Contents

Standards covered by this document		
ISO 15189:2012	4.8, 4.9, 4.10, 4.11, 4.12	Resolution of complaints Identification and control of nonconformities Corrective action Preventive action Continual improvement

Related documents

Title	Q-Pulse No.
COSHH Assessments	
Not Applicable	
Risk Assessments	
Not Applicable	
Others	
BS EN ISO 15189:2012 (Medical laboratories — Requirements for quality and competence)	QMS-EXTD-2
Error/Incident Reporting Flowchart	QMS-COM-36
Q-Pulse How to - Raise a CAPA	QMS-INF-34
Blood Sciences Quality and Governance Report	BS-QUAL-COM-7
Cellular Pathology Exception (quality) Reports 2017	CP-QUAL-COM-51
LCL QAG report	QMS-COM-37
AUH Clinical Biochemistry quality control procedure	BS-CAUH-SOP-15
Immunophenotyping Laboratory - Internal Quality Control (IQC)	BS-HODS-SOP-20
Internal Quality Control in Haematology"	BS-QUAL-SOP-6
Non-Cervical Cytology Internal Quality Control Steps	CP-NCER-SOP-21
Autoimmune Internal Quality Control	I&I-CI-AI-SOP-4
Monitoring Internal Quality Control in Clinical Immunology	I&I-CI-QUA-IQC-2
I&I Quality & Governance Reports - 2017	I&I-GEN-COM-8
Medical Microbiology Department Internal Quality Control Procedures	I&I-MM-SOP91
Virology IQC operational policy	I&I-VI-POL-2
Error/Incident Reporting Flowchart (currently in draft in Q-Pulse)	QMS-COM-36
Management Review (previously AMR)	QMS-POL-18
Internal Quality Control in the BMT Laboratory	RBS-BMT-SOP-14
Investigation of Errors Accidents and Adverse Events in the BMT Laboratory	RBS-BMT-SOP-67
Incident Reporting Policy and Procedure	RLBUHT Intranet
Policy for Management of Complaints, Concerns, Comments and Compliments	RLBUHT Intranet
Risk Management Policy	RLBUHT Intranet
Transfusion and BMT Quality Risk Analysis tool for Severity grading of incidents	QMF-INF-35
Recall Procedure	RBS-BMT-SOP-9
Blood Component and Product Recall Transfusion RLUH, BGH and LWH.	BS-TRAN-SOP-53
Blood Component Recalls	BS-TAUH-SOP-23
Incident Improvement Form	QMS-FOR-67
LCL CAPA Completion Flow	QMS-INF-37

Significant changes from previous version:

Read as new

Introduction

Non-conformity is a process or activity which doesn't fulfil its intended purpose. This could be because there has been a failure to follow the procedures outlined in the management system, or because the documented procedures are not fit for purpose. For example, multiple complaints about a particular area may highlight a recurring product or service issue that could point towards a non-conformity – which is why gathering customer feedback and maintaining a documented complaints procedure is invaluable.

On their own, non-conformities can lead to a bad customer experience for an individual, but if left untreated, can also lead to a cascade of bad experiences for multiple customers. This is why it is important to not only identify these areas but address them in good time and adequately.

Non-conformity can also be recorded as an incident which has either been a near miss or caused harm to a patient or to a member of staff.

Purpose and scope

The purpose of this procedure is to ensure there are systems in place to identify nonconformities in any aspect of the quality management system (QMS), including pre-examination, examination or post-examination processes within Liverpool Clinical Laboratories (LCL).
ISO15189:2012 clause 4.8, 4.9, 4.10, 4.11, 4.12 states we must have a procedure for the management of non-conformities and that the necessary corrective and preventative actions have been appropriately implemented and embedded.

Roles and responsibilities

Clinical Directors/Senior Management

Ensure that all employees are aware of their responsibilities and that they are adhering to the reporting procedures. That appropriate investigations were conducted with regards to serious incidents. Have assurance that all appropriate preventative action has been taken in all cases.

Service / Laboratory Managers

Must ensure immediate action was undertaken to prevent a recurrence. Ensure incident report forms are completed within the identified time period.

Must ensure local investigations are carried out to a satisfactory and prompt conclusion, upload findings, action plans and documentation relevant to the investigation on Trust systems and Q pulse. Ensure that the patient, relatives or other persons responsible for the patient, who need to have details of the event, receive timely and adequate explanations from the appropriate member of staff, and that the Duty of Candour Policy has been implemented where appropriate.

Quality manager/Quality Practitioners

Have a duty to oversee all non-conformities and ensure that all aspects of the non-conformity reporting are adhered and that appropriate investigations have occurred. They must ensure that staff have the appropriate training and competency to undertake management of non-conformities. They have a duty to report all non-conformities to the departmental monthly quality and governance report (QAG). Through this reporting mechanism ensure that all non-conformities have been dealt with in the timeframe set.

All staff

All staff must comply with the policy and its reporting procedures. If needed assist with any non-conformity investigation. They must take all reasonable steps to minimise risks.
It is the responsibility of all staff to report incidents when they are observed, and complete any details in 'real time' – capturing any reasons for delay in reporting, where necessary.

