardiogenic shock (INTERMACS profile 1-2) and the device strategies available for single and biventricular failure with shock.
7. Review the components and operation of extracorporeal membrane oxygenation
8. Understand the outcomes and adverse events for patients who require support with ECMO

### Selected References for the Current State of MCS


1. Miller, Pagani, Russell et al NEJM 2007; 357:885-896.
2. Pagani, Miller, Russell et al JACC 2009;54:312-321.
3. Starling, Naka, Boyle et al JACC 2011;57:1890-8.
4. Slaughter et al. New Engl J Med 2009;361:2241-51.
5. Aaronson, Slaughter, Miller, et al. Circulation 2012;125:3191-3200.
6. Kirklin, Naftel, Kormos, et al. J Heart Lung Transplant 2012;31:117-26.
7. Genovese, Dew, Teuteberg, et al. J Heart Lung Transplant 2010;29:981-9.
8. Rastan et al. J Thorac Cardiovasc Surg 2010;139:302-311.
9. Brogan, Thiagarajan, Rycus, et al. Intensive Care Med 2009;35:2105-14.
10. Beurtheret, Mordant, Paoletti, et al. Eur Heart J 2012; epublished.
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12. Hasin T, et al. J Am Coll Cardiol. 2013 Jan 15;61(2):153-63.
13. Cowger J et al. J Am Coll Cardiol. 2013 Jan 22;61(3):313-21
14. Uriel N et al. J Am Coll Cardiol. 2012 Oct 30;60(18):1764-75.
15. Garan R et al. J Am Coll Cardiol. 2013 Jun 25;61(25):2542-50.
16. Slaughter MS et al. J Heart Lung Transplant. 2013 Jul;32(7):675-83.


## III. Patient Selection

### Learning Objectives for Patient Selection

1. Understand the variability in short- and long-term patient survival following MCS support and the importance of a multidisciplinary assessment of preoperative patient risk.
2. Understand the difficulties in prognostication of end-stage heart failure and survival on MCS.
3. Identify several means of estimating prognosis in end-stage heart failure and operative risk with MCS.
4. Understand the preop, intraop, and postoperative contributors to RV dysfunction
5. Apply risk modeling and imaging techniques to assess the possibility of RV dysfunction
6. Recognize the limitations to current imaging and risk prediction models of RV failure
7. Understand mechanisms of improving RV function in the preoperative setting

8. Identify other comorbidities and patient characteristics that may impact short- and long-term survival after MCS implant
9. Learn the importance of identifying and addressing renal and hepatic dysfunction prior to MCS
10. Understanding important preoperative optimization interventions to minimize MCS operative risks
11. Identify the triggers for MCS referral

