Clinical Guidelines for Adult Heart Transplantation in British Columbia

REVISED: DATE: OCTOBER 28, 2025

The contents of this Clinical Guideline have been prepared by members of the transplant team and reviewed and endorsed by Dr Anson Cheung, Surgical Director Adult Heart Transplant Program and Dr Brian Clarke, Medical Director Adult Heart Transplant Program & Wynne Chiu, Clinical Nurse Specialist:

Signed: Anson Cheung

Signed: Brian Clarke

Signed: Wynne Chiu

Table of Contents

<u>1</u> <u>II</u>	NTRODUCTION	
1.1	BACKGROUND	
1.2	PHILOSOPHY AND DECISION-MAKING	
1.2.1		
1.3	THE HEART TRANSPLANT TEAM	
<u>2</u> R	EFERRAL AND WORKUP FOR HEART TRANSPLANT	9
2.1	Referral	
2.1	URGENT INPATIENT REFERRALS FROM OTHER HOSPITALS	
2.2	PEDIATRIC REFERRALS	
2.3 2.4	REFERRAL FROM THE VIRANI PACIFIC ADULT CONGENITAL HEART CLINIC (VPACH) FOR PATIENTS WITH FONTAN	
	CIATED LIVER DISEASE	10
2.5	PATIENT ASSESSMENT	
2.5.1		
2.5.1		
2.5.2		
2.5.4		
2.6	PATIENT AND FAMILY PREPARATION	
2.7	PSYCHOSOCIAL ASSESSMENT	
2.7.1		
2.7.2		
2.7.3		
	SELECTION OF CANDIDATES	
2.8.1		
2.8.2	•	
2.8.3		
<u>3</u> <u>T</u>	RANSPLANT LISTING	28
3.1	PATIENT LISTING	
3.2	PRIORITIZING PATIENTS ON THE HEART TRANSPLANT WAIT LIST	
3.3	COMBINED HEART AND KIDNEY TRANSPLANTATION.	
3.3.1		
	IMMUNOLOGICAL SCREENING AND MONITORING WHILE WAITING FOR TRANSPLANT	
	HEPATITIS C DONORS	
3.3	TILFATTIS C DONORS	
<u>4</u> <u>T</u>	HE TRANSPLANT	44
4.1	MATCHING DONOR TO RECIPIENT - IMMUNOLOGY	
4.2	DONOR CRITERIA	
4.3	EXCEPTIONAL DISTRIBUTION OF ORGANS	
4.4 4.5	CALL IN FOR HEART TRANSPLANT PRE-OPERATIVE PROTOCOL	
4.5 4.5.1		
4.5.1	•	
4.3.2	I NAINOFLAIN I NEAR I IIVIIVIUNUSUPPKESSIUN (IVIULIIPHASE)	45

4.5.3	Transplant Heart Antithymocyte Globulin Rabbit (Multiphase) – if applicable	50
4.6	THE TRANSPLANT SURGERY	50
<u>5</u> <u>P</u>	OST-HEART TRANSPLANT	51
5.1	Most Responsible Physician	51
5.2	POST-OPERATIVE ORDERS	51
5.2.1	CARD SURG HEART TRANSPLANT POST OPERATIVE (MULTIPHASE), CSICU ADMISSION	51
5.3	IMMUNOSUPPRESSION INTRA- AND IMMEDIATELY POST-OPERATIVELY	55
5.3.1		
5.3.2	ANTITHYMOCYTE GLOBULIN (RATG) INDUCTION	55
Post-	HEART TRANSPLANT DESENSITIZATION THERAPY	56
5.4	POST-TRANSPLANT RECOVERY	57
5.4.1	EARLY POST-OPERATIVE PHASE	57
5.4.2	COMBINED HEART-KIDNEY TRANSPLANT	57
5.5	TRANSFER TO 5A (POST-OPERATIVE WARD)	58
5.5.1	Transfer orders	58
5.5.2	Most Responsible Physician on 5A	58
5.5.3	Infection Control	58
5.5.4	IMMUNOSUPPRESSION	58
5.5.6	PATIENT EDUCATION	59
5.6	DISCHARGE	60
5.6.1	DISCHARGE PRESCRIPTIONS	60
<u>6</u> <u>L</u>	ONG-TERM	61
6.1	FOLLOW-UP	61
6.2	BIOPSY SURVEILLANCE	
6.4	IMMUNOLOGICAL SURVEILLANCE POST-TRANSPLANT	
6.5	ALLOMAP	
6.6	LONG-TERM CARE - APPROACH	
6.6.1		
6.6.2		
6.7	IMMUNOSUPPRESSION	
6.7.1		
6.7.2		
TIME	Post Transplant (Months)	
	DSPORINE TROUGH CONCENTRATION (NG/ML)	
	Post Transplant (Months)	
	OSPORINE C ₂ CONCENTRATION (NG/ML)	
6.7.3	• • •	
6.7.4		
7.1	CELLULAR REJECTION TREATMENT	
7.2	ANTIBODY MEDIATED REJECTION	
7.2.1		
	, ,	
7.2.2		
7.2.2 7.3	INFECTION PROPHYLAXIS	

7.3.2		
7.3.3	3 PNEUMOCYSTIC JIROVECI PNEUMONIA (PJP)	82
7.3.4	4 Toxoplasmosis	82
7.3.5		
7.3.6		
7.3.7		
7.4	NEUTROPENIA/LEUKOPENIA	84
7.5	OTHER POST-TRANSPLANT MEDICATIONS	
7.5.:		
7.5.2	2 CANCER SURVEILLANCE	87
7.5.3		
7.5.4		
7.5.5	5 Pregnancy	88
<u>8</u> !	REFERENCES	89
9 /	APPENDIX	92

1 Introduction

1.1 Background

British Columbia's first heart transplant was performed at Vancouver General Hospital in 1988. One hundred and eleven transplants were performed at that site until 1996. At that time, the program was moved to St Paul's Hospital (SPH) when the site was named the Provincial Heart Centre. Since 1996, over 400 heart transplants have been performed at SPH

This Clinical Guideline contains the current practices in the BC Adult Heart Transplant Program. Program members are a part of the Canadian Cardiac Transplant Network (CCTN). This network is an affiliate of the Canadian Cardiovascular Society (CCS) and works closely with the Canadian Society of Transplantation (CST), The International Society for Heart and Lung Transplantation (ISHLT) and the Canadian Blood Services (CBS). The CCTN sets policy for Heart Transplant Programs across the country.

The Adult Heart Transplant Program annually reviews its outcomes and has a mechanism to review practices weekly. An annual report is created by BC Transplant and presented to the team for discussion and planning. A copy of this report is available upon request to the Clinical Nurse Specialist (wchiu@providencehealth.bc.ca).

The Program follows the Canadian Cardiovascular Society Consensus (CCS) Statements and Guidelines as well as resources released by the Canadian Cardiac Transplant Network (CCTN) as a basis for its protocols pre-and post-heart transplant (see hyperlink below). As well, the team refers to the International Society for Heart and Lung Transplant Consensus documents and Guidelines.

1.2 Philosophy and Decision-making

The team recognizes that decision making around transplant candidacy can be complex as every person referred to us has unique circumstances. Hence very few "absolute" rules exist.

1.2.1 Guiding Principles

Our primary focus is the well-being and autonomy of the patient in our care.

Resource utilization impacts on staff, and program or system issues are not considerations in decision-making for individual patients.

Communication with the patient is clear, respectful, and avoids false hope. In conjunction with the patient, assessment will focus on whether transplantation is the best option given the patient's full medical, lifestyle and psychosocial situation.

It should be remembered that possible alternatives include no intervention and palliative care

The team's responsibility for stewardship of donated organs is enacted by basing practice on the best available evidence including current peer reviewed guidelines for transplantation.

Exclusion criteria are based on those of the Canadian Cardiovascular Transplant Network, the Canadian Cardiovascular Society, and the International Society for Heart and Lung Transplantation, all of which are publicly available. When not clear in the guidelines, where possible, decisions regarding aspects of assessment should be evidence-based.

The decision-making process for heart transplantation is clear and there is transparency regarding the reasons for decisions that are made.

Decisions are informed by assessments from the psychosocial team and external specialists (when consulted). Decisions and the decision-making process are documented in the patient's chart.

The decision to implant a VAD and/or list a patient for heart transplant shall be made by the on-service transplant surgeon, the on-service cardiologist and one other cardiologist in the program with input and discussion from colleagues, consulting specialists and the allied health team. If the decision is made outside of normal working hours, the VAD Coordinator on call shall provide input regarding psychosocial information available. In cases where a stalemate exists, the final decision will be made by the heads of cardiac surgery and cardiology or designate/s. This process shall be reviewed at the annually.

All patients suitable for assessment are viewed as potential transplant candidates and, if identified, every effort is made to mitigate any exclusion criteria.

Medical and psychosocial issues may change over time. Reassessment will be considered when these changes are sustained for a predetermined length of time; or if there are marked changes in the patient's home environment, coping or health behaviors. Mechanical circulatory support (MCS) as a bridge to heart transplant candidacy is considered in cases where modifiable exclusion criteria exist and more time is needed to determine if successful change is possible.

There is a culture of respect among colleagues.

Different perspectives and opinions are expected and valued among colleagues. All are given serious consideration. The expertise and scopes of practice of all team members are respected.

Care providers are mindful of their own set of personal values and beliefs and their potential impact on decisions.

Care must be taken to be cognizant of personal biases that arise both negatively (e.g., patient criminal history, developmental disability, racist patient attitudes) and positively (e.g., patient likeability, expressions of remorse, age, verbal skills, parenting status). "Care must be taken to ensure that psychosocial factors predictive of outcome are not confused with judgments of an individual's social worth." (Journal of Heart and Lung Transplantation listing criteria 2006, Page 1034 http://www.jhltonline.org/article/S1053-2498(06)00460-8/pdf)

1.3 The Heart Transplant Team

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Virani, Sean	Heart Transplant Cardiologist	svirani3@providencehealth.bc.ca	604-682-2344

2 Referral and Workup for Heart Transplant

2.1 Referral

The Adult Heart Transplant Program accepts referrals from around the province of British Columbia and Yukon Territory. From time to time the program also receives out-of-province referrals.

The program provides advanced heart failure therapies for patients who are being assessed for transplant candidacy. Early referral to the program is crucial as late referral significantly affects outcomes. In general, criteria for referral for transplantation candidacy are as follows:

- Age although no absolute age cutoff, referrals over the age of 70 should have no major co morbidities.
- End-stage heart failure not responding to medical therapy and/or cardiogenic shock with inotrope dependence.
- No other medical or surgical therapies available.
- Absence of
 - Life limiting co morbidities.
 - o Life-threatening non-adherence to medical therapy.

Adult patients should be referred to the Pre-Transplant Clinic. Non-emergent referrals should be made using this <u>form</u>. For emergent referrals or questions please call the Transplant Cardiologist on call.

Business Hours: 604-806-8602

After Hours (Transplant Cardiologist on call): 604-877-2240

Toll Free: 1-800-663-6189

Address: St. Paul's Hospital Pre Heart Transplant Clinic 5C, 1081 Burrard Street Vancouver, BC, V6Z 1Y6

Sometimes admission is required to complete the assessment process, depending on the patient and their condition. If the patient is a potential heart transplant candidate, the Pre-Transplant clinic will monitor their progress. If the patient is not a candidate – either because they are too well or not suitable, the patient will be transferred to Heart Function clinic or discharged back to the referring physician or clinic, clearly outlining reasons for transfer and criteria for re-referral.

2.2 Urgent Inpatient Referrals from other Hospitals

Urgent referrals from other centres can be made by contacting the Heart Transplant (HTx) Cardiologist or HTx Surgeon on-call through BC Transplant 604-877-2240 or St Paul's Hospital (604) 682-2344.

2.3 Pediatric Referrals

Pediatric patients should be referred to the Pediatric Heart Transplant Program at BC Children's Hospital.

2.4 Referral from the Virani Pacific Adult Congenital Heart Clinic (VPACH) for patients with Fontan Associated Liver Disease

Patients with Fontan-associated liver disease may require referral for a heart and/or liver transplant. Due to the complexities of diagnostic testing, the need for input from various specialists, and the involvement of multiple clinical team members, the following SOP was developed to clarify the referral process between the two specialty cardiac clinics within the Heart Center—VPACH and Pre-Transplant. This process ensures that all necessary parties are involved and that the most appropriate determination is made regarding the patient's need for a combined transplant and their candidacy





Referral process for heart and/or liver transplant for patients with Fontan associated liver disease

Site Applicability & scope:

This SOP applies to all clinical members of the St. Paul's Hospital heart transplant & the VPACH program

Procedures:

- Once VPACH team has determined need for possible combined heart or heart/Liver transplant; in concordance with the <u>ISHLT Guidelines for evaluation of cardiac transplant candidates</u> (page 37-40)
 - 1.1. Complete "Heart Transplant Referral Checklist" (See appendix A), to be sent along with referral)
 - 1.2. Use of Cerner "Referral to Heart Transplant Program" order
 - 1.3. RN to RN handover (review checklist together and any other pertinent information) via email
- Heart transplant clinic RN to review referral with on call MD, confirm initiation of the TRANSPLANT HEART AMB Heart Transplant Assessment (Routine). Cross reference checklist sent by VPACH team with referral & ensures the following is ordered as part of assessment if needed:
 - 2.1. Cardiac MRI if not done in last 12 months
 - 2.2. RHC if not done in past 12 months
 - 2.2.1. Ensure RHC is ordered to be performed by Dr. Ron Carere or Dr. Scott Lim
 - 2.3. CT Cardiac with contrast (to assess for VV, AP collaterals):
 - 2.3.1. Priority: Routine
 - 2.3.2. Pertinent Clinical Information/Indication: assess transplant known FONTAN
 - 2.3.3. Special instructions: To be done at SPH by Drs. Ellis, Leipsic, Blanke
 - 2.3.4. Scheduling Location: SPH Med Imaging
 - 2.4. CT Abdomen Multiphase w/+w/o contrast:
 - 2.4.1. Pertinent Clinical Information: Fontan liver cirrhosis. Pre heart transplant assessment
 - 2.5. Fibroscan
 - 2.5.1. Reason for exam: Fontan associated liver disease
 - 2.5.2. Use specified paper requisition (see appendix B)
 - 2.6. GI referral for upper endoscopy IF there is an ultrasound or CT report of "cirrhosis" 2.6.1. Reason for exam: Fontan liver disease/cirrhosis, rule out varices
 - 2.7. Referral to Dr. Vlad Marquez (not to pre-liver transplant)
 - 2.7.1. Fax and email referral please (vladimir.marquez@vch.ca)
- 3. Heart transplant program assumes the "Most responsible Physician" (MRP) role and directs care

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Effective date: 07/Aug/2025 Page 1 of 7





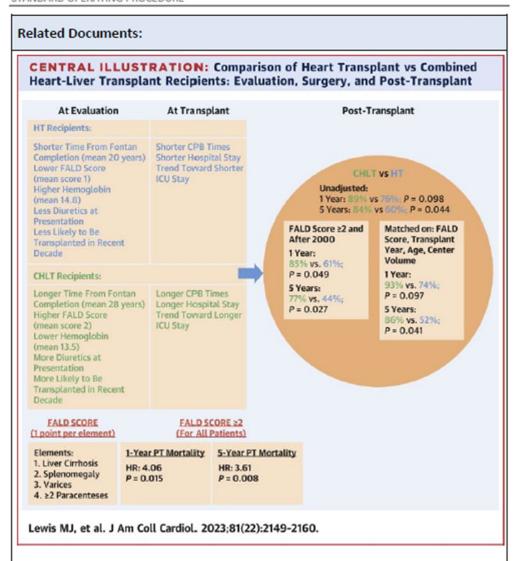
- Once assessment testing is completed, patient case is to be brought to heart transplant team multidisciplinary rounds
 - 4.1. Submit order "Cardiac Case Conference Order" Heart Transplant, when the following team members can attend:
 - 4.1.1. Dr. Gnalini Sathananthan VPACH
 - 4.1.2. Patient's VPACH primary physician
 - 4.1.3. Jillisa Byard VPACH CNS
 - 4.1.4. Dr. Vlad Marquez VGH Medical Director, Liver Transplant
 - 4.1.5. Dr. Peter Kim VGH Surgical Director, Liver transplant
 - 4.2. Attending MD &/or Fellow to calculate the following scores to be presented during discussion presentation
 - 4.2.1. VAST Score: Varices (1), Ascites (1), Splenomegaly (1), thrombocytopenia (1) (>2 higher risk of major adverse events including death, liver transplant, hepatocellular carcinoma
 - 4.2.2. Foster Score: Cirrhosis (1) Esophageal Varices (1) Splenomegaly (1) ≥ 2 paracentesis (1). A score ≥ 2 associated with worse survival and combined heart liver had superior survival with scores ≥ 2.
 - 4.2.3. FonLiver score: See "Related Documents" section
 - Determine if additional testing is required (i.e. liver biopsy, or other testing based on preliminary discussions)
 - 4.4. If no additional testing required and decision is ready to be made, determine transplant candidacy and timing
- If combined Heart & Liver transplant is required, the heart transplant program will initiate referral to Edmonton or Toronto transplant program
- 6. Referral to the Toronto transplant program:
 - 6.1. SPH transplant program will make the referral to the heart transplant program at University Health Network (UHN) through regular referral process: https://www.uhn.ca/Transplant/Heart_Transplant_Program/Heart_Transplant_Clinic
 - 6.2. Send referral requests with the following information:
 - 6.2.1. Most recent notes from: Heart transplant team, VPACH, Dr. Vlad Marquez
 - 6.2.2. Most recent clinic notes
 - 6.2.3. Any other specialist's consultations,
 - 6.2.4. Most recent discharge summary
 - 6.2.5. Summary of interdisciplinary team meetings (if applicable)
 - 6.2.6. If performed: Echo, TEE
 - 6.2.7. Tests from 2.1-2.6
 - 6.3. Obtain hard copies of all imaging (echo, TEE if there, cardiac CT, cardiac MRI, abdominal CT, chest CT) onto a CD and courier to:
 - Dr. Michael McDonald, Medical Director, Heart Transplant Program, 585 University Ave, Toronto General Hospital, Mars 9 9081, Toronto, ON, M5G 2C4

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Effective date: 07/Aug/2025 Page 2 of 7





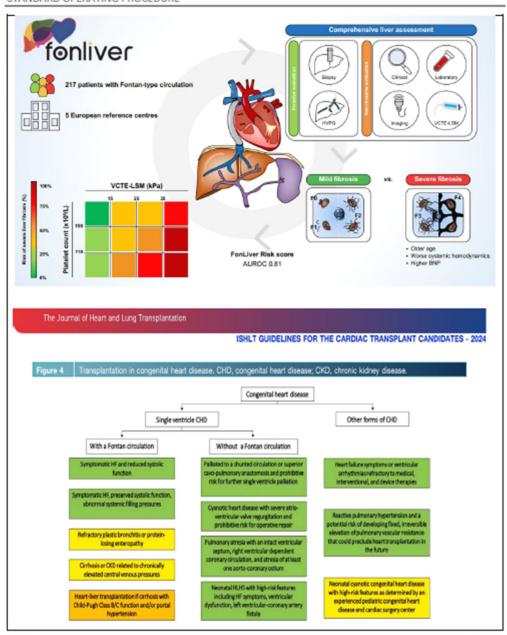


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Effective date: 07/Aug/2025 Page 4 of 7