Stage Owners:

Are responsible for completing the assigned stage and recording actions on Q-Pulse by set target dates

Confidentiality and Duty of Candour are paramount considerations when dealing with all matters associated with Incident / Complaint management and communications, and efforts should be made at all times by staff to adhere to these expectations in accordance with Terms and Conditions of employment and or relevant training in these aspects (more can be found on this via the Human Resources Department and or relevant Policies and Staff Handbook)

HTA Designated Individual (DI)

All SAE or SAR must be reported to the Human Tissue Authority (HTA) within 24 hours of discovery via the Designated Individual or in their absence a designee. DI must ensure that all BMT staff are aware of their responsibilities and that they are adhering to the reporting procedures.

Terms and definitions

Term	Definition
Remedial Action	Immediate action taken at the time of the non-

	conformity to mitigate it's affect
Corrective Action	Action to eliminate the cause of a detected nonconformity or other undesirable situation.
Preventive Action	Action to eliminate the cause of a potential NC or other undesirable potential situation
Occurrence	An incident or event.
Reoccurrence	A further or repeated occurrence
Non – Conformance	"A non-fulfilment of a need or expectation that is stated, generally implied or obligatory
Incident	an occurrence that has either caused harm or has the potential to cause harm, and or dissatisfaction to customers, patients and or staff
Complaint	Is an expression of discontent or concern associated with any aspect of the service provided and or results delivered
Never Events	Are serious, largely preventable patient safety incidents that should not occur if the available preventive measures have been implemented.
Audit findings	A classification of deficiency or deviation determined by an auditor whilst conducting an audit
Serious Incident (SI)	is defined as an incident which has resulted in one or more of the following; • Unexpected or avoidable death or severe harm of one or more patients, staff or members of the public; • All never events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. The National List of Never Events is produced annually by NPSA. All Never Events are defined as serious incidents, although not all necessarily result in severe harm or death. • Scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;

	• Allegations, or incidents, of physical abuse and sexual assault or abuse; and/or • Loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.
Serious Adverse event (SAE)	Any untoward occurrence that might lead to death or life threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity
HTARI	Human Tissue Authority Reportable Incident
Serious adverse reaction (SAR)	Any unintended response that might lead to death or life threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity
Near miss	Any incident that has / had the potential to cause harm but was prevented (usually in a fortuitous circumstance rather than planned), resulting in no harm
Designated Individual (DI)	Person with the legal duty to ensure that statutory and regulatory requirements are met. They are responsible for supervising licensed activities and ensuring suitable practices are taking place. An establishment licensed under the HT Act or Q&S Regulations must have a DI.

Policy

Identification of non-conformity

Non-conformities are identified through various processes. Such as:

- Auditing
- Failure of systems
- Failure of equipment or reagents
- EQA or IQC failure
- Complaints
- Incidents
- Injury
- Breaches in policy
- Review of processing records

This list is not exhaustive.

Within Q-Pulse there are a number of different wizards available for raising Non conformities according to the source, see table below:

CA/PA Source	CA/PA Numbering	Comments
Nonconformity	NC-xx	Normally this Wizard is referring to Incidents/ Errors and or DATIX raised against the departments.
Internal audit	NC-AUD-xx	NC-AUD are to be raised if the non-conformity has been observed as part of the audit process.
External audit	EA-UKAS-xx EA-MHRA-xx etc.	These wizards are to be used to record NC/findings raised by external organisations.
EQA	EQA-INC-xx	EQA-NC wizard is used to record and manage any EQA out of consensus report and /or receipt of poor performance letter.
IQC	IQC-INC-xx	IQC-INC wizard is used to record and manage any Internal Quality Control failures
Field Safety Notices/Alerts	FSN-xx	FSN wizard is used to record and manage any field safety notices/alerts received
External services and supplies	EXT-ISS-xx	EXT-ISS is used to record any delays/problems relating to suppliers performance
Complaints	COMP-xx	COMP wizard is used to record and manage and formal complaints received
Staff suggestions/quality improvements	QIMP-xx	QIMP wizard is used to record and manage quality improvements and/or staff suggestions.
Compliments	COMPLIMENT-xx	COMPLIMENT wizard is used to record and manage any formal compliments received
Change control	CC- xx	CC wizard is used to record and manage the change control process for the evaluation, approval and implementation of changes within Liverpool Clinical Laboratories (LCL)
Q-Pulse changes	QPul-CC-xx	QPul-CC wizard is used by the quality team only to record and manage changes made to the Q-Pulse system

Non-conformity is addressed the same way regardless of what the non-conformity is.

Q-Pulse incorporates a staged approach to CA/PA management in which nonconformity/compliment/QIMP etc. records are broken down into stages. A stage is defined as a managed group of actions that drive to an overall conclusion. The CA/PA module has been customised to incorporate the following stages for LCL nonconformities:

1. Assess if DATIX/Externally reportable
2. Remedial Action
3. Root Cause Analysis
4. Corrective Action
5. Preventive Action
6. Monitoring
7. Quality Assurance Review

Nonconformities related to audits

NCs can be raised from the audit module. A finding raised from the audit module will appear in both the CA/PA module and in the audit module. In the audit module it will appear in the findings section of the audit. In the CA/PA module it will appear as a normal record but with a hyperlinked Number/Title displayed on the main details of the record. Clicking on the hyperlink will open the audit record. Please refer to QMS-POL-8 Management of Audits Policy for further details.