**Selected References for Patient Selection**


1. Stevenson LW et al. INTERMACS profiles of advanced heart failure: the current picture. J Heart Lung Transplant 2009; 28: 535-41
2. Kirklin JK et al. Fifth INTERMACS annual report: risk factor analysis from more than 6.000 mechanical circulatory support patients. J Heart Lung Transplant 2013; 32:141-56.
3. Peura et al. Recommendations for the use of mechanical circulatory support : Device strategies and patient selection. Circulation 2012; 126: 2648-2667.
4. Ronco C. Cardio-renal syndromes: from foggy bottom to sunny hills. Heart Fail Rev 2011; 16: 509-17
5. Soloman SD et al. Influence of nonfatal hospitalization for heart failure on subsequent mortality in patients with chronic heart failure. Circulation 2007; 116: 1482-87
6. Furukawa, et al. Right ventricular failure after left ventricular device implantation: the need for an implantable right ventricular assist device. Artif Organs 2005:29;369-377.
7. Matthews et al. The right ventricular risk score: a predictive tool for assessing the risk of right ventricular failure in left ventricular assist device patients. J Am Coll Cardiol 2008:51;2163-72
8. Fitzpatrick et al. Risk score derived from pre-operative data analysis predicts the need for biventricular mechanical support. J Heart Lung Transplant 2008;27:1286-92
9. Kormos et al. Right ventricular failure in patients with the HeartMateII continuous-flow left ventricular assist device: incidence, risk factors, and effect on outcomes. J Thorac Cardiovasc Surg 2010;139:1316-24.
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12. Patlolla, V, et. al. Outcomes of patients with symptomatic cerebrovascular disease undergoing heart transplantation. J Am Coll Cardiol 2011;58:1036–41
13. Teuteberg et al. Characteristics of patients who die with heart failure and a low ejection fraction in the new millennium. J Card Fail 2006;12:47
14. Boyle AJ et al. Clinical outcomes for continuous-flow left ventricular assist device patients stratified by per-operative INTERMACS classification. J Heart Lung Transplant 2011; 30: 402
15. Russell SD, Miller LW, Pagani FD. Advanced heart failure: a call to action. *Congest Heart Fail.* 2008;14:316-321
16. Cowger J, Sundareswaran K, Rogers J, et al. The HeartMate II Risk Score: Predicting survival in candidates for left ventricular assist device support. J Am Coll Cardiol 2013; 61:313-21.
17. Cameli M, Matteo L. Speckle tracking echocardiography as a new technique to evaluate right ventricular function in patients with left ventricular assist device therapy. J Heart Lung Transplant 2013; 32:424-30.
18. Cogswell R, Substance abuse and adverse events after VAD. J Heart Lung Transplant. 2014; 33:1048-


# IV. SURGICAL CONSIDERATIONS

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**Learning Objectives for Patient Selection**

1. Understand criteria used to determine best patient-pump match - role of body habitus, prior surgery, right heart function and end-organ among others.
2. Determine optimal pump placement, outflow graft anastomosis creation and tunneling of driveline
3. Learn standard and minimally invasive techniques for VAD implantation
4. Learn alternative techniques for VAD implantation in challenging clinical scenarios
5. Learn different techniques for intraoperative hemodynamic support (CPB vs. ECMO vs. off-pump)
6. Recognize intra-operative hemodynamic and ventilatory goals

7. Learn optimal technique for separation from cardiopulmonary bypass - role of TEE and hemodynamics in determining best use of inotropic, pressor and pulmonary vasodilator therapies.
8. Learn to identify patients that will benefit from temporary mechanical right heart support.
9. Learn techniques for temporary mechanical right heart support (temporary RVAD, ECMO).
10. Understand indications for concomitant surgical procedures with particular attention to the tricuspid and aortic valves and patent foramen ovale. Learn to balance risk and benefit of concomitant surgical procedures.
11. Determine the risk and utility associated with concomitant operative procedures
12. Understand the potential risks associated with untreated aortic valve insufficiency at the time of VAD implantation
13. Learn to understand strengths and weaknesses of current devices. Optimize device selection for particular patient characteristics.

## Selected References for Patient Selection


1. Slaughter et al. Clinical management of continuous-flow left ventricular assist devices in advanced heart failure. J Heart Lung Transplant 2010;29: S1-S39.
2. Dranishnikov et al., Simultaneous aortic valve replacement in left ventricular assist device recipients: Single-center experience. Int J Artif Org 2012
3. John et al. Aortic valve pathophysiology during left ventricular assist device support. J Heart Lung Transplant 2010; 29:1321-9.
4. Krishan et al. Liberal use of tricuspid-valve annuloplasty during left ventricular assist device implantation.
5. Saeed et al. Tricuspid valve repair with left ventricular assist device implantation: is it warranted? J Heart Lung Transplant 2011; 30: 530-5.
6. Haberl et al. Viennese approach to minimize the invasiveness ventricular assist device implantation. Eur J Cardiothorac Surg. 2014 Dec;46(6):991-6
7. Noly et al. Temporary right ventricular support following left ventricle assist device implantation: a comparison of two techniques. Interactive cardiovascular and thoracic surgery 2014; 19:49-55.
8. Jorde et al. Prevalence, significance, and management of aortic insufficiency in continuous flow left ventricular assist device recipients. Circ Heart Fail. 2014 Mar 1; 7:310-9.
9. Robertson et al. Concomitant aortic valve procedures in patients undergoing implantation of continuous-flow left ventricular assist devices: An INTERMACS database analysis. J Heart Lung Transplant. 2015 Jun; 34 (6):797-805.
10. Robertson JO. Concomitant tricuspid valve surgery during implantation of continuous-flow left ventricular assist devices: a Society of Thoracic Surgeons database analysis. J Heart Lung Transplant. 2014 Jun; 33 (6):609-17.

