GUIDELINE

INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION GUIDELINES FOR THE EVALUATION AND CARE OF CARDIAC TRANSPLANT CANDIDATES—2024

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The "International Society for Heart and Lung Transplantation Guidelines for the Evaluation and Care of Cardiac Transplant Candidates—2024" updates and replaces the "Listing Criteria for Heart Transplantation: International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates—2006" and the "2016 International Society for Heart Lung Transplantation Listing Criteria for Heart Transplantation: A 10-year Update." The document aims to provide tools to help integrate the numerous variables involved in evaluating patients for transplantation, emphasizing updating the collaborative treatment while waiting for a transplant. There have been significant practice-changing developments in the care of heart transplant recipients since the publication of the International Society for Heart and Lung Transplantation (ISHLT) guidelines in 2006 and the 10-year update in 2016. The changes pertain to 3 aspects of heart transplantation: (1) patient

Endorsed by the Pediatric Heart Transplant Society.

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selection criteria, (2) care of selected patient populations, and (3) durable mechanical support. To address these issues, 3 task forces were assembled. Each task force was cochaired by a pediatric heart transplant physician with the specific mandate to highlight issues unique to the pediatric heart transplant population and ensure their adequate representation. This guideline was harmonized with other ISHLT guidelines published through November 2023. The 2024 ISHLT guidelines for the evaluation and care of cardiac transplant candidates provide recommendations based on contemporary scientific evidence and patient management flow diagrams. The American College of Cardiology and American Heart Association modular knowledge chunk format has been implemented, allowing guideline information to be grouped into discrete packages (or modules) of information on a disease-specific topic or management issue. Aiming to improve the quality of care for heart transplant candidates, the recommendations present an evidence-based approach.

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KEYWORDS:
Heart transplant candidates; Durable mechanical circulatory support; Guideline-directed medical therapy; Pediatric heart transplant; Collaborative treatment

Contents

TOP 10 TAKE-HOME MESSAGES

1. In the assessment of heart transplant candidacy, the document focuses on an individualized approach rather than absolute thresholds contraindicating eligibility, specifically for parameters including age and obesity as well as conditions such as cancer, vascular disease, kidney disease, liver disease, and connective tissue diseases (CTD).
2. With the changing landscape of candidates' characteristics, particular attention is devoted to assessment of candidacy in patients with amyloidosis and congenital heart disease (CHD), as well as to issues of re-transplantation. Systematic candidate evaluation should assess the severity and natural history of extra-cardiac involvement with a particular focus on the downstream effects of malnutrition and frailty. Retransplantation for cardiac allograft vasculopathy (CAV), or in highly sensitized patients with end-organ damage, requires careful planning and emphasis on shared decision-making with patients and their families.
3. History of malignancy is common in patients undergoing evaluation for heart transplantation (HT) and confers a higher risk for post-transplant malignancies. The incidence of de novo malignancy post-transplant in the recent era is also increasing. The document provides extensive recommendations regarding the timing of HT in patients with a history or presence of malignancy (skin cancer, hematological, and solid organ malignancies) based on tumor grade and stage at diagnosis, the time from treatment, and cancer screening surveillance.
4. The psychosocial evaluation of heart transplant candidates is a key component of the multifaceted pre-transplant screening process, aimed at identifying those candidates at increased risk for poor post-transplant outcomes due to inadequate support, substance use, adherence, or optimal mental health. In particular, the evaluation of pediatric candidates warrants careful assessment of cultural considerations, the impact of intellectual and developmental disabilities, and parental refusal of vaccination.
5. Given the complexity of the medical and psychosocial issues faced by heart transplant candidates, a multidisciplinary approach is paramount, including but not limited to a heart failure (HF) cardiologist, cardiac surgeon, transplant nurse coordinator, transplant infectious diseases specialist, transplant pharmacist, immunologist, mental health expert, social worker, registered dietician, physical and occupational therapist, and palliative care specialist, with other specialists included based on the patient's specific needs. For pediatric heart transplant candidates, additional specialists may be required, including those with expertise in

assessing capacity to assent; child-life specialists to optimize education and participation of the pediatric patient and family in the transplant process; and mental health experts with specific expertise in pediatric mental health.

6. Maximally tolerated doses of guideline-directed medical therapy (GDMT) should be maintained while patients await HT. For patients on anticoagulant and/or antiplatelet therapy, a plan for perioperative management should be established at the time of heart transplant listing. For those with worsening HF, optimal support with inotropes and mechanical circulatory support (MCS) should be considered before the onset of significant end-organ dysfunction. It is also important to consider percutaneous interventional procedures and devices for monitoring [e.g., pulmonary artery (PA) pressure monitor] and management [e.g., implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy (CRT), transcatheter edge-to-edge repair, transcatheter valve replacement, arrhythmia ablation] in patients meeting appropriate indications.
7. For patients who are awaiting HT, it is recommended to continue, at appropriate intervals, evaluation including noninvasive testing [cardiopulmonary exercise test (CPET), renal and liver function, panel-reactive antibody (PRA) and ABO titers, biomarker assessment, imaging for malignancy surveillance], invasive testing (hemodynamic assessment), nutritional/frailty and psychosocial evaluation and malignancy screening. Also, it is important to provide appropriate recommended vaccinations during the waitlist period. For patients who are improving, discussion around removal from the list to continue medical therapy, and for those who are worsening, discussions around care escalation (inotropic support/MCS) or de-escalation should be taken.
8. The heart transplant team should establish a preoperative plan focusing on pharmacological therapy adjustment at the time of transplant—that is, when to stop select HF medications to avoid vasoplegia, to reverse anticoagulation, to initiate antibiotic treatment for methicillin-resistant *Staphylococcus aureus* (MRSA) colonization, ventricular assist device (VAD) infections, and antiviral treatment for possible exposure to hepatitis B virus (HBV), hepatitis C virus (HCV), coronavirus disease 2019 (COVID-19).
9. Durable mechanical circulatory support (DMCS) is a useful bridging strategy for transplant-eligible patients refractory to optimal medical therapy (OMT), avoiding further end-organ injury, improving quality of life (QOL), and prolonging survival. Given the availability of reliable and lower-risk left ventricular assist devices (LVADs) for clinical use, it is essential to revisit the indications for bridge-to-transplantation LVAD therapy and the optimal timing for MCS support. In patients with DMCS, candidacy for HT must be assessed longitudinally during follow-up regardless of the intended initial strategy. Preoperative planning is vital to ensure successful HT in this population.
10. In transplant candidates supported with a DMCS, the occurrence of a life-threatening complication, device-related, or patient-related adverse events refractory to conventional medical or surgical treatment warrants evaluation for urgent HT. Patients with severe sepsis secondary to a device-related or device-specific infection should not be transplanted until end-organ functions recover and the sepsis is controlled. The presence of an irreversible clinical condition that might impair post-transplantation survival (e.g., disabling stroke) in patients with DMCS should preclude HT. For patients in cardiogenic shock refractory to medical therapy, support with temporary MCS (tMCS) is a viable bridging strategy for urgent HT.

1. INTRODUCTION

1.1. Rationale

There have been significant practice-changing developments in the evaluation and care of heart transplant recipients since the publications of the previous guidelines and updates (Table 1). The changes pertain to 3 aspects of HT: (1) patient selection criteria, (2) care of selected patient populations, and (3) durable mechanical support. The areas that have evolved dramatically in recent decades include recipient age, frailty assessment, pulmonary hypertension (PH) evaluation, substance use, combined heart and other solid organ transplantation (SOT), adult CHD, cardiac amyloidosis, high sensitization and management of antibodies to human leukocyte

antigen (HLA), infections and antiviral therapies (i.e., HCV, HIV, etc.), and the long-term noncardiac care. Notably, the introduction of MCS devices has changed the characteristics of patients and the landscape for patients with severe HF, necessitating adaptations in heart allocation policy.

1.2. Purpose and Structure of the Document

Evaluation for heart transplant candidacy is a multidisciplinary endeavor, integrating medical, psychosocial, environmental, and genetic parameters. The purpose of the document is to provide tools that will help integrate the various variables involved in evaluating patients for transplantation, with an emphasis on updating the collaborative treatment while waiting for a transplant. To address these issues, 3 task forces were assembled. Each task force was cochaired by an adult and a pediatric heart transplant physician with the specific mandate to highlight issues unique to the pediatric heart transplant population and to ensure their adequate representation.

Table 1 Associated Guidelines and Statements

Guidelines (Title)	Organization	Publication Year
Rationale and Process: International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates—2006	ISHLT	2006[1]
Optimal Pharmacologic and Non-pharmacologic Management of Cardiac Transplant Candidates: Approaches to be Considered Prior to Transplant Evaluation: International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates—2006	ISHLT	2006[2]
Listing Criteria for Heart Transplantation: International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates—2006	ISHLT	2006[3]
Heart Rhythm Considerations in Heart Transplant Candidates and Considerations for Ventricular Assist Devices: International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates—2006	ISHLT	2006[4]
The 2016 International Society for Heart Lung Transplantation Listing Criteria for Heart Transplantation: A 10-year Update	ISHLT	2015[5]
The 2018 ISHLT/APM/AST/ICCAC/STSW recommendations for the Psychosocial Evaluation of Adult Cardiothoracic Transplant Candidates and Candidates for long-term mechanical circulatory support	ISHLT; APM; AST; ICCAC; STSW	2018[6]
ISHLT Consensus Statement on Donor Organ Acceptability and Management in Pediatric Heart Transplantation	ISHLT	2020[7]
Donor Heart Selection: Evidence-Based Guidelines for Providers	ISHLT	2022[8]
The ISHLT Guidelines for the Care of Heart Transplant Recipients	ISHLT	2022[9]
The ISHLT/HFSA Guideline on Acute Mechanical Circulatory Support	ISHLT; HFSA	2023[10]
The 2023 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support: A 10-year Update	ISHLT	2023[11]
Dual-Organ Transplantation: Indications, Evaluation, and Outcomes for Heart-Kidney and Heart-Liver Transplantation: A Scientific Statement From the American Heart Association	AHA (endorsed by ISHLT)	2023[12]
Assessing and Managing Frailty in Advanced Heart Failure: An International Society for Heart and Lung Transplantation Consensus Statement	ISHLT	2023[13]

Abbreviations: AHA, American Heart Association; APM, Academy of Psychosomatic Medicine; AST, American Society of Transplantation; ICCAC, International Consortium of Circulatory Assist Clinicians; ISHLT, International Society for Heart and Lung Transplantation; STSW, Society for Transplant Social Workers; HFSA, Heart Failure Society of America.

1.3. Task Forces

1.3.1. Task Force I: Evaluation for Heart Transplant Candidacy. Cochairs: Michelle Kittleson and Neha Bansal (Pediatric)

This Task Force aims to identify the patients with the greatest need and the highest potential for favorable outcomes of HT. The document will aid in integrating multiple factors, including indicators for poor prognosis without transplant and potential contraindications that may cause suboptimal outcomes post-transplant (subsection 1; Listing criteria for HT, led by Maryjane Farr). Following rigorous medical and psychosocial evaluation, the listing decision is made by a multidisciplinary team (subsection 2; Psychosocial evaluation of candidates for HT, led by Fabienne Dobbels). Task Force I will define the multidisciplinary team's composition and the division of roles and responsibilities (subsection 3; Multidisciplinary team, led by Brian Clarke).

1.3.2. Task Force II: Optimization of the Medical Surveillance of Patients on the Waitlist. Cochairs: Josef Stehlik and Shahnawaz Amdani (Pediatric)

The general aim is to maintain or even improve the level of function at listing until transplantation, that is, essentially to make sure that each patient remains an optimal candidate and is appropriately risk-stratified (subsection 1; Optimal pharmacologic management, led by Lazaros A. Nikolaidis). Advancements in nonpharmacologic management continue to improve outcomes. Percutaneous interventions may substantially alter HF trajectory and should complement aggressive attempts to maximize GDMT (subsection 2; Nonpharmacologic management of cardiac transplant candidates, led by JoAnn Lindenfeld). Patients should be frequently evaluated while on the waitlist to determine if they have developed potential contraindications to transplantation or have become too well to merit transplantation; this evaluation will focus on serial evaluation and repeat testing on the waitlist of HF symptoms, hemodynamic stability (including PH), exercise capacity, renal function, and multiorgan involvement. A notable proportion of waitlist patients is "sensitized"; thus, attention should be paid to considerations for desensitization therapy or waitlist prioritization consideration (subsection 3; Surveillance and management of decompensation/deterioration, led by Jignesh Patel). Preoperative preparation of the patient for transplantation incorporates standard and specialized considerations to maximize the chance of a favorable outcome (subsection 4; Preoperative preparation of the patient for transplantation, led by Richard Cheng).

1.3.3. Task Force III: Considerations for Mechanical Circulatory Support Systems.Chair: Diyar Saeed

The concept of MCS has developed concomitantly with the field of HT. Task Force III comprises a short section relating to the 2023 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support.[11] Patients selection, complications of DMCS and their implications for HT candidacy, and bridging to transplant with tMCS will be discussed.

1.4. Document Format: Modular Knowledge Chunk

The American College of Cardiology (ACC)/American Heart Association (AHA) formatting guidelines were adopted using the modular knowledge chunk.[14] This format allows guideline information to be grouped into discrete packages (or modules) of information on a disease-specific topic or management issue. The focus of the guideline is on the recommendations themselves, presented in the modular knowledge chunk format, consisting of

1. a table of related recommendations;
2. a brief synopsis, which may include important background information overarching management or treatment concepts;
3. more detailed recommendation-specific supportive text for each recommendation;
4. a flow diagram or additional information table(s) (when appropriate).

1.5. Grading the Evidence

In applying the ACC/AHA Class of Recommendation (COR) and Level of Evidence (LOE) to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care, the COR indicates the strength of recommendation, encompassing the estimated magnitude and certainty of benefit in proportion to risk. The LOE rates the quality of scientific evidence supporting the intervention or other clinical activity on the basis of the type, quantity, and consistency of data from clinical trials and other sources (Table 2).[15]

Table 2 Applying ACC/AHA Class of Recommendation and Level of Evidence

CLASS (STRENGTH) OF RECOMMENDATION	
CLASS 1 (STRONG)	Benefit >>> Risk
CLASS 2a (MODERATE)	Benefit >> Risk
CLASS 2b (WEAK)	Benefit > Risk
CLASS 3: No Benefit (MODERATE)	Benefit = Risk
CLASS 3: Harm (STRONG)	Risk > Benefit
LEVEL (QUALITY) OF EVIDENCE	
LEVEL A	
High-quality evidence from more than 1 randomized controlled trial	
Meta-analyses of high-quality randomized controlled trials	
One or more randomized controlled trials corroborated by high-quality registry studies	
LEVEL B-R (Randomized)	
Moderate-quality evidence from 1 or more randomized controlled trials	
Meta-analyses of moderate-quality randomized controlled trials	
LEVEL B-NR (Nonrandomized)	
Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies	
Meta-analyses of such studies	
LEVEL C-LD (Limited Data)	
Randomized or nonrandomized observational or registry studies with limitations of design or execution	
Meta-analyses of such studies	
Physiological or mechanistic studies in human subjects	
LEVEL C-EO (Expert Opinion)	
Consensus of expert opinion based on clinical experience	

Adapted from.[15]

1.6. Abbreviations

ACC, American College of Cardiology; ACEi, angiotensin-converting enzyme inhibitors; AdvHF, advanced heart failure; AF, atrial fibrillation; AHA, American Heart Association; AKI, acute kidney injury; AL-CM, amyloid monoclonal immunoglobulin light chain cardiomyopathy; ARB, angiotensin II receptor blocker; ARNi, angiotensin receptor-neprilysin inhibitor; ATTR-CM, amyloid transthyretin cardiomyopathy; ATTRv, variant transthyretin amyloid; ATTRwt, wild-type transthyretin amyloid; AUDIT, alcohol use disorder identification test; BHS, behavioral health specialists; BiV, biventricular; BiVAD, biventricular assist device; BMI, body mass index; BNP, B-type natriuretic peptide; BTC, bridge to candidacy; BTT, bridge to transplantation; BTR, bridge to recovery; CAV, cardiac allograft vasculopathy; CF, continuous flow; CHD, congenital heart disease; CKD, chronic kidney disease; CO, cardiac output; COR, class of recommendation; COVID-19, coronavirus disease 2019; CpcPH, combined post- and pre-capillary pulmonary hypertension; CPET, cardiopulmonary exercise test; CrCl, creatinine clearance; CRS, cardio-renal syndrome; CRT, cardiac resynchronization therapy; CT, computed tomography; CTD, connective tissue disease; CVP, central venous pressure; DAAs, direct-acting antivirals; DAPT, dual antiplatelet therapy; dFLC, difference between involved and uninvolved free light chain; DLCO, diffusing capacity of the lung for carbon monoxide; DMCS, durable mechanical circulatory support; DOAC, direct oral-anticoagulants; DRHR, donor-to-recipient height ratio; DRWR, donor-to-recipient weight ratio; DT, destination therapy; EF, ejection fraction; eGFR, estimated glomerular filtration rate; ELISA, enzyme-linked immunosorbent assay; ESCAPE, Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness; ETV, entecavir; EUROMACS, European Registry for Patients with Mechanical Circulatory Support; FALD, Fontan-associated liver disease; FEV1, forced expiratory volume in 1 second; FP, frailty phenotype; FVC, forced vital capacity; GDMT, guideline-directed medical therapy; GIB, gastrointestinal bleeding; GFR, glomerular filtration rate; GWTG-HF, Get With The Guidelines-Heart Failure; HbA1c, hemoglobin A1c; HBV, hepatitis B virus; HCM, hypertrophic cardiomyopathy; HCV, hepatitis C virus; HIT, heparin-induced thrombocytopenia; HIV, human immunodeficiency virus; HF, heart failure; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced

ejection fraction; HFSS, Heart Failure Survival Score; HLA, human leukocyte antigen; HLHS, hypoplastic heart syndrome; HT, heart transplantation; ICD, implantable cardioverter defibrillator; IDD, intellectual and developmental disabilities; IFA, immunofluorescent antibody assay; IGRA, interferon-γ release assay; INR, international normalized ratio; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; IVIG, intravenous immunoglobulin; ISHLT, International Society for Heart and Lung Transplantation; ISOs, isohemagglutinins; VAD, ventricular assist device; LV, left ventricular; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; LOE, level of evidence; MAGGIC, Meta-Analysis Global Group in Chronic Heart Failure; MCS, mechanical circulatory support; MECKI, Metabolic Exercise Test Data combined with Cardiac and Kidney Indexes; MNA, Mini Nutritional Assessment; MNA-SF, MNA-short form; MR, mitral regurgitation; MRAs, mineralocorticoid receptor antagonists; MRI, magnetic resonance imaging; MRSA, methicillin-resistant *Staphylococcus aureus*; NAT, nucleic acid tests; NYHA, New York Heart Association; NOAC, new oral anticoagulants; NP, natriuretic peptides; NT-proBNP, N-terminal pro-brain natriuretic peptide; OMT, optimal medical therapy; OPTIMIZE-HF, Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure; PA, pulmonary artery; PB, plastic bronchitis; PACT, Psychosocial Assessment of Candidates for Transplantation; PASP, pulmonary artery systolic pressure; PAP, pulmonary artery pressure; PAPi, pulmonary artery pressure index; PCWP, pulmonary capillary wedge pressure; PH, pulmonary hypertension; PDE5, phosphodiesterase 5; PGD, primary graft dysfunction; PLE, protein-losing enteropathy; QOL, quality of life; peak VO2, maximal oxygen consumption; pHM, predicted heart mass; PI, protease inhibitor; PRA, panel-reactive antibody; PSA, prostate-specific antigen; PVR, pulmonary vascular resistance; PVRI, PVR indexed to body surface area; RA, right atrial; RAASi, renin-angiotensin-aldosterone system inhibitors; RCM, restrictive cardiomyopathy; RHC, right heart catheterization; RHF, right heart failure; RV, right ventricular; RV-FAC, right ventricular fractional area change; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SGLT2i, sodium-glucose cotransporter-2 inhibitors; SHFM, Seattle Heart Failure Model; SHKT, simultaneous heart-kidney transplantation; SIPAT, Stanford Integrated Psychosocial Assessment for Transplant; SOT, solid organ transplant; TAH, total artificial heart; TB, tuberculosis; TDF, tenofovir disoproxil fumarate; TERS, Transplant Evaluation Rating Scale; tMCS, temporary mechanical circulatory support; TPG, transpulmonary gradient; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation; TST, tuberculin skin test; TTR, transthyretin; UNOS, United Network for Organ Sharing (United States); VAD, ventricular assist device; VTA, ventricular tachyarrhythmia.

2. TASK FORCE I: EVALUATION FOR HEART TRANSPLANT CANDIDACY

2.1. Listing Criteria for Heart Transplantation

2.1.1. Indications for Heart Transplantation

Recommendations for Indications for Heart Transplantation		
COR	**LOE**	**RECOMMENDATIONS**
1	B-NR	1. In patients with HF, when consistent with the patient's goals of care, the presence of clinical indicators of advanced HF (AvdHF) should trigger evaluation for AdvHF therapies, including HT.
1	B-NR	2. In ambulatory adult HF patients referred for transplant evaluation (and pediatric patients when age-appropriate), CPET should routinely be performed to quantify exertional intolerance, inform HF prognosis, and guide transplant listing.
1	C-LD	3. In adult HF patients evaluated for transplantation, right heart catheterization (RHC) should be performed prior to listing to assess for potentially prohibitive PH and for cardiogenic shock requiring inotropic support and/or temporary MCS.
2b	C-EO	4. In pediatric HT candidates, RHC may be performed prior to listing.
2a	C-LD	5. In adult HT candidates, HF prognosis scores can be considered in the context of other data collected during transplant evaluation to guide listing decisions.

Synopsis

A subset of patients with chronic HF will progress to advanced disease despite maximally tolerated guideline-directed medical and device therapies. The most common indications for HT are highly symptomatic HF, cardiogenic

shock, or uncontrolled ventricular arrhythmias. Other less common etiologies encompass restrictive cardiomyopathies (RCMs), including hypertrophic cardiomyopathy (HCM) and complex CHD after surgical palliation has failed. The first essential step in evaluation is to determine if the patient's clinical situation is limited enough to warrant transplant consideration, which requires confirmation that all attempts to optimize cardiac function—using OMT and intervenftions, such as CRT and transcatheter mitral valve repair, as indicated—have been exhausted. Measures to identify AdvHF include clinical indicators, CPET, right heart catheterization (RHC), and HF prognosis scores.

Recommendation-Specific Supportive Text

1. Because the presence of one or more clinical signs or symptoms of AdvHF is associated with a worse prognosis, recognition of these clinical indicators should prompt timely referral and evaluation for HT (Table 3). Encompassed by the mnemonic "I NEED HELP" are clinical clues to AdvHF. The components of this mnemonic are all risk factors that have been proven to increase all-cause mortality in HF patients.[16–30] Other similar definitions and indicators of AdvHF have been described.[31–34] Importantly, even patients with preserved left ventricular ejection fraction (LVEF) may have AdvHF in the setting of restrictive or valvular cardiomyopathy, isolated right ventricular (RV) failure, or congenital cardiac abnormalities when other clinical indicators are present.[35–37] Early recognition of these clinical clues and events is essential to ensure time-appropriate transplant evaluation, as late recognition risks patients being considered too unwell to undergo transplantation.
2. Parameters derived during CPET are strongly prognostic in ambulatory HF patients being considered for HT. In HFrEF, Guazzi et al showed that the prognostic value of maximal oxygen consumption (peak VO_2) and the minute ventilation/carbon dioxide production (VE/VCO_2) slope are comparable for both men and women, with a greater discriminative power of the VE/VCO_2 slope over peak VO_2 in female patients,[38] which has been confirmed recently.[39] A summary of CPET parameters supporting transplant listing in different populations is shown in Table 4. In ambulatory patients, the results of CPET should be evaluated in the context of other data collected during transplant evaluation rather than used as the sole criterion for listing. In patients limited enough to require urgent or semiurgent inpatient evaluation, there is no clear role for CPET except in select cases where sufficient clinical improvement occurs and allows hospital discharge to be considered. The use of CPET is challenging in pediatric HF patients due to wide variations in protocols and patients' ages, sizes, and muscle mass.[40] In addition, patients with single-ventricle physiology have poor exercise performance with peak VO_2 often less than 65% predicted. Thus, a peak VO_2 less than 50% predicted is often considered supportive of transplant listing in this population.[41]
3. Invasive hemodynamics obtained during RHC at initial listing inform the severity of HF, predict waitlist outcomes, guide medical optimization, and assess for the presence of PH that might contribute to post-transplant right heart failure (RHF) and survival.[42–44] Although elevations in pulmonary artery systolic pressure (PASP), transpulmonary gradient (TPG), and pulmonary vascular resistance (PVR) above certain thresholds have been proposed as contraindications to listing, the risk associated with each parameter is continuous from low to high values and absolute cutoffs do not exist.[45,46] This is discussed in detail in Pulmonary Hypertension.
4. Accurate assessment of PVR before transplantation and the related decision-making present specific challenges in the pediatric HF population. Limited data exist on the acceptable hemodynamics for HT listing in pediatrics and associated post-transplant outcomes. Assessment of PVR may be extremely difficult in patients with single-ventricle palliation, those with complex CHD, and those with long-standing dilated cardiomyopathy and either very poor function or mechanical assistance, and at times accurate determination may be impossible.[47] An elevated PVR was reported to be an independent risk factor for early and late post-transplant death and RV failure, with older patients experiencing greater PVR-related mortality after HT.[48] Thus, it might be reasonable to perform RHC in all pediatric patients when feasible.[49,50]
5. Multiple prognosis scores have been developed to risk stratify patients with HF.[51,52] The Heart Failure Survival Score (HFSS), Seattle Heart Failure Model (SHFM), Meta-Analysis Global Group in Chronic Heart Failure (MAGGIC) score, and Metabolic Exercise Test Data combined with Cardiac and Kidney Indexes (MECKI) score were developed for patients with chronic HF,[53–55] while other scores such as the Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF), Get With The Guidelines-Heart Failure (GWTG-HF), and Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) score were developed for patients with acute HF.[56–60] In circumstances where there is ambiguity regarding appropriateness for listing based on other data, scores that suggest an estimated 1-year survival $< 85\%$ may help guide decision-making. Importantly, because all scores have inherent limitations, few have been developed or validated in a contemporary cohort, and most perform poorly when applied to individuals (as opposed to populations). Thus, their values should not be used as the sole criteria for listing.[61,62]

Table 3 Markers of Advanced Heart Failure

	Parameter	Description
I	*I*notropes	Previous or ongoing requirement for dobutamine, milrinone, dopamine, or levosimendan
N	*N*YHA class/*N*atriuretic peptides	Persisting NYHA class III or IV and/or persistently high BNP or NT-pro-BNP
E	*E*nd-organ dysfunction	Worsening renal or liver dysfunction in the setting of heart failure
E	*E*jection fraction	Very low LVEF $<20\%$
D	*D*efibrillator shocks	Recurrent appropriate defibrillator shocks
H	*H*ospitalizations	More than 1 hospitalization with HF in the last 12 months
E	*E*dema/*E*scalating diuretics	Persisting fluid overload and/or increasing diuretic requirement
L	*L*ow blood pressure	Consistently low blood pressure with systolic <90-100 mm Hg
P	*P*rognostic medication	Inability to up-titrate (or need to decrease/cease) GDMP

Abbreivations: BNP, B-type natriuretic peptide; HF, heart failure; LVEF, left ventricular ejection fraction; NT-ProBNP, N-terminal pro–b-type natriuretic peptide; NYHA, New York Heart Association.
Adapted from.[16]

Table 4 Summary of CPET Parameters Supporting Transplant Listing in Different Populations

Patient population	Parameter supporting transplant listing
On beta-blocker[63–67]	Lower peak VO_2 cutoff is supportive of transplant listing, generally ≤12 ml/kg/min
Off beta-blocker[67,68]	Higher peak VO_2 may be considered supportive of transplant listing, generally ≤14 ml/kg/min
Patients with obesity (BMI ≥ 30 kg/m^2)[69]	Peak VO_2 adjusted for lean body mass ≤19 ml/kg/min
All, especially if submaximal CPET[70–75]	VE/VCO_2 slope >35
Women or patients ≤50 or ≥70 years[76–78]	Peak $VO_2 \leq 50\%$ predicted

Abbreviations: BMI, body mass index; CPET, cardiopulmonary exercise test; VE/VCO_2, the minute ventilation/carbon dioxide production.
Maximal CPET: respiratory exchange ratio (RER) > 1.05 and reaching anaerobic threshold.[79]

2.1.2. Comorbidities and Potential Contraindications to Heart Transplantation

Synopsis

Eligibility for and timing of HT evaluation requires a comprehensive survey of all comorbidities that may impact surgical risk, post-transplant QOL, and survival. ISHLT registry data indicates that over the last decade, heart transplant recipients have a higher body mass index (BMI), a greater burden of hypertension, diabetes, prior malignancy, prior cardiac surgery, and pre-transplant need for dialysis. Heart transplant recipients are becoming more complex, with a greater proportion of patients with allosensitization, older age, complex CHD, and need for dual-organ transplantation with kidney, liver, or lung transplantation.[80,81] In addition, allocation schemes prioritize the sickest patients, including those in hospital settings, on tMCS, and with prior infections, increasing medical complexity and thus creating a greater need for careful and expeditious assessment of comorbidities.

A general theme when considering extracardiac contraindications to HT is to consider whether the extracardiac condition will (1) confer mortality risk such that patients will not garner the expected improvement in survival after transplantation; (2) impact post-transplant QOL and impair rehabilitation efforts; and (3) worsen in the context of immunosuppression. One approach to improve the HT evaluation process, especially for those unstable patients requiring urgent expedited inpatient evaluations, is to consider all patients with AdvHF to be potential HT candidates and to prioritize guideline-directed health care maintenance (including age-appropriate screening with Pap smears, mammograms, and colonoscopies, for example), vaccinations, and control of comorbidities. In this manner, AdvHF patients, even those perhaps considered too well for transplant consideration, could preserve their potential for future HT eligibility.

2.1.2.1. Age

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Age		
COR	LOE	RECOMMENDATIONS
1	B-NR	1. In patients with AdvHF aged ≤ 70 years, evaluation for HT is recommended.
2b	B-NR	2. In patients with AdvHF who are over 70 years of age, evaluation for HT may be considered in carefully selected patients depending on their functional status and control of comorbidities, taking into account the need for specialized post-transplant care for older patients, including the need for tailored immunosuppression.

Recommendation-Specific Supportive Text

1. As life expectancy continues to increase, traditional age limits for HT may be expanded in select cases.[80,81] Older age does confer more risk of certain post-transplant complications; compared to recipients under the age of 60 years, older transplant recipients have more infections, renal dysfunction, and malignancy but less rejection.[82,83] Increasing recipient age is associated with an increase in post-transplant mortality, particularly in patients aged > 70 years at the time of transplant, with the incidence of specific causes of post-transplant mortality varying widely with recipient age.[82,83] Although survival in patients ≥60 years of age is lower compared with younger recipients, the 5-year survival is acceptable.[83] The difference in outcomes between older and younger transplant recipients underscores the need for tailored immunosuppression.[82,83] However, for patients aged ≤70 years, eligibility for HT should be based on the assessment of comorbidities without specific attention to age.
2. While some studies indicate that heart transplant recipients over 70 years of age have comparable survival, after adjusting for comorbidities, to younger transplant recipients,[84,85] this population is highly selected with careful attention to control and management of comorbidities. While older donors may be considered for older heart transplant candidates, this practice is of uncertain value given the observation that older donors are associated with worse post-transplant survival both in young and old recipients.[86] This issue raises the ethical question of using the scarce resource of young donor hearts for older recipients, with the question being further exacerbated by the potential need for dual-organ transplantation.[87] Strategies to mitigate these ethical dilemmas include limitations on dual-organ transplantation for patients over a given age, with program-specific thresholds based on consensus on clinical outcomes, and allocation systems that prioritize the listing of younger transplant candidates.[88] In summary, chronologic age alone should not constitute a contraindication for HT. However, careful patient selection criteria must be applied to identify those candidates most likely to derive acceptable QOL and survival.

2.1.2.2. Obesity

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Obesity		
COR	LOE	RECOMMENDATIONS
2a	B-NR	1. In adult heart transplant candidates with a pre-transplant BMI ≥ 35 kg/m^2, weight loss to achieve a BMI of < 35 kg/m^2 is reasonable before listing for HT to improve post-transplant outcomes.
2b	C-LD	2. In pediatric heart transplant candidates, the use of a BMI threshold in assessing transplant candidacy is not well established.

Recommendation-Specific Supportive Text

1. Increasing rates of obesity are observed in the heart transplant population, with a significant increase in BMI over time.[89] Obesity with BMI ≥35 kg/m^2 is associated with increased waitlist time, increased waitlist mortality,[90,91] and increased post-transplant mortality.[91] There is a graded relationship between increased BMI and worse post-transplant survival in multiple registry and meta-analyses,[92–94] with the best survival being observed in those patients with normal BMI but acceptable survival in those patients with BMI 30 to 35 kg/m^2.[95] Considering that obesity is a potentially modifiable risk factor, achieving a BMI under 35 kg/m^2 is preferred to optimize waitlist time and survival, and post-transplant QOL and survival. For some patients, options including bariatric surgery may be considered, depending on center expertise, resources, and patient stability.[96–98]

2. The role of a BMI threshold in transplant candidacy has not been established in pediatric heart transplant candidates.[99] Outcome data for obese pediatric heart transplant recipients are limited and conflicting: while some studies have demonstrated worse transplant outcomes for obese pediatric recipients, other studies have shown minimal or no difference in outcome.[99] There are insufficient data to support using any BMI cutoff as an absolute contraindication for HT in children. As childhood obesity is increasing and is unequally distributed by race and socioeconomic status,[100] exclusion of pediatric heart transplant candidates on the basis of obesity alone may be considered as contributing to health care disparities.

2.1.2.3. Cancer

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Cancer		
COR	**LOE**	**RECOMMENDATIONS**
2a **1**	**B-R**	1. All HT candidates should be screened for solid organ tumors as recommended for the general population:[101] A. **Colorectal cancer:** patients aged 45–49-year (Class 2a) or aged 50-75 years (Class 1) with an average risk of colorectal cancer should undergo regular screening with either a high-sensitivity stool-based test (fecal immunochemical, high-sensitivity, guaiac-based fecal occult blood test, multitarget stool DNA high sensitivity) or a structural (visual) examination (colonoscopy, computed tomography (CT) colonoscopy, flexible sigmoidoscopy), depending on patient preference and test availability. As a part of the screening process, all positive results of non-colonoscopy screening tests should be followed up with a timely colonoscopy.[102,103] B. Screening for **prostate cancer** is recommended with prostate-specific antigen (PSA) with or without digital rectal examination for patients beginning at age 50 years, for patients at higher risk (African American and men who have a first-degree relative diagnosis with prostate cancer before age 65 years) beginning at age 45 years, for patients at appreciably higher risk (multiple family members diagnosed with prostate cancer before age 65 years) beginning at age 40 years (Class 1).[101,104] C. **Breast cancer:** women aged 45 to 54 years should have annual screening mammogram. Women aged 55 years and older should have a screening mammogram every 2 years but can continue annually if the patient prefers (Class 1).[105] D. **Cervical cancer:** women aged 25 to 65 years should have a primary HPV test every 5 years (Class 1). If HPV testing is unavailable, screening may be done with either a co-test that combines an HPV test with a Papanicolaou (Pap) test every 5 years or a Pap test alone every 3 years.[106] E. **Lung cancer:** patients aged 50-80 years with 20 pack-year smoking history who have quit smoking within the last 15 years should have annual low-dose chest CT. Screening should be discontinued once a patient reaches 15 years of smoking cessation.[107] CT chest done in all heart transplant candidates should be evaluated for the early detection of lung cancer.
2a	**B-NR**	2. Skin cancer screening by a full-body skin examination completed by a dermatologist for all heart transplant candidates can be useful to reduce skin cancer morbidity and mortality.
1	**C-LD**	3. In heart transplant candidates with a history of malignancy, collaboration with oncology specialists is recommended for individualized risk stratification to assess malignancy-related survival and risk of recurrence in the context of immunosuppression.
1	**C-LD**	4. In heart transplant candidates with a history of malignancy, HT is recommended when malignancy-related survival will not impact post-transplant survival and the risk of recurrence is low based on tumor type, response to therapy, and negative metastatic evaluation.
2a	**B-NR**	5. New technologies (i.e., circulating tumor DNA) can detect and measure microscopic residual disease in patients who have undergone definitive treatment, provide information on the status of a patient's cancer, and offer unique advantages in certain settings.

Recommendation-Specific Supportive Text

1. Malignancy after HT remains a significant cause of morbidity and mortality in adult and pediatric recipients. All HT candidates should be screened for solid organ tumors as recommended for the general population, as there are little data to support malignancy screening recommendations specific to the heart transplant recipient.[101] Cancer screening guidelines from relevant expert societies may change over time, and the corresponding recommendations for heart transplant candidates should be updated accordingly.[102–107] The role of screening with positron emission tomography for occult solid organ neoplasia in otherwise asymptomatic individuals with no other evidence of potential neoplasia from standard screening tests is not clear. This strategy cannot be universally recommended in the absence of data indicating benefit, especially given the potential risks of subsequent invasive testing resulting from incidental findings of unclear significance (See also Frequency of Malignancy Screening, Table 19).
2. The development of skin cancer post-transplantation portends tremendous morbidity, adversely affecting QOL for many transplant recipients. Pre-transplantation skin cancer is a major risk factor toward the development of skin cancer post-transplantation.[108] Skin cancer screening by a full-body skin examination completed by a dermatologist for all heart transplant candidates can be useful to reduce skin cancer morbidity and mortality. Heart transplant recipients with a history of skin cancer should continue standard skin cancer surveillance as recommended by their dermatologists.[109] Recommended wait times pre-transplantation for patients with a history of skin cancer before transplantation are presented in Table 5.
3. Pre-existing neoplasms are diverse, and many are treatable with excision, radiotherapy, chemotherapy, or immunotherapy to induce cure or remission. An aging population, side effects from radiation and chemotherapy, and improved cancer survivorship have increased the number of patients undergoing evaluation for cardiac transplantation with a history of pre-transplant malignancy.[110,111] The presence of pre-transplant malignancy is strongly associated with the development of post-transplant malignancies and decreased post-transplant survival (both cancer related and noncancer related), especially if the pre-transplant malignancy is hematologic, high-risk, or present ≤1 year before transplant.[111–114] Collaboration with an oncologist is essential for an individualized approach to risk stratification.
4. Those candidates with low-risk pre-transplant malignancy, including early-stage cancers with complete resection and/or low-risk features, including prostate adenocarcinoma, renal cell carcinoma, cervical cancer, and bladder cancer, may undergo HT with minimal or no pre-transplant observation and plans for post-transplant intervention, after a comprehensive evaluation and shared decision with treating oncologists.[115] While a period of observation before transplant listing may be recommended, this will be unique and specific to the given patient's cancer history. These patients might have significant multiorgan dysfunction, and this might also preclude or at least complicate further HT candidature needing combined transplants. An individualized approach with multidisciplinary collaboration is essential, as arbitrary time intervals for observation may result in unnecessary delays in transplant listing. Further guidance is available in consensus statements from the American Society of Transplantation with granular recommendations on transplant candidacy for patients with a history of skin cancer (Table 5), hematological malignancies (Tables 6 and 7), and solid organ malignancies based on tumor-grade and stage (Table 8).[115,116]
5. With recent advances in cancer treatment, the prognosis for many cancers continues to improve, highlighting the potential need for new methods of risk stratification. The precision immune-oncology approach that seeks to better understand the immune system, the complexity of the tumor microenvironment, and the tumor signaling pathways that affect the individualized response to therapy provides a framework for evaluation of highly active anticancer therapies in the neoadjuvant context, wherein patients would potentially be spared from chemoradiotherapy and surgery while their tumor is treated when it is most likely to respond—namely, before exposure to other agents that might select for cells with a resistant phenotype.[117] The dynamic monitoring of the whole cancer journey, from detection to interception to monitoring of resistance in metastatic cancer, using new technologies is evolving.[118,119] Ultrasensitive technologies can detect and measure microscopic residual disease in patients who have undergone definitive treatment, allowing to apply interception strategies to eradicate cancer in those high-risk patients.

Table 5 Recommended Wait Times Pre-transplantation for Patients With a History of Skin Cancer Before Transplantation

Skin malignancy	Wait time before transplantation after treatment
Cutaneous squamous cell carcinoma (cSCC)	
No history of SCC but at risk for development of SCC	No delay necessary
Low risk	No delay necessary
High-risk SCC (not including perineural invasion)	2 years
High-risk SCC with perineural invasion or 2 risk factors	2-3 years
High risk with local nodal metastatic disease	5 years
Distant metastasis	Not eligible for transplantation
Merkel cell carcinoma	
Local with negative sentinel lymph node biopsy	2 years
Local with nodal metastasis	3-5 years
Distant metastasis	Not eligible for transplantation
Malignant melanoma	
In situ melanoma	No wait necessary, follow-up post transplantation 3 months
Stage IA melanoma	1 year
Stage IB melanoma	1 year
Stage IIA melanoma	1 year
Stage IIB melanoma	2-4 years
Stage IIC melanoma	2-4 years
Stage IIIA melanoma	1-2 years
Stage IIIB melanoma	2-4 years
Stage IIIC melanoma	At least 5 years
Stage IIID melanoma	At least 5 years
Stage IV melanoma	At least 5 years

Modified from Recommendations for Solid Organ Transplantation for Transplant Candidates with a Pre-transplant Diagnosis of Cutaneous Squamous Cell Carcinoma, Merkel Cell Carcinoma and Melanoma: A Consensus Opinion From the International Transplant Skin Cancer Collaborative.[108]
Abbreviation: SCC, squamous cell carcinoma.