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Appendices

A: Checklist to be completed by VPACH program and sent along with formal referral to the heart transplant program (Note: tests do not need to be completed by VPACH prior to referral, it just needs to be noted if they were completed or not so transplant clinic can order if necessary)

Completed in last 12 months?	Date completed:
Yes / No	
	ronths? Yes / No

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Effective date: 07/Aug/2025 Page 5 of 7





B: Specified paper requisition for ordering Fibroscan:



Providence Health Care

Heart Centre

Patient Label

DATE

Referral to:

PACIFIC GASTROENTEROLOGY ASSOCIATES

770 1190 Hornby Street Vancouver BC V6Z 2K5 PHONE: 604 688 6332 FAX: 604 689 2004

Attention: Dr Hin Hin Ko or Dr Alnoor Ramji

Reason for Referral:

☑ Fibroscan (Liver Surveillance for Fontan Associated Liver Disease)

Included documents:

most recent liver imaging result (available in care connect)

☑ most recent Pre-Heart Transplant clinic note

Referring physician: Dr. Brian Clarke (MSP# 37423)

Referral request:

Liver Surveillance due: month/year

Language spoken (if not English): ____

Interpreter required: Yes / No

Patient is aware of consult: Yes / No

*Please contact clinic to coordinate appointment (info below)

Referral from:

Pre-Heart Transplant Clinic St. Paul's Hospital, SCO Providence Building 1081 Burrard Street Vancouver, BC V6Z 1Y6 PHONE: 604-906-9602 FAX: 604-6752658

hearttransplant@providencehealth.bc.ca

August 2025

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Effective date: 07/Aug/2025 Page 6 of 7





APPROVALS				
Heart Transplant Medical Director		Brian Clarke		Aug 7. 2025
Heart Transplant Surgical Director		Anson Cheung	nson Cheung	
VPACH Medical Director/ MD		Jasmin Grewal / Gnalini Sathanathan		Aug 7. 2025
Clinical Nurse Specialist - Transplant		Wynne Chiu		Aug 7. 2025
Clinical Nurse Specialist - VPACH		Jillisa Byard		Aug 7. 2025
DEVELOPERS/OWNER				
		Brian Clarke/Wynne Chiu		Aug 7. 2025
REVISION HISTORY				
Revision#	vision# Description of Changes		Prepared by	Effective Date
O1 Initial Release		ase	Wynne Chiu	Aug 7. 2025

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2.5 Patient Assessment

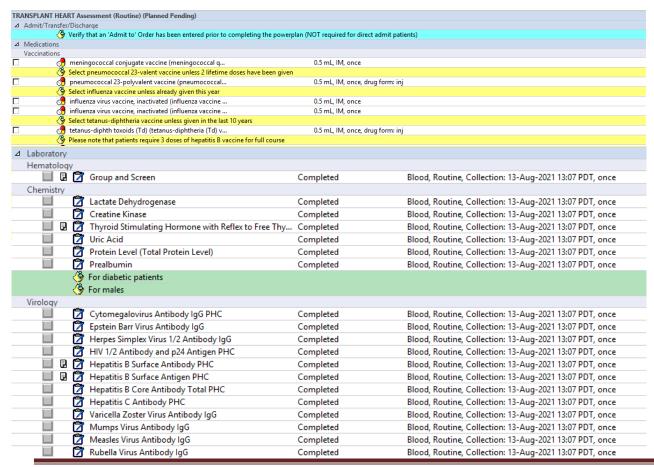
There are 3 levels of assessment for heart transplant candidacy.

2.5.1 Routine Heart Transplant Assessment

Routine assessment is reserved for stable patients where there is a lower level of urgency. Normally this assessment takes approximately 2 weeks to complete in an inpatient setting, and up to 3 months in an ambulatory setting. Time completion depends on availability of the patient for specialized testing and waiting times for other specialty opinions.

Prescriber Orders are entered as a "PowerPlan" (AKA order set) in the Cerner Electronic Medical Health Record (EHR) system. There is a separate powerplan in Cerner for inpatient use versus outpatient use. All the orders within the powerplan for both settings are identical, the difference lies in which department the order is directed to in the EHR once submitted (e.g. inpatient orders are all directed internally at SPH, but ambulatory orders may be organized with departments in patient's local community)

- Inpatient PowerPlan: "TRANSPLANT HEART Assessment (Routine)"
- Outpatient Powerplan: "TRANSPLANT HEART AMB Assessment (Routine)"

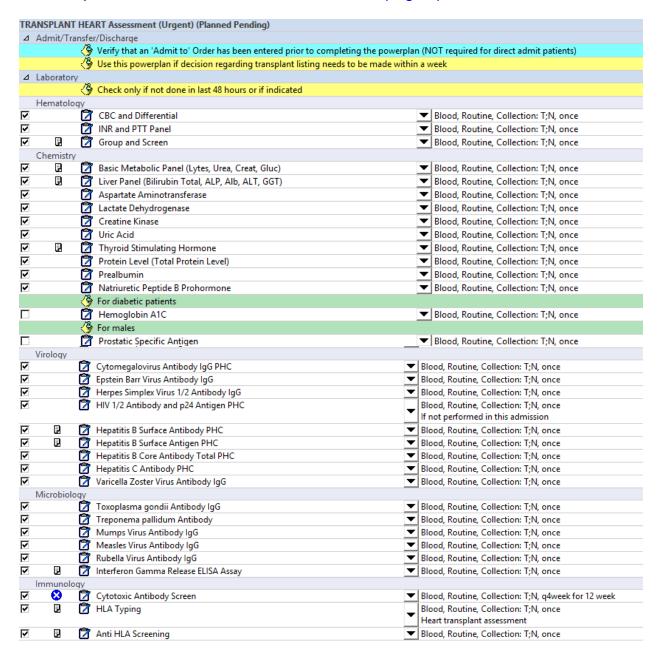


Microbiolo	gy			
		Toxoplasma gondii Antibody IgG	Completed	Blood, Routine, Collection: 13-Aug-2021 13:07 PDT, once
		Treponema pallidum Antibody	Completed	Blood, Routine, Collection: 13-Aug-2021 13:07 PDT, once
		Interferon Gamma Release ELISA Assay	Completed	Blood, Routine, Collection: 13-Aug-2021 13:07 PDT, once
Immunolog	gy			
		HLA Typing	Completed	Blood, Routine, Collection: 13-Aug-2021 13:07 PDT, once
		Anti HLA Screening	Completed	Blood, Routine, Collection: 13-Aug-2021 13:07 PDT, once
Urine Studio	es			
		Urinalysis Macroscopic (dipstick) with Microscopic if i	Completed	Urine, Routine, Unit collect, Collected, Collection: 13-Aug-2021 19:45 PDT, once, by SYSTEM, SYSTEM Cerner
	Ż	Urine Culture	Completed	Urine, Midstream, Routine, Unit Collect, Collected, Collection: 13-Aug-2021 19:45 PDT, once SPECIAL COLLECTION REQUIREMENTS: Please refer to specific site Laboratory Test Manual.
		Drugs of Abuse Screen Urine	Completed	Urine, Routine, Unit collect, Collected, Collection: 13-Aug-2021 19:45 PDT, once, by SYSTEM, SYSTEM Cerner
Stool Studie	es		·	
	Ż	Fecal Immunochemical Test	Completed	Faeces, Routine, Unit collect, Collected, Collection: 13-Aug-2021 21:07 PDT, once SPECIAL COLLECTION REQUIREMENTS: Please refer to specific site Laboratory Test Manual.
△ Diagnostic	Tests	5		
		XR Chest	Completed	14-Aug-2021 13:07 PDT, Urgent, Reason: heart transplant assessment, Transport: Portable
		US Abdomen	Completed	13-Aug-2021 13:07 PDT, Routine, Reason: heart transplant assessment to rule out malignancy and abnormalities
		Electrocardiogram 12 Lead	Discontinued	13-Aug-2021 13:07 PDT, Routine, Reason: Other (please specify), heart transplant assessment
	^3	Order CT Chest if any of the following are present: - Previous sternotomy - Smoking history more than 20 years - Over 50 with known vascular disease - Ventricular Access Device patients		
	-⟨%}	If patient has Coronary Artery Disease or over 40 years of	age	
	₹\$	Provider to fill out paper requisition to order Vascular Do	ppler Exam from Vascular Dia	ignostic Lab
	17	US Carotid and Doppler	Completed	13-Aug-2021 13:07 PDT, Routine, Reason: heart transplant assessment, rule out carotid stenosis
		BD Bone Density (Module)	Completed	13-Aug-2021 13:07 PDT
4 Consults/Re				
		Transplant Surgeon	rology, Endocrinology, BC Tra	insplant Infectious Diseases, Gastroenterology, Respirology, Hematology, Gynecology for PAP Smear, Dentistry and
		Social Work Consult	Completed	13-Aug-2021 13:07 PDT, Routine, Other (please specify), heart transplant assessment
	=		Completed	13-Aug-2021 13:07 PDT, Reason for Consult: Other (see special instructions), heart transplant assessment
	7	Dietitian Adult Consult		13-Aug-2021 13:07 PDT, Reason for Consult: Other (see special instructions), heart transplant assessment 13-Aug-2021 13:07 PDT, Routine, Reason for Consult: heart transplant assessment
	(2) (2)	Dietitian Adult Consult Psychology Consult		

2.5.2 Urgent Heart Transplant Assessment

Urgent assessment is a "fast-track" version of the routine assessment and designed to be completed within 7 days. This is reserved for patients who are in hospital and NYHA class IV. All other testing is reserved for after the patient is stabilized and the clinical picture is clearer.

Powerplan: TRANSPLANT HEART Assessment (Urgent):

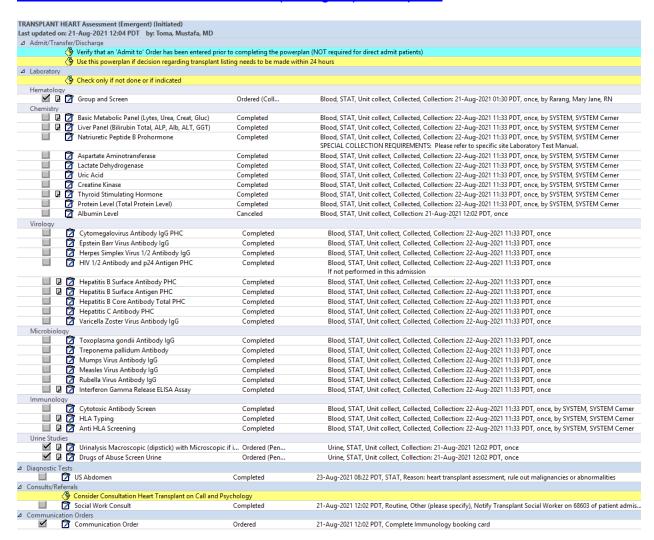




2.5.3 Emergent Heart Transplant Assessment

Emergent assessment is reserved for patients who present in cardiogenic shock and candidacy needs to be determined within 24 hours. Often, these patients will undergo assessment for Ventricular Assist Device implantation as a bridge to transplantation also.

TRANSPLANT HEART Assessment (Emergent) Powerplan:



2.5.4 High Risk Cardiac Surgery – Mechanical Support Backup

Since 2016, the program no longer offers long-term mechanical support backup to high risk patients except in rare circumstances. In these cases, short or intermediate-term support will be offered as a "bridge to decision". These devices buy time to make a more complete assessment and offer the possibility of weaning if appropriate.

2.6 Patient and Family Preparation

All patient information is reviewed by patients and families for readability and appropriate content.

When first referred, the patient and caregivers are given a copy of an <u>introductory booklet</u>. This booklet provides a short, easy to understand overview of heart transplantation and what to expect. Further information is offered once candidacy has been established.

If they would like more information, they are referred <u>BC Transplant</u> website and if they wish and demonstrate understanding, are given the longer, <u>more comprehensive manual</u>. The teaching plan for each patient and family member is prepared based on a number of key points:

- Clinical condition
- Where they are in the assessment process
- Ability to take in information due to low cardiac output
- Literacy
- Ability to speak and read English (The manual is available in Chinese)
- Environment
- Psychological state
- · Care plan established with the patient, family and team

It must be recognized that many patients are suffering from low cardiac output and as well, are likely to be overwhelmed by the medical information provided to them.

2.7 Psychosocial Assessment

Assessment performed by the psychosocial team is in concordance with <u>ISHLT 2024</u> <u>Guidelines for the evaluation and care of cardiac transplant candidates</u>, as well as per <u>Canadian Cardiovascular Society/Canadian Cardiac Transplant Network Position Statement on Heart Transplantation, 2020</u>

2.7.1 Psychology Assessment

The psychologist routinely assesses all stable patients being considered for heart transplantation using a semi-structured interview and following the Standard Integrated Psychosocial Assessment for Transplantation (<u>SIPAT</u>) evaluation tool. This assessment focuses on the following: 1. Patient's readiness level and illness management, 2. Social supports system level of readiness, 3. Psychological stability and psychopathology, and 4. Lifestyle and effect of substance use.

Psychological/psychiatric contraindications are first reviewed by the psychologist and where necessary a psychiatrist is consulted for further assessment and/or a second opinion. The Psychologist will also recommend referral for further neurocognitive testing if indicated.

2.7.2 Social Work Assessment

The Social Worker collects a detailed social history, which includes assessment of

- Social support
- Financial situation
- Relocation concerns
- Lifestyle issues
- Advance care planning
- Other relevant information

The Social Worker works with the team, the patient and family to establish a workable travel, accommodation and family support plan for presentation to the team.

As patients are medically recommended to stay 3 months immediately post-transplant in the lower mainland, the role of the social worker in helping patients find temporary accommodations for non-local patients is particularly important.

The Social Worker also provides ongoing counseling and assistance as required.

2.7.3 Dietary Assessment

A full dietary assessment is performed by a registered dietitian. Ongoing support and teaching is performed when required. This information is then used to aid in decision making when considering a patient for transplant/VAD candidacy.

2.8 Selection of Candidates

The team's decision-making process and plan is documented in Cerner EMR using the following:

- Conference Note Template
- Cardiology Multidiscipline Note type
- Auto-text ",,gridHTx"

Decisions are to be signed off by the physician team representing the majority: 3 cardiologist and 2 surgeons.

HEART TRANSPLANT PROGRAM CANDIDATE SELECTION

Date/Time of discussion:08-Aug-2025 14:22:23

Diagnosis:

Medical/Surgical Concerns:

Neurological	
Cardiovascular	
Respiratory	
GI/Hepatic	
Renal	
Urogenital	
Skin/Eyes	
Musculoskeletal	
Hematologic	
Endocrine	
OTHER	

ABO: _ V CI: PVR: cPRA%:

Lifestyle Management Concerns:

Smoking	
Substance use/abuse	
Exercise	
Medications	
Diet	
Weight	
Fluid restriction	
Missed appointments	
OTHER	

Psychosocial Concerns:

Psychiatric disorder	
Personality disorder	
Poor coping	
Cognitive deficits	
Social support system limitations	
Relocation concerns	
Financial concerns	
OTHER	

Additional Information:

An invitation for dissenting opinions: Yes
Input from all appropriate team members: Yes

TRANSPLANT TEAM DECISION:

Plan:

2.8.1 Smoking, Cannabis use and Vaping

2.8.1.1 Definitions

- Cannabis refers to cannabis, its by-products, and cannabinoids (natural or synthetic)
- Smoking can be of cannabis or nicotine
- Medically prescribed cannabis legally prescribed and obtained
- Ingested cannabis/cannabinoids eaten in the form of edibles, etc.
- Smoked cannabis ignited and inhaled
- E Cigarettes any portal where the user inhales vapor of any kind through an electronic cigarette currently marketed
- Vaping inhaling any vapor created by E Cigarettes
- Non-therapeutic not prescribed by a physician and/or where the patient's psychosocial workup shows that use is displaying substance use disorder or points to other high-risk behaviors.

2.8.1.2 Policy

Smoking of nicotine 6 months prior to transplant listing is an absolute contraindication.

Regular cannabis use is not recommended before or after transplant. We recommend 6 months of abstinence from **smoking**, **inhaling**, **or vaping** prior to transplant listing, and continued abstinence post-transplant. Regular cannabis use is known to interfere with post-transplant immunosuppressive drug levels.

If there is an element of addiction or substance use disorder for any substance determined by the psychology or psychiatry team during the pre-transplant assessment period (i.e. making quitting more challenging), efforts will be made by the team to connect patients with alternative therapies or addiction services in lieu of the substance (e.g. sleeping aid, analgesics, etc). Patients must show a period of abstinence, with a minimum of 3 months, and ideally 6 months if clinically stable to promote lasting behavioral change

Ventricular Assist Device (VAD) implantation can be considered for smokers and vapers as a Bridge to Candidacy if:

- They are deemed to have high likelihood of dying before the 6 months is complete and
- There is agreement by the team that there is a good likelihood of quitting given the evidence presented

2.8.2 Illicit Substance Use

Canadian and International Guidelines suggest recent (last 6 months) illicit substance use is a contraindication for heart transplant.

VAD implantation as bridge to candidacy could be considered where it is determined by experts in Addiction Medicine and psychosocial team that the patient has favorable

likelihood of abstaining. The patient and family must understand the implications of continued use (no chance of transplantation).

2.8.3 Team Meetings

The <u>multidisciplinary team</u> meets every Tuesday mornings over Microsoft Teams from 07:30-08:30.

Changes in patient status on the waitlist are discussed here and updated on the EMR "Patient Records and Outcome Management Information System" or <u>PROMIS</u>, by the transplant nurse & clerical team. External consultants are invited to join the discussion whenever applicable.

Each year, the team reviews patient outcome data and in turn, reviews and revises protocols in an "Annual Team Retreat", which are 4 hours in length. The agenda is determined collaboratively by the Clinical Nurse Specialist and Medical/Surgical Director of the program. Team members are invited to add agenda items as well.

Internal Mortality and Morbidity (M&M) Rounds are also held 4 times per year or as requested by team, to ensure timely review of untoward case outcomes. The team is invited to attend these rounds at 0700-0800 on the scheduled days on a Tuesday morning, and regular multidisciplinary rounds is shorted to 30 mins (0800-0830) when M&M rounds take place.

3 Transplant Listing

3.1 Patient Listing

Patients and families are seen by the team in the clinic or in hospital and informed of the listing decision. Coaching and education is commenced around expectations and life on the waiting list. In addition, detailed instructions around the call-in for transplant are reviewed.

