

# **‘Root Cause Analysis Toolkit for Transfusion Practitioners’**

to help investigate  
transfusion incidents

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## **Background**

Rebecca Gerrard, Transfusion Liaison Nurse, NHS Blood & Transplant (NHSBT) was seconded to SHOT (Serious Hazards of Transfusion) from December 2004 to May 2006 for one day per week to:

- Further raise the profile of SHOT in hospitals and strengthen the link between SHOT and hospital staff, particularly the Transfusion Practitioners (TP)
- Assist hospitals to investigate and report transfusion incidents
- Aid the implementation of the recommendations from the SHOT annual reports

As part of this role, she completed a 3 day training course run by the National Patient Safety Agency (NPSA) on Root Cause Analysis (RCA) and has worked with some TPs in their own Trusts, to assist them to investigate transfusion incidents and near misses.

This document was written to help introduce TPs to the techniques recommended by the NPSA for conducting a root cause analysis, provide some practical tips for investigating transfusion incidents and act as a guide on where to get more information.

The document has been reviewed by Tony Davies, Transfusion Liaison Practitioner for NHSBT/SHOT with no major changes, apart from updating relevant links within the toolkit.

## **Acknowledgements**

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- Dorothy Stainsby, National Co-ordinator, SHOT (Retired)
- Julie Yates, Transfusion Practitioner, Warrington General Hospital

## Introduction

Reporting when things go wrong is essential in healthcare. But it is only part of the process of improving patient safety. It is equally important that organisations look at the underlying causes of patient safety incidents and learn how to prevent them from happening again.

Links to NPSA resources, on developing a patient safety culture, and the NPSA Seven Steps to Patient Safety are below;

[www.nrls.npsa.nhs.uk/resources/patient-safety-topics/patient-safety-culture/](http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/patient-safety-culture/)

[www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/](http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/)

A '**root cause**' is the cause or causes that if addressed, will prevent or minimise the chances of an incident recurring.

**'Root cause analysis'** is a methodology that enables you to ask the questions 'How' and 'Why' in a structured and objective way, to reveal all the influencing and causal factors that have led to a patient safety incident. The aim is to learn how to prevent similar incidents happening again, not to apply blame.

The same techniques can be used to investigate incidents as well as near-misses, as there are lessons to be learned from both.

A RCA approach to incident investigation will achieve a number of benefits (NPSA 2004, Step 6). These include:

- Providing a structured and consistent approach to incident investigation
- Shifting the focus away from individuals and on to the system to help build an open and fair culture
- Increases awareness of patient safety issues
- Helping engage patients in the investigation
- Demonstrating the benefits of reporting incidents
- Focussing recommendations and change as a result of identifying the root cause(s) of an incident

There will usually be a facilitator who co-ordinates a RCA. Other people may be involved as members of the team gathering and exploring information about an incident. The people who were actually involved in the incident may also be part of the process, for example, by being interviewed.

## **The Role of the National Patient Safety Agency in RCA**

The National Patient Safety Agency (NPSA) is an arm's length body of the Department of Health, created to co-ordinate the efforts of all those involved in healthcare, and more importantly to learn from patient safety incidents occurring in the NHS.

NPSA website address: [www.npsa.nhs.uk](http://www.npsa.nhs.uk)

The National Reporting and Learning Service (NRLS) is one of three divisions of the NPSA, committed to improving patient safety by promoting active learning at all levels across the NHS. It believes that learning can be encouraged by:

- developing a supportive and open culture
- ensuring that there are robust and proven tools available to staff to learn from incidents and near misses.

In order to develop ways of minimising risk to patients in future, we need to understand the true causes of patient safety incidents. The NPSA is reliant on the efforts of NHS staff in developing this understanding and has therefore created an e-learning package to help give you a good understanding of the principles and practice of Root Cause Analysis and an opportunity to explore and practice the tools and techniques of investigation and analysis. It will also help you to identify how you can pursue further knowledge, experience and formal assessment in this field.