Table 6 Recommended Wait Times Pre-transplantation for Patients With a History of Hematological Malignancies Before Transplantation

Histology	Wait time before transplantation after treatment
Diffuse large B cell lymphoma	2 years
Follicular lymphoma	2 years
Peripheral T-cell lymphoma	2 years
Burkitt lymphoma	2 years
Hodgkin lymphoma	2 years PET scan negative patients after initial treatment have a low rate of relapse
Monoclonal B cell lymphocytosis	No wait time
Chronic lymphocytic leukemia	2-3 years after treatment

Modified from pre-existing melanoma and hematological malignancies consensus expert opinion statement.[116]
Abbreviation: PET, positron emission tomography.

Table 7 Criteria for Safe Transplant Candidacy for Candidates With a Prior History of Myeloma[a]

Criteria
Stringent complete response No monoclonal protein in serum or urine by immunofixation Normal free light chain ratio Bone marrow plasma cells < 1% by flow or immunohistochemistry
Performance status 0 or 1
FISH at diagnosis fail to demonstrate deletion (17p), t(4; 14), t(14; 16)
Hematologic remission > 6 months

Modified from pre-existing melanoma and hematological malignancies consensus expert opinion statement.[116]
Abbreviation: FISH, fluorescence in situ hybridization.
[a]Data are extrapolated from kidney transplant data.

Table 8 Recommended Wait Times Pre-transplantation for Patients With a History of Solid Organ Malignancy Before Transplantation

Risk/stage of solid organ malignancy	Wait time before transplantation after treatment[a]
History of breast cancer	
Ductal carcinoma in situ Stage I	No additional waiting time after the completion of all standard treatments
Stage II	1-2 years with no evidence of disease
Stage III	3-5 years with no evidence of disease
Stage IV	Not eligible for transplantation
History of colon cancer	
Stage I (T1 or T2, N0, M0)	1 year
Stage II (T3, N0, M0)	2 years, consider longer if high-risk features present[b]
Stage II (T4, N0, M0)	3 years5 years if high-risk features present[b]
Stage III (any T, N+, M0)	3 years5 years if high-risk features present[b]
Stage IV (any T, any N, M+)	5 years with no evidence of disease
History of prostate cancer	
PSA < 10 ng/ml; 3 or fewer cores of Gleason 6 with no greater than 50% of individual core; T1c-T2a	No wait time[c]
PSA < 10 ng/ml, Gleason 6 not meeting very low-risk criteria; T1c-T2a	No wait time[c]
PSA > 10 ng/ml; Gleason 7; T2b	Surveillance or treatment are optional treatments[c]If surveillance, no wait time If treatment initiated, and nomogram (www.nomog rams.org) predicts cancer-specific death over the next 15 years < 10%, no wait time necessary
PSA > 20 ng/ml or high-volume Gleason 7 or any Gleason 8-10; T3	If treatment initiated, and nomogram predicts cancer-specific death over the next 15 years < 10%, no wait time
Metastatic castration-sensitive	If stable disease for 2 years with prolonged estimated life expectancy, may consider transplant
Metastatic castration-resistant	Not eligible for transplantation
History of renal cell carcinoma[d]	
T1a (≤4 cm), N0, M0	No wait time[a]

Continued

Table 8 Recommended Wait Times Pre-transplantation for Patients With a History of Solid Organ Malignancy Before Transplantation

Risk/stage of solid organ malignancy	Wait time before transplantation after treatment[a]
T1b (> 4 cm ≤ 7 cm),N0, M0	Fuhrman grade 1-2: no wait time[a] Fuhrman grade 3-4: 1-2 years[a]
T2 (7-10 cm), N0, M0	2 years[a]
T3, N0, M0	Minimum of 2 years, then reassess[a]
T4, N0, M0	Minimum of 2 years, then reassess[a]
Any T, node positive, metastatic disease	Not a candidate (if solitary metastasis + resected, tumor board discussion on candidacy)
Any T with sarcomatoid and/or rhabdoid histologic features	Not eligible for transplantation
Collecting duct or medullary RCC	Not eligible for transplantation
History of lung cancer	
Stage I	
T1aN0	≥3 years[a]
T1bN0	≥3 years[a]
T1cN0	3-5 years[a]
Stage IB	
T2aN0	5 years[a]
Stage IIA	
T2bN0	5 years[a]
Stage IIB	
T3 N0	5 years[a]
Stage IIIA	5 years[a] (special caution with N2 disease)
Stage IIIB	Not eligible for transplantation
Stage IIIC	Not eligible for transplantation
Stage IVA	Not eligible for transplantation
Stage IVA	Not eligible for transplantation

Abbreviartion: PSA, prostate-specific antigen; RCC, renal cell carcinoma.

Modified from Consensus Expert Opinion Statement for Pre-transplant Solid Organ Malignancy and Organ Transplant Candidacy.[115]

[a]After the completion of all standard oncologic treatments.

[b]High-risk features of colon cancer include lymphovascular or perineural invasion, mucinous or signet histology, poorly differentiated histology, bowel obstruction, tumor perforation, < 12 lymph nodes examined.

[c]Immunosuppression does not increase the risks of a clinically meaningful prostate cancer, recurrence following previous treatment, or 5-year cancer-specific mortality (< 1%) after a post-transplant diagnosis of prostate cancer. Population-based data suggest that surveillance in men with prostate cancer who are being considered for transplant has become more common, without any apparent long-term adverse cancer-specific consequences.[120–125]

[d]Nephrectomy remains the standard approach for small renal mass treatment for patients on a transplant waiting list. For the general nontransplant population, active surveillance of small renal mass is a safe, standard-of-care option. Nonetheless, long-term safety data of surveillance in patients being considered for transplant are lacking and nephrectomy (radical/partial) remains the most popular treatment before transplantation.[126–128]

2.1.2.4. Diabetes

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Diabetes		
COR	**LOE**	**RECOMMENDATIONS**
2a	**C-LD**	1. In heart transplant candidates with diabetes with end-organ damage or poor glycemic control (glycosylated hemoglobin [HbA1c] > 7.5%), delay in HT evaluation and listing is reasonable until diabetic control is improved.
2a	**B-NR**	2. In heart transplant candidates, ophthalmologic consultation to determine the presence of retinopathy can be beneficial as a surrogate for duration of diabetes and degree of diabetic control and vascular/kidney involvement.

Recommendation-Specific Supportive Text

1. Approximately 30% of patients with AdvHF and 20% of heart transplant recipients have pre-existing diabetes.[129,130] The presence of uncomplicated post-transplant diabetes is not associated with worse post-transplant survival.[130] However, those heart transplant candidates with diabetes-related complications, including obesity, kidney dysfunction, cerebrovascular disease, or peripheral vascular disease, have worse post-transplant survival as well as an increased risk of post-transplant infections and kidney failure in one registry analysis[130] and additional risks of late graft failure and mortality in other cohorts.[131–136] Therefore, diabetes per se is not considered a contraindication for HT, but careful assessment of diabetic control and end-organ damage (atherosclerotic vascular disease, nephropathy, proliferative retinopathy) is necessary. Post-transplant use of calcineurin inhibitors and corticosteroids will worsen glycemic control,[137] so pre-transplant optimal control to achieve glycosylated hemoglobin (HbA1c) ≤7.5%[138] is highly encouraged. On a program-specific basis, centers may identify an HbA1c level that is considered a relative contraindication to transplantation. This level portends worse post-transplant outcomes, and may also, in some cases, be an additional indicator of suboptimal medical adherence.
2. Patients with complicated diabetes have significantly worse survival.[130] Diabetic retinopathy is a highly specific vascular complication of both type 1 and type 2 diabetes, with prevalence strongly related to both the duration of diabetes and the level of glycemic control. Thus, ophthalmologic consultation to determine the presence of retinopathy can be useful in patients with diabetes to assess the post-transplant risk associated with diabetes.[139] However, it is unclear how the presence of diabetic retinopathy, once identified, should affect transplant candidacy.

2.1.2.5. Cerebral and Peripheral Vascular Disease

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Cerebral and Peripheral Vascular Disease		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-EO**	1. In heart transplant candidates with a history of stroke or neurologic signs or symptoms suggestive of cerebrovascular disease, screening for cerebrovascular disease with carotid ultrasonography is recommended.
2b	**B-NR**	2. In heart transplant candidates with clinically severe symptomatic cerebrovascular disease not amenable to revascularization (as determined by a neurologist), the benefit of HT is uncertain due to the risks of perioperative stroke and impact on post-transplant rehabilitation efforts and QOL.
1	**C-EO**	3. In heart transplant candidates with symptoms of peripheral arterial disease, diminished peripheral pulses, atherosclerotic disease, or the presence of risk factors, screening for peripheral vascular disease with ankle-brachial indices is recommended.
2b	**C-LD**	4. In heart transplant candidates with clinically severe symptomatic peripheral vascular disease, especially associated with nonhealing ischemic ulcers (as determined by a vascular specialist), the benefit of HT is uncertain due to the risks of perioperative limb ischemia and impact on post-transplant rehabilitation efforts and QOL.

Recommendation-Specific Supportive Text

1. Postoperative stroke after HT is associated with reduced functional capacity,[140] dialysis,[141] and reduced survival.[142] While heart transplant recipients are at a lower risk for stroke compared with HF patients on the waitlist,[143] there are indications that the risk of stroke might be increasing after implementation of revised United Network for Organ Sharing (UNOS) allocation system in the United States in 2018.[141] Thus, efforts to reduce the risk of post-transplant stroke are paramount to the evaluation process. Heart transplant recipients with a history of transient ischemic attack or stroke are at increased risk of stroke after transplantation.[140] Screening for asymptomatic carotid artery stenosis in the general population has no benefit and may be harmful,[144] and for individuals requiring cardiopulmonary bypass, data on the management of asymptomatic carotid stenosis are limited.[145] Based on this, screening for carotid artery stenosis is recommended for all heart transplant candidates with a history of stroke or neurologic signs or symptoms concerning for cerebrovascular disease.[141] Several modalities are proposed for screening for carotid artery stenosis, including carotid duplex ultrasonography, magnetic resonance angiography, and CT, with carotid duplex ultrasonography having a 90% sensitivity and 94% specificity for detecting ≥70% stenosis.[144] Further testing with imaging of the brain and cranial vessels may be required, as dictated by neurologic consultation.
2. The benefit of carotid revascularization at the time of cardiac surgery is not well established.[146,147] Similarly, there is no evidence regarding the impact of revascularization of carotid disease in heart transplant candidates on post-transplant risk, and for asymptomatic carotid artery stenosis, there are no externally validated, reliable methods to determine who is at increased risk of stroke and at what degree of stenosis.[144] Carotid disease warranting revascularization independent of transplant evaluation should be addressed. Consultation with a neurologist and/or vascular surgeon can be useful in this assessment. Another potential contraindication to transplant listing would be deficits from prior cerebrovascular accidents that impair rehabilitation efforts or increase risk of aspiration and pulmonary infection. These decisions are necessarily individualized based on the patient's overall risk.
3. The diagnosis of peripheral arterial disease cannot rely solely on symptoms, as only a minority of patients with peripheral arterial disease present with intermittent claudication.[148] However, the presence of peripheral arterial disease portends worse survival in patients with HF[149–151] as well as in patients after HT.[152] Thus, evaluation for peripheral arterial disease with ankle brachial indices is recommended for all candidates with claudication, diminished peripheral pulses, atherosclerotic disease, or risk factors associated with peripheral arterial disease. Further testing with arterial ultrasound, CT angiography, or invasive angiography may be required, as dictated by results of initial testing and vascular surgery consultation.[153]
4. The impact of peripheral arterial disease revascularization on post-transplant outcomes is not established. However, certain characteristics of peripheral arterial disease would impact post-transplant outcomes and QOL and, therefore, could be considered contraindications. First, if a patient has disabling claudication not amenable to revascularization, transplantation would not offer an improvement in QOL, and the claudication would impair rehabilitation efforts. Second, if a patient has nonhealing ischemic ulcers, immunosuppression offers a prohibitive risk of infection and delayed wound healing.

2.1.2.6. Pulmonary Disease

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Pulmonary Disease		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-EO**	1. In heart transplant candidates, pulmonary evaluation with pulmonary function testing (spirometry, lung volume assessment, and diffusion capacity) and chest CT is recommended, ideally once optimized from a volume perspective.
2b	**C-LD**	2. In heart transplant candidates with severe parenchymal lung disease, as evidenced by chronic hypoxia from a pulmonary source or significant abnormalities in pulmonary function tests (as determined by a pulmonologist), the benefit of HT is uncertain due to the increased risk of post-transplant mortality.
2b	**C-EO**	3. In heart transplant candidates deemed ineligible for transplantation due to severe irreversible end-stage parenchymal lung disease, evaluation for combined heart and lung transplantation may be considered.

Recommendation-Specific Supportive Text

1. Up to one-third of unselected patients with HF have concurrent chronic obstructive pulmonary disease, largely attributed to the shared risk factor of smoking.[154] HF also commonly coexists with other lung diseases, including interstitial lung disease.[155] For some patients, distinguishing between pulmonary vs cardiac sources of dyspnea may be challenging and is beyond the scope of this guideline. However, patients with HF and lung disease are at increased risk for worse QOL, increased hospitalizations, and increased mortality,[156–159] and also increased risk for post-transplant longer hospital stay and increased mortality.[160,161] Thus, it is essential to screen heart transplant candidates for pulmonary parenchymal disease with pulmonary function testing, including spirometry, volume assessment, and diffusion capacity, as well as chest imaging, most commonly noncontrast CT, to assess for parenchymal disease. As pulmonary congestion may interfere with interpreting of these tests,[162,163] optimization of volume status with diuretic therapy should occur before pulmonary evaluation. Further testing may be required as dictated by a pulmonary specialist.
2. Few studies have analyzed pulmonary function testing and specific parameters that may be used to predict risk after HT, but the data are conflicting.[160,164] Patients with severe obstructive ventilatory defects or severely reduced diffusion capacity for carbon monoxide (DLCO) represent a high-pulmonary risk group. However, guidance on specific thresholds cannot be provided for patient selection; rather, the findings of pulmonary function testing can assist in the decision for listing.[164] The usefulness of spirometry to diagnose and grade pulmonary function abnormalities in transplant candidates may be further limited by the association of AdvHF with impaired spirometric values. There is a well-established association between clinically defined pre-existing pulmonary disease and worse outcomes after cardiac surgery; thus, the benefit of HT for severe parenchymal lung disease is uncertain due to the increased risk of post-transplant mortality.[164,165]
3. The primary indication for heart-lung transplant is PH, either secondary to idiopathic PH or CHD.[166] Severe pulmonary parenchymal disease, such as chronic obstructive pulmonary disease, in conjunction with AdvHF is not often an indication for heart-lung transplantation as the older age of such patients may contraindicate consideration of heart-lung transplantation. However, the decision about whether to list a patient for heart-lung transplant remains difficult,[167] as survival after heart-lung transplantation is inferior to that after HT alone,[89,166] and some patients may thrive after isolated lung transplantation.[168–171]

2.1.2.7. Pulmonary Hypertension

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Pulmonary Hypertension		
COR	**LOE**	**RECOMMENDATIONS**
1 **2a**	**C-LD**	1. In adult heart transplant candidates with pulmonary artery systolic pressure (PASP) ≥ 50 mmHg and either a TPG ≥ 15 mmHg or PVR ≥ 3 Wood units while maintaining a systolic arterial blood pressure > 85 mmHg, the following stepwise evaluation is recommended to assess transplant candidacy: 1) an acute vasodilator challenge to assess for reversibility of PH (Class 1); 2) hospitalization with continuous hemodynamic monitoring as often the PVR will decline after 24 to 48 hours of treatment consisting of diuretics, inotropic support, and vasodilators (Class I); and 3) temporary or durable MCS for unloading of the left ventricle (Class 2a).
2a	**B-NR**	2. In pediatric heart transplant candidates, HT is reasonable if PVR indexed to body surface area (PVRI) is less than 9 Wood units*m^2 on initial assessment or after treatment with diuretics, inotropic support, vasodilator therapy, or MCS.
2b	**C-EO**	3. In heart transplant candidates deemed ineligible for transplantation due to severe irreversible PH, evaluation for combined heart and lung transplantation may be considered in carefully selected patients.
3 No Benefit	**B-NR**	4. In heart transplant candidates with severe PH not reversible with measures including diuretic therapy, inotropic support, vasodilators, and temporary or durable MCS as indicated, HT alone is not recommended.

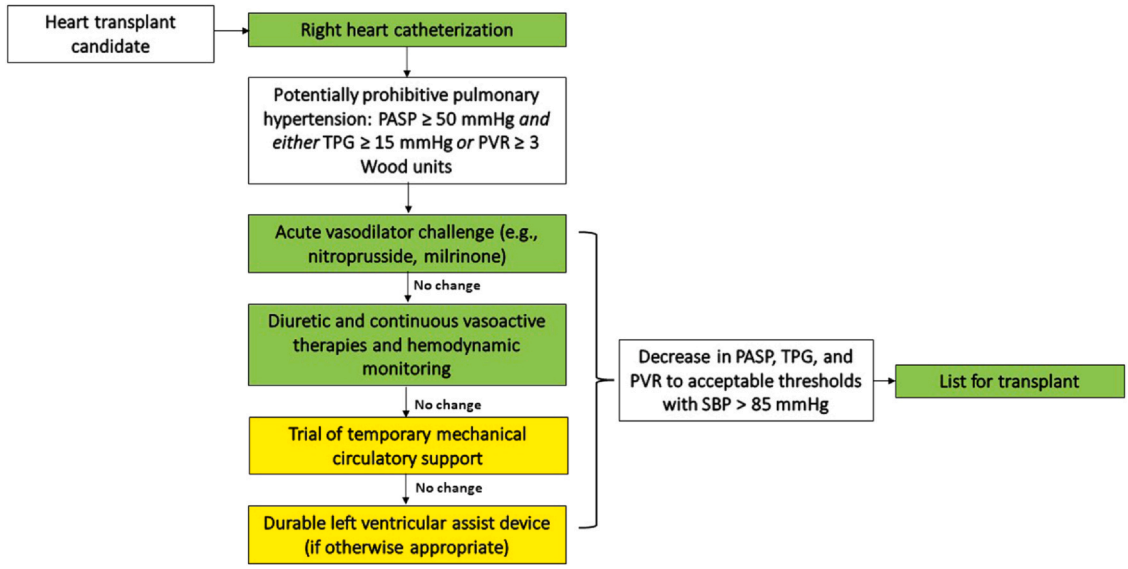
Recommendation-Specific Supportive Text

1. PH (mean PA pressure > 20 mm Hg), most commonly group 2 due to left heart disease [pulmonary capillary wedge pressure (PCWP) > 15 mm Hg],[172–174] is common in patients with HF,[175,176] and an elevated PVR ≥ 2.5

Wood units is associated with increased early post-transplant mortality.[177] Although elevations in PASP, TPG, and PVR above certain thresholds have been proposed as contraindications to HT listing, the risk associated with each parameter is continuous from low to high values and absolute cutoffs do not exist.[45,46] Even so, in patients with PASP ≥ 50 mm Hg and either TPG ≥ 15 mm Hg or PVR ≥ 3 Wood units, an acute vasodilator challenge should be administered during RHC to document acute reduction in the PVR to acceptable levels, while maintaining a systolic arterial pressure > 85 mm Hg.[178] An appropriate response to the vasodilator challenge would be if the TPG can be reduced to ≤12 to 15 mm Hg and the PVR to ≤2.5 to 3 Wood units. If the PVR is reversible but systolic blood pressure falls to < 85 mm Hg with pharmacologic maneuvers, the risk of RHF remains high.[178,179] When response to the acute vasodilator challenge is not acceptable, hospitalization with continuous vasoactive therapies and hemodynamic monitoring would be the next step in management,[180] followed by implantation of tMCS or a durable LVAD in eligible candidates (Figure 1).[181–187]

2. In pediatric heart transplant candidates, there is no association between elevated PVR indexed to body surface area (PVRI) on mortality at 30 days and up to 5 years post-transplant,[188] with increased mortality observed only in those pediatric heart transplant recipients with pre-transplant PVRI over 9 Wood units * m^2. This holds true for those pediatric heart transplant candidates with both CHD[189] and cardiomyopathy.[190] In pediatric heart transplant candidates with PVRI over 9 Wood units * m^2, unloading with diuresis and vasodilation (with vasoactive agents or MCS as needed) may be used to achieve acceptable PVRI. Patients with Fontan circulation present unique challenges; one cannot assume that PVR is low enough to tolerate HT based on the presence of passive circulation. Furthermore, estimating PVR in patients with Fontan failure can be difficult due to low cardiac output (CO) and systemic-to-pulmonary collaterals with possible unequal blood flow in the left and right lungs.[191]
3. The primary indication for a heart-lung transplant is PH, either secondary to idiopathic PH or CHD.[166] However, the decision about whether to list a patient for heart-lung transplant remains difficult[167] as survival after heart-lung transplantation is inferior to HT alone[89,166] and some patients with PH may do well after isolated lung transplantation.[168–171]
4. If a stepwise approach to achieving acceptable PA pressures is not successful, including an acute vasodilator challenge, diuretic therapy, inotropic support, vasodilators, and temporary and/or durable MCS, then the candidate would be deemed to have irreversible PH. This would be a contraindication to HT alone, as improved outcomes are evidence in patients who can achieve acceptable reversibility of PA pressures.[178, 179, 192–194]

Figure 1 Management of pulmonary hypertension in the adult heart transplant candidate. PASP, pulmonary artery systolic pressure; SBP, systolic blood pressure; TPG, transpulmonary gradient.



2.1.2.8. Kidney Disease

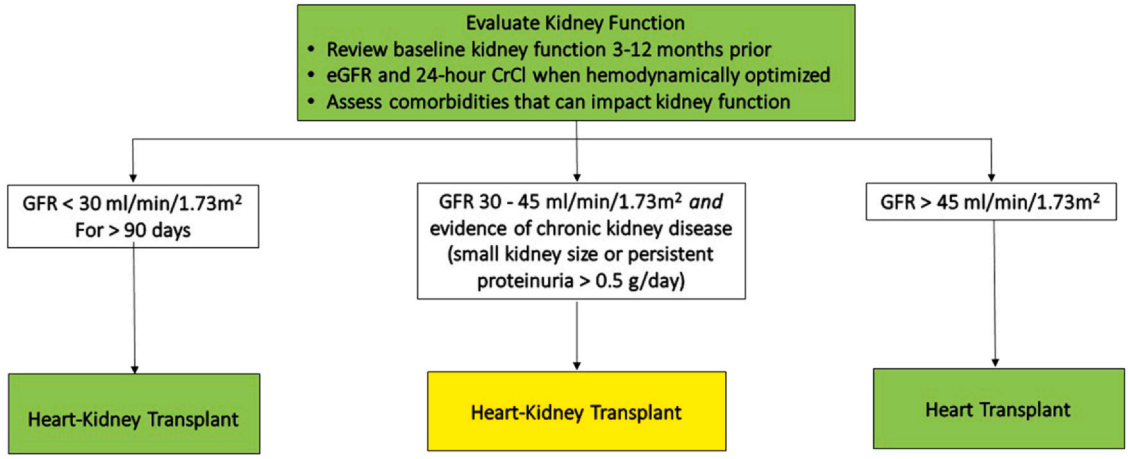
Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Kidney Disease		
COR	**LOE**	**RECOMMENDATIONS**
1	**B-NR**	1. In heart transplant candidates, a comprehensive assessment of kidney function is recommended, including: 1) historical trends in kidney function; 2) kidney function as measured by estimated glomerular filtration rate (GFR) and 24-hour creatinine clearance (CrCl) when hemodynamically optimized; and 3) comorbidities known to impact kidney function. If there is abnormal kidney function, further investigation is recommended, including nephrology consultation, renal ultrasonography, and estimation of proteinuria for assessment of intrinsic renal disease.
1	**B-NR**	2. In heart transplant candidates with established GFR < 30 ml/min/1.73 m^2, evaluation for simultaneous heart-kidney transplantation (SHKT) is recommended.
2a	**B-NR**	3. In heart transplant candidates with established GFR of 30–44 ml/min/1.73 m^2 and evidence of chronic kidney disease (CKD), such as small kidney size or persistent proteinuria >0.5 g/day in the presence of stable hemodynamics, evaluation for SHKT is reasonable.

Recommendation-Specific Supportive Text

1. The goal of the pre-transplant evaluation of kidney function is to differentiate CKD that will not improve post-HT from acute kidney injury (AKI) or CKD that may reverse with the hemodynamic optimization afforded by HT. This evaluation should take into account (1) historical trends in kidney function during the months to years before cardiac decompensation, (2) current trends in kidney function when the patient is hemodynamically optimized, ideally over a few weeks' duration, (3) comorbidities (e.g., diabetes, lupus) known to be associated with irreversible kidney damage, and (4) other findings such as the presence of proteinuria.[12,195] Transplant candidates should have 2 independent measurements for GFR at least 2 weeks apart using serum creatinine measurements and race-free equations for eGFR.[196–198] The confirmatory GFR measurement should be a measured GFR, such as 24-hour creatinine clearance.[199] According to international nephrology societies, the CKD-EPIKrea formula should preferably be used to estimate the GFR (estimated GFR); in the case of borderline findings (estimated GFR 45-59 ml/min/1.73 m^2), there is the option of determining cystatin C as an additional filtration marker (estimation of the GFR using the CKD-EPIKrea-Cys formula).[200] The results of ancillary testing may be used to assess the presence, severity, and chronicity of intrinsic renal disease, including the presence of cortical scarring on renal ultrasound or proteinuria. A kidney biopsy is rarely required.
2. While worse renal function pre-HT[201,202] and post-HT[203] portends worse outcomes post-HT, data demonstrating improved survival with SHKT vs HT when pre-transplant GFR is below a specific threshold are limited.[204–207] A UNOS registry analysis of over 26,000 recipients transplanted in 2000-2010 determined that transplant recipients derived increased survival for SHKT vs HT if they had eGFR < 37 ml/min/1.73 m^2, although the absolute difference in median post-transplant survival was small, 7.7 years for the SHKT cohort vs 7.1 years for the HT cohort.[205] Another challenge is marked changes in kidney function in a HT candidate while on the waitlist. In situations where there is inadequate time to assess for AKI recovery, both heart and kidney specialists should weigh all factors (i.e., perceived kidney reserve and recovery potential, risk or presence of CKD) in order to decide SHKT vs HT candidacy. Nonetheless, if eGFR < 30 ml/min/m^2 and patients are deemed ineligible for kidney transplantation, HT alone should generally not be pursued, given worse outcomes in recipients of HT alone compared with SHKT when eGFR < 30 ml/min/m^2.[208]
3. A key concern in SHKT eligibility is whether and how much an individual will benefit more from a SHKT. SHKT is associated with increased survival in dialysis-dependent patients (median survival SHKT: 12.6 vs HT: 7.1 years $p < 0.0001$) but not with nondialysis patients (median survival SHKT: 12.5 vs HT 12.3, $p = 0.24$).[209] Evaluation for CKD pre-transplant offers prognostic information on kidney function after HT but cannot fully predict the trajectory of kidney function post-HT, as it is also dependent on donor characteristics and the perioperative and post-transplant course. Moreover, prognosis is distinct from causation: pre-transplant CKD may predict worse kidney function and lower survival after HT, but whether these disadvantages are mitigated

by a SHKT is not established. Thus, collaboration with nephrologists is essential for optimal donor stewardship (Figure 2). Importantly, in the setting of organ scarcity, SHKT must balance the benefit to the individual with that of other candidates awaiting a single kidney transplant. Thus, efforts to explore other strategies (i.e., delayed multi-organ transplant) will optimize a fair allocation of the scarce resource of donor organs. In the United States, a Safety Net approach has been implemented to theoretically allow better prioritization of donor organs. In this policy, heart transplant recipients would qualify for the Safety Net kidney donor if they were (1) registered on the kidney waiting list before the 1-year anniversary of their HT and (2) were on chronic dialysis or had a measured or estimated creatinine clearance or GFR ≤ 20 ml/min/1.73 m^2 between day 60 to day 365 post-transplant.[210] Some critically ill heart transplant recipients face a high rate of renal allograft dysfunction due to perioperative hemodynamic instability and may benefit from this option, assuming a living donor is not available.

Figure 2 Assessment for heart-kidney transplantation (Adapted from Kittleson et al, AHA Scientific Statement 2023)[12]. CrCl, creatinine clearance; eGFR, estimated glomerular filtration rate; GFR, glomerular filtration rate.



2.1.2.9. Liver Disease

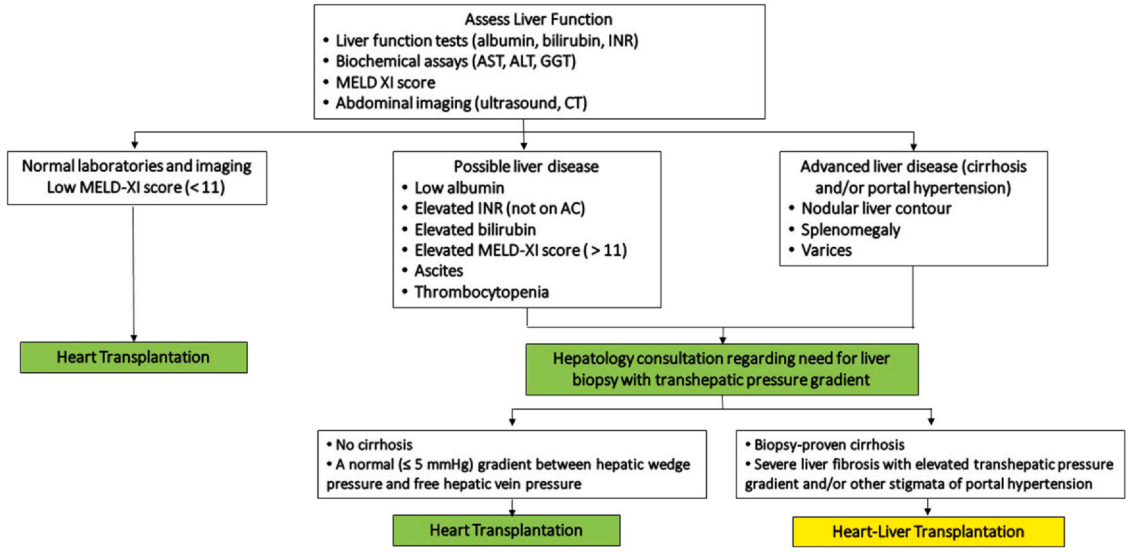
Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Liver Disease		
COR	**LOE**	**RECOMMENDATIONS**
1	B-NR	1. In heart transplant candidates, a comprehensive assessment of liver function is recommended, including: 1) liver function tests (albumin, bilirubin, INR); 2) biochemical assays (AST, ALT, GGT), 3) MELD-XI score; and 4) abdominal imaging with ultrasound or CT and/or magnetic resonance imaging (MRI). If there is abnormal initial liver evaluation, further investigation is recommended, including hepatology consultation and liver biopsy.
2a	B-NR	2. In patients with biopsy-proven cirrhosis and/or severe liver fibrosis with evidence of portal hypertension, evaluation for heart-liver transplantation is reasonable.

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma-glutamyl transferase; INR, international normalized ratio; MELD-XI, model for end-stage liver disease excluding INR.

Recommendation-Specific Supportive Text

1. Acute HF can lead to liver injury through either ischemia and/or congestion.[211] In chronic HF, ischemia and congestion also contribute to chronic liver disease, often related to RV failure, advanced biventricular (BiV) failure, severe tricuspid regurgitation, restrictive/constrictive cardiomyopathy, and CHD, particularly in single-ventricle physiology palliated with a Fontan operation [Fontan-associated liver disease (FALD) which is addressed in Congenital Heart Disease].[211,212] The evaluation of patients with AdvHF being considered for transplantation with concomitant liver disease focuses on whether the liver disease (1) may reverse with optimization of cardiac function and (2) is advanced enough to impact perioperative risk and/or require dual-organ transplantation. A modification of the MELD score (MELD-XI) that excludes INR, offers prognostic information in HT candidates.[213,214] Liver ultrasound, abdominal CT, and liver MRI comprise the most common imaging techniques. However, the diagnosis of cirrhosis in HT candidates should never rest on imaging findings alone, as imaging can neither accurately characterize the degree of hepatic fibrosis, nor distinguish cirrhosis from nodular regenerative hyperplasia[215] or noncirrhotic portal hypertension.[216] Hepatic elastography allows for noninvasive assessment of hepatic fibrosis. Liver biopsy remains the only accurate and reliable method of assessing hepatic histology in the process of assessing HT candidacy,[217] though also prone to sampling error due to the heterogeneity of liver fibrosis.[218] In FALD, the presence of bridging fibrosis or cirrhosis portends a worse survival and the degree of fibrosis correlates with temporal changes in platelet count and MELD-XI.[219,220] In pediatric heart transplant candidates, increases in MELD-XI score and total bilirubin, as well as abnormal serum albumin,[43,221] are associated with worse post-transplant survival.[213,222]
2. Advanced liver disease and cirrhosis are considered contraindications to isolated HT because patients with cirrhosis who undergo isolated HT have short-term mortality as high as 50%.[223–227] Transvenous liver biopsy is preferred as it allows for assessment of wedged and free hepatic vein pressure measurements. A normal (5 mm Hg or less) gradient between hepatic wedge pressure and free hepatic vein pressure excludes significant portal hypertension, providing important information regarding the presence of chronic liver disease, which may impact HT candidacy.[228] Collaboration with hepatologists is essential to determine if simultaneous heart-liver transplantation is warranted (Figure 3) and to ensure there are no liver-transplant-specific contraindications.[12]

Figure 3 Assessment for heart-liver transplantation (Adapted from Kittleson et al, AHA Scientific Statement 2023)[12]. ALT, alanine aminotransferase; AST, aspartate aminotransferase; CT, computed tomography; INR, international normalized ratio; MELD-XI, model for end-stage liver disease excluding INR.



2.1.2.10. Connective Tissue Diseases and Sarcoidosis

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Connective Tissue Diseases and Sarcoidosis		
COR	**LOE**	**RECOMMENDATIONS**
1	**B-NR**	1. In heart transplant candidates with connective tissue disease (CTD) or sarcoidosis, focused multidisciplinary collaboration is recommended to determine 1) the impact of the CTD on post-transplant survival, rehabilitation efforts, and QOL; 2) the impact of immunosuppression on the progression of the CTD; 3) the risk of cardiac recurrence; and 4) CTD-specific extracardiac manifestations such as PH, pulmonary parenchymal disease, aspiration risk, and/or arthritis.
3: No Benefit	**B-NR**	2. In heart transplant candidates with CTD that is expected to shorten post-transplant survival, that is associated with severe non-cardiac disease, or that is not controlled with pre-transplant immunosuppression, HT is not recommended.

Recommendation-Specific Supportive Text

1. The most common connective tissue diseases (CTD) with associated cardiomyopathies include systemic lupus erythematosus, systemic sclerosis, and rheumatoid arthritis.[229] While sarcoidosis is not a CTD, it is considered here, as it also treated with immunosuppression, may progress to require heart transplant consideration, and may have associated extracardiac manifestations that impact transplant candidacy. The largest heart transplant experience exists for cardiac sarcoidosis, where survival is generally comparable to that of heart transplant recipients without sarcoidosis.[230–232] In other conditions, heart transplant experience is limited to case reports or case series,[233–235] and while outcomes appear favorable, it is important to note that these heart transplant candidates are highly selected. There are case reports of recurrent sarcoidosis after HT, and collaboration with a specialist for CTD or sarcoidosis is essential to confirm that the planned post-HT immunosuppression regimen will be adequate to also control the CTD.
2. Multidisciplinary collaboration is required to determine that the CTD will not impact post-HT survival, QOL, or rehabilitation efforts. Specific attention to organ involvement is important in different CTDs. In sarcoidosis, evaluation of lung disease is paramount. For lupus, consideration of kidney disease, arthritis, and thromboembolism is warranted. For systemic sclerosis, attention must be paid to esophageal dysmotility, arthritis, PH, and kidney disease. If there is severe or uncontrolled extracardiac disease, HT should not be pursued, though in selected cases, multiorgan transplantation may be considered, including heart-lung transplantation for systemic sclerosis with cardiomyopathy and PH.[236]

2.1.2.11. Infections and Vaccinations

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Infections and Vaccinations		
LOE	**COR**	**RECOMMENDATIONS**
1	**C-EO**	1. In heart transplant candidates, screening for chronic or latent diseases that have the risk for post-transplant reactivation and may warrant pre-transplant treatment or post-transplant surveillance is recommended, including but not limited to human immunodeficiency viral (HIV) infection, Chagas disease, tuberculosis (TB), HBV and HCV infections (Table 9); surveillance for geographically restricted specific pathogens may be warranted.
3: No Benefit	**C-EO**	2. In heart transplant candidates with certain infections, HT is not recommended; these include 1) active infections requiring ongoing antibiotic treatment (except for infected durable LVADs); and 2) HIV with opportunistic infections or related malignancy, lack of stable antiretroviral regimen, detectable viral load, and/or low CD4 count.
1	**B-NR**	3. In heart transplant candidates, vaccine history and assessment of seroprotection (as appropriate) should be reviewed, and age-appropriate vaccinations administered ideally at least 2 weeks prior to transplantation are recommended (Table 10); live-attenuated vaccines should be avoided unless transplant can be deferred for 4 weeks after receipt due to concern for ongoing viral replication.

Recommendation-Specific Supportive Text

1. Heart transplant candidates should be screened for chronic or latent infection during the evaluation process with the aim of resolving or suppressing active infection before transplant and developing a post-transplant prophylaxis plan. A focused summary of screening most likely to impact pre-transplant management is shown in Table 9. Screening of heart transplant candidates should also include *Cytomegalovirus* IgG, *Epstein-Barr virus* (EBV) antibody (EBV VCA IgG, IgM), *Toxoplasma* IgG antibody, *Strongyloides* IgG and *Strongyloides* stool culture (if from endemic areas), *Coccidioides* serology (if from endemic areas), *trypanosomiasis* serology (if from endemic areas) and syphilis.[237]
2. Since there are no specific infections that would contraindicate HT, the goal is appropriate risk stratification and management of infections in the pre-transplant phase, as well as a plan for post-transplant prophylaxis if indicated. In most instances, active infection should be a reason to defer transplant. The exception is DMCS infection, as explantation of all MCS components at the time of transplantation is often the definitive cure for the device-associated infection.[238] While highly selected candidates with HIV can be successfully transplanted,[239] specific criteria should be met,[240] as outlined in Table 9. Consideration of HT in patients with active and refractory infective endocarditis is controversial. Apart from demonstrated success in sporadic case reports, there is currently a lack of any other robust body of evidence to endorse HT for infective endocarditis.[241] HT may be carefully considered in extreme cases where repeated operative procedures have failed to eradicate persistent or recurrent infective endocarditis.[242]
3. There are limited data specifically addressing vaccination of adults and children with AdvHF in the pre-transplant setting.[243,244] Nonetheless, vaccinations are part of health care maintenance, and as such, initiating or updating life-saving vaccines is best practice in contemporary transplant medicine.[243] Pre-transplant vaccination is essential, as the candidate is generally not immunosuppressed and is thus expected to mount a more robust immune response than after transplantation; this has been observed most dramatically with vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[245–248] Ideally, vaccination should be completed at least 2 weeks before transplantation to optimize immune response. Refusal to accept guideline-recommended vaccinations may be considered a contraindication to transplantation. If live-attenuated vaccines are utilized, the transplant should be deferred for 4 weeks to reduce the risk of active viral replication at the time of transplant.[243] Table 10 summarizes recommended pre-transplant vaccinations for adult candidates. Detailed vaccination schedules are also publicly available and regularly updated by organizations, such as the United States Advisory Committee on Immunization Practices.[249]

Table 9 Screening for Latent Disease Requiring Pre-transplant Treatment and/or With the Potential for Post-Transplant Reactivation

Infection	Who to check	What to check	Pre-transplant management	Contraindications to HT
HIV[240]	All candidates	HIV RNA CD4 count	Consultation with HIV specialist to ensure stable anti-retroviral regimen that is safe post-HT	• Opportunistic infections or related malignancy (Kaposi sarcoma, lymphoma) • Chronic wasting or severe malnutrition • Lack of stable antiretroviral regimen • Detectable HIV RNA • CD4 count < 200 cells/microliter during the 3 months before transplantation
Chagas disease[250,251]	Born in Latin America (Central and South America or Mexico) or have spent significant time in Latin America, those with a Latin American mother, or received unscreened blood products	• Chronic Chagas disease diagnosed by serologic methods to detect IgG antibodies to *T. cruzi*, most commonly enzyme-linked immunosorbent assay (ELISA) and immunofluorescent antibody assay (IFA). • A positive result by a single assay does not constitute a confirmed diagnosis; 2 serologic tests based on different antigens (e.g., whole-parasite lysate and recombinant antigens) and/or techniques (e.g., ELISA and IFA) are used in parallel to increase the accuracy of the diagnosis.	Benefit of prophylactic therapy is not established.	None
TB[252]	All candidates	Tuberculin skin test (TST) and/or interferon-γ release assay (IGRA) where available	• Candidates with a positive IGRA or TST ≥5-mm induration should be treated pre-transplant with isoniazid and pyridoxine, if tolerated. • Candidates from a TB-endemic area with a positive IGRA or TST ≥5-mm induration should have at least 1 other risk factor (evidence of a recent seroconversion, evidence of old TB lung disease, history of untreated or inadequately treated TB, close contact with a person with TB) before commencing isoniazid prophylaxis.	Treatment for latent TB infection should be for 6-9 months and should not interfere with the timing of transplantation
HBV[253]	All candidates	HBV surface antigen, HBV core antibody, HBV surface antibody	Resolved or prior HBV infection (HBcAb+ and/or HBsAb+ but HBsAg-): serology and DNA viral load testing at 3-month intervals while listed. Complete viral HBV evaluation before HT should also include HBV nucleic acid test, HBe antigen, HBe antibody, hepatitis delta virus (HDV) antigen, HDV antibody, serum alfa-fetoprotein	Presence of cirrhosis on liver biopsy; heart-liver transplantation may be offered in select patients
HCV[253]	All candidates	HCV antibody and nucleic acid test	Chronic HCV: direct-acting antiviral therapy, choice based on genotype and other medications to achieve sustained virologic response	Presence of cirrhosis on liver biopsy; heart-liver transplantation may be offered in select patients

Abbreviations: HBV, hepatitis B virus; HCV, hepatitis C virus; HT, heart transplantation; HIV, human immunodeficiency virus; HBcAb+, hepatitis B core antibody positive; HBsAb+, hepatitis B surface antibody positive; HBsAg-, hepatitis B surface antigen negative; HBe , Hepatitis B e.

