

HEART DONATION & TRANSPLANTATION FOLLOWING DEATH DETERMINATION BY CIRCULATORY CRITERIA (DCC)

Reference Package

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Heart Donation following Death Determination by Circulatory Criteria:

Fast Facts

Historically, heart recovery from donors following death determination by circulatory criteria (DCC) has not been possible due to concerns about physiological damage to the heart following withdrawal of life-sustaining measures (WLSM). Advancements in technology have led to changes in recovery and preservation techniques, making heart transplantation following DCC possible.

Current Status in Ontario

In summer 2024, heart surgeons from London Health Sciences, University Health Network and the University of Ottawa Heart Institute will be undergoing training for the Organ Care System (OCS™) Heart System. The OCS and other similar medical devices allow donor organs to be maintained for longer periods of time on an ex vivo perfusion pump prior to transplant and reduce the ischemic time for the heart, enabling heart donations following DCC. Prior to Ontario Transplant Programs recovering DCC hearts, Ontario DCC donor hearts will be offered through the United Network for Organ Sharing (UNOS) to U.S. jurisdictions recovering DCC hearts for transplant.

Practice Considerations for Heart Donation following DCC

Notification, approach planning, and consent aspects of the donation process remain the same. DCC donors will be screened for suitability and a potential recipient match as the donor's information is collected for assessment. Suitability for heart donation following DCC is highly selective (i.e., only donors 40 years of age and younger with limited risk factors are considered) and requires the addition of an echocardiogram for suitability testing, with a possibility of a cardiac angiogram if further testing is needed. In the event an angiogram is not available onsite, Ontario Health (Trillium Gift of Life Network [TGLN]) will reconfirm or obtain consent for the transfer to facilitate an angiogram and connect the substitute decision-maker (SDM) to an accepting interventional cardiologist directly to obtain consent to perform this procedure. Several units of blood will be needed for perfusion of the heart ex-vivo pump after procurement. An Ontario Health (TGLN) Specialist will be present to guide the testing process and relay request from the transplant team.

Education and Onsite Support

In the event a donor has been identified as a potential heart donor, Ontario Health (TGLN) will support healthcare teams with "Just in Time Education" and assist in organizing transplant program requests (i.e., angiography). An OR picklist, room setup, and other details will be circulated in advance to provide perioperative teams with the opportunity to refresh on the specifics of this type of organ recovery. An Ontario Health (TGLN) Specialist will be available onsite to help support teams throughout the donation process.

Overview of Hospital Considerations and Hospital Staff Responsibilities

Due to the use of the OCS™ Heart Machine, or similar medical device, and the larger team required to complete recovery of the heart, the largest OR is recommended. Recovery of a heart after DCC may extend the use of the OR up to two hours while the transplant team further assesses the heart for suitability. Therefore, the OR will need to be available for up to six hours or longer if a multi-organ case. Withdrawal of life-sustaining measures and determination of death will occur as per usual practice with the exception of the location of WLSM being close to the Operating Room (i.e., PACU) to reduce the functional ischemia time (FIT). After WLSM, vital signs will be monitored closely to determine the impact on FIT and if the heart will be suitable for recovery and transplant.

Critical Care Responsibilities

- Traditional donor management remains the same for DCC donors with the addition of cardiac angiography to assess the suitability of potential heart donors.
- An echocardiogram will be ordered to assess heart function.
- MRP will be asked to arrange an angiogram. This may necessitate the transfer of the patient to another facility to have the angiogram completed. The patient will return to the sending hospital.
- WLSM remains the responsibility of the ICU team and will take place in a location close to the OR.

Interventional Cardiologist

- A coronary angiogram is required to assess the presence and degree of coronary artery disease is required.
- Consent is required for this procedure from the SDM under the *Health Care Consent Act*. This is to be obtained by the interventional cardiologist who is performing this procedure.

Perioperative Team Responsibilities

- Set up room as per usual donation following DCC practice. An OR setup diagram will be provided.
- A pick list for heart recovery will be provided.
- The largest OR room will be required for special ex vivo perfusion equipment.
- Identify an accessible electrical outlet in the OR to plug in the OCS Heart Machine.
- The OR will need to be available for up to 6 hours.
- Recovery teams will arrive in advance of WLSM for OR setup and a huddle will take place prior to WLSM.
- If the patient does not die in the time window that permits donation for transplantation, they will be transported back to the ICU or another pre-arranged unit for continuation of end-of-life care.

Anesthetist and/or Registered Respiratory Therapist

- If lungs are being recovered in addition to the heart, an anesthetist/RRT will be required.
- The role of the anesthetist/RRT is to re-intubate as per traditional lung donation following DCC practices.

Heart Deceased Donor Criteria

Provincial Heart Working Group

Absolute Donor Exclusion Criteria for Heart Transplantation		
#	Factor	Criteria
1	Malignancy	<ul style="list-style-type: none"> • Donors with active cancer (donors receiving chemotherapy or radiation therapy or palliative cancer care within the last 5 years); excluding skin and primary brain tumours and prostate cancers (see below). • Donors with active or past history of melanoma
2	Age	<ul style="list-style-type: none"> • DCC neonatal donors < 36 weeks gestational age • Hearts are not considered from any donor > 70 years of age • <i>See next page – Transplant Hospital Specific Criteria for DCC exclusions</i>
3	Weight	<ul style="list-style-type: none"> • DCC neonatal donors < 2kg
4	Infection / Communicable Diseases	<ul style="list-style-type: none"> • Positive HIV, HbsAg, HTLV-I/II test results • West Nile Virus (WNV PCR) • Rabies diagnosis or within the last 6 months bitten by an animal proven to have rabies • Endocarditis • Active encephalitis or meningitis of unknown etiology • Active disseminated tuberculosis • Viral Hemorrhagic Fever including Ebola or known exposure to person with Ebola
5	Cardiac Abnormalities	<ul style="list-style-type: none"> • Donors with pre-existing cardiac abnormalities: <ul style="list-style-type: none"> ○ The presence of intractable ventricular arrhythmias

Relative Donor Exclusion Criteria for Heart Transplantation		
#	Factor	Criteria
1	Age	<ul style="list-style-type: none"> • Donor hearts younger than 45 years will have sufficient reserves to withstand the rigors of heart transplant even in the settings of relative prolonged ischemic time, recipient comorbidities and multiple previous recipient operations with hemodynamically destabilizing bleeding • Hearts from donors between the ages of 45 to 55 years should probably be used when the projected ischemic time is < 4 hours and the potential recipient does not have comorbidities or surgical issues where anything else less than a robust donor heart performance could prove fatal • Hearts from donors > 55 with an estimated cold ischemic time > 4 hours • The use of donor hearts > 55 years should only be used if survival benefit in early HT survival due to transplantation of a heart with limited myocardial reserves

Relative Donor Exclusion Criteria for Heart Transplantation

#	Factor	Criteria
2	Drug Toxicities	<ul style="list-style-type: none"> • Donors with a history of non-intravenous cocaine use may be used as long as cardiac function is normal and LVH is absent • Donor hearts from carbon monoxide poisoning may be used provided: <ul style="list-style-type: none"> ○ EKG and echocardiogram are normal; ○ Minimal elevation in cardiac markers; ○ Minimal inotropic requirements; ○ Relatively short ischemic time; ○ Favorable donor to recipient weight ratio; ○ Recipient has normal pulmonary vascular resistance.
3	Pre-existing cardiac abnormalities	<ul style="list-style-type: none"> • Donor hearts with hemodynamically abnormal aortic and mitral valves may be used with the valves undergoing a bench repair or replacement and subsequent transplantation of the heart
4	Donor Weight	<ul style="list-style-type: none"> • Donors whose body weight is no greater than 30% below that of the recipient is uniformly safe • Use of a female donor whose weight is more than 20% lower than that of a male recipient should be viewed with caution
5	Ischemic Time	<ul style="list-style-type: none"> • Should not be longer than 4 hours. Times longer than 4 hours should only be accepted with the following ideal situations: <ul style="list-style-type: none"> ○ Young donor age ○ Normal cardiac function ○ Absence of inotropic support
6	Risk Factors	<ul style="list-style-type: none"> • Risk Factors for Coronary Artery Disease with Potential Impact on Transplant Outcomes: <ul style="list-style-type: none"> ○ Smoking ○ Hypertension ○ Diabetes ○ Hyperlipidemia ○ BMI > 32 ○ Family history of cardiac disease ○ Prior history of coronary artery disease ○ Ischemia on electrocardiogram ○ Anterolateral regional wall motion abnormalities on echocardiogram ○ 2-dimensional echocardiographic assessment of ejection fraction of \leq 40% ○ Marginal donors due to high dose inotropes and diffuse wall motion abnormalities should be assessed individually with aggressive onsite resuscitation of donor by procurement team
7	Cardiac Abnormalities	<ul style="list-style-type: none"> • The need for excessive inotropic support (dopamine at a dose of $20\mu\text{g}/\text{k}/\text{min}$ or similar doses of other adrenergic agents despite aggressive optimization of preload and afterload • Discreet wall motion abnormalities on echocardiogram or LVEF < 40% despite the optimization of hemodynamics with inotropic support • The use of donor hearts with obstructive disease in any major coronary artery should be avoided. Donors who are over 50 or any donor with risk factors for coronary artery disease should have an angiogram completed as part of the donor suitability assessment • Donor hearts with LVH should not be used if there are associated EKG findings of LVH and LV wall thickness is >14mm

Relative Donor Exclusion Criteria for Heart Transplantation		
#	Factor	Criteria
8	Malignancy	<ul style="list-style-type: none"> • Prostate Cancers may proceed under ExD if: <ul style="list-style-type: none"> ○ No evidence of metastases ○ Gleason 6 PSA under 10 under active surveillance ○ If Gleason 7 or less and current PSA less than 2 treated by rad ○ If Gleason 7 and PSA undetectable after prostatectomy • Avoid Gleason 8 or greater and all PSA over 20. PSAs between 10-20 is controversial and should be discussed with a urologist.
9	Infection/Communicable Diseases	<ul style="list-style-type: none"> • Documented fungal sepsis • Severe untreated sepsis or sepsis with undermined etiology; • Sepsis due to Multi-drug resistant organism such as MRSA or CRE • Donors currently positive for COVID 19 should only be considered after consultation with TSP-ID
10	Vaccine-Induced Thrombotic Thrombocytopenia (VITT)	<ul style="list-style-type: none"> • Consult TSP-ID and CMO Transplant prior to proceeding if potential donor has a suspected diagnosis of vaccine-Induced thrombotic thrombocytopenia (VITT)

Transplant Hospital Specific Donor Exclusions

These transplant programs have established the following absolute exclusions for offers of exceptional distribution.

