SOP5963/4 – Standard Operating Procedure for Transplanting Centre Following a Cumulative Sum (CUSUM) Signal

Objective

A process for transplant centres to follow when a Cumulative SUM Signal is detected by NHSBT.

Changes in this version

Inclusion of information regarding identification of CUSUM and when investigations are required.

Clarification of roles in process.

Roles

- **Statistics and Clinical Research:** Identify CUSUM signal and communicate accordingly with key stakeholders outlined
- **NHS England Nominated Representative (NHSENR):** Will act on behalf of NHS England as well as the Commissioners in the other three devolved nations and all four national Departments of Health and will be responsible for ensuring that all interested parties are kept informed and involved as necessary where relevant
- **OTDT Medical Director:** Responsible for informing the relevant Advisory Group (AG) Chair
- **Advisory Group Chair:** Work with the statistical lead (for the organ involved) to ensure all relevant data is available. Responsibility to lead on clinical communication with transplant centre.
- **Transplant Centre Clinical Director:** Provide detail around each case identified.
- **OTDT AMD for Clinical Governance:** responsible for Clinical Governance at OTDT

Restrictions

- None

Items Required

- None

Instructions

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 transplanting centre. The document will include:

- assigning responsibilities and ownership of the investigative process,
- outlining the procedure of notifying the transplanting centre under review
- confirming the details of how a centre is expected to report back and to whom
- the reaction of NHSE and 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

For both Kidney and Pancreas transplantation NHSBT monitors 30-day patient outcomes while for Heart, Liver and Lung transplantation, 90-day patient outcomes are monitored. Only Kidney and Pancreas graft outcomes are currently monitored. The monitoring is done through centre specific CUSUM analyses. These are undertaken monthly for liver and cardiothoracic transplantation and quarterly for kidney and pancreas transplantation. These 'within centre' analyses enable prompt detection of any changes in mortality or graft failure rates, providing external assurance and enabling centres to compare current outcomes with their own past performance to assist in internal auditing.

Outcomes 'across centres' are analysed on an annual basis and results are presented in funnel plots showing short-term and long-term risk-adjusted patient survival for all organs and centres, and graft outcomes for kidney and pancreas transplants. These enable centre comparisons to be made and present outcomes in an intuitive way, clearly identifying any outliers. These results are published on the OTDT website as part of the organ specific reports.

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 patient mortality. Expected mortality has been determined from an unadjusted average mortality rate based on transplants in the baseline period (typically a recent 3 year period), with more recent transplants given greater weight. For some organs this rate is the national rate, while for others it is a centre-specific rate. The chart is not reset but continues to monitor each successive transplant in the monitoring period. The tabular CUSUM chart is used to identify when a significant increase in mortality 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 mortality compared with the baseline period (i.e. improved performance), whereas an upward trend points to an observed mortality rate that is higher than expected (i.e. inferior performance). CUSUM charts sequentially monitor post-transplant 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 mortality or failure rate whilst minimising the number of false-positive signals.

To detect a true change in performance it is important that the outcomes are risk adjusted which is only possible if all the variables contributing to patient risk have been identified. (Currently only kidney transplant charts are risk adjusted to some extent but are not included in the signal).

A 'signal' may be due to:

- Transplanting patients of higher risk than previously
- 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, including centre-specific signals for heart, lung, and liver, arising from the analysis will be dealt with according to the protocol agreed below by OTDT CARE.

- In the response to a signal being 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, the AMD for Clinical Governance, and NHS England Nominated Representative (NHSENR) will be notified. For renal transplant signals, the centre network lead will also be notified. The NHSENR will act on behalf of NHS England as well as the Commissioners in the other three devolved nations and all four national Departments of Health and will be responsible for ensuring that all these interested parties are kept informed and involved as necessary where relevant.
- The MD of OTDT (or nominated patient safety lead) will inform the relevant Advisory Group (AG) Chair (or nominated deputy if there is an actual or potential conflict of interest)
- The AG Chair will work with the statistical lead (for the organ involved) to ensure all relevant data is available. The AG Chair will write to the Clinical Lead 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 AG Chair (or deputy) together with the MD of OTDT, nominated patient safety lead and the NHSENR. 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. (For signals relating to organ retrieval, the National Retrieval Group will be informed). This will be recorded in the minutes of the OTDT CARE meeting.
- If further investigation (including site visit) is required/requested:
    - The NHSENR and NHSBT through Transplant Oversight Group (TOG) will be responsible for liaising with the appropriate commissioner of the service to ensure that there is an appropriate investigation including a site visit, where indicated, and outline any remedial action to be taken.
    - The NHSENR or appropriate commissioner of that service will lead the investigation. NHSBT will support any such investigation as requested.
    - The governance sub-group of TOG will be responsible for ensuring that all relevant interested parties, including the clinicians in the transplant centre, the Trust/Board, the Commissioners (where relevant), the Departments of Health, Regulators and NHSBT are kept informed as to the running and outcomes of any ongoing investigation including a pending or completed site visits
    - Where specified by the relevant Commissioners, the ‘interested parties’ will include those Commissioners of transplant services for patients who travel to another UK nation for transplant (e.g. North Wales to Liverpool)
    - NHSBT Statistics and Clinical Research Department will work with the NHSENR to provide any additional data that are required, but the NHSENR may seek additional data from any directorate of NHSBT