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Table 10 Pre-transplant Vaccinations for Adult Heart Transplant Candidates

Vaccine	Pre-transplant serology	Pre-transplant vaccination	Confirm response pre-transplant	Special circumstances
Hepatitis A	Yes	Yes	Yes	Recommended for those with increased risk; travel or residence in high-risk areas; occupational or lifestyle exposure risk
Hepatitis B	Yes	Yes	Yes	
Pneumococcus	Consider	Yes	Consider	PCV20 single dose or PCV15 followed by PPSV23
Tetanus (dT)	Yes	Yes	No	Administer Tdap to all who have not previously received Tdap
Pertussis (Tdap)	No	Yes	No	Administer Tdap to all who have not previously received Tdap
Influenza	No	Yes	No	Seasonally, vaccination is also recommended for close contacts
SARS-CoV-2	No	Yes	No	Vaccination is also recommended for close contacts; up-to-date booster vaccination is recommended.
Meningococcus	No	Yes	No	Recommended for those at increased risk, including asplenia/polysplenia, high-risk travel, terminal complement deficit, including before eculizumab
Rabies	No	No	No	Consider those with a risk of significant post-transplant exposure
Human papilloma virus	No	Yes	No	Approved age 9-26 years
Live viral vaccines				
Varicella	Yes	Yes	Yes	Not needed if seropositive
Herpes zoster		Yes		The recombinant subunit zoster vaccine is preferred over the live-attenuated vaccine for transplant candidates and should be given in accordance with local vaccination guidelines[254]
Mumps, measles, rubella	Yes	Yes	Yes	Not needed if born before 1957

Abbreviation: SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

2.1.2.12. Frailty

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Frailty		
LOE	**COR**	**RECOMMENDATIONS**
2a	**B-NR**	1. In heart transplant candidates, assessment of frailty can be beneficial to identify actionable targets for improvement in conditioning and perform risk assessment of transplant candidacy.
1	**C-LD**	2. In heart transplant candidates, regular exercise as tolerated is recommended, ideally in a structured program if available, to prevent or improve frailty.
3 No benefit	**C-EO**	3. In heart transplant candidates with severe frailty that will preclude adequate post-transplant rehabilitation efforts and is not expected to improve with restoration of cardiac function, HT is not recommended.

Recommendation-Specific Supportive Text

1. Frailty is a syndrome of reduced physiological reserve resulting in a reduced capacity for an individual to tolerate minor or major stressors[255,256] and can be observed in association with various chronic disease states and at any age. There is no universally accepted definition of frailty, and the lack of standardization makes using frailty as a definitive criterion for listing difficult. A commonly used frailty assessment instrument in patients with HF is the phenotype model, or frailty phenotype (FP). The phenotype, focusing on the physical aspects of frailty, is composed of 5 physical domains—slowness, weakness, weight loss, reduced activity, and exhaustion (Table 11).[255,257,258] The impracticability of performing some of the physical measures in unstable clinical settings

and the complicated cut points (dependent on sex, height, and BMI) led to multiple modifications of the FP. The unintended weight loss criterion was replaced with loss of appetite over the 3 months before assessment because weight loss could be masked by fluid retention. Chair stands replacing grip strength measurements are easily reproducible in clinical settings. Frailty, as measured by the FP, is common in HF, occurring in up to 50% of patients[257,259] and is an independent predictor of mortality, including those who were actively listed for HT.[259–261] Frail heart transplant candidates are also at increased risk for post-transplant mortality.[262] In patients with CHD, frailty is prevalent and can be measured using standardized tools adapted to this younger population.[263,264] Frailty can be partially reversible after LVAD implantation[265,266] and HT.[266] However, whether those patients who reverse frailty while awaiting transplantation have better outcomes after transplantation remains unclear.

2. Consensus-based guidelines for preventing and improving frailty recommend physical activity,[267–270] adequate protein intake, and targeting any contributing underlying disease processes.[269] In transplant candidates, exercise may take the form of "prehabilitation," a program to enhance the patient's functional capacity before transplantation to improve postoperative outcomes. Prehabilitation can improve frailty scores and exercise performance in candidates for SOT,[271–273] but it remains to be seen if such measures improve post-transplant outcomes.
3. An assessment of frailty can be useful as part of advanced care planning, incorporating both a patient's current functional status and future goal of care into the shared decision-making process.[274] The potential for successful post-transplant recovery should be considered when weighing the impact of a candidate's frailty; the ability to ambulate and quadriceps muscle strength may offer insight into recovery potential.[275] Therefore, there is no evidence of benefit for HT in frail patients with poor potential for recovery despite post-transplant rehabilitation.

Table 11 Physical Frailty Assessment

	Frailty phenotype criteria[255]			Modified frailty phenotype criteria[13]
Elements	Measurement			Measurement
Physical exhaustion	Self-reported. "In the last week, did you feel, on *at least 3 days*, that everything you did was an effort or you could not get going?" (No = 0; Yes = 1)			Self-reported. "In the last week, did you feel, *on at least 3 days*, that everything you did was an effort?" (No = 0; Yes = 1)
Weakness	Hand grip strength measured using handheld dynamometer (Yes = 1):			Rising from and sitting down on a chair 5 times without using arms/hands: ≤15 seconds (No = 0) >15 seconds or unable to complete (Yes = 1)
	Men	BMI ≤24 BMI 24.1-28 BMI >28	≤29 kg ≤30 kg ≤32 kg	
	Women	BMI ≤23 BMI 23.1-26 BMI 26.1-29 BMI >29	≤17 kg ≤17.3 kg ≤18 kg ≤21 kg	
Weight loss	Self-reported unintentional weight loss >10 pounds or >5% in the last year (No = 0; Yes = 1)			Self-reported. "Have you been eating the same/more than usual?" (Yes = 0) "or less than usual?" (Yes = 1)
Slowness	Time to walk 15 feet (Yes = 1):			Time to walk 5 meter: ≤6 seconds (No = 0) >6 seconds or unable to complete (Yes = 1)
	Men	Height ≤173 cm Height >173 cm	≥7 seconds ≥6 seconds	
	Women	Height ≤159 cm Height >159 cm	≥7 seconds ≥6 seconds	
Low physical activity	Self-reported kilocalories expended per week[a] (Yes = 1): Males <383 Kcals/week Females <270 Kcals/week			Self-reported. "How often do you engage in activities that require a low or moderate level of energy (gardening, cleaning the car, or doing a walk)?" ≥once/week (No = 0) <once/week (Yes = 1)
Total scoring: 0 criteria met = not frail; 1-2 criteria met = prefrail; 3-5 criteria met = frail				

Abbreviation: BMI, body mass index.
[a]Kcals per week expended are calculated using a standardized algorithm (short version of the Minnesota Leisure Time Activity questionnaire).

2.1.2.13. Surgical Risk

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Surgical Risk		
COR	**LOE**	**RECOMMENDATIONS**
1	**B-NR**	1. In HT candidates with prior cardiac surgery, this additional risk should be factored into the comprehensive assessment of transplant eligibility.
2b	**C-LD**	2. In heart transplant candidates with circular aortic calcification ("porcelain" aorta), the benefit of HT is uncertain due to the high risk of perioperative mortality and stroke.

Recommendation-Specific Supportive Text

1. Prior cardiac surgery increases the surgical risk and early morbidity and mortality of HT.[276–279] Nonetheless, despite the increased postoperative risk conferred by prior cardiac surgery, this history should not be considered an absolute contraindication to transplantation. Instead, this additional risk factor should be considered in the context of the clinical picture, including the urgency for transplantation and the extent of other comorbidities, including age and center-specific surgical experience.
2. Porcelain aorta is extensive calcification of the ascending aorta or aortic arch that can be completely or near completely circumferential and reflects an underlying atherosclerotic process or the consequence of mediastinal radiation. The presence of a porcelain aorta is important to assess because it precludes safe cross-clamping or entry to the ascending aorta. During aortic valve surgery, the presence of a porcelain aorta increases the risk of perioperative mortality and stroke[280,281] and this risk is extrapolated to HT. Although there are reports of surgical techniques adapted to reduce neuro-embolic risk and to achieve safe aortic insertion and closure, these are highly selected cases and not likely widely applicable.[282] Mediastinal radiation therapy for cancer can contribute to the formation of a porcelain aorta and result in perioperative complications.[283]

2.1.2.14. Bone Disease

Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation: Bone Disease		
COR	**LOE**	**RECOMMENDATION**
1	**B-NR**	1. Heart transplant candidates should be assessed for osteoporosis and fracture risk.

Recommendation-Specific Supportive Text

1. Both pre-transplantation bone disease and immunosuppressive regimens result in rapid bone loss and increased fracture rates. Given existing ample data confirming the high frequency of bone disease in patients awaiting SOT, osteoporosis and fracture risk should be assessed. A comprehensive evaluation would include a fracture history, a routine bone densitometry of the lumbar spine and femoral neck measured by dual X-ray absorptiometry and spine radiographs or vertebral fracture assessment to diagnose prevalent fractures. Patients with osteoporosis should be treated before and after transplantation.[284]

2.1.3. Assessment of Transplant Eligibility in Special Populations

2.1.3.1. Cardiac Amyloidosis

Recommendations for Assessment of Transplant Eligibility in Special Populations: Cardiac Amyloidosis		
COR	**LOE**	**RECOMMENDATIONS**
2a	**B-NR**	1. In heart transplant candidates with cardiac amyloidosis from immunoglobulin light chain deposition (AL-CM) or transthyretin deposition (ATTR-CM) with evidence of AdvHF as indicated by amyloid-specific staging systems (Table 12) and traditional risk factors (Table 13), heart transplant evaluation is reasonable, including multidisciplinary collaboration to evaluate the extent and control of extracardiac disease.
3 Harm	**B-NR**	2. In patients with AL-CM and high-grade albuminuria, significant hepatic infiltration, significant gastrointestinal involvement with malnutrition, pulmonary amyloidosis with refractory effusions, significant peripheral neuropathy with autonomic dysfunction, and/or projected reduced survival despite plasma cell-directed therapies as determined in collaboration with hematologists and other relevant specialists, HT is not recommended.
3 No Benefit	**B-NR**	3. In patients with ATTR-CM with significant gastrointestinal involvement with malnutrition, significant peripheral neuropathy with autonomic dysfunction, and/or advanced age, HT is not recommended.
2b	**B-NR**	4. In patients with ATTRv-CM, the role of heart-liver transplantation is not well established given the advent of TTR silencer therapy, which reduces the progression of amyloid neuropathy.
2b	**B-NR**	5. In patients with AL-CM or ATTR-CM, the role of durable LVAD support is not well established, given the small left ventricular (LV) cavity size and biventricular involvement.

Synopsis

Cardiac amyloidosis results in RCM caused by extracellular deposition of proteins in the myocardium, most commonly a monoclonal immunoglobulin light chains (AL) from an abnormal clonal proliferation of plasma cells, or transthyretin (ATTR), a liver-synthesized protein which can be variant (ATTRv) or wild-type (ATTRwt) gene. Clinical recognition and diagnosis of cardiac amyloidosis at an early stage of the disease is critical, as important advances in the treatment of both ATTR-CM and AL-CM, will allow prompt implementation of therapeutic interventions that may improve survival, physical function, and/or QOL. However, for carefully selected patients with advanced symptoms and limited extracardiac involvement, HT may improve QOL and survival.

Recommendation-Specific Supportive Text

1. Cardiac involvement is the most important prognostic indicator in patients with amyloidosis with both AL-CM or ATTR-CM.[285–288] For both AL-CM and ATTR-CM, troponin and NT-proBNP are powerful indicators of disease burden and prognosis.[289,290] Multiple staging systems have been developed that rely predominantly on these biomarkers (Table 12).[291–294] There are additional biomarkers uniquely prognostic to the type of amyloidosis as well: free light chains (dFLC) and kidney function for AL-CM and ATTR-CM, respectively.[293,295] However, traditional markers of poor prognosis in HF (as outlined in Task Force 1 Listing Criteria for Heart Transplantation) are also useful to best identify those candidates who are limited enough from a cardiac standpoint to warrant consideration of AdvHF therapies. The ideal timing of HT in AL-CM is challenging, as contemporary therapies may result in improved cardiac function, though patients with HF were excluded from key trials.[296] In ATTR, while tafamidis slows disease progression, it does not reverse disease and is less effective in patients with more advanced symptoms.[285] Thus, transplant evaluation should not be delayed in highly symptomatic patients to assess the response to tafamidis.

2. As multiorgan amyloid infiltration is common, the contraindications to HT in patients with cardiac amyloidosis center around the degree of extracardiac involvement and the impact of this involvement on post-transplant morbidity and mortality (Table 13). In AL-CM, it is critical to screen for the presence of significant extracardiac organ involvement, including high-grade albuminuria, significant hepatic infiltration, significant gastrointestinal involvement with malnutrition, pulmonary amyloidosis with exudative effusions,[297,298] and significant peripheral neuropathy with autonomic dysfunction. The presence of multiple myeloma in the setting of AL amyloidosis and response to administered plasma-cell-directed therapies will also impact transplant candidacy.[299,300] All patients undergoing consideration for HT should also be assessed by an experienced team for eligibility for stem cell transplantation, though this may not always be necessary in the current era of effective plasma cell-directed therapies.[296]
3. For ATTR-CM, potentially contraindicating extracardiac involvement includes gastrointestinal involvement and autonomic neuropathy (Table 13). Gastrointestinal involvement can result in malnutrition with risk for infection and poor wound healing. Disabling neuropathy will not improve after HT and may significantly impair rehabilitation efforts and QOL.
4. For ATTRv-CM, heart-liver transplantation has traditionally been considered in patients at risk for neuropathy, as neuropathy may progress with HT alone. However, the criteria for HT alone vs heart-liver transplantation are not well defined,[5] especially with the advent of transthyretin (TTR) silencer therapy that may have a role after HT.[301,302] TTR-specific therapy, including tafamidis or silencing agent (in patients with ATTRv-CM), should be prescribed following HT if coexistent neuropathy attributable to amyloidosis is present.[303]
5. Barriers to the successful use of DMCS devices include the small LV cavity and BiV involvement.[304,305] A second challenge arises from the fact that patients with cardiac amyloidosis typically have evidence of BiV dysfunction, resulting in the risk of RV failure when LVADs are placed. In this situation, a durable BiV assist device, such as the total artificial heart (TAH), may be placed.[306] Another concern for the use of DMCS in patients with amyloidosis is the risk of infection in those patients with AL amyloidosis upon receiving plasma-cell-directed therapies.[300] Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry data indicate worse survival in all patients with cardiac amyloidosis and MCS compared to those with dilated cardiomyopathy and nonamyloid RCM regardless of whether LVAD or BiV MCS was employed.[307]

Table 12 Staging Systems for Cardiac Amyloidosis

Variable	Mayo staging system[294]	UK staging System[295]	Mayo 2004[291]	Mayo 2004 with European modification[308]	Mayo 2012[293]	Boston University[309]
Population	ATTRwt-CM	ATTRwt-CM and ATTRv-CM	AL-CM	AL-CM	AL-CM	AL-CM
Parameters and thresholds	• Troponin T ≤ 0.05 ng/ml • NT-proBNP ≤ 3,000 pg/ml	• NT-proBNP ≤ 3,000 pg/ml • eGFR ≥ 45 ml/min	• Troponin: - TnT ≥ 0.035 mcg/liter or - TnI ≥ 0.1 mcg/liter or - High-sensitivity TnT ≥ 50 ng/liter • BNP: - NT-proBNP ≥ 332 ng/liter	• Troponin: - TnT ≥ 0.035 mcg/liter or - TnI ≥ 0.1 mcg/liter or - High-sensitivity TnT ≥ 50 ng/liter • BNP: - NT-proBNP ≥ 332 ng/liter	• Troponin - Troponin T ≥ 0.025 mcg/liter or - High-sensitivity troponin T ≥ 40 ng/liter • BNP - NT-proBNP ≥ 1800 ng/liter or - BNP ≥ 400 ng/liter • dFLC ≥ 18 mg/dl	• BNP > 81 pg/ml • TnI > 0.1 ng/ml
Median survival						
Stage I: no parameters above threshold	66 months	69.2 months	26.4-27.2 months	Median survival not reached; 60% survival at 10 years	94.1 months	Median survival not reached; > 12 years
Stage II: 1 parameter above threshold	40 months	46.7 months	10.5-11.1 months	49 months	40.3 months	113 months
Stage III: 2 parameters above threshold	20 months	24.1 months	3.5-4.1 months		14 months	52 months
Stage IIIA: 2 parameters above threshold and NT-proBNP < 8,500 ng/ml	n/a	n/a	n/a	14 months	n/a	
Stage IIIB: 2 parameters above threshold and NT-proBNP ≥8,500 ng/ml	n/a	n/a	n/a	5 months	n/a	12 months (if BNP > 700 mg/ml)
Stage IV: 3 parameters above threshold	n/a	n/a	n/a	n/a	5.8 months	n/a

Abbreviations: AL-CM, amyloid monoclonalimmunoglobulin light chain cardiomyopathy; ATTRwt-CM, wild-type transthyretin amyloid cardiomyopathy; BNP, B-type natriuretic peptide; dFLC, difference between involved and uninvolved free light chain; eGFR, estimated glomerular filtration rate; NT-proBNP, N-terminal pro-brain natriuretic peptide; TnT, Troponin T.

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Table 13 Extracardiac Complications of Amyloidosis

System involvement	AL vs ATTR	Common presentation	Tools for assessment	Considerations in the heart transplant candidate
Renal[310]	• AL	• Proteinuria • Nephrotic syndrome	• Urine protein • Serum creatinine	• Consider dual heart/kidney transplant in eGFR <50 ml/min/1.73 m^2 and albuminuria >0.5 g/day • Discussion with nephrology regarding reversibility post-transplant
Hepatic[311]	• AL	• Elevated alkaline phosphatase • Hepatomegaly • Splenomegaly	• Liver function tests • Biopsy	• Consider need for dual heart-liver transplant
Gastrointestinal[312]	• AL	• Gastrointestinal bleeding • Weight loss • Refractory dyspepsia	• Whole-body ^{123}I-labeled serum amyloid P scintigraphy • Biopsy	• Malnutrition • Impact on medication absorption
Autonomic nervous system[313]	• ATTR	• Carpal tunnel • Sensorimotor polyneuropathy • Orthostasis/ autonomic dysfunction	• Physical exam • Electromyography	• Impact on frailty and ambulation
Pulmonary[314]	• AL	• Rarely symptomatic • Pleural effusions	• CT-chest • Biopsy of effusions for light chains	• Functional limitations post-transplant • Possible PH, contribute to cardiopulmonary disease
Coagulation[315]	• AL	• Bleeding	• Factor X levels • Coagulation labs	• Surgical impact of bleeding

Abbreviations: AL, amyloid monoclonal immunoglobulin light chain; ATTR, amyloid transthyretin; CT, computed tomography; eGFR, estimated glomerular filtration rate; PH, pulmonary hypertension.

2.1.3.2. Restrictive and Hypertrophic Cardiomyopathy

Synopsis

Cardiomyopathy is the cause of several clinical presentations (e.g., HF and arrhythmia); it is characterized by a dynamic evolution of disease phenotypes across the life course, from childhood to adulthood. Etiological complexity with multiple disease processes (genetic and nongenetic) contributes to the various phenotypes. It is vital to recognize that different cardiomyopathy phenotypes may coexist in the same family, and that disease progression in an individual patient can include evolution from one cardiomyopathy phenotype to another. Morphological traits, at the time of presentation of the disease, are used to define the cardiomyopathy phenotype. Coupling cardiomyopathy phenotype at presentation with the underlying etiology has prognostic significance, with the emergence of novel etiology-focused therapies. The HCM phenotype is characterized by increased LV wall thickness or mass, which is not solely explained by abnormal loading conditions (i.e., hypertension, valvular, or congenial disease). The RCM phenotype is defined as restrictive left and/or RV pathophysiology in the presence of normal or reduced diastolic volumes (of one or both ventricles), normal or reduced systolic volumes, and normal ventricular wall thickness, and commonly present as biatrial enlargement.[316]

2.1.3.2.1. Restrictive Cardiomyopathy

Recommendations for Assessment of Transplant Eligibility in Special Populations: Restrictive Cardiomyopathy		
COR	**LOE**	**RECOMMENDATIONS**
1	B-NR	1. In patients with restrictive cardiomyopathy (RCM) and severe HF symptoms (NYHA Class III–IV), HT evaluation is recommended.
1	C-LD	2. In patients with RCM being evaluated for HT, a diagnostic evaluation to exclude treatable or reversible causes is recommended.
2b	C-LD	3. In patients with RCM, the role of DMCS is not well established.

Recommendation-Specific Supportive Text

1. RCM is characterized by the predominance of increased ventricular stiffness associated with markedly increased filling pressure and either normal or mildly reduced ejection fraction (EF).[316] Both adults and children with RCM have higher waitlist mortality compared to those with dilated cardiomyopathy,[317–321] likely related to the limited available therapies. Therefore, regardless of systolic function, the indications for HT listing in patients with RCM should be carefully assessed and include a hemodynamic evaluation with RHC to identify high-risk features for decompensation, namely, PH (Section Pulmonary Hypertension).[317,322] Owing to long-standing RHF, patients with RCM are at increased risk for advanced hepatic fibrosis and cirrhosis and liver biopsy may be required (Section Liver Disease).
2. Patients with restrictive physiology require evaluation to exclude constrictive pericarditis and elucidate underlying myocardial disease and its extracardiac involvement. RCM and constrictive pericarditis may sometimes coexist, for example, in radiation-induced cardiac disease, subacute or chronic myocarditis, or drug-induced cardiomyopathy. For these patients, treatment for constrictive pericarditis should precede assessment of the necessity/eligibility for HT listing. RCM may be idiopathic/genetic, toxic, infiltrative, inflammatory, or caused by other disorders. The endomyocardial biopsy can be valuable, although it often demonstrates nonspecific findings in idiopathic RCM.
3. The functional and morphologic pattern of RCM can be associated with a large spectrum of underlying nonmyocardial pathologies, including hypertension, coronary artery disease, and pericardial disease, all of which should be excluded during the diagnostic workup before considering these patients for HT.
4. RCM patients secondary to idiopathic, genetic, infiltrative, inflammatory, or storage diseases should be carefully assessed. Some conditions that may at times present with restrictive physiology are discussed in other sections, including sarcoidosis (Section Connective Tissue Diseases and Sarcoidosis) and amyloidosis (Section Cardiac Amyloidosis). Other rarer causes of RCM are hemochromatosis, glycogen storage diseases, and genetic deficiencies, such as Fabry disease. As disease-directed therapy may obviate the need for transplantation, a thorough assessment for a potentially treatable underlying cause is essential.[323]
5. Given that patients with RCM often have smaller LV cavities and BiV involvement, durable LVAD support may be less well tolerated. Compared to patients with dilated cardiomyopathy, patients with RCM are more likely to require BiV support, although post-transplant outcomes were comparable to patients without RCM who underwent DMCS as bridge to transplantation (BTT).[307,324,325]

2.1.3.2.2. Hypertrophic Cardiomyopathy

Recommendations for Assessment of Transplant Eligibility in Special Populations: Hypertrophic Cardiomyopathy		
COR	**LOE**	**RECOMMENDATIONS**
1	**B-NR**	1. In patients with nonobstructive hypertrophic cardiomyopathy (HCM) and AdvHF (NYHA Class III-IV despite GDMT) or with life-threatening ventricular arrhythmias refractory to maximal GDMT, evaluation for HT is indicated.
2a	**B-NR**	2. In patients with nonobstructive HCM and persistent or progressive HF symptoms (NYHA Class III-IV) despite GDMT who are otherwise suitable for HT, continuous-flow LVAD therapy is reasonable as a bridge to HT, in those with suitable anatomy.

Recommendation-Specific Supportive Text

1. AdvHF, commonly associated with but not limited to those with a reduced EF, arises in a small subset (3%-5%) of patients with nonobstructive HCM.[326–328] Although observational studies of patients with HCM and EF < 50% indicate that survival is worse than that of patients with HCM and preserved EF,[329–331] transplant referral does not absolutely require reduced EF, as patients with preserved EF may also develop AdvHF with restrictive physiology.[332,333] Patients with HCM, particularly those with LV outflow tract obstruction, whose symptoms respond to medical, interventional, surgical, or device therapy as indicated should not be referred for transplantation. Post-transplant survival in patients with HCM is comparable, and in some studies superior, to that of patients with other forms of heart disease in both adult and pediatric heart transplant recipients.[334–338] Children with HCM should also be considered for transplantation if they are not responsive to or appropriate candidates for other therapeutic interventions.[320]
2. Patients with HCM have traditionally been ineligible for LVAD support due to small LV cavities and relatively preserved EF. However, a number of case series have demonstrated that support with continuous flow (CF) LVADs is feasible in patients with HCM, with better increased post-LVAD survival in HCM patients with larger LV cavities (> 46-50 mm).[305, 339–341] There are little data on the role of BiV assist devices in patients with HCM. Data on the role of MCS in children with HCM are similarly limited.[342]

2.1.3.3. Congenital Heart Disease

Recommendations for Assessment of Transplant Eligibility in Special Populations: Congenital Heart Disease		
COR	**LOE**	**RECOMMENDATIONS**
1	**B-NR**	1. In heart transplant candidates with CHD, care at centers with established medical and surgical experience in both pediatric and adult CHD and transplantation is recommended to confirm that transplant evaluation is appropriate and that all non-transplant medical, interventional, and surgical therapies have been exhausted prior to evaluation.
1	**C-LD**	2. In heart transplant candidates with CHD, detailed assessment is recommended, including: a. The position and anatomy of the abnormalities within the chest (via cardiac MRI and/or chest CT) to guide the surgical strategy; b. Evaluation of PH, and all potential sources of pulmonary flow; c. Patency of major veins and arteries and venous collaterals across the chest wall; d. Disease in organ systems that can affect post-transplant care and/or cannot be reversed with transplantation (including but not limited to lung, liver, gastrointestinal, and kidney disease); e. Anti-human leucocyte antigen (HLA) antibody sensitization; f. Psychosocial evaluation of the patient, family, and caregiver support.
1 **2a**	**B-NR**	3. In patients with single ventricle CHD and a Fontan circulation (total cavopulmonary anastomosis), HT evaluation is recommended to improve QOL and survival in the following situations: a. Symptomatic HF and reduced systolic function (Class 1); b. Symptomatic HF, preserved systolic function, and abnormal systemic ventricular filling pressures (Class 1); c. Lymphatic abnormalities including plastic bronchitis and protein-losing enteropathy refractory to lymphatic interventions and medical management (Class 2a); d. Cirrhosis or CKD attributed to chronically elevated central venous pressures (Class 2a).
1	**B-NR**	4. In patients with single ventricle CHD, HT evaluation is recommended to improve QOL and survival in the following situations: a. Palliation to a shunted circulation or a superior cavo-pulmonary anastomosis (first procedure of a staged Fontan) and prohibitive risk for further single ventricle palliation; b. Cyanotic heart disease with severe atrio-ventricular valve regurgitation and prohibitive risk for operative repair; c. Pulmonary atresia with an intact ventricular septum, right ventricular dependent coronary circulation, and atresia of at least one aorto-coronary ostium; d. Neonatal hypoplastic left heart syndrome with high-risk features including HF symptoms, ventricular dysfunction, left ventricular-coronary artery fistulae.
1 **2a**	**B-NR**	5. In patients with CHD, HT evaluation is recommended to improve QOL and survival in the following situations: a. HF symptoms or ventricular arrhythmias refractory to medical, interventional, and device therapies (Class 1). b. Reactive PH and a potential risk of developing fixed, irreversible elevation of PVR that could preclude HT in the future (Class 1) c. Neonatal cyanotic CHD with high-risk features as determined by an experienced pediatric CHD and cardiac surgery center (Class 2a).

Continued

2b	**B-NR**	6. The benefit of HT for CHD is not well established and may be considered as significant risk in the following CHD-specific situations: a. Increased surgical risk including multiple prior cardiac surgeries, aortopulmonary collaterals not amenable to catheter-based or surgical interventions; and/or prior mediastinitis b. Congenital absence, or near-total venous thromboembolism, of major systemic venous connections.
2b	**B-NR**	7. In patients with Fontan-associated liver disease and cirrhosis, the specific indications for heart alone versus heart-liver transplantation are not well-established and include: a. HT alone in patients with no stigmata of liver disease based on Child-Pugh Class A function and no portal hypertension; b. Heart-liver transplantation in patients with stigmata of liver disease based on Child-Pugh Class B/C function and/or portal hypertension (varices, ascites, splenomegaly, and/or thrombocytopenia). For patients with FALD score ≥ 2 combined heart-liver transplants may confer a survival advantage vs. isolated HT.

Synopsis

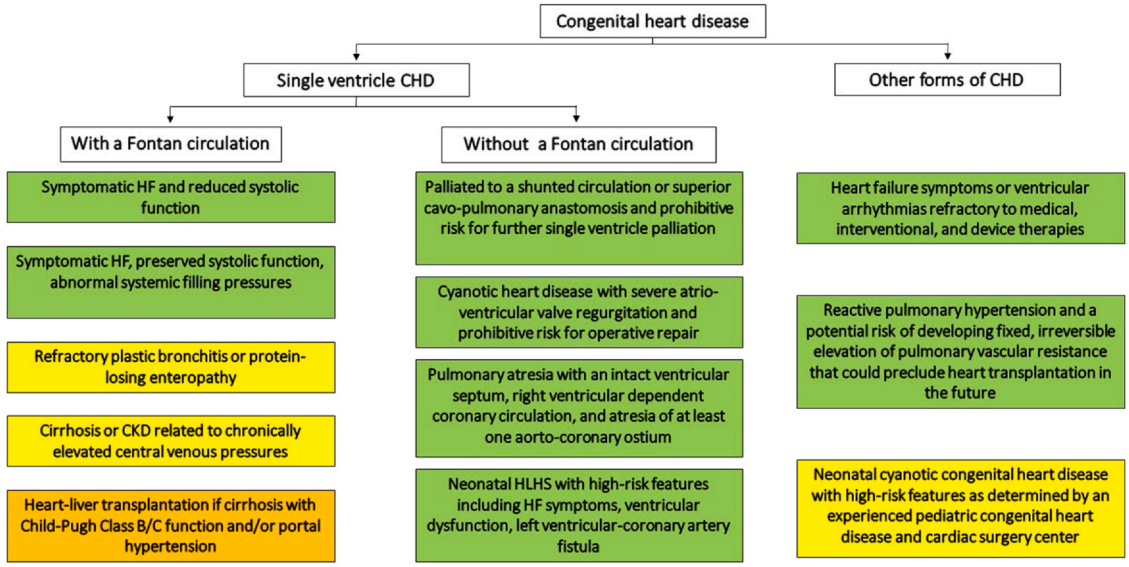
Due to advances in the medical, interventional, and surgical management of congenital heart defects, up to 90% of children born with CHD now survive to adulthood.[343] However, despite successful interventions to repair cardiac anatomy, many with CHD experience long-term morbidity and reduced survival relative to the general population, with HF being the leading cause of death.[344–349] One important consideration is preparing young patients and their families for the expectation of ultimate transplant, and the reassessment of the transplant option when patients require serial palliations over the years. The thresholds for multiorgan transplantation remain center-specific, although growing consensus supports heart-liver transplantation for failed Fontan physiology and FALD if associated with cirrhosis and/or severe fibrosis with evidence of portal hypertension.[220] For many patients with complex CHD, sensitization—from prior transfusions or from existing homografts—adds risk and complexity to the transplant operation and long-term management.

Recommendation-Specific Supportive Text

1. There are many causes of HF symptoms in patients with CHD that may be reversible, including valve dysfunction, shunts, arrhythmias, venous obstruction, and systolic and/or diastolic ventricular dysfunction, which require evaluation and treatment when possible. Unlike acquired HF, and despite the clinical importance of HF in adults with CHD, there is limited evidence of benefit of traditional GDMT for HF.[350] When patients with CHD develop refractory AdvHF, they may be evaluated for HT. However, patients may be denied due to a perceived higher risk based on prior cardiac surgeries, which increases surgical complexity and antibody sensitization from perioperative blood transfusions and the presence of homografts.[351,352] These factors result in longer waitlist times with increased waitlist mortality, less use of MCS, and an increase in perioperative and short-term post-transplant mortality.[41,353,354] Nonetheless, patients with CHD who undergo HT have equal or even superior long-term survival[41, 349, 353–357] and increased transplant center volume and CHD expertise are associated with improved post-transplant short-term outcomes.[358,359] Thus, heart transplant candidates with CHD should be cared for at centers with established medical and surgical experience in both pediatric and adult CHD and transplantation to confirm that nontransplant therapies have been exhausted and to ensure timely referral for transplantation when appropriate.
2. Indications for HT in patients with CHD are typically based on the physiological classification of the lesion and include mainly those patients with complex CHD,[360] although data on proper timing of transplantation are limited, particularly for individual lesions (Figure 4). Repaired 2-ventricle CHD will generally fit traditional indications for HT. Patients with 2-ventricle CHD (repaired dextro-transposition of the great arteries (D-TGA, also known as classic TGA), unrepaired levo-transposition of the great arteries (L-TGA, also known as congenitally corrected TGA), or double-outlet right ventricle), may present with HF later in life than patients with single-ventricle physiology (double inlet left ventricle, tricuspid atresia, hypoplastic left heart, any other anatomic abnormality with a functionally single ventricle) with "failed Fontan physiology."[361,362] While all patients with CHD require routine transplant evaluation as outlined throughout the document, CHD-specific evaluation comprises additional assessment of cardiac anatomy, end-organ function, and antibody sensitization.

3. Patients with single ventricle CHD who have undergone Fontan palliation surgery (total cavopulmonary anastomosis) may exhibit "failed Fontan physiology," which can manifest as (1) reduced systolic function; (2) preserved systolic function and abnormal filling pressures; (3) abnormal lymphatics manifesting as plastic bronchitis (PB) and/or protein-losing enteropathy (PLE); and 4) liver or kidney disease related to chronic congestion.[363] HT can improve QOL and survival in patients with a Fontan circulation and symptomatic HF.[41, 364–368] Patients with PB and PLE have improved QOL and survival after HT,[367, 369–371] although frailty needs to be carefully assessed.[264]
4. HT should be considered in patients with cyanotic CHD (shunted or bidirectional Glenn (cavopulmonary anastomosis)) who are not candidates for completion of Fontan palliation or repair of severe atrioventricular valve regurgitation,[372,373] Waitlist mortality is higher in patients listed for HT within 6 months of Fontan surgery compared to patients listed > 6 months after Fontan surgery. Such time-related mortality was notat observed in patients listed after bidirectional Glenn, indicating a role for early listing in patients who do poorly after the first stage of palliation.[27] Although most patients with pulmonary atresia with intact ventricular septum and right ventricular dependent coronary circulation can be palliated via a single ventricle pathway, while those with aorto-coronary ostial atresia represent a high risk subtype where HT is indicated.[374–377] Because hypoplastic heart syndrome (HLHS) with standard risk features has good intermediate outcomes with current surgical approaches and because of the limited availability of donor organs, HT is not indicated in neonates with HLHS and acceptable surgical risk for staged reconstruction.[378–380] Rather, listing for HT should be reserved for those patients with high-risk features, including HF symptoms, ventricular dysfunction, and left ventricular-coronary artery fistulae.[381,382]
5. Other indications for HT in patients with CHD include those common to all heart transplant candidates, namely, HF symptoms or ventricular arrhythmias refractory to medical, interventional, and device therapy. Reactive PH is a poor prognostic sign in CHD[383–385] and should prompt transplant consideration, including possible heart-lung transplantation.[166,168,170] Neonatal cyanotic CHD with high-risk features as determined by an experienced pediatric CHD and cardiac surgery center may be also warrant transplant evaluation.
6. Patients with CHD should be assessed for the standard contraindications to transplantation outlined throughout this document. However, there are CHD-specific contraindications to consider. Patients with repaired CHD commonly have anti-HLA antibody sensitization due to exposure to blood products and homograft material,[386–388] although the latter may be mitigated by pretreating homograft material with glutaraldehyde[389,390] or using decellularized homografts.[391] Prior cardiac surgeries increase the perioperative transplant risk due to scar formation resulting in increased bleeding risk and need for blood products; technical difficulties with vascular reconstruction; and the presence of aortopulmonary collaterals.[392,393] Venous thromboembolism is common in patients with CHD,[394,395] related to use of central venous lines and the low-flow Fontan state.[394,396] The presence of near-total or total occlusion of systemic veins can represent a contraindication to HT depending upon their severity and location.
7. Patients with CHD, particularly those with Fontan physiology and chronic systemic venous congestion, are at high risk for the development of liver fibrosis and cirrhosis. FALD is related to time from Fontan,[397] with near-universal evidence of liver disease by 20 years post-Fontan[398] and cirrhosis present in nearly half by 30 years post Fontan.[399] However, FALD is frequently associated with mild-to-moderate fibrosis[397] and liver biopsies may be subject to sampling error,[400,401] making the decision to proceed with heart alone vs heart-liver transplant challenging, especially given the lack of prospective studies with standardized criteria for heart vs heart-liver transplantation. Single-center reports demonstrate that heart transplant recipients with high Child-Pugh or MELD-XI scores have increased post-transplant mortality.[402,403] Nonetheless, advanced liver fibrosis alone can regress after HT, suggesting that assessment of hepatic function (rather than histology alone) would be preferable in determining need for heart-liver transplant,[404] especially as other single-center reports indicate that patients with hepatic fibrosis on biopsy and Child-Pugh Class A may have acceptable outcomes after HT alone.[191,404,405] A retrospective multicenter study of adult Fontan patients undergoing HT or combined heart-liver transplantation demonstrated that higher pre-transplant FALD scores (calculated 1 point for each of the 4 elements: (1) cirrhosis; (2) varices; (3) splenomegaly; or (4) ≥2 paracenteses) were associated with worse outcomes overall. Survival postcombined heart-liver transplantation may have been superior in patients with a FALD score ≥2 when performed at experienced centers.[406,407]

Figure 4 Transplantation in congenital heart disease. CHD, congenital heart disease; CKD, chronic kidney disease.



2.1.3.4. Retransplantation

Recommendation for Assessment of Transplant Eligibility in Special Populations: Retransplantation		
COR	**LOE**	**RECOMMENDATIONS**
2a	**B-NR**	1. In heart transplant recipients with ISHLT Grade 3 CAV, evaluation for retransplantation is reasonable.
2b	**C-LD**	2. In heart transplant recipients with the following, the benefit of retransplantation is not well established: a. Graft failure due to active rejection b. Advanced age c. Need for DMCS as a bridge to retransplantation.

Recommendation-Specific Supportive Text

1. The number of patients who are candidates for heart retransplantation is rising and comprises about 3% of adult heart transplant recipients, increasing to 7% of recipients between 18 and 39 years.[203] The most common indication for retransplantation is CAV. Treatment options with limited demonstrated efficacy include management of atherosclerotic risk factors,[408] use of proliferation signal inhibitors sirolimus[409] or everolimus,[410] and percutaneous intervention[411,412]; thus, retransplantation is often pursued. Grade 3 CAV is defined as (1) angiographic left main stenosis ≥50%; (2) 2 or more primary vessels ≥70% stenosis; isolated branch stenosis ≥70% in all 3 systems; (3) ISHLT CAV1 or CAV2 with allograft dysfunction (defined as LVEF ≤45% usually in the presence of regional wall motion abnormalities); or (4) evidence of significant restrictive physiology based on symptoms, echocardiogram, and/or RHC.[413] Grade 3 CAV is associated with worse outcomes,[414] up to 75% mortality at 5 years[412] and thus consideration of retransplantation is reasonable in this cohort. Registry analyses indicate worse survival in patients undergoing retransplantation compared with those undergoing primary transplant in adults[203,415] and children.[416] However, after matching for comorbidities, late retransplantation in the adult population is not associated with an increase in all-cause mortality, emphasizing the importance of assessing indication acuity and comorbid conditions when considering retransplant candidacy.[417] As heart transplant recipients often have kidney dysfunction from long-term calcineurin inhibitor use, SHKT may be considered.[418]
2. Candidate selection for retransplantation should follow the same recommendations established for primary transplants. There are conditions for which retransplantation portends worse outcomes, including transplantation for active rejection,[417,419] transplantation within the first 2 years after transplantation,[417,420] and need for DMCS as a bridge to retransplantation. Advanced age is potential barrier to retransplantation, with data showing increased 5- and 10-year post-transplant mortality after age 60.[421] Heart transplant recipients who require DMCS as a bridge to retransplantation are at high risk of death[422] and this may be considered a contraindication to transplantation. Given the ethical concerns of donor stewardship in retransplantation,[423,424] careful patient selection is paramount.

