The High-Status Heart Allocation, Offer Management, Notification and Recusal Process
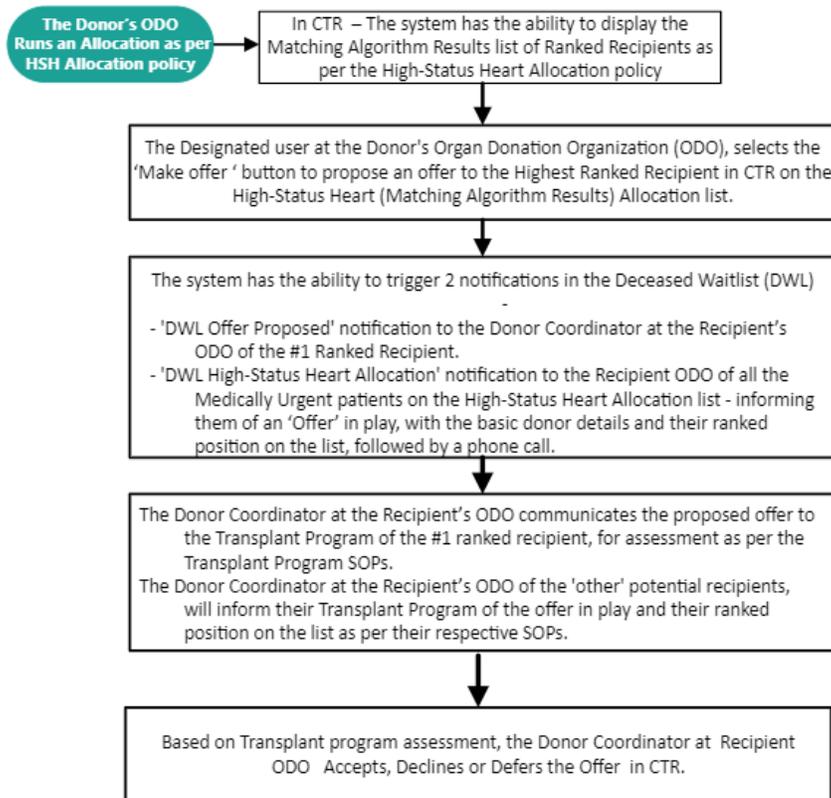
Purpose

The Canadian Transplant Registry (CTR) identifies transplant opportunities across Canada for heart transplant candidates who are designated as medically urgent (i.e., designated as medical status 4) and/or highly sensitized to Human Leukocyte Antigens (HLA). This document outlines the processes used to identify and rank medically urgent patients and highly sensitized (cPRA equal to or greater than 80%) who are potential matches to an available donor heart, and the offer management process. This process operationalizes the existing policies, CTR 10.002 and CTR 10.003, which were approved in February 2018 by all Provinces and by Provincial Funding Authorities in February 2019. These policies were also reviewed and approved by the Canadian Cardiac Transplant Network, Donation and Transplantation Expert Advisory Committee, Organ Donation and Transplantation Expert Advisory Committee, and National HLA Advisory Committee.

This document also defines the 'recusal' process, to exempt a specific recipient from the high-status heart (HSH) allocation for interprovincial organ sharing (IPOS) when deemed medically appropriate by the transplant team.

Processes Outlined

1. Allocation

2. Ranking Rules in the Matching Algorithm

3. Offer Management Process

4. Notification Rules

5. Recusal Process

High Level Process Flow

The Donor's ODO Runs an Allocation as per HSH Allocation policy → In CTR – The system has the ability to display the Matching Algorithm Results list of Ranked Recipients as per the High-Status Heart Allocation policy

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The Designated user at the Donor's Organ Donation Organization (ODO), selects the 'Make offer ' button to propose an offer to the Highest Ranked Recipient in CTR on the High-Status Heart (Matching Algorithm Results) Allocation list.

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The system has the ability to trigger 2 notifications in the Deceased Waitlist (DWL)
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- 'DWL Offer Proposed' notification to the Donor Coordinator at the Recipient's ODO of the #1 Ranked Recipient.
- 'DWL High-Status Heart Allocation' notification to the Recipient ODO of all the Medically Urgent patients on the High-Status Heart Allocation list - informing them of an 'Offer' in play, with the basic donor details and their ranked position on the list, followed by a phone call.

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The Donor Coordinator at the Recipient's ODO communicates the proposed offer to the Transplant Program of the #1 ranked recipient, for assessment as per the Transplant Program SOPs.
The Donor Coordinator at the Recipient's ODO of the 'other' potential recipients, will inform their Transplant Program of the offer in play and their ranked position on the list as per their respective SOPs.