In brief it comprises of six modules:

- Introduction
- Why Things Go Wrong
- Getting Started
- Gathering Information
- Analysing Information
- Generating Solutions

More information about the NPSA RCA toolkit can be found at:

<http://www.nrls.npsa.nhs.uk/resources/rca-conditions/>

The programme is also supported by a Resource Centre which contains downloadable documents in the following sections:

- tools to support the investigation report template;
- tools to help reduce the burden of RCA investigations; and
- other useful RCA investigation templates.

[www.nrls.npsa.nhs.uk/resources/?entryid45=59847](http://www.nrls.npsa.nhs.uk/resources/?entryid45=59847)

## The RCA Process

The RCA process consists of 6 main activities:

### 1. **Gathering the Data**

Information should be gathered about what happened from the site, equipment, policies and guidelines, the patient's notes and other documentation (see 'Tips for Data Gathering' p15).

### 2. **Mapping the Information**

The information gathered needs to be mapped or ordered in a useful way. This will clarify what is known and identify any gaps in the information. Tools to assist with this process include 'Narrative Chronology', a straight forward chronological account of what happened, and 'Tabular Timelines' that maps the chronological chain of events involved in an incident where it is anticipated that the incident contains more than one isolated episode of procedural failure. The whole incident can be viewed on one diagram and it will help identify gaps and questions needed for interviews (see p8 and p10 for more information on Tabular Timelines and a template).

### 3. **Identifying the problems**

A multi-professional review meeting may be organised by the Facilitator to help identify the key problems that emerge. Tools to enable this include 'Brainstorming' and 'Change Analysis'. Change Analysis compares a process when it is well defined and effective with the same process when it has not functioned well, or failed (see p9 and p11 for more information on brainstorming and change analysis and a template). Problems can be divided up into Care Delivery Problems (CDPs) and Service Delivery Problems (SDPs). CDPs are problems that arise in the process of care, usually actions or omissions by staff e.g. failure to monitor, observe or act, incorrect decision or action, not seeking help when necessary. SDPs are significant latent failures identified during the analysis of the patient safety incident, but are not associated with direct provision of care e.g. failure to undertake environmental risk assessment or failure to implement safe systems.

### 4. **Analysing problems for contributory factors**

Once data has been collected and mapped and problems have been identified and clarified, it is then necessary to prioritise problems and issues for analysis and identify contributory factors using tools such as a 'Fishbone diagram' or '5 Whys' technique. A 'Fishbone diagram' is a diagrammatic tool used to capture causes contributing to a single problem under 9 classification headings. The '5 Whys' technique allows deeper questioning as to the cause of the problem identified whether it is a symptom or a root cause. Factors that contributed to the incident may vary in significance of impact on the CDP/SDP and may have a negative or positive impact (see p9, 12 and 13 for more information on Fishbone diagrams, the 5 Why's Technique and templates).

### 5. **Identifying and agreeing the root causes**

Identify the contributory factors which have the highest impact on each problem and find those that are behind more than one problem, to enable the team to agree the root cause(s) that needs to be addressed. A root cause is a fundamental contributory factor which, if resolved, will eradicate or have the most significant effect on reducing likelihood of recurrence.

## 6. Making recommendations and reporting

It is important the lessons learned from the RCA can be used to improve patient safety. Identify the root causes, generate solutions and write a report that includes recommendations. This needs to be followed up with an action plan that includes roles, responsibilities and time-frames for actions to be completed by. The action plans need to be monitored so that solutions are implemented and their effectiveness evaluated (see p14 for Action Plan template).