The response from the unit Clinical Director

The Clinical director of the transplanting centre is expected to detail each case which contributed to the signal, and why the graft/s failed, or patient/s died ("what actually happened and why"). The cases that have contributed to the signal are identified by the Statistics and Clinical Research team and include the relevant failures/deaths since the tabular CUSUM was last at baseline. These are provided to the centre alongside the notification of the signal. 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 in kidney transplantation:

- Donor type – DCD/DBD
- Donor Age
- HLA mismatch (if appropriate)
- Operative Retrieval Information
- Cold ischaemia time – plus explanation of longer than 18h if DBD, 12h if DCD
- The use of NRP, NMP, OCS, EVLP
- Recipient age
- Recipient medical history and co-morbidities in brief including:
    - Cause of end stage organ disease
    - Any relevant pre-transplant events
    - Duration of time on dialysis (Renal)
    - Sensitisation status (CRF) (Renal)
- Operative details including grade of operating surgeon, and whether consultant was present
- Post-operative complications
- Cause of death or graft failure as appropriate
- Immunosuppression
- Complications in follow-up

In addition to describing "what happened and why", it is expected that any MDT decisions are included as well as the result of the local Root Cause Analysis (RCA) or Mortality and Morbidity (M&M) discussions that took place in relation to the graft losses/deaths. 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 relevant advisory group)

Response to the unit report

Following a review of the centre report by the MD of OTDT, the AMD for Clinical Governance, the NHSENR and chair of the relevant AG 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 NHSENR, AG chair, the MD of OTDT, AMD for Clinical Governance and the CD of the transplanting unit.
Prior to the visit the NHSENR in joint partnership with the AG 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 specific organ type for the panel to review from the lead NHSBT statistician. This may include additional deaths or graft losses 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.
- Any relevant patient information leaflets or consent documents
- The individuals case notes which were associated with the 'signals' should be available if required
- All internal serious incident reports 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 NHSENR and the AG chair in consultation with the MD of OTDT 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, usually the OTDT MD) *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:

- A commissioner (NHS England or NHS Scotland, NHS Wales, NHS Northern Ireland)
- A lay member (usually an AG member)
- MD of OTDT
- AMD for Clinical Governance
- The AG chair or representative. They should have an intimate knowledge of the CUSUM information and has an intimate knowledge of the team.
- Another medical professional of good standing in the community (If the AG chair is physician, he/she should be a surgeon to give the surgical perspective both for the recipient surgery and donor perspective and vice versa)
  It should not be a clinician with links to the centre under review
- A member of the NHSBT support team to record the discussion
- Nursing expert
- Other members may be enlisted depending on the specific details and needs of the visit:
  a. Trust Governance representative
  b. H+I expert
- *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 transplanting 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 and provide access to the hospital IT system, to review the electronic patient records if required.

The following core team would be expected to attend the meeting:

- The Clinical Director of the unit
- Senior representation from both the medical and surgical teams
- The hospital medical director or representative

- Senior management from both the directorate and the overriding hospital medical team
- Senior nursing representation
- A senior clinical scientist from the H&I lab if appropriate
- Senior anaesthetic or intensive care clinicians if appropriate
- 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 member of NHSBT support staff is responsible for taking minutes. 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. Confirm the output from local Serious Incident (SI) investigations explaining "how the team changed their practice to stop it happening"
    d. Help to support the team – especially if structural and staffing changes need to be brought to the attention of the trust management.
    e. Highlight and describe any good practice

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.
The NHSENR will ensure that the report is shared with appropriate representatives from the devolved nations where appropriate.

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 transplanting 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 NHSENR, the centre director and the trust management

Occasionally in exceptional situations a more bespoke ongoing review process may be agreed between commissioners, providers and NHSBT OTDT. If problems persist and appropriate changes/actions are not forthcoming NHSENR may request temporary centre closure to ensure patient safety until such time that a solution is found.