The transplant coordinators complete a checklist to ensure all requirements for listing have been completed (see below):

NURSE RESPONSIBILITY	Date Completed	Initials
Provide patient with the "Living With a Heart Transplant" manual & "Risk of Disease Transmission from Organ Donors"		
Review "While on the Transplant List" handout with the patient		
Obtain signed copies of the Canadian Blood Services Consent for Patients to Participate in the Canadian Transplant Registry (CTR)		
Review the patient's medication list. Notify physician & pharmacist if patient is on: Novel Oral Anticoagulant (NOAC) - ask MD if patient should switch to warfarin Sirolimus - ask MD if patient should switch to alternative Ensure patient has not received a live vaccine with 1 month of listing		
Confirm: Immunology has recent sample (1 month) for monthly tray Confirm patient has 2 resulted Group & Screen		
Clarify with Cardiologist if donor criteria is required in comment section (e.g. donor age older than 60 years; will accept beyond east of Manitoba)		
☐ Ensure the Heart Transplant Program Candidate Selection Form (#3674) is signed (signed twice if VAD patient is being re-listed)		
Complete the "Listing Status Log" located in the AdHoc - PreHeart Transplant Clinic Cerner form		
Ask Social Worker to:		
☐ Create a travel plan ☐ Confirm accommodation location		
Ask Program Assistant to:		
☐ Add patient to the Transplant List on PROMIS		
☐ Confirm with patient which 3 phone numbers to put on list		
☐ Distribute updated Transplant List to on-call Cardiologist, Cardiac Surgeon and on-call RN		
Add donor criteria if applicable to comment section		
☐ Obtain and distribute updated immunology list to cardiologist		
☐ Organize monthly standing orders for PRAs (copies for lab, patient and chart)		
☐ Fax booking form to VGH Immunology and email Michele Konevecki informing her of the new activation. Michele.Konevecki@vch.ca		
☐ Ensure patient is registered in the CBS National Organ Waitlist and comments are present if applicable		
☐ Ensure "5A COVID-19 NP & non-contrast CT testing for pre-transplant patients" note is placed on the front of the patient's chart		
□ Ensure Surgeon on call is aware that the following surgical consents need to be signed. Consent for Treatment; Consent for Transfusion of Blood and/or Blood Products		

3.2 Prioritizing Patients on the Heart Transplant Wait List

Once listed, the patient is activated on the PROMIS database. This database is administered by BC Provincial Renal Agency and BC Transplant. It links directly with the National Organ Waitlist which is administered by Canadian Blood Services. Urgently listed patients (classified as Status 4 or 4S) automatically appear on the National Organ Waitlist to initiate interprovincial organ sharing. For more details on how this relationship works, contact BC Transplant directly.

Priority for listing can be found in the Canadian Cardiac Transplant Network (CCTN) document – <u>Adult Heart Transplant Listing Criteria in Canada 2021</u> – which outlines the definitions for determining "status" on the transplant list.

3.3 Combined Heart and Kidney Transplantation

In otherwise eligible candidates with renal failure that is considered by the nephrologist to warrant renal transplantation, a decision re candidacy will be made collaboratively with nephrology.

Two approaches to combined transplantation can be taken.

- 1. Combined heart/kidney transplant from the same donor
- 2. Staged heart transplant followed by a kidney transplant from another donor

The first approach is preferred; however, it is recognized that due to long renal waitlists, it is not always possible to achieve this as these candidates "jump the queue" for cadaveric renal transplant.

If a dialysis patient were a suitable candidate for combined transplant then a simultaneous cadaveric transplant could be performed. If the patient was not on dialysis and had renal dysfunction a plan would be created in conjunction with renal and cardiac teams together on an individual basis.

Standard Operating Procedure and Flow Sheet are found below:

3.3.1 Standard Operating Procedure – Combined Heart and Kidney Transplant



Combined Cardiac & Renal Transplantation

Site Applicability:

Organ Donation Hospital Development (ODHD) team at BCT, the Pre-heart transplant team at St. Paul's Hospital, the Pre-Renal Transplant team at St. Paul's Hospital (SPH) and the Pre-Renal Transplant team at Vancouver General Hospital.

Scope:

To describe the process for activating and calling in recipients for combined heart and kidney transplant from the same deceased donor.

Requirements:

- 1.1. The heart recipient patient is selected by the Transplant Cardiologist and Surgeon.
- 1.2. Cross-checking crossmatch and ABO matching information is the responsibility of the Transplant Surgeon, Cardiologist and clinical team in the OR according to hospital protocols.
- 1.3. Patients that are considered for this combined procedure must first be found to be suitable candidates for cardiac transplantation alone
- 1.4. Relative contraindications to the combined procedure:
 - 1.4.1.Criteria that would prevent listing as cardiac recipient alone (other than renal impairment/failure
 - 1.4.2.Renal failure due to diabetes
 - 1.4.3. Potentially reversible renal failure
 - 1.4.4.Creatinine of greater than 200 that is not felt to be reversible with cardiac transplant alone but less than that requiring dialysis within the usual acceptable limits of listing for renal transplant would need to be assessed for a potential living donor.
- 1.5. All potential heart/kidney recipients should be seen by anesthesia in pre-admission clinic

Procedures:

2. ACTIVATION PROCEDURE

2.1. Upon decision and approval by both heart and kidney transplant team that a patient is a combined heart/kidney recipient candidate for the same deceased donor (from formal candidacy review discussion in multidisciplinary rounds with both teams present). Ensure all clinical members involved are familiar with details of this SOP

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Effective date: 08/12/2025 Page 1 of 5



- 2.2. SPH Pre-heart transplant team will activate patient per usual procedures but in addition:
 - 2.2.1. Liaise with renal transplant team regarding approval of combined transplant
 - 2.2.2. Ensure anesthesia consult is made
- 2.3. SPH Pre-Renal Transplant team will activate patient per usual procedures but in addition:
 - Liaise with heart transplant team regarding approval of combined transplant
 - Confirm whether candidate is eligible for kidney only if heart transplant doesn't proceed
 - Notify patient's hemodialysis unit regarding the collection of a specimen monthly for immunology
 - 2.3.4. Inform BCT data entry clerk re: heart/kidney combined transplant so that activation status is accurate in PROMIS, and patient will appear on the weekly renal waitlist
 - 2.3.5. Confirm in PROMIS patient is activated under Program: Heart
 - 2.3.6. Notify immunology via email of heart/kidney combined activation
- 2.4. Fax a note to immunology at VGH stating patient activated for combined heart/kidney transplant and that they are a priority on the renal list
- 2.5. Contact retrieval coordinator at BCT to notify of activation, send copy fo this SOP
- Contact Clinical Coordinator at St. Paul's Hospital renal program and VGH renal program of activation
- 2.7. Activate patient on PROMIS as Status 2
- 2.8. Notify Head of Anesthesia department when patient listed

3. RESPONSIBILITIES & PROCEDURE (When donor becomes available)

- 3.1.1. BC Transplant OHDH Coordinator:
 - 3.1.1.1. Organ Donor Coordinator (ODS) offers heart from BC donor to Tx cardiologist (usual process for clearing National HS listing patients, etc.) with relevant donor and organ function details (as per SOP: <u>Organ Offering and Allocation Extra Renal</u> ODHD-ODS.02.004).
 - 3.1.1.2. If Cardiologist indicates interest in using heart for heart/kidney combo recipient, ODS to request Tx Cardiologist for back up heart recipient (if available, in case Tissue Typing crossmatch is positive). If no matching BC recipients as a back up recipient, offer heart extra-provincially as a back-up offer.
 - 3.1.1.3. At time of kidney allocation, ODS to inform Transplant Nephrologist of prioritizing one of the kidneys for the heart/kidney combo recipient and allocate other kidney as per usual procedure.
 - 3.1.1.4. If the decision is made to allocate to the heart/kidney recipient ODS should give the nephrologist, the next patient on the list as a back up.

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Effective date: 08/12/2025 Page 2 of 5



STANDARD OPERATI	NG PROCEDURE DOCUMENT #004
3.1.2.	Transplant nephrologist confirms acceptance of kidney for heart/kidney combo recipient.
3.1.3.	ODS to confirm final acceptance of organs for heart/kidney combo transplant recipient with cardiologist and transplant nephrologist.
3.1.4.	If for any reason, heart/kidney combo transplant can not proceed, allocate heart to back up recipient, and kidney to the back up recipient (as per SOPs: Organ Offering and Allocation Extra Renal, Organ Offering and Allocation Renal). If no matching BC recipients, offer organs extra-provincially.
3.1.5.	In the unlikely scenario of an import heart offer, ODS will offer the heart to the transplant cardiologist as per usual practice. If the cardiologist indicates interest in the heart for the heart/kidney combo, ODS will enquire from the offering OPO if a kidney could also be received for transplant. Necessary arrangement for tissue typing cross match will be arranged as logistics allow.
3.1.6.	The cardiologist will:
3.1.6.1	. Informs retrieval heart coordinator and backup recipient details
3.1.6.2	. Notify the Nephrologist (through BCT after hours number or through Hotsheet) and decide on whether or not to proceed
3.1.6.3.	. Notify on call cardiac surgeon
3.1.6.4	. Arrange for backup recipient to be immunologically worked up in case heart/kidney crossmatch positive
3.1.6.5.	. Informs retrieval heart coordinator/units if backup recipient to be transplanted
3.1.7.	The Nephrologist will:
3.1.7.1	. Arrange possible backup patient in case of positive crossmatch
3.1.7.2	. Liaise with Cardiologist with results of the crossmatch
3.1.7.3	. Notify Renal Surgeon
3.1.7.4	. Arrange for dialysis if necessary
3.1.8.	Cardiac Surgeon will:
3.1.8.1	. Liaise with Renal Surgeon
3.1.8.2	. Perform usual transplant duties
3.1.9.	Urologist will:
3.1.9.1	. Liaise with Cardiac Surgeon and Nephrologist
3.1.9.2	. Perform usual transplant duties

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Effective date: 08/12/2025 Page 3 of 5



DOCUMENT #004

- Heart coordinator on call (via VAD hotline 604-250-2658) will perform usual transplant recipient call in procedures for both heart/kidney and backup recipients
- 3.1.11. Renal coordinator will
 - 3.1.11.1. Ensure monthly CAS are performed preoperatively
 - 3.1.11.2. Perform usual transplant call in procedures, if appropriate

Related Documents:

Form, Recipient Activation

Reference, VGH Transplant Checklist - Liver, Kidney, P/K

Reference, VGH Transplant Checklist - Lungs

Reference, Responsibilities for On-Call Nephrologist Regarding Cadaveric Kidney and/or Pancreas Transplantation

SOP-001- Heart Transplant Recipient Notification and Preparation

SOP -002- Call Triage for Heart Transplant patients after hours

SOP, Organ Offering and Allocation Extra Renal ODHD-ODS.02.004

SOP, Organ Offering and Allocation Renal ODHD-ODS.02.005

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Effective date: 08/12/2025 Page 4 of 5



DOCUMENT #004

APPROVALS						
Medical Director: Heart Transplant		Dr. Brian Clarke		August 11, 2025		
Surgical Director: Heart Transplant		Dr. Anson Cheung		August 11, 2025		
Medical Director: Renal Transplant		Dr. Jagbir Gill		August 12, 2025		
Patient/Nurse Educator		Rachel Milligan		August 8, 2025		
BC Transplant — Clinical Operations Manager		Kiran Khatar		August 11, 2025		
DEVELOP	DEVELOPERS/OWNER					
Clinical Nurse Specialist		Wynne Chiu		August 8, 2025		
REVISION	HISTORY					
Revision#	Description	n of Changes	Prepared/Approved by:	Effective Date		
00	Initial Rele	ase- 001	Dr. A. Ignaszewski, Dr. A. Cheung, Dr. D. Landsberg, Dr J. Bashir, A. Kaan	Mar 28, 2011		
01	Update-002		Dr. A. Ignaszewski, Dr. A. Cheung, Dr. D. Landsberg, Dr. J. Bashir BCT ODHD team, W Chiu, J Kealy, A Kaan	Aug 12, 2013		
02	02 Update-003		Dr. A. Cheung, Dr. M. Toma, Dr. D. Landsberg, BCT ODHD team, L Young, K Brownjohn, J Mackey, K Uy, W. Chiu	Sept 7, 2022		

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Effective date: 08/12/2025 Page 5 of 5

3.4 Immunological Screening and Monitoring while Waiting for Transplant

All patients undergoing transplant assessment require Cytotoxic Antibody Screen (also called calculated Panel Reactive Antibody – cPRA). This test is only performed at the Vancouver General Hospital Immunology lab. See below for pre-transplant

	All listed candidates with cPRA 0-80%	All listed candidates with cPRA >80%
Blood sample for flow crossmatch in case of transplant to Immunology	Monthly	Q Monthly + Consultation with Immunology at time of listing – to risk stratify & review potential removal of low-risk antibodies
cPRA	Q 6 Monthly	Q 2 Monthly + histogram sent for cardiologist review Re-consultation between Immunology & cardiologist if changes present

For all scenarios, if sensitizing event occurs – i.e. blood transfusion, major surgery (e.g.VAD implant), major infection requiring IV antibiotics, perform cPRA 3-4 weeks after event (e.g. blood transfusion date or date of DIAGNOSIS of infection) and then revert to above criteria.

3.5 Hepatitis C Donors

As of July 2021, in collaboration with BCT, the heart transplant program began the process to offer and allocated Hepatitis C (HCV) NAT RNA positive donor hearts to pre-consented recipients.

The SOP that encompasses the organ donation team's process is described <u>here</u>, and patient education material can be found <u>here</u>

This is the consent form that is to be signed and scanned into Cerner EMR and can be found <u>here</u> via the BCT internal document

INFORMED CONSENT FORM Willing to Accept a Donor Offer From HCV NAT- Positive Donors

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500	atieni	t I 12	PNOT

- 1. I understand that I may be offered an organ from a donor with hepatitis C infection (HCV NAT- positive). This will be because my transplant doctor feels the benefit of accepting this organ outweighs the risk. The specific benefits and risks of taking this organ have been explained to me and will be discussed again at the time of transplantation. I can refuse the organ and my status on the waiting list will not be affected.
- 2 I understand that receiving an organ from a hepatitis C infected (HCV NAT-positive) donor means that I will become infected with hepatitis C.
- 3 I understand that I will receive effective hepatitis C antiviral treatment immediately after my transplant.
- 4. I understand that the treatment for hepatitis C is very effective and more than 95% of patients with Hepatitis C infection can be successfully treated with 12 weeks of very safe and well tolerated medications.
- I understand that the cost of the hepatitis C treatment will be covered.
- 6 I understand that I can ask a transplant physician about any questions that I may have on receiving an organ from hepatitis C infected donors at any time to assist me in making an informed decision.

I understand the above and would be willing to be offered an organ from hepatitis C NAT-positive donor.

Name: (Mr., Mrs., M:	s.)	AME		
	SURN	AME	GIV	/EN NAMES
SIGNATURE:				
	(PATIENT OR GU	IARDIAN)	(PRINT NA	ME IF NOT THE PATIENT)
(Re	lationship to Patient if	not the Patient)		_
WITNESS				
WITNESS	(SIGN)		(PF	RINT NAME)
DATE:				
have translated the al	F A PROFESSION bove information to	NTERPRETER AL INTERPRETER IS the:Patient/Clier responses to the health	ntparent1	
SIGNATURE OF INT	ERPRETER	PRINT NAME		DATE SIGNED
	ouver stal Health	Providence No.	in the last	TO ANCOL ANT



DOCUMENT #01

Hepatitis C NAT Positive Donor Acceptance Heart Transplant Program

Site Applicability:

SPH Heart Transplant Program

Scope:

This protocol outlines the St. Paul's Hospital Heart Transplant Program's process in accepting a Hepatitis C Virus Nucleic Acid Amplification Testing (NAT) positive donor heart to transplant into a Hepatitis C negative recipient

INCLUSION CRITERIA

- Listed heart transplant candidate
- · Informed consent for Hepatitis C NAT+ donor obtainable
- Patient is registered for Fair Pharmacare

EXCLUSION CRITERIA

- Clinically significant liver disease, including any of the following:
 - o Active Hepatitis B infection or is Hepatitis B Core positive
 - o Previous Hepatitis C infection
 - Persistently elevated liver transaminases of any etiology
 - * Where there is concern regarding liver disease, hepatology consult should be sent (e.g. cirrhosis on imaging)

Procedures:

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Effective date: 19/AUG/2025 Page 1 of 7

Procedur



Considerations:

- Patient's cognitive ability to follow extensive medication regimen should be reviewed by the transplant psychosocial team
- Social work (SW) will be consulted once pt expresses interest for Hepatitis C donor
 considerations, to confirm if patient has active Fair Pharmacare registration (regardless of existing
 Pharmacare / extended health plan coverage). If new registration is required, SW will assist with
 process and work with patient to identify and overcome barriers to registration
- Once SW confirms that Fair Pharmacare registration is in place, patient may proceed to consent and change of Hepatitis C donor acceptance status on the list
- At the time of transplant, inpatient transplant pharmacist will secure special authority and in collaboration with companies, AbbVie or Gilead, obtains financial assistance for coverage of patient's deductible with Pharmacare

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Effective date: 19/AUG/2025 Page 2 of 7

OBTAINING CONSENT

- Discussion regarding appropriateness of accepting a Hep C donor should happen at the gridding process during interdisciplinary rounds
- Approaching patients for consent of Hep C donor should ideally happen once the patient is listed. However, it is recognized that this discussion may take place prior to listing for some patients depending on their scenario or clinical stability
- If the patient meets inclusion criteria, and it is deemed appropriate timing to approach
 patient for dialogue regarding Hep C donors, the on call transplant cardiologist will begin
 discussion with patient at their next scheduled clinic visit. Education material will be provided
 to the patient at this time.
- If the patient is agreeable to proceed, referral should be made to Transplant Infectious
 Disease with Dr. Alissa Wright
- Consent to Hep C donor should be signed by the patient & transplant cardiologist after patient has seen Dr. Wright, at the next scheduled clinic visit
- If patient is an inpatient, follow the same process but all discussions/referrals will be completed in an inpatient context during hospitalization

LISTING

- 1. Once consent is signed, Nurse will notify Clerk to update heart transplant active list.
- Clerk will select "Accept Hep C Donor" on PROMIS activation page as "yes". Updated list will be distributed to the cardiologist and on call nursing team as per usual process

OFFERING HEP C NAT + DONOR ORGAN

- Once a Hep C + organ has been accepted, the Cardiologist will phone the patient to have discussion about Hep C + donor offer and explain over phone If patient agrees to proceed. If patient agrees:
- 2. Cardiologist will notify On call RN as per usual process
- Organ Donation Specialist on call will send email to Dr. Alissa Wright, BCCDC & BCT Transplant Pharmacist, Polinna Tsai (+/- group pharmacist email) as per BCT SOP: Use of HCV NAT RNA Positive Donors & Resistance Testing

DURING HOSPITALIZATION

- Therapy should begin on POD 0. Using powerplan: TRANSPLANT HEART Immunosuppression (Multiphase) powerplan, add to 'Post Operative' Phase:
 - Cardiologist to order: MAVIRET (glecaprevir-pibrentasvir, 100mg-40mg) 3 tabs PO qHS, starting POD#0.