- **When writing the report:**

- Keep it simple
- Summarise the nature of the incident and its consequences
- Describe the investigation: methodology, incident grading information, the findings – CDPs, SDPs and contributory factors and root cause(s)
- Document positive features of the incident and good practice identified
- Include recommendations/key learning points

- **Who to send the report to:**

This may vary but you may like to consider:

- All Hospital Transfusion Team members
- Hospital Transfusion Committee
- Risk Manager

- **Other stakeholders who may expect to see the report:**

- Patient and carers
- Other Trust Management Committees
- Health Authority
- Coroners Office
- Trust Board
- Department of Health
- NHS Litigation Authority/Solicitors
- Local or National Media
- The General Public

### Examples from the NPSA Toolkit Matrix

<b>Tool</b>	<b>When to use</b>	<b>Description</b>	<b>Attributes</b>	<b>Difficulties</b>	<b>Useful for</b>
<b>Narrative chronology</b>	Best suited for compact and non-complex incidents. Fits well at the start of a more complex investigation report to give a concise overview of what happened.	Straightforward chronological account of what happened.	Well accepted format for presenting information.	Difficult to pick out the salient points. Not ideally suited to forming a complete understanding of what happened when multiple directorates / departments are involved.	Gathering and Mapping Information
<b>Tabular Timeline</b>	Any type of incident, very useful for those that involve a long time scale and those in primary care and mental health or where multiple agencies are involved.	Development of the timeline, but includes additional fields – supplementary information, good practice and care/service delivery problem.	Allows the investigation team to map the chronology in a diagrammatic format, but allows additional information (e.g. CDP/SDP, supplementary information and good practice) to be mapped at the appropriate point on the chronology. This makes the technique easy to read and resource efficient. Technique allows you to identify data gaps quickly. Additional information can be added where needed, without the need of reformatting.	Some people prefer to map a case in a more fluid and dynamic way than this format allows.	Gathering and Mapping Information
<b>Brain-storming</b>	To generate a list of problem areas that can be improved. Identify possible contributory factors Consider what error reduction strategies or recommendations the organisation should instigate.	Mechanism to generate as many ideas as possible around a given subject area. Can be: Unstructured – everyone is free to produce ideas. Structured – each participant produces an idea in turn.	Quick and simple. Does not have to involve detailed case review. Allows free thought and consideration of unusual ideas. Good for on the spot problem analysis and solution generation.	Can be unstructured. May result in group think as dominant voices may sway the group. May fail to consider deep-rooted organisational, cultural and leadership issues Can be dominated by individuals.	Analysing Information

<b>Tool</b>	<b>When to use</b>	<b>Description</b>	<b>Attributes</b>	<b>Difficulties</b>	<b>Useful for</b>
<b>Change analysis</b>	Flexible tool that lends itself to a variety of uses. When a system, task, piece of equipment has worked and then fails. When its difficult to know where to start with problem identification or exploration. Suspect a change may have contributed to inappropriate action or equipment failure.	Compares a process when it is well defined and effective with the same process when it has not functioned well or, following a failure.	Useful when the cause of the incident is obscure, not sure where to start, don't understand the specialty. To identify where a failure occurred in a process. Systematic, structured and rational process – reduces the risk of oversight. Can be used for both simple and complex incidents.	May raise more questions about the normal procedure, or the process employed in the care of the patient (s) than answers. May require the analyst to research the subject area further.	Analysing Information
<b>Fishbone diagram</b>	To represent contributory factor information related to a single problem.	Diagrammatic tool used to capture causes contributing to a single problem under nine classification headings.	Diagrams are easily constructed. Based on verified causal factors. Provides a base for reliable improvement plans.	Not all users feel comfortable with this tool. Causal data which has not been verified may lead to inappropriate improvement strategies.	Analysing Information
<b>Five whys</b>	To question each identified primary cause of a problem, to identify whether this is a symptom, an influencing factor or a root cause.	Allows deeper questioning as to the cause of a problem and identify whether it is a symptom or a root cause. To question each CDP / SDP identifying the primary cause of the problem.	Allows individuals / groups to drill down the causal pathway. Simple and effective tool Works well in a group and individually.	Causal analysis can be constrained by mind set and lack of breadth and depth. Why can be asked as frequently as required to get to the root cause, asking 5 times may be inappropriate.	Analysing Information

