Incident Management Guidance for Hospital Transfusion Teams

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Section 1 - Background and Introduction

Haemoviliglance in the UK is underpinned by the Serious Hazards of Transfusion (SHOT) reporting scheme and the UK Blood Safety and Quality Regulations (Statutory Instrument 50, 2005).

Improving patient safety is an increasingly important aspect of the statutory requirements and clinical governance, with incident management as an integral part of the process.

The role of the Hospital Transfusion Team (HTT) is an important one, ensuring that incidents are managed appropriately, utilising a timely and effective approach. The aim is to reduce risk whilst improving patient safety. Approaching the management of incidents consistently and learning lessons when things do go wrong, in an environment that promotes incident reporting, will avoid repetition of incidents.

Hospital Transfusion Laboratory (HTL) staff and Transfusion Practitioners (TPs) are actively involved with incident management as part of the wider HTT. The purpose of this guidance document is to improve patient safety by providing tools and practical advice for the hospital transfusion team when managing adverse events and incidents.

The aim of this document is to assist the HTT to understand:

- What should be reported
- Learn from adverse events and incidents
- Prevent incidents from occurring and therefore minimise the risks associated with transfusion

Reason (2000) advocates that we can reduce incidents by targeting contributing system failures; identifying these failures will allow redesign of systems which can prevent the incident from happening again.

This can best be achieved if there is a culture of openness, adopting a non confrontational approach to incident reporting. The focus of any incident should be on learning and improvement to ensure that the risk of recurrence is kept to a minimum and that lessons learned will be shared locally and nationally in the interests of improving patient safety (NNS HIS 2012).

The Apologies (Scotland) Act 2016 (**The Apologies Act**) came into force on 24 February 2016. This new piece of legislation makes it possible to apologise without fear of prejudicing the person making the apology or the apology being used to attribute blame in litigation. (Legislation.gov.uk,2008).

Duty of Candor The new organisational Duty of Candour on health, care and social work services came into effect on 1 April 2018. The overall purpose of the new duty is to ensure that organisations are open, honest and supportive when there is an unexpected or unintended incident resulting in death or harm.

This duty requires organisations to follow a Duty of Candour procedure which includes:

- notifying the person affected
- apologising and offering a meeting to give an account of what happened
- reviewing the incident and
- offering support to those affected.

The Adverse Events Programme Board supports integrating the statutory duty of candour requirements with existing arrangements for adverse events management.

The resources available on this community of practice for implementing and improving the management of adverse events will support organisations in carrying out the statutory duty of candour. (Knowledge.scot.nhs.uk,2018).

Section 2 - What is an Incident?

A significant (serious) adverse event can be described as an unexpected or avoidable event or deviation from approved procedure or practice that could have resulted, or did result in, unnecessary serious harm or death of a patient, staff, visitor or member of the public. (Adapted NHS HIS 2012).

To report incidents in the appropriate manner within your NHS Board it is essential that all reporters are familiar with local policies and can refer to these, for example:

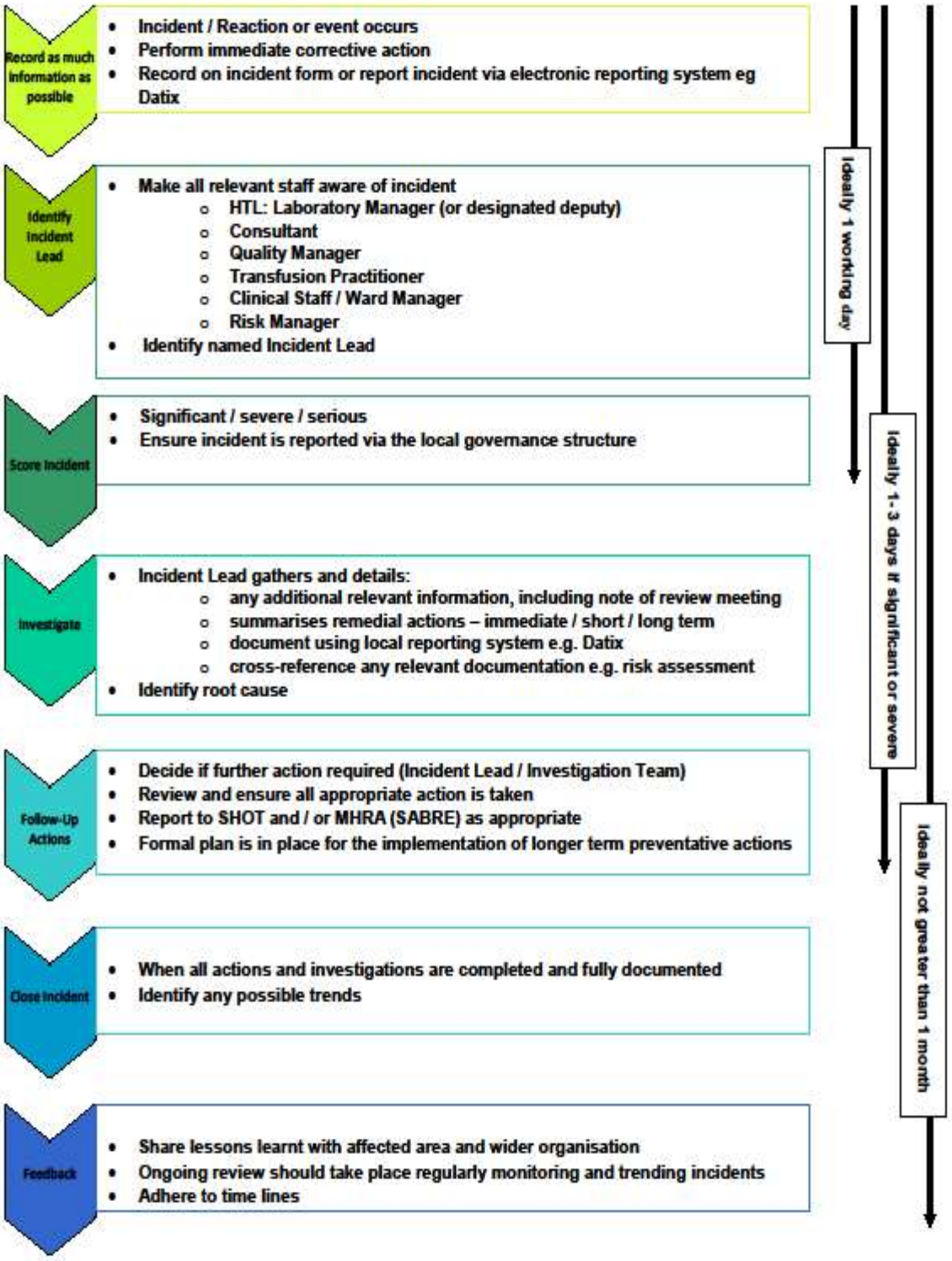
- NHS Boards Incident Management Policy
- Hospital Transfusion Laboratory Standard Operating Procedure for Incident Management
- Clinical Governance Policy

Incidents fall into one of three main categories:

1. Near miss
2. Clinical or Transfusion Laboratory incident
3. Serious or Significant clinical / laboratory incident

The checklist (Table 1, page 7) below has been developed to raise awareness of the types of incidents which should be reported and investigated as part of your local incident management procedures. Please note this is not an exhaustive list, but it does include the majority of incidents that may happen in both clinical and transfusion laboratory areas and blood establishments. The Transfusion Related Incident Reporting Pathway (Figure 1, page 5) follows the process of investigation, reporting and time scales in which this should be adhered to.

Transfusion Related Incident Reporting Pathway



Transfusion Related Incident Reporting Pathway – 7 Steps

Before any of the steps are undertaken the initial action is to ensure the safety and well being of the patient and any others involved.