## V. POST-OPERATIVE CARE

### Learning Objectives for Post-operative Care

1. How to assess the "fitness" of the right ventricle after surgery. This will include physiologic, anatomical and bedside clinical assessments.
2. Determine when to initiate anticoagulation, what type and how much after surgery. Adjustments in anticoagulation related to special considerations in unique patient populations and types of pumps will be covered.
3. Develop a deeper understanding of the advantages and limitations of the common imaging modalities and their clinical applications in postoperative VAD patients.
4. Development of a global treatment strategy to prevent, or consequently treat right ventricular dysfunction and failure after implantation of a left ventricular assist device.

## VI. TRANSITION TO HOME

### Learning Objectives for Transition to Home

Teaching/patient assessment:

1. Outline an approach to teaching MCS-related skills to patient, caregiver(s) and community
2. Learn methods to evaluate effectiveness of training

Outpatient management

1. Outline approaches to clinic structure
2. Summarize approach to outpatient visits
3. Highlight and review approaches to relevant long-term medical issues faced by MCS patients
4. Describe shared care models and discuss collaborative patient management between implanting and supporting centers in the community
5. Overview of pediatric management strategies

Quality of Life, functional capacity and end of life

1. Summarize measures of quality of life and functional capacity relevant to the MCS patient
2. Outline approaches to end-of-life discussion and care of the MCS patient
3. Describe pediatric quality of life with MCS.
4. Discuss quality of life of caregivers.

### Selected References for Transition to Home


1. Pamboukian SV, Tallaj JA, Brown RN et al. Improvement in 2-year survival for ventricular assist device patients after implementation of an intensive surveillance protocol. *J Heart Lung Transplant.* 2011;30(8):879-887.
2. Wilson SR, Givertz MM, Stewart GC, Mudge GH, Jr. Ventricular assist devices the challenges of outpatient management. *J Am Coll Cardiol.* 2009;54(18):1647-1659
3. Grady, K et al. Beyond Survival: Recommendations from INTERMACS for Assessing Function and Quality of Life with Mechanical Circulatory Support. *J Heart and Lung Transplant* 2012 Nov;31(11):1158-64.
4. Swetz K et al. Palliative care and end of life issues in patients treated with left ventricular assist devices as destination therapy. *Curr Heart Fail Rep.* 2011; 8: 212-218.
5. Levenson JW et al. The last six months of life for patients with congestive heart failure. *J Am Geriatr Soc.* 2000 May;48(5 Suppl):S101-9.
6. Epstep, JD et al. Continuous Flow Left Ventricular Assist Devices: Shared Care Goals of Monitoring and Treating Patients. *Methodist Debakey Cardiovasc J. 2015;11: 33–44.*
7. Schweiger, M et al. Outpatient Management of Intra-corporeal Left Ventricular Assist Device System in Children: a Multi-Center Experience. *Am J Transplant. 2015;15:453-60*
8. Miller, JR et al. Pediatric Quality of Life while Supported with a Ventricular Assist Device. *Congenit Heart Dis. 2015.*
9. Kirkpatrick, JN et al. Caregivers and Left Ventricular Assist Devices as a Destination, Not a Journey. *J Card Fail. 2015:15:S1071-9164.*

# VII. LONG-TERM MANAGEMENT OF PATIENTS AND COMPLICATIONS (XXX)

## Learning Objectives for Long-term Management

The Outpatient Clinic: Critical Clinical Assessments for Success

1. Understand the importance of echo, laboratory, and clinical follow-up during long term MCS support.
2. Understand the challenges of measuring blood pressure in the outpatient setting and risks associated with hypertension during VAD support.
3. Identify and respond appropriately to common alarms encountered on Device interrogations.