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Effective date: 19/AUG/2025 Page 3 of 7

- Add order comments: "Tablets preferred to be swallowed as whole. RN can crush and administer via NG/OG if patient is still intubated"
- Inpatient transplant pharmacist will coordinate medication procurement for hospital use
- Antivirals are preferably taken PO as intact tablets. Encourage patient to take tablets whole as soon as NG/OG no longer necessary and deemed appropriate per usual protocol to swallow medications.
- If hospitalization is prolonged Consult Transplant ID, Dr. Alissa Wright, who agreed to see inpatients under this protocol

Medication review/ interactions:

A thorough medication review by the inpatient pharmacist must be done on admission and prior to introduction of a new medication due to potential for many drug interactions with Maviret. Some of the drug interaction include (but not limited to):

- Amiodarone
- Carbamazepine
- Cyclosporine
- Digoxin
- Phenobarbital
- Pheyntoin
- PPI ** Weak minor interaction- ok to use daily dose immediately post op, but reassess if patient needs as soon as clinically feasible** refrain from BID dosing
- Rifampin
- Statin **note: pravastatin should stay at 20 mg/day dose until end of HCV treatment

DISCHARGE

- Post-Transplant RN will:
 - a. Ensure patient has follow up with the Transplant ID team as an outpatient
 - Ensure pt has follow up blood work in outpatient setting (as part of biopsy PP lab phase)
- 2. Inpatient transplant pharmacist/ Cardiologist will
 - Dictate on D/C summary cc to inform GP & Transplant ID that patient has received Hep C+ donor heart and will be on treatment and surveillance by the Post-Transplant Clinic
 - Ensure patient is discharged on Antivirals MAVIRET: Glecaprevir 100 mg & Pibrentasvir 40 mg, Three tablets once daily x 8 weeks:

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Effective date: 19/AUG/2025 Page 4 of 7

- Ensure patient be dispensed enough MAVIRET tablets on discharge until next transplant clinic appointment
- d. Review patient's Statin medication as Simvastatin and Atorvastatin has significant contraindication with Maviret and needs to be switched to another type of statin. Pravastatin dose should remain 20 mg/day until end of HCV treatment.
- Refill medications: will be dispensed monthly by Burrard Pharmasave due to high cost and importance of medication adherence, drug will be kept with and dispensed weekly (or intervals deemed appropriate) by the outpatient transplant pharmacist (Tania Alia) at subsequent clinic visit

SERIAL SURVEILLANCE SCHEDULE

The following blood test will need to be performed on a regular surveillance schedule. Orders for blood work needs to be entered "ad hoc" in Cerner CST, with options to add to existing Powerplan per below:

- HCV Quantitative RNA (NAT) by PCR
- · AST, ALT, Bilirubin
- INR, PTT

This will be aligned with the Post-Heart Transplant biopsy/blood work protocol when applicable:

HCV Quantitative RNA (NAT) Testing Schedule

Time point post-transplant	Powerplan where order located & should be placed
Daily for first 7 days	TRANSPLANT HEART Heart Transplant Post-Operative
	(Multiphase) – "CSICU Admission" phase
Week 1	TRANSPLANT HEART Heart Transplant Post-Operative (Multiphase) –"Transfer" phase
Week 2	TRANSPLANT HEART BIOPSY – Week 2
Month 1	TRANSPLANT HEART BIOPSY – Week 4
Month 2	TRANSPLANT HEART BIOPSY – Week 8
Month 3	TRANSPLANT HEART BIOPSY – Week 12
Month 6	TRANSPLANT HEART BIOPSY – Week 30
Year 1	TRANSPLANT HEART AMB Post Clinic Annual Visit
Year 2	TRANSPLANT HEART AMB Post Clinic Annual Visit
Year 3	TRANSPLANT HEART AMB Post Clinic Annual Visit

Screening is completed at year 3 unless otherwise specified by Transplant Infectious Disease team

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Effective date: 19/AUG/2025 Page 5 of 7

Implementation:

Patients currently on the heart transplant list under the 4S status should be the first set of patients approached for consent. Next, patient's wait time on the list should be prioritized, with the longest waiting patients first approached, and then move backwards.

Related Documents:

BCT Use of Hepatitis C (HCV) NAT RNA Positive Donors SOP: ODHD-ODS.02.007

Informed Consent Form

Pt education information

References: (if applicable)

Aslam, S., Yumul, I., Mariski, M., Pretorius, V. & Adler, E. (2019). Outcomes of heart Transplantation from hepatitis C virus-positive donors. *Journal of Heart and Lung Transplantation*, 38:1259-1269

Aslam, S. et al. (2020). Utilization of hepatitis C virus-infected organ donors in cardiothoracic transplantation: An ISHLT expert consensus statement. *Journal of Heart and Lung Transplantation*, 39(5):418-432

Bruno, S. et al. (2019). Heart Transplantation From Hepatitis C-Positive Donors in the Era of Direct Acting Antiviral Therapy: A Comprehensive Literature Review. *Transplant Direct*, 5: e486; doi: 10.1097/TXD.000000000000028

Frager, S. et al. (2019). Heart Transplantation for Hepatitis C Virus Non-Viremic Recipients from Hepatitis C Virus Viremic Donors. *Cardiology in Review*, 27(4): 179-181

International Society of Heart Lung Transplant, Press Release, April 4, 2019: https://ishlt.org/ishlt/media/Documents/ISHLT2019 Hep-C PressRelease.pdf

Kilic, A. et al. (2020). Outcomes of Adult Heart Transplantation Using Hepatitis C-Positive Donors. Journal of American Heart Association, 9:e014495. DOI: 10.1161/JAHA.119.014495.

Schelendorf, K. et al. (2020). Expanding Heart Transplant in the Era of Direct-Acting Antiviral Therapy for Hepatitis C. *Journal of American Heart Association Cardiology*, 5(2): 167-175

Woolley, A. et al (2019). Heartand Lung Transplants from HCV-Infected Donors to Uninfected Recipients. *The New England Journal of Medicine*, 380(17): 1606-1617

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Effective date: 19/AUG/2025 Page 6 of 7



DOCUMENT #01

APPROVALS									
Medical & . Heart Trans Program D	splant		August 19, 2025						
Transplant Disease Pro Director		Dr. Alissa Wright	August 19, 2025						
Clinical Nui Specialist	rse	Wynne Chiu	August 19, 2025						
Clinical Pho	ırmacist	Emma Stephens, Casara Hong	nma Stephens, Casara Hong						
BC Transple Operations		Kiran Khatar	August 19, 2025						
DEVELOP	ERS/OWNE	R							
Clinical Nu Specialist	rse	Wynne Chiu	August 19, 2025						
REVISION	HISTORY								
Revision#	Description of Changes		Prepared by	Effective Date					
00	Initial Rele	ase	Wynne Chiu	September 28, 2020					
01	Update		Wynne Chiu						

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Effective date: 19/AUG/2025 Page 7 of 7

4 The Transplant

4.1 Matching Donor to Recipient - immunology

The on-call transplant cardiologist when triaging a donor call from BC Transplant, will receive the following donor immunology information from the on call Organ Donation Coordinator:

- Blood group
- List of cross-referenced antibody status with potential recipients on our local transplant list done by the immunology team

 — This screening process is called a "Virtual Crossmatch"

After the virtual crossmatch, and whether it is negative or positive, the cardiologist will determine a maximum of 3 listed recipients who may be a potential match for the donor. The cardiologist determines this based on other matching criteria such as blood group, age, size, sex, ischemic time and clinical acuity. This is communicated to the immunology team on call through the organ donation coordinator. The immunology team will then perform the second screening/matching process, which is called a "Flow Crossmatch".

If this Flow Crossmatch is negative, then the donor would be considered an appropriate immunological match for the specified recipient(s). However, if the Flow Crossmatch is positive, then two options are possible:

- 1. The transplant cardiologist will choose an alternate recipient that had a negative Flow Crossmatch (if available)
- 2. The transplant cardiologist may confer with the immunologist on-call to determine the significance of the positive flow cross-match and the mean fluorescence intensity (MFI) of the donor specific antibody. In the case that an organ is transplanted with a positive crossmatch, there is a conversation with the cardiac surgeon on-call to discuss the clinical situation, rationale for transplanting in this scenario and for identifying pre-intra- and post-operative strategies to minimize the risk of rejection.

4.2 Donor Criteria

An organ donor deemed suitable first by the criteria outlined by BC Transplant (BCT) and then between the cardiologist and surgeon on call. The criteria is also based on the most recent literature, as published by the ISHLT in 2002: <u>Donor heart selection: Evidence-based guidelines for providers.</u>

Additionally, the HTx surgeon and cardiologist use the following exclusion criteria to assess donor suitability:

- Poor Ejection Fraction
- diffuse atherosclerosis
- congenital or valvular heart diseases that are not easily correctable.

4.3 Exceptional Distribution of Organs

Exceptional Distribution (ED) of organs refers to organs obtained from a donor for whom the donor suitability assessment identified an increased risk for disease transmission.

The decision & procedures regarding whether a donor is designated as ED is detailed on the BCT <u>ED Standard Operating Procedure</u> (SOP) document.

This <u>link</u> to BCT internal documentation can only be accessed from inside the PHC system and connects to our shared SOPs. A <u>Summary of ED Criteria</u> is also available through BCT.

Appendix A contains the PHC consent form, and the Patient Information Brochure can be accessed on the BCT website, which is provided to all patients prior to consent and listing.

The workflow to ensure education and consent of listed recipients for ED donors is detailed below:

Patient Listed consent

Sign

- •RN: provide ED education at time of listing & ensures pt receives education booklet "Risk of Disease Transmission from Organ Donors"
- •Clerk: schedules phone visit for pt with MD to review ED consent within 1-2 weeks of listing
 - •Clerk: print from FormsFast: "Informed Consent for Exceptional Distribution - Willing to Accept A Donor Offer With Increased Risk of Disease Transmission"
 - •MD: reviews consent, & completes form with pt, witness required if consent obtained virtually
 - •Clerk: scans consent into Cerner
 - •RN: make note on transplant list comment if pt does NOT consent to ED donor



- •MD: Calls pt to notify of ED donor & provide rational, ensure pt still in agreement to proceed.
- •RN: to proceed with usual call-in procedures

At time of transplant, the cardiac surgeon will receive, review and sign part B of the BC Transplant Exceptional Distribution Form, which would then be returned to BCT. The BCT quality assurance team will then send a copy of this completed form, and any applicable follow up treatment required to the implant team.

4.4 Call in for Heart Transplant

The recipient is agreed upon between the cardiologist and surgeon on call. The process for allocation is outlined previously.

The Heart Transplant Coordinator is notified (on call coordinator if after hours: 604-250-2658) by the Heart Transplant Cardiologist and informed as to who needs to be called in as well as approximate timing and any other pertinent information.

Once the patient has been called in and appropriate areas informed by the Coordinator on call, it is the responsibility of the Cardiologist and Cardiac Surgeon to manage the patient's clinical care.

The form used to call in patients is below:

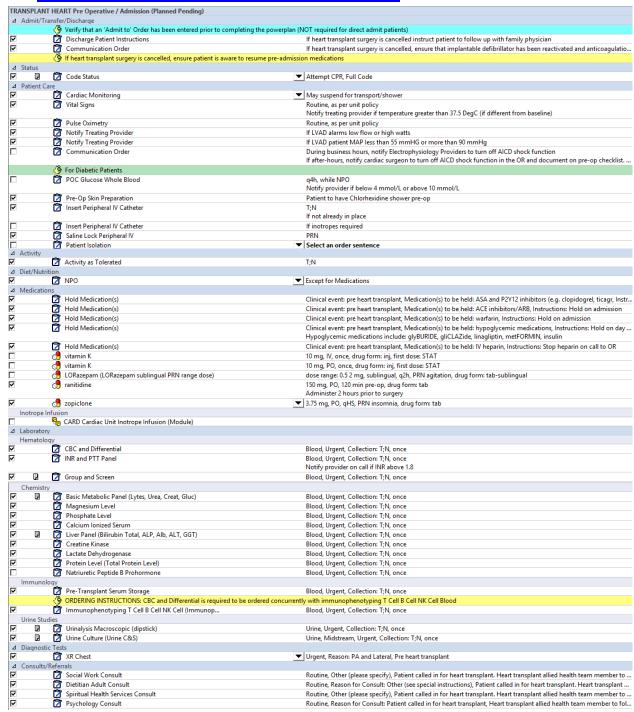
Heart Transplant Ro	ecipient Call-In	Progress	DOB:						
Notes			PHN:						
Date/Time									
Call received from									
Call-in	Primary	Backup							
Planned OR Time									
Latest acceptable arrival time to hospital									
Remind patient/s:	□NPO □Hold Coumad	lin & all meds	☐Bring meds (in case☐Possibility of dry ru						
Travel Instructions									
Where possible, patients t Discuss travel plan with pt			e latest acceptable time						
If standard flight or ferry	is NOT able to get	t the patient here at th	ne above ETA:						
Call Uniglobe for flight book Kimberly Walsh (24/7 on of the content of the conte	eall) r 1-866-252-4942 (p ncentre.com nation with travel plans for pat	oress 1)							
Obtain patients: vehicle colour_ license plate number	-	-							
Then call <u>BC Ferries</u> –1-888-223-3779 and inform them that the patient requires Medical Assured Loading Call patient back with instructions to board ferry									
ETA									
If Delay - Notify Cardiolog	ist on-call								
Notify following departm	ents / persons – in	nform of. SPH # 60	04-682-2344						
		emind to pick up chart	CNL/CN:						
	2117		CNL/CN:						
Form completed by:	Signature:		Print name:						

Last revised June 25, 2016

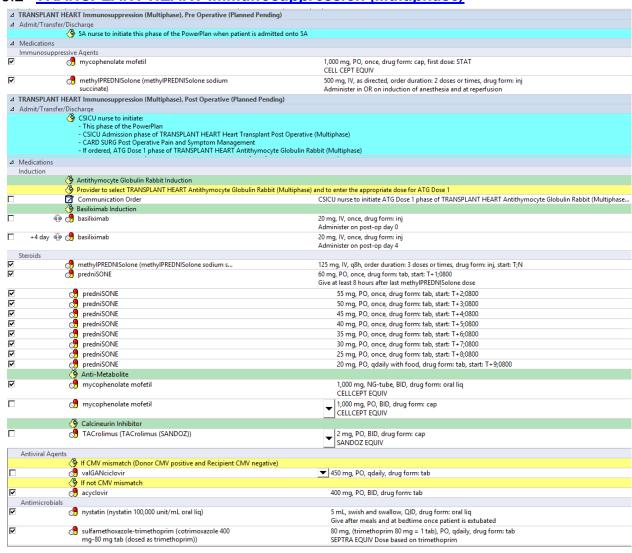
4.5 Pre-operative Protocol

The following Cerner Powerplans are ordered and initiated by the physician on call when a patient is called in for their heart transplant. Patients are admitted to the unit 5A (Cardiology), unless otherwise determined by the cardiologist:

4.5.1 TRANSPLANT HEART Pre Operative/Admission



4.5.2 TRANSPLANT HEART Immunosuppression (Multiphase)



4.5.3 Transplant Heart Antithymocyte Globulin Rabbit (Multiphase) – if applicable



4.6 The Transplant Surgery

The surgery is performed by the Transplant Cardiac Surgeon on-call.

It is the responsibility of the Transplant Cardiac Surgeon to verify with the OR and BC Transplant teams involved in the organ retrieval, the correct blood group of the organ donor and the organ recipient before the transplant procedure commences.

5 Post-Heart Transplant

5.1 Most Responsible Physician

The most responsible physician until transfer to 5A is the Transplant Surgeon.

5.2 Post-Operative Orders

The following Cerner PowerPlans would be used:

5.2.1 CARD SURG Heart Transplant Post Operative (Multiphase), CSICU Admission



	Audina	1-41-	Deverage		
	Anticoagu	-	n Reversals	50 IV 1	1
		07	protamine	50 mg, IV, once, drug form: 50 mg per 500 mL of pump	
		್ರೌ	protamine	150 mg, IV, once, administe Infuse at 25 mg/h for 6 hou	er over: 6 hour, drug form: inj Irs
	Stress Ulce	er Pro	phylaxis		
哮			pantoprazole	40 mg, IV, once, drug form:	: bag
	Modules				
			ICU Insulin Infusion - Critical Care (Module) Planne		
굣		4	CARD SURG Electrolyte Replacement (Module) Planne		
Δ	Laboratory				
	Hematolo	**			
☑		7	CBC and Differential	Blood, Urgent, Unit collect,	
☑		7	CBC and Differential		ct, Collection: T+1;0330, qdaily for 3 day
굣		7	INR and PTT Panel	Blood, Urgent, Unit collect,	
☑		7	INR and PTT Panel	Blood, AM Draw, Unit colle	ct, Collection: T+1;0330, qdaily for 3 day
哮		7	Nurse to place Lab Order	Nurse to place lab order for	r INR and PTT prior to chest tube removal
_	Chemistry				
哮	<u>.</u>		Electrolytes Urea Creatinine Panel	Blood, Urgent, Unit collect,	
☑	₽		Electrolytes Urea Creatinine Panel		ct, Collection: T+1;0330, qdaily for 3 day
굣		7	Magnesium Level	Blood, Urgent, Unit collect,	Collection: T;N, once
굣			Magnesium Level	Blood, AM Draw, Unit colle	ct, Collection: T+1;0330, qdaily for 3 day
☑	₽	7	Liver Panel (Bilirubin Total, ALP, Alb, ALT, GGT)	Blood, Urgent, Unit collect,	Collection: T;N, once
✓		7	Phosphate Level	Blood, Urgent, Unit collect,	Collection: T;N, once
☑		7	Phosphate Level	Blood, AM Draw, Unit colle	ct, Collection: T+1;0330, qdaily for 3 day
✓		7	Arterial Plus Blood Gas	Arterial Blood, Urgent, Unit	collect, Collection: T;N, once
	/irology	_			
⊽			Cytomegalovirus (CMV) Viral Load PHC	Blood, AM Draw, Collection: T+1;0330,	qMon for 5 week
	Diagnostic T			H + B OH / I '7)	COLCULA I
굣			lectrocardiogram 12 Lead	Urgent, Reason: Other (please specify), Unless V or AV paced	
굣		_	R Chest		nsport: Portable, Portable Reason: Requires constant monitoring/observation
굣		7 (Conditional Order - One Time	If/when chest tubes are removed, then	RN to place an order for XR Chest post removal
⊿ I	Respiratory	-	nvasive Ventilation	VA. 6 to 10 and /law DEED, 5 to 15 and 120	O Titute 03te less \$403.039' ex essetes BB below 35/min
V	ι	_ "	ivasive ventilation		 Titrate O2 to keep SpO2 92% or greater, RR below 25/min ments go above 10 cm H2O. When hemodynamically stable, wean from mec
⊿ (Consults/Re	ferral	s	acasing provider in the require	
굣			'hysical Therapy Consult	Reason for Consult: CSICU Admission	
			lietitian Adult Consult	Reason for Consult: Other (see special i	instructions), Reason: CSICU Admission
⊿ (ARD SURG	Hea	rt Transplant Post Operative (Multiphase), CSICU Admission, ICU Ir	nfusion - Critical Care (Module) (Planned Pend	ing)
	Patient Care				
⊽			Communication Order	ICU Insulin Infusion protocol	
	Continuous				
굣	මෙ		nsulin regular titratable infusion (1 unit/mL) in NS tandard		minimum rate, 20 unit/h maximum rate, titrate instructions: Titrate as per ins eiving insulin infusion Blood glucose: 4 mmol/L or LESS: administer 25 mL
	Medications				
✓	€ ∂ (nsulin regular (insulin regular - bolus dose from rotocol)		ted, PRN hyperglycemia, drug form: inj eiving insulin infusion Blood glucose: 4 mmol/L or LESS: administer 25 mL
✓	(9 •	lextrose 50% (dextrose 50% inj)	12.5 g, IV, q15min, PRN hypoglycemia, For blood glucose 4 mmol/L or LESS: a	drug form: inj dminister 12.5 g (25 mL) of dextrose 50% IV push and notify provider. Check
				-	