Incidents

LCL has a duty to report all incidents or errors in the organisation quality management system; Q-Pulse. This system allows for the correct recording and management of the non-conformity. LCL also has a duty to report any incident or error to the Trust DATIX system in accordance to the Trust policy (Incident Reporting Policy and Procedure) and other applicable reporting organisations.

Note that no patient identifiers except sample or hospital number l and/or staff names should be recorded on Q-Pulse.

Complaints

LCL receives complaints from various sources. Majority of complaints are reported through Patient Advisory Liaison Service (PALS), or via the Trust DATIX complaints system. These will be emailed to either the quality team or directorate manager. Once received, they will be reported in Q pulse for full management. LCL will manage PALS or DATIX complaints in accordance to Trust policy (Policy for Management of Complaints, Concerns, Comments and Compliments).

Some complaints will be reported directly to the quality team, customer care team or directorate managers. These will be reported in Q pulse and assigned to the correct manager and managed appropriately via Q pulse. If there has been any noted harm (identified through investigation of the complaint) with direct patients of the Trust then adequate reporting to DATIX should be undertaken. Patients from other Trusts that may have come to harm will be reported on that Trust system.

Note that no patient identifiers except sample or hospital number and/or staff names should be recorded on Q-Pulse.

For telephone or face to face complaints please ensure that you register the complainant details so a response letter can be issued after investigation.

Trust Reporting Systems

The Liverpool University Hospitals Foundation Trust currently operates one DATIX system which is accessible to all staff via the intranet. Access to manage non-conformity in DATIX is given to managers and senior members of staff. They will be given a log in and password and trained by the DATIX team.

Liverpool Women's Hospital (LWH) has a system termed ULYSSES and is only accessible via LWH staff or approved staff from LCL. Any incidents that directly affect LWH will be reported to our risk management team to liaise with LWH risk management team.

Liverpool Heart and Chest Hospital (LHCH) have a similar system to the Royal, however only approved staff can access this. This has been condensed to the quality team and a few operational managers. Any incidents that need to be raised against LHCH are to be communicated to the quality team to transcribe on their system. Incidents are discussed as part of the quarterly quality Service Level Agreement (SLA) meetings.

All incidents that are reported to external systems must also be recorded in Q-Pulse, using the appropriate CA/PA wizard. See "Error/Incident Reporting Flowchart" [QMS-COM-36] for guidance in choosing the correct wizard.

As the CA/PA and DATIX investigations progress the relevant stages should be updated, copying and pasting the text between the two systems.

The external reference number from DATIX must be referenced in the CA/PA keywords and the CA/PA number within the external system record to enable easy identification of the related records.

All incidents involving LCL and its services are discussed at the weekly safety meeting. This meeting is held to inform the medical director/clinical directors of the outcome of investigations, determination of root causes and corrective action taken to stop the error reoccurring. It is also where it is determined whether or not duty of candour applies to each incident. This meeting can also be attended by LCL staff from presenting Root Cause Analysis (RCA) reports or providing assurance on identified trends.

External Reporting Systems

Medicines and Healthcare products Regulatory Agency (MHRA).
An executive agency of the Department of Health and Social Care in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are acceptably safe. These are incidents involving a Medical Device or Medication which gives rise to, or has the potential to produce unexpected or unwanted effects involving the safety of patients, users or other persons. Such incidents will be reported when they did or could have led to:

- Death, life threatening illness or injury
- Deterioration in health
- The necessity for medical or surgical intervention
- Unreliable tests results leading to inappropriate diagnosis or treatment.

Serious Hazards of Transfusion (SHOT) and Serious Adverse Blood Reactions and Events (SABRE). SHOT is the United Kingdom independent, professionally-led haemovigilance scheme. Since 1996 SHOT has been collecting and analysing anonymised information on adverse events and reactions in Blood Transfusion from all healthcare organisations that are involved in the transfusion of blood and blood components in the United Kingdom. Where risks and problems are identified, SHOT produces recommendations to improve patient safety. The MHRA and SHOT collaborated in 2017 to improve haemovigilance reporting and reduce duplication. A new SHOT report, is done via the MHRA Serious Adverse Blood Reactions and Events (SABRE) reporting system.
After reporting via the SABRE reporting system, you will receive a link to the SHOT database (Dendrite) to complete the incident report. Also refer to BS-QUAL-FOR-10, BS-QUAL-SOP-12.

Transfusion Serious adverse events (SAE): MHRA Definition:
Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to death or life threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

Transfusion Serious adverse reactions (SAR): MHRA Definition:
An unintended response in a patient that is associated with the transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating or which results in or prolongs hospitalisation or morbidity
All transfusion transmitted infections (TTI) must be reported to MHRA.

Human Tissue Authority (HTA). The Human Tissue Authority's (HTA) regulatory remit is defined in the Human Tissue Act 2004 (HT Act). The HTA regulates the following activities through licensing:

a) post-mortem examination;
b) anatomical examination;
c) public display of tissue from the deceased; and
d) The removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training.

