Policy

Abdominal organ loss due to retrieval surgical damage is monitored by NHSBT using Cumulative Sum control charts. Any signals detected require investigation and response by the retrieval team involved.

Objective

A process for retrieval teams to follow when a Cumulative Sum signal is detected by NHSBT for organ loss due to retrieval surgical damage.

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Changes in this version

New

Roles

- **Statistics and Clinical Research**: Identify CUSUM signal and communicate accordingly with key stakeholders identified.
- **ODT Head of Commissioning**: Act on behalf of NHSBT as commissioners of the National Organ Retrieval Service.
- **OTDT Medical Director**: Responsible for informing the relevant Advisory Group (AG) Chair.
- **OTDT AMD for Retrieval**: Work with the statistical lead to ensure all relevant data is available. Responsibility to lead on clinical communication with centre.
- **Retrieval Unit Clinical Director**: Provide detail around each case identified.
- **National Surgical Lead – Patient Safety**: Involved in technical review of any potential CUSUM signal
- **Head of Service Delivery – ODT Hub**: Involved in technical review of any potential CUSUM signal

Process Description

Executive Summary

The Cumulative Sum (CUSUM) control chart is a statistical technique originally validated in industry to monitor performance in repetitive engineering processes and in particular to detect change. It has been increasingly used in a medical context to monitor surgical outcomes and it is employed by the governance and statistical teams at NHSBT to monitor performance of individual units and can provide an early warning system for adverse changes that may affect patient safety. The purpose of the document is to detail the standard operating procedure when a CUSUM signal is detected by NHSBT (OTDT) and Statistics and Clinical Research in relation to a particular retrieval team. The document will include:

- assigning responsibilities and ownership of the investigative process,
- outlining the procedure of notifying the centre under review
- confirming the details of how a centre is expected to report back and to whom
- the reaction of NHSBT to the response including the consideration of a site visit
- the procedure to be followed if a site visit is undertaken including how the final report is prepared and distributed and any follow-up actions needed.

Introduction

NHSBT monitors organ loss due to retrieval damage. The monitoring is done through centre specific CUSUM analyses. These are undertaken on a quarterly basis. These 'within centre' analyses enable prompt detection of any changes in damage rates, providing external assurance and enabling centres to compare current outcomes with their own past performance to assist in internal auditing.

Damage rates 'across centres' are analysed on a six monthly basis for different organs and donor types, with results presented in bar charts. These enable centre comparisons to be made and present outcomes in an intuitive way, clearly identifying any outliers. These results are presented to the Retrieval Advisory Group.

The continuous monitoring performed combines the use of two types of cumulative sum (CUSUM) chart; the 'Observed – Expected' (O-E) chart and the tabular CUSUM. The O-E chart plots the cumulative difference between the observed and expected organ loss due to damage rates. Expected organ loss due to damage rate has been determined from an unadjusted average organ loss due to damage rate based on retrievals in the baseline period (typically a recent 3 year period). This is using a national rate. The chart is not reset but continues to monitor each successive retrieval in the monitoring period. The tabular CUSUM chart is used to identify when a significant increase in the organ loss due to damage rate has occurred. The tabular CUSUM chart plots the cumulative sum of a statistic that reflects the extent to which the current outcomes are out of line with the baseline value. The larger the value of this statistic the stronger the evidence that there has been a change in the underlying rate.

Triggering a signal

The O-E chart is used for observing centre performance over time. A downward trend indicates a lower than expected rate of organ loss due to damage compared with the baseline period (i.e. improved performance), whereas an upward trend points to an observed organ loss due to damage rate that is higher than expected (i.e. inferior performance). CUSUM charts sequentially monitor retrieval outcomes. Although not risk adjusted, they are designed to 'signal' when the tabular CUSUM crosses a pre-defined threshold known as the chart limit. Threshold levels have been determined from simulations and have been selected to enable the quick detection of a significant change in organ loss due to damage rate whilst minimising the number of false-positive signals.

A 'signal' may be due to:

- An actual deterioration in the centre's performance
- A 'bad run' of adverse events
- A 'by chance' event with no underlying cause (i.e. a false positive result)

It should be emphasised that one signal is not usually a sign that there are systemic problems – and often there are simple explanations.

Response to a signal from NHSBT

All signals arising from the analysis will be dealt with according to following protocol.

When a signal is identified by Statistics and Clinical Research, the Medical Director (MD) for Organ and Tissue Donation and Transplantation (OTDT), the NHSBT Associate Director for Statistics and Clinical Research, Associate Medical Director (OTDT) for Retrieval, and the Head of Commissioning OTDT (NHSBT) will be informed that a potential signal has occurred. This will trigger a technical review of events for verification.

The technical review team will comprise the Lead Statistician for Retrieval, the Medical Director, the AMD (Retrieval), the National Surgical Lead – Patient Safety, and the Head of Service Delivery – ODT Hub.