A CAI	RD SI	IRG H	eart Transplant Post Operative (Multiphase), CSICU A	dmission CARD SURG Flactrolyte Replacement (Module) (Planned Panding)
	KD SU edicatio		eart transplant rost Operative (Multiphase), CSICU A	dmission, CARD SURG Electrolyte Replacement (Module) (Planned Pending)
			nagement	
Ele	ctrolyt		potassium chloride	20 grant IV and instead DDN handledonic administration of 20 minute description
				20 mmol, IV, as directed, PRN hypokalemia, administer over: 30 minute, drug form: bag For central line use only. For serum potassium level of 4 mmol/L or less
7		ೆ	magnesium sulfate	2 g, IV, as directed, PRN hypomagnesemia, administer over: 30 minute For serum magnesium 1 mmol/L or less
7		ಿ	SODIUM phosphate	15 mmol, IV, as directed, PRN hypophosphatemia, administer over: 2 hour For serum phosphate 0.8 mmol/L or less
1 CAI	DD CII	IDG U	eart Transplant Post Operative (Multiphase), Medica	· ·
			r/Discharge	on management (named rending)
Au	iiiiii, ii		Bed Transfer Request	Admit to Cardiology, New Attending Provider Accepted, Ward, Telemetry
	edicatio		bed Hallstei Kequest	Authit to Cardiology, New Attending Provider Accepted, Ward, Telemetry
	uretics			
]	arctics	ಿ	furosemide	40 mg, PO, BID, drug form: tab
1			furosemide	Until dosing weight reached
J		03	turosemide	40 mg, IV, qdaily, drug form: inj Until dosing weight reached
Ant	tihype			
			hydrALAZINE	▼ 10 mg, PO, TID, drug form: tab
			amLODIPine	▼ 2.5 mg, PO, qdaily, drug form: tab
	gioten		onverting Enzyme Inhibitors	
			ramipril	▼ 2.5 mg, PO, qdaily, drug form: tab
Stre	ess Ulce		phylaxis	
			ranitidine	▼ 150 mg, PO, BID, drug form: tab
	69		pantoprazole	40 mg, IV, qdaily, drug form: bag
	G-S	-	pantoprazole	40 mg, PO, qdaily, drug form: tab
		್ರ	esomeprazole	40 mg, NG-tube, qdaily, drug form: tab-EC Put tablet in syringe with 50 mL of water and 5 mL of air. Shake for 2 minutes to disperse. After administration, flu
Bov	vel Ma	inten	ance	
		ಿ	polyethylene glycol 3350 (PEG 3350 powder)	17 g, PO, qdaily, drug form: powder Give until bowel movement
VTE	Proph	hylaxis	;	
	•		enoxaparin	40 mg, subcutaneous, qPM, drug form: syringe-inj
			heparin	5,000 unit, subcutaneous, q12h, drug form: inj, start: T;1000
Oth	ner Med			-,
			Insulin Subcutaneous for Patients Eating or NPO (Slidi	
			Insulin Subcutaneous for Patients on TPN or Continuo.	
Mo	dules			
		95	Bowel Protocol (Module)	Planned Pen
			ICU Standard Bowel Protocol (Module)	
			Venous Thromboembolism (VTE) Prophylaxis - Surger.	
CAF	RD SU	RG H	eart Transplant Post Operative (Multiphase), Medicati	on Management, Bowel Protocol (Module) (Planned Pending)
	dicatio			
		- ⟨%}	If patient has GFR less than 30 mL/min use Bowel Proto	col Renal
		- ⟨%	This is a general bowel protocol (General Medicine). It of	oes not include specialized bowel protocols such as elderly care, palliative care, and spine patient
		∕ 🌣	CONTRAINDICATIONS: Complete howel obstruction of	arrhea, colostomy, ileostomy, short howel syndrome
		₹,	Do NOT give SUPPOSITORIES or ENEMA if Leukemia /	MT patient or if pancytopenic or neutropenic
		Ŕ	Additional Diet Information	Fruit Lax, 30 mL, PO, BID
		ک	/ data and other mornation	Do not use if eGFR LESS than 30 mL/min. Hold if patient has diarrhea
			Day 1	50 not act if contracts that some implications and activities
			Select polyethylene glycol 3350 (preferred) OR lactulose	
		o d	polyethylene glycol 3350 (PEG 3350 powder)	17 g, PO, qdaily, PRN constipation, drug form: powder (Bowel Protocol Day 1) -Mix in 250 mL of water
		ಿ	lactulose (lactulose 10 g/15 mL oral liq)	10 g, PO, qdaily, PRN constipation, drug form: oral liq (Bowel Protocol Day 1)
		og g	lactulose (lactulose 10 g/15 mL oral liq)	20 g, PO, qdaily, PRN constipation, drug form: oral liq (Bowel Protocol Day 1)
		/%	Day 2 (continue Day 1 treatment)	
			Select sennosides (preferred) OR magnesium hydroxide	with cascara
1			sennosides	12 mg, PO, qHS, PRN constipation, drug form: tab
				If no bowel movement after 48 hours. Please continue day 1 treatment (Bowel Protocol Day 2)
		<9∕	Select magnesium hydroxide AND cascara liquid	
	60	og 9	magnesium hydroxide (magnesium hydroxide 1.2 g/15 mL oral liq)	2.4 g, PO, qHS, PRN constipation, drug form: oral liq If no bowel movement after 48 hours. Give with cascara. Do not use if eGFR below 30 mL/min. Please continue day
]	60	್ಟ್	cascara	15 mL, PO, qHS, PRN constipation, drug form: oral liq
				If no bowel movement after 48 hour. Give with magnesium hydroxide (MILK of MAGNESIA EQUIV). Do not use if e

		<u>/&</u>	Day 3 (continue Day 1 and Day 2 treatment)	
ī			Day 3 (continue Day 1 and Day 2 treatment) bisaCODYL	10 mg, rectal, qdaily, PRN constipation, drug form: supp
	(O	DISACOUYL	If no bowel movement after 72 hours. Please continue day 1 and day 2 treatment. (Bowel Protocol Day 3 step 1)
	(og 1	glycerin (glycerin adult supp)	1 suppositiony, rectal, qdaily, PRN constitution, drug form: supp If no bowel movement after 72 hours, Please continue day 1 and day 2 treatment (Bowel Protocol Day 3 step 1)
	(sodium biphosphate-SODIUM phosphate (phosphates (FLEET) 130 mL enema)	130 mL, rectal, qdaily, PRN constipation, drug form: enema If no response to bisacodyl AND/OR glycerin suppository in 1 hour. Do not use if eGFR below 30 mL/min. Please
CF	ARD SURG		art Transplant Post Operative (Multiphase), Transfer (Planned Penc	
	dmit/Trans			
_			Complete Transfer Medication Reconciliation	
			Nurse to Discontinue Order Set/Phase	Discontinue CSICU Admission Phase
St	tatus	_		
		1	Code Status	▼ Attempt CPR, Full Code
P	atient Care			
	(Ż	Cardiac Monitoring	May suspend for transport/shower Discontinue on post op day 4 if normal sinus rhythm for 24 hours
	- 1	Ż	Vital Signs	Routine, as per unit policy
		_		Notify provider of any new fever above 38 DegC
	- 1	2	Communication Order	Remove pacing wires post op day 4 if normal sinus rhythm for 24 hours
			Weight	qdaily
		Ż	Remove Staples	Remove every other staple on post-op day 10 and the rest on post-op day 14
		Ż	Remove Sutures	Remove sutures 10 days after chest tubes removed
	- (7	Refer to Transplant Patient Competencies	T;N
A	ctivity	_		
	[Ø	Activity as Tolerated	T;N, Encourage increasing mobilization
0	Diet/Nutrit	tion		
		⟨9	Review the most current diet order for therapeutic requirements,	, food texture and fluid thickness. Add anything to be carried forward to the new Diet Order
	වෙ	• 🗖	General Diet.	No salt packages
	69		Diabetes Diet	Diabetes Standard
		7	Fluid Restrictions	■ 1.5 L/day, Including feeds, Including IV fluids
(Continuou		fusions	
			Saline Lock Peripheral IV	When off telemetry and IV therapy
N	Medication		·	
			Ilopathy Prevention	
ĺ	mograte t		ASA (ASA EC)	81 mg, PO, qdaily, drug form: tab-EC
			pravastatin	20 mg, PO, qdaily, drug form: tab
	notrope In			
	notrope in		CARD Cardiac Unit Inotrope Infusion (Module)	
V	/itamins a		upplements	
			calcium carbonate (calcium carbonate (dosed as	500 mg, (elem calcium 500 mg = calcium carbonate 1250 mg), PO, BID with food, drug form: tab
		٥٥	elemental calcium))	Dose based on elemental calcium
		ď	cholecalciferol (vitamin D3)	1,000 unit, PO, qdaily, drug form: tab
	aboratory			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	Hematolog			
Ė	Terriacoro		CBC and Differential	Blood, AM Draw, Collection: T+1;0330, qMonWedFri for 4 week
(Chemistry			,,,
	3		Electrolytes Urea Creatinine Panel	Blood, AM Draw, Collection: T+1;0330, qMonWedFri for 4 week
	<u> </u>	ă		RN to enter tacrolimus level at 0730 prior to 0900 TACrolimus dose
	•	Ď		Blood, AM Draw, Collection: T+1;0330, qMon for 4 week
	us .	ď	Lactate Dehydrogenase (LDH)	Blood, AM Draw, Collection: T+1,0330, qMon for 4 week
			Creatine Kinase (CK Level)	Blood, AM Draw, Collection: 1+1;0530, qMon for 4 week
V	/irology		Creatine Alliase (CR Level)	Blood, AM Diaw, Collection: 1+1,0330, QMOINTOL4 WEEK
٧		17	Cytomegalovirus (CMV) Viral Load PHC	Blood, AM Draw, Collection: T+1;0330, qMon for 4 week
D	Diagnostic T			at the second account of the second decreases () thank
_			XR Chest	Routine, Reason: Post operative evaluation
			Electrocardiogram 12 Lead (ECG 12 Lead)	Routine, Post operative evaluation On arrival to ward
	8	M	CARD Echo	Urgent, Schedule as: Inpatient Scheduling Location: SPH Echo, Primary Indication: Heart Transplant, Special Instru
R	Respiratory			- Jan
			Oxygen Therapy	Titrate O2 to keep SpO2 92% or greater
C	Consults/Re			
			Referral to Heart Post Transplant	Next Available Appointment, SPH Heart Post, Post Heart Transplant
			Physical Therapy Consult	T;N, Reason for Consult: Post Heart Transplant
		Ż	Dietitian Adult Consult	Reason for Consult: Diet Order (Therapeutic), Post Heart Transplant, May advance or modify
-	Communica			
C			Unit Clerk Communication Order	Print Transplant Patient Education Competencies form and place on chartlet

5.3 Immunosuppression Intra- and Immediately Post-Operatively

Immunosuppressive regimen immediately prior to transplant and intra-operatively can be found in the Heart Transplant Admission PPO.

Selection of induction agent depends on patients cPRA level pre-operatively or whether they have donor specific antigens (DSA) identified. The table below outlines the current process.

VIRTUAL CROS			
NEGATIVE	POSITIVE		
Usual induction with Basiliximab on Day 0 and Day 4	Induction with rATG Monitor DSA as per protocol	NEGATIVE	П
Discuss with Immunologist to determine whether the result is clinically relevant or not. May require further testing. If not a clinically relevant result, usual induction with Basiliximab on Day 0 and Day 4 If relevant, induction with rATG as per post-transplant order set.	Commence desensitization therapy as per protocol including rATG induction.	POSITIVE	FLOW CROSSMATCH

5.3.1 Basiliximab Induction

 All patients who have cPRA <20% and negative virtual and/or flow crossmatch will receive Basiliximab induction as order per the <u>TRANSPLANT HEART</u> <u>Immunosupression (Multiphase)</u>, <u>Pre Operative Phase</u>

5.3.2 Antithymocyte Globulin (rATG) Induction

All patients with cPRA ≥ 20% OR high-risk as outlined above will receive rATG induction as per TRANSPLANT HEART Antithymocyte Globulin Rabbit (Multiphase) – cardiologist to

enter orders for "Day 1" as induction therapy (and leave in planned state, to be activated by bedside CSICU nurse)

In cases where there is concern over higher risk of infection, (e.g. chronic VAD driveline infection) the cardiologist may consider using Basilixamab versus rATG. Similarly in patients who are Epstein - Barr virus donor positive and recipient negative, rATG should be avoided.

Post-Heart Transplant Desensitization Therapy

- rATG induction
- Other immunosuppression as per standard protocol/powerplan
- Refer to Antibody Mediated Rejection treatment <u>section</u>
- Discuss Plan with Renal Team in general:
 - PLEX every day x 5 runs
 - PLEX every second day x 5 runs
 - IVIG 0.1g/kg after each PLEX
 - Discuss timing of Rituximab at team rounds. Only necessary if DSA continues to be positive

5.4 Post-Transplant Recovery

5.4.1 Early Post-Operative Phase

Close surveillance by the CSICU team and early intervention are the key. <u>Postoperative Powerplans</u> address prophylactic and preventative measures used to minimize complications.

Daily rounds by the Heart Transplant team occur in collaboration with the CSICU and other relevant teams.

5.4.2 Combined Heart-Kidney Transplant

In the case of combined heart and kidney transplantation, the Renal Transplant Team controls the immunosuppressive regimen.

5.5 Transfer to 5A (post-operative ward)

Most patients can be transferred to the ward within 2-5 days. Once hemodynamically stable and no longer requiring critical care surveillance, Heart Transplant Transfer Orders (below) are completed.

5.5.1 Transfer orders

Refer to CARD SURG Heart Transplant Post-Operative (Multiphase), Transfer

5.5.2 Most Responsible Physician on 5A

The most responsible physician is now the Heart Failure/Transplant Cardiologist. The patient is seen daily by a member of the Transplant Cardiology team.

5.5.3 Infection Control

Where possible, patients are nursed in a private room. This is primarily to enable more undisturbed time for rest and patient teaching. Standard infection control measures are used. Isolation procedures are only implemented with a specific order (e.g. severe neutropenia).

5.5.4 Immunosuppression

Triple therapy primarily with tacrolimus, mycophenolate mofetil and prednisone are initiated in the majority of patients. This is tailored according to clinical condition. The <u>Heart Transplant Transfer Orders</u> outline the immunosuppressive regimen used.

In the case of heart-kidney transplant recipients, the Renal Transplant Team controls the immunosuppressive regimen.

See <u>BC Transplant Clinical Guidelines for Transplant Medications</u> for the current accepted target blood levels for heart transplant recipients. This manual also contains detailed information about immunosuppressant medications.

5.5.6 Patient Education

Patient education is initiated as soon as feasible. The program uses a competency-based teaching program that is performed by all experienced nurses and allied health team members on 5A.

The post-transplant Patient Educator sees the patient and family to ensure they understand what they have learned and to provide outpatient information.

The Dietitian, Social Worker and Physiotherapist spend time with the patient and family to provide information around going home. The Psychologist is also available if required.

Patients learn to self-medicate while in the hospital and either the patient or a family member must show competence before discharge.

The following documents are available for print via Cerner EMR "FormFast" application and are used to facilitate and standardized patient education:

- PHC Transplant Patient Education Competency Record (FORM ID-3705 (nf266) VERSION 2021 JAN 05)
- PHC Heart Centre Heart Transplant Patient & Caregiver test (FORM ID-9550 (HH192) VERSION 2021 JUN 29)
- PHC Post Heart Transplant Checklist Prior to Discharge (FORM ID-8613 (PHC-HH188) VERSION 2024 FEB 26)

5.6 Discharge

Discharge from hospital occurs when the patient has completed education training and has demonstrated understanding and/or competence with self-medication, self-reporting of symptoms and other aspects of self-care. Patients are usually discharged within 10-14 days of surgery.

5.6.1 Discharge Prescriptions

Discharge medications are carefully reconciled by the pharmacist and cardiologist prior to prescriptions generated using the Cerner EMR. Transplant specific medications as listed below are prescribed and organized by the SPH Ambulatory Pharmacy and will be supplied to the patient prior to discharge. Ongoing refill of these transplant specific medications are done through SPH ambulatory pharmacy or BCT specified pharmacies in the community.

Place Patient Form Label Here	
HEART TRANSPLANT DISCHARGE BCTS PRESCRIPTION (SPH)	
* 3 2 9 0 * Prescription Management	
(To be dispensed by St. Paul's Hospital Pharmacy) St. Paul's Hospital 1081 Burrard Street, Vancouver, BC V6Z 1Y6 604-682-2344	
Date:	
(Items must be selected to be ordered)	
TACrolimus mg PO BID	
cycloSPORINE mg PO BID	
mycophenolate mofetil mg PO BID	
predniSONE mg PO daily	
☐ ValGANciclovir 450 mg PO daily	
Supply for above prescriptions: 1 month	
Refills for above prescriptions: 3 refills	
Rejection Treatment Pack x 1 (predniSONE 100 mg PO daily x 3 days ONLY to be taken who directed by Heart Transplant Clinic for treatment of rejections)	
Physician's Signature: College ID #:	_
Printed Name: Contact #:	_
Fax to St Paul's Hospital Outpatient Pharmacy (68675) at least 3 hours prior to discharge.	
FORM ID - 3290 (PH061) VERSION 2020 SEP 22	Page 1 of 1

6 Long-Term

6.1 Follow-up

Regular and frequent early follow-up ensures close surveillance as well as ongoing education regarding medications, diet and exercise.