Step 1 – Record as much information as possible

- Perform immediate corrective action – remembering Duty of Candor (2018)
- Confirm that investigation into the incident has been instigated and a report has been initiated
- Any member of staff can report incidents from the clinical or transfusion laboratory area
- Collect information relating to the incident from relevant documentation, staff, any interventions undertaken and where and when the incident took place
- The level of investigation will depend on the severity of the incident. Some incidents will require an in depth investigation using Root Cause Analysis (RCA) tool

Step 2 - Identify Incident Lead

- The person reporting the incident should ensure that information has been communicated to all appropriate staff for example HTC, HTT, HTL and or TP. This may vary depending on the nature of the incident and the area that the incident occurred
- Although there is likely to be more than one member of staff involved in the investigation it is important that there is a designated lead person, for example;
  - Clinical incident – TP could lead
  - Transfusion Laboratory incident - Lab Manager /BMS or Compliance Officer could lead
- Appropriate staff should be involved, this could include clinical ward staff and the patient depending on the circumstances

Step 3 – Score Incident

- Score severity of the incident, ensuring all high risk incidents are notified using local governance structure. For example many NHS Boards have Red / Orange / Amber / Green scoring matrix, to identify high risk or Significant / Severe / Serious incidents

Step 4 – Investigate

- Investigator needs to identify if full RCA required, depending on the severity or significance of the incident
- If required there are numerous tools that can be used to assist, examples can be found at **https://www.transfusionguidelines.org/document-library/documents/root-cause-analysis**
- A near miss for example may not require a full RCA investigation to be performed as the root cause may be easily identifiable
- Record on local incident reporting system, for example Datix or non conformance log

Step 5 – Follow – Up Actions

- Is there further actions or follow up required, develop an action plan, ensure that actions are performed and completed
- Report to – All incidents should be recorded on the appropriate reporting system
  - Serious Hazards of Transfusion (SHOT)
  - Medicines and Healthcare products Regulatory Agency (MHRA)

Step 6 – Close Incident

- Continuous review of actions and timescales during the investigation, until the incident is agreed
- Close by a local incident team, once actions are completed

Step 7 – Feedback

- On lessons learned, best practice, common themes / areas of concern
- Formal plans in place if necessary for implementation of preventative actions and recommendations
- Monitoring and trending and review of all incidents should be ongoing
- Adhere to time lines

Table 1- Incident Checklist

NB: Sample errors rejected before testing are not classed as near miss errors and are not required to be reported to SABRE and SHOT. However they should be recorded for monitoring trends.

Sampling/requesting errors
Wrong blood in tube
Incorrectly or unlabelled sample/form
Mix up of maternal and cord bloods
Failure to request (eg no pre op sample)
Special Requirements not Met (SRNM)
Blood collection
Wrong blood removed from fridge (error detected before administration)
Blood not signed out/register incomplete
Wrong patient details on collection slip
Electronic release mechanism – failure to follow protocol
Failure to notify Hospital Transfusion Laboratory when emergency blood used
Administration errors
IBCT (eg right blood to wrong patient, wrong blood to right patient)
Special requirements not met (eg CMV, irradiated, blood warmer or antibodies). Can also be lab error
Right Blood right Patient
Transfusion of expired unit
Excessive time to transfuse
Absence/incomplete prescription/authorisation or patient observations
Administration through incorrect giving set
Wrong component administered (e.g. platelets instead of FFP)
Adverse reactions
All transfusion reactions
Failure to notify labs of transfusion reaction
Inappropriate/unnecessary transfusion
Transfusion in response to wrong/ inaccurate FBC/coagulation results
Over/under transfusion
Cold Chain/transport/storage errors
Incorrect storage at ward or lab level
Avoidable clinical wastage
Inappropriate transfer of components (clinical areas and hospitals)
Alarm failure or alarm not responded to appropriately
Lab errors
Sample selection error
Failure to check historical records
Processing/testing/transcription error
Component/product selection error
Labelling error
Stock inventory/reconciliation error
Documentation missing/incomplete
Quality control/assurance error
Analyser/equipment/IT system error
Premises/equipment not properly validated/serviced/cleaned
Component defect/recall
Anti D errors (including RAADP)
Omission/late administration
Incorrect dose/wrong patient etc
Other
Poor management of major haemorrhage
No evidence of final fate traceability
Inadequate training/competency of any staff involved in transfusion process
Customer complaint
Cell salvage related error

Section 3 - Management

Why should I report an incident?

It is important that incidents are recorded for a number of reasons:
- The risk introduced by the incident is communicated and managed
- To allow appropriate and effective remedial action to be taken, remove the hazard and subsequently to prevent a recurrence
- It allows for trending of incidents, looking for increased or decreased numbers in specific types of incident

What level of investigation is required into each incident?