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Based on Transplant program assessment, the Donor Coordinator at Recipient ODO Accepts, Declines or Defers the Offer in CTR.

Note: There may be conversations amongst the Transplant programs as to the most optimal allocation of that donor organ to fulfill the principles of organ donation and allocation.

1. Allocation

When a donor heart is made available, the CTR will generate a ranked list of all potential recipient matches.

All recipients who are active in CTR, designated as 'urgent' (i.e., medical status of 4) and/or those that are highly sensitized to HLA (cPRA equal to or greater than 80%) are eligible to be included in the high-status heart allocation process for interprovincial organ sharing.

When a donor heart is made available, the designated staff at the donor's organ donation organization (ODO) run an Allocation.

As per policy CTR.10.002, the allocation list for high-status heart will return the following potential matches to the donor:

- Recipients who are medically 'urgent', regardless of virtual crossmatch (vXM – POS or NEG) outcome or their HLA compatibility.

  - *Note: The Recipient with an 'Urgent' status can participate without the HLA input (but are required to be available clinically to participate in the HSH IPOS program), at point of allocation, but will be required to have their HLA data input by the next business day.*

- Recipients who are highly sensitized with a negative virtual crossmatch ONLY (vXM – NEG).

- Recipient who are ABO compatible to the donor or identified as 'accept ABO Incompatible = Yes' for their donor acceptance criteria.

- Recipients who meet the minimum and maximum donor weight acceptance criteria.

HSP Kidney	**HS Heart**	Lung		Liver	Small Bowel	Stomach	Pancreas	Kidney	Heart						

HS Heart Allocation Run On:
2021-06-16 21:21:18 ET

Print

[Allocate] [Preview Allocation]

Not Allocated Reason:
Please Select ▼

Action	Threshold	Rank	ODO	National Patient ID	Local ID	TX Type	Organ	MS	Highly Sensitized	State	ABO	Age	ABO Match	VXM
Make Offer	No	2	ON-TGLN	CTR013147	34678	Single	Heart	4	No	Active	O	58.5	Yes	NEG
Make Offer	No	3	ON-TGLN	CTR038101	52809	Single	Heart	4	No	Active	O	33.2	Yes	NEG
Make Offer	No	4	ON-TGLN	CTR033529	49210	Single	Heart	4	Yes	Active	A	51.1	Yes	POS
Make Offer	No	5	QC-TQ	CTR022912	7814	Single	Heart	4	No	Active	A	61.2	Yes	NO VXM
Make Offer	No	5	ON-TGLN	CTR036230	49952	Single	Heart	4	Yes	Active	A	50.8	Yes	POS
Make Offer	No	5	QC-TQ	CTR033421	13539	Single	Heart	4	No	Active	A	60.4	Yes	NO VXM
Make Offer	No	8	AB-EDM-HOPE	CTR029318	415958881 ULI	Single	Heart	4	Yes	Active	A	59.6	Yes	POS

Policy CTR.10.002 - Ranking Rules in the Matching Algorithm.

When an allocation is run, the matching algorithm considers the following criteria when generating the list of potential recipients (i.e., matches) for a heart from a deceased donor who has been registered in the CTR:

1. Blood Group (ABO) Compatibility

2. Minimum and Maximum Weight

3. HLA Compatibility (for highly sensitized recipients ONLY)

The matching algorithm returns the allocation results based on donor acceptance criteria and the ranking rules (for multiple recipients, e.g. "tie-breaking rules") as follows:

- Ranking rules applicable to multiple recipients designated as 'urgent' (i.e. medical status of 4):

Tier	Description of Tier
1	If Recipient's Organ Request Medical Status = '4' (medically urgent)
2	If Recipient is Paediatric (<19) and Donor is Paediatric (<19)
3	If Recipient is Paediatric at time the allocation is run
4	The number of days the Recipient's Organ Request Medical status is listed on current status
5	If Recipient's Transplant Centre region = Donor's ODO region

- Ranking rules applicable to multiple recipients designated as highly sensitized (with a cPRA equal to or greater than 80%):

Tier	Description of Tier
1	If Recipient is Paediatric (<19) and Donor is Paediatric (<19)
2	Recipient's cPRA higher value displays (ranks) above lower value: • cPRA= 100 • cPRA= 99 • cPRA= 98 • cPRA = 90-97

	• cPRA= 80-89
3	If Recipient is Paediatric at time the allocation is run
4	The Recipient's Organ Request Medical Status higher value ranks above lower value: • MS = 3.5 • MS = 3 • MS = 2 • MS = 1
5	The number of days the Recipient's Organ Request Medical status is listed on current status
6	If Recipient's Transplant Centre region = Donor's ODO region

N.B. If there are other program-specified comments in the CTR regarding parameters for donor acceptance, these are not considered for the purposes of IPOS Heart ranking and matching. These are considered at the level of the provincial ODO as per established SOPs with individual programs.