Follow-up plans are documented on a detailed patient biography in Cerner EMR using the *Post Transplant Assessment PowerForm.* Below is a summary of the approximate surveillance schedule for post heart transplant patients in the first year:

Week 2 ☑ 7.5mg	Week 3 ✓	Week 4 ✓ 12.5mg	6	Week 8	Week 10	Month 3	Month 4	Month 4.5	Month 5.5	Month 7.5	Month 9 ☑	1 Year ☑	Visits every 6 months up to 5 years Annual Visit testing
7.5mg						_	Ø	N	abla		K	V	
	15mg	12.5mg	10mg	☑	☑							_	
	15mg	12.5mg	10mg				☑	☑	☑	Ø		☑	
			rong	7.5mg	5mg	2.5mg	off						
												V	Ø
☑	S	N	V	N	\triangleleft	Ø	Ø	Ø	Ø		Ø	3 6 monthly	
												S	Ø
												Ø	Ø
				✓								\square	1, 2 5 years
													at 10 years, every 5 years after that
						V						S	Ø
tes, BU	N, Creat,	CyA or sir	olimus Ta	c level									
/	tes, BU hile pat	tes, BUN, Creat, hile patient on Pr	tes, BUN, Creat, CyA or sir hile patient on Prednisone	tes, BUN, Creat, CyA or sirolimus Ta hile patient on Prednisone for immun	BC, diff, plats, lytes, BUN, Creat, LFTs, alb, tot tes, BUN, Creat, CyA or sirolimus Tac level hile patient on Prednisone for immune suppres	BC, diff, plats, lytes, BUN, Creat, LFTs, alb, tot prot, tot/ tes, BUN, Creat, CyA or sirolimus Tac level hile patient on Prednisone for immune suppression, the	BC, diff, plats, lytes, BUN, Creat, LFTs, alb, tot prot, tot/dir bili, Ca, ptes, BUN, Creat, CyA or sirolimus Tac level hile patient on Prednisone for immune suppression, the time points	BC, diff, plats, lytes, BUN, Creat, LFTs, alb, tot prot, tot/dir bili, Ca, phos, Mg, Hg tes, BUN, Creat, CyA or sirolimus Tac level hile patient on Prednisone for immune suppression, the time points are a guide	GC, diff, plats, lytes, BUN, Creat, LFTs, alb, tot prot, tot/dir bili, Ca, phos, Mg, HgbA1C (for tes, BUN, Creat, CyA or sirolimus Tac level hile patient on Prednisone for immune suppression, the time points are a guide only and the patient on Prednisone for immune suppression, the time points are a guide only and the patient on Prednisone for immune suppression, the time points are a guide only and the patient of the province	BC, diff, plats, lytes, BUN, Creat, LFTs, alb, tot prot, tot/dir bili, Ca, phos, Mg, HgbA1C (for diabetics), tes, BUN, Creat, CyA or sirolimus Tac level hile patient on Prednisone for immune suppression, the time points are a guide only and time points a	BC, diff, plats, lytes, BUN, Creat, LFTs, alb, tot prot, tot/dir bili, Ca, phos, Mg, HgbA1C (for diabetics), TSH, lipids, tes, BUN, Creat, CyA or sirolimus Tac level hile patient on Prednisone for immune suppression, the time points are a guide only and time points are determine	BC, diff, plats, lytes, BUN, Creat, LFTs, alb, tot prot, tot/dir bili, Ca, phos, Mg, HgbA1C (for diabetics), TSH, lipids, CyA or Tates, BUN, Creat, CyA or sirolimus Tac level hile patient on Prednisone for immune suppression, the time points are a guide only and time points are determined by pred	BC, diff, plats, lytes, BUN, Creat, LFTs, alb, tot prot, tot/dir bili, Ca, phos, Mg, HgbA1C (for diabetics), TSH, lipids, CyA or Tac, sirolimus

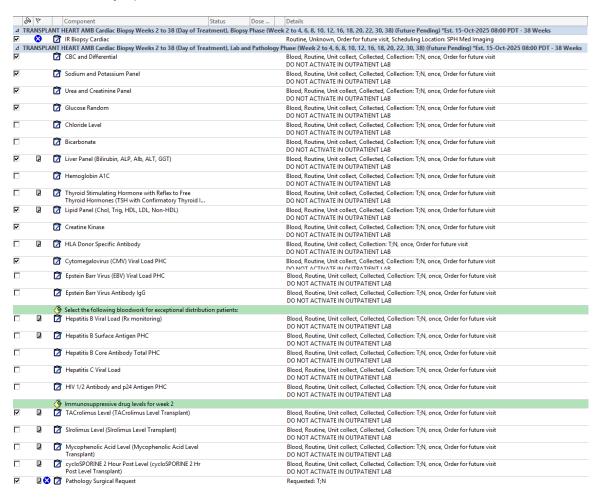
6.2 Biopsy surveillance

Biopsy surveillance is managed using the <u>TRANSPLANT HEART AMB Cardiac Biopsy</u> Weeks 2 to 38) Day of Treatment Powerplan.

A special consent form was created to ensure proper consenting of patients for potential complications specifically tied to biopsies. A copy of this consent form can be found in the Appendix section of this document.

This multiphase Powerplan allows the team to manage the biopsy schedule, blood work that needs to be drawn during the biopsy, as well as the pathology order to ensure timely transport of the specimen and diagnosis by the cardiac pathology team.

The powerplan gets ordered when the patient is transferred to 5A and continues to be used during the first year of the patient's post-transplant journey, and spans into the ambulatory space.



Biopsy Phase:

TRA	TRANSPLANT HEART AMB Cardiac Biopsy Weeks 2 to 38 (Day of Treatment), Biopsy Phase (Week 2 to 4, 6, 8, 10, 12, 16, 18, 20, 22, 30, 38) (Future Pending) *Est. 15-Oct-2025 08:00 PDT - 38 Weeks							
		Component	Week 2	Week 3	Week 4	Week 6	Week 8	Week 10
	2 2		Future Pending					
	00 K		*Est. 15-Oct-2025 08:	*Est. 22-Oct-2025 08:	*Est. 29-Oct-2025 08:	*Est. 12-Nov-2025 08:	*Est. 26-Nov-2025 08:	*Est. 10-Dec-2025 08:
			Actions ▼					
✓	•	IR Biopsy Cardiac						
		Routine, Unknown, Order for future visit, Scheduling Locatio	Planned	Planned	Planned	Planned	Planned	Planned

Lab & Pathology Phase:

TR	ANSI	PLANT	HEART AMB Cardiac Biopsy Weeks 2 to 38 (Day of Treatmen	t), Lab and Pathology P	hase (Week 2 to 4, 6, 8,	10, 12, 16, 18, 20, 22, 3	0, 38) (Future Pending)	*Est. 15-Oct-2025 08:0	0 PDT - 38 Weeks
				Week 2	Week 3	Week 4	Week 6	Week 8	Week 10
	D	7	Component	Future Pending	Future Pending	Future Pending	Future Pending	Future Pending	Future Pending
	000	,	Component	*Est. 15-Oct-2025 08:	*Est. 22-Oct-2025 08:	*Est. 29-Oct-2025 08:	*Est. 12-Nov-2025 08:	*Est. 26-Nov-2025 08:	*Est. 10-Dec-2025 08:
				Actions ▼	Actions ▼	Actions ▼	Actions ▼	Actions ▼	Actions ▼
☑			CBC and Differential						
			Blood, Routine, Unit collect, Collected, Collection: T;N, once						
			DO NOT ACTIVATE IN OUTPATIENT LAB	Planned	Planned	Planned	Planned	Planned	Planned
☑			Sodium and Potassium Panel						
			Blood, Routine, Unit collect, Collected, Collection: T;N, once						
_			DO NOT ACTIVATE IN OUTPATIENT LAB	Planned	Planned	Planned	Planned	Planned	Planned
굣			Urea and Creatinine Panel						
			Blood, Routine, Unit collect, Collected, Collection: T;N, once						
_			DO NOT ACTIVATE IN OUTPATIENT LAB	Planned	Planned	Planned	Planned	Planned	Planned
✓			🔁 Glucose Random						
			Blood, Routine, Unit collect, Collected, Collection: T;N, once						
_			DO NOT ACTIVATE IN OUTPATIENT LAB	Planned	Planned	Planned	Planned	Planned	Planned
			Chloride Level						
			Blood, Routine, Unit collect, Collected, Collection: T;N, once						
_			DO NOT ACTIVATE IN OUTPATIENT LAB						
			Bicarbonate						
			Blood, Routine, Unit collect, Collected, Collection: T;N, once						
		П	DO NOT ACTIVATE IN OUTPATIENT LAB						
굣		₽	Liver Panel (Bilirubin, ALP, Alb, ALT, GGT)						
			Blood, Routine, Unit collect, Collected, Collection: T;N, once			D			
-			DO NOT ACTIVATE IN OUTPATIENT LAB			Planned			
			Hemoglobin A1C						

6.4 Immunological Surveillance Post-Transplant

A new finding of Donor Specific Antibodies with a mean fluorescence intensity (MFI) over 5,000 is considered to require treatment.

	DSA	Echo	Endomyocardial Biopsy
DSA present and/or	Day 1	Week 1	As per routine (specify C4D staining required)
Virtual/Flow XM POSITIVE	Week 1, 2	Month 3, 6, 9, 12	
	Month 1, 3, 6	Annually and if indicated	
	Year 1 2, 3, 4, 5		
	Thereafter if indicated		
Post AMR Treatment	Week 1, 4	Month 3, 6, 9, 12	If < 1 year post transplant, Bx as per
	Month 3, 6, 9	Annually and if indicated	routine
	Year 1, 2, 3, 4, 5		Otherwise, month 1, 3, 6, 12 post-treatment
	Thereafter if indicated		(specify C4D staining required)
No DSA present	Month 1, 3, 6	As per routine	As per routine
	Year 1		
	If DSA found, discuss plan with cardiologist		
DSA found for any reason	If DSA found, repeat in three months	Echo x 1 and if dysfunction follow	As per routine
other than above	Discuss plan with cardiologist	AMR pathway	

DSA = Donor Specific Antibody; XM = Crossmatch; cPRA = Calculated Panel Reactive Antibody; AMR = Antibody mediated rejection; Bx = Biopsy

Reference: Canadian Blood Services, National HLA Advisory Committee, CTR.70.003, V5.0 (2023-08-17)

6.5 AlloMap

AlloMap® (by CareDx) is a non-invasive blood test that measures the expression of 20 genes to help monitor acute cellular rejection in heart transplant patients. Performed in a single U.S. laboratory, it provides a score from 0 to 40, with higher scores more closely associated with rejection. A large clinical trial showed AlloMap® to be as effective as routine biopsies, and **a score of 34 or higher was used to trigger biopsy**. FDA-approved and included in international guidelines, AlloMap® helps reduce the need for invasive biopsies and their associated risks in patients with stable graft function.

As of August 2025, our program was funded 10 tests by BC Transplant as a pilot project, with hope for future sustainment.

Our program agreed to use AlloMap® for selected 2-3 patients serially. Especially for pt who may benefit due to psychosocial issues or technical difficulties. Potential candidates are to be brought to rounds for discuss to reach consensus.

The following SOP was developed to address the use of AlloMap®:



AlloMap® blood test for post heart transplant recipients

Site Applicability:

St. Paul's Hospital (SPH) Heart transplant program and laboratory

Scope:

AlloMap® (by CareDx) is a non-invasive blood test that measures the expression of 20 genes to help monitor acute cellular rejection in heart transplant patients. Performed in a single U.S. laboratory, it provides a score from 0 to 40, with higher scores more closely associated with rejection. A large clinical trial showed AlloMap® to be as effective as routine biopsies, and a score of 34 or higher was used to trigger biopsy. FDA-approved and included in international guidelines, AlloMap® helps reduce the need for invasive biopsies and their associated risks in patients with stable graft function.

This SOP covers the 10 test that has been funded by BC Transplant as of August 2025.

Indication for use:

Patients must: (all)

- be 18 years or older
- be at least 55 days post-transplant
- · be on less than 20 mg/day of prednisone
- not have signs or symptoms of allograft dysfunction (e.g.: heart failure, graft dysfunction, hemodynamic compromise)
- have LVEF > 45%
- · be able to provide informed consent

AlloMap® is not a suitable test for patients who: (Any)

- · are monitored for the purpose of excluding AMR
- have severe CAV (ISHLT grade 3)
- have been treated for rejection within the past 2 months
- have been transfused (any blood product) within 30 days of testing
- have received hematopoietic growth factors (e.g.: Neupogen®) within 30 days of testing.
- have end-stage renal disease requiring renal replacement therapy
- · are pregnant at the time of testing

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Effective date: 22/Aug/2025 Page 1 of 8

- had a major change in immunosuppression therapy (e.g.: discontinuation of CNI, transition to PSI) within the preceding 30 days
- have signs or symptoms suggesting rejection (ie AlloMap® must not be used in a 'for-cause' situation)
- are multi-organ transplant recipients
- have active CMV / EBV viremia
- have absolutely no access for EMBx (i.e. cannot perform an embx for a positive CareDx result)
- have had 2 abnormal scores in the absence of pathological demonstration of cellular rejection (ISHLT 2R or greater) by EMBx

Procedures:

1. Criteria for use:

- 1.1. Patients who may be candidates for AlloMap will be brought to discussion at Tuesday's multidisciplinary rounds to confirm that patient meets criteria and ensure AlloMap test is suitable per indications for use
- 1.2. Clinical Nurse Specialist (CNS) to document decision if a candidate
- 1.3. Primary RN to notify patient of decision if appropriate candidate

2. Steps for Allomap lab Request:

- 2.1. RN will fill out 2 requisitions with the kit. One from SPH LAB and one from CareDx along with the collection kit (See Appendix)
- 2.2. For the CareDx requisition, only need to fill in the following:
 - 2.2.1. Patient last name: enter "CareDx"
 - 2.2.2. Patient's first name: enter the pt's real first & last initials (e.g. Elizabeth Taylor = ET, so the final name would read "CAREDX, ET")
 - 2.2.3. DOB: enter patient's real birth year, real birth month, but "01" as the birth date
 - 2.2.4. Sex: enter real patient info
 - 2.2.5. Transplant (tx) date: enter patient's real tx year, real tx month, but "01" as the tx date
- 2.3. For the requisition: SPH Lab Clinical Trial Study: 2023 CareDx AlloMap:
 - 2.3.1. "Coordinator" field: Primary RN's name
 - 2.3.2. "Available Contact Number": Primary RN's phone #
 - 2.3.3. CareDx Identification Number: leave blank (lab will enter MRN of pt)
 - 2.3.4. Subject last name, first name: Enter real pt info, and fake info per 2.2.2
 - 2.3.5. DOB: enter real patient info & fake info per 2.2.3
 - 2.3.6. Sex: enter real patient info
 - 2.3.7. PHN enter real patient info
- 2.4. Primary RN will document the following in Cerner,

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Effective date: 22/Aug/2025 Page 2 of 8

- 2.4.1. Use a free-text nursing note and called the document "AlloMap testing info"
- 2.4.2. Enter date pt planned for lab work
- 2.4.3. Enter the first AlloMap label number per the green sticker sheet (without the dash) within the kits that are on the accession labels

3. Scheduling a lab appointment

- 3.1. Ask patient to schedule appointment per our clinic's instruction through following website: https://www.labonlinebooking.ca/
- 3.2. Ask patient to add "ALLOMAP "to the end of their last name
- 3.3. Patient to confirm booked appointment with Primary RN & CNS

4. Notification of appointment to lab team:

- 4.1. Primary RN to send email the patient's name, PHN, and appointment date/time to the following individuals to notify of upcoming test:
 - 4.1.1. Anna Lew & Catherine Wang (Lab Team Lead): <u>alew@providencehealth.bc.ca</u>; catherine.wang@phc.ca
 - 4.1.2. Azaram Akhavien (Lab Clinical Research Coordinator):

aakhavien1@providencehealth.bc.ca

- 4.1.3. Dr. Daniel Holmes (Lab Medical Lead): dtholmes@providencehealth.bc.ca
- 4.1.4. Dr. Brian Clarke bclarke@providencehealth.bc.ca
- 4.1.5. Clinical Nurse Specialist: wchiu@providencehealth.bc.ca

5. Sample collection by lab:

- 5.1. A blood sample is taken from the patient at the SPH Outpatient Lab. Lab research MLA, June Song will process the blood sample according to the guidelines given by CareDx. Once the samples are processed, they are sent to a specific facility, CareDx, that is equipped to process the AlloMap test.
- 5.2. After the research MLA sends the samples to CareDx, the requisition will be given to lab research coordinator, Azarm Akhavien. She will keep track of the anonymized patients This list is needed to correlate the anonymized report with the real patient.

6. Examination processing and reporting by lab:

6.1. The blood sample undergoes quantitative real-time polymerase chain reaction (qRT-PCR) to evaluate the expression levels of 20 particular genes. This information is subsequently transformed into an AlloMap Test Score using a proprietary algorithm. The findings are completed by clinical laboratory scientists at the testing center and forwarded to the requesting physician.

7. Steps for Result Delivery:

7.1. CareDx will email anonymized lab results to Dr. Dan Holmes: <u>dtholmes@providencehealth.bc.ca</u>, Dr. Brian Clarke: <u>bclarke@providencehealth.bc.ca</u> & CNS, Wynne Chiu: <u>wchiu@providencehealth.bc.ca</u>

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Effective date: 22/Aug/2025 Page 3 of 8

- CareDX will also fax results to SPH Laboratory, attention Azarm Akhavien, research coordinator, by fax at 604-682-8342.
- 7.3. The lab staff will receive the faxed lab report and deliver it to the research coordinator.
- 7.4. The research coordinator will examine the tracking list of anonymized patient outcomes and record the real patient's name, date of birth, gender, and PHN on the report.
- 7.5. After the data is on the report, it will be handed to Dr. Holmes by the research coordinator
- 7.6. Dr. Holmes will send the results to the ordering physician with the AlloMap Test Score, which is an integer ranging from 0 to 40. This score is used in conjunction with other clinical assessments, such as endomyocardial biopsy results, to determine the patient's risk of acute cellular rejection (ACR). A low AlloMap score suggests a low probability of ACR, potentially reducing the need for more frequent or invasive biopsies.

Results interpretation

- 8.1. The physician utilizes the AlloMap results, in conjunction with other clinical evidence, to inform decisions regarding the patient's ongoing treatment strategy, which might involve additional monitoring, changes in medication, or the necessity for an endomyocardial biopsy
- 8.2. Results ≥ 34, EMBx to be booked within 5 calendar days. EMBx reviewed per usual protocol
- 8.3. Results < 34 will be reviewed by on call cardiologist + fellow for further IS adjustments.
- 8.4. Patients are notified of the AlloMap® score results by the primary RN with medications changes made based on the results and future need for further AlloMap® testing.
- 8.5. On call MRP or fellow to document in Cerner EMR of clinical decision made in concordance to the results

Reference:

Crespo-Leiro, M. G., Stypmann, J., Schulz, U., Zuckermann, A., Mohacsi, P., Bara, C., Ross, H., Parameshwar, J., Zakliczyński, M., Fiocchi, R., Hoefer, D., Colvin, M., Deng, M. C., Leprince, P., Elashoff, B., Yee, J. P., & Vanhaecke, J. (2016). Clinical usefulness of gene-expression profile to rule out acute rejection after heart transplantation: CARGO II. European heart journal, 37(33), 2591–2601. https://doi.org/10.1093/eurheartj/ehv682

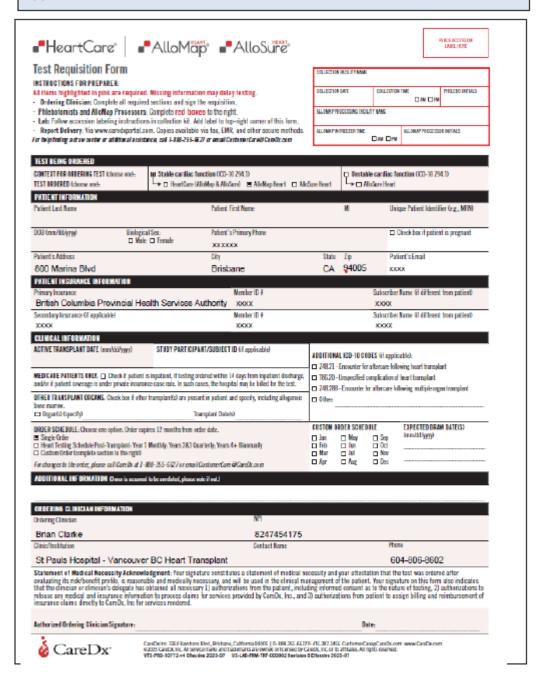
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Effective date: 22/Aug/2025 Page 4 of 8

Appendices



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Effective date: 22/Aug/2025 Page 6 of 8

			Time:				
			Time.				
St. Paul's Hospital		STUDY: 2023 CareDx Allomap					
		Department: Cardiology					
St. Paul							
1081 Burrard Street Vancouver, BC V62 1Y6 (604) 806-8810 CLINICAL TRIALS LABORATORY TEST ORDER FORM		Coordinator					
				Place the SQ/Cerner Label Here:		Subject last name, first name	
					_	Date of Ri	rth (Day/ Month/ Year)
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Effective date: 22/Aug/2025 Page 7 of 8

APPROVALS						
Heart trans Medical Di	•	Dr. Brian Clarke	August 22, 2025			
SPH lab Me Director	edical	Dr. Daniel Holmes	August 22, 2025			
SPH Lab Te	Lab Team Lead Anna Lew		August 22, 2025			
	lab Clinical earch coordinator Azarm Akhavien		August 22, 2025			
Clinical Nurse Specialist		Wynne Chiu	August 22, 2025			
DEVELOPERS/OWNER						
Clinical Nui Specialist	inical Nurse wecialist Wynne Chiu			August 22, 2025		
REVISION HISTORY						
Revision#	Description of Changes		Prepared by	Effective Date		
00	Initial Release		Wynne Chiu	August 22, 2025		

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Effective date: 22/Aug/2025 Page 8 of 8

6.6 Long-term care - Approach

The heart transplant clinic aims to improve long-term survival of heart transplant recipients under their care by providing support through:

- Self-management education and counseling
- Heart Transplant related follow-up
- Providing support to primary care providers
- Providing an efficient and safe service

6.6.1 Primary Care Involvement

Establish a partnership with Primary Care Providers (PCP), recognizing that active involvement in patient management with clear communication is a key factor in influencing outcomes.

