

## **Root Cause Analysis Investigation Tools**

Guide to investigation report writing   
following Root Cause Analysis  
of patient safety incidents

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# Section 1: Introduction

## 1.1 How to use this guide

The purpose of this guide is to provide practical help and support to those writing patient safety Root Cause Analysis (RCA) investigation reports. It may also prove useful to those writing Significant Event Audit (SEA) reports.

The guidance is provided as:

- an overview and general background advice;
- guidance on the sections needed in an investigation report.

It is useful background reading for those new to investigation. The guidance is also designed for quick reference, providing notes on each section of the investigation report; for access as and when required.

The following associated documents will also be useful and are available from [www.npsa.nhs.uk/rca](http://www.npsa.nhs.uk/rca)

- **Guide to investigation report writing following RCA:** Guidance on completing an investigation report.
- **Three levels of RCA investigation:** Designed to help when considering what level of detail is appropriate and proportionate when investigating an incident.
- **Concise RCA investigation report examples:** For demonstration purposes.

# Section 2: Overview

## 2.1 The purpose of the investigation report

The investigation report presents the culmination of all the work undertaken by the investigation team. It conveys all necessary information about the incident, the investigation process and the outcome of the investigation.

The audience will use the investigation report as the basis for judging the quality of the investigation process, the findings, conclusions and recommendations. The audience will also judge the competence of the investigation team by the content, style and tone of the report.

The purpose of the report is to provide:

- a formal record of the investigation process;
- a means of sharing the learning.

The report should explain

1. **what** happened (i.e. chronology of events);
2. **who** it happened to;
3. **when** it happened;
4. **where** it happened;
5. **how** it happened (i.e. what went wrong);
6. **why** it happened (i.e. what underlying, contributory or deep-rooted factors caused things to go wrong).

The report should be clear and logical, and demonstrate that an open and fair approach has taken place.

### Help box

**Unless there are specific exceptions, the patient or family of a patient have a right to the full investigation report as defined in the Data Protection Act 1998 (available from [www.ico.gov.uk](http://www.ico.gov.uk)).**

## 2.2 Principles of investigation

A key purpose of the patient safety RCA investigation and subsequent report is to share learning from patient safety incidents, claims and complaints.

Before writing the report, it is useful for the investigator or team to consider whether general principles of investigation have been followed. Include the following in your considerations:

### Some general principles of investigation

Was the investigation process conducted with the appropriate level of independence? <sup>1</sup>	Yes	No
Was the investigation process proportionate to the incident and any associated risks?	Yes	No
Did the investigation begin and end in a timely manner?	Yes	No
Was the investigation process open and transparent?	Yes	No
Did the investigation team kept relevant parties appropriately informed?	Yes	No
Was the investigation based on evidence?	Yes	No
Did the investigation look for improvements and not to apportion blame?	Yes	No

<sup>1</sup> An element of independence to the ward, unit or service where the incident took place. This is distinct from an independent inquiry which meets HSG(94)27 criteria and *Investigation of adverse events in mental health services* (June 2005 - amends paras 33-36 of circular).

## 2.3 Hindsight and outcome bias

It is important when analysing investigation findings to be aware of, and try to avoid, hindsight and outcome bias.

### Hindsight bias

Hindsight bias is the tendency for people with the 'benefit of hindsight' to falsely believe, once all the facts become clear, that the actions that should have been taken to prevent an incident seem obvious, or that they could have predicted the outcome of an event<sup>2</sup>.

Although considered a serious pitfall in investigation terms, hindsight bias has been documented as a potentially useful mechanism in terms of the specific focus of learning from incidents. Hoffrage, et al<sup>3</sup> argue that it is a by-product of an adaptive mechanism that can make human memory more efficient. The basic idea of this 'RAFT' model (Reconstruction After Feedback with Take the Best) is that any feedback or correct information received (in this case in the form of a now known, but previously unpredicted, incident outcome) is used to automatically update a person's knowledge base.