Transplant Hospital Specific Heart Donor Exclusions	
Site	Criteria
Toronto General Hospital	<ul style="list-style-type: none">• >6 hours CIT (4 hours as the ideal time)• DCC Donors• MAID Donors• Will not consider U.S. heart offers from donors > 50 kg for status 1, status 2 or status 3 recipients
The University of Ottawa Heart Institute	<ul style="list-style-type: none">• >5 hours CIT• DCC donors
The Hospital for Sick Children	<ul style="list-style-type: none">• DCC hearts for paediatric recipients are only considered from donors at The Hospital for Sick Children who are < 1 year of age
London Health Sciences Centre	<ul style="list-style-type: none">• DCC donors

U.S. Transplant Program Specific Donor Exclusions

The following criteria has been established exclusively for hearts offered to the U.S. from a death Determination by Circulatory Criteria (DCC) donor.

U.S. Transplant Program Specific Donor Exclusions	
Factor	Criteria
DCC heart donor	<ul style="list-style-type: none">• Hearts from donor > 40 years old

QUALITY ASSURANCE:

The Provincial Heart Working Group will review and approve the Heart Deceased Donor Criteria annually as a means of quality assurance.

Heart Donation Following Death Determination by Circulatory Criteria (DCC)

Participating Hospitals

All Ontario hearts from donors that meet the exclusion criteria are eligible for US DCC heart recovery. The list of hospitals that meet the distance criteria for the Ontario DCC heart program will be finalized when the procurement and training processes are complete.

In the event resources are not available at the hospital for the purposes of testing (e.g. angiogram) or organ recovery, or where potential challenges have been identified, the next of kin of potential donors will be approached for consent to transfer their loved one to another hospital for the purposes of DCC heart recovery.

Heart Donation Following DCC Process Comparison

	Traditional Donation after DCC	Heart Donation after DCC
Notification	<ul style="list-style-type: none"> As per GIFT+ trigger 	<ul style="list-style-type: none"> As per GIFT+ trigger
WLSM Decision	<ul style="list-style-type: none"> S-OTD on site 	<ul style="list-style-type: none"> S-OTD on site
Approach	<ul style="list-style-type: none"> Donation opportunities discussed with family Information on donation process is shared 	<ul style="list-style-type: none"> Donation opportunities discussed with family Information on donation process is shared
Consent for Donation	<ul style="list-style-type: none"> Family consents to organ donation after DCC, interventions and transfer, if required 	<ul style="list-style-type: none"> Family consents to organ donation after DCC, interventions and transfer, if required
Donor Screening and Testing	<ul style="list-style-type: none"> As per current practice 	<ul style="list-style-type: none"> As per current practice, with DCC heart transplant criteria applied
Consent for Angiography	<ul style="list-style-type: none"> Not applicable 	<ul style="list-style-type: none"> Consent for angiography transfer, if applicable Consent for angiography
Allocation	<ul style="list-style-type: none"> Organ allocation as per current practice Organ acceptance 	<ul style="list-style-type: none"> Organ allocation as per current practice Heart acceptance +/- other organs
Recovery Planning	<ul style="list-style-type: none"> Determine location of WLSM and timing Confirm OR time 	<ul style="list-style-type: none"> Confirm WLSM location close to OR and timing Request the largest OR Heart team will bring OCS™ Machine
Death Determination	<ul style="list-style-type: none"> As per current practice Time from WLSM to death determination <3 hours 	<ul style="list-style-type: none"> As per current practice Time from WLSM to death determination <3 hours FIT must be ≤30 minutes to proceed with heart donation
Recovery	<ul style="list-style-type: none"> As per current practice 	<ul style="list-style-type: none"> Larger recovery team and use of OCS™ Machine

Heart Donation Following Death by Circulatory Determination (DCD)

“Just in Time” Response Team Activities

Background

Historically, heart recovery from donors following death determination by circulatory criteria (DCC) has not been possible due to concerns about physiological damage to the heart following withdrawal of life-sustaining measures. Today, heart recovery after DCC is possible due to advances in technology. The heart is recovered and placed on a portable external heart machine, which pumps blood and a special solution to maintain oxygen to the heart, allowing for the heart to be assessed before transplant.

Starting May 2024, Ontario DCC donor hearts will be offered through the United Network for Organ Sharing to US jurisdictions recovering DCC hearts for transplant.

Goals

The goals of the JIT Response are:

1. Ensure TGLN staff have the most current information on DCC hearts
2. Confirm hospital ability and staffing capacity to support US DCC heart offers, and confirm image transfer plans
3. Ensure hospital stakeholders are supported through various communication channels
4. Support logistic planning with US recovery teams and Ontario/Canadian teams
5. Trouble-shoot in real-time and handle questions, concerns or clarify misconceptions;
6. Plan for educate and support for operating room (OR) staff;
7. Ensure confidentiality.

JIT Team Members

- Director, Hospital Programs or designated management representative*
- Manager On Call or equivalent for on-site
- Donation Support Physician
- Referral Triage Coordinator, Provincial Resource Centre – Organ
- Clinical Services Coordinator, Provincial Resource Centre – Organ
- Organ and Tissue Donation Coordinator / Hospital Development Coordinator

*Note – a Case Manager will be appointed for initial cases for support during initial cases

Process

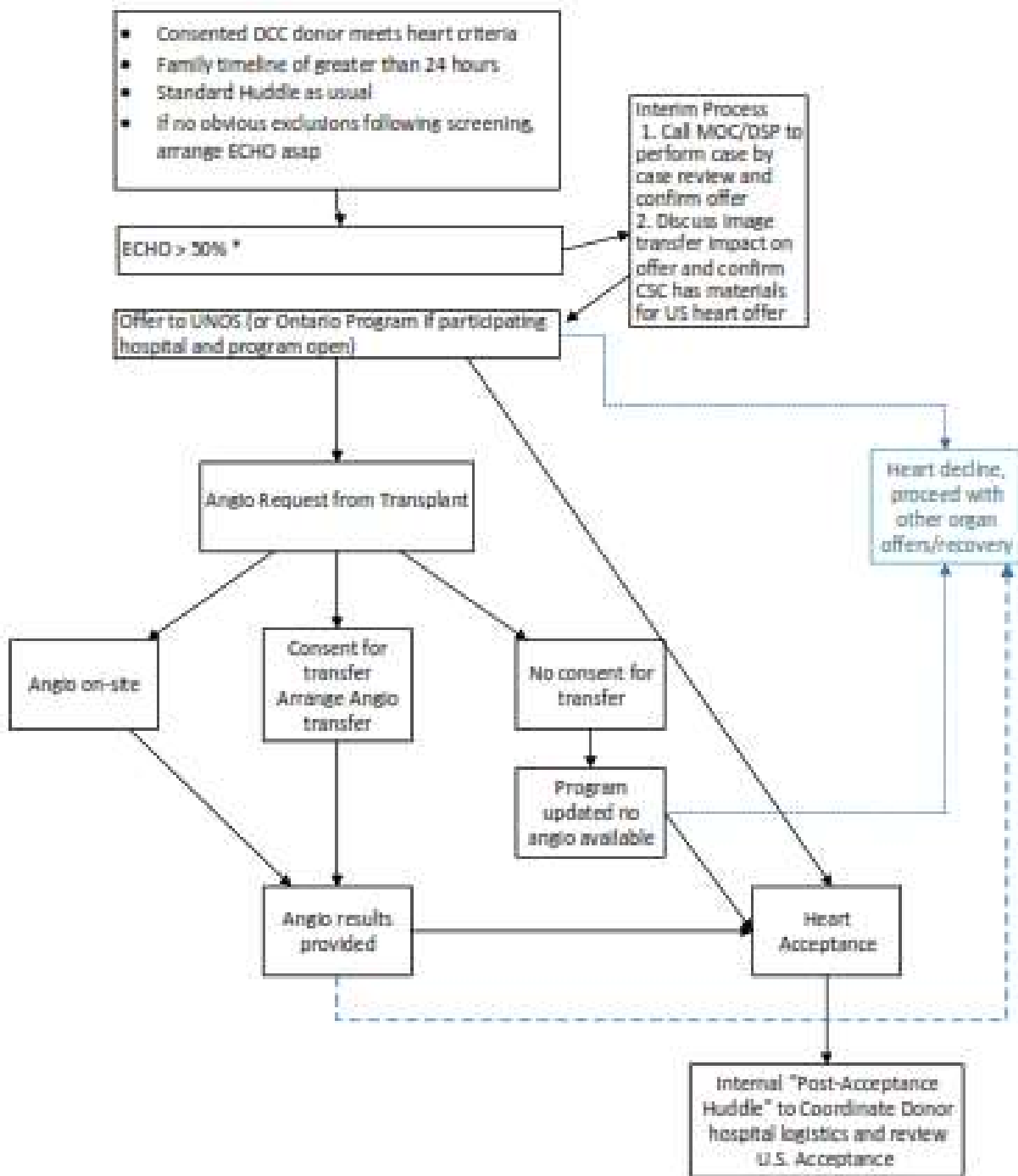
The roles and responsibilities of team members are noted in Table 1 . Acceptance of a DCC heart will trigger a post-acceptance team huddle (please see the Post Huddle Acceptance Huddle Checklist)