Below is an example letter that is sent to the patient's PCP when they first go home.

Dear Dr,

Please find attached a copy of the discharge summary for x

Now that $\frac{x}{x}$ has been discharged, we would like to outline what you can expect from our clinic in relation to care of your patient. We would like to enter into a partnership with you.

Summary of Heart Transplant Clinic visit schedule

Testing	1 month	Up to 6 months	6 months to 1 Year	Annually
Heart Biopsy	Weekly until 1 month	Second weekly until 5 months	Then month 6, 8 and 1 year	After 1 year, only if indicated
Renal function and immunosuppressive levels	As above	As above	As above	As above
Coronary artery disease screening tests				Yearly

Our commitment - We will:

- Manage the patient's immunosuppression for life.
- Continue to manage specific medications that we prescribe.
- Manage lipids and hypertension.
- Order cardiac diagnostic procedures
- Refer to cardiac rehab
- Send you a summary sheet of each clinic visit with our plans.
- · Send a yearly summary letter
- Phone you if we have any concerns.
- Send you a discharge summary if the patient has been hospitalized here.

We ask that you:

- Manage other non-cardiac chronic conditions such as diabetes
- Keep the program here informed of major changes to the patient's condition
 - Malignancies
 - o Infections
 - SurgeryMajor morbidities
 - Death
- Administer yearly flu shots
- Organize routine malignancy screening particularly
 - o Bowel
 - Breast
 - Gynae
 - Skin (at least 6 monthly)

We look forward to managing this patient with you. We would appreciate feedback if you have any so that we can continue to provide consistent care with you.

Who to call

Business hours 604-806-8374
After hours local 604-877-2240
After hours toll-free 1-800-663-6189

6.6.2 Readmissions to Hospital

6.6.2.1 Heart Transplant and Immunosuppression related issues

Patients readmitted to St. Paul's hospital where possible, will be cared for directly by the Heart Transplant Cardiologist in 5A. Recognizing that there may be logistical or medical issues that prevent this, the Heart Transplant Cardiologist should be actively involved in their management plan.

6.6.2.2 Non-heart transplant related issues

It is the role of the Heart Transplant Cardiologist to provide advice in a consultative manner around immunosuppression and cardiac medications. Regular updates will be sought by the team members in order to provide input when necessary.

6.7 Immunosuppression

See <u>BCT Pharmacy Manual</u> for detailed information about suggested dosing and blood levels

6.7.1 Tacrolimus

Time Post-Transplant (Months)	Tacrolimus* Trough Blood Concentration (ng/mL) 12 hours Post-Dose	
Less than 3	9 to 12	
3 to 6	8 to 9	
6 to 12	6 to 8	
Greater than 12	4 to 8	

6.7.2 Cyclosporine

Time Post Transplant (Months)	Cyclosporine Trough Concentration (ng/mL)
0 to 3 months	300 to 350
3-6 months	200 to 300
6 to 12 months	150 to 250
Greater than 12 months	100 to 150

Time Post Transplant (Months)	Cyclosporine C2 Concentration (ng/mL)	
Less than 1 month	1200 to 1400	
2 to 3 months	1000 to 1200	
4 to 5 months	800 to 1100	
6 to 12 months	700 to 1000	
12 to 24 months	600 to 800	
Greater than 24 months	400 to 600	
When eGFR is le	ss than 45mL/min/1.73m ²	
Less than 1 month	1000 to 1200	

2 to 3 months	800 to 1100
4 to 5 months	700 to 900
6 to 12 months	600 to 800
12 to 24 months	400 to 600
Greater than 24 months	300 to 400

6.7.3 Sirolimus

Time Post Transplant (Months)	Sirolimus Trough Concentration (ng/mL)* (When sirolimus is used with tacrolimus or cyclosporine +/-mycophenolic acid and steroids)	Sirolimus Trough Concentration (ng/mL)* (When sirolimus is used as a single agent +/- steroids)
All 4 to 8		8 to 12

6.7.4 Mycophenolate

Patient Status	Mycophenolic Acid* Trough Blood Concentrations (mg/L) 12 hours Post Dose	
Stable and no transplant rejection	1.7 to 4	
Has transplant rejection	2.5 to 4	
Has MPA side effects and is stable	1.7	

^{*}In clinical situations where MPA levels are required to guide therapy, an MPA AUC is recommended. Please consult clinical pharmacist

7.1 Cellular Rejection Treatment

Acute cellular rejection monitoring is performed using the endomyocardial biopsy (EMBx). The first one is usually performed prior to discharge at around 10 – 14 days post-operatively. EMBx are performed on Wednesday mornings and prn for emergencies. The standard EMBx surveillance protocol is outlined earlier.

An endomyocardial biopsy result of ISHLT 2R or above is considered significant enough to treat actively. In general, the following schedule is followed at the discretion of the Heart Transplant Cardiologist. Treatment protocol is as follows:

Protocol for Treatment of Acute Rejection - St Paul's Hospital

As much as is possible, patients with cardiac rejection will be treated on an outpatient basis. The severity of the rejection and accompanying signs and symptoms such as low BP, shortness of breath, arrhythmia, fever, decreased exercise capacity may require inpatient treatment.

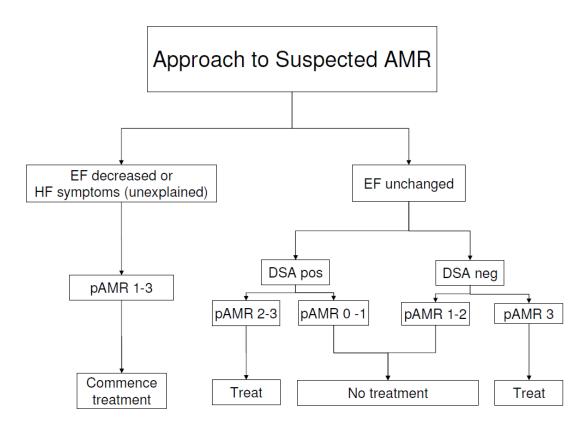
ISHLT Grade of Rejection	< 3 months post-Tx	> 3 months post- transplant	Hemodynamic Compromise
Grade 0R	Nil	Nil	Assessed individually
Grade 1R	Nil	Nil	1g IV Solumedrol x 3 days Admit to CCU Echo Monitor +/- inotropes Consider ATG
Grade 2R	100mg Prednisone po x 3 days	100mg Prednisone po x 3 days	1g IV Solumedrol x 3 days Admit to CCU
Grade 3R	1g IV Solumedrol x 3 days Admit 5a • Consider ATG • Optimize immunosuppr ession	1g IV Solumedrol x 3 days Admit 5a	1g IV Solumedrol x 3 days Admit to CCU Echo Monitor -/- inotropes Consider ATG Optimize immunosuppression

Nursing Considerations:

- Close monitoring of hemodynamic parameters such as BP, heart rate, rhythm and symptoms of pump failure such as fluid retention and shortness of breath should be carefully monitored and reported immediately.
- · Prednisone is discontinued while the patient is receiving Solumedrol.
- If the patient was a CMV mismatch, or if they required Acyclovir post transplant due to HSV prophylaxis, they will need prophylactic antiviral treatment reinitiated as per infection protocol.
- · Septra will need to be reinitiated as per infection protocol
- If the patient had steroid induced Diabetes in the immediate post-transplant period, this will likely re-occur. Check with the physician to see if he wants to order any therapy.

7.2 Antibody Mediated Rejection

Guideline for approach to AMR management is per algorithm below. However, each case is individualized, and plan/treatment is brought to multidisciplinary team for discussion. Patient's symptomology, graft function, transplant date, infection and rejection history is taken into careful consideration.



Reference for pathology antibody-mediate rejection category per ISHLT, 2022:

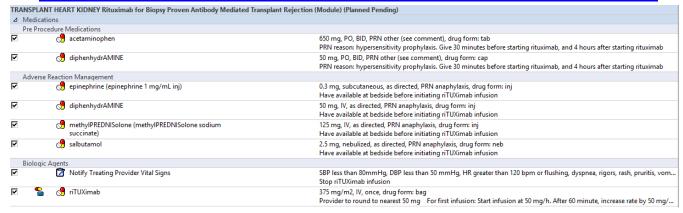
- pAMR 0—negative for pathologic AMR: histopathologic and immunopathologic studies are both negative.
- pAMR 1 (H+)—histopathologic AMR alone: histopathologic findings present and immunopathologic findings negative.
- pAMR 1 (I+)—immunopathologic AMR alone: histopathologic findings negative and immunopathologic findings positive; that is, CD68+ and/or C4d+ for IHC and C4d+ with or without C3d+ for IF.
- pAMR 2—pathologic AMR: histopathologic and immunopathologic findings are both present.
- pAMR 3—severe pathologic AMR: interstitial hemorrhage, capillary fragmentation, mixed inflammatory infiltrates, endothelial cell pyknosis, and/or karyorrhexis and marked edema and immunopathologic findings are present.

7.2.1 Antibody Mediated Rejection (AMR) Treatment TRANASPLANT HEART Antibody Mediated Rejection (AMR) (Multiphase), AMR Initiation (Example below only shows Plex 1, additional day orders available on the PowerPlan)

	TD ANICDI AI	ATTIFACT A ST. I AND II ALL CANDO CANDO CANDO CALLED CO.	
		NT HEART Antibody Mediated Rejection (AMR) (Multiphase), AMR Initiation (Planne	d Pending)
Δ		sfer/Discharge	
		48 hours prior to commencing PLEX treatment, provider to communicate plan via AMI	R Planning and Summary Flowsheet
		Provider to consult Nephrology to set up PLEX every second day for 5 runs	
Δ	Medication /8		
	(9	To order rituximab administration, select TRANSPLANT SERVICES Rituximab Infusion to immediately after first PLEX	or Biopsy Proven Antibody Mediated Transplant Rejection PowerPlan. If not possible to give 48 hours before, administer
	™ /8.		
		BC Transplant Antibody Mediated Rejection (AMR) Cardiac Protocol	
므		TRANSPLANT HEART KIDNEY Rituximab for Biopsy Pr	
□ ▼		Hypersensitivity / Anaphylaxis Treatment (Module)	
	<u></u>	methylPREDNISolone (methylPREDNISolone sodium s	500 mg, IV, qdaily, order duration: 3 doses or times, drug form: inj
₹	07	sulfamethoxazole-trimethoprim (cotrimoxazole 400	80 mg, (trimethoprim 80 mg = 1 tab), PO, qdaily, drug form: tab
	/8.		SEPTRA EQUIV. Dose based on trimethoprim
		Consider providing patient with prescription for cotrimoxazole-trimethoprim as patient	
		If patient CMV positive, Donor positive/negative or if patient is CMV negative/ donor p	
		valGANciclovir	900 mg, PO, qdaily with food, order duration: 4 week, drug form: tab
Δ	Laboratory		
		Order Cytotoxic Antibody Screen if not done in the last month	
		HLA Donor Specific Antibody	Blood, Routine, Collection: T;N, once
	(9)	If patient CMV positive, Donor positive/negative or if patient is CMV negative/ donor p	ositive, select valGANciclovir
	2	Cytomegalovirus (CMV) Viral Load PHC	Blood, Routine, Collection: T;N, qweek 8 week
⊿ .	TRANSPLAI	NT HEART Antibody Mediated Rejection (AMR) (Multiphase), AMR Orders for PLEX 1	l (Planned Pending)
		sfer/Discharge	
		Nurse to initiate this phase of the PowerPlan when patient is receiving PLEX 1	
Δ	Medication		
			or Biopsy Proven Antibody Mediated Transplant Rejection PowerPlan. If not possible to give 48 hours before, administer
	3	immediately after first PLEX	, ,,, sarry sarry and the sarry
	.	TRANSPLANT HEART KIDNEY Rituximab for Biopsy Pr	
П		Hypersensitivity / Anaphylaxis Treatment (Module)	
Δ	Blood Prod		
		Patient to receive 0.1 g/kg IV after each PLEX run	
v	⊗ 🕌		
۸.		NT HEART Antibody Mediated Rejection (AMR) (Multiphase), AMR Orders for PLEX 1	TM IVIG Innatient (Module) (Planned Pending)
	Medication		, im the inputer (module) (i mined i chang)
ゼ			50 ml. IV as directed DBN other (see comment) order duration; 1 deces or times, days form has
•	00		50 mL, IV, as directed, PRN other (see comment), order duration: 1 doses or times, drug form: bag PRN Reason: routine line flush following the completion of blood product transfusion
	DI I D I	•	FIVE reason. Totalife internastronowing the completion of blood product transfersion
Δ	Blood Prod	Approved medical conditions and prerequisites	
		Consultation with site Pathologist is available - contact TM	
		Order Group and Screen if patient has no ABO/Rh on record	
		Refer to Adjusted Body Weight Calculator to calculate ideal & dosing weight	
	<u></u>	PRIMARY AND SECONDARY IMMUNE DEFICIENCY: Dose is 0.4 g/kg every 3-4 weeks	
		Pre-infusion IgG level required every 6 months	
	- ⟨∳	Monitor trough levels to maintain low normal range	
	🕏 🕏	Baseline IgG Result	
	- ⟨%	Steady state IgG concentrations are achieved after 4-5 IVIG doses given monthly, as the	same dose/interval. Obtain a trough level and adjust the dose accordingly
	2	lgG	Blood, Routine, Collection: T;N, once
	65 📆	Administer - IV Immune Globulin Transfusion	Routine, g, once, IV, Immunology: Primary Immune Deficiency, T;N
			Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
	- ⟨%	FETAL NEONATAL ALLOIMMUNE THROMBOCYTOPENIA (F/NAIT): Dose is 1 g/kg ever	
		Administer - IV Immune Globulin Transfusion	Routine, g, once, IV, Hem: Fetal Neonate Alloimmune Thrombocyt, T;N
	ك		Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
	./8.		second dose within 48 hours if the platelet count has not increased to above 20 x 10^9/L
		Administer - IV Immune Globulin Transfusion	Routine, g, once, IV, Hem: Adult ITP, T;N
ш	۷	Administer 17 Illinoine Giobuilli HalistusiOff	Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
	<u>/8</u> .	Chronic IDIODATHIC THROMROCYTOPENIC PURPLIPA (ITD) noct colon-stress Description	
		Chronic IDIOPATHIC THROMBOCYTOPENIC PURPURA (ITP) post-splenectomy: Dose	
	2	Gradually decrease to minimum effective dose at maximum intervals to maintain safe	platelet levels
	্ৰ	Re-evaluate every 3 to 6 months	
	<u>(9</u>	Consider alternative therapies for patients who do not receive a durable response for a	
	Z	Administer - IV Immune Globulin Transfusion	Routine, g, once, IV, Hem: Adult ITP, T;N
			Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
	- 9	GUILLAIN-BARRE SYNDROME (GBS), incl. Miller-Fisher syndrome and other variants: E	
			Routine, g, qdaily, for 2 doses or times IV, Neuro:GBS, MFS, panautonomic polyneuropa, T;N
		<u> </u>	Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
	⊘	CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP): Initial dose	is 2 g/kg over 2-5 days. Maintenance therapy: lowest dose to maintain clinical efficiency, 0.5-1 g/kg every 4-8 weeks
	(Ž	Administer - IV Immune Globulin Transfusion	Routine, g, qdaily, for 2 doses or times IV, Neuro: CIDP, including MADSAM variant, T;N
	_		Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
	∕ %	MULTIFOCAL MOTOR NEUROPATHY (MMN): Initial dose is 2 g/kg over 2-5 days, Mair	ntenance therapy: lowest dose to maintain clinical efficiency, 0.5-1 g/kg every 3-6 weeks
			Routine, g, qdaily, for 2 doses or times IV, Neuro: Multifocal Motor Neuropathy, T;N
	ك		Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
	/8.	MYASTHENIA GRAVIS (MG): Initial dose is 2 g/kg over 2-5 days. If short-term maintena	
	۷		Routine, g, qdaily, for 2 doses or times IV, Neuro: Myasthenia gravis, T;N
	/2		Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
_		PEMPHIGUS VULGARIS: Dose is 2 g/kg over 5 days	
	Z	Administer - IV Immune Globulin Transfusion	Routine, g, qdaily, for 5 doses or times IV, Dermatology: Pemphigus vulgaris, T;N
			Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on

	/8	
	STAPHYLOCOCCAL TOXIC SHOCK: Dose is either 1 g/kg on day one and 0.5 g/kg per day on days two and three, or	
	0.15 g/kg on day one and 0.5 g/kg per day on days two and three, or	
	Administer - IV Immune Globulin Transfusion	Routine, g, once, IV, Infect: Staphylococcal toxic shock, T;N
		DAY ONE: Dose is 1 g/kg on day one. Informed consent must be present on patient record. Transfuse dose as issued b
	🔅 🛜 Administer - IV Immune Globulin Transfusion	Routine, g, qdaily, for 2 doses or times IV, Infect: Staphylococcal toxic shock, T;N
		DAYS TWO AND THREE: Dose is 0.5 g/kg on days two and three. Informed consent must be present on patient record
	Administer - IV Immune Globulin Transfusion	Routine, g, qdaily, for 5 doses or times IV, Infect: Staphylococcal toxic shock, T;N
	ю.	Dose is 0.15 g/kg per day for 5 days. Informed consent must be present on patient record. Transfuse dose as issued by
	INVASIVE GROUP A STREPTOCOCCAL FASCIITIS with associated toxic shock: Do 1 g/kg on day one and 0.5 g/kg per day on days two and three, or	se is either
	0.15 g/kg per day one and 0.5 g/kg per day on days two and three, or	
	Administer - IV Immune Globulin Transfusion	Routine, g, once, IV, Infect: Inv Group A Strep w/ Toxic Shock, T;N
	•	DAY ONE: Dose is 1 g/kg on day one. Informed consent must be present on patient record. Transfuse dose as issued by
	Administer - IV Immune Globulin Transfusion	Routine, g, qdaily, for 2 doses or times IV, Infect: Inv Group A Strep w/ Toxic Shock, T;N
		DAYS TWO AND THREE: Dose is 1 g/kg on day one and 0.5 g/kg on days two and three. Informed consent must be pre
	Administer - IV Immune Globulin Transfusion	Routine, g, qdaily, for 5 doses or times IV, Infect: Inv Group A Strep w/ Toxic Shock, T;N
	ю.	Dose is 0.15 g/kg per day for 5 days. Informed consent must be present on patient record. Transfuse dose as issued by
	RHEUMATOLOGY: Order dose as approved by IVIG Rheumatology Consultant	
_	Recordinating Office IVIG Rheumatology program	
	Administer - IV Immune Globulin Transfusion	Routine, g, IV, Other- Rheum Conditions for Panel Review, T;N Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
	OTHER NEUROMUSCULAR: Order dose as approved as per program guidelines	informed consent must be present on patient record. Hansiuse dose as issued by TW. Dose may be adjusted based on
	Provincial Blood Coordinating Office IVIG Neuromuscular program	
П	Administer - IV Immune Globulin Transfusion	Routine, g, IV, Other- Neuro Conditions for Panel Review, T;N
	Administer 17 miniare Globalin Halistasion	Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
	OTHER INDICATIONS: Order will be reviewed by Pathologist	
	Administer - IV Immune Globulin Transfusion	Routine, g, IV, Other - Specify in Comments, T;N
	_	Informed consent must be present on patient record. Transfuse dose as issued by TM. Dose may be adjusted based on
굣	🕜 Communication Order	If the patient exhibits signs or symptoms of a Transfusion Reaction, Print Transfusion Reaction Form from FormFast an
ΔL	aboratory	
	☑ Group and Screen	Blood, Routine, Collection: T;N, once
	🖫 才 Immunoglobulin Panel (IgA, IgG, IgM)	Blood, Routine, Collection: T;N, once
	Consults/Referrals	
V	TM IVIG Dose Information	Select an order sentence
	RANSPLANT HEART Antibody Mediated Rejection (AMR) (Multiphase), AMR Orders for	PLEX 2 (Planned Pending)
⊿ A	Admit/Transfer/Discharge Nurse to initiate this phase of the PowerPlan when patient is receiving PLEX 2	
4 D	Blood Products	
2 0	Patient to receive 0.1 g/kg IV after each PLEX run	
⊽	TM IVIG Inpatient (Module) Planned Pen	
4.	Tallica Cha	

7.2.2 Transplant HEART KIDNEY Rituximab for Biopsy Proven AMR Rejection (Module)



7.2.2.1 After Initial AMR Treatment

If 50% drop in DSA MFI not seen following treatment, a second round of Section 5.2 can be considered.