Each incident should be analysed for root cause. The level of the RCA should be commensurate with the level of risk. For a minor isolated incident an informal assessment of the cause(s) of the incident will normally be sufficient. For more serious or persistent incidents a full RCA is recommend.

Who should be involved in the incident investigation and reviewing?

When investigating incidents it is important to include all relevant staff. This may include NHS Clinical staff, Laboratory staff, Transfusion Practitioner, Risk Management, and Quality Manager. Health Improvement Scotland (2012) recommend that investigators should consider involving the patient and their family as this can give another perspective of what went wrong in the incident.

Some NHS Boards have a dedicated incident management meeting led by the HTT to review all transfusion related incidents. This type of meeting allows the HTT to confirm that the remedial actions are appropriate and that there is no increase in specific trends.

Reviewing, monitoring and trending of incidents will:
- Identify significant trends
- How actions and learning outcomes are achieved
- How lessons learned are communicated to the clinical area involved, the NHS Board and NHS Scotland

How can we learn from incidents?

Learning from incidents involves following governance reporting structures in your NHS Board and crucially feedback to the relevant staff groups involved.

Each Hospital Transfusion Committee should provide regular updates to the NHS Board as part of the Clinical Governance and Risk Management agenda.

On occasions it will be appropriate to consider escalation of an incident or outcome of an incident to the departmental or NHS Board risk register via the Clinical Governance Department. This allows the details of the incident, its cause and any potential risks to be reviewed; assessed and his enables the department or NHS Board to action plan accordingly.

What should I include in an incident report?

As an example the following information could be included:
- Introduction and background information
- Details of investigation procedure
- Members of investigation team and identified lead team
- Context of incident
- Time line of events
- Findings including root cause
- Conclusions
- Recommendations

What should I include in an action plan?

As an example the following information could be included:
- Clearly set out recommendations
- What needs to happen to achieve the recommendations
- Identified person(s) who are responsible for the action
- Specific timescales with review dates if on-going
- Governance mechanism

Section 4 – Hospital Transfusion Team Role

Involvement in incident management is a fundamental aspect of the HTT remit playing an important role in the management of incidents both in respect of transfusion laboratory incidents and clinical incidents.

Time Allocation
Involvement in incident management can place excessive demands on HTT member's time. In order to promote effective and efficient closure of an incident, the HTT should consider current workload and assess which member of the HTT is best placed to manage a specific incident.

Training

It is essential that all staff receive appropriate training:
- In their local incident management systems and root cause analysis techniques
- Relevant incident management Standard Operating Procedures (SOPs) should have been read, signed and the date recorded
- Evidence of staff training should be retained in their personal development folder (Health Professional Council (HPC) portfolio or Nursing and Midwifery Council (NMC) Revalidation and included in the relevant dimensions within electronic Knowledge and Skills Framework.

Investigation

Laboratory Incidents
The Quality Manager and Transfusion Laboratory staff should be responsible for investigating, reporting, recommending and implementing follow up actions for incidents which have originated in the laboratory. TPs should not investigate incidents which solely occur within the Transfusion Laboratory.

Clinical Incidents
The TP should be assisted by the Transfusion Laboratory staff, as appropriate, in investigating, reporting, and recommending and implementing follow up actions plans for clinical incidents.

Clinical Loses
Inappropriate clinical loses may be investigated by either the Transfusion Laboratory staff or Clinical area manager or both depending on the circumstances. A local system should be in place to enable the monitoring of wastage in clinical areas and trending. Transfusion Laboratory staff should be responsible for recording all clinical wastage and this information should be made available to the TP to enable reporting the local to HTT and HTC.

Traceability
There should be a local system for Traceability and the follow up of non-return of individual labels. This should be the responsibility of Transfusion Laboratory staff.

Rejected Samples
Samples which have been rejected should be managed by the individuals responsible for the departments concerned, for example, if a sample has been rejected by the laboratory the clinical area

/ phlebotomist should be contacted and a repeat sample sent. Rejected sample figures should be recorded for monitoring trends and contact made with the clinical area if increasing trends identified.

Section 5 – MHRA and SHOT Definitions

The MHRA and SHOT (Serious Hazards of Transfusion) have collaborated to improve haemovigilance reporting by producing an integrated single SHOT and MHRA incident reporting process by linking the SABRE and SHOT online reporting systems.