Table 1. Roles and Responsibilities

Role	Responsibility
Clinical Services Coordinator, Provincial Resource Centre – Organ	<ul style="list-style-type: none"> ○ Confirm MOC/DSP support of offer to US while interim process in place ○ Call Huddle following acceptance of heart
Manager on Call	<ul style="list-style-type: none"> ○ identify potential DCC heart donor (report, communication with SOTD or CSC, standard huddle or bullets) ○ confirm location of testing (angio), recovery (ID and transfer hospital?) and if consent to transfer ○ Confirm hospital ability and staffing capacity to support US DCC heart offers <ul style="list-style-type: none"> ○ establish feasibility with DSP (consult with PRC re: case volume, staffing of CSCs, SRCs and availability of senior SOTD in region) ○ ensure staff have link to resource package (or latest material) ○ discuss availability of ECHO and impact on timing of offer to US if proceeds ○ contact Director(s) to assign a case manager if ECHO LVEF > 50% and offer to UNOS is going ahead ○ attend DCC heart huddles after heart is accepted ○ work with Case Manager to confirm responsibilities with case
Case Manager (interim process)	<ul style="list-style-type: none"> ○ Provide TGLN management presence to reflect leadership and clinical support ○ with MOC, assess need for out of region support to determine if experienced SOTD is required ○ Ensure hospital stakeholders are supported through various communication channels <ul style="list-style-type: none"> - with SOTD discuss communication to hospital: <ul style="list-style-type: none"> ▪ consider frequency of donation at hospital ▪ consider leadership/HDP support ▪ resent DCC heart FAST FACTs, provide OR Education material ▪ ensure emphasis on confidentiality ○ attend DCC heart huddles after heart is accepted ○ Escalate issues to hospital leadership or TGLN Administrator on Call/DSP or PMD-D when required <ul style="list-style-type: none"> - trouble shoot any credentialing, 4 units blood request as needed ○ Identify and record bottlenecks in the process for future cases ○ Update Director Public Education and Marketing (Business hours or urgently if required). <u>Note</u>: all media inquiries should be directed to Ontario Health Media Relations at mediainquiries@ontariohealth.ca

Role	Responsibility
Specialist Organ and Tissue Donation - Primary (onsite)	<ul style="list-style-type: none"> ○ SOTD planning an approach with the family/patient a DCC heart eligible patient (under 40) to obtain resource package and/or connect with MOC/designate to obtain/confirm the most current information. ○ Manage donor on site ○ Confirm the image transfer process ○ If the echo is greater than 50%, the SOTD connects with MOC/designate to complete a review with DSP of hospital capability and staffing resources to confirm the offer to UNOS should be completed. ○ Navigate consent to transfer for imaging, if required ○ Confirm WLSM near or in OR as part of OR booking
Specialist Organ and Tissue Donation	<ul style="list-style-type: none"> ○ Provide education and support to ICU and OR staff ○ Assist Primary SOTD as required

Figure 1. Just in Time Process



Heart Donation Following Death Determination by Circulatory Criteria (DCC) For ICU (Intensive Care Unit) Nurses

Why are we now assessing the heart of potential DCC donors?

- Historically, DCC heart recovery has not been possible due to concerns about physiological damage to the heart following withdrawal of life-sustaining measures (WLSM).
- Advancements in technology have led to changes in recovery and preservation techniques, making DCC heart transplantation possible.
- Ontario Health (Trillium Gift of Life Network [TGLN]) has been working with the heart transplant teams in Ontario and the United States (U.S.) to facilitate the implementation of a protocol for DCC heart recovery.

What does this mean for you?

- Continue to look after and care for your patient as a critically ill patient.
- Follow your hospital or Ontario Health (Trillium Gift of Life Network [TGLN]) Organ Donor Order Set.
- Note that the following testing may be required to assess these potential donors:
 - Bloodwork which includes Troponin
 - 12 Lead ECG
 - 2D Echocardiogram
 - Cardiac Angiogram (at the request of the transplant program). This may necessitate the transfer of the patient to another facility to have the angiogram completed and if indicated, the process will follow standard hospital protocols and policies for patient transfer. In most cases, the patient will return to the sending hospital.
 - **The heart has been accepted, now what?**
- The timing of WLSM will be arranged based on patient, family, hospital, and transplant considerations.
- To recover a heart from a DCC donor for transplantation, WLSM must occur in a location close to the OR or in the OR to accommodate the short functional ischemic time.

- Shortly before the planned time for WLSM, the patient and all required supplies for WLSM and end-of-life care will be moved to the location close to the OR, or to the OR, accompanied by the ICU team.
- The WLSM will occur in the same manner as any donation following DCC case. The WLSM will be the responsibility of the ICU staff. The Most Responsible Physician (MRP) will be present during the WLSM and available until skin cut. Family may be present throughout WLSM interventions.
- After the WLSM, the heart recovery team will be kept informed of the patient's vital signs and will wait up to 3 hours for the patient to pass away. This is determined by individual transplant teams based on their criteria.
-
- During this time, you or a member of the health care team will continue to support the family. After DCC has been confirmed by two physicians Typically, a team member such as a social worker or chaplain may be present to support the family and would help guide them out of the area, if the patient has been moved from the ICU for WLSM.
- If the patient does not pass away within the pre-determined time window, then the patient's end-of-life care will continue as per hospital policy. This would include the transfer of the patient from the location of WLSM to a mutually arranged area.

Heart Donation Following Death Determination by Circulatory Criteria (DCC)

For Peri-Operative Nurses

Why are we now assessing the heart of potential DCC donors?

- Historically, DCC heart recovery has not been possible due to concerns about physiological damage to the heart following withdrawal of life-sustaining measures (WLSM).
- Advancements in technology have led to changes in recovery and preservation techniques, making DCC heart transplantation possible.
- Ontario Health (Trillium Gift of Life Network [TGLN]) has been working with the heart transplant teams in Ontario and the United States (U.S.) to facilitate the implementation of a protocol for DCC heart recovery.
-

The heart has been accepted, what does the OR set up look like?

- Set up the room as you normally would for a donation following DCC case. Please also set up a side table near the head of the patient, a back table for the heart recovery teams, and remove all unnecessary equipment to optimize space. (See OR Set-up Diagram)
- A large room will be needed as special perfusion equipment will be brought into the OR, and a larger team will be involved in the heart recovery.
- A pick list for the heart recovery team will be provided, and the team may supply their own specific instruments as well. (See OR Pick-list)
- The ex-vivo pump/medical device used for the heart, may require an accessible electrical outlet in the OR which the recovery team may access to plug in the OCS™ Heart Machine or alternate medical device.
- Confirm and provide clothing cover requirements for family members if withdrawal of life-sustaining measures (WLSM) is occurring in the OR.

What additional team members can you expect to be there?

- In addition to the abdominal and thoracic teams from Ontario or U.S., an Ontario Health (TGLN) Surgical Recovery Coordinator dedicated to working with the heart recovery

team will be there along with one or two heart surgeons, as well as a perfusionist or clinical specialist to operate the extracorporeal perfusion heart machine.

- **What can you expect from a timing perspective?**
- After the WLSM, the heart recovery team will be kept informed of the patient's vital signs and in general, will wait up to 3 hours for the patient to pass away. Organ viability is determined by individual transplant teams based on their own criteria and will be discussed in the OR Planning Huddle.
- Recovery of a heart after DCC may extend the use of the OR up to two hours while the transplant team further assesses the heart for suitability. Therefore, the OR will need to be available for up to 6 hours.

What is your role when withdrawal of life sustaining measures happens in the OR?

- Withdrawal will occur in a location close to the OR or in the OR. The ICU team is responsible for the withdrawal procedure including all the medications required.
- The OR nurse will stay in the OR. The OR nurse may attach drapes to IV poles to separate the instruments and back table from the donor/family if WLSM occurs in the OR, as well as monitor open instruments.
- Family presence may have been arranged with the OR administration if applicable.
- Typically, a team member such as a social worker or chaplain may be present to support the family.
- If WLSM occurs in the OR, the health care team will escort the family from the OR once the donor's heart stops. You may be asked to ensure the supporting staff knows the best way to exit the OR.

What happens if the patient does not die in time to support a heart recovery?

- If the patient does not die in the time window to donate organs, they will be transported either back to the ICU or to another pre-arranged unit where they can be with their family for continuation of end-of-life care.

Are there other planning considerations?

- An Ontario Health (TGLN) Specialist will be available onsite to support teams throughout the donation process and will employ "just-in-time" education and guidance as necessary.

- The heart team will attempt collect 1 to 1.5 L of donor blood (preferred over banked blood). The heart team will explain how this process will be performed and what type of equipment or support they need.
- Usually, the blood collection can take up to 3 minutes from skin cut.
- Several units of crossmatched banked (washed or not washed) will be planned as a back-up for the heart ex-vivo pump after procurement if the amount of donor blood is not sufficient.
- The Ontario Health (TGLN) Specialist will have arranged the ordering of blood products with the MRP before the recovery surgery and will be available as per hospital's standard blood banking protocols and policies.

Heart Donation Following Death Determination by Circulatory Criteria (DCC)

For Referral Triage Coordinator

Why are we now assessing the heart of potential DCC donors?

- Historically, heart recovery from DCC donors has not been possible due to concerns about physiological damage to the heart following withdrawal of life-sustaining measures (WLSM).
- Advancements in technology have led to changes in recovery and preservation techniques, making DCC heart transplantation possible.
- Ontario Health (Trillium Gift of Life Network [TGLN]) has been working with the heart transplant teams in Ontario and the United States (U.S.) to facilitate the implementation of a new protocol for DCC heart recovery.

What does this mean for you?