Additional Rituximab dosing should be considered if no drop in CD 19/20 result.

If second round does not demonstrate a 50% drop in DSA MFI, discussion with the team should occur, with creation of an individualized treatment plan that should be documented on the patient biography outlining frequency of surveillance and what action is required.

In the long term, for all AMR patients, once initial round is completed, continue IVIG at 1g/kg which may be divided into 2 doses over 2 days if necessary monthly x 3. This is to be arranged via Medical Short Stay.

7.3 Infection Prophylaxis

The program refers to the <u>Clinical Guidelines for Transplant Medications</u> for directions towards post-transplant infection prophylaxis

After transplantation, and depending on donor/recipient virology history status, all patients are placed on prophylaxis and/or undergo routine surveillance for:

- Cytomegalovirus
- Herpes Simplex Virus
- Pneumocystis jiroveci Pneumonia
- Candidiasis
- Toxoplasmosis
- Epstein Barr Virus

7.3.1 Cytomegalovirus (CMV)

In addition to following the <u>CMV Prophylaxis and Treatment Regimen for Heart Transplant Recipients</u> in the BCT Medication document, depending on the induction agent given, the type of prophylaxis would be adjusted to further lower the chance of CMV reactivation post-transplant.

CMV Status Donor Recipient			
		Prophylaxis	
Negative	Negative	No prophylaxis	
Positive	Negative	Val GAN ciclovir 900mg PO daily for 6 months*	
Any	Positive	Basilixamab induction: No prophylaxis	
		rATG induction: ValGANciclovir 900mg PO daily* for 3 months (or Ganciclovir 5mg/kg/dose IV q24 when cannot tolerate PO dose).	

^{*}Dose adjust per renal function

7.3.2 Herpes Simplex Virus (HSV)

HSV status			
Donor	Recipient	Prophylaxis for 3 months post-transplant	Treatment
Any or not available	Any	ValAcyclovir 500mg BID* Patients on valganciclovir or ganciclovir (for CMV prophylaxis) are covered for HSV – no need to prophylax with ValAcyclovir If any treatment for rejection is administered, consider re-initiation of HSV prophylaxis for 2-4 weeks	Val A cyclovir 1g TID (duration dependent on infection severity)

^{*}Dose adjust per renal function

7.3.3 Pneumocystic jiroveci Pneumonia (PJP)

PJP PROPHYLAXIS

Continue until prednisone weaned post-transplant Reinitiate for 2-4 weeks if treatment for rejection initiated Continue for as long as a patient is on prednisone any dose

DRUG OF CHOICE

Trimethoprim-sulfamethoxazole (Septra ®) one single strength tablet daily*

ALTERNATIVES IF SULFA ALLERGIC

- Desensitization to trimethoprim-sulfamethoxazole is preferred if possible
- Dapsone 100mg po every Mon/Wed/Fri, until off Prednisone. Requires testing for G6PD prior to initiation
- Aerosolized pentamidine 300mg once monthly via Respirigard Nebulizer (requires respiratory therapist), until off Prednisone
- Atovaquone 1,500mg po daily. This is the last choice given cost

7.3.4 Toxoplasmosis

TOXOPLASMOSIS PROPHYLAXIS					
TOXOPLASI	MA STATUS				
DONOR	RECIPIENT	PROPHYLAXIS	DURATION		
Negative	Negative	Per PJP prophylaxis	Until prednisone discontinued. Reinstitute prophylaxis (per PJP dose) if treated for rejection		
Positive	Negative	Trimethoprim- sulfamethoxazole one double strength tablet daily*	Minimum 12 months – consult Transplant ID as outpatient		

^{*}Dose adjust per renal function

Any	Positive	Per PJP prophylaxis	Until prednisone discontinued. Reinstitute prophylaxis (per PJP dose) if treated for rejection
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^{*}Dose adjust per renal function

7.3.5 Candidiasis

CANDIDIASIS PROPHYLAXIS

ALL PATIENTS until discharge (longer if indicated)

Nystatin 500,000 units/ml, swish and swallow 1mL QID post op during hospital stay.

7.3.6 Hepatitis B

Organ	Donor HBV Status	Recipient HBV Status	Anti-Viral Therapy Post Tx
Heart	HBV core positive AND Hep B DNA detectable	Any hepatitis B status	Refer to Transplant ID to determine treatment
HBV core positive AND Hep B DNA		HBV core negative regardless of HBV surface	Monitor for HBV reactivation*
	undetectable	antibody status	No prophylaxis
HBV core negative		HBV core positive	Monitor for HBV reactivation* May consider a referral to Transplant ID or hepatologist to monitor for Hep B reactivation

^{*}Monitor for HBV reactivation at every 3 months for one year then every 6 months. Tests to be done: hepatitis B surface antigen, hepatitis B core antibody, hepatitis B surface antibody and hepatitis B DNA

7.3.7 Epstein-Barr virus

EBV Surveillance status		If surveillance EBV PCR positive:	If symptoms* or unexplained cytopenia	
Recipient negative; regardless	EBV PCR with every biopsy first year of transplant	Monitor EBV PCR weekly until viral load peak levels starts coming down	Repeat EBV PCR if no recent one done (>1 month ago)	

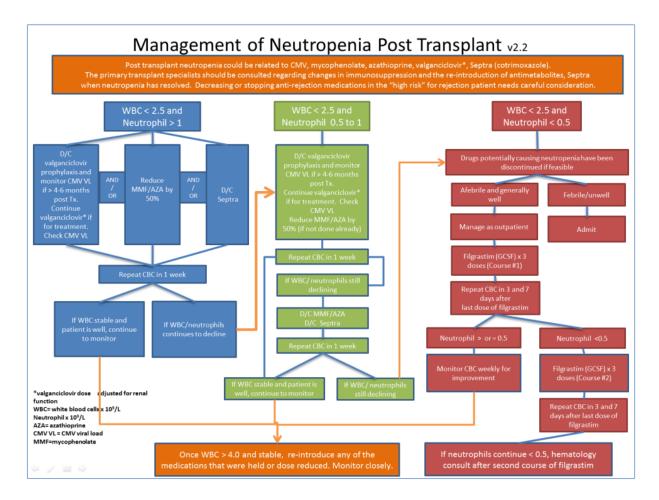
of Donor status	2. Post infection, defined as EBV negative (<1000copies/mL) or at new set point (i.e. a stable EBV level with no log ↑or ↓over 3 measurements): Q3 months EBV PCR x 1 year 3. EBV IgG at 6- and 12-months post-transplant, then annually until IgG becomes positive	Decrease EBV PCR to q2 weeks until negative or at new set point RN to review immunosuppressants (IMS) with MD: - Goal: Reduce IMS if no contraindications - Clarify IMS dose targets - Order CT chest/abdo/pelvis to assess for PTLD when:	Por D+/P. abovo
Recipient positive; regardless of Donor status	No surveillance required		Per D+/R- above

*Symptoms:

Symptoms/complaints	Signs
Swollen lymph glands	Lymphadenopathy
Weight loss	Hepatosplenomegaly
Fever or night sweats	Subcutaneous nodules
Sore throat	Tonsillar enlargement
Malaise and lethargy	Tonsillar inflammation
Chronic sinus congestion and discomfort	
Abdominal pain	Signs of bowel perforation
Anorexia, nausea, and vomiting	Mucocutaneous ulceration
Gastrointestinal bleeding	Mass lesions
Symptoms of bowel perforation	Focal neurologic signs

7.4 Neutropenia/Leukopenia

Refer to <u>Clinical Guidelines for Transplant Medications</u> page 35-38 for details for treatment. The following is the algorithm that is followed to determine treatment:

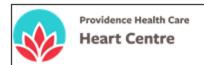


7.5 Other Post-Transplant Medications

In general, the following medication changes apply, depending on the individual's situation.

- Pantoprazole is generally discontinued when prednisone is discontinued (unless patient was on pantoprazole prior to admission and/or has an indication to remain on it)
- Calcium decreases or is discontinued (depending on dietary intake) when prednisone is discontinued. This will be determined with the dietitian if needed.
- Vitamin D supplements are continued for life.
- Statin/Aspirin/Antiplatelet medications are continued for life unless contraindicated (for prevention of Cardiac Allograft Vasculopathy)
- Antihypertensive and other cardiac medications are provided as indicated.

7.5.1 Graft Vasculopathy Surveillance and Treatment



Surveillance for Cardiac Allograft Vasculopathy (CAV)

Created.: June 2016
Revised: October 2022

Purpose

To outline surveillance for CAV

Scope

Adult heart transplant recipients

3. Responsibilities

Cardiologist

- · Ensure clear plan exists for each patient
- · Individualize plan according to clinical situation
- Initiate appropriate treatment if necessary

Post Transplant Clinic Nurse

- Ensure up to date plan and summary record is updated in the "Post Transplant Assessment"
 Powerform, specifically in the following sections:
 - Transplant Patient Biography Overall Care Plan
 - Surveillance Log Coronary Artery Vasculopathy

Post Transplant Clinic Clerk

- Ensure tests are booked in accordance with plan
- Ensure PROMIS is kept up to date

4. Procedure

DONOR SURVEILLANCE

Donor angiograms should be sought in the following situations

Males ≥40 years

High risk donors

- eg. Females with risk factors, cocaine use, etc

RECIPIENT SURVEILLANCE

eventual schedule)

Discussion at team rounds should occur if there are unusual circumstances.

DSE's no longer indicated unless specific indications exist

In the presence of normal renal function:

ш	has established epicardial disease, should be performed at month 2, years 1, 2 and 5
	Thereafter, SCA (without OCT) at year 10, then q5 yearly if normal (patients transferred to our program in between these years should have an individual plan prepared to fit in with our

If abnormal, SCA frequency should be individualized and the plan charted on the patients Biography. The following should be considered

- Severity of disease
- Speed of progression
- Renal function
- Type of disease
- Symptom burden
- If PCI performed, follow-up SCA should be performed 6 months after procedure and follow-up plan individualized.

In the presence of abnormal renal function:

Surveillance should be individualized and documented on the PowerForm. In general, dobutamine stress echo should be performed instead.

TREATMENT

- If CAV diagnosed through SCA on OCT with intimal-medial thickness (IMT) increase by 0.5mm (incremental) or 1mm (absolute):
 - ASA
 - Statin targeting LDL < 2.0
 - Consider conversion to sirolimus, substitute in place of MMF discuss at team rounds especially if patient is >2 years post-transplant
 - Reduce CNI 50% at initiation
 - PCI if lesions amenable
 - Individualize frequency of surveillance angiography (document on Biography)
 - Consider re-transplant
 - Consider ICD
 - At relisting stop sirolimus

5. Revision history

Revision	Description of Changes	Effective Date	Approved By:
00	Initial Release	August 2016	Cheung, Toma
01	Revision	September 2017	Toma, Cheung
03	Revision	Oct 2022	Toma, Cheung

7.5.2 Cancer Surveillance

Patients are encouraged to visit their Primary Care Provider regularly to screen for potential malignancies. Skin cancers are the most frequent cancer found in transplant recipients and therefore the following skin cancer precautions are in place:

- Patients are encouraged to visit their GP regularly for skin screening
- Where possible, referral to dermatology for yearly screening

Mammography, colon, cervical, prostate and lung screening should be done in accordance with recommendations by BC Cancer Agency and organized by Primary Care Provider.

7.5.3 Dental care

Patients should be encouraged to have regular dental checkups every 6 months or as indicated. Antibiotic prophylaxis regime is based on the Canadian Dental Association position on <u>Prevention of Infective Endocarditis</u>.

7.5.4 *Immunization*

Yearly influenza vaccinations are advised by the program for heart transplant recipients. We recommend all patients pre or post-transplant to have their vaccinations up to date. Prior to travel, patients are encouraged to discuss vaccinations with the team in collaboration with vaccination clinics.

Live vaccines are not recommended for transplant recipients.

We align our practice and recommendations to the <u>BC Transplant's Vaccinations for Solid</u>
<u>Organ Transplant Recipients</u> document

7.5.5 **Pregnancy**

Male and female patients are encouraged to discuss conceiving children and pregnancy with the Heart Transplant Cardiologist prior to planning a family. Patients are informed that some drugs may harm the unborn child and so careful planning with Primary Care Provider, the transplant team and referral to the Cardiac Obstetrics clinic at St Paul's prior to conceiving.

Pregnancy is not recommended in the first year after heart transplant at this program.

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9 APPENDIX

PHC Exceptional Distribution Consent form

		Place Patient Form Label Here				
INFORMED CONSENT FOR EXCEPTION WILLING TO ACCEPT A DONOR OFFER RISK OF DISEASE TRANSMISSION						
* 6 9 3 0 *	Consent Ot	her				
bacterial or viral infection (e.g.	hepatitis C) and cance	disease including but not limited to er. Some organ donors have a higher risk of nese donors are called increased risk donors.				
these diseases may not be ide	ntified until after my tra ection). I may need to b	imitations. I understand that some of ansplant has occurred (e.g. the donor had an be monitored after my transplant as a result. If alists about this.				
because my transplant doctor benefits and risks of taking this	3. I understand that I may be offered an organ from an increased risk donor. This will be because my transplant doctor feels the benefit of accepting this organ outweighs the risk. The specific benefits and risks of taking this organ will be explained to me at the time of transplantation. I can refuse the organ and my status on the waiting list will not be affected.					
Transmission from Organ Don	4. I have been provided with a copy of the Patient Information Guide - "Risk of Disease Transmission from Organ Donors". I understand that I can ask a transplant nurse or physician about any questions that I may have on infectious disease from donors at any time to assist me in making an informed decision.					
I understand the information aborincreased risk donor.	ve and would be willing	ng to be offered an organ from an				
NAME: (Mr. Mrs. Ms.)						
SU	RNAME	GIVEN NAMES				
SIGNATURE:						
PATIENT OR SUBSTITU	TE DECISION MAKER*	PRINT NAME IF NOT THE PATIENT *Identification of Substitute Decision Maker form must be completed (Form ID-2760)				
55		DATE:				
S						
STATEMENT BY PROFESSIONAL INTERPRETER Complete ONLY if a professional interpreter is used to obtain consent.						
I have translated the above information to Guardian or representative and I have inte	the Patient/Client	Substitute Decision Maker Legal				
SIGNATURE OF INTERPRETER	PRINTED NA	ME DATE SIGNED				
	TRITTED IN					
FORM ID - 6930 VERSION 2017 NOV 21		Page 1 of 1				

Consent for Endomyocardial Biopsies:



PHC INFORMED CONSENT FOR POST HEART TRANSPLANT SURVEILLANCE ENDOMYOCARDIAL BIOPSY PROCEDURES Place Patient Label Here

An endomyocardial (heart) biopsy is a procedure that involves the removal of small sample of heart muscle tissue from the inner lining of the heart (endocardium). People who have had a heart transplant often need periodic heart biopsies after their transplant. These biopsies check for early signs that the body is treating the new heart like a foreign invader (organ rejection). A heart biopsy can help detect organ rejection even before symptoms develop. Biopsies are performed regularly for the first year after transplant. Most patients get about 14 biopsies in the first year. After the first year, biopsies are done less often (if any). Agreeing to have surveillance biopsy procedures is a requirement for receiving a heart transplant as there are currently no other methods to assess for rejection.

Endomyocardial biopsies are performed in the radiology department or in the cardiac catheterization lab. You will be given local anesthesia to numb the area where the catheter (a thin flexible tube) is inserted through blood vessels into your heart. A special tool called a bioptome is passed through the catheter, past the tricuspid valve (TV) to the right ventricle. The bioptome takes several small tissue samples from the heart that are sent to the laboratory for examination. The procedure typically takes 15 to 20 minutes. Most patients do not experience any pain during the procedure.

While complications arising out of endomyocardial biopsies are rare, the major potential risks include:

- Bleeding: At the catheter insertion site or internally.
- · Arrhythmias: Irregular heartbeats during or after the procedure.
- Valve injury: Injury to the TV can occur when the bioptome collects samples. There is a 1 to 2% risk
 of TV injury PER biopsy procedure. Injury to the TV may result in further procedures to repair the
 valve.
- Perforation of the heart wall: Very rare and can be serious.
- 1. I have been informed of the nature of the procedure, its purpose, and potential benefits.
- 2. I have been informed about the potential risks and complications of the procedure.
- I have had the opportunity to ask questions and discuss concerns with my physician, and all of my questions have been answered to my satisfaction.

I understand the information above and provide my consent to undergo serial surveillance endomyocardial biopsies after my heart transplantation.

Patient Las	st Name:	First Name:	Date:(dd/mmm/yyyy)	
Signature:	Patient or Substitute Decision Make	ker	Print Name if Not the Patient	
Physician:	Signature		Printed Name	Date Signed

FORM ID PHC-MR126 VERSION (10 Feb 2025)

Page 1 of 1