MHRA

Guidance on all Reporting to MHRA is available in the User guide for mandatory and professionally mandated haemovigilance reporting in the UK, this can be accessed at https://www.shotuk.org/wp-content/uploads/myimages/Joint-UK-Haemovigilance-user_guide-2017.pdf).

Serious Adverse Event (SAE)
"Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to the death or life threatening, disabling or incapacitating for patients or which results in or prolongs, hospitalisation or morbidity" (Shotuk.org, 2018).

All incidents reportable to SABRE or SHOT are reportable using the SABRE website. They will be allocated to the correct category by the MHRA and SHOT, an email will be sent to inform you of the category.

For adverse events that only involve clinical staff or Anti D for example, will not be reportable to the MHRA, however these type of incidents are repeatable to SHOT, they are all reported via the SABRE reporting system and allocated to the correct bodies.

Serious Adverse Reaction (SAR) –

"An unintended response in a donor or in a patient that is associated with the collection or transfusion of blood or blood components that is fatal, life threatening, disabling or incapacitating, or which results in or prolong hospitalisation or morbidity". (Shotuk.org, 2018).

All SAR will be reportable to MHRA and SHOT via the SABRE webpage.
https://www.shotuk.org/reporting/

Further guidance documents can be obtained at **https://www.shotuk.org/reporting/**

SHOT

The most current definitions, what to report and SHOT reports can be accessed at **https://www.shotuk.org**

Appendix 1 - References

NHS Health Improvement Scotland 2012. The Management of Significant Adverse Events in NHS Ayrshire and Arran, NHS Health Improvement Scotland, Edinburgh.

Reason, J. 2000. Education and debate: Human error: Models and management. *British Medical Journal,* vol. 320, no. 7237, pp. 768 - 70.

Knowledge.scot.nhs.uk. (2018). *Duty of Candour - Adverse Events*. [online] Available at: http://www.knowledge.scot.nhs.uk/adverse-events/duty-of-candour.aspx [Accessed 28 Jun. 2018].

Legislation.gov.uk. (2018). [online] Available at: https://www.legislation.gov.uk/asp/2016/5/pdfs/asp_20160005_en.pdf [Accessed 28 Jun. 2018].

Shotuk.org. (2018). [online] Available at: https://www.shotuk.org/wp-content/uploads/myimages/Joint-UK-Haemovigilance-user_guide-2017.pdf [Accessed 28 Jun. 2018].

Appendix 2 – Glossary of Terms

Adverse Event: Any incident/near miss, event or circumstance arising that could have or did lead to unexpected harm, loss or damage.

Blame: Undesirable practice of attributing responsibility for an adverse event to an individual. Blame is undesirable because adverse events are usually due to system failures.

Incident: Any event or circumstance arising during treatment of a patient, procedure or process that could have or did lead to unintended or unexpected harm, loss or damage.

Imputability: score given to the incident and adverse outcome for the patient. Generally the higher the score the more likely the event is attributed to the transfusion

Near Miss: Where no harm, loss or damage is caused but could have resulted in harm, loss or damage in other circumstances

Reduce risk: Take action to control the risk either by taking actions which lessen the likelihood of the risk occurring or the consequences of occurrence

Risk: The chance of something happening that will impact on the patient or NHS Board

Risk Management: Incorporates the activities required to identify and control the exposure to risk which may have an impact on the achievement of an organisations objectives

Risk Register: A database of risks which change to reflect the nature of the risk and our management of these. Its purpose is to help NHS Boards prioritise available resources to minimise risk to best effect and provide assurances that progress is being made.

Root Cause Analysis (RCA): A systematic investigation technique that looks beyond the individuals concerned and seeks to understand the underlying causes and the environmental context in which the incident occurred (NPSA, 2004)

Significant Risk: Any risk that could adversely affect NHS Boards objectives or present a large loss. A ‘significant’ risk could be defined as one with a risk grading of ‘moderate’ (orange) or ‘high’ (red) determined using the Risk Grading Matrix

System Failure: The most likely cause of an adverse event. Can be due to a defect or flaw in the design or operation of a system of work rather than an individual’s action.