- You will include assessment of medical suitability of hearts from DCC referrals received from participating hospitals.
- DCC heart donation will only be possible if a strict set of criteria is met. Please refer to the “**Heart Donor Exclusion Criteria**” for details.
- DCC heart donation is now available in Ontario.

What do you have to do?

- Following receipt of notification, you will begin screening a potential DCC patient using existing criteria, as per usual practice.
- In addition to screening for the liver, kidneys, pancreas and lungs, you will also screen for DCC heart donation using the **Heart Donor Exclusion Criteria**.

What happens next?

- Once consent has been obtained, the case should be passed to a Clinical Services Coordinator (CSC) as per current practice.

Heart Donation Following Death Determination by Circulatory Criteria (DCC)

For Clinical Service Coordinators

Why are we now assessing the heart of consented DCC donors?

- Historically, heart recovery from DCC donors has not been possible due to concerns about physiological damage to the heart following withdrawal of life-sustaining measures (WLSM).
- Advancements in technology have led to changes in recovery and preservation techniques, making DCC heart transplantation possible.
- Ontario Health (Trillium Gift of Life Network [TGLN]) has been working with the heart transplant teams in Ontario and the United States (U.S.) to facilitate the implementation of a protocol for DCC heart recovery.

What does this mean for you?

- You will be offering medically suitable hearts from DCC consented donors.
- DCC heart donation will only be possible if the strict set of criteria are met. Please refer to the “**Heart Donor Exclusion Criteria**” for details.

What do you have to do?

- Following DCC consent, you will begin the process of screening the patient using existing criteria, as per usual practice.
- In addition to reviewing the criteria for allocating the liver, kidneys, pancreas and lungs, you will also review the **Heart Donor Exclusion Criteria** for DCC heart donation.
- During the huddle, review the Huddle Checklist. Confirm the location of testing (e.g. if angiography required and not available at hospital), recovery and any transfer requirements. Confirm WLSM will take place close to or in the OR.

Who do you make DCC heart offers to?

- DCC hearts will be offered to the U.S. through United Network for Organ Sharing (UNOS). Refer to CPI-9-313, Organ Allocation.
- CSCs will send the DCC heart donation letter and package to prospective U.S. heart programs

- DCC hearts will be offered to the US through UNOS. CSCs will send the DCC heart donation letter and package to prospective US heart program

Heart Donation Following Death Determination by Circulatory Criteria

For Surgical Recovery Coordinators

Why are we now assessing the heart in potential DCC donors?

- Historically, heart recovery from DCC donors has not been possible due to concerns about physiological damage to the heart following withdrawal of life-sustaining measures (WLSM).
- Advancements in technology have led to changes in recovery and preservation techniques, making DCC heart transplantation possible.
- Ontario Health (Trillium Gift of Life Network [TGLN]) has been working with the heart transplant teams in Ontario and the United States (U.S.) to facilitate the implementation of a protocol for DCC heart recovery

What does this mean for you?

- Following the heart's acceptance from a potential DCC donor, you will be notified that the DCC case includes recovery of the heart.
- For hearts accepted by U.S. programs, the accepting program will be responsible for recovering the heart.
- Outside of heart recovery, your role in the operating room does not change.

Heart Donation Following Death Determination by Circulatory Criteria (DCC)

For Specialists, Organ and Tissue Donation

Why are we now assessing the heart of potential DCC donors?

- Historically, heart recovery from DCC donors has not been possible due to concerns about physiological damage to the heart following withdrawal of life-sustaining measures (WLSM).
- Advancements in technology have led to changes in recovery and preservation techniques, making DCC heart transplantation possible.
- Ontario Health (Trillium Gift of Life Network [TGLN]) has been working with the heart transplant teams in Ontario and the United States (U.S.) to facilitate the implementation of a protocol for DCC heart recovery.

What does this mean for you?

- A list of participating Ontario hospitals will be updated when the Ontario Program procurement and training is complete.

What is functional ischemic time (FIT) or function warm ischemic time (fWIT)?

- FIT or fWIT is the time from the systolic blood pressure dropping below 50 mmHg with an O₂ saturation of 70% to the time of donor cross-clamp.
- In general, the heart recovery team will wait up to 3 hours for the donor's SBP to drop below 50 mmHg with an O₂ saturation of 70% after WLSM to proceed with DCC heart recovery. Organ viability will be determined by individual transplant teams based on their own criteria and will be discussed during the Recovery Team Huddle in advance of the recovery surgery.
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- The following must occur within **30 minutes** from the start of FIT or fWIT:
 - Patient meets death criteria as per current practices
 - Five-minute hands-off observation period
 - Confirmation of DCC
 - Skin cut
 - Organ flush
 - Placement of the heart onto the extracorporeal heart perfusion machine
- If at anytime during the 5 minute observation period the SBP recovers, the 30-minute FIT or fWIT clock restarts.

What do you have to do?

Phase of process	Action
<p>Approach</p>	<ul style="list-style-type: none"> • Discuss donation with the patient and/or family as per usual practice. • Share information on donation following DCC as per usual practice.
<p>Consent</p>	<ul style="list-style-type: none"> • Obtain consent for organ donation and DCC interventions, including authorization for transfer for pre-mortem interventions (CSF-9-26) • Discuss the need for potential transfer for coronary angiography if not available on site. Please refer to the “Letter for Angiography” document. • Discuss the need for potential transfer for the purposes of recovery if resources to support recovery are not available on site. Note that Ontario Health (TGLN) will cover the costs of travel for the next of kin, if transfer to another hospital is required. • Refer to the additional scripting developed for use during the first few DCC heart cases. Please refer to the “Scripting for OTDCs” document. • Since DCC heart is new to Ontario and Canada, there is an increased potential for media attention. Be vigilant in protecting the identity of the recipient and donor. Maintain confidentiality as per usual protocols.
<p>Donor Screening and Testing</p>	<ul style="list-style-type: none"> • Screening and testing for organs other than the heart will be completed as per usual practice. • Heart exclusion criteria will be applied by the PRC staff to determine suitability of the heart. Please refer to the “Heart Donor Exclusion Criteria” for reference. • Toxoplasmosis serology should be sent with standard blood work if the patient meets the criteria for a DCC heart donor. • Request an echocardiogram and troponin (if not already done). To note, T4 is not required.

Phase of process	Action
	<ul style="list-style-type: none"> • Refer to the hospital profile for image-sharing details as each hospital will have different capabilities. • If heart recovery team requests cardiac angiogram, provide Most Responsible Physician with the “Letter for Angiography” and assist healthcare team as necessary in arranging for a cardiac angiogram. • If transfer is required to facilitate the angiogram, a community DNR form must be completed. Electronic and written orders are not sufficient. The form is controlled and numbered. All hospitals have the forms, though they may not be readily obtained. • Document assessment Q12H: level of ventilatory/oxygen support and neurological status (i.e., Glasgow Coma Scale [GCS], Richmond Agitation-Sedation Scale [RASS]). • If heart transplant team requests an estimated likelihood of dying, do not provide an opinion. This is not permitted in Canada. Connect with the Chief Medical Officer or the Donation Support Physician for the next steps.
<p>Allocation</p>	<ul style="list-style-type: none"> • Organ allocation will proceed as per usual practice. • Hearts from potential DCC donors will be offered as per provincial algorithm. • Hearts must be accepted to move forward with the case.
<p>Recovery Planning</p>	<ul style="list-style-type: none"> • If the heart is accepted, a Just-in-time huddle will be arranged. Ensure to include Specialist, Hospital Development if an HD site. • Arrange for the WLSM to occur in a location close to the hospital OR or in the OR. • If the hospital is unable to accommodate WLSM in a location close to the OR, the Manager on Call and Donation Support Physician should be consulted to determine if further escalation in the hospital is warranted. • Due to the use of the OCS™ Heart Machine or similar medical device and the larger team required to complete recovery of the heart, a larger OR is required. Confirm the largest available OR can be used for recovery.

Phase of process	Action
	<ul style="list-style-type: none"> ● Identify the location of an accessible plug in the OR that may be used for the OCS™ Heart Machine (or similar device), and provide this information to the PRC. ● Please note that recovery of a heart after DCC may extend the use of the OR up to two hours while the transplant team further assesses the heart for suitability. Therefore, the OR will need to be available for up to 6 hours. Considerations for total length of OR: <ul style="list-style-type: none"> ○ OR set-up ○ Donor transfer and preparation ○ WLSM time ○ Organ recovery (multi-organ cases) ○ Assessment of Heart on ex-vivo /medical device ● Please refer to the “OR Pick List” and note the following related to OR set-up: <ul style="list-style-type: none"> ○ A back table will need to be set-up for the heart team ○ A side table will need to be set-up for the heart team, near the head of the patient. ○ Remove all unnecessary equipment to provide the most amount of space. ● Request MRP to order requested number of units of crossmatched banked (washed or not washed) blood to be ready for the heart ex-vivo pump after procurement. Note: washed blood is ordered through Canadian Blood Services and takes time to arrive onsite. ● Huddle with Recovery Teams onsite and ensure a Recovery Lead is identified who will organize the recovery surgery flow and organ viability timelines. Typically, this is a physician from the Heart Recovery Team and is especially important in multi-organ cases. ● The heart recovery team will use 1 to 1.5L of blood from the donor that will be obtained in the OR. Heart recovery team to explain how this process will be performed and what type of equipment or support they need.