2.1.4. Special Considerations Regarding Transplant Eligibility in Pediatric Patients

Recommendations for Special Considerations Regarding Transplant Eligibility in Pediatric Patients		
COR	LOE	RECOMMENDATIONS
1	B-NR	1. In pediatric heart transplant candidates with extracardiac conditions that would increase the risk of post-transplant morbidity or mortality, including but not limited to neuromuscular disease or chromosomal abnormalities, individualized assessment is recommended to assess transplant eligibility.
1	B-NR	2. In pediatric heart transplant candidates under the age of 2 years, ABO-incompatible HT is recommended to increase the donor pool.
3 No Benefit	C-LD	3. In pediatric heart transplant candidates with severe hypoplasia of the central branch pulmonary arteries or pulmonary veins, HT is not recommended due to increased surgical risk.

Synopsis

Where pertinent, the special pediatric-specific considerations for heart transplant candidacy are discussed in the relevant sections above. However, there are some conditions that are unique to pediatric heart transplant candidacy discussed here, including neuromuscular disease and chromosomal abnormalities, ABO-incompatible HT, and surgical considerations.

Recommendation-Specific Supportive Text

1. Any condition that limits post-transplant survival and QOL or would impact successful adherence to the complex post-transplant regimen should be considered a relative contraindication to transplantation. These are discussed in detail in other sections, but those unique to pediatric HT include conditions with concomitant cardiac and extracardiac disease, including neuromuscular disease such as Duchenne muscular dystrophy[425] or chromosomal abnormalities with significant developmental delay.[426,427] For pediatric transplant candidates with neuromuscular disease, specific attention should be paid to respiratory muscle strength, aspiration risk, and potential for rehabilitation.[425] Of note, exclusion of children from transplantation based solely on intellectual and developmental disabilities (IDD) from transplantation is not justified.[426–430] Children with IDD can experience improved QOL after transplantation,[431–435] and survival comparable to other pediatric transplant recipients.[426, 427, 436–440] However, the potential for medical nonadherence due to IDD with lack of adequate caregiver support would be concerning, as nonadherence occurs in a significant number of children after HT and is associated with a substantial risk of death.[40,441] Thus, children with neuromuscular disease or extracardiac disease require an individualized assessment to determine candidacy.[40,442,443]
2. Waitlist mortality of pediatric heart transplant candidates ranges between 15% and 30%.[7,444,445] The immaturity and malleability of the infant immune system have allowed for the evolution of ABO-incompatible HT; antibodies against the non–self blood group antigens, which are ubiquitous in adults and older children, are absent in infants and slowly evolve starting around 18 months of age. ABO-incompatible HT has evolved to close this gap between waitlist candidates and donor supply and in children under 2 years of age, ABO-incompatible HT offers comparable outcomes to ABO-compatible transplantation.[7,446–450] The UNOS is extending ABO-incompatible HT eligibility to all patients under 18 years of age who have low titers to non–self blood group antigens,[451] although there are paucity of data on outcomes in those recipients of ABO-incompatible transplants over 2 years of age.
3. Severe hypoplasia of the central branch pulmonary arteries or pulmonary veins is considered an absolute contraindication to HT due to concern for surgical risk.[452] Such patients may, however, be considered for heart-lung transplantation or lung transplantation with the repair of cardiac abnormalities.[453]

2.2. Psychosocial Evaluation

2.2.1. Evaluation of Substance Use

Recommendations for Psychosocial Evaluation: Evaluation of Substance Use		
COR	LOE	RECOMMENDATIONS
1	C-EO	1. In heart transplant candidates with a history of active illicit drug use, at least 6 months of abstinence is recommended prior to transplant listing.
2a	B-NR	2. In heart transplant candidates with a history of active cannabis use, recommendation for abstinence prior to evaluation and listing is reasonable due to reported infectious risk and potential drug-drug interaction post-transplant.
1	B-NR	3. In heart transplant candidates with a history of active alcohol use disorder, at least 6 months of abstinence is recommended prior to transplant listing.
1	B-NR	4. In heart transplant candidates with a history of active tobacco smoking, at least 6 months of abstinence is recommended prior to transplant listing.

Synopsis

Illicit drug use, alcohol use, and tobacco smoking before HT can increase the candidate's risk for poor postsurgical outcomes and mortality.[6, 454–456] A thorough evaluation of the heart transplant candidate's substance use history should be performed and should include assessment of any past or current illicit drug use, alcohol use, and tobacco use. Such an evaluation should examine frequency, amount, duration of use, and length of abstinence as well as the level of impairment that affects the candidate's health, job, and relationships. Any current treatment for substance abuse and the patient's willingness to seek treatment should also be assessed. The presence of substance abuse should be assessed by patient reporting, questionnaires, and biochemical testing. Referrals to addiction services should be made for patients with active substance use disorders (Figure 5).

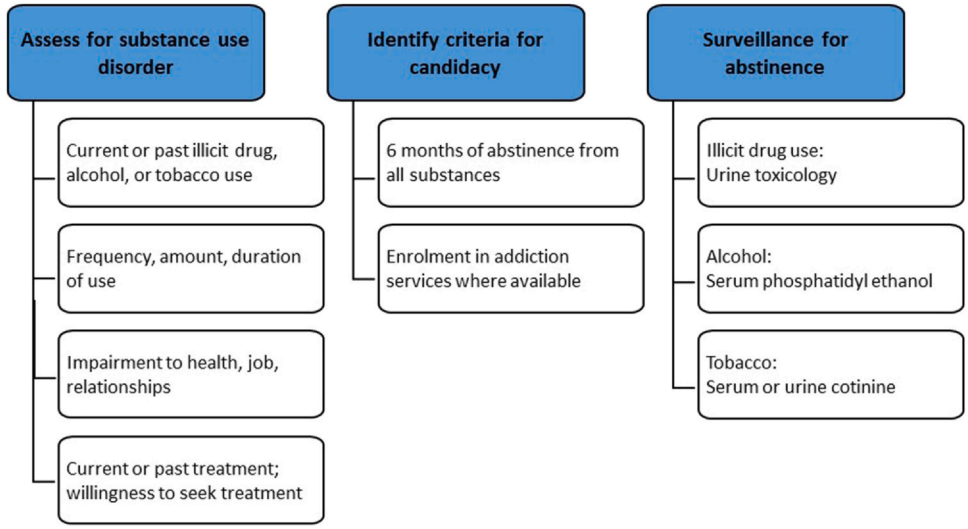
Recommendation-Specific Supportive Text

1. Use of opiates is associated with increased mortality after kidney[457] and liver transplantation, and these findings have been extrapolated to other illicit substances and other organ transplants.[6, 454–457] Given the risk of relapse, the transplant candidate should have a period of abstinence of at least 6 months, demonstrated by negative biochemical drug screening. Rehabilitation programs and counseling should be encouraged in patients with a history of illicit drug abuse.
2. The common modes of cannabis use include inhalation (smoking or vaporizing) and oral ingestion (common forms include edibles and beverages). Inhaled cannabis (the most common method of use) is characterized by rapid absorption and can be detected in the blood within 1 minute of circulation; it has a fast onset with a strong effects peak and a rapid decline. By-products of smoked cannabis include carcinogens, which increase the risk of bronchitis, and pulmonary infections, including tuberculosis. Vaporized cannabis contains propylene glycol and vitamin E acetate, which cause acute lung injury and severe pneumonitis. Edible cannabis has a long latency period, delayed effect onset, and peak serum concentration. Edible cannabis does not appear to have adverse pulmonary manifestations, but psychiatric and cardiovascular complications are common with edible cannabis.[458] Inhaled cannabis use post-transplant has been linked to increased infection risks and fungal lung infections.[459] In addition, cannabis may alter the metabolism of immunosuppressive medications.[459] Cannabis interacts with other medications commonly used in HT, such as antifungals (azoles), diltiazem for hypertension, warfarin, sulfamethoxazole-trimethoprim and dapsone (*Pneumocystis jirovecii* prophylaxis) and increased statin exposure. Thus, programs will likely continue to make their own center-specific decisions regarding cannabis use and transplant candidacy, although it would be safest to emphasize avoidance of cannabis, regardless of legalization. Exceptions for approved cannabis substances prescribed legally by medical care provider, may be made under certain conditions, to qualify for HT listing.
3. Excessive alcohol use is associated with poor medication adherence and adverse outcomes post-transplant,[454,460] including increased mortality, and is an absolute contraindication for HT. Large international variation exists on acceptable alcohol intake; hence, the national recommendations and standards may be useful in defining excessive alcohol use. Methods of evaluation for alcohol use disorder (both dependency and abuse) should include self-reporting by the candidate and biochemical testing. The alcohol use disorder identification test is a reliable tool used to detect harmful drinking patterns in candidates and can be considered in the candidate's evaluation.[460–462] A structured rehabilitative program may be considered for patients with a recent history of alcohol abuse if transplantation is being considered. Because of the association of shorter time periods of abstinence with relapse

post-transplant, the recommended period for abstinence from alcohol is at least 6 months.[463] Abstinence can be monitored using phosphatidylethanol, an abnormal phospholipid produced only in the presence of ethanol and can be measured in the serum.[464] A patient with an alcohol use disorder can demonstrate candidacy after abstaining from alcohol use for 6 months or more, as proven by frequent biochemical testing.

4. Active tobacco smoking is a contraindication to HT due to the significant increase in malignancy, CAV, renal dysfunction, and death associated with tobacco use in heart transplant recipients.[465–467] A patient should demonstrate candidacy for transplant by abstaining from tobacco use for at least 6 months. Abstinence from tobacco can be monitored using serum or urine cotinine levels.[468] The candidate should be educated on reducing environmental and secondhand exposure to tobacco smoking. The use of other tobacco products has not been well studied. As the prevalence of e-cigarette use increases, research will be required to determine if this is detrimental to the transplant population. Given the lack of information currently, avoidance of all nicotine products is preferred.

Figure 5 Summary of substance use disorder assessment.



2.2.2. Evaluation of Support, Adherence, and Mental Health

Recommendations for Psychosocial Evaluation: Evaluation of Support, Adherence and Mental Health		
COR	**LOE**	**RECOMMENDATIONS**
1	**B-NR**	1. In heart transplant candidates, confirmation of social support is recommended, including caregivers who: 1) understand the severity of patient's illness and their role as caregiver toward a potential transplant recipient; 2) can support both the patient's emotional and physical needs; 3) are dedicated to providing dependable care.
1	**B-NR**	2. Heart transplant candidates should exhibit adherence to medical recommendations, medications, and healthy lifestyle behaviors including optimal diet and physical activity as well as an understanding of expectations regarding the post-transplant regimen of medications and follow-up.
1	**B-NR**	3. In heart transplant candidates, assessment of adequate control of mental health problems is recommended with screening by a healthcare professional with expertise in mental health for 1) past and current mood disorders (including suicidal ideation or other self-injurious behavior), anxiety disorders, and other mental health problems (e.g., psychosis, personality disorders); 2) willingness, response, and adherence to treatment for past or current mental health problems; and 3) mental health issues in their social support network.
2a	**B-NR**	4. In candidates for HT, the use of psychosocial screening tools (e.g., PACT, SIPAT, TERS) can be useful as part of a comprehensive and multifaceted psychosocial evaluation to highlight risk factors for which further supportive interventions pre- and post-transplant are needed.

Synopsis

Psychosocial assessment is routinely performed at the time of initial HT evaluation and involves behavioral health specialists, such as psychiatrists, psychologists, or social workers. HT requires significant engagement from patients and their caregivers, as post-transplant care is typically complex and necessitates regular clinic visits and testing, strict adherence to medications, and adoption of healthy lifestyle measures. The psychosocial evaluation is a key component of the multifaceted pre-transplant screening process, aimed at identifying those candidates at increased risk of poor post-transplant outcomes due to inadequate support, adherence, or optimal mental health; deficits in these factors are associated with poor post-transplant outcomes. The 2018 ISHLT/APM/AST/ICCAC/STSW recommendations for the psychosocial evaluation of adult cardiothoracic transplant candidates offer a detailed assessment aligned with the recommendations here. The psychosocial evaluation should identify any evidence that cognitive status may compromise patients' ability to make decisions, give informed consent, and assess patients' personal, social, and environmental resources and circumstances; these issues are detailed in the 2018 ISHLT Consensus.

Recommendation-Specific Supportive Text

1. The social support network refers to the emotional, physical, practical, informational, and relational support offered by the patient's social contacts.[469,470] Important characteristics of caregivers that have been shown to improve

Table 14 The Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT)[502]

Item	Questions	Score
	Patient's readiness level and illness management	
Item 1	Knowledge and understanding of medical illness process (that caused specific organ failure)	0–4
Item 2	Knowledge and understanding of the process of transplantation	0–4
Item 3	Willingness/desire for treatment (transplant)	0–4
Item 4	History of treatment adherence/compliance (pertinent to medical issues)	0–8
Item 5	Lifestyle factors (including diet, exercise, fluid restrictions, and habits, according to organ system)	0–4
		(0–24)
	Social support system level of readiness	
Item 6	Availability of social support system	0–8
Item 7	Functionality of social support system	0–8
Item 8	Appropriateness of physical living space and environment	0–4
		(0–20)
	Psychological stability and psychopathology	
Item 9	Presence of psychopathology (other than personality disorders and organic psychopathology)	0–8
Item 10	History of organic psychopathology or neurocognitive impairment (i.e., illness or medication induced psychopathology)	0–5
Item 11	Influence of personality traits vs disorder	0–4
Item 12	Effect of truthfulness vs deceptive behavior	0–8
Item 13	Overall risk for psychopathology	0–4
		(0–37)
	Lifestyle and effect of substance use	
Item 14	Alcohol use, abuse, and dependence	0–8
Item 15	Alcohol abuse—risk for recidivism	0–4
Item 16	Illicit substance abuse and dependence	0–8
Item 17	Illicit substance abuse—risk for recidivism	0–4
Item 18	Nicotine use, abuse, and dependence	0–5
		(0–29)
	Total score *	**0–110**

*0-6 = excellent candidate; 7-20 = good candidate; 21-39 = minimally acceptable candidate; 40-68 = high risk candidate; and > 69 = poor candidate.

survival include understanding the severity of patient's illness and available treatment options, identifying a backup system, and providing logistical support.[471,472] Better social support is associated with less substance use relapse,[454] although there is variable impact on adherence.[473,474] Nonetheless, caregivers play an important practical role through assistance with medications, transportation to appointments, and emotional support.[475–477] Adequate caregiver support may also be helpful in mitigating the impact of other psychosocial barriers to successful transplant outcomes, including mental health problems such as depression.[478–480] The absence of stable and appropriate caregiver support should therefore be considered a contraindication to HT. In addition, mental health problems in caregivers should be evaluated in the assessment of transplant candidacy.[481]

2. Assessment of adherence is an essential component of the evaluation process. Adherence to a strict medication regimen and to a healthy lifestyle after transplantation prevents rejection, infection, and other poor outcomes.[478,482,483] Pre-transplant medication nonadherence is a predictor of post-transplant medication nonadherence; notably, adherence-enhancing intervention can improve medication adherence in the transplant population.[484–487] Serious and sustained nonadherence together with poor collaboration with adherence supportive initiatives should be considered a contraindication for HT.
3. Depression and anxiety are common in heart transplant candidates,[488] pre-transplant depression is a risk factor for post-transplant depression,[489] and post-transplant depression, in turn, increases the risk of post-transplant nonadherence and mortality.[489–493] The impact of other mental health problems, such as anxiety, psychosis, or personality disorders, on post-transplant outcomes is not well studied, but careful assessment is essential to identify factors that would negatively impact post-transplant adherence, abstinence from substance use, or adequate social support. The presence of mental health problems is not necessarily a contraindication to HT, as many may be effectively managed in conjunction with therapists, psychologists, or psychiatrists. However, inadequately controlled mental health problems with associated nonadherence, substance use, or a lack of social support are contraindications to transplantation. Mental health problems in caregivers should also be considered in the assessment of transplant candidacy.[6, 481, 494–501]
4. As the content of the psychosocial evaluation focuses on substance use, caregiver support, adherence, and mental health history, mental health professionals and social workers would be best qualified to execute this multifaceted assessment.[6] The psychosocial evaluation is inherently subjective, relying not only on extraction of information from the patient, but also on individualized interpretation from the evaluator. The use of standardized psychosocial screening tools (e.g., Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT),[502] Transplant Evaluation Rating Scale (TERS),[503] and Psychosocial Assessment of Candidates for Transplantation (PACT)[504];

Table 15 Psychosocial Assessment of Candidates for Transplantation (PACT)[504]

Domain	Subscale	Score
Social support	Family or support system stability	1-5
	Family or support system availability	1-5
		(2-10)
Psychological health	Psychopathology, stable personality factors	1-5
	Risk for psychopathology	1-5
		(2-10)
Lifestyle factors	Healthy lifestyle, ability to sustain change in lifestyle	1-5
	Drug and alcohol use	1-5
	Adherence/compliance with medications and medical advice	1-5
		(3-15)
Understanding of transplant and follow-up	Relevant knowledge and receptiveness to education	1-5
		(1-5)
Total score[a]		**8-40**
Final rating[b]		**0-4**

Bold values represent the minimal and maximal scores possible for each category.
[a]Of note, as opposed to other assessments, higher scores are associated with lower psychosocial risk.
[b]Subjective global impression: 0 = poor candidate; 1 = borderline, acceptable under certain conditions; 2 = acceptable with some reservations; 3 = good candidate; and 4 = excellent candidate.

Table 16 Transplant Evaluation Rating Scale (TERS)[503]

Psychosocial characteristics and weight	Level 1	Level 2	Level 3	Weight	Score[a]
Prior psychiatric history: axis I	None	Current adjustment disorder, due to health; previous axis I disorder, treated and now resolved; current significant symptoms of axis I disorder	Current axis I diagnosis (not adjustment disorder due to health); continuing symptoms of chronic axis I disorder	4	4-12
Prior psychiatric history: axis II	No diagnosis; subdiagnostic symptoms of cluster C disorder	Cluster C axis II diagnosis; subdiagnostic symptoms of cluster A or B disorder	Cluster A or B axis II diagnosis	4	4-12
Substance use/abuse	No history of heavy use/abuse of alcohol or drugs; true social drinking; very limited drug experimentation	History of significant use/abuse; successful treatment or stopped before current diagnosis	History of use/abuse stopped only after significant time since current diagnosis; ongoing use/abuse	3	3-9
Compliance	Appropriately compliant throughout treatment	Only partially compliant or compliant only with difficulty throughout treatment	Noncompliant until very recently or still noncompliant	3	3-9
Health behaviors	Practiced good health behaviors (exercise, no smoking, diet, etc.) before developing illness	Changed health behaviors only after diagnosis was made	Continues to practice poor health behaviors	2.5	2.5-7.5
Quality of family/social support	Good-excellent: friends/family members present and available; willing to focus on patient's needs	Fair-good: some separation difficulties; some conflict or dependency problems	Fair-poor: enmeshed or disengaged boundaries; extreme conflicts; focused on individuals' needs at patient's expense	2.5	2.5-7.5
Prior history of coping	Good-excellent: adapts to problems and changes flexibly; has extensive repertoire of coping behaviors	Fair-good: some flexibility in coping repertoire and some variations in coping responses, with general limitations; some negativistic patterns of responding when under stress	Fair-poor: decompensations under stress; negativistic patterns; rigid style; history of self-destructive behaviors; impulsive and/or aggressive responses	2.5	2.5-7.5
Coping with disease and treatment	Resolution of feelings about diagnosis; considers treatment options with realistic balance of hope and concern for future	Denial; lack of clarity; ambivalence over treatment choice	Extreme denial; confusion over disease course; severe ambivalence about treatment	2.5	2.5-7.5
Quality of affect	Appropriate fears; some anxiety; appropriate sadness	Moderate fears and anxiety; moderate depression	Generalized anxiety; severe depression; extreme fears and anger	1.5	1.5-4.5
Mental status (past and present)	No cognitive impairment or disorder of attention; normal sleep-wake cycle; normal activity level and responsiveness	Some past or current impairment in cognitive function, attention, sleep-wake cycle, activity level, and/or responsiveness	Global disorder of cognitive functions, attention; severe disruption of sleep-wake cycles; reduced or heightened activity level and responsiveness	1	1-3
Total score[b]					26.5-79.5

[a]Obtained by multiplying the level by the weight.
[b]Higher scores are associated with higher psychosocial risk.

Tables 14-16) as part of a comprehensive and multifaceted psychosocial evaluation can be effective as a means to summarize the findings of the psychosocial evaluation and to highlight aspects of psychosocial functioning for which further interventions or follow-up are indicated.[475,502] However, studies of these tools in transplant recipients are limited by their single-center, retrospective design, and small sample size. Thus, using these tools as sole determinants of suitability for transplantation is not recommended. The SIPAT is the most recent and comprehensive psychosocial tool with the greatest published experience in HT candidates. A worse SIPAT score has been associated with worse post-transplant adherence[505] and a higher risk of rejection.[506] PACT and TERS have not been explicitly studied in HT candidates.

2.2.3. Special Considerations in Pediatric Psychosocial Assessment

2.2.3.1. High-risk Psychosocial Assessment in Pediatric Heart Transplant Candidates

Pediatric-specific standards for psychosocial assessment and subsequent care for pediatric heart transplant recipients and their families do not exist,[507,508] although, notably, approximately 40% of families of pediatric heart transplant candidates endorse psychosocial risk.[508] As in adult heart transplant candidates, assessment of psychosocial function is essential in pediatric heart transplant candidates because psychosocial functioning, particularly socioeconomic status, family functioning, and quality of social support, impacts health-related outcomes, including adherence[509–519] and hospitalizations.[520] Similar to the evaluation in adult heart transplant candidates, the psychosocial assessment of pediatric candidates should be performed by mental health professionals and/or social workers.

The unique and central challenge of the pediatric heart transplant candidate psychosocial assessment is that children are not responsible for, nor do they have control over, their environment or family functioning.[521,522] The family-centered care of the pediatric SOT recipient begins during the pre-transplant evaluation and should continue until transition to adult health care. Specifically in pediatric heart transplant candidates, the focus of the psychosocial assessment should be on identifying strengths and opportunities for optimization rather than reasons to deny transplant.[521]

2.2.3.2. Cultural Considerations in the Pediatric Heart Transplant Candidate Evaluation

2.2.3.2.1. Race/Ethnicity and Socioeconomic Status. Black children tend to have a higher risk of graft loss and death after HT, attributed to genetic and immunologic factors, such as donor-recipient HLA mismatch and more rapid metabolism of calcineurin inhibitors, as well as health care and socioeconomic disparities.[523–529] The impact of low socioeconomic status on worse outcomes in heart transplant candidates and recipients is well established,[530-532] and Black and Hispanic children are more often socioeconomically disadvantaged, contributing to worse outcomes due in part to reduced health literacy impacting adherence.[532–534]

Racial and ethnic disparities also impact outcomes in transplant candidates and recipients through implicit bias. Poor patient-clinician communication can result in reduced adherence.[535–539] Specifically among pediatric heart transplant clinicians, survey findings indicate that there is an implicit preference for individuals who are White and from higher socioeconomic status, and an explicit preference for educated people.[540] These attitudes may impact the care of pediatric heart transplant candidates.

An awareness of the potential for implicit and explicit bias in the evaluation process is essential. Efforts to improve access to AdvHF therapies for children from disadvantaged communities, creating and fostering organizational and institutional commitment to a culture of inclusivity, committing to hiring a diverse and inclusive workforce, and promoting cultural competency and diversity training may mitigate barriers to equitable transplantation.

2.2.3.2.2. Religion. Religious considerations may impact how families perceive pediatric organ donation. As feasible, the multidisciplinary pediatric heart transplant evaluation team should work on a case-by-case basis toward understanding the religious factors that may impact families' perceptions and wishes regarding their child's need for HT. Although Jewish[541] and Islamic[542] law do not prohibit organ transplantation, this is an important consideration in Jehovah's Witnesses. Jehovah's Witnesses refuse blood component transfusion (red blood cells, plasma, and platelets) and regard nonconsensual transfusion as a physical violation. Nonetheless, transplantation may be feasible in highly selected transplant candidates.[543]

2.2.3.3. Impact of Intellectual and Developmental Disabilities on Pediatric Heart Transplant Candidacy

A major challenge in pediatric HT is the inconsistency with which IDD are defined and the threshold for which transplantation is considered contraindicated.[428,429,544] Exclusion of children with IDD from transplantation is not justified.[428,429,544] In fact, children with IDD can experience improved QOL after transplantation,[430–434] and survival comparable to other pediatric transplant recipients.[426, 435–440]

Cognitive testing alone is inadequate to characterize an individual's level of disability. It is more important during the transplant evaluation process to assess an individual's level of adaptive functioning. Adaptive functioning refers to impairments in conceptual, practical, and social skills needed for communication, self-care, self-direction, home living, and use of community resources and better describes the skills with which individuals live in their environment.[545,546]

Thus, the evaluation of a pediatric heart transplant candidate with IDD should comprise an assessment of adaptive functioning as well as social and caregiver support to ensure optimal adherence. Transplant programs also have a responsibility to educate families about the risks and benefits for heart transplant in the context of a potential transplant recipient's IDD, and the psychosocial evaluation should include the functioning of the family unit rather than only that of the child with IDD.[428]

2.2.3.4. Parental Refusal of Vaccination

Although vaccine hesitancy may occur in families of pediatric heart transplant candidates, few pediatric transplant programs have a written policy regarding their approach to candidates who decline recommended vaccinations.[547]

There are multiple medical concerns regarding vaccine refusal. Pediatric transplant recipients have an increased risk of acquiring and experiencing morbidity and mortality from vaccine-preventable illnesses compared to the general pediatric population. This risk is not confined to the unvaccinated pediatric transplant recipient but can impact other vulnerable individuals through the possible increased risk of transmission. There is also a concern that parents who refuse vaccination may refuse other medical recommendations that will impact post-transplant care, although evidence for this association is lacking.[548]

Transplant centers should prioritize all vaccinations for both pre- and post-transplant care for which all candidates and their families are eligible. However, denying transplantation to a child who is unvaccinated based on parental beliefs and wishes is ethically problematic. At this time, the most reasonable approach would be individualized consideration based on other medical and psychosocial factors impacting transplant candidacy.

2.3. Multidisciplinary Team Approach

Recommendations for Multidisciplinary Team Approach		
COR	**LOE**	**RECOMMENDATIONS**
1	B-NR	1. Heart transplant candidates should be cared for by a multidisciplinary collaborative team comprising HF cardiologist, cardiac surgeon, transplant nurse coordinator, experts in transplant infectious diseases, transplant pharmacist, immunologist, mental health expert, social worker, registered dietician, physical and occupational therapist, and palliative care specialist, with other specialists included based on the patient's specific needs.
1	C-EO	2. The responsibilities of the multidisciplinary heart transplant team should include 1) coordination of care unique to their area of expertise; and 2) participation in heart transplant selection committee meetings, held on a regular basis, to assess heart transplant candidacy.
1	C-EO	3. Pediatric heart transplant candidates should be cared for, in addition to the multidisciplinary specialists assembled for the care of adult heart transplant candidates, by specialists with expertise in assessing capacity to assent; child-life specialists to optimize education and participation of the pediatric patient and family in the transplant process; and mental health experts with specific expertise in pediatric mental health.

Synopsis

Optimal medical and psychosocial evaluation of a patient for transplantation necessitates the collaborative efforts of a multidisciplinary team (Table 17). Integration of input from multidisciplinary team members is essential during the assessment for candidacy. The multidisciplinary team of the heart transplant evaluation process incorporates health care professionals with unique expertise to deliver comprehensive and collaborative care that adequately addresses medical, behavioral, and psychosocial needs (Table 18).

Recommendation-Specific Supportive Text

1. The optimal composition of the multidisciplinary team for heart transplant evaluations is outlined in Table 17. The multidisciplinary team approach enhances the management of chronic illnesses and improves post-

transplant outcome.[549–551] As patient complexity increases, it is often necessary to collaborate with other specialists, including but not limited to those with expertise in pulmonology, nephrology, gastroenterology, hepatology, neurology, oncology, adult CHD, or other SOT fields.

2. The value of multidisciplinary collaboration lies in the division and coordination of tasks comprising the optimal medical and psychosocial assessment of the heart transplant candidate. The benefit of specific team members has been demonstrated; for example, the presence of an HF pharmacist as part of the care team is associated with better survival[552] and reduced hospitalization,[553] and cardiology societies support the inclusion of a pharmacist as part of an HF multidisciplinary team.[554] Physical activity is a benefit in patients with HF,[555] and these observations can be extrapolated to heart transplant candidates.[556,557] Palliative care, aimed at improving QOL, is associated with increased patient satisfaction at the end of life.[558] Formal meetings to assess transplant candidacy should occur on a regular and recurring basis and include the core members of the multidisciplinary team with additional specialists as dictated by the patient's clinical situation. The outcome of the meeting would include decisions regarding (1) transplant eligibility (accepted, declined, deferred pending additional evaluation as specified); (2) transplant urgency; and (3) candidacy for temporary or durable MCS if needed.
3. The multidisciplinary care of the pediatric heart transplant recipient includes unique challenges as outlined in Section Psychosocial Evaluation. Pediatric heart transplant recipients benefit from a team approach, including comparable expertise to the adult heart transplant team. However, the unique challenges of pediatric transplantation also warrant additional support from pediatric specialists with expertise in the assent process and support patients and families, such as the child life team, pediatric social workers, and pediatric-trained mental health experts, such as psychologists and psychiatrists.

Table 17 Roles and Responsibilities of the Multidisciplinary Heart Failure Team

Team member	Roles and responsibilities
Heart failure cardiologist	• Medical assessment and optimization of heart transplant candidates • Evaluate alternative/complementary options for the HF patient • Integrate pre-transplant evaluation testing to determine relative/absolute contraindications • Lead multidisciplinary team in decision-making on candidacy for HT
Cardiothoracic surgeon	• Evaluate candidates to determine if patients are adequate surgical candidates for HT • Identify surgical-specific considerations and risks for HT • Communicate risks, benefits, and potential surgical complications directly to the patient
Transplant coordinator/nurse	• Provide education to the patient regarding transplant evaluation process, surgery, postsurgical recovery process, and life post-transplant • Review medical evaluation of the patient and assist in determining medical candidacy for transplantation
Experts in transplant infectious diseases	• Promote education in the prevention of infection complications pre- and post-transplant • Prevention strategies to reduce post-transplant infectious complications (i.e., vaccinations, etc.) • Diagnosis and treatment of infections • Management of infectious etiologies
Clinical pharmacist	• Optimize medication therapy and participate in complex medication management/drugs interaction for the heart transplant candidate. • Assess medication compliance and develop plan for post-transplant medication regimen based on the patient's medical history
HLA specialist/immunology	• Assist in determining immunologic risk and considerations for donor/recipient matching
Social worker	• Complete psychosocial evaluation assessing for presence of social support and adherence to current medical therapies.
Psychologist/psychiatrist	• Complete psychosocial evaluation for heart transplant candidate • Develop, recommend, and implement individualized treatment/support plan
Registered dietician	• Nutritional assessment and recommendations for optimization preheart transplant
Physiotherapy	• Physical assessment preheart transplant and rehabilitation plan • Rehabilitation post-LVAD/transplant • Participate in frailty assessment
Palliative care specialist	• Palliative care is aimed at improving QOL by the prevention and relief of suffering for patients with AdvHF

Abbreviations: AdvHF, advanced heart failure; HF heart failure; HT, heart transplantation; LVAD, left ventricular assist device; QOL, quality of life.

Table 18 Summary of Heart Transplant Evaluation

Test (COR)	Baseline	While listed	Comments
Assessment of HF severity			
CPET (Class 1, Baseline; Class 2b Waitlist)	x	x	Table 4 Should not be used as the sole determinant of need/ listing status for HT
RHC (Class 1)	x	x	For patients with potentially prohibitive PH, a vasodilator challenge should be administered to document reversibility to acceptable levels
HF prognosis scores (Class 2a)	x	x	Should not be used as the sole determinant of need for HT
Evaluation of organ function and comorbidities			
Frailty assessment (Class 2a)	x	x	Table 11
Nutritional status (Class 1)	x	x	Table 20
BMI ≥35 kg/m^2 is a potential contraindication (Class 2a)	x	x	
Routine laboratories (comprehensive metabolic profile, complete blood count, PT/INR)	x	x	
Natriuretic peptides (Class 1, Baseline; Class 2a Waitlist)	x	x	
HbA1c >7.5% is a potential contraindication (Class 2a)	x	x	
Ophthalmologic examination (if diabetic) (Class 2a)	x	x	
Urinalysis	x	x	
Serum creatinine, eGFR (Class 1)	x	x	Use race-free equation for eGFR
24-hour urine for creatinine clearance (Class 1)	x	x	If there is abnormal kidney function, further investigation with nephrology consultation, renal ultrasonography, and estimation of proteinuria for assessment of intrinsic renal disease
Liver function tests (albumin, bilirubin, INR); biochemical assays (AST, ALT, GGT); MELD-XI score (Class 1)	x	x	Further investigation should be considered when worsening liver function is suspected
Abdominal ultrasound or CT (Class 1)	x	x	If there is abnormal liver function further investigation with hepatology consultation and liver biopsy
Pulmonary function testing (spirometry, lung volume assessment, and diffusion capacity; Class 1)	x	x	
Chest CT (Class 1)	x		Pulmonary evaluation, risk assessment (presence of circular aortic calcification, porcelain aorta)
Carotid ultrasound in select patients (Class 1)	x	x	For patients with history of stroke or neurologic signs or symptoms concerning for cerebrovascular disease
Ankle brachial indices in select patients (Class 1)	x		If symptoms of peripheral arterial disease, known atherosclerotic disease, risk factors for atherosclerotic disease

Continued

Table 18 Summary of Heart Transplant Evaluation

Test (COR)	Baseline	While listed	Comments
Infectious serologies (Class 1): CMV IgG, EBV (EBV VCA IgG, IgM), Toxoplasma IgG, Syphilis, HAV serology Tetanus serology Varicella serology (IgG) HSV IgG Mumps serology Measles serology Rubella serology *Strongyloides* IgG, *Strongyloides* stool culture (if from endemic areas) *Coccidioides* serology (if from endemic areas) Trypanosomiasis serology (if from endemic areas)	x	x	Table 9 Repeat screening waitlist for >1 year or relevant infectious disease exposure
Screen for latent infection (Class 1): HIV serology and/or viral load IgG antibodies to *T. cruzi*, TST/IGRA HBVsAg, HBVcAb, HBVsAb, HBV nucleic acid test HCV antibody and nucleic acid test	x	x	Table 9
Vaccination (Class 1)	x	x	Table 10
Dual X-ray absorptiometry (DEXA scan) (Class 1)	x		
Immunocompatibility			
ABO HLA tissue typing PRA and flow cytometry	x x x	x	HLA antibody every 3-6 months/3 weeks after sensitizing event
Age-appropriate routine health maintenance			
Dental evaluation	x	x	
Skin cancer screening (Class 2a)	x	x	Section Cancer, Table 19
Colorectal cancer screening (Class 1-2a)	x	x	Section Cancer, Table 19
Mammogram (Class 1)	x	x	Section Cancer, Table 19
HPV/Pap smear (Class 1)	x	x	Section Cancer, Table 19
Prostate-specific antigen with/without digital rectal exam (Class 1)	x	x	Section Cancer, Table 19
Consultations			
Psychosocial evaluation (Class 1)	x	x	Evaluation of substance use, support, adherence and mental health; Figure 5, Tables 14-16

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index; CMV IgG, Cytomegalovirus Immunoglobulin G; CPET cardiopulmonary exercise test; CT, computed tomography; EBV, Epstein-Barr virus; eGFR, estimated glomerular filtration rate; GGT, gamma-glutamyl transferase; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; HF, heart failure; HLA, human leukocyte antigen; HPV, human papillomavirus; HT, heart transplantation; INR, international normalized ratio; IGRA, interferon-γ release assay; LVAD, left ventricular assist device; MELD-XI, model for end-stage liver disease excluding INR; PH, pulmonary hypertension; PRA, panel-reactive antibody; PT, prothrombin time; QOL, quality of life; RHC right heart catheterization; TST, tuberculin skin test.

3. TASK FORCE II: OPTIMIZATION OF THE MEDICAL SURVEILLANCE OF PATIENTS ON THE WAITLIST

3.1. Optimal Pharmacologic Management of Heart Transplant Candidates

3.1.1. Standard Heart Failure Guideline-Directed Medical Therapies

Recommendations for Optimal Pharmacologic Management of Heart Transplant Candidates: Standard Heart Failure Guideline-Directed Medical Therapies		
COR	LOE	RECOMMENDATIONS
1	A	1. Standard maximally tolerated GDMT for HF should be continued in heart transplant candidates with reduced ejection fraction (HFrEF).
2a	B-NR	**2.** Standard maximally tolerated HF GDMT can be beneficial for patients with durable LVAD listed for HT.
1	C-LD	**3.** Dose reduction or discontinuation of some drugs that are part of standard GDMT is recommended when patients exhibit drug intolerance, such as persistent symptomatic hypotension (not due to over-diuresis), secondary organ dysfunction (renal or liver failure), or cardiogenic shock.
2a	C-LD	4. In patients with non-dilated phenotype of cardiomyopathies (HCM, RCM, infiltrative cardiomyopathy such as cardiac amyloidosis) who develop LV systolic dysfunction, HF GDMT is beneficial; however, tolerance can be limited.

Synopsis

Most HF patients evaluated for HT receive standard GDMT for HF with HFrEF. While on the waitlist, efforts should be made to continue and further optimize GDMT to avoid further clinical and hemodynamic decline. This approach is extrapolated from evidence from broader HF trials, acknowledging that data are limited in this subgroup of AdvHF patients since patients listed for HT and those supported by MCS are frequently excluded or under-represented in randomized HF clinical trials.

Recommendation-Specific Supportive Text

1. Standard maximally tolerated GDMT should be continued in patients with HFrEF listed for HT. The main pillars of GDMT are angiotensin receptor-neprilysin inhibitors (ARNi) or renin-angiotensin-aldosterone system inhibitors (RAASi) [angiotensin-converting enzyme inhibitors (ACEi) or angiotensin II receptor blockers (ARB)], beta-blockers, mineralocorticoid receptor antagonists, and sodium-glucose cotransporter-2 inhibitors (SGLT2i).[350] Additional therapies for specific patient populations include hydralazine-nitrate combination, ivabradine, vericiguat, and digoxin.[19,31,350,559,560]
2. Existing evidence supports the continuation of GDMT in patients supported with durable LVAD in general.[561] Data specific to LVAD-supported patients listed as heart transplant candidates are limited. Specific clinical circumstances that may prompt certain LVAD-supported patients to be listed for HT may limit the application of certain classes of GDMT medications; for example, RV failure may limit beta-blocker use.[562–564] Conversely, LVAD implant may present an opportunity to optimize GDMT in previously intolerant patients.
3. Dose reduction or discontinuation of standard GDMT is recommended when patients exhibit drug intolerance, such as persistent hypotension, secondary organ dysfunction (renal or liver failure), or cardiogenic shock. Cardiogenic shock can manifest acutely, often following acute coronary syndrome, cardiac surgery or due to acute myocarditis, or in the setting of acute decompensation of chronic HF.[565]
4. Patients with a nondilated phenotype of cardiomyopathies who develop LV systolic dysfunction can have limited tolerance to GDMT. This is especially true for cardiac amyloidosis.[566,567]

3.1.2. Diuretics and Volume Management

Recommendations for Optimal Pharmacologic Management of Heart Transplant Candidates:: Diuretics and Volume Management		
COR	LOE	RECOMMENDATIONS
1	B-NR	1. Diuretics should be used in HT candidates at the minimal dose necessary to accomplish decongestion.
1	B-NR	2. In refractory congestion not responding to intravenous administration and escalation of loop diuretic dose, addition of a thiazide (e.g., metolazone) or a carbonic anhydrase inhibitor (e.g. acetazolamide) to treatment with a loop diuretic should be considered.
2b	B-R	3. For those unresponsive to diuretics, utilization of mechanical unloading via ultrafiltration therapies in HT candidates may be considered.

Synopsis

Diuretics are the mainstay of decongestive therapy in HF patients, including those listed for HT. In advanced stages of HF, diuretic therapy may provide inadequate relief of congestion underscoring the importance of alternative decongestive strategies to manage volume overload. Among these is the removal of volume by ultrafiltration.