The MD of OTDT (or nominated patient safety lead) will inform the Retrieval Advisory Group Chair (or nominated deputy if there is an actual or potential conflict of interest), the Head of Commissioning and the NORS centre lead if the signal is confirmed after technical review.

The Lead Statistician (Retrieval) will ensure all relevant data are available leading to the CUSUM signal, working with members of the above group as well as other co-opted senior representatives from the Hub and patient safety as appropriate, so that as much detail as possible can be gathered around those events leading to a signal. This technical review will occur in advance of any further actions, so that only verified events are considered to trigger a signal.

This review process will clarify whether contributing events are indeed true events, or whether they are re-classified and no longer contribute to the CUSUM signal, which may result in the CUSUM no longer reaching the signal threshold.

Once the technical review has concluded, Statistics and Clinical Research will confirm by email that a signal has or has not occurred to the group mentioned above.

Should it transpire that a signal has not occurred, the process will be stood down with the express agreement of the MD. If a signal has occurred, the following process will apply.

The Medical Director will write to the NORS lead and the CD of the centre involved requesting a timely response from them. There will be a mutually agreed timeframe for the response. If a response is not received within this time frame (usually 4-6 weeks), a reminder will be sent and if no response is received, then the issue will be escalated to the MD within the relevant hospital Trust/Board.

The centre response will be reviewed by the MD of OTDT, the AMD (Retrieval), the Lead for Patient Safety, the Head of Commissioning and the Chair of RAG. If, following assessment of the report, the signal appears to represent an inherent variation in practice with no underlying cause for concern, no further investigation will be carried out. The assessment outcome will be documented and the MD of OTDT will be responsible for informing all interested parties as well as reporting to OTDT Clinical Audit, Risk and Effectiveness (OTDT CARE) Group.

Actions after a confirmed signal

- The MD (NHSBT) will be responsible for liaising with the centre retrieval service to ensure that there is an appropriate investigation including a site visit, where indicated, and outline any remedial action to be taken.
- The MD and AMD Retrieval (NHSBT) will lead the investigation and will be supported by HO commissioning, Chair of RAG, Surgical lead for Patient Safety and a lay member, and other NHSBT staff as appropriate.
- The MD (NHSBT) will be responsible for ensuring that all relevant interested parties, including the clinicians in the retrieval centre, the Trust/Board, OTDT Commissioning, the HTA and NHSBT are kept informed as to the running and outcomes of any ongoing investigation including pending or completed site visits
- NHSBT Statistics and Clinical Research Department will work with the MD, AMD Retrieval and HO commissioning to provide any additional data that are required, but the Head of Commissioning may seek additional data from any directorate of NHSBT.

The response from the unit

The NORS lead/CD of the retrieval centre is expected to detail each case which contributed to the signal and how the grafts came to be damaged (“what actually happened and why”). This response is expected to be produced within 4-6 weeks of receipt of the letter. The response should be in writing and should be comprehensive and concise. A minimal data set is required for each case, for example:

- Donor type – DCD/DCD
- Donor Age
- Donor Height, Weight, BMI.
- Operative Retrieval Information as provided in the lead surgeon's report.
- The use of NRP (TANRP)
- Date when lead surgeon was fully registered with NHSBT.

In addition, any "lessons learned" should be included as well as the changes in protocol or remedial actions that needed to be implemented (this will be reported back to the Retrieval Advisory Group).

Response to the unit report

Following a review of the centre report by the MD of OTDT, AMD Retrieval, The Surgical Lead for Patient Safety, the Head of Commissioning and chair of RAG, a written response will be issued to the unit clinical director by the MD. Based on their evaluation a site visit may be initiated if:

- A centre has had multiple or successive 'signals'
- The explanation was deemed unsatisfactory or lacking in clarity
- The signal is thought to be possibly indicative of a systemic problem within the unit/team
- Requested by a unit to do so (Usually when the unit/team need help in resolving internal issues)

Preparation for a site visit

The visit will be arranged at a mutually convenient time between the Head of Commissioning, RAG chair, the MD of OTDT, AMD Retrieval, the CD and NORS lead of the unit.

Prior to the visit the MD in joint partnership with the AMD for retrieval and RAG chair (acting on behalf of NHSBT) will request some or all of the following which will be available for the panel to review:

- An up to date centre-specific report for the panel to review from the lead NHSBT statistician. This may include additional events that have occurred since the signal in the same unit.
- Comparison data for peer centres.
- All relevant unit protocols and process documentation including on call rotas.
- The individual notes which were associated with the 'signals' should be available if required.
- Any other SAE reports (organ loss reported to HTA) should be shared with the panel.