LVAD Infections

1. Understand the impact of infectious complications on the long term outcome of implantable VAD therapies.
2. Understand diagnostic strategies available for diagnosis of device related infections.
3. Become familiar with latest definitions of device-related and device-associated infections
4. Learn the common pathogens involved in device-related infections
5. Understand medical and surgical therapies available for the prevention and management of device-related infections

Bleeding Complications after VAD Support

1. Understand the frequency, timing, and etiologies of bleeding complications after MCS implant
2. Understand the frequency and etiology gastrointestinal bleeding in recipients of continuous flow VADs
3. Understand the entity “acquired von Willebrand’s disease” and its potential role in the genesis of occult gastrointestinal bleeding
4. Understand new algorithms for the diagnosis and management of recurrent gastrointestinal bleeding as it relates to imaging (nuclear, endoscopy), antiplatelet and anticoagulation therapies and role of adjuvant therapies like estrogen, octreotide and dDAVP for patients with occult (non-upper, non-lower) gastrointestinal bleeding.

Pump Thrombosis

1. Learn what is known regarding blood-device surface interactions
2. Comprehend the reported incidence of VAD thrombosis in major clinical trials
3. Understand medical and surgical factors that can predispose to the development of VAD thrombus
4. Understand options for the diagnosis of VAD-related thrombus vis-à-vis thrombus location
5. Understand options for management from anti-thrombotics to thrombolytics, pump exchange and transplantation
6. Acquaint themselves with a working algorithm for the diagnosis and management of pump thrombus

Aortic Insufficiency in LVAD Recipients

1. Gain an understanding of the high-flow/low perfusion constellation of LVAD associated aortic insufficiency
2. Understand the prevalence and impact of de novo aortic insufficiency in continuous flow VAD recipients.
3. Acquaint themselves with the potential etiologic factors involved in the development of aortic insufficiency including pre-existing AI, outflow conduit placement, aortic valve fusion and lack of pulsatility and valve opening
4. Understand important patient management strategies that may impact AI development
5. Understand surgical options for the treatment of pre-existing AI at the time of LVAD implantation.
6. Understand indications and medical and surgical options for the management of de novo aortic insufficiency after MCS implant including blood pressure control, percutaneous devices and TAVR, and reoperation.

## Suggested References for Long-term Management

The Outpatient Clinic: Critical Clinical Assessments for Success


1. Nassif et al JHLT 2015; 34:503-08 (washU SBP >100 lead to CVA)
2. Saeed et al Circ HF epub (high BP = AI, isc CVA, hem CVA)
3. Lamper Ann thorac Surg 2014; 97:139-46
4. Pagani et al ISHLT 2015- ENDURANCE and MAP >90

5. Jajjar et al JHLT 2014; 33:23-34. ADVANCE and MAP >90
5. ISHLT MCS guidelines (BP section) JHLT 2013; 32:157
6. Lanier Circ HF 2013; 6: 1005-12. How Aline, Terumo, Doppler differ