Recommendation-Specific Supportive Text

1-2. Loop diuretics, oral or parenteral, are recommended for decongestion, with proper electrolytes and renal function monitoring. Diuretics should be maintained at the lowest dose necessary to avoid congestion and minimize the possible adverse metabolic effects. In refractory congestion not responding to moderate or high dose loop diuretics, addition of a thiazide or thiazide-like diuretic (e.g., metolazone) to treatment with loop diuretic enhances natriuresis.[568–570] The addition of acetazolamide, a carbonic anhydrase inhibitor that reduces proximal tubular sodium reabsorption, to loop diuretic therapy in patients with acute decompensated HF resulted in a greater incidence of successful decongestion.[571]

3. Data regarding the benefits of ultrafiltration in the decompensated HF population resistant to diuretic therapy are mixed, with some data suggesting greater fluid loss and decrease in rehospitalizations compared to diuretics without systematic escalation. However, any possible ultrafiltration benefits need to be weighed against concerns of intravenous catheters associated adverse events.[572–574] Ultrafiltration may be considered in patients who are listed for HT where hemodynamic optimization and diuretics are insufficient to achieve decongestion.

3.1.3. Antianginal Therapy

Recommendations for Optimal Pharmacologic Management of Heart Transplant Candidates: Anti-Anginal Therapy		
COR	LOE	RECOMMENDATION
2a	C-LD	1. In patients with ischemic heart disease and angina listed for HT, anti-anginal therapies can be continued for symptom relief.

Synopsis

Angina is a prevalent and morbid condition, impairing functional capacity and QOL. Despite the aggressive use of medical therapies and myocardial revascularization procedures, angina remains prevalent.

Recommendation-Specific Supportive Text

1. Antianginal therapies have not been specifically studied in patients listed for HT. In addition to beta-blockers, antianginal therapies include oral nitrates, calcium channel blockers, ranolazine, ivabradine, and trimetazidine.[575–577] The potential systemic effects of these medicines (hypotension, vasoplegia, etc.) need to be considered in patients on the waitlist.

3.1.4. Pulmonary Hypertension Therapy

Recommendations for Optimal Pharmacologic Management of Heart Transplant Candidates: Pulmonary Hypertension Therapy		
COR	**LOE**	**RECOMMENDATIONS**
3: Harm	**B-R**	1. The use of endothelin receptor antagonists and prostanoids in HT candidates with Group 2 PH associated with left heart disease is not recommended.
2b	**C-LD**	2. The use of phosphodiesterase 5 (PDE5) inhibitors to improve hemodynamics and exercise capacity in PH and HFrEF, and in patients with heart failure with preserved ejection fraction (HFpEF) -associated combined post- and pre-capillary PH (CpcPH) may be reasonable.
3: No Benefit	**C-LD**	3. The use of PDE5 inhibitors in patients with HFpEF and isolated post-capillary PH is not recommended.

Synopsis

PH, in which reversal cannot be demonstrated, is considered a contraindication to HT (Section Pulmonary Hypertension, Figure 1). Elevation of pulmonary pressures and PVR in patients evaluated for HT typically results from left-sided heart disease (Group 2, PH associated with left heart disease). The primary strategy in managing PH-left heart disease is optimizing the treatment of the underlying cardiac disease. Diuretics remain the cornerstone of medical therapy in the presence of fluid retention due to PH-left heart disease. There is limited and conflicting evidence for the use of drugs approved for PH in patients with group 2 PH. Some medications may have variable and potentially detrimental effects in such patients and are therefore not indicated in PH-left heart disease.

Recommendation-Specific Supportive Text

1. The use of pulmonary arterial hypertension-specific therapies, such as endothelin antagonists and prostacyclin derivatives in HT candidates with group 2 PH, to reduce PVR before transplant is not recommended as they might increase filling pressures and lead to HF decompensation.[172, 578–580] Bosentan was assessed in a multicenter randomized study of patients with pulmonary arterial hypertension associated with HFrEF, showing no efficacy but an increase in adverse events compared with placebo, predominantly related to fluid retention.[581]
2. Phosphodiesterase 5 (PDE5) inhibitors, mostly sildenafil, have been used in an attempt to reduce PVR in patients in whom acute reversal with short-acting agents was not demonstrated. Whether this approach, in patients with or without LVAD support, leads to reduced post-transplant risk of RHF is unknown.[582–587] Small studies have suggested that sildenafil may improve hemodynamics and exercise capacity in PH and HFrEF, but randomized clinical trials are lacking.[172, 588–590] In patients with HFpEF with a predominantly combined post- and pre-capillary PH (CpcPH) profile, sildenafil improved hemodynamics, RV function and QOL at 6 and 12 months vs placebo,[172,591] and retrospective analyses and registry data suggest improvement in exercise capacity with PDE5 inhibitors therapy in patients with HFpEF-associated CpcPH and with a severe pre-capillary component.[172,592,593]
3. In patients with HFpEF with a predominantly isolated postcapillary PH, sildenafil had no effect on mean pulmonary artery pressure (PAP) or other hemodynamic and clinical measures vs placebo.[594]

3.1.5. Anticoagulant and Antiplatelet Therapy

Recommendations for Optimal Pharmacologic Management of Heart Transplant Candidates: Anticoagulant and Antiplatelet Therapy		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	1. In patients with indications for anticoagulation or dual antiplatelet therapy (DAPT), a plan for perioperative management should be established at the time of listing for HT.
1	C-EO	2. In patients with indications for chronic anticoagulation listed for HT, vitamin K antagonists or heparin-based agents are more established.
1 1 2a	B-NR B-NR C-LD	3. Agents available for reversal of vitamin K antagonists include a. vitamin K b. fresh frozen plasma c. prothrombin complex concentrate.
2a	C-LD	4. When direct oral-anticoagulants (DOAC) need to be continued prior to HT, on-site availability of reversal agents can be useful.
2a	B-NR	5. Anti-platelet therapy with P2Y12 receptor antagonists should be interrupted pre-operatively if possible, to decrease the risk of bleeding.
1	B-NR	6. Heparin should be avoided in patients with heparin-induced thrombocytopenia (HIT) listed for transplant. Patients with HIT should be managed with warfarin, DOACs, argatroban, bivalirudin, or fondaparinux, depending on the clinical scenario.

Synopsis

Patients listed for HT often require systemic anticoagulation. Because of the lack of predictability of the timing of HT, the ability to reverse anticoagulation rapidly and safely to reduce the risk of intraoperative bleeding is paramount. The widespread use of the direct oral-anticoagulants (DOAC) is challenging because the data and clinical experience of their reversal in this setting are limited. Antiplatelet therapy, including P2Y12 receptor antagonists, ideally should be interrupted perioperatively to decrease the risk of bleeding. However, this may not be always feasible due to the half-life of the drugs and the indications for antiplatelet therapy.

Recommendations-Specific Supportive Text

1. Decisions regarding anticoagulation and dual antiplatelet therapy (DAPT) including plans for anticoagulation reversal should be established by the multidisciplinary team, considering the anticoagulation and DAPT indications, urgency of HT, inpatient vs outpatient status, and other logistical factors.
2. Although specific DOAC reversal agents have been approved, various factors complicate the use of these agents in clinical practice, particularly in the setting of a need for an urgent unplanned procedure (i.e., HT). These factors include availability, risk of thrombosis, cost, preparation, and a lack of data on the comparative effectiveness of different reversal strategies. Moreover, reversal agents are not indicated for use with all DOACs.[595] Patients receiving DOAC-based therapy at the time of listing should be considered to transition to vitamin K antagonists (outpatients) or heparin-based agents (inpatients).
3. Of the several agents available for the reversal of vitamin K antagonists, it is suggested to start with vitamin K. Due to the delayed effects of vitamin K, fresh frozen plasma should be administered when there is a need for rapid reversal. Prothrombin complex concentrate containing vitamin-K-dependent clotting factors can also be beneficial. The cost and availability of prothrombin complex concentrate should also be weighed vs the potential advantage of reducing transfusion requirements and the risk of sensitization and future rejection in this setting.[596,597]
4. The risks and benefits of continuing DOAC with a plan to reverse at transplant can be considered over the more conventional practice of transitioning to heparin or warfarin anticoagulation in every HT candidate. Specific reversal agents for DOAC exist; however, they may be costly or not universally available. While there may be slightly more available evidence regarding dabigatran reversal with idarucizumab in the setting of HT, oral factor Xa inhibitors, such as apixaban or rivaroxaban, may be reversed with andexanet.[597–604]
5. Antiplatelet therapy with P2Y12 receptor antagonists is associated with increased risk of bleeding and higher mortality (as extrapolated from non-HT cardiac surgery).[605] The risk of waiting for DAPT termination (i.e., in the setting of a recent percutaneous intervention) before listing the patient for HT must be weighed against the risk of HF mortality if listing is delayed. Platelet transfusion is unlikely to reverse platelet inhibition with P2Y12 receptor antagonists.[606] Antibody-based agents for P2Y12 receptor antagonist reversal are currently under

development and testing.[607] Case reports describe the feasibility of conversion to a prolonged cangrelor (short-acting continuous-infusion P2Y12 inhibitor with a half-life of 3-6 minutes) infusion, without complication as abridge to successful heart/liver transplantation.[608,609]

6. Heparin should be avoided in patients with heparin-induced thrombocytopenia (HIT) listed for transplant. Depending on the clinical scenario and anticipated proximity of the transplant, patients with HIT should be managed with warfarin, DOACs, argatroban, bivalirudin, or fondaparinux. Rechallenge with heparin at the time of HT may be considered; however, the evidence is limited. In patients with ongoing thrombocytopenia and/or HIT syndrome with thrombotic complications, the use of intraoperative plasmapheresis has been utilized.[610–615] A plan for anticoagulation at the time of HT should be established ahead of time with the multidisciplinary team. Decisions on addressing anticoagulation in HT candidates who develop HIT should be individualized involving a multidisciplinary team.

3.1.6. Systemic Disease Modifying Therapies

Recommendations for Optimal Pharmacologic Management of Heart Transplant Candidates: Systemic Disease Modifying Therapies		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	**1.** Disease-modifying drugs for systemic conditions with immune suppressive effects should be continued during the period of listing for HT.
1	C-EO	2. A plan should be established for the use of disease-modifying drugs for systemic conditions perioperatively and after transplant.

Synopsis

Patients on the waitlist may have systemic conditions related or unrelated to their heart disease, including sarcoidosis, amyloidosis, connective tissue disorders, etc. A clear plan should be established for modifying this therapy while awaiting HT, perioperatively and after transplant to avoid complications.

Recommendation-Specific Supportive Text

1. Disease-modifying drugs used for systemic conditions may have immune suppressive effects. Typically, these medications should be effectively continued during the period of listing for HT.[89, 616–618]
2. A customized plan for use of these therapies in the perioperative period and following HT should be established in consultation with the appropriate specialists—rheumatologists, pulmonologists, hematologists, etc. There may be interactions or potentiation of the immunosuppressive effect when disease-modifying therapies for systemic conditions and immunosuppressive for heart transplant are combined. The aim is to avoid over-suppression of the immune system, reduce the risk of infection, and minimize other potential drug-related side effects.[285, 287, 301, 619–621]

3.1.7. Special Considerations for Combined Organ Transplant Candidates

Recommendations for Optimal Pharmacologic Management of Heart Transplant Candidates: Special Considerations for Combined Organ Transplant Candidates		
COR	**LOE**	**RECOMMENDATIONS**
3	C-EO	1. In candidates for SHKT with low eGFR, SGLT-2i should not be used.
2b	C-EO	2. Mineralocorticoid receptor antagonists (MRAs) and RAASi may be used with caution in patients listed for SHKT but are contraindicated in those on dialysis. Potassium-binding agents (patiromer or sodium zirconium cyclosilicate) might be considered to favor the tolerability of these agents.
2b	C-EO	3. In candidates for combined heart-lung transplantation, oral, inhaled or parenteral pulmonary vasodilator therapies may be useful to slow the progression of the disease according to standard PH guidelines.

Synopsis

Limited data exist as to the optimal pharmacotherapy of HF in patients listed for combined organ transplantation. There may be specific considerations regarding medication interactions and contraindications in patients with multiorgan failure awaiting combined heart transplantation.

Recommendation-Specific Supportive Text

1. In the randomized clinical trials demonstrating the benefit of SGLT2i on outcomes in patients with HF, patients with eGFR < 20 or eGFR < 30 ml/min/1.73 m^2 were excluded. Most patients listed for SHKT will not be candidates for SGLT2i therapy due to low eGFR.[622,623]
2. Mineralocorticoid receptor antagonists (MRAs) and RAASi may be used with caution in patients listed for SHKT, especially in those with residual renal function. These patients may be at risk of hyperkalemia and further worsening of eGFR. Potassium-binding agents (patiromer or sodium zirconium cyclosilicate) might be considered to treat hyperkalemia and favor the tolerability of these agents in patients not on hemodialysis (MRAs, RAASi, and SGLT2i are contraindicated in this cohort).[624–629]
3. Patients listed for combined heart-lung transplantation with group 1 PH can have conventional indications for pulmonary vasodilator therapies to slow the progression of the disease, according to American College of Clinical Pharmacy (ACCP) guidelines.[167,172] These therapies are otherwise not indicated in most patients with HFrEF listed for HT, the majority of which have group 2 PH, because they may result in increased PCWP, increased risk of pulmonary edema and worse clinical outcomes.[630,631]

3.1.8. Special Considerations for Pediatric Heart Failure Patients

Recommendations for Optimal Pharmacologic Management of Heart Transplant Candidates: Special Considerations for Pediatric Heart Failure Patients		
COR	**LOE**	**RECOMMENDATIONS**
2b	**C-EO**	1. Pediatric patients with AdvHF listed for HT may be treated with triple therapy consisting of ACEi or ARB, beta-blockers, and MRA, as long as these therapies are well tolerated and not otherwise contraindicated.
2b	**C-EO**	2. Evidence regarding ARNi and SGLT2i among pediatric patients with AdvHF awaiting HT remains limited.
2a	**B-NR**	3. Digoxin added to standard HF therapy can be beneficial in pediatric heart transplant patients with interstage single ventricle physiology.
2b	**C-EO**	4. The use of continuous inotropes may be considered in pediatric patients with acute decompensated HF, including those listed for HT, with or without MCS.

Synopsis

Medical therapy for pediatric patients with HF is not as well established as in adults. Pediatric patients with cardiomyopathies have better waitlist outcomes compared to patients with CHD. Overall mortality for children waiting for HT is higher compared to other solid organs.

Recommendation-Specific Supportive Text

1. Although there is less evidence regarding optimal therapy for pediatric HF patients listed for HT compared to adults, pediatric patients with AdvHF may be treated with triple therapy: ACEi or ARB, beta-blockers, and MRA, unless contraindicated. Diuretics can be used to achieve euvolemia.[632–636]
2. There is limited evidence regarding the utility of ARNi in children with HF. Preliminary results from the Panorama-HF study showed NT-proBNP reduction with ARNi after 12 weeks of therapy in children who were > 1-year old.[636–638] Limited data suggest dapagliflozin use in pediatric HF, when added to GMDT, is well tolerated.[639]
3. Digoxin is often used as a second-line agent.[640] Several observational studies reported higher interstage transplant-free survival in infants treated with digoxin after Norwood procedure, but prospective controlled data are unavailable.[641–644]
4. Intravenous inotropes are routinely utilized for children presenting with acute decompensated HF and those with AdvHF listed for HT.[325,353,526,645] For patients with evidence of hemodynamic decompensation on continuous intravenous inotropic support, the use of VAD should be considered early before evidence of end-organ dysfunction as that portends poor outcomes.[325,353,526,646,647]

3.2. Nonpharmacologic Management of Cardiac Transplant Candidates: Approaches to Be Considered

3.2.1. Percutaneous Interventional Procedures in Heart Transplant Candidates

Recommendations for Non-pharmacologic Management of Cardiac Transplant Candidates: Percutaneous Interventional Procedures in Heart Transplant Candidates		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	1. Patients with AdvHF and structural heart disease should be evaluated by a multidisciplinary heart team if intervention is considered.
1	C-EO	2. GDMT should be optimized by an HF cardiologist, and CRT implanted if appropriate prior to percutaneous mitral valve intervention for moderately-severe and severe secondary mitral regurgitation (MR) and AdvHF.
2a	B-R	3. In patients with chronic severe secondary MR with LVEF 20-50% who have NYHA II-IV symptoms and an LV end-systolic dimension <7 cm despite GDMT and CRT, if appropriate, mitral transcatheter edge-to-edge repair is reasonable.
1	C-EO	4. In patients with right-sided HF and edema and or ascites attributable to severe secondary tricuspid regurgitation (TR) diuretics are indicated.
2a	C-EO	5. In patients with right-sided HF attributable to severe secondary TR, therapies to treat the underlying causes (PH, RV failure, and HFrEF) can be effective prior to transcatheter valvular consideration.
2b	B-R	6. In patients with RHF attributable to severe TR despite optimization of therapy who are deemed high surgical risk, transcatheter edge-to-edge repair may be reasonable.
2a	B-R	7. In patients with symptomatic HF, remote monitoring of PAP with an implanted PAP sensor to reduce risk of hospitalizations and improve QOL is reasonable.

Synopsis

Patients with AdvHF may have concomitant valvular, coronary, or other structural abnormalities. Adequate coronary revascularization and treatment of primary valvular diseases by percutaneous or surgical methods according to established guidelines should be performed. In a proportion of patients with AdvHF, structural or valvular abnormalities are secondary to atrial and/or ventricular enlargement and/or volume overload. Transcatheter approaches to the management of these abnormalities may substantially alter HF trajectory. In the current era, transcatheter edge-to-edge repair for moderately-severe and severe functional mitral regurgitation (Mitraclip) has therapeutic benefits in patients with HF who meet the criteria. Transcatheter tricuspid valve repair has an emerging role in patients with RHF and severe TR. Other device platforms for transcatheter valvular repair or replacement, percutaneous mitral and tricuspid annuloplasty, interatrial shunts, cardiac contractility modulation, and autonomic nerve modulation are under evaluation and may change the landscape of AdvHF management in the future, but insufficient data are currently available to provide guideline recommendations.

Recommendation-Specific Supportive Text

1. Given the complexity of decision-making, patients with AdvHF and structural heart disease for whom structural intervention is considered should be evaluated by a multidisciplinary heart team.[1] It is important to emphasize that percutaneous interventions should complement and not replace aggressive attempts to maximize GDMT, and complex decision-making is best performed in a multidisciplinary manner.
2. GDMT and CRT therapy should be optimized, and the severity of valvular disease should be reassessed after a sufficient period to ascertain whether the patient is likely to benefit from percutaneous mitral valve intervention.[648–651]
3. The 2 randomized trials of Mitraclip in functional MR, COAPT, and Mitra-FR had divergent results. COAPT showed a significant reduction in HF hospitalization (HR 0.53) and all-cause mortality at 24 months (HR 0.62) in the Mitraclip arm, whereas Mitra-FR showed no difference in hospitalization or all-cause mortality between the device and medical therapy groups.[650,651] Multiple factors may explain these findings: GDMT was better optimized in the COAPT group; COAPT had more severe MR (ERO 0.41 cm^2 vs 0.31 cm^2 in Mitra-HF) and

smaller LV size (Left ventricular end-diastolic diameter 62 mm vs 69 mm in Mitra-HF); patients in the COAPT group were more likely to receive more than 1 clip, and residual MR was less in COAPT (5% vs 17% in Mitra-HF).[652,653] These results underscore the need to maximize medical therapy and optimize procedural techniques for successful functional MR management. In the MitraBridge registry of 119 patients in 17 centers undergoing Mitraclip implantation, freedom from the composite endpoint of death, urgent transplant/LVAD, or first rehospitalization for HF was 64% at 1 year. Significant clinical improvement led to the removal of patients from transplant listing in 23.5%.[654] However, the specific demographics of the patients removed from the list were not reported, nor was the use of GDMT, including sacubitril/valsartan and SGLT2i, making the results less generalizable.

4-6. In patients with right-sided HF and edema and or ascites attributable to severe secondary TR, the severity of TR should be reassessed after full decongestion with diuretics.[649] The severity of secondary TR may be dynamic, depending on RV function and PH, thus management entails focusing on underlying causes, such as PH, RV failure, and HFrEF.[2] The TRILUMINATE single-arm study enrolled 85 patients with high surgical risk, predominantly functional severe TR and NYHA III-IV symptoms at baseline in 75% of patients. Transcatheter tricuspid edge-to-edge repair (TEER) with the Triclip device resulted in a sustained reduction in TR, improved functional class with 83% NYHA I/II, and improved right heart size and function at 1-year follow-up.[655] In a prospective randomized trial of percutaneous TEER for symptomatic severe TR enrolling 350 patients, Tricuspid TEER was safe, reduced the severity of tricuspid regurgitation, and was associated with an improvement in QOL but with a trend for a higher hospitalization rate, no change in diuretic dose and no effect on mortality.[656]

7. In patients with symptomatic HF and NYHA Class III symptoms with a previous HF hospitalization, the CHAMPION trial demonstrated that remote PAP monitoring with an implanted PAP sensor (CardioMEMS) led to a reduction in HF hospitalizations at 6 months (hazard ratio 0.70, 95% CI 0.60-0.84, $p < 0.0001$).[657] GUIDE-HF enrolled NYHA Class II to IV patients with either a previous HF hospitalization or elevated NPs to hemodynamic monitoring or control. The overall primary end-point was not significant, but a prespecified analysis to account for the effects of COVID-19 was significant for a reduction in HF hospitalizations. Therefore, the Food and Drug Administration expanded the indication for the device to NYHA Class II and III patients with either a previous hospitalization or elevated NPs.[658] The randomized trial MONITOR-HF demonstrated that PAP monitoring (CardioMEMS-HF system) vs standard care in a European health system cohort substantially improved QOL and reduced HF hospitalizations in patients with moderate-to-severe HF.[659]

3.2.2. Heart Rhythm Considerations in Heart Transplant Candidates

Recommendations for Non-pharmacologic Management of Cardiac Transplant Candidates: Heart Rhythm Considerations in Heart Transplant Candidates		
COR	**LOE**	**RECOMMENDATIONS**
2a	B-NR	1. ICD is reasonable in NYHA IV patients who are candidates for HT.
1	B-R	2. CRT is indicated in patients with LVEF ≤ 35%, sinus rhythm, left bundle branch block (LBBB) with QRS duration ≥ 150 ms, and ambulatory NYHA IV symptoms who are being considered for HT.
2a	B-NR	3. CRT can be beneficial in patients with LVEF ≤35%, sinus rhythm, LBBB with QRS duration 120-149 ms and ambulatory NYHA IV symptoms who are being considered for HT.
2b	B-R	4. Catheter ablation may be considered for selected patients with symptomatic atrial fibrillation and HFrEF.
2b	B-NR	5. AV nodal ablation and CRT may be considered in medically refractory AF and HF.
2b	C-LD	6. Catheter ablation may be considered for heart transplant candidates with NYHA IV symptoms and recurrent ventricular tachycardia.
2a	B-NR	7. Amiodarone dose reduction or discontinuation can be considered on an individualized basis in patients listed for HT.

Synopsis

Arrhythmias can cause hemodynamic decompensation, significant morbidity and mortality in AdvHF patients, and may lead to waitlist mortality. Many patients with chronic HF already have implantable cardioverter defibrillator (ICDs), but those with new-onset or rapidly progressive cardiomyopathy may need to be evaluated for ICD or wearable defibrillators during transplant evaluation, particularly if they will not be hospitalized until transplantation or are discharged on inotropes which increase arrhythmic risk. CRT should be considered in transplant candidates with appropriate electrocardiographic criteria to improve symptoms and delay or even prevent the need for a transplant. Antiarrhythmic choices are limited in AdvHF, and the risk-benefit ratio of catheter ablation for atrial and ventricular arrhythmias remains uncertain.

Recommendation-Specific Supportive Text

1. ICDs are not generally recommended for refractory NYHA IV patients with less than 1-year survival, but heart transplant candidates represent a subset of NYHA IV patients who may benefit from this therapy. In a multicenter analysis of 32,599 patients listed for HT, having an ICD was associated with decreased mortality in patients with or without LVADs (HR 0.81 and 0.87, respectively).[660] In a meta-analysis including 36,112 patients awaiting heart transplant, those with ICDs had decreased total mortality (Relative Risk 0.6) and decreased sudden cardiac death risk (Relative Risk 0.27).[661] The wearable cardioverter defibrillator can be a reasonable noninvasive alternative approach, though data on its use in patients awaiting HT are limited.[662–664]

2-3. CRT is indicated in patients with LVEF ≤35%, sinus rhythm, left bundle branch block with QRS duration ≥150 ms, and ambulatory NYHA IV symptoms who are being considered for HT as CRT decreased time to death or hospitalization (HR 0.64) in ambulatory NYHA IV patients in the COMPANION trial.[665] CRT-D implant in patients with sinus rhythm, QRS duration 120 to149 ms is reasonable.[665]

4-5. Several randomized clinical trials of AF ablation in HF patients showed improvements in hospitalization and mortality but primarily enrolled NYHA II and III patients.[666,667] The AMICA trial enrolled mostly NYHA III and IV patients, and a subgroup analysis of the CASTLE-HF trial of NYHA III and IV patients did not show a difference between ablation and medical therapy.[668–670] In the randomized CASTLE-HTx single-center trial involving AdvHF patients with symptomatic AF referred for HT evaluation, the combination of catheter ablation and GDMT was associated with a lower likelihood of a composite of death from any cause, implantation of an LVAD, or urgent HT than medical therapy alone.[671] Atrioventricular nodal ablation and CRT may be considered in medically refractory AF and HF as an alternative to AF ablation.[672–674]

6. Catheter ablation with substrate modification may effectively suppress ventricular arrhythmias in patients with AdvHF, including those with LVADs. In high-risk cases, based on presentation and hemodynamic conditions, tMCS may be beneficial. In patients on the waitlist who have recurrent ventricular tachycardias, catheter ablation may be considered.[675,676]

7. Amiodarone is effective against ventricular and atrial arrhythmias in AdvHF but can have substantial adverse effects. A multi-institutional analysis of 14,944 patients revealed higher adjusted mortality 1 year after transplant (HR 1.15) in those with pre-transplant amiodarone use compared to those without difference in early graft failure rate.[677] A meta-analysis of 9 studies did not find an association of pre-transplant amiodarone use with post-transplant mortality.[678] A single-center study of 269 patients showed an association of amiodarone with primary graft dysfunction (PGD) in a dose-dependent manner[679] and a subsequent report from the same group reported lower incidence of PGD if amiodarone was discontinued 74 days [interquartile range, 38-137] before transplantation.[680] A SRTR analysis of 25,394 adults revealed association of amiodarone use with higher graft dysfunction (OR 1.30), higher 30-day (HR 1.25), and 1 year (1.13) but not 5 or 10-year mortality (OR 0.81).[681] It seems prudent to assess the continued need for amiodarone in patients on the transplant waiting list and consider discontinuation when possible.

3.2.3. Nonpharmacologic Management of Pediatric Transplant Candidates

Recommendations for Non-Pharmacologic Management of Pediatric Transplant Candidates		
COR	LOE	RECOMMENDATIONS
2b	C-EO	1. ICD implantation may be considered in pediatric patients with CHD.
2b	C-EO	2. ICD implantation may be considered in pediatric patients with non-ischemic dilated cardiomyopathy.
3: No Benefit	C-EO	3. ICD implantation is not recommended in pediatric patients with AdvHF who will remain hospitalized until transplantation.
2b	C-EO	4. CRT may be considered in CHD patients with symptomatic HF and electrical dyssynchrony.

Synopsis

The role of ICD while listed for HT in the pediatric age group is to mitigate the risk of sudden death while waiting. Nonetheless, there are limited clinical data regarding ICD benefits in pediatric patients. There is also an extensive range of patient age, size, disease pathogenesis, and potentially complicating anatomic factors. ICD implantation requires case-by-case analysis and a shared decision-making approach.

Recommendation-Specific Supportive Text

1. In pediatric patients with CHD, case-based clinical judgment with a shared decision-making approach is warranted for ICD implantation.[682] There are limited clinical data, and consideration, including patient age, size, and disease pathogenesis, is warranted. ICD implantation in waitlisted CHD patients is generally considered in the setting of documented ventricular tachycardia with syncope and additional risk factors, including ventricular dysfunction or severe aortic valve insufficiency. In addition, the underlying anatomy, which can consist of intracardiac shunts and irregular vascular, may influence decisions.[683–685]
2. Convincing evidence for ICD implantation for primary prevention in pediatric patients with nonischemic dilated cardiomyopathy and no additional risk factors is lacking.[682] ICD implantation may be considered in those with LVEF < 35%, and additional clinical factors include the etiology and the clinical phenotype of cardiomyopathy, for example, the degree of ventricular dysfunction, the presence of cardiac arrhythmias, and overall estimated cumulative risk of sudden cardiac death.[686]
3. ICD implantation is not recommended in pediatric patients with AdvHF who will remain hospitalized until transplantation.[682]
4. While earlier studies on CRT use in pediatric patients with CHD have been conflicting, more recent data suggest that in CHD patients with symptomatic HF and electrical dyssynchrony, CRT may provide benefit.[687–689]

3.3. Surveillance and Management on the Waitlist

3.3.1. Serial Evaluation (Guidelines for Repeat Testing on the Waitlist)

3.3.1.1. Cardiac Catheterization to Assess Hemodynamic Stability

Recommendations for Repeat Testing on the Waitlist: Cardiac Catheterization to Assess Hemodynamic Stability		
COR	LOE	RECOMMENDATIONS
1	C-LD	1. RHC should be performed on all adult candidates periodically after listing until transplantation. For patients with potentially prohibitive PH, a vasodilator challenge should be administered to document reversibility to acceptable levels.
2b	C-EO	2. In pediatric heart transplant candidates, RHC may be performed periodically while waitlisted to evaluate PVRI, reaffirm heart-only transplant suitability, indicate a potential need for MCS, and address aortopulmonary collaterals particularly in those with CHD.
2a	C-LD	3. If medical therapy fails to achieve acceptable hemodynamics and if the left ventricle cannot be effectively unloaded with mechanical adjuncts, including an intra-aortic balloon pump and/or LVAD, it is reasonable to conclude that the PH is irreversible. Reevaluation of hemodynamics can be done 3 to 6 months after LVAD to ascertain reversibility of PH.

Synopsis

Patients listed for HT should continue to receive OMT. Given the progressive nature of patients with AdvHF of diverse etiologies, hemodynamics is essential to optimize their management. Some patients are urgently listed for HT in the setting of cardiogenic shock and are intolerant to standard GDMT. In some of these patients, GDMT may be started if hemodynamic status improves. A unique aspect pertains to the unplanned nature of HT surgery.

Recommendation-Specific Supportive Text

1. RHC hemodynamic is a significant predictor for survival on the waitlist.[42–44, 690] Serial RHCs in HT candidates are beneficial to optimize medical therapy, define candidacy urgency, assess end-organ injury, and as a guide for temporary and durable MCS implantation.[690,691] The optimal timing of RHCs, while waitlisted, has not been ascertained and should be at the discretion of the transplant team guided by clinical stability, echocardiographic findings suggestive of PH (i.e., systolic pulmonary arterial pressure, signs of RV overload and/or dysfunction), and the degree of PH on initial testing. It is reasonable to do surveillance RHC every 3 to 6 months while awaiting HT or more frequently as clinically indicated. A vasodilator challenge should be administered to assess reversibility to acceptable levels for a potentially prohibitive PH, as detailed in Section Pulmonary Hypertension.
2. Serial evaluation of PVR may be helpful to ensure patients remain heart-only transplant candidates, optimize vasodilator therapy, and indicate a potential need for MCS.[185] Fontan circulatory failure requires special considerations especially when driven by relatively high PVR and chronic diastolic dysfunction.[363]
3. Temporary or durable MCS should be considered for PH if medical therapy fails to achieve acceptable hemodynamics. Although durable LVADs improve hemodynamics[692] and enable patients to survive longer while awaiting transplantation,[693] hemodynamic variability upon serial reassessment can occur even among patients with PVR < 3 Wood units increasing the risk of RV failure post-HT.[694] Durable LVADs have been shown to unload the LV and reverse PH over time.[692–696] When comparing LVAD candidates with persistent PH to those who improved PH over time, there is an increased risk of post-transplant mortality with persistent PH.[13] Therefore, if medical therapy and MCS fail to achieve acceptable hemodynamics after effectively unloading the LV for 3 to 6 months, it is reasonable to conclude that the PH is irreversible.

3.3.1.2. Exercise Capacity: Frequency of Assessment

Recommendations for Repeat Testing on the Waitlist: Exercise Capacity: Frequency of Assessment		
COR	**LOE**	**RECOMMENDATIONS**
2b	**C-EO**	1. Serial CPET testing after initial listing for HT may be considered in patients with change in clinical status or in patients who remain on a waitlist for >1 year.
3: No Benefit	**C-EO**	2. Changing patient listing status solely on the criterion of a peak VO_2 measurement should not be done.

Synopsis

CPET is a useful tool to assess the pathophysiologic mechanisms of exercise intolerance. It provides important prognostic information in HF and is used as one of the clinical parameters to guide listing for transplant.

Recommendation-Specific Supportive Text

1. The utility of serial CPET in listed patients has not been determined, therefore, the utility of repeat testing in the absence of change in patient symptoms or management is unclear. However, repeat CPET testing may be helpful to reclassify the severity of illness and reassess prognosis when HF symptoms and/or signs change—either worsen or improve. For instance, peak VO_2 and risk of mortality can change with exercise training, GDMT, and device therapy. In the HF-ACTION trial, patients randomized to exercise training had improved peak VO_2 by 0.6 [−0.7 to 2.3] ml/kg/min in 3 months compared to control with a change of 0.2 [−1.2 to 1.4] ml/kg/min, $p < 0.001$. There was also a 5% lower risk of mortality or hospitalization for every 6% increase in peak VO_2.[697] CRT has also been shown to have improvement in peak VO_2 and survival.[698] In patients who remain on the waitlist for an extended period, repeat CPET testing may be considered, for example, annually, even without an overt change in symptoms to confirm the accuracy of the initial prognostic assessment.
2. Decisions regarding listing changes should not be based solely on the criterion of a peak VO_2 measurement and should include additional CPET variables and other clinical factors that may affect the overall prognosis,

including the risk of waitlist mortality. The predictive value of CPET variables is additive, such as the incorporation of VE/VCO_2 slope and percentage of predicted peak VO_2 in the MECKI risk model.[699]

3.3.1.3. Assessment of Extracardiac Organ Function (Renal and Liver Function)

Recommendations for Repeat Testing on the Waitlist: Assessment of Extracardiac Organ Function		
COR	**LOE**	**RECOMMENDATIONS**
1	**B-NR**	1. Serial assessment of serum creatinine and estimated GFR is recommended for patients on the waitlist. The frequency of monitoring of kidney function is dictated by the clinical status of the patient.
1	**B-NR**	2. Serial assessment of liver function is recommended, with serum liver function tests (serum albumin, bilirubin, INR), biochemical assays (AST, ALT, GGT) and MELD-XI score. Further investigation should be considered when worsening liver function is suspected, including consideration of repeat abdominal imaging, hepatology consultation and liver biopsy.

Synopsis

Extracardiac organ function is carefully considered when determining HT candidacy and risk of postheart transplant mortality. AdvHF can lead to dynamic changes in noncardiac organ function, such as renal and liver failure. Systemic diseases, such as diabetes and ,hypertension can also cause or contribute to noncardiac organ dysfunction. Therefore, serial assessment of renal and liver function is recommended, and its frequency is guided by the clinical condition of the patient. Indications for dual organ transplant are discussed in Sections Kidney Disease and Liver Disease.

Recommendation-Specific Supportive Text

1. Renal dysfunction at the time of listing and time of transplant is one of the most powerful predictors of waitlist mortality and post-transplant survival.[42,43,201,221,700,701] An eGFR < 30 ml/min/1.73 m^2 has an adjusted HR 1.5, 95% CI (1.4-1.7), $p < 0.001$ compared to eGFR 45-59 ml/min/1.73 m^2. Although the best method to calculate eGFR and the frequency of renal function assessment on the waitlist remain controversial, serum creatine and calculated eGFR are the most practical tests and strong predictors of pre- and post-transplant survival.[43,201,221,701] Dynamic changes in renal function can substantially alter estimated mortality on the waitlist.[702] The frequency of monitoring of renal function is dictated by the clinical status of the patient, ranging from daily monitoring in critically ill intensive care unit (ICU) patients to monitoring approximately every 3 months in stable outpatients. Worsening renal function should trigger an assessment by a multiprofessional team that includes a nephrologist to determine the etiology and appropriate treatment plan to stabilize renal function and the need for SHKT if kidney function recovery is unlikely.[195]
2. Liver disease in AdvHF is assessed with biochemical assays, MELD-XI score,[402] abdominal imaging, and liver histopathology as needed. Abnormal serum albumin at time of listing and time of transplant is also an important mortality risk factor pre- and post-HT.[43,222,703] Serial assessment of liver function is recommended for patients on the waitlist, especially in patients with history of liver function abnormalities or those at risk of liver fibrosis and cirrhosis, for example, patients with CHD and patients with RHF or RCM. The frequency of monitoring of liver function is dictated by the clinical status of the patient. Worsening liver function should trigger further investigation, including repeat abdominal imaging, hepatology consultation, and liver biopsy.

3.3.1.4. Updating Vaccinations and Screening for Infections on the Waitlist

Recommendations for Repeat Testing on the Waitlist: Updating Vaccination and Screening for Infections on the Waitlist		
COR	**LOE**	**RECOMMENDATION**
1	**B-NR**	1. Should the patient remain on the waitlist for >1 year, annual influenza vaccine is recommended prior to the influenza season, and COVID-19 vaccination per regional recommendations.
2b	**C-EO**	2. Repeat screening of patients may be considered in patients who remain on the waitlist for >1 year.
1	**C-EO**	3. Repeat screening of patients on the waitlist should be done after a known relevant infectious disease exposure.

Synopsis

Vaccine-preventable diseases continue to be a considerable cause of morbidity and mortality in SOT candidates and recipients. Vaccination should be completed before transplantation (Table 10).

Recommendation-Specific Supportive Text

1. Should the patient remain on the waitlist for more than 1 year, an annual influenza vaccine and potentially other immunizations are recommended based on the current epidemiological situation.[243] COVID-19 vaccination recommendations vary according to the emergence of new variants, epidemiological situation, new variant-updated vaccines; these recommendations are regularly updated.[704]
2. Screening of transplant candidates and donors is a crucial component of pre-transplant assessment,[237,243] given the potential risk for reactivation. Screening allows the determination of the candidate's immunity, identifies latent infections that may be reactivated in the immunosuppression setting and helps guide immunization counseling and preventive strategies to reduce the risk of infectious complications after transplantation. Repeat screening of patients may be considered in patients who remain on the waitlist for > 1 year.
3. Repeat screening should also be done after an exposure to a known relevant infectious disease. At the time of transplantation, particular attention should be paid to donor-recipient match in previous exposure to specific infections and assessment of subsequent risk of reactivation of latent infection and risk of donor-transmitted infection.[237,243,704]

3.3.1.5. Frequency of Malignancy Screening

Recommendations for Repeat Testing on the Waitlist: Frequency of Malignancy Screening		
COR	**LOE**	**RECOMMENDATION**
1	**A**	1. Patients on the waitlist should undergo age-appropriate cancer screening per current clinical guidelines for the general population (Table 19).

Synopsis

SOT recipients incur an increased risk of malignancy when compared with the general population. Cancer is the second leading cause of death; its incidence increases significantly over time and with recipient age and depends on cancer type and site (Table 19).

Recommendation-Specific Supportive Text

1. Currently, there is no evidence that more extensive cancer screening of transplant candidates vs the general population translates into reduced post-transplant risk of malignancy.[3,5,167] While close surveillance for EBV seroconversion could be important in pediatric SOT recipients, guidelines do not support cancer screening in pediatric waitlisted patients. Surveillance guidelines specifically for transplant candidates with a prior history of malignancy are not available; thus, screening decisions should incorporate shared decision-making. The incidence of colorectal cancer in heart and kidney candidates is similar to the general population.[705] The incidence of prostate cancer is similar in SOT candidates and the general population.[706] KDIGO Kidney Transplant Candidate Work Group proposed pre-transplant cancer screening consistent with the general population guidelines for breast, colorectal, cervical, liver, prostate, and lung cancers.[707,708] Recommendations of the American Cancer Society and the USA Preventive Services Task Force outline age-appropriate screening and surveillance for breast, lung in at-risk groups, colorectal, and cervical malignancies.[102–107] Dermatologic follow-up for skin cancer screening pre-transplantation and education regarding sun protection are imperative, especially for those at high risk for skin cancer, as an increased risk of developing subsequent skin cancer in SOT recipients has been demonstrated.[108,709] Predictive index scores that may help to provide a comprehensive and cost-effective, targeted surveillance of skin cancer are reported[710–713] and can be helpful in prioritizing and providing better screening and surveillance for HT candidates. Suggested cancer screening on the waitlist, based on the appropriate cancer screen per current clinical guidelines, is presented in Table 19.[713]

Table 19 Suggested Cancer Screening on the Waitlist: for the Early Detection of Cancer in Average-Risk, Asymptomatic Adults

Cancer site and population	Screening modality and frequency
Colorectal cancer screening[102,103]	
Screen all adults aged 45-75 years at average risk of colorectal cancer	Either a stool-based test or a visual examination, depending on patient preference and test availability. All positive results of noncolonoscopy screening tests should be followed up with a timely colonoscopy Stool tests FIT every year HSgFOBT every year sDNA-FIT every 1-3 years (as stated by the manufacturer) Direct visualization tests Colonoscopy every 10 years CT colonography every 5 years Flexible SIG 5 every years Flexible SIG every 10 years plus FIT every year
Prostate cancer screening[104]	
a) Men aged 50 years at average risk of prostate cancer. b) Men aged 45 years with increased risk of developing prostate cancer (African American men or men with first-degree relative diagnosed with prostate cancer younger than age 65) c) Men aged 40 years at highest risk (those with more than one first-degree relative who had prostate cancer at an early age)	PSA ≥ 2.5 ng/ml, screening should be conducted yearly PSA < 2.5 ng/ml, screening intervals can be extended to every 2 years PSA ≥ 4 ng/ml, referral for further evaluation or biopsy
Breast cancer screening[105]	
Women aged 45-54 years Women > 55 years	Mammogram annually Mammogram every 2 years
Cervical cancer screening[106]	
Women aged 25-65 years	Primary HPV (alone) test every 5 years (preferred). HPV test + Pap test every 5 years (a cotest) Pap test alone every 3 years
Lung cancer[107]	
Patients aged 50-80 years with 20 pack-year smoking history who have quit smoking within the last 15 years	Annual low-dose chest CT
Skin cancer[108,709]	
All HT candidates	Specialist exam annually Patients at high risk owing to susceptible skin type, history of high sun exposure, or history of skin health concerns undergo physician screening more frequently than yearly

Abbreviations: CT, computed tomography; FIT, fecal immunochemical test; HPV, human papillomavirus; HSgFOBT, high-sensitivity guaiac fecal occult blood test; HT, heart transplantation; Pap, papanicolaou; PSA, prostate-specific antigen; sDNA, stool DNA; SIG, sigmoidoscopy.