It is important to remember, however, that failure to recognise hindsight bias in incident investigation can result in misinterpretation of findings and may ultimately mask the real lessons to be learned.

<sup>2</sup> Fischhoff, B. (1975). 'Hindsight is not foresight: the effect of outcome knowledge on judgement under uncertainty.' *Journal of Experimental Psychology, Human Perception and Performance* 1(3): 288-299.  
Henriksen, K. and H. Kaplan (2003). 'Hindsight bias, outcome knowledge and adaptive learning.' *Quality & Safety in Health Care* 12 Suppl 2: ii46-50

<sup>3</sup> Ulrich Hoffrage, Ph.D., Ralph Hertwig, Ph.D., and Gerd Gigerenzer, Ph.D., Max Planck, Institute for Human Development. (2000). 'Hindsight Bias: A By-Product of Knowledge Updating?,' *Journal of Experimental Psychology: Learning, Memory and Cognition*, Vol. 26, No. 3: 566-581

## Outcome bias

Outcome bias is the tendency to judge a past decision or action by its success or failure, instead of based on the quality of the decision made at the time. No decision maker knows for sure whether or not the future will turn out for the best following any decision they make.

Individuals whose judgments are influenced by outcome bias can hold decision makers responsible for events beyond their control.

Similarly, if an incident leads to death it is often considered very differently and critically, compared to an incident that results in no harm, even where the incident or error is exactly the same.

When people are judged one way when the outcome is good, and another when the outcome is poor, accountability levels become inconsistent and unfair.

To avoid the influence of outcome bias, one should evaluate the decision or action taken at the time it was taken and given what was known or going on at that time, irrespective of the success or failure of the outcome.

## 2.4 Audiences

A discussion should have already taken place with the commissioners of the investigation to agree who the audience of the final report will be. Knowing who the report is being shared with and who will read it helps the investigation team to decide on the style of the report.

As a rule, keep the report clear, free of jargon, acronyms and names, and use plain English. Where technical terms are necessary, a glossary may be required.

The report should not assume the reader understands normal processes in the department or the normal progress of the patient's condition; these need to be clearly explained in a way lay people can understand in order to put the incident in context.

## 2.5 Report writing and presentation style

The report should be written in the organisation style and font (a clear, good print size gives best access to everyone). Presentation style pointers are listed below.

### Report presentation style checklist

- organisation name;
- date of the incident;
- incident code or number;
- author(s) of the report;
- date of the report;
- annotated page numbers;
- numbered paragraphs to aid referencing;
- computer file path to indicate where the report is stored;
- status, for example 'draft' (with number of draft version) or 'final'.

Bullet points are appropriate for sections of the report conveying lists of facts or findings, but free text is more appropriate elsewhere.

Reports should be written in the third person e.g. refer to 'the patient', 'the doctor', 'the organisation', 'the investigating team' rather than 'I', 'we' or 'you'.

Names of staff should not typically feature in the investigation report. Location, exact title or gender, e.g. 'Charge Nurse Y in ITU', can identify individuals, particularly in specialist departments or roles. More general terms such as 'the nurse in charge', or 'Ms Y' or 'Dr X' may be more acceptable. A key to these terms must be retained as part of the investigation file.

An acceptable pseudonym for the patient is best agreed with the patient or family themselves. Sometimes the family may prefer a real first or full name to be used.

The report should ensure it presents the patient(s) or staff involved as individuals, without being overly personal or compromising confidentiality.

Whilst a report must be evidence-based, the lead investigator/ investigating team are required to do more than simply summarise findings, but must not move into speculation. Terms such as 'from the evidence it was observed/ concluded' are useful for distinguishing analysis from evidence. Source material, evidence, and theories which back up analysis should be appropriately referenced.

Prior to final release, the report author must arrange for the final draft to be proof-read and checked for factual accuracy, grammar and spelling.

## 2.6 Record keeping and information security

Working documents, such as timelines and analytical work used in the investigation, should be filed and stored safely, and clearly labelled with the investigation code and number. If there is outside scrutiny or a further investigation, working records and evidence may be needed and should be easy to find.