2. Offer Management Process

The HSH allocation list returns the potential recipient matches in a ranked order based on ranking rules and donor acceptance criteria from the matching algorithm.

As per the inter-provincial sharing heart policy CTR10.003, the offer must be proposed to the #1 ranked recipient on the allocation list and notified to all medically urgent listed recipient ODOs via the CTR generated email or SMS/Text and phone call.

When the #1 ranked recipient is proposed an offer, a CTR generated 'DWL Offer Proposed' notification is sent to the donor coordinator at the Recipient ODO and simultaneously a 'DWL High-Status Heart Allocation' notification is sent to all donor coordinators at the ODOs of the medically urgent recipients on the allocation list, informing them of an offer in play, basic donor information, and their rank on the list.

This notification is required to provide the opportunity for the transplant physicians to have a discussion when there are multiple medically urgent potential recipients as to the most optimal allocation of that donor organ to fulfill the principles of organ donation and allocation. This could potentially involve multiple centres/physicians with a goal of a consensus decision on a recipient for the donor organ.

The transplant program physician or surgeon representing the #1 ranked potential recipient must provide the outcome of the discussion to their ODO (Accept, Decline, Defer). The donor coordinator at the Recipient ODO with the proposed offer must record the offer acceptance, decline (with reason), or deferral in the CTR. If multiple physicians from multiple programs were involved in the discussion, then each must notify their ODOs of the consensus decision on the recipient of the donor organ.

If only one medically urgent potential recipient appears on the allocation list, then the donor ODO must make the offer, and no other Recipient ODO needs to be notified.

When the offer is declined or deferred, the donor ODO must make the offer to the next potential recipient on the allocation list, following protocol of proposing in a sequential order. If the consensus recipient is further down the allocation list, then the ODO for each higher ranked recipient must indicate the reason for decline as "deferred" in the CTR until the consensus recipient is reached to make the offer for it to be accepted.

3. Notification Rules

The HSH notification is called the 'DWL High-Status Heart Allocation'.

When the #1 ranked recipient on the HSH allocation list is proposed an offer, the system can trigger 2 notifications, provided designated users at ODOs have subscribed to receiving alerts (i.e. 'Send Alert = Yes'):

- 'DWL Offer Proposed' notification, sent to the Donor Coordinator at the Recipient ODO, to inform them of the proposed offer.

- 'DWL High-Status Heart Allocation', sent to donor coordinators at each recipient ODO that have recipients listed with a medical status of '4' ONLY, to notify them of a 'Heart' organ/offer in play.

When the HSH allocation is run and the allocation list returns only one or no outcome, only the 'DWL Offer Proposed' Notification is sent when the offer is proposed. The 'DWL High-Status Heart Allocation' is not required if there are no other potential recipients.
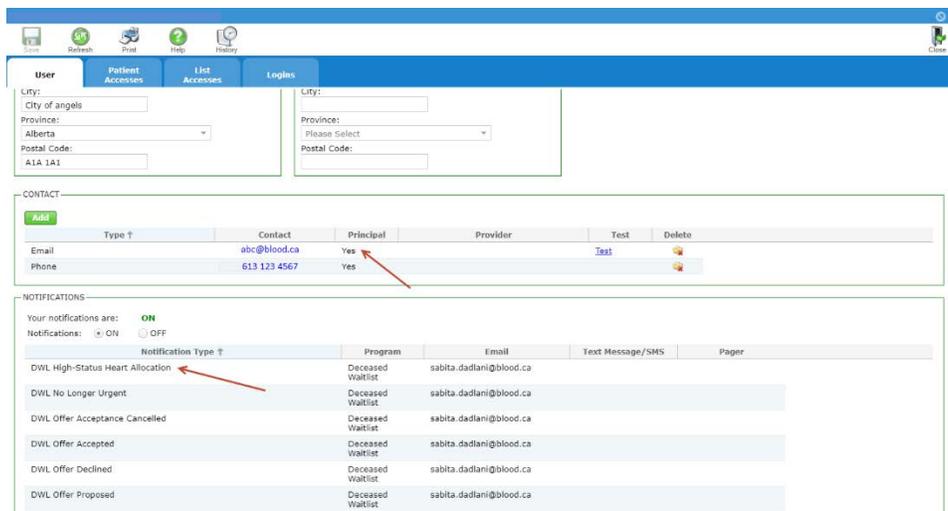
As per existing functionality, each time an offer is proposed, accepted, or declined/deferred the system will generate the following relevant notifications:

- DWL Offer Proposed – received by the designated user at the recipient ODO.