3.3.1.6. Dynamic Psychosocial Evaluation

Recommendations for Repeat Testing on the Waitlist: Dynamic Psychosocial Evaluation		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-EO**	1. HT candidates should undergo periodic assessments of psychosocial status while on the waitlist.
1	**C-EO**	2. HT candidates undergoing therapy or treatment for a mental health disorder should be monitored and reassessed at agreed-upon time periods.
1	**C-EO**	3. HT candidates with abstinence from smoking, alcohol, or substance use should be monitored and reassessed at agreed-upon time periods.
1	**C-EO**	4. HT candidates with a history of medical regimen nonadherence should be monitored and reassessed at agreed-upon time periods.
1	**C-EO**	5. Pediatric HT candidates transitioning to an adult program while on the waitlist should have a structured transition plan and be monitored closely during the transition.

Synopsis

The goals of psychosocial interventions recommended during the initial HT evaluation and the strategies outlined to assess the progress should be dynamically monitored and reassessed. Exact timepoints for psychosocial re-evaluation of transplant candidates while on the waitlist are not well determined. Psychosocial evaluation in children is complex and multifactorial, also involving parents and families. The assessment of children tends to focus more on potential modifiable risk factors aimed at improving post-transplant outcomes.

Recommendation-Specific Supportive Text

1. Dynamic psychosocial evaluation includes a review of a candidate's adherence to a medical regimen, mental health status, cognitive function, substance misuse, and level of social support.[5,6,714] Exact timepoints for psychosocial re-evaluation of transplant candidates while on the waitlist are not well determined.
2. Mental health disorders and depression have been linked to post-transplant mortality in HT recipients.[5] Patients experiencing depressive or anxious symptoms or other mental health disorders should be referred for treatment with medication or psychotherapy and may require reassessment while on the waitlist.[5,6,493,714]
3. Patients with a recent history of alcohol abuse (within 24 months) may benefit from a structured rehabilitation program. Adherence to smoking cessation and abstinence from substance abuse should be monitored while on the transplant waitlist. Behavioral health specialists may use substance abstinence or behavioral contracts to outline expectations before HT.[6,714]
4. History of medical regimen nonadherence is a risk factor for worse post-transplant outcomes.[715] Adherence to a medical regimen while on the transplant waitlist should be monitored and reassessed at agreed-upon periods.
5. Evaluation of neurocognitive function, age, and developmental level is important in pediatric psychosocial assessment.[511,517,716,717] Numerous studies report nonadherence in adolescents compared to younger children, associated worse outcomes. Determining modifiable risk factors remains challenging and understanding barriers to adherence in pediatric transplant candidates/caregivers can aid in development of strategies to overcome these obstacles.[511,517,716,717] For pediatric HT candidates transitioning to an adult program while on the waitlist, a structured transition plan is recommended,[718,719] as adolescence may be a critical period for self-care and acquisition of healthy lifestyle habits, including compliance with medical therapies with psychosocial, social and financial contributions to nonadherence.[720–722]

3.3.1.7. Evaluation of Malnutrition and Frailty on the Waitlist

Recommendations for Repeat Testing on the Waitlist: Evaluation of Malnutrition and Frailty on the Waitlist		
COR	LOE	RECOMMENDATIONS
1	B-NR	1. Nutritional status should be established in all listed patients and reassessed regularly.
1	B-NR	2. Goals of nutritional therapy should be established in those with suboptimal nutrition.
2a	C-LD	3. In listed heart transplant candidates, periodic reassessment of frailty is reasonable to identify actionable targets for improvement in conditioning and perform risk assessment of transplant candidacy.

Synopsis

Malnutrition is a common comorbidity in patients with HF associated with poor prognosis. Cachexia is a complex metabolic wasting syndrome characterized by unintentional edema-free weight loss (muscle mass loss, with or without fat mass loss), anorexia and systemic inflammation biochemistry. Malnourished patients are at higher risk of postsurgical complications and mortality after HT.

Frailty is common in AdvHF patients who are awaiting HT and affects mortality on the waitlist and in the post-transplant period (Section Frailty and Table 11).

Recommendation-Specific Supportive Text

1. Malnourished patients are at higher risk of morbidity and mortality after HT, and malnutrition may worsen while patients await transplantation. Preoperative weight loss ≥10% is associated with reduced survival in patients listed for HT.[723] Nutritional status should be assessed at the time of transplant evaluation and on a regular basis, more frequently in hospitalized patients (Table 20). Parameters typically included in the assessment are anthropometrics (height, weight, % unintentional weight loss, BMI), nutritional screening and serum markers (prealbumin [albumin in ambulatory patients], C-reactive protein, sodium, potassium, magnesium, phosphorus).[724] Commonly used tools that have shown an association with mortality in HF include Mini Nutritional Assessment (MNA), MNA-short form (MNA-SF), Nutritional risk index,[725,726] and Geriatric Nutritional Risk Index.[727–729]
2. Patients with nutritional deficits should receive nutritional supplements. Assessment, supplementation if needed, and follow-up from the nutrition service is recommended in patients with more severe forms of malnutrition (Table 20).[724]
3. Reassessment of frailty can be beneficial to identify actionable targets of transplant candidacy, especially if on tMCS and for high urgency status awaiting HT in the hospital. Patients with an acceptable level of frailty, when listed as outpatients, may no longer be suitable for transplantation after prolonged bed rest.[262, 730–732]

Table 20 Suggested Nutritional Assessment in Patients on the Waitlist Awaiting Transplantation: Frequency of Nutritional Assessment and Recommended Intervention

MNA-SF score[a]	Frequency of nutritional assessment and recommended intervention
Ambulatory patients	
MNA-SF score 12-14	Repeat every visit (or at least every 3 months)
MNA-SF score 8-11	Re-evaluate every 1-2 months; if no improvement, refer to nutrition service
MNA-SF score 0-7	Start nutritional support; refer to nutrition service
Hospitalized patients	
MNA-SF score 12-14	Repeat weekly
MNA-SF score 8-11	Repeat weekly or more often; if no improvement, referral to nutrition service
MNA-SF score 0-7	Start nutritional support; refer to nutrition service

Abbreviation: BMI, body mass index.

[a]The Mini Nutritional Assessment-Short Form (MNA-SF; scored 0-14)[724] consists of 6 questions that assess food intake, weight loss, mobility, acute events, neuropsychological problems, and BMI. Subjects with an MNA-SF score of 12-14 have normal nutritional status, and those with an MNA-SF score of 8-11 and ≤7 have mild and ≥moderate malnutrition, respectively. Subjects with an MNA-SF score ≤11 are classified as malnourished.

3.3.1.8. Monitoring of HLA and ABO Sensitization while Awaiting Transplantation

Recommendations for Repeat Testing on the Waitlist: Monitoring of HLA- and ABO Sensitization while Awaiting Transplantation		
COR	**LOE**	**RECOMMENDATIONS**
1	**B-NR**	1. Screening for HLA antibody is recommended every 3-6 months for all actively listed patients.
1	**B-NR**	2. Screening for HLA antibody is recommended approximately 3 weeks after a potentially sensitizing event.
2a	**C-EO**	3. Screening for HLA antibody can be considered as soon as 7 days after potentially sensitizing event in patients with previous sensitization/expected memory response.
1	**B-NR**	4. Screening for isohemagglutinin (ISO) antibodies against the non-self blood group(s) is recommended for all children listed for ABO-incompatible transplantation every 4 weeks, or 1-3 weeks after sensitizing events.
2a	**B-NR**	5. In patients awaiting transplantation, it is reasonable to reduce the risk of *de novo* sensitization by minimizing exposure to HLA antigens using leukodepleted blood products, single donor or matched thrombocytes and decellularized homografts when possible.

Synopsis

Sensitization toward HLA antigens in all patients awaiting HT and toward blood group antigens (isohemagglutinins, ISOs) in children listed for ABO-incompatible transplantation is a dynamic process. This may include new or reactivated sensitization, alteration of sensitization in response to therapies, or natural decline and disappearance of antibodies, especially if passively acquired. For ISOs, changes are also result of natural maturation. Accordingly, assessment of plasma levels of HLA antibodies and ISOs is recommended in regular time intervals for all listed patients as appropriate, and after events associated with sensitization.

Recommendation-Specific Supportive Text

1. HLA antibody screening is performed for every patient before listing and while listed for transplantation every 3 to 6 months by most centers following the technical and interpretation guidance of the STAR working group recommendations.[733,734] Donor hearts are not selected on the basis of HLAs because of time restrictions related to cardiac preservation; therefore, tissue type should be determined for retrospective analysis and may assist with determination of donor-specific antibodies. Flow cytometry is an immunofluorescence method for identifying cell surface antigens by detecting conjugated antibody. Results from flow cytometry allow for assessment regarding the risk of a positive crossmatch at the time of transplant. Patients at risk for suboptimal outcome post-transplant are defined as having a PRA > 10% or donor-specific antibodies at the time of transplantation. Decisions can be made with more confidence regarding the need for a prospective vs retrospective crossmatch, as well as giving providers more insight into the likelihood of antibody-mediated rejection after transplantation.
2. Antibody production is a dynamic process, and changes in HLA antibody levels can happen even in the absence of a clear sensitizing event.[735] A recent antibody screen while actively listed minimizes the chance of an unexpected positive crossmatch result at the time of transplant. Production of de novo or reactivated production of previously known antibodies can be triggered by certain sensitizing events. Potentially sensitizing events include pregnancy, transfusion of blood products, especially thrombocytes which express HLA antigens,[735] surgical procedures with use of human tissues (e.g., vascular grafts),[736,737] MCS devices,[737,738] or renal replacement therapy.[739] De novo sensitization via T-mediated B-cell activation takes approximately 21 days until peak response.[740] Use of single donor or HLA-matched blood products[741] and decellularized tissue-grafts[390] can prevent de novo sensitization.
3. Reactivation of immune memory occurs within 5 to 7 days of a sensitizing event and can therefore be detected earlier than in de novo antibody production.[740] HLA antibody screening is recommended after potentially sensitizing events, such as blood product transfusions, and infections which can sensitize through cross-reactivity between bacterial or viral epitopes and HLA antigens.[733]
4. Children naturally develop adult titers of ISOs between 6 and 24 months of age.[742] Therefore, in children listed for ABO-incompatible transplantation, screening for ISO antibodies against the non–self blood group(s) is

recommended every 4 weeks, or 1 to 3 weeks after sensitizing events to confirm eligibility for ABO incompatible organs.[743]

5. For all patients on the transplant list, if possible, potentially sensitizing events should be avoided or minimized.[735] Transfusion of blood products should be done only for clear indications. Current common practice of leukodepleting red cell products decreases HLA exposure with transfusion. Platelet transfusions pose a risk of exposure to a wide range of HLA antigens.[733] Use of single donor or matched thrombocytes may be preferred over pooled platelet products when possible.[744] Use of decellularized homografts also reduces the risk of sensitization.[390] Desensitization strategies have been advocated in patients who are highly sensitized.[734]

3.3.1.9. Role of Biomarkers

Recommendations for Repeat Testing on the Waitlist: Cardiac Biomarker Assessment		
COR	**LOE**	**RECOMMENDATIONS**
1 2a	B-R	1. Natriuretic peptides (NP) should be determined at the time of initial evaluation of a patient with AdvHF (Class 1). Periodic assessment of NP in a patient on the waitlist can be useful for early detection of clinical deterioration (Class 2a).
2a	C-LD	2. Progressive significant reduction of NP levels, accompanied by meaningful clinical improvement, and in the absence of other poor prognostic features, can help identify patients on the waitlist whose disease has improved on GDMT to the point where removal from the waitlist can be considered.
1	C-LD	3. In patients with cardiogenic shock, or with suspected cardiogenic shock, monitoring of blood lactate levels allows for stratification of severity and can be used to guide treatment escalation.

Synopsis

The natriuretic peptides (NP), BNP, and NT-proBNP are secreted by cardiomyocytes in response to increased atrial or ventricular wall tension. They promote myocardial relaxation, natriuresis, and vasodilation and reduce the activity of the sympathetic nervous system and the renin-angiotensin system.[745] Elevated NP levels are supportive of the diagnosis of HF with, but with less utility in certain situations, including decreased sensitivity with obesity and HF with mildly reduced or preserved EF. Although there is no specific marker for diagnosing cardiogenic shock, serum lactate is a biomarker that supports the cardiac mechanism of hemodynamic decompensation and hypoperfusion of organs. Lactate provides important information regarding the condition of a shock patient at presentation and prognostic information. However, end-organ hypoperfusion may be present with normal lactate and lactate elevation due to local tissue ischemia from noncardiac conditions that may occur in the absence of cardiogenic shock.

Recommendation-Specific Supportive Text

1. Serum NP levels are part of the routine pre-transplant evaluation, and serial testing helps identify early deterioration of the patients on the waitlist.[746,747] Serum levels of NT-proBNP or BNP are used in the initial diagnosis of HF and are useful for prognostication. Persistent elevation despite optimal treatment is a poor prognostic factor in identifying patients that may need a referral to an advanced HF center.[16,748] Increased NT-proBNP in patients on the waitlist has been associated with adverse events.[746,747] However, the usefulness of NT-proBNP in assessing the prognosis of patients on the waitlist is limited as it must also take into account fluctuation resulting from organ congestion and hepatic and renal dysfunction,[749] and decreased specificity in the setting of sepsis.
2. A progressive significant reduction of NP levels, in the absence of other poor prognostic features, can identify patients on the waitlist who have significant improvement of their clinical condition, either as a result to favorable response to GDMT or resolution of certain reversible factors that lead to their HF.[559]
3. Serum lactate is a helpful marker that reflects tissue hypoperfusion. In patients in cardiogenic shock, monitoring of serum lactate levels can stratify the severity of hemodynamic derangement and help in planning for escalation of therapies such as initiation or increase in vasoactive medications or initiation of MCS. Lactate is used to distinguish between SCAI SHOCK stage B—hemodynamic instability without hypoperfusion, and stage C—hypoperfusion with or without overt hemodynamic instability. A lactate level of > 2 mol/liter is consistent with at least SCAI SHOCK Stage C.[559,750] However, there may be other manifestations of end-organ

hypoperfusion with normal lactate, as well as other causes of lactate elevation, for example, local tissue ischemia from noncardiac conditions, that need to be taken into consideration.[750]

3.3.1.10. Improvement and Removal from the Waitlist

Recommendations for Improvement and Removal from the Waitlist		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-LD**	1. Ambulatory patients on GDMT should be re-evaluated at 3–6-month intervals for maximal pharmacologic and device therapy. If they have improved significantly, they should be considered for delisting.
2b	**B-NR**	2. Patients on LVAD therapy with myocardial recovery resulting in device explant may be delisted.
1	**B-NR**	3. After delisting, follow-up every 3-6 months by HF specialists is recommended to identify deterioration.

Synopsis

A subset of patients on the waitlist will respond favorably to ongoing HF management to the point where the benefit of HT may need to be reassessed and patients are considered for delisting.[5] These will include patients with higher recovery potential, such as those with potentially reversible HF etiologies, for example, acute myocarditis, acute cardiogenic shock after myocardial infarction, etc., but also patients with a more chronic course of HF responding to the expanding GDMT.[751,752]

Recommendation-Specific Supportive Text

1. Listed patients who are ambulatory and not requiring inotropes should be continually evaluated for maximal pharmacologic and device therapy. Response to GDMT should be re-evaluated at 3- to 6-month intervals. If patients significantly improve over time and no longer have survival benefit from transplantation, they should be considered for delisting.[5,751,752] Approximately 6%-8% of candidates removed from the waitlist are due to medical improvement.[752,753] Indications for delisting for medical improvement include objective improvement in symptoms, NYHA Class, maximal VO_2, and biomarkers. Importantly, outcomes are improved with attentive follow-up care provided within a HF disease management program.[751]
2. LVAD patients who have achieved myocardial recovery resulting in device explant, with stable cardiac function and symptoms on maximally tolerated GDMT, should also be delisted for improvement.[754–756] After delisting, close follow-up by HF specialists every 3 to 6 months is recommended to identify possible deterioration.
3. Approximately 30% of patients delisted for improvement eventually present again with worsening HF, including reaching AdvHF with an increased risk of death.[2] Patients delisted for HF improvement should continue to be followed by AdvHF teams and assessed serially for evidence of decompensation. Numerous studies have shown improved outcomes in those under the care of an HF team and ongoing GDMT.[751,757] Further studies are required to better risk-stratify patients delisted after improvement with medical therapies or with LVAD unloading.

3.3.2. Acute Decompensation on the Waitlist

3.3.2.1. Considerations for Status Upgrade on the Waitlist

Recommendations for Acute Decompensation on the Waitlist: Considerations for Status Upgrade		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-EO**	1. Listing urgency status should be assessed at regular intervals and at the time of change of clinical status.
2a	**C-LD**	2. Listing status adjustment based on corresponding allocation rules is reasonable when acute hemodynamic decompensation does not improve despite appropriate treatment.
3: No Benefit	**C- LD**	3. Status upgrade is not indicated for candidates whose symptoms and end-organ dysfunction resolve with adjustment of baseline therapies such as oral anti-congestive therapies, successful treatment of arrhythmias, and device optimization.

Recommendation-Specific Supportive Text

1. Waitlist management should include regular assessment of urgency status and determination whether changes in the level of urgency are needed to provide equal access to scarce organs to those with the highest waitlist mortality while maintaining transplant survival benefit.[758]
2. Mortality risk has been shown to increase in ambulatory HF patients after each episode of HF hospitalization; thus, acute HF decompensation is an important clinical event for waitlisted candidates.[759] Many mortality risk factors are accounted for in current allocation schema. However, acute decompensated HF is marked by other clinical factors associated with increasing risk for death in HF and worse waitlist outcomes. Strong predictors of mortality in adults with HF include higher blood urea nitrogen and NP, lower hemoglobin, and cardiac cachexia.[760,761] Predictors of waitlist mortality include lower renal function, lower albumin, new neurologic events, initiation of dialysis, cumulative respiratory complications, rising bilirubin, rising creatinine, and RHF.[43,702,762] Status upgrade based on corresponding local allocation rules can be considered in candidates with acute decompensation where hemodynamic derangement does not improve despite appropriate treatment.
3. If after acute hemodynamic decompensation or other clinical worsening on the waiting list (e.g., arrhythmias) therapies are optimized and the candidate returns to baseline clinical condition, then status upgrade is not indicated.

3.3.2.2. Inotropic and Vasoactive Therapy

Recommendations for Acute Decompensation on the Waitlist: Inotropic and Vasoactive Therapy		
COR	**LOE**	**RECOMMENDATIONS**
2a	**B-NR**	1. Continuous administration of intravenous inotropic drugs (dobutamine and/or milrinone) can be considered in heart transplant candidates with cardiogenic shock, low cardiac output and/or secondary organ dysfunction.
2a	**B-R**	2. Periodic administration of levosimendan, as a continuous infusion for 24-48 hours or intermittently over a shorter time, in patients with advHF with evidence of organ hypoperfusion awaiting HT, can improve the hemodynamic status, congestion, and QOL, enable the optimization of GDMT, and reduce symptoms and hospitalizations.
2a	**C-EO**	3. Initiation and titration of IV inotropes in heart transplant candidates is recommended following hemodynamic profiling using a PA catheter. Implantable PA monitoring can be effective for hemodynamic-guided therapy in HT candidates.
2b	**C-LD**	4. The effectiveness of long-term use of inotropes as an alternative bridging strategy to the use of DMCS may lead to further deterioration.
2a	**B-NR**	5. Additional intravenous vasoactive drugs with vasoconstrictive or vasodilating properties can be effective in individual patients listed for HT according to their specific hemodynamic profile.
3: No Benefit	**C-EO**	6. Routine use of oral vasoconstrictor medications (midodrine or droxidopa) to increase blood pressure or avoid the need for inotropic therapy in HF patients listed for HT is not recommended.
2b	**C-EO**	7. Oral vasoconstrictor medications (midodrine or droxidopa) may be beneficial for specific subgroups of HT candidates, such as those with cardiac amyloidosis or to maintain blood pressure in patients requiring renal replacement therapy.
2b	**B-R**	8. Vericiguat may be considered in high-risk patients with HFrEF to reduce the incidence of a composite of an HF event or cardiovascular death.

Synopsis

The advanced nature of HF may present hemodynamic scenarios where inotropic drugs can be effective while patients await HT under close clinical and hemodynamic monitoring. The effective use of vasoactive drugs is founded on accurately assessing the etiology of decompensation and the specific patient's hemodynamic profile. When congestion and hypertension predominate, vasodilators and diuretics are preferred to unload the heart and mobilize fluid. Inotropic therapy and, possibly, vasopressors are indicated for "wet and cold" patients. The intermittent use of the calcium sensitizer levosimendan is safe and well tolerated and represents a viable therapeutic option as a "bridge to transplant" strategy.

Recommendation-Specific Supportive Text

1. Intravenous inotropes improve hemodynamics in the short-term but may be associated with increased risk of long-term mortality in HF.[350,763,764] The use of intravenous inotropes is a reasonable option in a bridge-to-HT strategy in patients with cardiogenic shock, low cardiac output, and/or secondary organ dysfunction if needed in conjunction with temporary or durable MCS. Outpatient inotrope use for adult waitlisted patients has been shown to be safe and effective in selected patients with an ICD but increases the risk of catheter-related infections.[765,766] Outpatient inotrope therapy can also be considered in the pediatric population awaiting transplant.[767] The most commonly used agents include the beta-1 agonist dobutamine and the phosphodiesterase-3 inhibitor milrinone, administered as a continuous intravenous infusion. Limited studies have compared the 2 drugs directly, without a clear advantage of one vs the other. Each drug needs to be tailored to systemic and pulmonary hemodynamics, renal function, and other relevant clinical characteristics.[768,769]
2. Periodic levosimendan infusion can be effective in patients with AdvHF with evidence of organ hypoperfusion awaiting HT. Levosimendan, administered intermittently, can improve congestion, QOL, and hemodynamic status, reduce symptoms and hospitalizations, and enable the optimization of GDMT.[770,771] Nonetheless, the optimal administration strategy has not yet been identified.[772–780] Consideration for the first administration of levosimendan to be performed in an inpatient setting and in 24-hour infusion at a dose of 0.1 to 0.2 µg/kg/min according to blood pressure to verify both safety (particularly in terms of the appearance of symptomatic hypotension and ventricular tachycardias) and efficacy. The response to levosimendan infusion can be assessed as an objective improvement of BiV systolic function and reduction of pulmonary pressure or by RHC. Subsequent dosing can be given in either an infusion of 12.5 mg of levosimendan at the dose of 0.1 µg/kg/min every 4 weeks or an infusion of 6.25 mg at a dose of 0.2 µg/kg/min every 2 weeks [for SPB > 100 mm Hg, eGFR ≥ 45 ml/min/1.73 m^2, and absence of a history of ventricular tachyarrhythmia (VTA)].
3. Initiation and titration of intravenous inotropes in HT candidates is recommended following hemodynamic profiling using a PA catheter. In patients with moderate to severe HF, hemodynamic monitoring (CardioMEMSHF system, Abbott Laboratories, Abbott Park, IL) substantially improved QOL and reduced HF hospitalizations.[659] Although implantable PA monitoring systems can be effective for hemodynamic-guided therapy in HT candidates, listed HT candidates on inotropes were excluded from the pivotal clinical trials of this device.[659,781]
4. The effectiveness of the long-term use of inotropes as an alternative bridging strategy to the use of DMCS may lead to further deterioration, especially if the patient is expected to spend significant amount of time on the waitlist.[782–785]
5. Additional intravenous vasoactive drugs with vasoconstrictive properties (norepinephrine, epinephrine, vasopressin, dopamine) for refractory hypotension or vasodilating properties (nitroglycerin, nitroprusside) to decrease systemic or pulmonary afterload can be effective in individual patients listed for HT according to their specific hemodynamic profile. Continuous vasoactive drugs are often given in combination with inotropes and diuretics.[786]
6. There is no evidence of benefit of oral vasoconstrictors, such as midodrine or droxidopa, in most HT candidates with HFrEF. There is a concern for possible harm with vasoconstriction and afterload increase, especially in those with ischemic cardiomyopathy.[787,788]
7. Oral vasoconstrictor medications (midodrine or droxidopa) may be beneficial for treatment of hypotension in cardiac amyloidosis patients with concomitant autonomic dysfunction and in patients with end-stage renal disease requiring renal replacement therapy (who may be candidates for combined heart-kidney transplantation).[789]
8. The novel oral vasodilator, vericiguat, a soluble guanylate cyclase stimulator, may be considered in high-risk patients with HFrEF and recent worsening of HF already on GDMT to reduce HF hospitalization or cardiovascular death.[790] Vericiguat significantly reduced NT-proBNP levels in patients with deteriorating HFrEF compared to the placebo[791], but the QOL with the Kansas City Cardiomyopathy Questionnaire Clinical Summary Score did not significantly improve.[792] However, limited data are available regarding its use in HT

candidates, as they were excluded from the major clinical trial that established the benefit of this drug.[790] Because of its potent vasodilatory properties, it is reasonable to discontinue vericiguat (such as other vasodilators) once the HT surgery is confirmed.

3.3.2.3. Cardio-Renal Syndrome

Recommendations for Acute Decompensation on the Waitlist: Cardio-Renal Syndrome		
COR	**LOE**	**RECOMMENDATIONS**
1	B-NR	1 Patients listed for HT who develop cardio-renal syndrome (CRS) should be managed as per published best practices for CRS in HF.
2a	C-LD	2. It is reasonable to consider PA catheter placement in selected patients with worsening renal function not responsive to diuresis or with hemodynamic compromise requiring parenteral vasoactive agents.
1	B-NR	3. Patients with CRS secondary to cardiogenic shock refractory to initial stabilization attempts should be managed with parenteral vasoactive agents, with early consideration for MCS.
2a	B-NR	4. It is reasonable to re-evaluate the appropriateness of heart-only transplant listing in patients with progressive renal deterioration.

Recommendation-Specific Supportive Text

1. Patients on the waitlist who develop CRS should be treated based on published guidelines addressing CRS in HF patients.[1,2] The general management of CRS is explored elsewhere, including stepped pharmacological therapy and screening for intra-abdominal hypertension, although data on specific targeted interventions are lacking.[574,793–795]
2. It is reasonable to consider hemodynamic profiling using a PA catheter in patients listed for HT who experience decompensation with CRS, especially if refractory to diuresis or hemodynamically unstable (in cardiogenic shock).[796] Furthermore, PA catheter may help gauge the contribution of RHF in CRS, which is often under-recognized,[797] impacting tailored management, including decisions around MCS.
3. The limited data on either temporary or durable MCS in CRS suggest poor outcomes in patients with severe renal dysfunction.[798] However, MCS undertaken before significant deterioration of renal function may lead to acceptable outcomes as bridge to recovery, decision, HT alone, or even for SHKT.[799]
4. In patients with progressive renal deterioration, re-evaluation of heart-only transplant listing is reasonable for the early identification of irreversible renal dysfunction and eligibility for SHKT.[12,195] (refer to Section Kidney Disease). If the patient is deemed no longer eligible for advanced therapies, referral to palliative care should be undertaken.[800]

3.3.2.4. End-of-Life Care and Removal from the Waitlist

Recommendations for Acute Decompensation on the Waitlist: End-of-Life Care and Removal from the Waitlist		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	1. Advanced care planning with a multidisciplinary team should be done with focus on symptom management and emotional support.
1	C-EO	2. Shared decisions should be pursued with emphasis on improving or maintaining an acceptable QOL for the patient and caregivers/family.

Synopsis

End-of-life care and removal from the waitlist raises ethical challenges. The search for course-modifying therapies for AdvHF must be balanced and integrated into a multidisciplinary palliative approach. Patients maintain optimism for prolonged life, value QOL, and hope through drug and surgical interventions. Discussions about possible removal from the transplant list should be with patients and caregivers in consultation with palliative care during the initial phase of the evaluation for transplant.

Recommendation-Specific Supportive Text

1. Palliative and end-of-life care of patients with HF is an integral part of international guidelines[350,559,801,802] with consensus about important key areas in the end-of-life care. Cultural differences related to beliefs and expectations for positive results of surgical strategies, such HT and MCS, must be considered.[803] A multidisciplinary team should be involved with a focus on symptom management and emotional support.
2. Shared decision-making is crucial and should emphasize improving or maintaining acceptable QOL in both the patient and the caregivers.[804] Symptoms should be assessed frequently with the primary goal of providing therapeutic relief. Advanced care planning in cooperation with the multidisciplinary team, patient, and caregivers should include a discussion of:
   - The effects of medications on symptom relief and QOL and when to stop medications in the absence of the desired effects.
   - Desired use of life-sustaining interventions and resuscitation attempts.
   - Timing of deactivation of ICD.
   - Timing of discontinuation of temporary or durable MCS or removal from the heart transplant waitlist.
   - Psychosocial or spiritual support to the patient, family, and caregivers.

3.3.3. Managing Special Populations on the Waitlist

3.3.3.1. Retransplant and Multiorgan Transplant

Recommendations for Managing Special Populations on the Waitlist: Retransplant and Multi-Organ Transplant		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-EO**	1. Patients listed for heart retransplantation should undergo serial evaluation as recommended for all transplant candidates and be closely followed by the transplant team.
2a	**C-EO**	2. It is reasonable to avoid mTOR inhibitors in patients awaiting retransplantation to prevent delayed surgical wound healing and a higher incidence of pleural and pericardial effusions after transplant.
1	**C-EO**	3. Multidisciplinary management of patients awaiting multi-organ transplant is recommended to optimize waitlist and post-transplant survival.
1	**C-EO**	4. A plan should be established for perioperative and post-transplant management, including immunosuppression protocol, in patients awaiting multi-organ transplant.

Synopsis

Retransplant candidates tend to be younger, more sensitized, and more critically ill, with an increased likelihood of hospitalization or being supported with renal replacement therapy, mechanical ventilation, inotropes, or extracorporeal membrane oxygenation compared to primary heart recipients. Multiorgan heart transplant accounts for 4% to 7% of all heart transplants, with the majority (> 85%) being heart-kidney transplants.

Recommendation-Specific Supportive Text

1. Patients awaiting retransplantation are receiving immunosuppression and are likely to have a higher comorbidity burden than primary HT candidates.[805] The most common indication for a heart retransplant is CAV, followed by chronic graft dysfunction.[5,195,356,805–807] Since both short- and long-term survival after retransplantation is lower than in primary transplantation, careful follow-up of retransplant candidates by the transplant team is recommended.[415,417,808,809]
2. Patients awaiting retransplantation are already receiving maintenance immunosuppressive therapy. It is reasonable to avoid mammalian target of rapamycin inhibitors in patients awaiting retransplantation to prevent delayed surgical wound healing and a higher risk of pleural and pericardial effusions after transplant.[810]

3. Multiorgan transplantation is appropriate in selected patients with multiple organ failure according to established transplant candidacy guidelines for each respective organ or when multiple organ transplantation confers a significant benefit to the patient with primary organ failure.[12,195,356,811,812] Multidisciplinary management of patients awaiting multiorgan transplant is recommended in order optimize management on the waitlist and optimize post-transplant survival.
4. Plan for perioperative and post-transplant management, including an immunosuppression regimen agreed upon by the respective transplant teams, should be established ahead of time in patients awaiting multiorgan transplantation.[12]

3.3.3.2. Pediatric and Congenital Heart Disease Considerations

Recommendations for Managing Special Populations on the Waitlist: Pediatric and Congenital Heart Disease Considerations		
COR	**LOE**	**RECOMMENDATIONS**
1	B-NR	1. Recurrent detailed monitoring of HLA antibodies is recommended, especially for failed Fontan physiology and other single ventricle patients, to guide antibody removal strategies and post-transplant immunosuppression therapy.
2b	B-NR	2. Desensitization treatment may be considered for allosensitized pediatric waitlisted patients to shorten waitlist time.
1	B-NR	3. Vascular occlusions should be assessed at time of evaluation and periodically while waitlisted and interventions to prevent or treat venous and arterial thromboses are recommended.
1	B-NR	4. Due to neurocognitive and mental health risk in pediatric patients awaiting transplant, mental health assessment and support for children and caregivers are recommended.
1	C-EO	5. Multidisciplinary management of patients with failing Fontan physiology is recommended to optimize waitlist and post-transplant survival.
1	C-EO	6. Failing Fontan patients should receive ongoing surveillance for FALD while awaiting transplantation.
1	C-LD	7. EBV and CMV IgM and IgG should be retested periodically in a patient awaiting transplant to reflect changes in infection status.

Synopsis

Infants and children have special considerations while waitlisted due to increased prevalence of CHD, prior cardiac surgery, and greater likelihood of allosensitization increasing waitlist time. A multidisciplinary approach is paramount to address the unique challenges of pediatric transplantation while awaiting HT. Immunological risk with sensitization to HLA and ABO requires monitoring and management. CHD remains a risk factor for waitlist mortality; periodic imaging and hemodynamic assessment (refer to Section Cardiac Catheterization to Assess Hemodynamic Stability) to evaluate the need for MCS are essential in the management of CHD patients on the waitlist, especially in patients with failed Fontan physiology and risk of FALD.

Recommendation-Specific Supportive Text

1-2. There are high rates of HLA sensitization and risk of immune memory reactivation due to previous use of human tissue grafts. HLA and ABO sensitization may be underestimated in the setting of protein-losing enteropathy[185,736,813] Over half of the children listed for HT have CHD, and the majority of these have had cardiac surgery before—or while awaiting HT,[814] increasing the likelihood of allosensitization that can increase waitlist time.[386,815] Desensitization treatment may be considered for allosensitized pediatric waitlist patients to shorten waitlist time and increase the likelihood of a negative crossmatch.[816] However, it may not be beneficial to require a prospective, negative crossmatch in pediatric candidates when waitlist mortality and 1-year HT survival are considered.[817]

3. Venous thrombosis and thromboembolism are common in critically ill children. Major infection or inflammatory state, infancy, central venous lines, immobility, CHD, and extended hospitalization are independent risk factors.[818,819] Vascular occlusions should be assessed at time of evaluation and periodically while waitlisted, and interventions to prevent or treat venous and arterial thromboses are recommended.
4. Waitlisted candidates with CHD and those with significant pre-transplant illness and morbidity have worse neurocognitive outcomes[820] and QOL after transplant.[821] Interventions while on the waitlist, where feasible, are recommended, including mental health support for children and caregivers to improve transplant outcomes.[822,823]
5. Problems of Fontan circulatory failure can include collateral blood vessel development, lymphatic abnormalities, nutritional insufficiency, renal dysfunction, and hepatopathy.[824] A multidisciplinary team is needed to optimize patients for successful transplant. The composition of team members and the division of roles and responsibilities are discussed in Section Multidisciplinary Team Approach.
6. New literature and guidelines regarding FALD are rapidly evolving, with ongoing surveillance necessary to rule out development of malignancy or irreversible cirrhosis which would prompt consideration for heart-liver transplantation.[825,826]
7. Changes in CMV and EBV status and adjustment of false positive serologies[827] should be monitored while awaiting transplant.

3.4. Preoperative Preparation of the Patient for Transplantation

3.4.1. Standard and Specialized Preoperative Measures

Recommendations for Pre-Operative Preparation of the Patient for Transplantation: Standard and Specialized Pre-Operative Measures		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	1. Standard pre-operative considerations for preparation of the recipient should include identification of changes in clinical status to confirm the patient continues to be a good candidate for transplantation.
2a	C-LD	2. SGLT2i and vasodilators may be associated with postoperative complications, and it is reasonable that these drugs are discontinued before HT.
1	C-EO	3. Patients on systemic anticoagulation should undergo anticoagulation reversal.
1	C-EO	4. Standard pre-operative pacemaker and ICD reprogramming should be done.
2a	B-NR	5. In patients with cPRA>50%, desensitization is reasonable to improve access to donor hearts.
1	B-NR	6. In sensitized patients, donor organ consideration should proceed according to the plan established along with the histocompatibility and immunogenetics team.
2a	C-EO	7. In allosensitized patients, induction therapy can be considered to reduce the risk of rejection.
1	C-LD	8. Perioperative antibiotics should be administered to reduce the risk of infection after cardiac surgery. The recommended prophylaxis includes a single pre-incision dose of first- or second-generation cephalosporin.
1	C-EO	9. Vancomycin or clindamycin is an acceptable alternative in patients with a documented beta-lactam allergy for perioperative antibiotics.
1	C-EO	10. Vancomycin for perioperative prophylaxis should be considered for patients with known MRSA colonization or infection.

Synopsis

The preoperative preparation of a patient for HT incorporates multiple considerations to maximize the chance of a favorable outcome. When a potential donor is identified, the patient is admitted and prepared for the transplant surgery. It should be determined whether there are any relevant changes to the patient's clinical status

since the last follow-up and whether the patient continues to be a good candidate for transplantation. It should also be confirmed that serial evaluation of the patient has confirmed any outlying concerns have been addressed before transplant. Standard preoperative considerations for preparation of the recipient for surgery relate to specific medications that might be associated with postoperative complications, particularly SGLT2i and vasodilators, assessment of PA pressures, management of allosensitization, reversal of anticoagulation, and ICD device reprogramming. Infectious disease considerations include the use of perioperative antibiotic prophylaxis as well as additional antimicrobial therapy in patients with ongoing infection (e.g., in patients with a history of LVAD infection).

Recommendation-Specific Supportive Text

1. Standard preparation of the recipient for transplant surgery involves clinical review directed at assessing changes in health status that might impact the decision to proceed with transplantation. Clinical events that may impact the risk of surgery or postoperative survival include acute infection, worsening end-organ function, such as renal and liver dysfunction, active bleeding, recent sensitizing event, or other conditions of significance that have developed since the last patient follow-up.
2. Most oral medications are discontinued once a potential donor is identified, with particular attention on timely discontinuation of SGLT2i to lessen the risk of ketoacidosis after surgery,[828] and discontinuation of vasodilators, particularly ACEi/ARB/ARNi, to avoid postoperative vasoplegia.[829] In patients in high urgency status where HT is anticipated within days, avoidance of SGLT2i and of longer-acting oral vasodilators is reasonable.
3. For additional details regarding anticoagulation and reversal before HT, please refer to Section Anticoagulant and Antiplatelet Therapy.
4. Patients with pacemakers require device reprogramming to asynchronous pacing mode (e.g., DOO, VOO). Patients with ICDs require antitachycardia pacing and shock therapies turned off.
5. Sensitization decreases access to donors, prolongs wait times, and increases risk of removal from the waitlist and risk of rejection and death after transplant.[830,831] Candidates with CPRA > 50% have a significantly lower likelihood of transplantation and a higher risk of waitlist removal/death, with CPRA > 80% having the most negative impact.[830] Despite limited data, desensitization strategies may shorten wait times without compromising outcomes.[832,833] The general approach to desensitization is mechanical removal of antibodies (plasmapheresis or plasma exchange) or suppression of antibodies [intravenous immunoglobulin (IVIG), rituximab, bortezomib]. Both plasmapheresis and IVIG can effectively reduce HLA antibodies; however, they are associated with rebound.[834] IVIG may be more effective and have a better safety profile than plasmapheresis.[835] Adjuvant therapies are commonly added to plasmapheresis and IVIG and may prevent rebound. In kidney transplant candidates, IVIG with rituximab significantly decreased PRA and was associated with shorter duration to transplant.[836] Compared to IVIG alone, rituximab and IVIG appear to have less rebound and less antibody-mediated rejection.[833] In HT candidates unresponsive to IVIG and rituximab, bortezomib and plasmapheresis reduced HLA from 62% to 35%.[837] Bortezomib has demonstrated greater efficacy against HLA Class I than HLA Class II.[838,839] Other emerging and promising therapies exist and have been investigated in small studies.
6. In sensitized patients, a specific plan for acceptable donor organs should be established by the transplant team ahead of time. At the time the prospective organ donor is identified, the clinical team should work along with the histocompatibility and immunogenetics team to confirm the donor will represent an acceptable immunologic match. This process may include virtual crossmatch with avoidance of donors with specific alloantigens, prospective direct crossmatch, and alteration of standard perioperative immune suppression.[840,841] It is also important to identify potential sensitizing events that may have taken place since the last patient follow-up. If these exist, repeat assessment of HLA antibodies should be considered.