Documentation should be stored in a lettered or numbered index file, with each item of evidence given an individual reference.

# Section 3: Guidance on the sections needed in a report

## 3a Cover page

### Contents of a cover page

- organisation name;
- title and/or brief outline of the incident;
- incident date;
- incident number;
- author(s) of the report;
- date of the report;
- annotated page numbers;
- version number (draft or final);
- computer electronic file pathway.

## 3b Contents

### 3.1 Executive summary

There should always be an executive summary at the beginning of any full report. This should comprise one or two pages only, listing key points, under these headings:

- Incident description and consequences. A summary including the following:
  - o brief incident description;
  - o incident date;
  - o incident type;
  - o healthcare specialty where incident occurred;
  - o actual effect on the patient and/or service;
  - o actual incident severity.
- Level of investigation (level 1: concise; level 2: comprehensive; level 3: independent).<sup>4</sup>
- Involvement of the patient and/or relatives;
- Care and service delivery problems;
- Detection of incident;
- Contributory factors;
- Root causes;
- Lessons learned;
- Recommendations;
- Arrangements for sharing and learning lessons.

## 3c Main report

### 3.2 Incident description and its consequences

Provide a clear, concise description of the incident and its effect on (or outcome for) the patient, the staff, the service and any other stakeholders.

### What to include in the description of the patient safety incident

- a concise description of the incident;
- incident date;
- incident type;
- healthcare specialty in which the incident occurred;
- actual effect of the incident on patient and/or service and others;
- actual severity rating of the incident (consequences).

The impact and consequences described should only be those relevant to the incident and may not solely be based on physical harm. For example, psychological injury, social or political consequences, or reputation of service or individuals might also be considered:

- avoid emotional, judgemental or value laden words to describe events;
- consider the careful and limited use of photographs or diagrams to support the description.

### 3.3 Pre-investigation risk assessment

A baseline assessment of the incident should be conducted by the investigation team to estimate the realistic likelihood and consequence of recurrence (prior to preventative action), and to help assess the level/detail of investigation indicated and more immediate action required.

### 3.4 Background and context of the incident

This section should be used to set the scene.

A brief description should be given of the type of care and/or treatment being provided. Information on the size of the service, how long this type of service has been provided and the make up of the clinical team will help the reader understand the context of the incident.

### 3.5 Terms of reference

Terms of reference describe the plan and latitude allowed to those conducting the investigation.

These should be agreed between the commissioner and the investigation lead prior to the investigation.

Have regard for previous internal investigations findings, and identify:

- specific problem or issues to be addressed;
- who commissioned the investigation (and at which level in the organisation);
- Investigation lead and team;
- aims and objectives of the investigation and desired outputs (see examples below);
- scope (see 3.7) and boundaries beyond which the investigation should not go (e.g. disciplinary process);
- timescales for the report and for reviewing progress on the action plan;
- project administration arrangements (including accountability, meetings, resources, reporting and monitoring arrangements);
- timescales;
- actual or potential for involvement of the police, Health and Safety Executive and plans for this to be addressed and managed effectively at the earliest point.<sup>5</sup>

### Help box

**North and East Yorkshire and Northern Lincolnshire Trusts have identified a useful list of prompts which may help to develop more detailed terms of reference. This is available in Appendix 1.**

Concise terms of reference should be included in the report. If a long, detailed terms of reference document exists this should be added to the appendix.

<sup>4</sup> Taken from 'Three levels of RCA investigation'. Available at: [www.npsa.nhs.uk/rca](http://www.npsa.nhs.uk/rca)

<sup>5</sup> Memorandum of understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm. [www.dh.gov.uk/en/Consultations/Closedconsultations/DH\\_4090170](http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4090170)

It may be appropriate and possible to set organisation-wide aims for patient safety investigations, for inclusion in the terms of reference section.