The HTA also assesses applications for organ, bone marrow and peripheral blood stem cell (PBSC) donations from living people. Also refer to CP-MOR-POL-2, RBS-BMT-SOP-67

Bone marrow transplant Serious Adverse Event (SAE): defined as: "any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of cells intended for human application and which, in relation to a donor or recipient of cells: - (a) might lead to the transmission of a communicable disease, to death or life threatening, disabling or incapacitating conditions, or (b) might result in, or prolong, hospitalization or morbidity". BMT events which are commonly referred to as 'near misses' should be reported as serious adverse events if any of the above criteria are met.

Serious Adverse Reaction (SAR): defined as: an unintended response, including a communicable disease, in a donor of cells intended for human application or a recipient of cells, which may be associated with the procurement or human application of cells that is fatal, life threatening, disabling, incapacitating or which results in, or prolongs hospitalization or morbidity.

Adverse events reportable to the HTA

An adverse event can be detected at any stage from donation to transplantation. A suspected serious adverse event should be reported to the HTA when one or more of the following applies:

- Inappropriate cells have been distributed for clinical use even if not used.
- The event could have implications for other patients or donors because of shared practices, services, supplies or donors.
- The event resulted in loss of any irreplaceable autologous cells or any recipient specific allogeneic cells.

Any serious adverse reaction in a donor which may influence the quality and/or safety of cells should be reported to the HTA.

Any serious adverse reaction in a recipient observed during and/or after clinical application which may be linked to the quality and safety of cells should be reported to the HTA.

Suspected serious transmitted infections (e.g. bacterial, fungal, viral, prion, parasitic) should always be reported to the HTA.

Screening Quality Assurance Services (SQAS). All providers of local NHS screening services in England should apply the 'Managing Safety Incidents in NHS Screening Programmes' policy when a Trust incident is suspected of involving screening patients. These patients may be directly or indirectly by affected by services provided by the Trust. Safety concerns and incidents in screening services need special attention because of the characteristics of screening. Screening is the process of identifying healthy people who may be at increased risk of disease or condition. Local screening services offer information, further tests and treatment. This is to reduce the risks or complications of the disease or condition. Screening is a pathway not a test. Local screening services may span several clinical departments, organisations and geographical boundaries. Screening rarely benefits all sections of the population and needs to be targeted. As some false positives and false negatives are unavoidable there is potential harm for an individual. There is an ethical responsibility to do as little harm as possible.

The Strategic Executive Information System (StEIS). The CCG Commissioners manage StEIS for serious clinical incident reporting. Serious Incidents will be reported to the CCG Commissioners by the Risk Management Department. Investigation Reports will be shared with the CCG Commissioners on completion of the investigation and within their timescales of 60 working days for Serious Incidents and Never Events. Serious incidents Requiring Investigation (SIRIs) in healthcare are rare, but when they do occur, everyone must make sure that there are systematic measures in place to respond to them. These measures must protect patients and ensure that robust investigations are carried out, which result in organisations learning from serious incidents to minimise the risk of the incident happening again. When an incident occurs it must be reported to all relevant bodies. The purpose of the serious incident reporting and learning process is:

- To demonstrate assurance of good governance and safety for the most serious incidents;
- To facilitate the wide sharing of learning arising from serious incidents, locally, regionally, and nationally where appropriate;
- To help prevent reoccurrence where the incident occurred and reduce the chance of a similar incident happening elsewhere;
- To support health service improvement by providing information, guidance and recommendations to support health care managers in directing resources where they are most needed to improve quality and safety.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR). Many incidents will be reportable to the HSE under the RIDDOR, these need to be raised

on Q-Pulse and Datix however reporting of these incidents to HSE is done by the trust H&S team. Further information can be found in the H&S policy

- Incidents which result in an employee or a self-employed person dying, suffering a major injury, or being absent from work or unable to perform their normal duties for more than seven days.
- Incidents which result in any person suffering an injury and being taken to hospital, or if an incident happens at a hospital suffering a major injury.
- An employee or self-employed person suffering one of the specified work related disease

Continual Improvement

Continual improvement reflects an ongoing effort to improve products, services, or processes. It can be incremental improvement over time or breakthrough improvement all at once. For instance, an organisation's delivery processes are constantly monitored and evaluated in light of the fact that they are already considered being effective; improvement may come in the form of making the processes more efficient. Improved efficiency could lead to a decrease in administrative and operations costs, thereby lowering the costs of goods and services and providing an opportunity to lower prices to be more competitive and win more business.

The aim of continual improvement is to increase the probability of enhancing satisfaction; they could include:

- Analysing and evaluating the existing situation to identify areas for improvement by reviewing staff suggestions and quality improvements
- Establishing objectives
- Searching for possible solutions to achieve objectives
- Evaluating these solutions and making a selection
- Implementing the selected solution
- Measuring, verifying, analysing and evaluating the results for the implementation to determine that objectives have been met
- Formalise changes by utilising the change control process detailed in QMS-POL-41

Procedure for recording nonconformities on Q-Pulse

Any member of staff with a Q-Pulse account can record a non-conformity when logged into the system. Staff are directed to raise nonconformity through the Wizard tool, which guides the user through a selection of types of nonconformities:

NC
Audit N/C
EQA/IQC Incident
External Services and Supplies

FSN/Alerts

This tool also requires staff to record the stage of analysis, the exact area where the nonconformity occurred, and an owner, which initially should be the designated person within the department (within the BMT Laboratory this must be the Laboratory Manager or in their absence Deputy). Once raised, the owner will immediately receive an email containing a link to the CAPA on Q-Pulse. Please see QMS-INF-34 Q-Pulse How to - Raise a CAPA for further details of how to raise a CAPA.