7. In allosensitized patients, particularly those with a positive crossmatch, induction with antithymocyte globulin or basiliximab can be considered.[842] There are also limited data on the use of intraoperative plasmapheresis in those with a positive crossmatch to decrease the risk of early rejection.[843,844]

8-10. Surgical site infections occur in 4% to 19% of heart transplant recipients and can present as soft tissue infections or sternal infections and mediastinitis. The most common organisms involved are Gram-positive (*Staphylococcus* species including MRSA, *Enterococcus* species), lactose fermenting, and non-fermenting Gram-negative (*Enterobacterales*, *Pseudomonas aeruginosa*, *Stenotrophomonas*). The choice of antimicrobial agent must take into consideration beta-lactam allergy and colonization with multidrug-resistant organisms. First-generation cephalosporin (i.e., cefazolin) for 24 to 48 hours is recommended as primary prophylaxis for HT, with an alternative regimen of vancomycin plus cefazolin for MRSA colonization. For patients with beta-lactam allergy, vancomycin or clindamycin is acceptable alternatives. For a patient with an active infection at the time of transplant, the antibiotic regimen should target the specific pathogen(s).[845–848]

3.4.2. Infectious Disease Considerations

3.4.2.1. Hepatitis B and C Viral Infections

Recommendations for Pre-Operative Preparation of the Patient for Transplantation: Infectious Disease Considerations: HBV and HCV		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-EO**	1. Screening for HBV to include serum anti-HBs, anti-HBc and HBs Ag tests should be done prior to HT.
1	**C-EO**	2. Non-HBV immune candidates should be vaccinated against HBV.
1	**C-EO**	3. Candidates with chronic HBV (HBs Ag positive, anti-HBc positive) infection should be referred to a hepatitis specialist to guide management.
2a	**C-LD**	4. It is reasonable for candidates with past HBV infection (anti-HBc positive, anti-HBs positive, HBs Ag negative) to undergo HBsAg and HBV DNA monitoring every 3-6 months for the first year after transplantation and be referred to a hepatitis specialist should HBsAg or HBV DNA become detectable.
2b	**C-EO**	5. Utilization of a donor with active HBV infection (HBsAg positive) may be considered but is associated with a risk of infection transmission. A consultation with an infectious disease specialist is recommended.
2b	**C-EO**	6. Utilization of a donor with isolated anti-HBc may be considered as it is associated with a very low risk of seroconversion (0.28%). Ideally, all candidates should be immunized prior to transplantation. Non-immune recipients (anti-HBs negative) receiving an organ from anti-HBc positive donor should receive antiviral prophylaxis with lamivudine for the first 12 months after transplantation. Non-immune recipients should undergo routine monitoring of liver enzymes, HBsAg, anti-HBs, anti-HBc and HBV DNA every 3 months for the first 12 months after transplantation.
1	**C-EO**	7. Screening for HCV should be performed in all heart transplant candidates.
1	**C-EO**	8. Candidates with active HCV infection should be referred to a transplant infectious disease specialist to guide management.
2a	**C-LD**	9. Organs from HCV viremic donors can be considered for HCV-negative patients. Due to the high rate of HCV transmission to the recipient, a plan for post-transplant treatment with direct-acting antivirals should be in place prior to transplant.
1	**C-EO**	10. Recipients of increased-risk donors should be monitored for HBV, HCV and HIV at 1, 3 and 12 months after transplantation.

Synopsis

Hepatitis B and hepatitis C status of the recipients and the donors need to be considered in HT. Transplant candidates should be tested and vaccinated for hepatitis B before heart transplant as appropriate (Table 10). Organs from donors with isolated positive anti-HBc should be considered as the risk of HBV infection in an immunized recipient is negligible. Transplant candidates should also be tested for hepatitis C; if confirmed to have active infection, they should be referred to a specialist for genotyping and liver assessment, as well as establishing a treatment plan preferably before transplant. Due to organ scarcity as a limited resource and to reduce wait-list time, a growing number of programs are utilizing HCV viremic donors. While the risk of HCV transmission from HCV viremic donors is high, treatment with direct-acting antivirals (DAAs) yields a very high cure rate even in the setting of immunosuppression and survival is similar to recipients of HCV-negative donors. Caution must be exerted in increased-risk donors, where recipients should be monitored for HBV, HCV, and HIV at 1, 3, and 12 months after transplantation.

Recommendation-Specific Supportive Text

1. HBV screening should be done before transplantation and should include HBsAg, anti-HBs, and anti-HBc.[253]
2. **Non-HBV immune** candidates should be vaccinated before transplant to decrease the risk of developing active HBV infection after transplant.[253]
3. In candidates with **chronic HBV infection** (HBs-Ag positive), additional testing including HBeAg, anti-HBe, quantitative HBV DNA, liver enzymes, and abdominal ultrasound should be done. Hepatic fibrosis assessment by liver biopsy or noninvasive methods is recommended. If treatment is indicated, preferred treatment options include entecavir (ETV), tenofovir disoproxil fumarate (TDF), and tenofovir alafenamide due to their efficacy and high barrier to resistance; therapy should be continued indefinitely pre- and post-transplantation.[849,850] Patients with chronic HBV who did not receive treatment before transplantation are at risk of disease progression after transplantation and should be started on therapy after transplantation and continue treatment indefinitely.
4. Candidates with **past HBV infection** (HBsAg negative, anti-HBc positive ± anti-HBs positive) have a low risk of reactivation (around 5%) and do not require routine antiviral therapy. Monitoring of HBbsAg and HBV DNA should be performed every 3 to 6 months for at least the first years after transplantation and therapy should be initiated if HBsAg or HBV DNA become detectable.[253,851]
5. The use of organs from **donors testing positive for HBV** may be considered to expand the donor pool. If the donor **is HBsAg positive**, there is a risk of HBV transmission to the recipient.[852,853] Indefinite antiviral prophylaxis with ETV or TDF is recommended. HBIg for the first 6 to 12 months after transplantation may be considered if the recipient's anti-HBs titers are below 100 IU/ml.[851]
6. Utilization of **donor with isolated positive anti-HBc** in HT carries a risk of infection transmission of 2% to 5%.[854,855] If the recipient is immunized against HBV (anti-HBs titer > 10 IU/ml), the risk of transmission is negligible, and no treatment is required.[856] If the recipient is not adequately immunized against HBV, antiviral prophylaxis (with ETV, TDF, or lamivudine) is recommended for the first 12 months.[253,851,857]
7. Screening for antibodies to HCV should be done at the time of transplant assessment, with HCV RNA used to confirm active infection.[253,858,859]
8. In candidates with active HCV infection, genotyping and hepatic fibrosis assessment by liver biopsy or by noninvasive methods is recommended. Patients with chronic HCV should be referred to a hepatitis C specialist.[860,861] Optimal timing (before or after transplant) of therapy remains controversial and must be individualized, considering access to therapy, severity of liver disease, expected wait time, and willingness to consider organs from HCV donors.[860,861] Sofosbuvir-containing DAA regimens may be associated with symptomatic bradycardia in patients taking amiodarone. Certain DAAs significantly increase the concentration of statins and the combination should be used with caution.
9. The high potency of the DAAs combined with organ shortage has led to expanding utilization of HCV donors for organ transplantation. **Organs from HCV Ab-positive/RNA-negative donors** should be considered routinely for waitlisted candidates.[253] **Organs from** HCV viremic donors may be transplanted to HCV-negative recipients. Informed consent and a clear plan for post-transplant treatment should be established. The risk of HCV transmission from HCV viremic donors is nearly 100%. Treatment with DAA in recipients that seroconvert demonstrates excellent short-term outcome (cure rates ~100%), but there are limited long-term data.[253,862,863] Optimal management and timing of DAA remains unknown but either a prophylaxis or a pre-

emptive strategy have been proposed[864,865] (Table 21). For transplant recipients treated with DAA, it is important to monitor for drug interactions with immunosuppression (refer to Table 22).[860,861,864]

10. Recipients of increased-risk donors (donors who have behaviors, such as active intravenous drug use, that are at higher risk of HIV, HBV, and HCV, may yield negative viral test at the time of organ donation (eclipse period) but may harbor the infection) should be monitored for HBV, HCV, and HIV at 1, 3, and 12 months after transplantation, as they are at risk for seroconversion after transplant.[253,858]

Table 21 Summary of Strategies for HCV Viremic Donor Management

Parameter	Prophylaxis	Pre-emptive
Objectives of strategy	DAA is initiated immediately (within a few hours) after transplantation to prevent transmission from donor to recipient	DAA is initiated when HCV infection transmission to the recipient has occurred, diagnosed by HCV RNA detection; this strategy's goal is a sustained virologic response at 12 weeks
DAA regimen	Sofosbuvir/velpatasvir (4 week) or Glecaprevir/pibrentasvir (8 wk)	Sofosbuvir/velpatasvir (12 week) or Glecaprevir/pibrentasvir (8-12 week) *Alternatives:* Ledipasvir/sofosbuvir (12 week) or Elbasvir/grazoprevir (12 week)
Advantages	Shorter duration of DAA Prevention of the onset of HCV latency Prevention of HCV-related adverse events	Knowledge of genotype Improved hemodynamic stability Less variability in drug absorption/kidney function
Disadvantages	Difficulty of administration in critically ill patients, variability in drug exposure due to early shock, renal failure, ECMO, dialysis support, upfront access to drug may be a barrier.	Adverse events related to HCV infection, extrahepatic manifestation, unknown long-term effect on allograft

Abbreviations: DAA, direct-acting antivirals; HCV, hepatitis C virus; RNA, Ribonucleic acid.

Table 22 Drug Interactions Between Immunosuppressive and Direct-Acting Antiviral (DAA) Agents

DAA agents	Interaction with tacrolimus	Interaction with cyclosporine	Interaction with mTOR inhibitor
Ledipasvir/ sofosbuvir	No significant interaction	No significant interaction	Not reported
Daclatasvir	No significant interaction	No significant interaction	Not reported
Elbasvir/grazoprevir	Grazoprevir ↑ tacrolimus concentration	Cyclosporine ↑ grazoprevir concentration	↑ mTOR concentration
Sofosbuvir/ velpatasvir	No significant interaction	No significant interaction	Not reported
Sofosbuvir/ velpatasvir/ voxilaprevir	No significant interaction	Cyclosporine ↑ voxilaprevir—not recommended	Not reported
Glecaprevir/ pibrentasvir	No significant interaction	Cyclosporine ↑ glecaprevir; Cyclosporine ↑ pibrentasvir; Doses of cyclosporine >100 mg/day are not recommended	May ↑ mTOR

Adapted from Aslam et al ISHLT expert consensus statement; mTOR, mammalian target of rapamycin.[864]

3.4.2.2. Coronavirus Disease 2019

Recommendations for Pre-Operative Preparation of the Patient for Transplantation: Infectious Disease Considerations: COVID-19		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-LD**	1. Heart transplant candidates should be fully vaccinated for COVID-19 prior to transplantation.
1	**C-LD**	2. All potential donors should undergo universal screening by nucleic acid tests (NAT) for SARS-CoV-2. NAT should be performed within 72 hours of donation, but ideally be as close to procurement as possible. NAT results should be available at the time of organ offer.
2b	**C-LD**	3. The use of organs from a deceased donor with positive NAT may be used for non-lung transplantation provided the donor's death is not related to COVID-19 complication (including myocarditis or pericarditis) and there is no evidence of hypercoagulability or COVID-19 induced hyperinflammatory state.
2a	**C-EO**	4. The risk of SARS-CoV-2 transmission from deceased donors who test negative for SARS-CoV-2 but who have had a household contact who tested positive for COVID-19 in the last 10 days is unknown.
1	**C-EO**	5. Healthcare workers should adhere to local infection control guidance to minimize the risk of SARS-CoV-2 transmission during organ recovery and transplantation.
2b	**C-LD**	6. There is no recommendation regarding optimal peri-transplant therapies (antivirals, monoclonal antibodies) to minimize the risk of transmission to recipients of organs from donors with positive SARS-CoV2-NAT.
1	**C-EO**	7. All transplant candidates should undergo COVID-19 screening with SARS-CoV-2 NAT and an epidemiological questionnaire about history of disease or exposure.
3: No Benefit	**C-LD**	8. For candidates with new onset active COVID-19 infection, transplantation should be deferred.
2b	**C-LD**	9. The candidate may be reactivated on the list once the three conditions are met: 1) complete resolution of symptoms; 2) no COVID-19-related end-organ damage, and 3) >14-28 days from the onset of symptoms, considering the risk of the candidate's waitlist mortality.

Synopsis

The COVID pandemic caused by the SARS-CoV-2 virus emerged in 2019 and has dramatically impacted the landscape of organ donation and transplantation. The epidemiology of SARS-CoV-2 continues to evolve, and our knowledge base is rapidly expanding.

Recommendation-Specific Supportive Text

1. All heart transplant candidates should be fully vaccinated against COVID-19 to decrease the risk for acquiring active COVID infection while on the transplant waiting list and after transplant.[866]
2. All donors should be screened for known contacts with COVID-19 and for a history of known or suspected COVID-19 infection. Universal screening with nucleic acid tests (NAT) for SARS-CoV-2 is indicated for all potential donors. NAT should be performed within 72 hours of donation, but ideally be as close to procurement as possible. Upper respiratory tract sample is acceptable for nonlung donors while lower respiratory tract sample is recommended for potential lung donors. NAT results should be available at the time or organ offer.
3. Data on the utilization of extrapulmonary organs from **donors with positive SARS-CoV-2 NAT** have reported a low risk of transmission and good post-transplant outcomes.[867–875] Donors with positive SARS-CoV-2 NAT can be found in the following scenarios:
   a) Past resolved infection with symptom onset between 11 and 90 days prior;
   b) Recent active infection with symptom onset between 1 and 10 days prior;
   c) No history of infection with asymptomatic positive SARS-CoV-2 NAT.

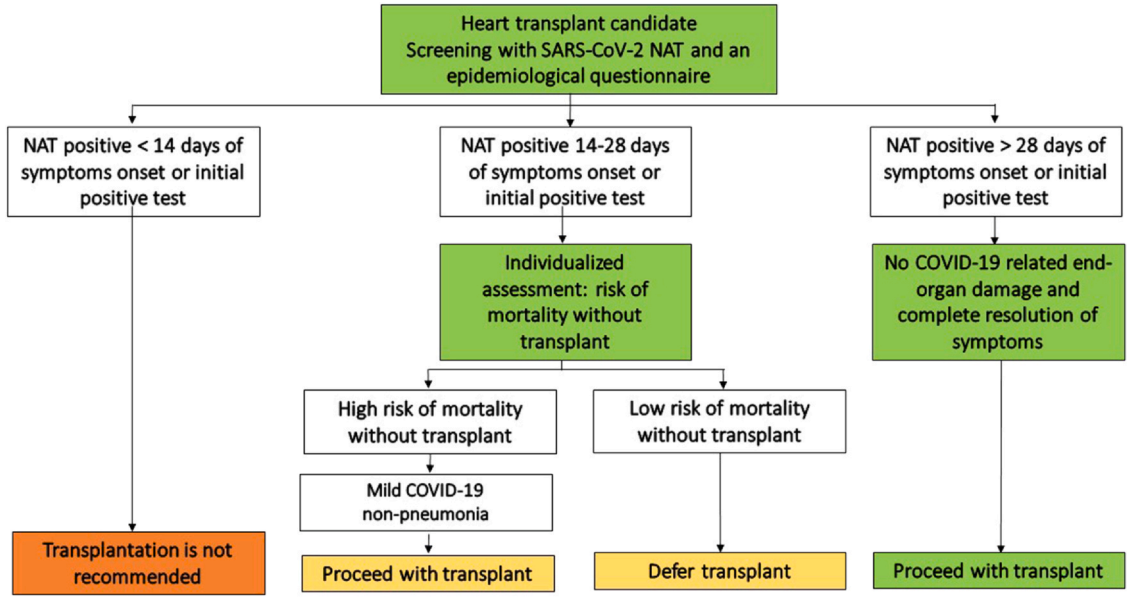
   Donors with past infection with symptom onset between 11 and 90 days previously likely have resolved infection with persistent noninfectious viral shedding and the organ can be safely used. Donors with active infection with symptom onset within 10 days are considered to have active COVID-19 infection. Similarly, donors with no history of infection who are otherwise asymptomatic with a positive SARS-CoV-2 NAT are considered to have active infection. To date, there have been 3 cases of SARS-CoV-2 transmission to lung transplant recipients from donors with negative upper

respiratory tract NAT testing but who were subsequently found to have positive NAT in a sample from the lower respiratory tract.[876] On the other hand, there are no known transmissions to nonlung recipients of organs recovered from donors with positive upper respiratory or lower respiratory SARS-CoV-2 NAT results. Recipients of nonlung organs from SARS-CoV-2 polymerase chain reaction-positive donors have short-term patient and graft survival similar to those who received organs from SARS-CoV-2 polymerase chain reaction-negative donors. As such, organs from SARS-CoV-2 NAT-positive donors may be used for nonlung transplantation provided there is no evidence of hypercoagulability or COVID-19 induced hyperinflammatory state during terminal hospitalization. While the long-term allograft outcomes from donors with COVID-19 remain unknown, the decision to recover organs from donors with positive SARS-CoV-2 NAT testing should take into account the recipient's risk for mortality while remaining on the waiting list and donor factors, including severity of illness, time from symptom onset, and organ quality.[877] Any transplant candidates in whom COVID-19 positive donors are being considered should undergo informed consent before transplantation.

4. The risk of SARS-CoV-2 transmission from a deceased donor who tests negative for SARS-CoV-2 but who has had close contact with a person with active COVID-19 in the last 10 days is unknown. To date, there have been no reported case of transmission from a donor in this scenario.
5. Donors with active infection are contagious and may transmit infection during an aerosol generation procedure. As such, health care workers should adhere to local infection control guidance to minimize the risk of SARS-CoV-2 transmission during organ recovery and transplantation. Eye protection and use of an N95 or equivalent respirator are recommended for aerosol-generating procedures and surgical procedures that may pose a higher risk for transmission if the patient was to have COVID-19. Additionally, all health care workers should be vaccinated against COVID-19.[876]
6. Currently, there is no recommendation regarding optimal peritransplant therapies (antivirals, monoclonal antibodies) to minimize the risk of transmission to recipients of organs from donors with positive SARS-CoV-2 NAT. The recommendations are subject to change based upon emerging data.
7. All transplant candidates should undergo COVID-19 screening with SARS-CoV-2 NAT and an epidemiological questionnaire about history of disease or exposure.

8-9. For a candidate with a recent history of COVID-19 infection or with a positive screening SARS-CoV-2 NAT, the optimal timing of transplantation remains unclear. For candidates with new onset active COVID infection, transplantation should be deferred. The candidate may be relisted once the 3 conditions are met: (1) complete resolution of symptoms; (2) no COVID-19-related end-organ damage, and (3) > 14 to 28 days from the onset of symptoms, considering the risk of the candidate's waitlist mortality.[866,878] Transplantation within 4 weeks of COVID-19 infection is not recommended unless the risk of deferring transplantation outweighs the risk of postoperative morbidity and mortality associated with COVID-19 (Figure 6).[879,880]

Figure 6 Heart transplantation after COVID-19. COVID-19, coronavirus disease 2019; NAT, nucleic acid tests; SARS-Cov-2, severe acute respiratory syndrome coronavirus 2.



3.4.2.3. Human Immunodeficiency Viral Infection

Recommendations for Pre-Operative Preparation of the Patient for Transplantation: Infectious Disease Considerations: HIV		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	1. All heart transplant candidates should be screened for human immunodeficiency virus (HIV) infection at the time of listing and after possible infectious exposures.
1	C-EO	2. HIV-infected individuals with undetectable viral load and CD4 count of >200 cells/mL on a well-tolerated antiretroviral regimen should be considered for HT.
1	C-EO	3. HIV-infected candidates should be closely followed by an HIV-experienced provider for management of antiretroviral therapy and screening for HIV-associated malignancies, opportunistic infections, and the appropriate prophylaxis and treatment.
3	C-EO	4. The use of HIV+ organs for transplantation outside of research protocols is not recommended.

Synopsis

HIV-infected individuals with undetectable viral load and CD4 count > 200 cells/ml on a well-tolerated antiretroviral regimen should be evaluated for heart transplantation. If deemed appropriate transplant candidates, they should be managed by a provider experienced in the care of HIV patients. Favorable survival after transplant has been reported in carefully selected HIV-infected patients. The use of HIV+ organs for transplantation outside of research protocols is not recommended.

Recommendation-Specific Supportive Text

1. All heart transplant candidates should be screened for HIV infection using serology and/or viral load testing. Testing should be repeated after possible infectious exposures while on the waiting list.
2. Carefully selected HIV-infected individuals should be evaluated for HT. Such candidates should have well-controlled HIV with undetectable viral load and CD4 > 200 cells/ml in the 4 to 6 months before listing. There is now significant experience with favorable outcomes in the abdominal transplant setting and data demonstrate that immunosuppression regimens should be followed as per center policy and do not need to be altered based on the HIV diagnosis alone.[881,882] Experience for cardiothoracic transplant is increasing as well showing overall comparable survival as HIV-negative patients undergoing heart transplant.[883,884]
3. HIV-infected candidates should be closely followed by an HIV-experienced provider for specialized disease management.[885] The antiretroviral regimen should ideally consist of a nonprotease inhibitor (PI) based regimen as PI have significant drug interactions with some immunosuppressives. If the candidate is on a PI-based regimen at listing, switch to a non-PI regimen should be considered if possible. If a PI-based regimen is needed based on genotypic/phenotypic resistance data, dose adjustment and close monitoring of the immunosuppressives will be needed. The HIV-infected candidate should also be assessed for prior or current opportunistic infections and HIV-related malignancies, including cryptococcal meningitis, other invasive fungal infections, disseminated atypical mycobacterial infection, tuberculosis, cytomegalovirus disease (retinitis), wasting syndrome, anal metaplasia, Kaposi's sarcoma, and lymphoproliferative disease, among others. Resolution of opportunistic infections and HIV-related malignancies needs to be documented and appropriate prophylaxis regimens implemented.
4. The use of HIV+ organs for heart transplant remains experimental, and the use of HIV+ organs for transplantation outside of research protocols is not recommended.[886–888]

3.4.3. Donor-Recipient Matching Considerations

Recommendations for Pre-Operative Preparation of the Patient for Transplantation: Donor-Recipients Matching Considerations		
COR	LOE	RECOMMENDATIONS
2a	B-NR	1. Donor-recipient height, weight, and predicted heart mass (pHM) ratio can be useful to improve donor-recipient matching.
2a	B-NR	2. For pediatric candidates, weight- and height-based matching can be effectively utilized for donor-recipient matching. It is reasonable that acceptable donor weight and height range be periodically reassessed to account for somatic growth of the pediatric candidate on the waitlist.
2b	C-LD	3. For pediatric candidates, total cardiac volume or virtual 3D fit assessment may help to safely increase the donor pool.

Synopsis

Different metrics have been used to determine appropriate matching of donors and recipients, including weight, height, predicted heart mass (pHM), and predicted lean body mass. In adults, size matching using pHM is widely accepted. In pediatrics, weight- and height-based matching are commonly utilized.

Recommendation-Specific Supportive Text

1. An accepted rule has been to advise against matching donors with body weight < 70% of recipient's weight[889] due to increased 30-day and cumulative mortality.[890] The adverse consequences of under-sizing have also been shown using pHM in adults, both in single-center[891] and multi-center database studies.[203,892–894] The pHM ratio, which is derived from the right and left ventricular mass equations from the Multi-Ethnic Study of Atherosclerosis, has been proposed as the optimal size parameter for donor-recipient size matching. Recipients with PH with undersized grafts by pHM are at increased risk compared to those with size matched or oversized donor hearts.[5,6] Avoidance of undersizing might be sufficient to avoid this, as no survival benefit has been demonstrated for oversizing donors in recipients with moderate PH (PVR 2.5-5.0 Wood units or TPG 10-18 mm Hg) at either 90 days or 1 year; similarly, there was no advantage shown to oversizing female donors for male recipients with moderate PH.[894] An increase in post-transplant mortality has been reported with a donor-recipient pHM ratio < 0.86. The ISHLT 2022 donor heart selection guidelines indicate donor pHM within 20% to 30% of the donor is acceptable.[8,895,896]
   Sex matching may be relevant particularly in the context of donor size and/or the presence of PH in the recipient. Male recipients of female allografts have been reported to have increased 1-year and cumulative mortality compared to male recipients of male allografts.[890,895,896] Sex mismatch may predominantly influence short-term outcomes, with no survival differences reported beyond 1 year.[896] Some of the risks associated with sex mismatch can be explained by differences in heart mass in males and females of the same height and weight. Therefore, the use of pHM can be especially advantageous when a transplant with donor-recipient sex mismatch is being considered.[8,890,893]
2. In children, donor-to-recipient weight (DRWR) and height ratio (DRHR) are commonly used to identify suitable donors. However, consideration must be given to the differences in heart size due to complex CHD vs cardiomyopathy.[897–899] Extending the DRWR upward to 3.0 has been reported with equivalent short-term outcomes.[8, 897–899] Caution should be exercised when accepting donors who are undersized by weight relative to the pediatric candidate, given the association with increased post-heart transplant mortality. DRHR of 0.7 to 1.2 does not increase post-transplant mortality, while DRHR > 1.2 is associated with increased 5-year post-heart transplant mortality.[899] Caution should be exercised when accepting donors oversized by height for pediatric candidates. Acceptable donor weight and height ranges should be periodically reassessed to account for somatic growth of the pediatric candidate on the waiting list.
3. In children, newer imaging techniques, such as echo-derived total cardiac volume[900] or virtual 3D volumetric fit assessment,[901–903] may provide more granular detail to safely widen the donor pool for pediatric candidates.

3.4.4. Recommendations for Preoperative Preparation of Pediatric Patients for Transplantation

Recommendations for Pre-Operative Preparation of Pediatric Patients for Transplantation		
COR	LOE	RECOMMENDATIONS
1	C-EO	1. Pediatric patients with complex CHD should have optimal (typically cross-sectional) imaging to allow planning for safe re-sternotomy, cannulation and implantation strategy, and to identify unique donor organ retrieval needs.
1	C-EO	2. For pediatric patients listed for ABO-incompatible HT, isohemagglutinin titers should be closely monitored perioperatively to guide need for antibody removal and immunosuppression strategy.

Synopsis

Pediatric patients have unique preoperative considerations to optimize them for HT. Detailed knowledge of the anatomy of patients with CHD is necessary when preparing for donor organ retrieval. Patients with multiple past surgeries (e.g., complex congenital, VAD) may require earlier admission to the operative room before donor heart arrival to facilitate extensive dissection and minimize cold ischemic time.

Recommendation-Specific Supportive Text

1. Cross-sectional imaging facilitates safe sternal re-entry, surgical cannulation (e.g., need for femoral bypass), implantation strategies, and donor organ retrieval to support vessel reconstruction (e.g., aorta, PA, venous return) at transplant.[813, 904–906]
2. For young children listed for ABO-incompatible HT, ISO titers should be sent upon acceptance of the donor organ and should be rechecked before cross-clamp removal to facilitate perioperative decision-making regarding need for ISO antibody removal strategy (e.g., need for plasma or whole blood exchange pre-/intraoperatively, type and timing of vascular access, immunosuppression strategy, need for plasma exchange postoperatively).[446,450] Tailoring of blood products utilized is required to facilitate ABO-incompatible transplants.[907]

3.5. Ethical Considerations

Utility, respect for patient autonomy, and a shared decision-making process are the foundational ethical principles that create the ethical framework for listing a patient for HT. Respect for patient autonomy requires that patients be fully informed about their disease and treatment options, empowering them to refuse or consent to proposed interventions. Donor heart is a scarce resource and is a gift made to the community of patients in need, heightening the responsibility of the transplant team in the shared decision-making process and requiring the team to adhere to a higher standard to assure the heart is allocated in a way that is likely to result in significant benefit to the recipient (representing the principle of utility).[908–910] Thus, the transplant team uses its professional expertise to set screening protocols and requirements for potential recipients to promote behaviors that increase the likelihood of successful long-term transplant outcomes. Other considerations include the physician's obligation to avoid harming the patient (the principle of "primum non nocere") and, when that is not possible, to take appropriate steps to alleviate that harm; also, consideration of a "support team" maintaining certain qualifications that correlate with successful outcomes. Heart transplant recipients are "harmed" by the physician subjecting them to immunosuppression to prevent graft rejection. Being immunocompromised places the HT recipient at increased risk of cancer and infections, many of the latter are avoidable through vaccination. Therefore, a basic requirement is that the candidate be "up to date" on range of vaccinations that are proven to be efficacious against infections that would significantly jeopardize the benefit of organ transplantation.[909] The eligibility of the patient for listing is dependent on candidates' respect for and agreement to the integrity of the shared decision-making process to increase successful outcomes. The ethical framework should be adopted to clarify controversies. Thus, assessment of whether an apparent "controversial" requirement is consistent with the current standard of care and respects the integrity of the shared decision-making process to ensure successful outcomes. Areas of controversy may include vaccination or therapies for which the benefit is unknown; patient prioritization and urgent cases criticized and monitored to ensure no harm is done; and the use of medical cannabis, which requires further clarification of concerns of heightened predisposition to fungal infection or heavy use that impairs cognitive ability and that could lead to medication nonadherence.

4. TASK FORCE III: CONSIDERATIONS FOR MECHANICAL CIRCULATORY SUPPORT SYSTEMS

4.1. Scope of the Problem

4.1.1. Trends in Utilization of Durable Mechanical Support Devices

LVADs are an important treatment option for patients with AdvHF refractory to OMT, avoiding further end-organ injury, improving QOL, and prolonging survival. The last several years have been characterized by a shift in device type and indication. Advances in bioengineering have led to the introduction of durable CF LVADs with more favorable side-effect profiles, yielding progressive gains in short- and long-term survival.[561, 911–914] In 2021, the newest technology, fully magnetically levitated CF HeartMate3, accounted for 92.7% of all CF-LVAD implants. Destination therapy (DT) is now the predominant indication in the USA, with 81.1% of patients in 2021 implanted as DT (vs 56.5% in 2018), whereas the number of implants for the BTT indication has now been nearly eliminated (5.3% in 2021 vs 18.9% in 2018).[911] This change in BTT-DT ratio coincided with the modification in the USA heart allocation system (that lowered the transplant priority for patients on DMCS), approval of the HeartMate3 device for DT and the simultaneous growth of stand-along DT programs, together with its improved survival and reduction in readmissions. In Europe, however, the indication for the vast majority of patients to undergo LVAD implantation remained BTT.[915,916]

4.1.2. Waitlist Outcomes

The rate of HT remains significantly higher in the USA, as compared with most European countries.[917] For DMCS patients, the probability of receiving an HT at 1 and 3 years has declined after the 2018 UNOS allocation change (7.3% and 17.2%, respectively) and is comparable to data from the European Registry of 7.5% and 20.2% at 1 and 3 years, respectively.[911,915,916] These findings underscore the improved overall adverse events profile of the currently implanted device and the lower listing priority status of the BTT patients with no to minimal device complications in the 2018 UNOS allocation policy. Despite LVAD patients being older and more ill, 1- and 5-year survival (83% and 51.9%, respectively) as well as the incidence of adverse events improved in the newer era (2017-2021).[911] The > 50% 5-year survival after LVAD implantation confirms LVADs as serious competitor with HT.

4.1.3. Indications for Durable Mechanical Support Devices

Indications for Durable Mechanical Support Devices		
COR	**LOE**	**RECOMMENDATIONS**
1	**A**	1. Patients with low LVEF and AdvHF symptoms (NYHA Class IIIB-IV) refractory to maximal medical management or with inotrope dependence or on tMCS should be considered for DMCS as a bridge to transplant or candidacy or as DT (for patients who are ineligible for HT).
2a	**B-NR**	2. It is reasonable to consider DMCS as a bridge to recovery in patients with dilated cardiomyopathy, particularly of recent onset, and non-ischemic etiology refractory to maximal medical therapy. Pharmacological treatment should be with maximally tolerated neurohormonal modulation and surveillance for recovery of LV function should be undertaken.
2a	**C-EO**	3. It is reasonable to perform routine risk stratification at regular intervals to determine the need for and optimal timing of DMCS in patients with advanced systolic who do not fall into recommendations 1 and 2 above. This determination may be aided by risk assessment calculators and CPET.
2b	**C-LD**	4. Patients presenting with INTERMACS 1 and 2 status, with laboratory evidence of elevated bilirubin, INR, creatinine, and blood urea nitrogen and clinical manifestations of severe malnutrition, in conjunction with a hemodynamic profile of prohibitive RV failure, with elevated RA pressure and lower pulmonary artery pressure index (PAPi) may be considered for TAH or biventricular assist device (BiVAD), with the choice related to selection issues of patient size, flow demand, fit and related individual considerations.

Synopsis

Identifying the optimal timing for MCS and selection of the device remains a major clinical challenge in managing patients with AdvHF.[918–921]

Recommendation-Specific Supportive Text

1. DMCS should be considered in patients whose ventricular function is unlikely to recover or who are too ill to maintain normal hemodynamics and vital organ function without MCS. The use of LVAD in patients with AdvHF vs OMT resulted in a clinically meaningful survival benefit and improved QOL. The newest CF HeartMate3 has further reduced mortality with a 5-year survival of 58.4%.[918,920,922-924] LVAD therapy allows patients and care providers to address modifiable risk factors for HT, especially organ dysfunction. The support provided by LVAD therapy improves end-organ function, nutritional status, PVR, and functional capacity.[912,925,926]
2. A subset of patients may exhibit myocardial recovery after LVAD implantation, permitting weaning from the DMCS device. Myocardial recovery often presents within a 6- to 9-month period.[912,917,925,927] Reverse remodeling with LVAD support and a standardized pharmacological regimen improved the rate of LVAD explantation.[754] Independent predictors of myocardial recovery include younger age, nonischemic etiology, normal renal function, and a shorter duration of HF.[754,917,927-931]
3. Prognostic stratification of patients with HF is important to identify the optimal timing for referral to a specialized center providing AdvHF therapies. Postimplantation survival is closely related to preimplantation clinical status. Prompt referral for DMCS implantation is, therefore, crucial. Unfortunately, no single marker enables the identification of patients at risk for deterioration; thus, regular assessment by a dedicated multidisciplinary AdvHF team is recommended.[932–934]
4. Patients classified as INTERMACS profiles 1 and 2 tend to have a high incidence of RV dysfunction and failure.[935] Preimplant characteristics, such as elevated levels of creatinine, blood urea nitrogen, bilirubin, INR, and lower albumin, and prealbumin ratio in patients presenting with INTERMACS 1 reflect worsening organ perfusion implying a BiV support may be considered. A low cardiac index (< 2.2 liter/min/m^2) or cardiac power < 0.6 W coupled with hemodynamic evidence of elevated central venous pressure (CVP) (> 16 mm Hg) or CVP/PCWP > 0.63 or PAPi < 1.85 in conjunction with the above clinical characteristics support the need for an upfront BiV support strategy.[936,937] However, a thorough diagnostic work-up to identify reversible causes of BiV HF should be completed before considering any form of BiV DMCS.[938] Patients who require BiV support tend to have a higher rate of perioperative complications.[935] One-year survival in patients with biventricular assist device (BiVAD) remains below 60%.[939,940]

4.1.4. Indications for Durable Mechanical Support Devices in Pediatric Patients

Recommendation for Indications for Durable Mechanical Support Devices in Pediatric Patients		
COR	**LOE**	**RECOMMENDATIONS**
2a	**B-NR**	1. DMCS as BTT or BTR can be considered in pediatric patients in the case of progressive decompensation with objective measures of congestion and/or inadequate cardiac output despite optimal medical therapy. Optimal timing should be determined by the assessment of the patient's risk profile and device type.

Synopsis

AdvHF is associated with high morbidity and mortality in the pediatric population.[941,942] Hospitalization with HF increases the risk of mortality in children by 20-fold, with an overall in-hospital mortality rate of 7% to 10%.[943] Utilization of VADs in the pediatric population has demonstrated robust growth in the past 2 decades, from 11% in 2005 to 24% in 2016.[916,943] Among children with dilated cardiomyopathy, approximately 40% were bridged to transplant with some form of MCS, with most patients being supported with a VAD. Among children with CHD, the utilization of MCS was less common, especially among infants.[944,945] Most devices are implanted as either a BTT or a bridge to candidacy (BTC), whereas DT remains uncommon.[916,943]

Recommendation-Specific Supportive Text

1. During the last decade, a 50% reduction in waitlist mortality with a 4 times higher likelihood of surviving to transplantation was reported in the pediatric population.[946,947] The overall mortality differs according to the patients' profile and device type, with significantly inferior outcomes in infants, in Pedimacs patient profile level 1, with paracorporeal continuous VADs, and with CHD.[646,916,943,948] Preimplant kidney and liver dysfunction are associated with postimplant adverse events and mortality.[949,950] Interestingly, outcomes of patients with single ventricle CHD were similar to those with BiV CHD.[943] Notably, survival after HT in VAD-supported children does not differ

from that in medically supported patients.[947,951,952] Moreover, despite being at an increased risk of sensitization pre-transplant (42% of device-supported patients becoming sensitized as opposed to 30% of medically supported patients), there is no increased risk of rejection in pediatric patients bridged to transplant with a VAD.[947,953]

4.2. Candidate Selection for Durable Mechanical Circulatory Support

4.2.1. Patient Evaluation and Risk Factors

Recommendations for Candidate Selection for DMCS: Patient Evaluation and Risk Factors		
COR	**LOE**	**RECOMMENDATIONS**
1	A	1. All potential DMCS patients should be managed by an AdvHF team for optimization of therapies, risk assessment, and shared decision-making.
1	C-LD	2. All patients should be assessed for nutritional status prior to DMCS implantation.
1	B-NR	3. All patients should be screened for diabetes with HbA1c prior to DMCS. Patients with established diabetes should be assessed for the degree of end-organ damage (retinopathy, neuropathy, nephropathy, and vascular disease) and their diabetes management must be optimized before implant.
1	B-NR	4. In patients evaluated for DMCS, comprehensive assessment of liver function is recommended. In patients with abnormalities in liver function tests, a history of liver disease, chronic RHF, or Fontan physiology, screening for fibrosis or cirrhosis with ultrasonography or CT scan should be performed. For patients with suspected cirrhosis, further radiologic and tissue confirmation should be performed in conjunction with a hepatology consult.
1	C-EO	5. Patients should undergo an assessment of thoracic anatomy prior to DMCS implantation. The assessment should include transthoracic and/or transesophageal echocardiogram and CT/MRI imaging to facilitate identification of thoracic aorta calcifications and anatomical features.
1	C-EO	6. Candidates for DMCS therapy should be assessed for coagulopathies and hypercoagulable states.
1	C-EO	7. All patients should be screened for psychosocial risk factors prior to DMCS.
2a	B-NR	8. In patients undergoing evaluation for DMCS, it is reasonable to include an objective evaluation to assess the burden of frailty.
1	C-EO	9. A. The presence and severity of chronic lung disease should be assessed by evaluating patient-related risk factors and performing pulmonary imaging (Class 1).
2b	C-EO	B. Pulmonary function testing (spirometry) may be beneficial for screening patients with suspected lung disease (e.g., chronic obstructive pulmonary disease) for pre-operative optimization and peri-operative management (Class 2b).
1	C-LD	10. All patients considered for DMCS should have an invasive hemodynamic assessment of PVR.
1	C-LD	11. Invasive hemodynamic evaluation of the RV combined with multimodality imaging focused on quantitative parameters of RV function and tricuspid valve integrity should be performed prior to DMCS implantation. Pre-operative optimization of RV function with invasive hemodynamic monitoring is recommended.
1	C-EO	12. A. Kidney function after hemodynamic optimization should be performed in all patients being considered for DMCS. For patients with decompensated HF and severe kidney dysfunction, initial hemodynamic support with inotropes and/or tMCS to assess the potential of kidney recovery before implanting DMCS should be performed (Class 1).
2a	C-LD	B. Patients with severe kidney dysfunction can be carefully selected for DMCS (Class 2a).
2b	B-NR	C. DMCS as a bridge to SHKT may be considered in carefully selected patients with a plan for long-term hemodialysis in an experienced center (Class 2b).