**Possible organisational aims, objectives and outcomes for the investigation**

- establish the facts:
  - o what happened (*the chronology and effect*)?
  - o to whom?
  - o when?
  - o where?
  - o how? (*what went wrong*)
  - o why? (*contributory factors and root causes*)
- establish whether failings occurred in care and/or treatment (*care and service delivery problems*);
- look for learning points and improvements rather than apportion blame;
- establish how recurrence may be effectively reduced or eliminated;
- formulate realistic recommendations which address root causes, and learning points to improve systems and services;
- present the key findings in a report as a record of the investigation process;
- provide a consistent means of sharing learning from the incident.

It is important to protect the integrity of the RCA investigation process from situations where there is the probability of disciplinary action, or criminal charges.

**Help box**

**The Incident Decision Tree is a key component of work to move away from asking ‘Who was to blame?’ to asking ‘Why did the individual act in this way?’ when things went wrong.**

**The Incident Decision Tree has been created to help NHS managers and senior clinicians decide whether they need to suspend (exclude) staff involved in a serious patient safety incident and to identify appropriate management action. The aim is to promote fair and consistent staff treatment within and between healthcare organisations.**

**Learn more about the Incident Decision Tree at: [www.npsa.nhs.uk/idt](http://www.npsa.nhs.uk/idt)**

The following four types of incidents, or mid-investigation findings, should be referred to alternative investigating bodies or processes for resolution, for example human resources, professional regulatory body, the police etc:

1. Events thought to be the result of a criminal act by care providers/staff.
2. Purposefully unsafe (malicious) acts by care providers intending to cause harm.
3. Acts related to substance abuse by care providers/staff.
4. Events involving suspected patient abuse of any kind.

As the Secretary of State and NHS bodies have a duty to secure the safety and well being of patients, the investigation to determine the root causes and learning points should still be progressed in parallel with other investigations, ensuring early and robust solutions are put in place as necessary to reduce the likelihood of recurrence. A memorandum of understanding ([www.dh.gov.uk](http://www.dh.gov.uk)) exists to assist organisations with the planning and scoping of investigations where the police or the HSE are also involved.

In the event of any referral to alternative bodies or processes arising from the patient safety investigation, it is open and transparent practice to make an anonymised reference to this in the lessons learned or recommendations section of the report.

Root cause analysis techniques are used by professionals conducting other types of investigation, but it is important that all participants are aware of the clear distinction between the aims and boundaries of patient safety investigations, which are solely for the identification and reporting of learning points, compared with disciplinary, regulatory or criminal processes.

**3.6 The investigation team**

The level of investigation undertaken will dictate the degree of leadership, overview and strategic review required.

The table below shows the headings you should use in this section, to list the core investigation team members and any chair, facilitators, service users, experts, or other individuals that joined the extended team.

**Capturing the details of the investigation team**

<b>Name and title</b>	MR C Jones
<b>Job title</b>	Risk Manager
<b>Qualifications</b>	EXAMPLE
<b>Background experience</b>	EXAMPLE
<b>Investigation team role</b>	EXAMPLE
<b>Internal department or reference to their independence from the service</b>	EXAMPLE

**3.7 The scope and level of the investigation**

Explain how far back you decided to go with the investigation and the level of investigation conducted (see ‘Three levels of RCA investigation’), and justify why. For independent investigations, the scope of the investigation could be included under terms of reference.

**Help box**

**Sometimes the investigation team might find it needs to amend the level of investigation once data gathering has commenced.**

An explanation as to which relevant services or other agencies have or have not been included in the investigation and why, should be provided.

At the start of the investigation a lessons learned log should be set up to capture learning points (see 3.17).

Lessons learned may be described as ‘key safety and practice issues identified which did not materially contribute to the incident’. They may be related to the:

- incident itself;
- investigation process;
- implementation of recommendations/action plans.