The receiving unit will usually discuss each case in the form of a comprehensive presentation at the start of the visit. The presentations that will be delivered on the day of the visit should be emailed to the panel at least one week prior to the visit for review.

Assembling the review panel

Jointly, the MD, in consultation with the AMD, Head of Commissioning and the RAG chair will convene a review panel. (A review panel chair will be appointed ahead of time and will be responsible for directing communication and compiling an agenda). *It is important that no clinician involved in the review has any links or conflicts with centre under review.*

The visiting panel will usually include:

- MD OTDT
- AMD Retrieval
- A senior member of the commissioning team
- A lay member (usually an AG member)

- The RAG chair or representative. They should have an intimate knowledge of the CUSUM information and has an intimate knowledge of the team.
- Another surgeon of good standing in the retrieval community (*It should not be a clinician with links to the centre under review)*
- A member of the NHSBT support team to record the discussion

Other members may be enlisted depending on the specific details and needs of the visit:

- a. Patient Safety representative
- b. Senior SNOD/RHN

The panel chair will be responsible for ensuring that all panel members are adequately briefed prior to the visit to ensure smooth running of the visit.

What's expected from the retrieval centre –
The visit will take the form of a 'face to face' meeting. The local team should provide an appropriate environment to conduct interviews, ensure audio-visual access facilities are available.
The following core team would be expected to attend the meeting:

- The Clinical Director of the unit
- Senior representation (surgical and perioperative) from the NORS team
- The hospital medical director or representative
- Senior management from both the directorate and the overriding hospital medical team
- Junior team members to present the cases

Conducting the site visit

The review team would expect each of the relevant cases to be presented in turn to the panel as if in an 'MDT' setting, with time for discussion and questions. The chair will direct the questioning and ensure that minutes are kept for the report. The meeting should be conducted in a mutually respectful manner with shared objectives to ascertain exactly what happened and why.

During the review:

- The review panel should meet 1 hour before the meeting to allow the chair to brief members and have at least a 30-minute de-brief at the end of the review.
- All cases must be presented for discussion
- All relevant clinicians and /or ancillary staff involved in the cases should be present to ensure accurate and open and fair discussion
- All issues relating to structure, process and outcome need to be reviewed in an open and transparent way in order to allow the panel to understand the context and help the home team reach solutions.
- The chair will normally need to collate views off site before compiling a report which will be shared with the centre in due course
- The central tenet of the review process is that it is a supportive process and not a destructive one

The Report

As a minimum the final report will include the following:

- Acknowledgment and gratitude to all the attendees
- Identification of all attendees
- A description of the background to the CUSUM signal/s
- A Summary of the cases with identification of any particular issues requiring attention
- Specific recommendations:

a. Describing any process changes that is seen to be appropriate
b. Highlight Clinical practices that all agreed - “could be done differently next time”
c. Help to support the team – especially if structural and staffing changes need to be brought to the attention of the trust management.

The chair will write up the report and then share it with the review team and the MD of OTDT (if not in attendance at the site visit). All members of the review team must carefully proofread the report to ensure accuracy. It will then be shared with the Clinical Director at the unit under review. It is expected that this review will also be shared with senior clinicians and management at the transplant centre. Further distribution remains at the discretion of the unit under review.

It is expected that the report will then be approved by the Unit director for accuracy **but not for content**. Once the report has been approved by the retrieval centre it can be signed off by the MD at OTDT and the relevant commissioners. It will then be issued as a final report.

The Follow-up

There should be an agreement with the commissioners, the MD of OTDT and the Unit Director to have a follow-up report at 6 months to confirm the changes and/or progress made towards the recommendations. Under certain circumstances:

- A return visit may be required
- A regular 3 monthly teleconference with the HO Commissioning, the centre director and the trust management

Occasionally in exceptional situations a more bespoke ongoing review process may be agreed between Commissioning, Providers and NHSBT OTDT. This may be in the form of more intense support and nuanced training initiatives to ensure governance standards are met.

Definitions

- **RAG** – Retrieval Advisory Group
- **CUSUM** – Cumulative Sum
- **MD** – Medical Director
- **AMD** – Associate Medical Director
- **DCD** – Donor following circulatory death
- **DBD** – Donor following Brain Stem Death (confirmed by Neurological Death Testing)
- **NRP** – Normothermic Regional Perfusion
- **TANRP** – Thoraco-Abdominal Normothermic Regional Perfusion
- **NORS** – National Organ Retrieval Service
- **CD** – Clinical Director
- **SAE** – Serious Adverse Event
- **HTA** – Human Tissue Authority
- **SNOD** – Specialist Nurse – Organ Donation
- **RHN** – Regional Head of Nursing
- **MDT** – Multi-disciplinary team
- **OTDT CARE** – Organ and Tissue Donation and Transplantation Clinical Audit, Risk and Effectiveness Group

Related Documents / References

- None

Appendices

- None