Phase of process	Action
	<ul style="list-style-type: none"> • Usually, the blood collection can take up to 3 minutes from skin cut. A timer will be set for 3 minutes by the SOTD/designate in the OR following skin cut (This is usually well in advance of liver surgeons being ready to flush). • Confirm that blood collection will be possible. If liver recovery teams are ready to flush and it is approaching their organ viability time limit, heart recovery team may have 90 seconds to 2 minutes for blood collection. • Establish a plan for FIT/fWIT communication to the heart recovery team and discuss the heart recovery team's time they will wait based on their organ viability criteria. • Following WLSM, document vital signs as per usual donation after DCC practices as well as FIT/fWIT. • • Ensure a member of the healthcare team (e.g. social worker, chaplain, ICU nurse) will be present in the location of WLSM to support the family.
<p>Death Determination</p>	<ul style="list-style-type: none"> • Confirmation of DCC will occur as per current practice. • In general, the heart recovery team will wait up to 3 hours from the WLSM time to death determination to proceed with DCC heart recovery. Organ viability will be determined by individual transplant teams based on their own criteria.
<p>Recovery</p>	<ul style="list-style-type: none"> • Asystole must occur within the FIT/fWIT(30 minutes or less) for the heart to be recovered. If this does not occur, the heart will not be recovered. • If the lungs are also being recovered for transplantation, re-intubation must occur as per current practices and be completed by an anesthesiologist/RRT. If the lungs are not being recovered for transplantation, re-intubation is not necessary. • The heart recovery team will include one SRC, two heart surgeons, and two perfusionists. • Organs will be recovered in the following order: <ul style="list-style-type: none"> ○ Heart ○ Liver/multi-abdominal ○ Lung(s)

Phase of process	Action
	<ul style="list-style-type: none"> ○ Kidney ● The heart recovery team will use 1 to 1.5L of blood from the donor that will be obtained in the OR. Ensure processes and timelines for blood collection are discussed in the planning phase as indicated above. ● In the circumstance where donor blood collection is not possible, the standby crossmatched banked (washed or not washed) blood will be used. ● Once the heart is recovered, it will be placed immediately on the OCS™ Heart Machine or similar device for assessment. ● The heart will remain on the machine and assessed in the OR for approximately 60 - 120 minutes before being transported on the machine to the transplant hospital. ● If the heart is the only organ recovered, one of the heart surgeons will close the donor.
Debrief	<ul style="list-style-type: none"> ● Following a case, ensure that you provide an informal debrief with the Operational Lead, Hospital Donation Physician/Donation Physician Champion, and OR staff. This may be the first time that staff have been involved in heart donation following DCC, and, if applicable, the first time WLSM has occurred in a hospital's OR. The hospital staff may wish to discuss this experience. ● A formal debrief may be arranged following the case if requested by the hospital. The site's primary S-OTD and/or Specialist, Hospital Development are available for support.
Case Closure & Follow-up	<ul style="list-style-type: none"> ● Case closure and follow-up are as per usual practices.

Heart Donation Following Death Determination by Circulatory Criteria (DCC)

For Specialists, Hospital Development

Why are we now assessing the heart in potential donors following DCC?

- Historically, heart recovery following DCC has not been possible due to concerns about physiological damage to the heart following withdrawal of life-sustaining measures (WLSM).
- Advancements in technology have led to changes in recovery and preservation techniques, making heart transplantation following DCC possible.
- Ontario Health (Trillium Gift of Life Network [TGLN]) has been working with the heart transplant teams in Ontario and the United States (U.S.) to facilitate implementation of a protocol for heart recovery following DCC.

What does this mean for you?

- Please refer to the “**Heart Donation following DCC – Participating Hospitals**” list for reference.
- This document outlines several key pieces of information related to heart recovery following DCC, including a definition of functional warm ischemic time (fWIT)/functional ischemic time (fIT) and the differences in the process compared to traditional donation following DCC.

How does it work?

- The donation discussion and information shared with the family/substitute decision-maker follows traditional donation after DCC practices.
- The family will consent to organ donation and interventions associated with DCC as per usual practice, including the need for transfer of the patient to facilitate recovery of organs and/or tissues when applicable.
- Heart suitability testing will be required, which may include transferring the patient to another facility for a cardiac angiogram. Please refer to “**Angiogram Letter**” for reference.
- The most responsible physician will assume the responsibility of obtaining consent to transfer for cardiac angiogram from the family/substitute decision-maker. Note that the healthcare team will also be responsible for coordinating all transfer arrangements and caring for the patient throughout the transfer process as per standard hospital policies.

- If a potential donor is at a hospital where heart recovery cannot be supported or if the hospital is located outside of 2.5 hours driving distance from an Ontario heart recovery program the patient will be transferred to a hospital within 2.5 hours of the Ontario heart recovery program where WLSM and heart recovery following DCC can take place. As transfer to facilitate organ recovery is obtained during the initial consent process, additional consent to transfer will not be required in these circumstances.
- Ontario Health (TGLN)'s PRC staff will apply heart exclusion criteria to determine the suitability of the heart. Please refer to "**Heart Deceased Donor Exclusion Criteria**" for reference.
- Due to timing, WLSM must occur in a location close to the OR. (e.g., PACU)
- The S-OTD must confirm the largest available OR can be used as part of the recovery planning. This is to accommodate a larger recovery team and the extracorporeal heart perfusion machine.
- If the hospital is unable to accommodate WLSM close to the OR, the Manager on Call and Donation Support Physician should be consulted to determine if further escalation in the hospital is warranted.
- The OR should be set up to include a back table and side-table near the head of the donor for use by the heart recovery team. Please refer to the "**DCC Heart OR Set Up**" and "**DCC Heart OR Requirements**" for additional details.
- Death determination will occur as per current practice. In general, the heart recovery team will wait up to 3 hours for the Systolic Blood Pressure to drop below **50mmHg with an O2 saturation of 70% after WLSM** to proceed with DCC heart recovery. The specific time-window will be determined based on the recovering team's own criteria.
- DCC must occur within the **functional ischemic time fWIT/fit** of 30 minutes or less for the heart to be recovered. If this does not occur, the heart will not be recovered. Please refer to the "**Calculating and Coding fWIT/fit**" information sheet for details.
- Once the heart is recovered, it will be placed immediately on the extracorporeal heart perfusion machine for assessment. Assessment of the heart in the OR takes approximately 60 minutes before being transported on the machine to the transplant hospital.

- Recovery of a heart after DCC may extend the use of the OR up to two hours while the transplant team further assesses the heart for suitability. Therefore, the OR will need to be available for up to 6 hours or longer if a multi-organ case. Considerations for total length of OR time include the following: OR set-up; donor transfer and preparation; WLSM time; organ recovery (including for multi-organ cases).

How can you support your hospital(s)?

- Familiarize yourself with the educational materials and resources developed as part of the heart donation following DCC and transplantation implementation so that you are well-versed in what it is and how it works.
- Consider offering support to the onsite S-OTD.
- For HD-supported hospitals:
 - Touch base with the Operational Lead and offer assistance;
 - Provide education and just-in-time education to the hospital team;
 - Familiarize yourself with the process at the hospital, particularly the escalation process for ensuring WLSM is completed in a location near the OR and identifying the largest available OR for recovery,
- Following a case, ensure that you debrief with the Operational Lead, hospital physician and OR staff. This may be the first time the hospital or staff have been involved in heart donation following DCC and may wish to debrief about this experience.
- Follow-up with any requested education/information.
- As this is a new type of donation in Ontario and Canada, there may be some media coverage following the first few cases, in particular. Should you be approached by the media, please inform the MOC and/or Director who will then reach out to the Director and/or Manager of Public Education and Marketing to respond to the inquiry.

Heart Donation Following Death Determination by Circulatory Criteria (DCC)

For Manager on Call

What do you have to do to prepare?

- Prior to Ontario Transplant Programs recovering DCC hearts, Ontario DCC donor hearts will be offered through the United Network for Organ Sharing (UNOS) to U.S. jurisdictions recovering DCC hearts for transplant.
- Proceed as per current practices for any DCC donation case but also make note of the following:
 - Suitability for DC heart donation is highly selective and an extensive list of exclusion criteria have been identified to identify potential donors. Please refer to “**Heart Donor Exclusion Criteria**” for reference.
- If there is a DCD case AND the potential donor’s heart is accepted by the heart transplant team, the heart will be included in the recovery process.

What do you have to consider when planning for DCD heart recovery?

- To support DCC heart recovery, hospitals will be requested to complete the withdrawal of life-sustaining measures (WLSM) close to or in the hospital Operating Room (OR). This is to decrease the amount of time between death and start of the recovery surgery. As part of the Huddle, you will need to **confirm where WLSM will occur**.
- If the hospital is unable to accommodate WLSM in or near the OR, consult the Donation Support Physician (DSP) to determine if further escalation in the hospital is warranted.
- To support DCC heart recovery, the Organ and Tissue Donation Coordinator (OTDC) will request the **largest available OR** to ensure ample space for both the larger recovery team and the machine.
- Death determination is completed as per current practice. The **time from WLSM to death determination for DCD heart donation is 3 hours**.
- Please note that for those DCD cases where the heart and other organs have been accepted for recovery, the order of organ recovery is as follows:
 1. Heart
 2. Liver/multi-abdominal

3. Lung(s)
4. Kidney

What happens during the recovery?

- Suitable organs will be recovered from DCD donors in the above-mentioned order.
- In conjunction with heart recovery, there will be 1 – 1.5L of donor blood collected in the OR to prime extracorporeal perfusion pump and the process for collection will be discussed in advance of the OR. Banked packed red blood cells (washed or unwashed) will also be available if donor blood collection volume does not meet the requirements for priming the perfusion pump
- Hearts are suitable for recovery if the **functional warm ischemic time (fWIT) is 30 minutes or less**. Refer to “**Calculating and Coding Functional Warm Ischemic Time**” for additional details.
- Once the heart has been recovered, it will be placed on the ex vivo perfusion pump for completion of preliminary assessment in the OR. The heart recovery team will continue to assess the heart while it is on the machine. This will last approximately 60 minutes.
- Recovery of a heart after DCC may extend the use of the OR up to two hours while the transplant team further assesses the heart for suitability. Therefore, the OR will need to be available for up to 6 hours or longer if a multi-organ case. Considerations for total length of OR time include the following: OR set-up; donor transfer and preparation; WLSM time; organ recovery (including for multi-organ cases).
- Once the heart has been recovered, the remaining organs accepted for transplantation will be recovered as per current protocols.