- DWL Offer Accepted – received by the designated user at the donor's ODO.

- DWL Offer Declined – received by the designated user at the donor's ODO.

- DWL Cancelled Acceptance - received by the designated user at the donor's ODO.

Each time the allocation list is re-run, and if the #1 ranking medically urgent recipient on the list is sent an offer, the system will generate the DWL High-Status Heart Allocation Notification.

To receive this or any notification the designated users at ODOs and transplant centers must ensure their CTR user profile is updated with the current email and cell phone number for receipt of the notification.

Note: *A designated CTR user can unsubscribe to stop receipt of the DWL High-Status Heart Allocation Notification.*

The email format of the notification will provide the following deceased donor information, as well as inform the ranked position of the recipient on the Allocation list.

DWL HIGH-STATUS HEART ALLOCATION NOTIFICATION – EMAIL FORMAT

Email –

Subject:

HS Heart Allocation List [DONOR-ODO-ABBREVIATION] [RANK] of [ALL-STATUS-4] / [French equivalent]

Body:

You are being notified that your recipient with a Medical Status of 4 has appeared in a High-Status Heart Allocation List, where an offer is being made to the top-ranked recipient at [RECIPIENT-TXC].

Top-Ranked Recipient

Transplant Centre: [RECIPIENT-TXC]

CTR Recipient ID: [OFFERED-CTR-RECIPIENT-ID]

Your Recipient Information

CTR Recipient ID: [CTR-RECIPIENT-ID]

Allocation Ranking: [RANK] of [ALL-STATUS-4]

Donor Information

Offering ODO:	[DONOR-ODO-ABBREVIATION]
CTR Donor ID:	[CTR-DONOR-ID]
Height:	[DONOR-HEIGHT] cm
Weight:	[DONOR-WEIGHT] kg
Age:	[DONOR-AGE] years
ABO:	[DONOR-ABO]
Gender:	[DONOR-GENDER]

[French Equivalent]

DWL HIGH-STATUS HEART ALLOCATION NOTIFICATION – SMS/TEXT FORMAT

SMS –

Body:

HS Heart Offer proposed [DONOR ID] [DONOR-ODO-ABBREVIATION] - [CTR-RECIPIENT-ID] [RECIPIENT-TXC]. Your recipient [Recipient ID] is ranked [# RANK] of [Total Number] of recipients with Medical Status =4.

[French Equivalent]

4.1 Offer Management Scenarios

WHEN AN OFFER IS PROPOSED

When the donor's ODO proposes the offer to the #1 ranked medically urgent recipient on the allocation list, the system triggers 2 notifications as discussed above:

- 'DWL Offer Proposed' notification will be sent to the Donor coordinator at the /Recipient ODO.

- 'DWL High-Status Heart Allocation' will be sent to all the donor coordinators at the recipient of all the recipients with a medical status of '4' ONLY.

The recipient's ODO forwards the proposed offer to the transplant program for assessment to accept, decline, or defer based on their own standard operating procedures (SOPs).

The offer proposal is also communicated to the recipient's ODO via a phone call.

In case an offer is proposed to the #1 ranked recipient on the allocation list that is not a 'medically urgent' recipient, (i.e. not a status 4 recipient) the CTR will not generate the 'DWL High-Status Heart Allocation' notification..

Once the offer is proposed to the #1 ranked recipient and subsequently declined or deferred, the donor ODO can propose an offer to subsequent recipients on the allocation list in a sequential order.

When the first medically urgent offer is proposed and all other potential matches are notified, the receiving/recipient ODO, based on their standard operating procedures, must provide the opportunity for discussion between transplant program physicians as indicated above.

WHEN AN OFFER IS ACCEPTED

When an offer is accepted after the transplant program has assessed the offer, based on their decision-making processes, this is communicated back to the recipient ODO.

The recipient ODO with the proposed offer must record the offer acceptance in the CTR.

The acceptance must also be communicated via a phone call to the Donor's ODO.

WHEN AN OFFER IS DECLINED

If after the transplant program assesses the offer and decides to decline it, this decision must be communicated to the recipient's ODO who then should communicate it to the donor's ODO.