Target dates for Non Conformities

Target dates should be achievable and allow for completion of corrective actions, implementations and follow up actions. Once the nonconformity has been raised on Q-Pulse the overall target date is automatically set to 28 days for NC and 90 days for Audit NC. Predefined target dates are also established within Q-Pulse for each stage of non-conformity. These stage target dates must also be amended to reflect the severity of the nonconformity as follows:

Stage	**Number of days after raised date**	
	NC	**Audit NC**
Assessing a nonconformity	1 Day	1 Day
Remedial Action	1 Day	1 Day
Root Cause Analysis	7 Days	7 Day
Corrective Action	28 Days	90 Days
Preventive Action	28 Days	90 Days
Monitoring	28 Days	90 Days
Overall Target Date	28 Days	90 Days

Target Date extensions

All nonconformities should be closed within the timeframes set in Q-Pulse and determined by the Trust (e.g. RCA and SIs). However in some instances, due to multiple factors, it may not be possible to close the CAPA within the set timeframe. In such instances the owner of the CAPA can request an extension to a reasonable timeframe, note that the overall target date and any outstanding stage target dates must be updated in accordance. At these instances the reasons for the extension must be documented on Q-Pulse, in the Properties section (bottom stage). Please see below examples of possible comments:

“CAPA Target date extended from 1/1/19 to 1/2/19 due to member of staff involved being off sick.”
“CAPA Target date extended from 1/6/19 to 1/8/19 due to work required to perform re verification of analyser”

"CAPA Target date extended from 1/8/19 to 17/8/19 as staff needs to be trained against the new procedure".
"CAPA Target date extended from 1/8/19 to 17/10/19 to monitor next EQA returns, due in October 2019"

An email should be sent to the quality team so the team can update the target dates on Q-Pulse accordingly.
The maximum period of extension is 3 months for low risk incidents, 2 months for medium risk incidents and 1 month for high risk incidents.
Please note that only one extension should be submitted per incident. If a particular incident requires a further extension to the target date this should be discussed and approved at the departmental QAG. At these instances a note must be made on Q Pulse, in the Properties section, stating the date of the meeting to ensure traceability.

It is the record owner's responsibility to ensure the nonconformity is reviewed when first reported to determine the severity.

For Blood Transfusion related incidents severity will be discussed and agreed, upon review with the quality practitioner. Blood Transfusion laboratory managers and the quality practitioner meet fortnightly to discuss incidents.

Risks identified through nonconformity reporting must reflect the urgency and degree of action required to eliminate or reduce the risk and further occurrences of errors and incidents.

Stages in Q Pulse for Non Conformities, Complaints, IQC and EQA failures

Assess if DATIX/ externally reportable

The nonconformity must be reviewed within 24 hours, in order to assess if it is DATIX or externally reportable.
It is important to determine the level of harm and/or severity of the incident (i.e. high, medium or low), and how this level of harm was determined e.g. may require named clinician to confirm. This information must be recorded in this stage.

Non-conformity is deemed DATIX reportable in the following circumstances:

- Serious Incident
- Accident – possible injury
- Internal errors detected POST authorization e.g. amended reports
- Impact on patient care / treatment
- May put the trust in an adverse legal / media interest position
- Reported to external body

To support staff when raising a Non – Conformity guidance is available within the each stage of the non-conformity. For this stage the following guidance is available:

- Was this a near miss which could have potentially caused harm, or was harm to a patient, visitor or staff member caused by this incident? *If your answer is yes, it is* DATIX reportable.
    - Examples of patient harm/near miss incidents:
      ~ If results have been reported, even if they have not been viewed this requires a DATIX (potential harm)
      ~ If a patient needs to be re-bled this is harm
- Ensure the prompt creation of a DATIX (same day) if indicated.
- Ensure you Record the DATIX number in the keywords above and record this CA/PA number in the DATIX. If a DATIX is not required please state this clearly and explain your reasoning. Unless otherwise stated, the owner of this stage will be presumed to be the person responsible for having made this decision.
- Clinical advice may be required to determine the severity of the harm in incidents affecting patients. The explanation of how the level of harm decision was made should be included in this box.

Please note the nonconformity may also be reportable to another external body e.g. MHRA/ SHOT/ SABRE/ HTA as detailed previously. This external body reference number should also be recorded in Keywords and Details section.

Please note additional information may emerge during the non-conformity investigation; this may result in a change in harm level, which will change the DATIX.

It is necessary to grade all BMT and Blood Transfusion non-conformities using QMS-INF-35 Transfusion and BMT Quality Risk Analysis Tool for Severity Grading of Incidents.
Record the Likelihood/Impact and final Risk Classification as a note in the Properties section of the CAPA.

Remedial Action

It is the responsibility of the person raising the CAPA on Q Pulse to document which remedial actions were taken.
Immediate actions are those taken at the time of the nonconformity to mitigate its effect. This is often referred to as remedial action. The guidance available for staff on this stage is the following:
Remedial action = First action taken to rectify the error e.g. label equipment as out of use, update database etc.