Heart Donation Following Death Determination by Circulatory Criteria (DCC) For Donation Support Physician (DSP)

What do you have to do to prepare?

- Proceed as per current practices for any DCC donation case but also make note of the following:
 - Ontario Health (Trillium Gift of Life Network [TGLN]) has been working with the heart transplant teams in Ontario and the United States (U.S.) to facilitate the implementation of a protocol for DCC heart recovery
 - Suitability for DCC heart donation is highly selective and an extensive list of exclusion criteria has been developed to identify potential donors. Please refer to “**Heart Donor Exclusion Criteria**” for specifics.
 - DCC hearts will be offered to the U.S. through United Network for Organ Sharing (UNOS).
 - Potential paediatric DCC hearts should continue to be offered to UHN and will be discussed on a case-by-case basis. If these donors meet any of the exclusion criteria, they will be excluded.

What do you have to consider while supporting a DCC heart recovery?

- To support DCC heart recovery, hospitals will be requested to complete the withdrawal of life-sustaining measures (WLSM) in a location close to the OR. This is to decrease the amount of time between death and start of the recovery surgery. If the hospital is unable to accommodate WLSM near the OR, you will be consulted by the Manager on Call to determine if further escalation in the hospital is warranted.
- To support DCC heart recovery, the Specialist Organ and Tissue Donation (SOTD) will request the **largest available OR** to ensure ample space for both the larger recovery team and to accommodate the extracorporeal perfusion machine. The heart recovery team will need easy access to an electrical outlet in the OR for the machine.

- Death determination is completed as per current practice. The **time from WLSM to death determination for DCC heart donation is 3 hours**. Please refer to “Calculating and Coding fWIT/fIT” for reference.
- Please note that for those DCC cases where the heart and other organs have been accepted for recovery, the order of organ recovery is as follows:
 1. Heart
 2. Liver/multi-abdominal
 3. Lung(s)
 4. Kidney
- If lungs have also been accepted by the transplant team, an anesthetist will also be required in the OR for re-intubation.

What happens during the recovery?

- Suitable organs will be recovered from DCC donors in the above-mentioned order.
- Once the heart has been recovered, it will be placed on the extracorporeal heart perfusion machine for completion of preliminary assessment in the OR. The heart recovery team will continue to assess the heart while it is on the machine. Please note that recovery of a heart after DCC may extend the use of the OR up to two hours while the transplant team further assesses the heart for suitability. Therefore, the OR will need to be available for up to 6 hours.
- Once the heart has been recovered, the remaining organs accepted for transplantation will be recovered as per current protocols.

What might you be asked to do as the DSP?

- Join the Manager on Call, SOTD, and Clinical Service Coordinator for the team huddle.
- Advocate for and explain the need for echocardiogram(s) with timely completion and reporting.
- If ECHO > 50%, join a case-by-case review and confirm offer.
- Advocate for and explain the need for the requested angiogram with timely completion and reporting.
- Advocate for and explain the need for consent to transfer, if required, to support donation.

- Provide explanation for the mandatory completion of a community Do Not Resuscitate (DNR) Form if transportation to facilitate testing and/or donation is required
- Explain the process for collecting 1 to 1.5L of donor blood that will be used to prime the extracorporeal perfusion machine.
- Explain the need for banked packed red blood cells (washed or unwashed) for situations where donor blood collection is not possible or required donor blood collection does not meet the desired volume to prime the extracorporeal perfusion machine.
- Navigate coroner blocks and coroner familiarization with DCC heart process.
- Provide explanation to hospital physicians that their WLSM and DCC responsibilities remain unchanged.
- Provide explanation for length of time required in OR.
- Provide explanation regarding US heart allocation and recovery processes.
- Advocate for and explain the requirement for the largest available OR.
- Clarify any perceived conflict of interest for OR staff.
- Give explanation to Health Care Providers for organ acceptance or decline.
- Escalate and collaborate to navigate unresolved barriers, as per regular practice.
- Participate in any case debriefs set-up after the first few cases.

Other Considerations:

- If U.S. program requests estimate likelihood to die, this is not permitted in Canada. Transplant Lead – Donation or DSP may be consulted to address this by speaking to the MRP to get a sense of clinical status and write a short paragraph for the transplant program.

Heart Recovery Following Death Determination by Circulatory Criteria (DCC)

Scripting for SOTDs

Key Lessons from the UK:

- Families generally did not know that this was not normal and no negative feedback received
- Media coverage was less intrusive than they thought and mostly focused on the recipient

For first few DCC Heart consents:

“One of the things we are able to offer you is the ability to recover your loved one’s heart. The ability to support this in your loved one’s situation is relatively new in transplant medicine. The heart is the rarest of organs transplanted and with this ability; one more person can start a new life”.

Consistent with the *Gift of Life Act*, and confidentiality requirements, TGLN does not routinely provide the donor family with information about the location the recovery team is coming from.

In response to past media coverage, if families ask if the heart is going to the U.S., Specialists may use the following language:

“it is important to respect the generous gift that you have provided by giving consent for your loved one to help as many people as possible. When an organ can’t be matched with a patient in Ontario, we do look for a recipient match in North America. For heart recovery in your loved one’s situation, training is scheduled to begin later this year for Ontario teams. While the Ontario teams are learning from the experienced teams from the U.S., your loved one will be able to save another life. “Messaging about media coverage when hearts are accepted for Ontario recipients:

“Because this may be a ‘first’/one of the first for (Hospital name, Canada, etc.), there will probably be an interest from the media at some point. At TGLN,

we are committed to following Ontario’s privacy laws and cannot give you specific information about who your loved one might help. However, due to the potential interest in this medical advancement, the identity of a recipient may become known through media coverage or, perhaps, on social media. Our commitment to you is to let you know about any future media interest that might have information about this type of donation and transplant.”

Version date: June 2024

Date

Recipient Name
Recipient Job Title
Organization Name
Street Address
City, Province, Postal Code

Dear Dr.,

The family of _____ has generously consented to donation after death determination by circulatory criteria (DCC) (non-heart-beating donation). Historically, hearts were not recovered in DCC donation due to the heart's sensitivity to ischemia. It is now possible for the heart to be reanimated and put on a pump system to ensure that it is perfused, decreasing ischemia and damage. DCC heart donation has been available for several years in other jurisdictions, including the United Kingdom, USA, and Australia.

In order to help facilitate a thorough evaluation of the heart function of this patient, a coronary angiogram only assessing the presence and degree of coronary artery disease (CAD) is required. Consent is required for this procedure from the SDM under the *Health Care Consent Act*. This is to be obtained by the interventional cardiologist who is performing this procedure or hospital designate.

Please do not perform a left ventriculogram as this does not add additional information to the echocardiographic assessment.

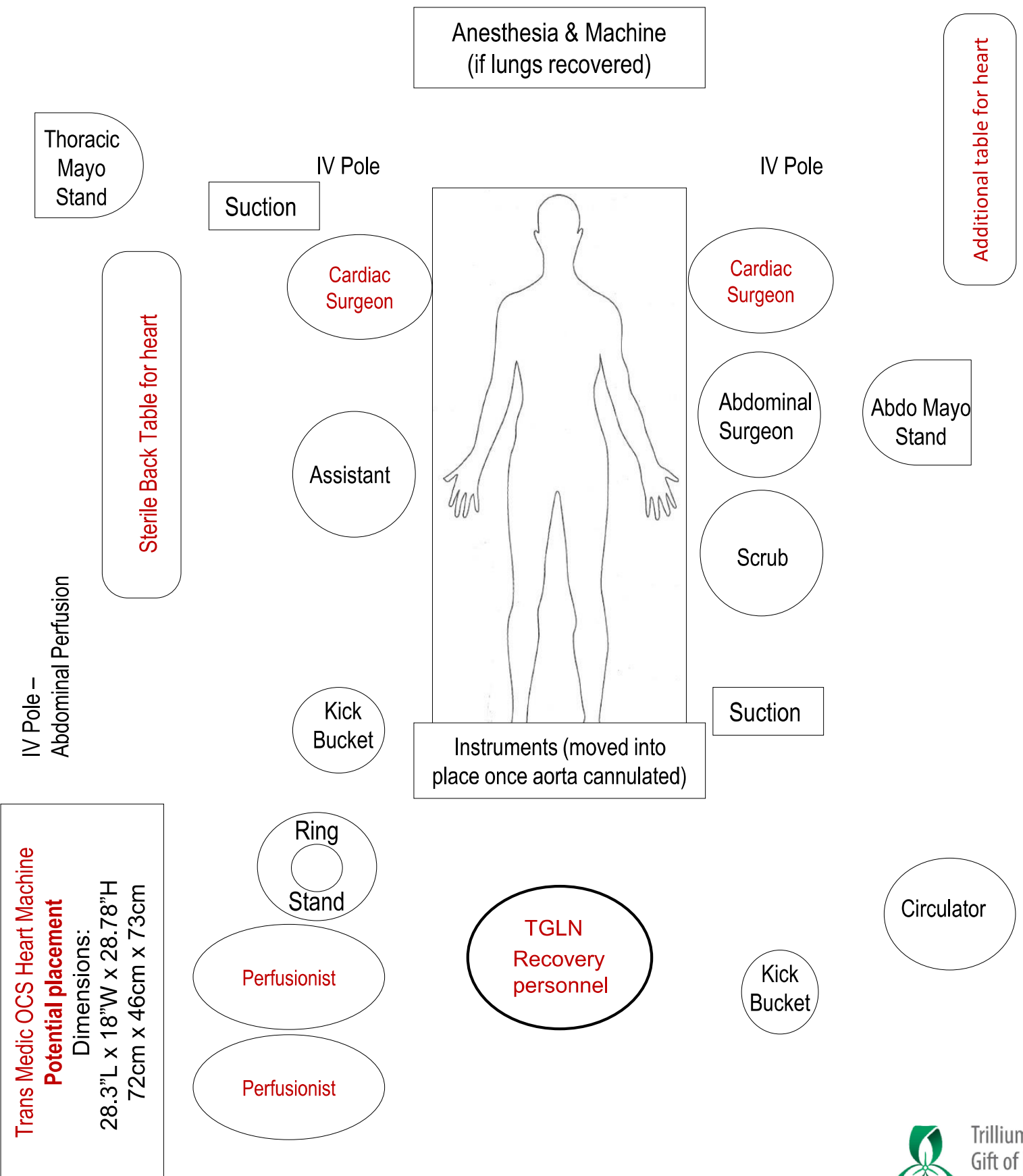
Thank you for your involvement with this patient and the donation process.

