

Notice of Changes to OPTN Data Collection

Update to Refusal Codes

Sponsoring Committee:	Data Advisory
Instrument Affected:	<i>DonorNet® Offer Details</i>
Public Feedback:	March 8-21, 2021
Board Approved:	June 14, 2021
Effective Date:	Pending implementation and notice to OPTN members

Purpose of Data Collection Changes

Primary refusal and secondary refusal reason code updates in DonorNet® offer details will capture actionable data about why an offered organ is refused. By providing more relevant and granular options, the insights gathered will improve upon the current list by reducing the overutilization of the refusal code “donor age or quality” which accounted for 66% of the primary refusal reasons entered between July 2019 and June 2020.¹ Last revised in 2004, the new list of refusal codes has incorporated multiple rounds of feedback received from various stakeholder groups, OPTN committees, and the larger transplant community between 2019-2021.

Proposal History

In June of 2019, the System Performance Committee provided a recommendation to the Board of Directors to update the list of refusal codes.² The updated list of refusal codes was developed by an OPTN Data Advisory Committee sponsored workgroup. The Committee gathered feedback from 11 OPTN committees as well as the larger transplant community through a request for feedback. The feedback received included recommendations for additional refusal codes or language revisions to increase clarity and usability. All feedback was considered and additional codes recommended were added to the list if it improved the list by adding a discrete reason for refusals not already captured. Other suggestions informed changes to the refusal code title, description, or category.

Summary of Changes

The options under the primary refusal and secondary refusal reason code drop downs in the offer details form section of DonorNet® will be updated. The currently implemented refusal codes will be removed and replaced with the list below.

Implementation

Transplant programs and organ procurement organizations will need to be familiar with the updated list of refusal reasons and descriptions when submitting refusal reasons.

¹ Based on OPTN data as of September 18, 2020.

² OPTN, Ad Hoc Systems Performance Committee Report, June 2019, https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf (accessed June 18, 2021).

These updates are not anticipated to affect the operations of histocompatibility laboratories.

The OPTN will be responsible for notifying members of the changes to the refusal codes as well as programming the new refusal codes into DonorNet®. Educational material will be created to assist members with the transition. The OPTN will monitor the use of updated refusal codes post-implementation.

List of Revised Refusal Codes

Refusal Code	Description
Donor and Candidate Matching	
Donor age	Donor age is not clinically suitable for potential recipient
Organ size, specify **	Donor organ expected to be too large or small for potential recipient
Organ Specific Reasons	
Organ preservation: Unacceptable method or findings	Method or findings of organ preservation does not meet acceptable criteria (pump pressures, pumping issue, not pumped, on pump, etc.).
Organ anatomical damage or defect	Surgical damage, non-surgical trauma, diseased organ, organ vasculature, en bloc kidneys or any other anatomical reason
Actual or projected cold ischemic time too long	The actual or projected cold ischemic time is too long for the organ
Warm ischemic time too long	The warm ischemic time is too long for the organ
Biopsy not available	Organ biopsy not performed or results are not available
Organ biopsy results unacceptable	Organ biopsy results do not meet acceptable criteria
Organ specific test results not available, specify **	Organ specific test results not performed or results not available at the time of the organ offer (e.g., HIV NAT testing, cardiac catheter results, etc.). Do not use for unavailable biopsies.
Unacceptable organ specific test results, specify *	Organ specific test results do not meet acceptable criteria (e.g., low PaO2, high creatinine, low ejection fraction, or imaging findings). Do not use for unavailable biopsies.
Candidate Specific Reasons	
Candidate temporarily medically unsuitable	Potential recipient temporarily too sick, medically contraindicated, or not optimized to attempt transplant
Candidate transplanted or pending transplant	Patient transplanted, transplant in progress, or other offer being considered
Candidate's condition improved, transplant not needed	Potential recipient's condition has improved and transplant is currently unnecessary
Candidate requires different laterality	Potential recipient requires organ of a different laterality (e.g., right lung is specified)
Candidate requires multiple organ transplant	Potential recipient requires a multiple organ transplant (e.g., heart offered without kidney)