Synopsis

A comprehensive evaluation of the patient for DMCS and preoperative optimization using a multisystem approach prepares the patient for the best outcome. Nevertheless, emergency situations may occur, precluding the ability to perform a thorough or ideal evaluation. Preoperative risk scoring systems have been used to prognosticate postoperative outcomes, but their guidance yields less help in preoperative organ optimization. Although the algorithms are helpful, they cannot replace experienced clinical judgment.[933,954–959] Psychosocial assessment specific to patients under consideration for MCS is detailed in the 2018 ISHLT/Academy of Psychosomatic Medicine/American Society of Transplantation/International Consortium of Circulatory Assist Clinicians/ociety for Transplant Social Workers (ISHLT/APM/AST/ICCAC/STSW) recommendations for the psychosocial evaluation of adult cardiothoracic transplant candidates and candidates for long-term MCS.[6]

Recommendation-Specific Supportive Text

1. Potential DMCS candidates should be managed by a dedicated AdvHF team for optimization of therapy, comprehensive risk assessment, and early facilitation of shared decision-making to define goals of care as well as education regarding therapeutic options, including MCS and transplant when appropriate. Continuous assessment by a dedicated team is aimed at reducing the probability of patients' deterioration to cardiogenic shock and multiorgan failure.[922,923,960,961]
2. Routine evaluation for candidacy for DMCS should include nutritional assessment and consultation with a nutritional support team.[962–966] Improvements in albumin following DMCS implantation have been associated with improved outcomes, but the impact of active nutritional intervention is unknown.[954,967]
3. Diabetes has been associated with infection and late mortality in LVAD patients.[968–972] Poor perioperative glycemic control is predictive of high mortality[973–975]; therefore, optimization of diabetes management before implantation of DMCS is warranted. Although preoperative HbA1c has not been specifically associated with mortality or adverse events, it may be a practical laboratory test to assess overall glycemic control before surgery.
4. Preoperative liver dysfunction is associated with worse survival and adverse events, including the onset of RV failure, acute kidney injury, and bleeding.[976] The reversibility of liver injury following LVAD implantation and the precise characterization of patients with liver dysfunction who will benefit from treatment with DMCS are yet to be assessed. For example, it was suggested that liver fibrosis might not negatively affect survival following LVAD implantation, and more studies are warranted to determine the impact of liver biopsy characteristics on LVAD outcomes.[977] Biochemical markers of liver disease and scores, such as MELD XI, are promising prognostic tools for risk stratification in the LVAD population. Yet, robust validation in prospective randomized studies is needed. Patients with cirrhosis or end-stage liver disease are poor candidates for DMCS. [978,979]
5. Assessment of intrathoracic anatomy is essential. Transthoracic and/or transesophageal echocardiogram provide information regarding cardiac geometry, ventricular size, protruding apical thrombus, and concomitant valvular disease or septal defects. CT imaging allows visualization of anatomical features that affect cannulation strategy, thus optimizing surgical planning. In the setting of prior cardiothoracic surgery, special attention should be paid to the distance to heart/major vessels/sternum.[980] Special efforts should be made to improve surgical techniques to preserve the native anatomy in case of re-entry for HT, myocardial recovery, or device explant.[981,982]
6. Evaluation of factors predisposing to bleeding or thrombotic events should be performed before implantation of DMCS to optimize outcomes. Patients with a history of thrombophilia should undergo hypercoagulable assessment before DMCS. To minimize the risk of bleeding, coagulation abnormalities should be corrected. Continuing P2Y12 receptor inhibitors until the operation increases the risk of bleeding, transfusions, and re-exploration for bleeding.[983–987] It is recommended to discontinue DOAC and thienopyridine antiplatelet agents before elective DMCS implantation.
7. All DMCS candidates should undergo a comprehensive psychosocial evaluation.[6,988] The goals of the evaluation are to assess risk factors for poor postimplantation outcomes; collect information on factors related to patients' knowledge, understanding, and capacity to engage in decision-making about DMCS; collect information to characterize patients' personal, social, and environmental resources and circumstances, including factors that may mitigate the impact of any psychosocial risk factors on postimplantation outcomes; and evaluate patients' knowledge about and capacity to operate the device.[989]
8. Given its significant impact on postsurgical morbidity and mortality, assessment of frailty is gaining increasing attention as part of the patient evaluation for DMCS.[990–992] Since frailty is partly attributed to underlying HF, it has been suggested that some of the FPs may be modifiable with implantation of an LVAD—the LVAD "responsive" patient.[265,266]
9. In patients with suspected pulmonary disease, evaluation with CT or MRI is reasonable. The incremental additive value obtained by spirometry in patients undergoing LVAD surgery is limited. In special circumstances, such as in

planned off-pump LVAD implantation through a left lateral thoracotomy and with the need for single lung ventilation, preoperative measurements of forced expiratory volume in 1 second (FEV1) and DLCO can help in planning the operative procedure.

10. Durable LVADs have been successfully used in patients with refractory elevated PVR. Several studies have demonstrated that LVAD therapy can effectively reduce left-sided filling pressures and improve PH.[181–184,993–997] A reduction in PVR may be seen as early as 1 month post-VAD implantation. However, it may take as long as 3 to 6 months, or even more, to achieve maximum reversibility.[181,996] Once PVR reversal is achieved, long-term post-transplant survival in patients bridged with an LVAD is comparable to that of HT recipients without PH.[186,998,999]
11. RV failure before LVAD implantation is associated with a 3- to 4-fold increase in mortality after LVAD implant.[1000,1001] Post-LVAD RV dysfunction can impair LVAD performance due to decreased preload, leading to low QOL and functional status. Echocardiographic evaluation is limited by the complex geometry, preload dependence and retrosternal positioning of the RV. Standard quantitative parameters, such as TAPSE, RV-FAC, and tricuspid annular systolic velocity, are load and angle-dependent and are of limited value. New techniques, such as RV strain, 3D imaging, and deep-learning algorithms, are emerging.[1002,1003] Cardiac MRI remains the gold-standard method for assessing function and performance and for volumetric assessment of RV function.[1004,1005] RV hemodynamics should be evaluated via RHC within 1 to 2 weeks before surgery in elective cases or preoperatively in the ICU with a PA catheter in patients deemed euvolemic and optimized.[1006,1007] A goal of CVP of ≤12 to 15 mm Hg should be achieved before LVAD implantation. Patients with refractory BiV dysfunction, despite OMT, may be considered for ECMO or planned BiVAD implantation.[1008,1009]
12. Kidney dysfunction before LVAD implantation is associated with increased morbidity and mortality in post-operative DMCS patients, and hemodialysis before DMCS is associated with dismal outcomes.[921, 1010–1014] Careful selection of patients with severe renal dysfunction (CKD Stage IV-V), combined with applying a comprehensive strategy that focuses on preoperative maximization of renal function (including tMCS), can result in acceptable postoperative outcomes.[1015–1017] Patients undergoing SHKT in the modern era with pre-transplant DMCS have equivalent survival to those undergoing SHKT without DMCS.[1018–1021]

4.2.2. Pediatric Patients

Recommendations for Candidate Selection for DMCS: Pediatric Patients		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	1. It is recommended to have recent documentation of cardiac morphological and ventricular physiological data, including the presence of shunts, collateral vessels, and the location and course of great vessels in pediatric patients undergoing evaluation for MCS.
1	B-NR	2. Pediatric patients should undergo a pre-implant evaluation, including an assessment of end-organ function, surgical planning, and psychosocial and neurocognitive assessment. It is beneficial that MCS evaluation be performed early before the progression of end-organ dysfunction.

Synopsis

Device selection in children differs significantly from that in adults with anatomically normal hearts and varies substantially among pediatric groups, depending on age and the type of CHD of the patient.[1022–1025]

Recommendation-Specific Supportive Text

1. The optimal surgical technique depends on the device and the patient's unique characteristics. In all pediatric MCS patients, determination of the presence of intra- and extracardiac shunts is required.[1017,1022,1026–1028] Large-scale studies on the use of MCS in patients with a single ventricle are lacking. The feasibility of VAD support for Glenn circulation has been reported with mixed results.[1029–1031] For patients with failing Fontan circulation, TAH might be considered.[1032]
2. Pediatric patients with cardiogenic shock who undergo DMCS implantation exhibit worse outcomes.[646,984,1025,1033] Nevertheless, recent reports from Pedimacs and Paedi-Euromacs registries reveal that 27T to 32% of pediatric patients were INTERMACS 1 or had end-organ dysfunction at the time of the implant.[646,984] Approximately 20% of patients had eGFR < 60 ml/min/1.73 m^2.[984,1025] Abnormal bilirubin was found in up to 36.5% of children at the time of VAD implantation, and elevated hepatocellular enzymes were reported in 22% to 25%.[646,984,1025] The use of mechanical ventilatory support was reported in up to 55% of

patients, with lower incidence in a subgroup of children assisted with intracorporeal CF-VADs.[646,984,1025] The use of tube feeding or parenteral nutrition was also common.[1013,1014] A thorough patient and family psychosocial assessment is critically important. The goal is to identify patient and family strengths, weaknesses, and intervention needs, particularly as they relate to VAD care demands. Primary domains of the pre-VAD psychosocial evaluation should include patient and family treatment adherence, barriers to medical management, disease, VAD-related knowledge, cognitive and/or neurodevelopmental functioning, current and historic mental health, substance use, social support, family functioning, and abuse and legal history.[1033,1034]

4.3. Surgical Planning and Operative Considerations in Transplant Candidates Bridged With Durable Mechanical Circulatory Support

Recommendation for Surgical Planning and Operative Considerations in Transplant Candidates Bridged with Durable Mechanical Circulatory Support		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	1. HT in patients with DMCS should be performed by a dedicated and experienced transplant team.
1	C-EO	2. In transplant candidates with DMCS, a CT scan of the chest and the entire aorta is recommended to guide chest reentry. The following elements need special attention: - Position of the outflow graft - Position of the driveline - Calcifications of the ascending aorta - Alternative vascular access routes.

Synopsis

HT following DMCS explant is a longer and more technically complex procedure that necessitates redo-sternotomy and careful outflow graft, driveline, and pump excision.[1035]

Recommendation-Specific Supportive Text

1. Preoperative planning is vital to ensure successful HT in this population. Contemporary pumps are associated with significant adhesions at the left ventricular apex site, particularly if the pump is not well covered at the time of primary implant. The growing adaption of less invasive implant techniques may significantly reduce the complexity of subsequent HT. Centers that routinely perform less invasive DMCS implantations report reduced surgical complexity and bleeding and blood product used during HT.[1036–1039]
2. A preoperative CT scan of the chest and the aorta should be available in all patients before HT.[1040,1041] The CT scan aids in planning resternotomy and vascular access. It reveals potential hazards, including proximity of the outflow graft or driveline to the sternum and calcifications in the ascending aorta and alternative vascular access routes.[1042,1043]

4.4. Complications of Durable Mechanical Circulatory Support and Their Implications for Candidacy

4.4.1. General Considerations

Recommendations for Complications of Durable Mechanical Circulatory Support and Their Implications for Candidacy: General Considerations		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	1. In patients with DMCS, candidacy for HT must be assessed longitudinally during follow-up regardless of the intended strategy (BTT, BTC, DT).
1	C-EO	2. Occurrence of a life-threatening complication in transplant candidates supported with a DMCS warrants evaluation for urgent HT.
1	C-LD	3. Occurrence of device-specific, device-related, or patient-related adverse events refractory to conventional medical or surgical treatment in transplant candidates with DMCS warrants evaluation for urgent HT.
3: Harm	C-EO	4. The presence of an irreversible clinical condition that might impair post-transplantation survival (e.g., disabling stroke) in patients with DMCS should preclude HT.

Synopsis

Over the last several years, there has been a significant decline in the early and late adverse events after the DMCS implant.[911] The outcomes of the HeartMate3 have been superior to any previous devices, particularly regarding pump thrombosis and stroke.[1044,1045] Nonetheless, because the duration of LVAD support increases, so will the possibility of adverse events. However, long-term follow-up data in patients supported with HeartMate3 LVAD are limited.[912,1046] Using the UNOS database, it was suggested that bridge to HT with LVAD confers higher early mortality.[1047] These findings were recently expanded demonstrating that post-transplant survival of patients bridged with a HeartMate3 remains inferior in the postallocation era.[1046] Whether this phenomenon is related to device-related adverse events remains unknown. Certain device-associated complications may render patients at higher risk for HT. Specifically, patients with chronic RHF and device infections are at high risk for perioperative vasoplegia, excessive bleeding, postoperative multiorgan failure, and infections. As such, these higher-risk patients should be even more carefully optimized and consideration regarding the best timing for surgery. Patients with hemocompatibility-related adverse events remain good transplant candidates, except for those with disabling strokes.

Recommendation-Specific Supportive Text

1. Strategy designations at the time of device implant are fluid, as the patient's candidacy for transplantation may change over time. About half of patients being implanted as BTT are listed for transplantation at the time of DMCS implant, and only 30.4% are transplanted at 1 year following implant.[911] Among patients implanted as BTC and DT, 15.9% and 4.7% are transplanted at 1 year.[911]
2. Life-threatening complications (e.g., intractable ventricular arrhythmias, severe RHF) in patients with DMCS refer to several clinical scenarios in which patients are at high risk of dying or have an irreversible complication. Patients remain sufficiently ill to warrant ongoing hospitalization and must continue to be deemed transplant candidates. The development of complications refractory to medical or surgical treatment warrants an evaluation for urgent HT. In several allocation systems worldwide, DCMS complications in transplant candidates qualify for prioritization for HT.
3. Severe adverse events (e.g., pump thrombosis, device infection, gastrointestinal bleeding (GIB)) are associated with increased mortality following DCMS implant.[1048] The only curative treatment for most device-specific and device-related adverse events is pump removal and HT. If the transplantation team is of the opinion that (1) a revision or exchange of the VAD will be too high risk, or (2) if the risk of death before HT exceeds the risk of post-transplant mortality, then an urgent transplant should be considered with or without temporary support.
4. Patients with DMCS and severe adverse events that could justify prioritization for HT but who have an irreversible clinical condition (e.g., disabling stroke, irreversible end-organ dysfunction) that will impair post-transplantation survival should not have their transplant prioritization changed and should be disqualified as candidates for HT.

4.4.2. Gastrointestinal Bleeding

Recommendations for Complications of Durable Mechanical Circulatory Support and Their Implications for Candidacy: Gastrointestinal Bleeding		
COR	**LOE**	**RECOMMENDATIONS**
2a	C-EO	1. For patients with DMCS and refractory gastrointestinal bleeding (GIB) who are deemed candidates for HT, when the expected wait time is short, it is reasonable to consider urgent HT to decrease the burden of blood transfusion.
2b	C-EO	2. In the setting of recurrent and refractory mucocutaneous bleeding with no identified source or a source that is not amenable to therapy, it may be reasonable to consider prioritization for HT.

Synopsis

Bleeding complications are the most frequent hemocompatibility-related adverse events in LVAD recipients, most frequently in the form of mucocutaneous bleeding events.[11, 1048–1050] Of mucocutaneous bleeding, GIB is the most common complication, occurring in 15% to 30% of patients on LVAD support.[561] In patients who suffer an initial mucocutaneous bleeding event, recurrence can be encountered in 30% to 40% of patients on LVAD support. GIB in patients on CF-LVAD support is most commonly the result of nonreversible conditions leading to arteriovenous malformations developing in the gastrointestinal tract.[1051]

Recommendation-Specific Supportive Text

1. There are currently no robust data to support the safety or efficacy of HT in patients with refractory GIB. However, bleeding is often accompanied by the need for transfusions, which is associated with important clinical implications. First, previous cardiac surgery studies suggest that blood transfusion induces an immunosuppressive state that can contribute to the development of nosocomial infections.[1052,1053] Second, blood transfusions have been associated with pulmonary insufficiency.[1054] Transfusion-associated lung injury is thought to be induced by passive transfusion of complement-activating antibodies. These antibodies may be particularly troublesome to DMCS recipients awaiting transplantation due to an increased risk of allosensitization and elevated PRAs. Thus, focused efforts must be devoted to minimizing GIB and the need for transfusion.
2. Before considering urgent HT for DMCS patients with recurrent GIB, the transplant team should ensure that the cause of GIB is related to the CF-LVAD support. Investigation should be undertaken to identify the source of bleeding, and all medical therapies should be exhausted in collaboration with a gastroenterologist before HT consideration.

4.4.3. Pump Thrombosis

Recommendations for Complications of Durable Mechanical Circulatory Support and Their Implications for Candidacy: Pump Thrombosis		
COR	**LOE**	**RECOMMENDATIONS**
2a	**C-EO**	1. In transplant candidates with confirmed device thrombosis who are hemodynamically stable and the expected wait time for a HT is short, it is reasonable to defer the pump exchange for urgent transplantation if the patient is otherwise a suitable candidate.

Synopsis

Device thrombosis refers to the progression or de novo development of a clot within the pump's flow path, including the inflow cannula, the mechanical rotor, or the outflow graft.[11] Pump thrombosis is associated with a high rate of morbidity (hemolysis, bleeding, ischemic, and hemorrhagic strokes) and increased mortality[1055] despite therapeutic anticoagulation.[1056–1058] The newest generation CF-LVAD HeartMate3 has significantly lower rates of pump thrombosis than the earlier generation of heart pumps.[918]

Recommendation-Specific Supportive Text

1. Patients for whom device exchange is deemed necessary should also be considered for HT or decommissioning (or removal), if they are hemodynamically stable and without disabling embolic phenomena. HT should receive additional consideration specifically if the expected wait time is short[937] and ventricular recovery is unlikely. It should be noted that recurrent device thrombus rates after device exchange are higher with replacement pumps.[1059,1060] In this regard, the initial experience with device exchange from HeartMate II or HVAD to a HeartMate 3 has been promising, with lower recurrent device thrombosis rates.[1061] This decision should be individualized based on patient factors, surgical expertise, and local jurisdiction.

4.4.4. Right Heart Failure

Recommendations for Complications of Durable Mechanical Circulatory Support and Their Implications for Candidacy: Right Heart Failure		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-LD**	1. Transplant candidates who remain dependent on a temporary RV device or inotropic support because of **early moderate/severe RHF** despite optimal management following DMCS implantation should be considered for urgent HT.
1	**C-LD**	2. In transplant candidates supported with a DMCS who present progressive **late post-implant RHF** despite optimal management, prioritization or urgent HT should be considered.
2b	**C-EO**	3. Pulmonary hypertension-specific therapies might be considered for acute therapy in patients with persistent PH who exhibit signs of RHF and have failed conventional medical therapy.

Synopsis

New or progressive RHF occurring in patients following LVAD is associated with an increased risk of GIB, renal failure, more frequent hospitalizations, lower QOL and functional capacity, and decreased survival.[1012, 1049, 1062–1066] RHF occurring after the operative LVAD period, "**late post-implant RHF**," can result from worsening of pre-existing pre- or postoperative RV dysfunction or can occur de novo in those with presumed normal preoperative right heart function. **Early RHF** can manifest as "**early acute**" (need for right ventricular assist device (RVAD) implant concomitant with LVAD) or "**early postimplant RHF**" (need for temporary or durable RVAD or ECMO within 30 days of LVAD implant, failure to wean off inotropes or inhaled pulmonary vasodilators within 14 days, or death due to RV failure).[1049] Management of patients with DMCS and RHF is outlined in the 2023 ISHLT guidelines for MCS.[11]

Recommendation-Specific Supportive Text

1. The risk of complications and death is high in patients with DMCS and severe **early RHF** (dependent on RVAD support or inotropic support). The increased risk of death associated with RHF is markedly attenuated following HT, with post-transplant survival similar to that in non-RHF patients.[1067] Thus, urgent HT should be considered for persistent severe early RHF despite optimal management.
2. In transplant candidates supported with a DMCS, **late postimplant RHF** is associated with significantly higher mortality. Late RHF can develop in the setting of complications that lead to volume loading (e.g., bleeding), hypoxia (e.g., pneumonia), or stimulation of the systemic inflammatory response system (e.g., infection) with concomitant hypotension and/or renal malperfusion. De novo late postimplant RHF could be the result of pulmonary embolism, acute hypoxic respiratory failure with ARDS, or excessive LVAD speeds causing LV suction and septal shift. A thorough investigation should be undertaken to look for reversible resources for RHF.[11]
3. PH-specific therapies, such as PDE5 inhibitors, might be considered for acute therapy in patients with persistent PH who exhibit signs of RHF and have failed conventional medical therapy, although the effectiveness of these therapies is unclear.[1068]

4.4.5. Infection

Recommendations for Complications of Durable Mechanical Circulatory Support and Their Implications for Candidacy: Infection		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	1. HT is the definitive cure for deep driveline infection (infection deeper than subcutaneous fascia) or pocket/ pump/ cannula infection.
1	C-EO	2. Patients with recalcitrant infection should be considered for transplant listing.
1	C-EO	3. At the time of transplant, it is important to remove all hardware (including defibrillators or pacemakers) and any infected tissue.
2a	C-EO	4. In the setting of any prior driveline or pump infection, administration of systemic pathogen-specific antibiotic therapy initiated preoperatively and continued for approximately four to six weeks after HT can be beneficial.
2a	C-LD	5. After transplantation and removal of infected LVAD (or total artificial heart), extensive irrigation with an antibiotic solution at the time of transplant and prolonged drainage can be useful to prevent recurring mediastinal infection.
3: Harm	C-EO	6. Patients with severe sepsis shock secondary to a device-related or specific infection should not be transplanted until end-organ functions recover and the sepsis is controlled.

Synopsis

The most common adverse event in the early and late periods after CF LVAD implant is major infection (early, 1.30; late, 0.43 events per patient-year).[911] Infection following DMCS implant (DMCS-specific and/or DMCS-related infections)[1049,1069] carries a high burden of morbidity and mortality, with a 3-fold risk of death compared to noninfected patients.[1070–1075] Management of DMCS-specific and related infections is detailed in the 2023 ISHLT guidelines for MCS.[11]

Recommendation-Specific Supportive Text

1-2. The only curative treatment for pump-specific infection is the removal of all device components. Patients with DMCS infections who are not transplanted have poor outcomes (55% and 34% survival at 1 and 2 years, respectively).[1076] Nonetheless, the impact of DMCS infection on HT outcomes is not well established. Studies from high-volume centers showed good outcomes following transplantation, with only a few

infections relapse.[1047,1077,1078] Still, a meta-analysis suggested that LVAD-related infections result in a 30% increase in post-transplantation mortality.[1079] Thus, in transplant candidates with pump-specific or related infection refractory to conventional therapies, prioritization or urgent HT should be considered.

3. To reduce the risk of recurrence of infection after transplantation and during immunosuppression, it is important to remove the whole system and not leave any pump parts or pieces of graft behind at the time of device explant. All precautions to avoid any intraoperative contamination should be taken.[1069,1080]
4. When transplanting a patient with a DMCS infection, administration of systemic pathogen-specific antibiotic therapy initiated preoperatively and continued postoperatively for 4 to 6 weeks can be an effective means to prevent any infection relapse.[1069,1081]
5. After transplantation and removal of infected LVAD (or TAH), extensive irrigation with antibiotic solution at the time of transplant and prolonged drainage can be useful to prevent recurring mediastinal infection.[937]
6. Patients with active infections often develop a systemic inflammatory response that leads to other organ dysfunctions,[1082] which can preclude a patient from being transplanted. Before transplanting a patient with a device-related or device-specific infection, the sepsis must be controlled, and all the end-organ functions must recover to ensure optimal outcomes following HT. [1083]

4.4.6. Neurological Complications

Recommendations for Complications of Durable Mechanical Circulatory Support and Their Implications for Candidacy: Neurological Complications		
COR	**LOE**	**RECOMMENDATIONS**
2b	**C-EO**	1. In transplant candidates with DMCS and a history of non-disabling neurological complications, it might be reasonable to consider non-urgent HT.
3: Harm	**C-EO**	2. Patients with DMCS and a history of disabling neurological complications should not be transplanted.

Synopsis

Neurological complications are common adverse events seen in patients with DMCS and are strongly associated with disability, impaired QOL, and mortality.[11,1048,1049,1084–1087] Stroke rates are highly dependent on the device model, with the lowest frequencies noted in those on HeartMate 3 support (10% at 2 years), and can be either ischemic or hemorrhagic in etiology.[913,1088,1089] Other risk factors for stroke include patient age (older patients are at a greater risk of ischemic stroke; younger patients are at a greater risk of hemorrhagic stroke), female sex, prior history of cardiovascular disease, anticoagulation dysregulation, device complication (device thrombosis, infection, root thrombus), and systemic hypertension.[1088,1090]

Recommendation-Specific Supportive Text

1. There is a sparse amount of literature and no previous specific recommendations regarding the decision to transplant a patient with neurological complications secondary to DMCS. However, the type and location of the neurological event and the clinical status of the patient often dictate management. In this setting, eligibility for HT assessed by a multidisciplinary team, including neuro specialists, might be considered.
2. HT should not be performed in DMCS patients with a history of disabling stroke and neurological complications. The risks associated with HT surgery for patients after disabling stroke and neurological complications are potentially harmful.

4.4.7. Ventricular Arrhythmias

Recommendations for Complications of Durable Mechanical Circulatory Support and Their Implications for Candidacy: Ventricular Arrhythmias		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-EO**	1. DMCS patients with refractory ventricular arrhythmias leading to device malfunction, RHF, hemodynamic compromise, or implantable ICD shocks for electrical storm should be prioritized for HT.
2a	**C-LD**	2. DMCS patients with refractory, hemodynamically unstable ventricular tachyarrhythmias can be considered for ablation therapy by an experienced electrophysiologist prior to an urgent listing for HT.

Synopsis

Refractory sustained VTA that persist despite best attempts at medical suppressive therapy and electrophysiological ablation occur in 20% to 50% of DMCS recipients, and may lead to RHF and portend poor outcomes, especially in nonischemic cardiomyopathy.[11,1091,1092]

Recommendation-Specific Supportive Text

1. Transplant candidates with DMCS and refractory VTA leading to device malfunction, RHF, hemodynamic compromise or persistent ICD shocks for electrical storm should be prioritized for urgent HT.
2. Catheter ablation for VTA can be safely and effectively performed in patients with LVAD, although LVAD-specific intricacies must be considered. Epicardial mapping and ablation after LVAD are complicated because of the presence of adhesions, and alternative strategies to target epicardial substrate should be considered. Intraoperative VTA ablation during LVAD implantation can be effective in high-risk HF patients who present with a high VTA burden before LVAD placement. Additional studies are needed to identify the optimal intraoperative mapping modalities and ablation strategies for intraoperative VTA intervention during LVAD implantation.[1093–1095]

4.4.8. End-Organ Dysfunction

Recommendations for Complications of Durable Mechanical Circulatory Support and Their Implications for Candidacy: End-Organ Dysfunction		
COR	**LOE**	**RECOMMENDATIONS**
1	C-EO	1. Transplant candidates with DMCS and acute end-organ dysfunction before device implant should be monitored closely to assess end-organ function recovery.
1	C-EO	2. In patients with DMCS and acute end-organ dysfunction and otherwise suitable for transplantation, efforts should be made to optimize organ function recovery before listing for HT.

Synopsis

End-organ dysfunction secondary to decreased perfusion and venous congestion is frequent in AdvHF patients requiring DMCS.[1096,1097] A benefit of LVAD therapy is the improvement in end-organ function to allow reappraisal of transplant eligibility. The positive influence of LVAD therapy in end-organ recovery appears to take place early during the postoperative course, within the first 1 to 3 months after implant, which can influence the duration of LVAD support and the timing of listing.[912] In patients with chronic end-organ dysfunction, recovery following DMCS implantation is less predictable and depends on the etiology and underlying mechanism.

Recommendation-Specific Supportive Text

1. A close follow-up of all organ function is recommended in patients with DMCS, regardless of the intended implant strategy.[11] In transplant candidates, organ recovery might impact transplant eligibility and the timing of listing or prioritization for HT.
2. To optimize post-transplant outcomes and organ utilization, transplant candidates with DMCS and renal and/or hepatic dysfunction should have a period of hemodynamic optimization (with inotropic and/or tMCS if clinically indicated) with the goal of volume optimization, before being transplanted.[1096,1098]

4.4.9. Complications of DMCS and Their Implications for Candidacy in the Pediatric Population

Recommendations for Complications of Durable Mechanical Circulatory Support and Their Implications for Candidacy: The Pediatric Population		
COR	**LOE**	**RECOMMENDATIONS**
1	C-LD	1. In pediatric patients with hepatic and/or renal dysfunction prior to DMCS implant, evaluation of its severity and reversibility is recommended before HT.
2b	C-EO	2. Although effectiveness is unknown, simultaneous heart-liver or SHKT transplantation might be considered in selected children with DMCS and persistent significant liver or kidney dysfunction, in high-volume centers with expertise in multi-organ transplantation.
2b	C-EO	3. Urgent transplantation may be considered in pediatric transplant candidates with DCMS and life-threatening device-related or specific complications that cannot be successfully treated medically or surgically.

Recommendation-Specific Supportive Text

1. Children with underlying liver disease may face higher operative mortality and should be evaluated carefully by an experienced multidisciplinary team. The MELD-XI score has been shown to stratify the mortality risk of pediatric patients undergoing HT.[402,1099] In an analysis of the Pedimacs registry, patients with increasing or continued high MELD-XI scores early following DMCS implant had the worst survival.[647] Renal dysfunction is an independent risk factor for waiting list mortality in children, with or without MCS.[1100] Although a minority of children have persistent acute kidney injury following DMCS,[1101] the extent and rate of recovery of renal function are difficult to predict and depend on the extent of renal damage before DCMS initiation. Improvement of renal function, usually observed within a few weeks, is associated with a better post-transplant survival.[1100–1102] Failure to normalize renal function 30 days following DMCS implant is highly associated with CKD,[1100] prolonged hospital stay,[1103] and decreased survival after HT.[1102]
2. Only very few children or adults with CHD who underwent simultaneous heart-liver transplantation had DMCS at the time of transplantation.[227,1104] Similarly, there is limited evidence of the benefit of a SHKT in pediatric patients with DMCS.[1105] More data are needed to define thresholds of liver and kidney disease that should preclude HT alone, especially in the pediatric population.
3. Adverse events in children with DMCS are frequent and associated with increased morbidity and mortality.[1106] Several studies showed similar post-transplant survival in DMCS and non-DMCS children,[945,1107,1108] but the impact of each type of adverse event on HT outcomes remains unknown.

4.5. Considerations for Patients With Temporary Mechanical Circulatory Support

Recommendation for Indications and Eligibility for Heart Transplantation in Patients with Temporary Mechanical Circulatory Support		
COR	**LOE**	**RECOMMENDATIONS**
1	**C-LD**	1. Patients in cardiogenic shock refractory to medical therapy supported with tMCS* (right, left, or biventricular) should be considered for urgent HT: • If there is a high likelihood that heart function will not recover • If they are otherwise deemed suitable for HT • If another option for DMCS or cardiac replacement is not appropriate • If the anticipated waiting time is short • When hemodynamic parameters are stabilized • When end-organ functions recovered if initially impaired • In experienced centers.
1	**C-LD**	2. In patients with tMCS, indication and eligibility for urgent HT should be assessed promptly by a dedicated and specialized multidisciplinary team.
1	**C-EO**	3. A thorough assessment of the neurological status must be performed before considering urgent HT in transplant candidates with tMCS.
3: Harm	**C-EO**	4. Patients with tMCS and ongoing end-organ dysfunctions should not be considered for HT alone until recovery or demonstration of the reversibility before HT.

*tMCS support refers to intra-aortic balloon pump, veno-arterial membrane oxygenation, percutaneous microaxial rotary pump, percutaneously or surgicallyimplanted external centrifugal or pulsatile pump.

Synopsis

With the increasing use of tMCS in patients with refractory cardiogenic shock, the BTT strategy with tMCS (BTT-tMCS strategy) is expanding.[80] Depending on the country, the allocation system, and the type of device, the proportion of heart recipients with tMCS at the time of transplantation varies from almost zero to 25%.[80,88,1109,1110] These numbers have increased with the change in the allocation system in the USA, favoring tMCS for urgent status prioritization.[1111] This subpopulation represents the sickest patients with the highest risk of death before HT and patients for whom HT may provide a survival benefit.[1110] Therefore, patients with tMCS are allocated to the highest priority status in most allocation systems (Table 23). However, the optimal balance between the risk of imminent death and good outcomes after HT is difficult to define. Contemporary, retrospective observational studies analyzing the effect of tMCS on survival after HT have produced mixed results.[1110–1118] The clinical status, comorbidities, and end-organ function recovery at the time of HT highly impact post-transplant survival rates in

this population. The success of the BTT-tMCS strategy also relies on donor availability, the local allocation system, and the center's expertise.

Recommendation-Specific Supportive Text

1. Most allocation systems across the world prioritize patients with the highest risk of early death, including patients with tMCS. However, selection criteria vary among countries and teams, and more work is needed to define appropriate candidates for BTT-tMCS. The BTT-tMCS strategy has been shown to be safe and effective in some studies,[1124] but the appropriateness of the use of tMCS in this setting and its effect on post-transplant survival remain controversial.[1116,1125,1126] Importantly, variability in survival following HT and BTT-tMCS has been observed, ranging from 50% to 90% at 1 year.[1113] An analysis of a large international cohort of patients BTT with MCS identified ECMO and percutaneous temporary LVADs as predictors of mortality after transplant.[1118] Patient selection for BTT-tMCS strategy is key to ensuring good outcomes. Individualizing the bridging decision based on clinical risk profile in patients supported tMCS may improve patient outcomes, organ utilization, as well as post-transplant outcomes.
2. Pre-transplant assessment must be performed rapidly (within a few days) when HT is considered in patients with tMCS. The risks of complications and death are associated with the duration of support.[1125,1127] In most studies, the time between tMCS initiation and HT is less than 15 days, and the waitlist mortality varies between 0% and 28%.[1113,1114] Other long-term strategies must be considered when the anticipated waiting time is long (e.g., highly sensitized, extreme weights).
3. Neurological complications, such as hemorrhagic or ischemic strokes, are common in patients with tMCS.[1125] In patients sedated and mechanically ventilated, the transplant team must ensure neurological integrity to avoid futile HT and organ loss. All efforts must be made to inform the patient and seek his/her consent for HT.
4. End-organ function is frequently impaired in patients with refractory cardiogenic shock.[1128] Acute kidney injury occurs in 13% to 28% in patients with cardiogenic shock, and 20% will require continuous renal replacement therapy.[1129–1132] Although tMCS may restore adequate systemic perfusion and allow end-organ functions to recover, dynamic assessment of end-organ function is essential to determine transplant suitability. Liver dysfunction, mechanical ventilation, and renal insufficiency are strongly associated with early mortality following HT.[1133–1135] Post-transplant survival decreases incrementally with the number of failing organs. Several studies suggested the utility of a scoring system for organ failure in predicting survival after HT.[88,1134] In very selected patients, multiorgan transplantation could be considered.

Table 23 Comparison of the Highest Priority Groups and tMCS Between the Current Allocation Systems in the USA, Canada, France, Spain, Eurotransplant, Italy, and the United Kingdom

Countries	High priority listing status		
USA[a],[1119]	***Status 1*** - VA-ECMO (< 7 days) - Nondischargeable BiVAD	***Status 2*** - Nondischargeable LVAD, IABP, or percutaneous MCS - MCS with malfunctioning - TAH, BiVAD, RVAD, or VAD for single ventricle	***Status 3*** - MCS with complications -ECMO ≥7 days - Any other tMCS after 14 days
Canada[1120]	***Status 4—National prioritization*** - Dependent on temporary BiVAD, RVAD, or LVAD (excluding IABP), unable to wean, and not a candidate for durable LVAD therapy - TAH that is nondischargeable from the hospital - Hospitalized durable LVAD patients with severe LVAD complications - Mechanically ventilated on high dose single (milrinone > 0.5 mcg/kg/min OR dobutamine > 10 mcg/kg/min) or > 2 inotropes/ vasoactives and not a durable LVAD candidate	***Status 3.5—Provincial prioritization*** - Temporary surgical paracorporeal LVAD not meeting status 4 criteria - Temporary percutaneous LVAD excluding IABP (i.e., tandem heart, Impella) not meeting status 4 criteria - High dose single or multiple inotropes/vasoactives in patients requiring ICU/CCU admission who are NOT candidates for durable LVAD - Refractory life-threatening arrhythmias requiring continuous intravenous antiarrhythmic drug therapy and not amenable to, or failed, ventricular tachycardia ablation	
France[88]	***Candidate National Risk Score*** (from 0-1,151 points) - Including: VA-ECMO, natriuretic peptides, renal function, total bilirubin - HT candidate with the highest national score - Time allowed for ECMO patients bridged to HT to stay in the highest priority group < 12-16 days		
Spain[1109]	***Urgency status 0***- Dependent on tMCS, including ECMO for at least 48 hours (without multiorgan failure)		
Eurotransplant-[b],[1121]	***High Urgent National/International*** - Short-term MCS	*Status 1A (only Netherlands)* - Unstable patient dependent on high dose inotropes and/ or IABP with restored organ function.	
Italy[1122]	***Status 1*** - ECMO - IABP - Mechanical ventilation + IV inotropes + IABP		
United Kingdom[1123]	***Super-urgent heart allocation scheme (SUHAS)*** - Short-term MCS - HT candidate (a) on IABP support (b) at imminent risk of death or irreversible complications. Meets criteria for urgent listing		

Abbreviations: BiVAD, biventricular assist device; HT, heart transplantation; IABP, intra-aortic balloon pump; ICU, intensive care unit; MCS, mechanical circulatory support; LVAD, left ventricular assist device; TAH, total artificial heart; VAD, ventricular assist device; VA-ECMO, veno-arterial membrane oxygenation; RVAD, right ventricular assist device; CCU, critical care unit.

[a]As of October 2018.

[b]Countries that are members of Eurotransplant: Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, The Netherlands, and Slovenia.

EVIDENCE GAPS AND FUTURE RESEARCH DIRECTIONS

Future research is needed to address the perceived gaps in different areas to improve future guidelines for the care of HT candidates. The following issues were raised by the various coauthors of the current document; they encompass areas for which there was not enough evidence to make recommendations at the time but could be achieved by ongoing analyses of registry data worldwide and multicenter collaborative studies (Table 24).

Table 24 Evidence Gaps and Future Research Directions

Definition

- Improving the prioritization of HT candidates for optimal clinical outcomes.
- Defining the optimal matching phenotypes between donor and recipient to maximize organ usage and outcomes.
- Defining the optimal timing and frequency of frailty assessments in AdvHF.

Screening

- Timing of listing after malignancy: a personalized approach using precision immune-oncology and new tools, such as circulating tumor DNA, may detect microscopic residual disease in patients in remission. This approach may significantly reduce the wait time before transplant consideration and listing.
- Improved delineation of the need for SHKT (or liver) vs HT alone by defining optimal biomarker thresholds for eGFR, MELD score, or other biomarkers.
- Defining cut-off values for NPs as a screening tool to assess candidacy.
- Uniformizing policy screening for HLA antibodies.

Diagnostics and monitoring

- Developing threshold/clinical milestones for listing patients with hypertrophic/restrictive cardiomyopathies.
- The impact of applying precision medicine approach tailoring HF therapies to individual patient profiles on HT candidacy.
- Integrating artificial intelligence and machine learning in HF management to enable the development of predictive models for early intervention, risk stratification, and personalized treatment recommendations.

Medical therapies and emerging technologies

Well-conducted clinical trials are needed to define the optimal medical management in different areas such as:

- Desensitization strategies.
- Anticoagulation strategies beyond warfarin, incorporating NOAC and the new reversal agents, compared to usual care.
- The advent of new specific disease-modifying therapies, such as cardiac myosin inhibitors, Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) and other genetic modification techniques for hypertrophic cardiomyopathy (and potentially other diseases), and their impact on post-transplant outcomes.
- Pharmacologic agents for obesity and their potential impact on transplant candidacy.
- Improved treatments for viral infection (HIV, hepatitis, etc.) and their potential impact on transplant candidacy and management.
- The effect of many drugs on the occurrence of PGD, such as antiarrhythmics (mainly amiodarone) and their combination, and SGLT2 inhibitors, in addition to those mentioned above.
- Use of induction therapies: when, for whom, which agent, and optimal dosing.
- Exploring emerging therapeutic approaches focusing on underlying mechanisms of HF rather than on alleviating symptoms, and investigating their implications for time-appropriate transplant evaluation (i.e., gene-editing techniques, such as CRISPR-Cas9, for correcting genetic mutations that contribute to HF; regenerative medicine approaches, including stem cell therapy and tissue engineering for repairing damaged cardiac tissue and restoring function).

Device management and advanced therapies

Well-conducted clinical trials are needed to define the optimal device selection and management of HT candidates in areas such as:

- Indications for and individualized selection of the optimal tMCS.
- The optimal timing for listing patients on tMCS (including ExtraCorporeal Life Support or ExtraCorporeal Membrane Oxygenation).
- The impact of integrating regenerative medicine (stem cell therapy and tissue engineering) to repair damaged cardiac tissue and restore function on DMCS explantation and delisting.

Clinical outcomes

- The long-term impact of desensitization therapies on the occurrence of antibody-mediated rejection and CAV.
- The impact of increasing use of donor organs after circulatory death on wait times, outcomes, and thresholds for transplant.
- Investigating the relationship between pre-transplant frailty and post-transplant outcomes.
- Defining the mechanism of the relationship between pre-transplant frailty and post-transplant outcomes (association vs causation). Can frailty be reversed, and if so, will outcomes improve?

Comorbidities

- The candidacy and timing of listing for patients with “rare” diseases, such as amyloidosis, sarcoidosis, systemic lupus erythematous, etc.
- The impact of liver dysfunction (liver fibrosis vs cirrhosis on histology) on post-transplant outcomes.
- Role of heart-liver transplant in highly allosensitized individuals.
- Delineating the biological mechanisms of frailty and understanding the trajectories of frailty will help to define the timing and the aggressiveness of specific interventions.

Abbreviations: AdvHF, advanced heart failure; CAV, cardiac allograft vasculopathy; DMCS, durable mechanical circulatory support; eGFR, estimated glomerular filtration rate; HF, heart failure; HIV, human immunodeficiency virus; HLA, human leukocyte antigen; HT, heart transplantation; MELD, model for end-stage liver disease; NOAC, new oral anticoagulants; NP, natriuretic peptides; PGD, primary graft dysfunction; SGLT2, sodium-glucose cotransporter-2; SHKT simultaneous heart-kidney transplantation; tMCS, temporary mechanical circulatory support.

APPENDIX

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