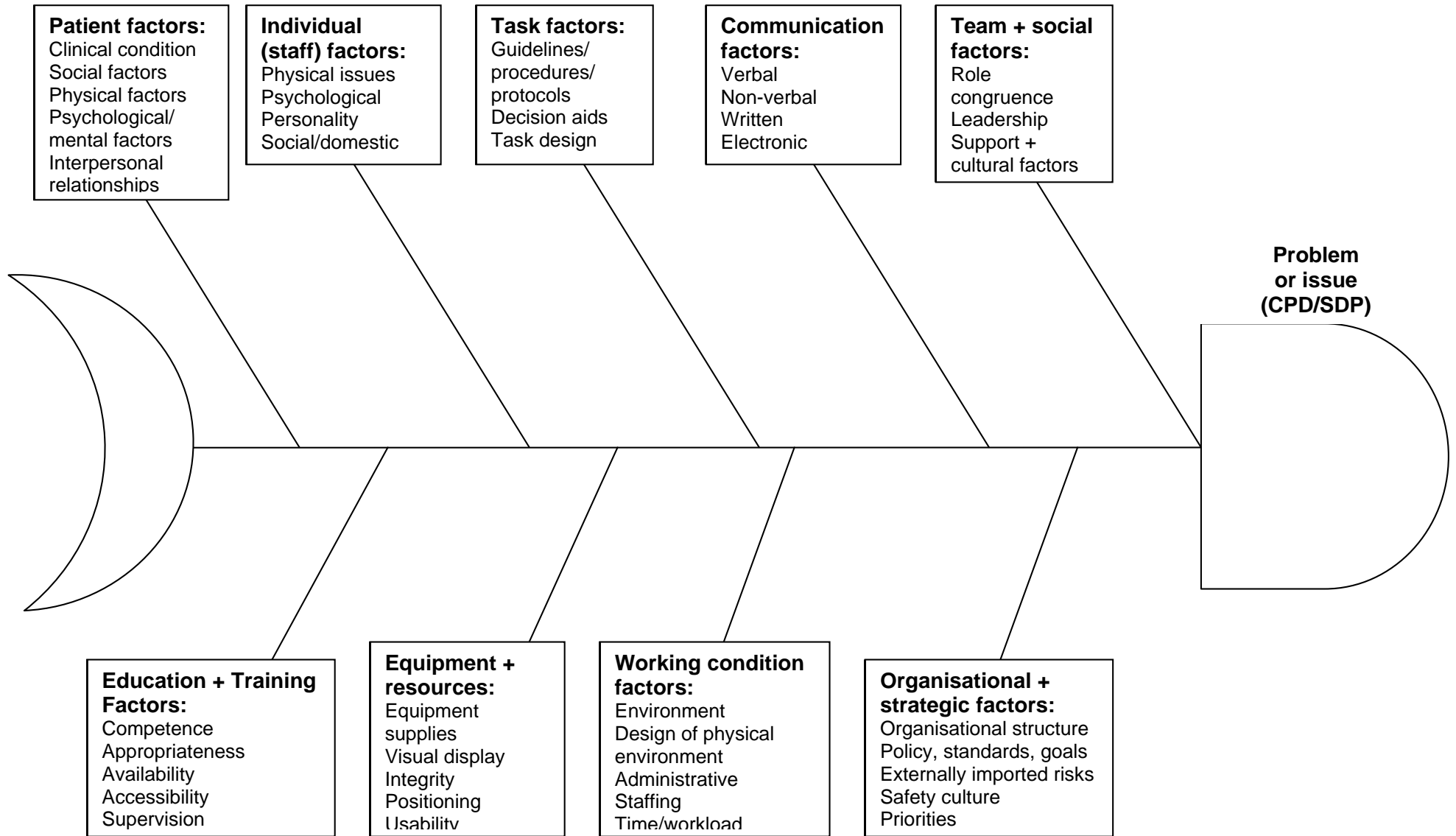
**Tools for gathering, mapping and analysing information**  
**1. Tabular Timeline**

<b>Event date and time</b>				
<b>Event</b>				
<b>Supplementary information</b>				
<b>Notable Practice</b>				
<b>Care / Service delivery problems</b>				