The guidance information below can be used to record details of remedial actions taken and any supporting information can be attached in the properties section.

1. Has the work been halted? (Y/N, N/A, comment):
2. Has repeat testing been carried out? (Y/N, N/A, comment):
3. Have tests results been withheld? (Y/N, N/A, comment):
4. Have test results 'already released' been recalled? (Y/N, N/A, comment):
5. Has an amended report been issued? (Y/N, N/A, comment):
6. Have users been informed? (Y/N, N/A, comment):
7. Has the requesting clinician/ward been informed? (Y/N, N/A, comment):
8. Repeat sample requested? (Y/N, N/A, comment):
9. Other Blood Components affected (not listed):
10. Is there a critical risk to the patient? (Y/N, N/A, comment):
11. Does this incident have the potential to cause high, medium or low harm? (Please specify which in your answer)

Details of any remedial action may be copied and pasted from the details section completed by the reporter at the time of raising the nonconformity. Any supporting information should be attached in the properties section.

Remedial action must be implemented ASAP, and not greater than 24 hours to prevent further risk. The member of staff that has identified the non-conformity should either implement the remedial action, if within their knowledge and expertise and/or escalate the non-conformity to a senior member of staff. All actions (action to remove Non-conformity and escalation process) must be recorded on the remedial action stage on Q-Pulse.

Halting examinations and withholding reports

Where the incident is related to laboratory testing, the process must be halted and no further results issued whilst the reason for the nonconformity is investigated. Samples must be retained and stored appropriately in case repeat testing is required. Specimen numbers must be included in the Details box of the nonconformity record. The decision to suspend testing will be made by the most senior member of staff available. Once it has been established that it is safe to do so it is the responsibility of the manager/senior staff available within the department to authorise when examination can be resumed. An assessment should be made of the risk and impact on patient care. Where such an impact is identified then the Clinical Lead must also be informed as they will have overall responsibility for assessing clinical impact.

Identification/recall of results affected by nonconformity

If results of a nonconforming examination have been released then it must be determined whether these results need to be recalled or appropriately identified. If it is determined

that the results need to be recalled then all the affected reports must be identified and either amended reports issued, or users contacted to be informed to identify the reports from nonconforming examinations.

Consideration of blood and blood product recall

Any errors or incidents involving blood or blood products must always consider whether or not it is appropriate to recall these products. Refer to relevant Transfusion and BMT documentation for details: RBS-BMT-SOP-9 Recall Procedure, BS-TRAN-SOP-53 Blood Component and Product Recall Transfusion RLUH, BGH and LWH BS-TAUH-SOP-23 Blood Component Recalls.

Notifying DI in BMT and Mortuary

The DI must be notified immediately of any SAE or SAR. Under HTA Directions 003/2010 it is the responsibility of the DI to ensure that the HTA is notified of any SAE or SAR via the HTA's online submission system within 24 hours of discovery. This responsibility is delegated in circumstances where the DI is unavailable to the BMT Consultant or BMT Laboratory Manager.

Root Cause

It is the responsibility of the Owner of the CAPA to either conduct the investigation of the root cause or assign this stage to the relevant member of staff.
Root Cause Analysis (RCA) is a popular and often-used technique that helps people answer the question of why the problem occurred in the first place. It seeks to identify the origin of a problem using a specific set of steps, with associated tools, to find the primary cause of the problem, so that you can:

- Determine what happened.
- Determine why it happened.
- Figure out what to do to reduce the likelihood that it will happen again.

It is important to establish causes of the nonconformity based on objective evidence and identifying any contributing factors. All findings from the root cause analysis shall be recorded in Q-Pulse along with the information gathered. Attach any supporting information in the properties section.

You'll usually find three basic types of factors:

- Physical causes – Tangible, material items failed in some way (for example, a car's brakes stopped working).
- Human causes – Failure to follow documented procedure, deviation from documented procures due to external reasons. Human causes typically lead to

physical errors (for example, no one filled the brake fluid, which led to the brakes failing).

- Organisational causes – A system, process, or policy that people use to make decisions or do their work is faulty (for example, no one person was responsible for vehicle maintenance, and everyone assumed someone else had filled the brake fluid).

RCA looks at all three types of causes. It involves investigating the patterns of negative effects, finding hidden flaws in the system, and discovering specific actions that contributed to the problem. Within the Root Cause Analysis stage on Q-pulse there are 2 actions that require completion:

1. Record of the investigation and root cause analyses, summarised guidance is included to ensure we are looking into all the areas that may be the root cause of the NC. Staff must record which documents/evidence they have reviewed as part of their investigation (Rotas, Batch records, equipment records, etc.) including evidence of good practice.
2. Record of any contributory factor, i.e. anything that was not identified as the root cause of the NC however did contribute to the outcome,
3. As part of incident investigations, it may be necessary to have discussion with staff in order to establish root cause/contributory factors of the incident. It
4. It is particularly important that discussions with staff during investigation of non-conformities are documented using QMS-FOR-67. Staff should be given the opportunity to reflect on the incident for their continued professional development and to identify new ways to improve processes ways that limit opportunities for errors. The completed forms must be anonymised before uploading on qpulse (attached to the NC) and the paper copy kept by the Manager and the member of staff.