Refusal Code	Description
Epidemic/Pandemic - Candidate	Transplant hospitals should use this refusal when refusing an organ offer due to a candidate related epidemic/pandemic reason (e.g., COVID-19). This may include reasons such as the candidate has a potential exposure, is symptomatic, is being tested, or has a positive test result. Do not use this code if the candidate is refusing all organ offers at this time due to the pandemic.
Candidate temporarily ineligible due to insurance or financial issue	Potential recipient is temporarily ineligible for transplant due to insurance or financial related reasons
Candidate unavailable	Potential recipient unavailable (e.g., traveling) or could not be contacted
Candidate refused	Potential recipient refused offered organ
Histocompatibility Related Reasons	
No candidate serum for crossmatching	No candidate serum for crossmatching
Donor cells (or specimen) unavailable for crossmatching	No donor cells (or specimen) for crossmatching or no time to complete a crossmatch
Positive physical crossmatch	Physical crossmatch results between donor and potential recipient is positive
Positive virtual crossmatch/unacceptable antigens	Virtual crossmatch results between donor and potential recipient is positive or potential recipient has donor-specific antibodies that are considered contraindications to transplant
Number of HLA mismatches unacceptable	Number of HLA mismatches between donor and potential recipient unacceptable
Disease Transmission Risk	
PHS risk factor or social history	PHS risk factor for donor or other reasons related to social history. (If a candidate refuses the offer for PHS risk criteria, please select "Candidate refused" as the refusal reason for the offer.)
Positive infectious disease screening test: CMV, HBV, HCV, etc.	CMV, HBV, HCV, HIV, HTLV, VDRL, etc. donor testing is positive
Donor infection/positive culture	Donor has an active infection or positive culture results (e.g., meningitis)
Malignancy or suspected malignancy	A malignancy or potential malignancy is suspected with the organ
Epidemic/Pandemic - Donor	Transplant hospitals should use this refusal code when refusing an organ offer due to a donor related epidemic/pandemic reason (e.g., COVID-19). This may include reasons such as donors with high exposure risk, no testing available, positive or indeterminate test results, or if a different specimen type is preferred.
Donor Specific Reasons	
Donor medical history, specify *	Donor medical history is not clinically suitable for potential recipient
Donor instability/high vasopressor usage	Donor has prolonged hemodynamic instability and/or requiring high vasopressor use

Refusal Code	Description
Prolonged downtime/CPR	Donor has experienced prolonged downtime or CPR
DCD donor neurological function/not expected to arrest	DCD donor has high neurological function and is not expected to arrest in time
Graft appearance/quality (VCA ONLY), specify **	Graft is unsuitable due to visible or quality reasons such as incompatible skin tone, tattoos, scars, bruising, ecchymosis, hematoma, or other
Logistics	
Resource time constraint (OPO, TXC, donor hospital, etc.)	Time constraint for transplant imposed by the OPO, TXC, donor hospital, etc.
Recovery team availability	Recovery team or local recovery team is unavailable to perform procedure (heavy workload, etc.)
Transplant team or facility availability	Transplant team is unavailable to perform transplant procedure (heavy workload, etc.)
Transportation availability	Transportation for the transplanted organ cannot be attained
Donor family time constraint	Time constraint imposed by the donor family
Exceeded policy defined response time (OPO ONLY)	Response was not received from center within the time period specified in policy
Other	
Disaster/emergency management consideration	Use only in the event of a natural disaster, regional emergency, etc. that is affecting the operations or recovery of organs.
Other, specify *	Use only if the refusal reason does not fit the above categories. Be sure to write in the other reason, UNOS staff will review the OTHER reason and may recode if necessary.

* When this field is selected as a refusal reason, a text box will appear requiring members to further specify the refusal reason

** When this field is selected as a refusal reason, a text box will appear allowing members an option to further specify the refusal reason

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