## 2. Change Analysis

<b>Normal Procedure</b>	<b>Actual Procedure at time of Incident</b>	<b>Was there a change (Y/N)</b>	<b>CDP/SDP</b>

### 3. Fishbone Analysis



**4. 5 Why's**

**Issue to be explored:**

**Why?**

**Why?**

**Why?**

**Why**

**Why?**

**5. Action Plan**

Root Cause	Actions to Address Root Cause	Level of Recommendation (Individual Team, Directorate, Organisation)	By Whom	By When	Resources required	Evidence of Completion	Sign Off

## Tips for Data Gathering

This stage of the review process is of critical importance in the investigation and can result in a vast array of documents which have come from many sources in the organisation. Information needs to be collected from people, documentation, equipment and the site.

The following points should be considered during the data collection process:

- when collecting documentary evidence regarding the protocols, guidelines etc that may have been used during the planning and delivery of care, ensure the documents collected are the same as those used at the time of the incident
- ensure that all relevant copies of the documentation are preserved within the investigation file
- you may need to use an information tracking system so you know which information you have requested, whether or not it has been received, and where you have put it. Reference all documentary evidence collected and include reference numbers as an integral part of your document tracking system
- store information in a ring binder with numbered or lettered index system, this leads to easy access and less likelihood of documents accidentally being destroyed
- **Patient's medical records:** Ensure these contain
  - pathology reports
  - any other disciplines involvement e.g. psychiatrist's report
  - nursing records
  - observation measurement charts e.g. TPR, fluid balance
  - records from other health professionals involved e.g. physiotherapy
  - any patient risk assessment records e.g. nutritional assessment
  - consider making a copy of these to enable access to the records if the patient is currently receiving treatment or could be readmitted whilst the investigation is taking place.
- **Care protocols, policies and procedures:** Ensure any local protocols are included, and that the document received has the same content as the document used in the events that led up to the incident.
- **Staff rotas:** include rotas from all care areas where the patient received care at the time of the incident.
- **Statements:** Ensure staff receive written guidance to assist them in preparing their statements. The guidance should include the timeframe for returning their statements and information about why they have been requested and where help and support is available to them.
- **Equipment involved in the incident:** ensure the asset number is recorded, this may help to track equipment that has been involved. Any equipment involved which it is believed may have precipitated or caused harm, must be quarantined and should not be released until it has been checked and

certified safe for use. The equipment settings must be recorded. Request maintenance records to the equipment specified.

- **Training records:** Request/review training and competency assessment records for staff involved in the incident.
- **Copies of SHOT/SABRE reports submitted**
- **Consider the other documents listed below which may assist with investigations:**
  - Patient Safety Incident reports
  - Switchboard records
  - Proof of registration/qualifications
  - Audit reports: include local, regional and national e.g. the National Comparative Audit
  - Risk assessments
  - National guidelines

## Lessons learnt from experience

- Link with personnel in your Trust that have completed the 3-day RCA training course run by the NPSA, to obtain local help and support. (Free places were offered to a small number of staff in every Trust.)
- Choose the incidents you wish to do a full RCA on carefully, as not all are suitable and it can be a very time consuming process. Patient safety incidents to consider for a RCA include those causing death or severe harm, those that occur frequently or one's that could/should have been prevented.
- There should be a team of multi-disciplinary people (at least 3) working on the analysis to prevent bias and allow all factors to be considered.
- Don't underestimate the value of speaking to all those involved, including the patient where appropriate.
- Don't make any assumptions.
- Try to carry out the analysis as soon as possible after the event.
- Visit all the locations involved as soon as possible after the incident, as a great deal can be learnt from the environment/equipment involved.
- There are usually several contributory factors to an incident. Considering and documenting these will minimise the stress caused on the staff involved.
- Take your time – RCA won't be done properly if it's rushed.
- RCA of an incident often reveals more than one error/problem.
- You will sometimes get results you don't expect and these are not always easily accepted by staff.