Sincerely,

Andrew Healey MD RDCS RDMS FRCPC (EM CCM) (he, him)
Specialist in Emergency and Critical Care Medicine
Provincial Medical Director - Donation
Clinical Institutes & Quality Programs
Ontario Health (Trillium Gift of Life Network)

OR Setup for DCD Heart Organ Recovery

Note: this diagram outlines the *potential* set-up and is provided as an example only. Hospital Operating Rooms vary in size and shape, so the exact set-up may need to be adjusted to meet existing dimensions.



Heart Donation Following Death by Circulatory Determination (DCD)

Operating Room Pick List

The following outline the donor operating room (OR) requirements:

- Largest available OR
- Access to an electrical outlet for the OCS™ Heart Machine
- Side table set up for recovery team
- Back table set up
- OR to be available for 6 hours
- Internal defibrillator machine and paddles, if available at hospital
- Organ recovery equipment checklist (see tables below)

Donor OR Equipment

Equipment for Room Set-up
Large volume suction apparatus (~16 litres)
Small tables (2)
High Stands
IV poles (2)
Blood warmer
Bovie (2)
Nitrogen tank
Gerhardt table
Ring stands
Slush machine (if available)
Flexible bronchoscope (if recovering lungs)

Drugs
Heparin 1:1000
Lasix
Neuromuscular blocking agents
Mannitol (20% - 100cc)
1-4 units packed red blood cells (check with the TGLN coordinator)

Sutures	Quantity
Bone Wax	2
Ligaclip large	1
Ligaclip medium	1
Umbilical tape	2
Silk 3-0	2
Silk 0	2
Silk ties 0	2
Silk ties 2	1
Silk ties 3-0	2
Silk ties 2-0	2
Vicryl 2-0 Reel	1
Double-loaded cardiovascular Prolene 5-0	1
Double-loaded cardiovascular Prolene 4-0	1
Tevdek 5	8
Maxon 3-0	1
Note: Recovery team to bring their own sutures for cannulation	

Equipment	Qty	Equipment	Qty
Major abdominal tray	1	Tubing smoke evacuator w/adaptor (standard)	1
Sternal or oscillating saw	1	Tubing - IV administration	2
Prep tray	2	Sponge – tonsil single strung (Raytec pushers)	1
Basic basin set	1	Sponge – cylindrical dbl.strung	1
ENT basins	2	Opsite (45 cm x 55 cm)	4
Deep sharp Balfour retractor and blade	1	Sponge – laparotomy (12x12)	20
Gibson retractor	1	Cautery tip	2
Draping – CV pack	1		
Gown single – gortex	4		
Gown bundle (3/pk) – gortex	3	Cautery holder	1
Drape – overhead table cover	2	Fogarty clamp inserts	1
Cover – table (50x90)	3	Needle counter	2
Towel – green (6/pk)	3	Suction tip – hi-capacity	2
Pack – universal	1	Suction tip – low capacity	1
Towel – adhesive	3	Suture boots mini cartridge (3 pr)	1
#20 blade	2	Syringe – 60 ml irrigation bulb	1
#15 blade	2	Suction tip – Poole	1
Yankauer suction	1	Clip Appliers – medium 10.5”	2

Tubing – suction	2	Clip Appliers – large 10.5”	2
Electro tip cleaner	1	Retractor – chest medium (square hole)	1
Vessel loops – blue mini	1	Forceps – Swedish Debakey 11”	2
Vessel loops – yellow maxi	1	Forceps – Allis 9”	5
Bottle suction liner with cap 3000cc	6	Forceps – Fraser straight 7.25”	2
Staple – skin TW-35	2	Forceps – Fraser curved 7.25”	2
Asepto syringe	1	Forceps – Fogarty Hydragrip curved 8.75”	1
Pickups – Debakey medium 12”	2	Forceps – Lee bronchus 9.25”	2
Pickups – Debakey insulated medium 8”	2	Forceps – Semb dissector 9.25”	1
Pickup – Pott Smith	1	Forceps – Satinsky medium 10”	2
Bulldogs – Cross Action 1.25”	2	Forceps – Debakey regular 7”	3
Rummel rods 12” (1 large, 1 small)	2	Scissor – Mayo straight 6.75”	1
Retractor Alar 6”	1	Scissor – Metzenbaum 9”	1
Retractor Alar 10”	1	Needle holder – arterial 7”	2
Tourniquets (4 large, 2 small)	6	Needle holder – Mayo Hegar 7”	2
Scalpel handle #4	1		



Do Not Resuscitate Confirmation Form
To Direct the Practice of Paramedics and Firefighters after February 1, 2008
Confidential when completed

When this form is signed by a physician (M.D.), registered nurse (R.N.), registered nurse in the extended class (R.N. (EC)) or registered practical nurse (R.P.N.), a paramedic or firefighter **will not** initiate basic or advanced cardiopulmonary resuscitation (CPR) (see point #1) and **will** provide necessary comfort measures (see point #2) to the patient named below:

Patient's name – please print clearly	
Surname	Given Name

1. **“Do Not Resuscitate”** means that the paramedic (according to scope of practice) or firefighter (according to skill level) **will not** initiate basic or advanced cardiopulmonary resuscitation (CPR) such as:
 - Chest compression;
 - Defibrillation;
 - Artificial ventilation;
 - Insertion of an oropharyngeal or nasopharyngeal airway;
 - Endotracheal intubation;
 - Transcutaneous pacing;
 - Advanced resuscitation drugs such as, but not limited to, vasopressors, antiarrhythmic agents and opioid antagonists.
2. For the purposes of providing comfort (palliative) care, the paramedic (according to scope of practice) or firefighter (according to skill level) **will** provide interventions or therapies considered necessary to provide comfort or alleviate pain. These include but are not limited to the provision of oropharyngeal suctioning, oxygen, nitroglycerin, salbutamol, glucagon, epinephrine for anaphylaxis, morphine (or other opioid analgesic), ASA or benzodiazepines.

The signature below confirms with respect to the above-named patient, that the following condition (check one

- A current plan of treatment exists that reflects the patient's expressed wish when capable, or consent of the substitute decision-maker when the patient is incapable, that CPR not be included in the patient's plan of treatment.
- The physician's current opinion is that CPR will almost certainly not benefit the patient and is not part of the plan of treatment, and the physician has discussed this with the capable patient, or the substitute decision-maker when the patient is incapable.

Check one of the following:

- M.D.
 R.N.
 R.N. (EC)
 R.P.N.

Print name in full	
Surname	Given Name
Signature	Date (yyyy/mm/dd)

- Each form has a unique serial number.
- Use of photocopies is permitted only after this form has been fully completed.

Heart Donation Following Death Determination by Circulatory Criteria (DCC)

Communications Information Sheet

This document provides a brief outline of heart donation following death determination by circulatory criteria (DCC), as well as responses to questions you may be asked when speaking with families or health care providers.

Note: Should you receive any media inquiries, please direct these to Ontario Health Media Relations at mediainquiries@ontariohealth.ca

Background

Previously, hearts were not recovered in cases of DCC donation because of the heart's extreme sensitivity to ischemia (inadequate blood supply to an organ). In the process of dying, the heart would become too damaged for transplant.

Today, heart recovery after DCC is possible due to advances in technology. The heart is recovered and placed on a portable external heart machine, which pumps blood and a special solution to maintain oxygen to the heart, allowing for the heart to be assessed before transplant.

Key Messages

- Hearts are the least likely organ to be transplanted. The implementation of DCC heart donation will save more lives.
- Ontario hopes to become a leader in implementing this groundbreaking practice in Canada. Training is scheduled to begin later this year for select Ontario teams.
- There is a collaborative opportunity for Ontario teams to observe and learn from experienced US medical teams during heart recovery after DCC in Ontario, an approach that will support Ontario as we build expertise and capacity in heart recovery and transplantation after DCC.
- This initiative will offer hope to the 45 to 60 individuals who are on the heart transplant waitlist in Ontario at any given time, and potentially reducing the average four-month wait time, preventing the approximately 10 deaths that occur annually while awaiting transplantation.

Frequently Asked Questions

1. How does the process of recovering hearts from DCC donors differ from the typical DCC donation process?

The organ recovery process remains the same. What's new is the technology that allows us to recover the heart, and place it in a portable pump that will assess and keep the organ viable for transplant.

2. Does this impact the experiences of the donor family? And how so?

Based on the experience in other jurisdictions, and the situations in Ontario where DCC hearts have been recovered, the opportunity to donate hearts following DCC has, if anything, improved the family's satisfaction in being able to help even more people. Our donor families are incredible individuals, and because of this advancement, more families will be offered the opportunity to have their loved one live on in an exceptional way – through the gift of a heart transplant.

3. Does this take away the opportunity to donate other needed organs and tissues?

No. This approach will allow us to save more lives as more donor families will be provided with the opportunity to donate the heart of their loved one in addition to other needed organs and tissues. By recovering hearts from DCC donors, it gives us a chance to transplant hearts, which previously could not be used for donation.

4. How can you ensure that health care professionals in the Emergency Room or Intensive Care Unit are not treating patients with donation in mind?