End of Procedure

Definitions

- **AG** – Advisory Group
- **CUSUM** – Cumulative SUM
- **NHSENR** - NHS England Nominated Representative
- **MD** – Medical Director
- **H+I** – Histocompatibility and Immunogenetics
- **RCA** – Root Cause Analysis
- **M+M** – Mortality and Morbidity
- **OTDT CARE** – Organ and Tissue Donation and Transplantation Clinical Audit, Risk and Effectiveness Group
- **DCD** – Donor following Circulatory death
- **DBD** – Donor following Brain Stem Death (confirmed by Neurological Death Testing)
- **NRP** – Normothermic Regional Perfusion
- **OCS** – Organ Centre System
- **EVLP** – Ex vivo lung perfusion
- **CRF** – Chronic Renal Failure
- **MDT** – Multi-disciplinary team
- **CD** – Clinical Director
- **AMD** – Associate Medical Director
- **TOG** – Transplant Oversight Group

Related Documents / References

- None

Appendices

- None

Training Plan for Documents:

Document Title	Standard Operating Procedure for Transplanting Centre Following a Cumulative Sum (CUSUM) Signal	
Document Number & Revision Number	SOP5963/4	
Type of Change	Change to Existing Process	
Stakeholders who require training	**Trainee new to the process**	**Trainee trained to the previous revision.**
	OTDT AMD for Clinical Governance	Statistics and Clinical Research OTDT Medical Director
Knowledge required prior to training	None – formalising role in process.	Trained to previous version.
Critical aspects of process	Detailing process to be followed after a CUSUM signal relating to negative transplant outcome has occurred. Details response expected from NHSBT as well as process to be followed by centre against whom the signal has occurred, including reporting guidelines and review panel details.	

Training Plan:

	Trainee new to the process	**Trainee trained to the previous revision.**
Recommended Training Method	Read only	

Read only

Assessment	• FRM511	FRM511
Cascade Plan	Self-directed	Self-directed

Training Score – Training Plan Risk Matrix (Collapsible – Click ▶ icon to open/close)

Use the *Training Plan Risk Matrix* to identify the training method and assessment required.

The *Process Criticality Score* is determined by the potential impact on donor/patient safety and/or product quality using the table below for guidance.

	Impact on Donor, Patient safety or product quality
1. Negligible	A process whose failure, in full or in part, **cannot** impact product quality, patient/donor safety or the ability to supply products/services.

2. Minor	A process whose failure, in full or in part, **may**: (i) impact other processes thereby indirectly impacting product quality, patient/donor safety (e.g. harm only results where multiple failures in multiple processes align) (ii) result in the discard of a small number of replaceable products and/or (iii) result in an inconvenient delay to the supply of products/services (e.g. delay of 1-3hrs of non-urgent product/service).
3. Moderate	A process whose failure, in full or in part, **may**: (i) indirectly impact product quality, patient/donor safety (e.g. harm only results where failures in more than 1 process align) (ii) result in the discard of a medium number of replaceable products and/or (iii) result in a temporary delay to the supply of products/services (e.g. delay of 4-12hours of non-urgent products/services).
4. High	A process whose failure, in full or in part, is **likely** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
5. Very High	A process whose failure, in full or in part, is **certain** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
Process Criticality Score	3

The *Criticality of Change Score* is determined by assessing the nature of change(s) and complexity of the process using the table below for guidance.

	Change to Trainee(s)
1. Negligible	An existing process to which no material changes are made. E.g. format changes, minor clarifications of existing practice, fixing typos.
2. Minor	An existing process to which new information is added but where changes to existing knowledge and practices are minimal. E.g. clarifications that tighten existing practices
3. Moderate	An existing process of low complexity with material changes requiring different people to take action and/or people to change the tasks they perform. E.g. new roles/responsibilities, changes to the order of existing tasks, new tasks
4. High	A new process of moderate complexity, OR An existing process of moderate complexity with material changes requiring different people to take action and/or changes to the way tasks are performed.

	E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
5. Very High	A new process of high complexity, OR An existing process of high complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
Criticality of Change Score	1

Training Plan Risk Matrix:

Process Criticality →

Criticality of Change ↓

	1. Negligible	2. Minor	3. Moderate	4. High	5. Very High
1. Low	1	2	3	4	5
2. Moderately Low	2	4	6	8	10
3. Moderate	3	6	9	12	15
4. High	4	8	12	16	20
5. Very High	5	10	15	20	25

	Trainee new to the process	**Trainee trained to the previous revision.**
Process Criticality Score	3	
Criticality of Change Score	1	1
Training Score	3	3

Recommended Training Method:

Training Score	Level of Risk	Examples of Training Methods	Examples of Assessment
1 - 3	Low	Read only	Record on FRM511 only
4 - 8	Manageable	Email, team brief, word brief	Knowledge/Observation Check & FRM511
9 - 14	Medium/Significant	Formal training package	Knowledge/Observation Check & FRM511 or FRM5076
15 - 25	High	Practical	FRM5076 or equivalent