THE RECIPIENT ODO WITH THE PROPOSED OFFER MUST RECORD THE OFFER DECLINE (WITH REASON) IN THE CTR, AND CONFIRM THIS DECLINE VIA A PHONE CALL TO THE DONOR'S ODO WHEN AN OFFER IS DECLINED DUE TO A DEFERRAL

When the donor's ODO proposes the offer to the #1 ranked recipient on the allocation list, all other potential matches are notified via a CTR generated notification and a phone call to the

recipients ODO's. Each transplant program will be required to establish standard operating procedures with their ODO's, to include when notification to on-call transplant physician needs to occur when their rank is $\leq$ 2 of a heart in play.

The notification to all ODO's, and subsequently to the transplant physician as guided by local SOPs, with listed medically urgent patients, is intended to enable national discussion between physicians to best allocate the heart in play to the recipient most in need.

If there is a situation where, after discussion with other physicians with medically urgent recipients, the decision is to defer the organ to a lower ranked recipient, the recipient ODO who has the #1 ranked medically urgent recipient must record the offer decline (with reason entered as deferred) in the CTR.

If after the discussion the transplant program declines the offer (with reason - deferred), then the ODO associated to the #1 ranked potential recipient must notify the donor ODO so that the donor ODO can make the offer to the next potential recipient on the allocation list, in a sequential order, until they reach the recipient to whom the heart is being deferred to.

All offer declines in case of deferral must be captured with a reason 'Deferred'.

The deferral is also communicated via a phone call to the donor's ODO.

WHEN AN OFFER ACCEPTANCE IS CANCELLED
If the 'Accepted' offer is cancelled by the recipient ODO for medical or logistical reasons, the recipient's ODO must communicate to the donor ODO of the availability of the heart again.

The cancelled acceptance and availability of the organ is all communicated via a phone call to the donor's ODOs..

4.2 Frozen List

As per the Inter-Provincial Sharing: Heart policy CTR10.003, when an offer is **verbally accepted** by the recipient ODO, the Allocation list is considered **'frozen'**.

When an accepted offer is **cancelled** by the recipient ODO, the allocation list is considered **'unfrozen'.**

4.3 Rerun Allocation: When can an Allocation be Rerun

If a new medically urgent recipient gets listed on the National Organ Waitlist before the allocation list is frozen, then the donor ODO must re-run the allocation.

The donor's ODO is notified of a new medically urgent recipient on the National Organ Waitlist via a notification

The recommended best practice would be to 'preview' the allocation list prior to re-running the allocation to review impact to the verbal and CTR offer already made, due to the latest addition of the medically urgent recipient.

5. Recusal Process

The High-Status Heart Allocation Recusal Notification Process is applicable to any potential highly sensitized recipient in the CTR that meets criteria for high-status heart allocation.

An internal process/SOP will need to be developed by individual provinces to gain authorization from their transplant program's designated representative as per their SOP for the recusal form completion.

The recipient ODO will provide the Canadian Blood Services customer support team with the completed 'High-Status Heart Allocation Recusal Notification Form', with the required authorization and details of the recipient for the 'Recusal' process date stamped and signed by the designated representative of the transplant program as per provincial SOPs.

The recusal process form will be available in a PDF format in English and French in the CTR. The recusal will be processed within 1 business day.

The 'Recusal' process will be handled manually by Canadian Blood Services and will ensure that the identified recipient will not be included in the pool of participants for high status heart allocation.

The 'recusal' process can also be reversed to add the identified recused recipient into the pool of participants for high-status heart allocation.

While the recused recipient ID will no longer be displayed on the (matching algorithm result) allocation list, they will remain displayed on the National Organ Waitlist.

This process can only be used for highly sensitized patients. If a physician expresses the need to recuse a medically urgent (status 4) recipient from national sharing, the notes section in the CTR should be used.

Glossary of Terms

DWL - Deceased Waitlist: list of recipients waiting for an organ from a deceased donor.

Designated User - a person given certain access or permissions to execute functions per their assigned role within their institution. For example, a designated user at a Organ Donor Organization could be the donor coordinator running an allocation or a donor coordinator assessing an offer received for a recipient on their list.

Deferral - an offer state that refers to the situation in which a lower ranked medically urgent recipient on the high status heart allocation list is designated to receive an offered heart after discussion amongst physicians of these recipients that have determined the most optimal allocation of the donor organ to fulfill the principles of organ donation and allocation

Recusal - a process that results in a highly sensitized patient being excluded from the Inter Provincial Organ Sharing Process for Heart Allocation upon request by the Transplant Program and/or Physician.

Reinstatement – a process that removes a patient from Recusal