The first and foremost duty of all healthcare professionals is to save a life. Donation is only considered once all life-saving efforts have failed, and there is no chance for recovery.

5. Will the Ontario heart transplant recipient know that the organs were recovered using this new approach?

Yes, the heart transplant recipients will provide consent to this new approach. However, there are no reported differences from the outcomes of receiving a heart from a DCC donor or a heart recovered from a donor after determination of death by neurologic criteria.

6. What is the goal of this new approach? How will it affect the transplant waitlist?

The goal of this new approach is to save more lives. By recovering hearts from DCC donors, it gives us a chance to transplant hearts, which previously could not be used for donation.

DCC HEART POST-ACCEPTANCE HUDDLE:

As Ontario currently does not transplant hearts from DCC donors, eligible DCC donor hearts will be offered to the United Network for Organ Sharing (UNOS) and allocated as per UNOS allocation policies. Post-acceptance of the heart the US OPO must participate in a huddle before their arrival on-site with Ontario recovery teams and the TGLN team.

- This huddle will include the heart team, lung team, abdominal team, MOC, case manager, SOTD, SRC, CSC, and CMO Donation or DSP in their absence a delegate.
- CMO donation/DSP will assume the role of moderator.
- The CSC will arrange a huddle time and a Zoom set up between all parties involved.
- Please allow at least 30 minutes to discuss important details.

HUDDLE POINTS OF DISCUSSION:

1. Introduction of members on the call and their roles.
2. Confirmation of medical license, proof of insurance.
3. Quick overview of the DCC process in Ontario and death determination process and 5 minutes hands-off period – *refer to Appendix A*.
4. Heart Team Logistics: Travel time, set up time.
 - Airport details of arrival- proximity to the hospital.
 - Travel to and from the airport and the method.
 - Travel back to the airport and method.
5. Location of withdrawal and time from WLS location to the OR.
6. Heparin administration dose and process.
7. Heart wait times up to 3 hrs **or** until all organs are closed.
8. Share and confirm with other organ programs how long they plan to wait (lung, kidney, liver, pancreas).
9. Determine which recovery team will close the patient post-recovery. Ensure that all situations are addressed (e.g. abdominal team declines organ due to time and heart team is only team remaining) Responsibility for closing the patient lies with a recovery team and hospital staff will not be asked to do this.
10. Confirm: Heart fWIT definition = SBP < 50 to heart flush 30 minutes. If in first 5 minutes, the SBP recovers, the clock restarts. After that, no reset. - Heart team to discuss.
11. All other organs should speak about fWIT.
12. The heart team plans for blood collection from the donor – explain the process and confirm if the abdomen team still able to cut/canulate during these 3 minutes. The heart team must communicate to the liver team when it's appropriate for flushing.
 - The heart team needs to try to collect 1 to 1.5 L of donor blood (preferred over banked blood). Heart team to explain how this process will be performed and what type of equipment or support they need.
 - Usually, the blood collection can take up to 3 minutes from skin cut. The timer will be set for 3 minutes by the OTDC/designate in the OR. (This is usually well in advance of liver surgeons being ready to flush.)
 - Confirm that this will be possible. If the liver is ready to flush and it is approaching its time limit, it may only be able to give the heart 90s-2 minutes.
 - In the circumstance where blood collection is not possible from the IVC, x-matched banked (washed or not washed) blood can be made available.
13. Washed blood to be ordered ahead of time by SOTD.

14. Which machine will be used for recovery? *will need a maintenance log and electrical information?*
1. OCS = HC approved.
 2. XVIVO = Not HC approved. Have to follow FDA regulations. Formal opinion from HC already gathered.
15. Is additional equipment required to recover the heart at the donor hospital?
- Own solo back table
 - Mayo stand
 - Sternal saw
 - Sternal retractor
 - Internal defibrillator
16. Case Manager to arrange SOTD support and ensure SOTDs have education material for OR.
17. Any other questions or concerns from any team members.

Appendix A:

Withdrawal of Life-Sustaining Measures (WLSM) / Invasive Physiologic Support

- This occurs at agreed upon time (family, hospital, recovery teams) at a location near the operating room, with usually less than 2 minutes travel time after death is determined by two physicians according to the *Gift of Life Act*.
- We do not use the timing of death prediction tools and actively discourage their use in general.
- The hospital team determines end-of-life care (palliative medications, timing of extubation) without advice or requests from the recovery teams. Transplant teams usually request either 500 units/kg or 1000 units/kg of heparin be administered 5 minutes before withdrawal of support. The dose is determined by the abdominal recovery team.
- Ontario Health (TGLN) staff facilitate transfer and communication of timed events (extubation, vital signs, determination of death.)
- By policy and law, clear separation of the donation support teams and any personnel related to transplant are required during this phase and afterwards.
- Recovery teams are staged in the operating room or close to the OR (in a sterile core hallway).
- Preparation and draping of the patient or positioning of the patient during the withdrawal of life sustaining measures process is not done in Canada.
- Current practice is to wait up to 3 hours for the patient to die. Organ viability is determined by individual transplant teams based on their own criteria.

Death Determination by Circulatory Criteria

- Death is determined when:
 - a. Absence of pulse pressure monitored by a continuously functioning arterial line; AND
 - b. Absence of respiratory effort (apnea);
AND
 - c. Absence of palpable pulse at the beginning and end of the 5-minute observation period
- A 5-minute “hands off period” is observed in all cases. The patient will not be moved or transferred during this period.
- Two physicians completely outside of the transplant process are required to determine death.

Operating Room Set Up

- Recovery teams must arrive 1 hour prior to the withdrawal time.
- Recovery teams may be required to bring a sternal saw and retractor if not available at the donor hospital.
- Thoraco-Abdominal normothermic regional perfusion is currently **not** permitted in Ontario.
- Recovery teams will be provided regular updates on patient condition post-WLSM
- When lungs are being recovered, an anesthesiologist or respiratory therapist will provide for reintubation and lung inflation after death is determined.
- Inflation of the lung is permitted after death determination. Tidal volume ventilation must not occur until 10 minutes post death determination. At no time is *in situ* cardiac massage permitted.
- An Ontario Health (TGLN) Surgical Recovery Coordinator is present for the duration of the recovery OR and facilitates the packaging and transportation of recovered organs. However, the heart team must bring all required supplied and be prepared to be entirely self-sufficient in recovery.
- OR staff (scrub nurse, circulating nurse, anesthesia) is provided by the recovery hospital.
- A surgical note describing the recovery must be left at the hospital prior to departure.

Post-Transplant Donor Family & Recipient Communication

- The Gift of Life Act prohibits the identification of the patient as a donor without the donor's consent which is usually not obtainable.
- Connection between the recipient and donor is not possible under current law in Ontario.
- Our coordinators will connect with the program to confirm successful transplant within 24 hours.
- Culture result follow up will be provided to transplant programs by the Provincial Resource Centre (PRC) Staff as soon as results are available.
- The recipient or family may wish to write an anonymized letter of thanks or communicate an update to the family. This is facilitated by our family services department who can be reached at familyservices@ontariohealth.ca

Sharing Donor Imaging

Images are shared in one of two forms:

- via *PocketHealth* link with a password (this is sent in an email separate to this)
- via *SyncLink*
- Images without an extension are in DICOM format and need to be read using a DICOM viewer.
- For Mac/Apple computers, the downloadable *BeeDICOM* viewer works well.
- For PCs, there are many (including MicroDicom, dicomviewer.net, and others).
- It is possible the echo images will also appear in a different format for viewing.

DCC Heart to U.S. OPO Huddle Checklist

The CSC is responsible for arranging the team huddle and should include at a minimum: the CSC, SOTD, MOC, Transplant Medical Lead – Donation and/or Transplant Medical Lead – Transplant, and SRC, if applicable.

TGLN #: _____ Date: _____ Time: _____

CSC: _____ MOC: _____ SOTD: _____

Transplant Medical Lead – Donation or Transplant: _____ SRC: _____

<u>Overview by OTDC</u>	<u>Completed</u>	<u>Requires Follow-Up</u>
• Scheduled withdrawal time?	<input type="checkbox"/>	<input type="checkbox"/>
• Location of withdrawal?	<input type="checkbox"/>	<input type="checkbox"/>
• Plan for OTDC staffing?	<input type="checkbox"/>	<input type="checkbox"/>
• Other Hospital or family specific concerns	<input type="checkbox"/>	<input type="checkbox"/>

<u>Overview by CSC</u>	<u>Completed</u>	<u>Requires Follow-Up</u>
CSC to review information provided by US OPO in Appendix A of the DCC Heart Offer to U.S. Hospitals package, including but not limited to, the following:		
• Is the heart being recovered by the transplant team or a third party?	<input type="checkbox"/>	<input type="checkbox"/>
• Number of team members with heart recovery team?	<input type="checkbox"/>	<input type="checkbox"/>
• Required credentials received for heart recovery team members?	<input type="checkbox"/>	<input type="checkbox"/>
• Have credentials been forwarded to Transplant Medical Lead to provide to donor hospital administrators?	<input type="checkbox"/>	<input type="checkbox"/>
• Is recovery support required from Dr. Alvarez?	<input type="checkbox"/>	<input type="checkbox"/>
• What heart perfusion machine is the team bringing?	<input type="checkbox"/>	<input type="checkbox"/>
• Have we received the required machine documents?	<input type="checkbox"/>	<input type="checkbox"/>
• How will the team get from the donor airport to the donor hospital?	<input type="checkbox"/>	<input type="checkbox"/>
• How will the team get from the donor hospital to the donor airport?	<input type="checkbox"/>	<input type="checkbox"/>
• If TGLN is required to assist with transportation, are there any specific transportation requirements TGLN needs to be aware of?	<input type="checkbox"/>	<input type="checkbox"/>
• Confirmed that the heart recovery team has their own required supplies/solutions?	<input type="checkbox"/>	<input type="checkbox"/>