

PROPOSAL FOR MONITORING ORGAN DAMAGE THROUGH CUSUM METHODS

Background

In July 2021, the organ damage grading system was updated to a new scale to allow for less subjective recording of organ damage. The grades are listed below along with the definitions collected on the HTA-B form:

- *No Effect/No Damage. Surgical damage was absent or had no clinical effect.*
- *Mild Effect. Damage was present but organ was repaired for transplant.*
- *Moderate Effect. Damage contributed, along with other serious concerns, to the decision not to use the organ.*
- *Severe Effect. Damage was the primary factor in the decision to decline for transplantation. The organ would have been used if no damage was present.*

These definitions were created by a working group reviewing damage and potential performance indicators. By creating more robust definitions, it launched the potential for monitoring organ damage through CUSUM monitoring. The aim of these CUSUMs would be to identify any problems with organ damage early and to minimise graft loss from damage.

Data on new scale so far

Data on all damage recorded for UK deceased donors between 22 July 2021 and 31 October 2021 were extracted on 8 December 2021. The table below shows the highest level of damage recorded by organ group for the donor. Numbers of moderate and severe effect damage incidences for abdominal organs are relatively low with a few instances a month, and for cardiothoracic organs, none have yet been recorded.

Table 1 Highest level of damage recorded on the HTA-B for donors, by organ group, 22 July 2021 – 31 October 2021

Highest damage grade	Abdominal organs	Cardiothoracic organs
No effect/no damage	280 (72%)	75 (90%)
Mild effect	93 (24%)	5 (6%)
Moderate effect	2 (1%)	0
Severe effect	7 (2%)	0
Not performed/not reported	7 (2%)	3 (4%)
Total	389	83

Proposed inclusion/exclusion criteria

The cohort will include all UK deceased donors attended by a NORS team who proceeded to donate at least one organ.

Exclusions:

- Where no organs are retrieved for the purpose of transplantation
- Any organs retrieved solely for research
- Small bowel and associated organ retrieval (colon, abdominal wall, stomach, spleen)
- DCD heart retrieval

Event to be monitored

Where a recipient centre has recorded moderate or severe effect damage on the HTA-B form for any organ this will be counted as an event. Both moderate and severe effect damage result in an organ ultimately not being transplanted because damage contributed to this. This will be on a donor basis by abdominal/cardiothoracic team. The highest damage grade for abdominal organs will be considered for abdominal teams, similar for cardiothoracics. For example, if the liver was retrieved with no effect/no damage, the kidney with mild effect damage and the pancreas with severe effect damage then severe effect damage would be considered against the donor. Due to the low number of events, teams will be monitored against the national rate.

Baseline period

Different baseline periods will be required for abdominal and cardiothoracic teams due to lower rates of graft loss due to damage for cardiothoracic organs. There are two potential options for the baseline period: use historic severe damage data, or using only the new damage scale.

- Under the damage scale previously used, severe damage captured any organ not used due to damage, therefore if an organ not transplanted due to damage is the main event of interest, this may be a feasible comparison. Between 1 April 2016 and 31 March 2021, there were 304 cases where the highest abdominal organ damage was severe, and 10 for cardiothoracics.
- Using exclusively the new damage scale, a baseline period for a minimum of two years for abdominal teams and longer for cardiothoracic teams would need to be observed before CUSUM monitoring can begin.

Chart limits

The increase in damage of interest needs to be decided. This is the point on the CUSUM chart which would trigger a signal to be investigated.

Use of risk adjustment

Due to the low number of expected events, risk adjustment will not be possible.

Proposed monitoring interval

Based on the low event rate expected, CUSUM reports will be produced on either a quarterly or six-monthly basis.

Implementation of reporting

If it is agreed to use historic “severe” damage data for the baseline period, it may be possible to implement CUSUM monitoring for organ damage in Autumn 2022. If it is felt this is not a suitable approach, then it will be several years before CUSUM monitoring can commence as there will need to be enough time of the new damage scale to allow a sufficient baseline period to have occurred.

Review period

Once CUSUM reports have been set up for organ damage as agreed, there will be a review after the first year of reporting to ensure reports are working as expected and if any update is needed to the baseline period.