In the first action of the Root Cause analysis stage we ask staff to summarise their investigation findings and rationale for the root cause analysis.

Examples of guidance given to staff when investigating a non-conformance, (note this list is not exhaustive):

SOP

- Is the SOP up to date?
- Does the SOP lack detail or clarity?
- Is the SOP too complicated? Could flow charts be used?

Training

- Was the member of staff properly trained? Check training and competency records.
- Was the member of staff inexperienced?
- Was the member of staff performing an unfamiliar task?

Personal

- Did stress, distraction, pre-occupation play a part?
- Did domestic/ lifestyle/ health problems play a part?
- Work environment
- Was there an inappropriate staff mix e.g. lack of senior staff, trained staff, and use of locums?
- Is there poor or inappropriate area design e.g. provision of space?
- Were noise levels too high?
- Were there distractions e.g. manning phones or intercom, receiving visitors?

Equipment

- Was the equipment unreliable?
- Was maintenance programme adhered to?
- Was there insufficient equipment/ emergency backup?
- Is the equipment designed to make detection of problems obvious?
- Were there calibration problems?

Reagent/Kit/Assay

- Was the reagent / kit / assay in date?
- Was the reagent / kit / assay correctly stored?
- Was reagent reconstituted correctly?

Communication

- Was there lack of effective communication towards/clinics/GPs?
- Was there lack of effective communication between lab staff?

For Serious Incidents (SI) LCL follows Trust policy, where a Root Cause Analysis Investigation Report must be issued, investigation must be undertaken and completed within 60 working days and submitted to the Trust Risk Team. All corrective actions raised as part of a SI must be raised on DATIX and progress will be monitored locally at the QAG meetings and at the Trust Patient Sub Committee.

In BMT and Mortuary a follow-up report must be provided to the HTA within 90 days, which outlines the root cause analysis and the corrective and preventative actions indicated to prevent recurrence. Following notification of any SAE or SAR, the HTA may organize an inspection of the licensed establishment and can require the establishment to carry out such control measures as deemed appropriate.

Corrective Action

It is the responsibility of the owner of the CAPA to either record the corrective actions or assign the stage to the relevant member of staff.
Corrective action is the actions put in place to remove the root cause and prevent this type of error occurring again. Note that is most cases corrective actions are different from the

remedial actions. Corrective actions should address the root cause identified in the stage above.
The corrective action should be implemented and recorded in a timely manner. Any evidence available relating to the corrective actions taken should be attached to the Q-Pulse record to ensure compliance. If action has been considered however is not deemed possible/appropriate, please document this in the corrective action e.g. change to LIMS considered to exclude human error however present LIMS cannot be altered to support this.

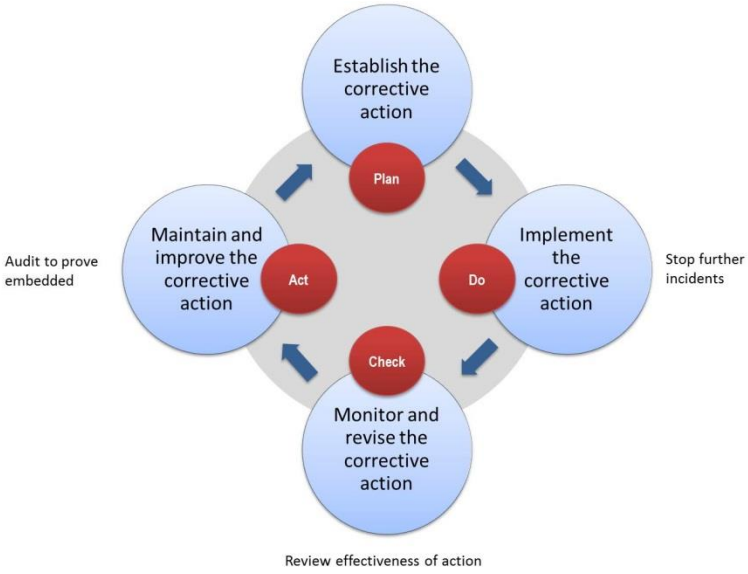

Figure 1 Closed loop process of corrective action

Preventive Action

It is the responsibility of the owner of the CAPA to either record the preventive actions or assign the stage to the relevant member of staff.
Preventive action is a change implemented to address a weakness in a management system that is not yet responsible for causing nonconforming product or service. Have any lessons learned from this incident/error resulted in actions (not the corrective actions described above) being taken to prevent the same incident in another section/department etc.? An important preventive action is to share with staff and/or other departments the investigation, root cause, contributory factors and corrective actions

When nonconformity has been detected the need and extent of corrective action should be determined to avoid recurrence of the problem.

Preventive action is a proactive process in which you identify opportunities for improvement rather than reaction to the problem or complaint. In addition to review of the operational procedures, preventative action might involve analysis of data, including trend and risk analysis.

Monitoring/Effectiveness

It is the responsibility of the owner of the CAPA to either record the actions or assign the stage to the relevant member of staff.
Monitoring is within the stages to review the effectiveness of both the corrective action and the preventive actions. This can be via auditing of the actions put into place, adding to the risk register with mitigating actions or it could be just a simple review through quality and governance meetings and reports.