## Where to get more information

- **NPSA**

The National Patient Safety Agency (NPSA) is an arm's length body of the Department of Health created to co-ordinate the efforts of all those involved in healthcare, and more importantly to learn from patient safety incidents occurring in the NHS [www.npsa.nhs.uk](http://www.npsa.nhs.uk).

- RCA - More information about RCA training and the NPSA toolkit can be found on the website:

<http://www.nrls.npsa.nhs.uk/resources/rca-conditions/>

- **Your local risk management department/team**

- **The SHOT Office**

For help and advice about reporting transfusion incidents to SHOT, contact:  
The SHOT office, Manchester Blood Centre  
Plymouth Grove, Manchester M13 9LL  
Tel: 0161 251 4208  
Fax: 0161 251 4395  
Email: [shot@nhsbt.nhs.uk](mailto:shot@nhsbt.nhs.uk)  
Website: [www.shot-uk.org](http://www.shot-uk.org)

- **MHRA**

The Blood Safety and Quality regulations 2005 require that serious adverse events and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety.  
To report an incident to MHRA log on to their website [www.mhra.gov.uk](http://www.mhra.gov.uk) and choose the link: 'Report a suspected safety problem' then select 'Blood'.

## References and Further Reading

- Blood Safety and Quality Regulations 2005 (Statutory Instrument 2005/50 and Statutory Instrument 2005/1098 as amended)
- Department of Health, Chaired by CMO (2001) An organisation with a memory (Report of an expert working group on learning from adverse events in the NHS). HMSO
- National Audit Office (2005) A Safer Place: Learning to improve patient safety. The Stationary Office, London
- NPSA (2004) Seven steps to patient safety, Learn and share safety lessons
- SHOT Annual Report (2008) [www.shot-uk.org](http://www.shot-uk.org)

Incident Investigation and Root Cause Analysis Report template:

**(Trust)**

**Department of Blood Transfusion**

**Incident Investigation and  
Root Cause Analysis Report**

**Incident Number:**

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## 1 Introduction

1.1 This report constitutes a Root Cause Analysis (RCA) investigation of Incident *[incident number]*, which occurred on *[date]* at *[hospital]* on *[ward /department]* and was of the type categorised as *[type e.g. SHOT type]*.

1.2 A root cause is the cause or causes that if addressed, will prevent or minimise the chances of an incident recurring. Root cause analysis is a technique for undertaking a systematic investigation that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened. Retrospective and multi-disciplinary in approach, it is designed to identify the sequence of events, working back from the incident. This allows the real causes of an incident to emerge so that organisations can learn and put remedial action in place.

1.3 It should be emphasised that the purpose of this report is to identify 'system errors' and provide learning points to improve practice, it is not designed to apportion blame to individuals or teams.

## 2 Summary of the case

2.1

2.2 Outcome:

## 3 Methodology

3.1 The RCA methods used to investigate this incident included *[insert type e.g. a 'Tabular Timeline', 'Change Analysis' and a 'Fishbone Analysis' as recommended by the National Patient Safety Agency (NPSA). The Timeline was used to track the events occurring prior to, during and after the incident, to discover all parts of the process where problems or errors had occurred. The Change Analysis was used to identify the care and service delivery problems. The Fishbone Analysis was used to identify all the contributory factors.]*

3.2 The documents analysed in production of this timeline were:

- 1.
- 2.

3.3 The following people were interviewed by *[insert interviewer's name(s)]*

- 1.
- 2.

3.4 The Tabular timeline for this incident is provided in Appendix A etc.

#### **4 Incident Grading**

The system for incident grading in this report was *[insert system e.g. The DATIX Classification System for Incidents in Healthcare]*.

*Consequence of Incident:*

*Likelihood of Recurrence:*

***Incident classification:***

#### **5 RCA chronology**

See Appendix A

#### **6 Discussion**

e.g. Care and Service Delivery Problems and Contributory Factors

#### **7 The Root Cause(s)**

- 1.
- 2.

#### **8 Key Learning Points**

- 1.
- 2.

#### **9 Acknowledgements**

#### **10 References and Further Reading**

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