LVAD infections

1. Califano S et al. Left ventricular assist device associated infections. Infect Dis Clin North Am 2012;26:77-87
2. Hannan MM et al. Working formulations for the standardization of definitions of infections in patients using ventricular assist devices. J Heart Lung Transpl 2011;30:375-84.
3. Spelman D et al. Ventricular assist device infections. Curr Infect Dis Rep 2012; 14:359-66.
4. Stulak JM. Prevention of percutaneous driveline infections. *ASAIO* 2013; 59:570-74
5. Trachtenberg BH. Persistent blood stream infection in patients supported with a continuous-flow left ventricular assist device is associated with an increased risk of cerebrovascular accidents. J Card Fail. 2015; 21:119-25.
6. Brewer et al. Extremes of BMI after VAD. JHLT 2012; 31:167-72.
7. Tarzia V, et al. Occult gastrointestinal bleeding in patients with a ventricular assist device axial flow pump: diagnostic tools and therapeutic algorithm. J Thorac Cardiovasc Surg 2012; 143: e28-31.
8. Aggarwal A, et al. incidence and management of gastrointestinal bleeding with continuous flow assist devices. Ann Thorac Surg 2012; 93;1534-40.
9. Crow S, et al. Acquired von Willenbrand's syndrome in continuous flow ventricular assist device recipients. Ann Thorac Surg 2010; 90:1263-9
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11. Bunte, Major bleeding during HM2. JACC 2013; 62: 2188
12. Boyle 880 Preop Risks for Bleeding and Stroke JACC 2014; 63

Pump Thrombosis

1. Kiernan MS, et al. Management of Heartware LVAD thrombosis using intracavitary thrombolytics. J Thorac Cardiovasc Surg 2011;142:712-14.
2. Al-Quthami AH, et al. Eptifibatide for the treatment of HeartMate II LVAD thrombosis. Circ Heart Fail 2012;5:e68-70.
3. Kanouh A, et al. Successful treatment of early thrombosis of the Heartware LVAD with intracavitary thrombolytics. Ann Thorac Surg 2012;94:281-3
4. Najjar J Analysis of pump thrombosis events in patients in the Heartware ADVANCE bridge to transplant and continued access protocol trial. Heart Lung Transplant 2014; 33: 23-34.
5. Goldstein DJ, John R, Salerno C, Silvestry S, Moazami N, Horstmanshof D, Admason R, Boyle A, Zucker M, Rogers J, Russell S, Long J, Pagani F, Jorde U. Algorithm for the Diagnosis and Management of Pump Thrombus JHLT 2013 Jul;32(7):667-70
6. Starling et al Unexpected abrupt incrase in left ventricular assist device thrombosis. NEJM 2014 370:33-40.
7. Kirklin et al Interagency Registry for Mechanically Assisted Circulary Support (INTERMACS) analysis of pump thrombosis in the Heartmate II left ventricular left ventricular assist device. JHLT 2014; 33:12-22.
8. Uriel et al. JHLT 2014;33:51-59
9. Cowger Hemolysis: A harbinger of adverse outcome after left ventricular assist device implant. JHLT 2014;33:35-43
10. Pagani et al. JHLT 2015 (oral presentation, assume in press soon). Heartware HVAD for the treatment of patients with advanced heart failure ineligible for cardiac transplant. Results of the ENDURANCE destination therapy trial.

Aortic Insufficiency

1. Hatano M, et al. Less frequent opening of aortic valve and a continuous flow pump are risk factors for postoperative onset of aortic insufficiency in patients with a left ventricular assist device. Circ J 2011;75:1147-55.
2. Adamson RM, et al. Aortic valve closure associated with HMII LVAD support: technical considerations and long term results. J Heart Lung Transpl 2011;30:576-82.
3. Cowger J, et al. Development of aortic insufficiency in LVAD supported patients. Circ Heart Fail 2010;3:668-71.

4. Pak SW, et al. Prevalence of de novo AI during long-term support with a LVAD. J Heart Lung Transpl 2010;29:1172-6.
5. Cowger J, et al Consequences of Aortic Insufficiency During Long Term Axial Continuous Flow LVAD Support. *J Heart Lung Transplant* 2014; 33; 1233-40
6. Comprehensive review and suggested management strategies for the detection and management of aortic insufficiency in patients with continuous flow left ventricular assist devices. *J Heart Lung Transplant* 2015; 34:149-57.
7. Jorde UP, et al. Prevalence, significance, and management of aortic insufficiency in continuous flow left ventricular assist recipients. Circ HF 2014; 7; 310-19.