Activities may be performed to verify that actions have been implemented satisfactorily, these could include running quality control material, performing a follow up audit, reassessing competency, examining training records, checking documentation, reviewing data, performing quality assurance etc. Record details of any monitoring undertaken to review the effectiveness of the action taken. In addition to this if no monitoring is required enter N/A.

Quality Assurance Review

This stage is to provide assurance that NC are being reviewed and addressed appropriately. When all the previous stages (1-6) are completed, including all the mandatory fields, staff should make the appropriate Quality Practitioner (QP) owner of this stage. The QP will get a notification to complete their stage which will include a review of the investigation, root cause and corrective actions, checking for compliance and if evidence is attached as required. If at this stage the NC is deemed to be compliant with appropriate investigation and corrective actions and completion of all mandatory fields, the QP will close the Quality Assurance Review stage and the NC. If the NC is deemed to be not compliant and more consideration or evidence is required, this will be documented in the details box. The QP will close the Quality Assurance Review stage, and send the owner an email detailing observations/comments for consideration. The NC Owner is required to review these observations/comments and must either accept and implement or reject and document the rationale by adding a note (Under Properties). The NC Owner will then close the NC.

Closing Nonconformity

To close a CA/PA record all mandatory fields in the initial details marked with a red star must be completed.

Check if the initial fields, completed by the person reporting the Non-Conformity, are correct and appropriate:

- Fault Category
- Externally/DATIX Reportable
- Root Cause - By reviewing the information in the root cause analysis section please select the appropriate option within the drop down menu.

Ensure the following fields are completed:

- Detection of incident (at what stage of the process was the incident detected)
- Standard
- Harm (ensure this matches any External reporting systems e.g. DATIX if not reportable to External reporting systems please align the level of harm with the severity).
- Severity

Ensure the key words section include the DATIX/SHOT/HTARI number if applicable. Ensure all actions and/or stages have been closed. Nonconformities must never be closed where actions are outstanding.

For complaints please ensure the response letter is attached under the properties section. Additionally please ensure that any evidence (training records, Incident Improvement Form, equipment logs, etc.) is attached and any personal details are removed.
When non-conformances affecting examination procedures are resolved it is the responsibility of the manager/senior staff within the department to authorise when examination can be resumed. In some departments this step could be applied at the remedial action stage.

BMT CAPA

On completion of the CA/PA a copy of the report must be sent for review by the appropriate BMT Transplant Consultant. The form must be signed and dated as evidence of review and scanned and attached into the properties section of the CA/PA module.
The BMT Laboratory Manager will forward a copy of the report of any SAE or SAR to the Designated Individual.
If the non-conformity relates to the collection facility, a copy of the report must be sent to them.
A copy of the non-conformity must be kept with the patients processing records and alphabetically in the errors, accidents and adverse events file. A list of contents is recorded on RBS-BMT-FOR-21 Error, Accidents and Adverse Events Content Form.
The appropriate BMT Transplant Consultant must decide the fate of any cells affected by an adverse event or reaction or any deviation from the required quality and safety standards. This must be discussed at the BMT Quality meeting. All decisions must be documented in the appropriate non-conformity record.

Monitoring and review

Nonconformities from all sources, including equipment, downtime, EQA, IQC etc. must all be analysed regularly to looks for trends to identify preventive action. This analysis must be included in monthly departmental QAG reports and at management review (monthly, six monthly and/or annually. Identifying preventive action provides an opportunity for implementing quality improvements and contributes to continuous improvement.

Nonconformities that pose a risk to either the staff or the service provided by LCL are recorded on the Trust risk register. This is regularly reviewed and discussed at the monthly directorate and LCL QAG meetings, BMT Quality meeting and at other appropriate management meetings. Staff within LCL are informed of nonconformities via the lab meetings and feedback from departmental QAG meetings. The QAG reports are also available to all staff in Q-Pulse.

Monthly review of the nonconformities is undertaken to ensure appropriateness of the nonconformities being reported, this review is to assess demonstration of the effectiveness of the QMS.

Note that patient identifiers (except sample or hospital number) and/or staff names should NOT be recorded on Q-Pulse. However it is recommend that Service and/or Laboratory Managers maintain a log of the members of staff involved in each incident and/or complaint. The objective of maintaining a log is to be able to identify training needs, support, capability issues and/or health & safety risk. Nevertheless due to confidentiality this log should be saved in a secure, password protected location.

References

Title	Q-Pulse No.
Incident Reporting Policy and Procedure 2018	EQMS 3188
Policy for Management of Complaints, Concerns, Comments and Compliments 2018	EQMS 751
BS EN ISO 15189:2012 (Medical laboratories — Requirements for quality and competence)	QMS-EXTD-2
BS EN ISO 9000:2005 Quality management systems – fundamentals and vocabulary	QMS-EXTD-7
National Patient Safety Agency, National reporting and Learning Service: Root Cause Analysis Investigation Tools 2008	Online
National Patient Safety Agency, National reporting and Learning Service: Contributory Factors Classification Framework. 2009	Online
Blood Safety and Quality Regulations 2005	Online

HTA Codes of Practice and Standards	Online
FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration	QMS-EXTD-171