### 3.8 The investigation type, process and methods used

Describe the investigation type undertaken (for example, single RCA, RCA aggregation or multi-incident investigation) and describe the process and methods used.<sup>6</sup>

#### Help box:

- Gather information, for example:
  - interviews (for example cognitive interviewing);
  - brainstorming/writing;
  - retrospective clinical records;
  - multidisciplinary team reviews;
  - photographs, diagrams or drawings.
- Map the incident, for example:
  - narrative chronology;
  - timeline/tabular timeline;
  - time person grid;
  - cause and effect chart.
- Identify care and service delivery problems, for example:
  - multidisciplinary review meeting;
  - brainstorming/brainwriting;
  - nominal group technique;
  - change analysis.
- Analyse problems to identify contributory factors and root causes, for example:
  - fishbone;
  - contributory factors classification/framework;
  - 5 whys.
- Generate solutions and recommendations, for example:
  - barrier analysis;
  - risk benefit analysis.

### 3.9 Involvement and support of the patient, relatives or carers

In line with NPSA *Safer practice notice 10: Being open when patients are harmed*<sup>7</sup>, the report should demonstrate the extent to which those affected have:

- been given an accurate, open, timely and clear explanation of what has happened, regardless of, but with sensitivity to, the distressing nature of the incident;
- received an apology in the form of a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident;
- been informed of plans regarding what can be done medically to repair or redress the harm done;
- been given a clear statement of what is going to happen regarding any investigation.

The report should also explain to what extent the patient, relatives and/or carers were involved in the investigation. This might include detail on whether the patient or family were:

- asked how much involvement they want;
- interviewed to establish the questions they hope the investigation will address and to hear their recollection of events;
- asked how they would like their involvement and/or names referred to in the report;
- offered a point of contact (family liaison person) with regard to the investigation;
- given information on sources of independent support/advocacy;
- informed and kept up to date with the investigation process, including agreeing the frequency with which they wanted to be updated;
- advised that the report and/or findings will be shared with them as they wish, and that it will be written in plain English;
- advised of whom they can contact in the future (job title), should they want information on implementation of recommendations.

### 3.10 Involvement and support for staff involved in the incident

It is important to keep staff informed at all times, and to provide advice, support and opportunities for involvement in the process.

In the report, acknowledge help received from staff. Names of staff should not feature in the RCA investigation other than in the archived master, and staff should be advised that the report will be made anonymous before any circulation or publication.

Outline any support given or offered to staff after the incident and during the investigation, such as counselling, support during interviews, or debriefing. Refer to informal support from colleagues, as well as formal support, written materials or access to support networks. Good practice in this regard might include debriefing sessions. Consider support for all staff involved in the process including, for example, students, contractors and investigators.

<sup>6</sup> A guide to aggregated and multi-incident investigations: [www.npsa.nhs.uk/rca](http://www.npsa.nhs.uk/rca)

<sup>7</sup> *Being open when patients are harmed*  
[www.npsa.nhs.uk/nrls/alerts-and-directives/notices/disclosure](http://www.npsa.nhs.uk/nrls/alerts-and-directives/notices/disclosure)

### 3.11 Information and evidence gathered

The report (or appendix) should contain a summary list of all evidence gathered from people, documentation, plant/equipment and site visits.

Evidence can include the following items:

- o interview notes;
- o letters;
- o e-mails;
- o equipment;
- o equipment fault reports;
- o literature review findings, such as National Service Frameworks;
- o NICE and/or other good practice guidance;
- o national alerts;
- o legislation policies;
- o procedures;
- o site plans;
- o photos;
- o training records;
- o maintenance records etc, both in place and in use at the time of the incident.
- o contextual data such as local or national audits may also be valuable.

An outline summary or list of this information review will suffice, rather than including copies in the report (copies of the salient documents belong in the investigation file). List the version and date, as well as the actual document title.

Copies of key documents can be included in the appendix as appropriate and useful. Confidential or highly detailed documents should be retained as part of the master investigation file only.

To enable investigation report findings to be shared for learning purposes, investigators should ensure that consent to access/utilise **and** publish information from patient records has been obtained.

All evidence should be included whether it supports or contradicts your conclusions. Record an audit trail of key decisions made, and provide reasons for discounting any facts which contradict your conclusion. If there is a conflict of facts, explain why one version is more credible than the other.

#### Help box

**Formal signed witness statements would not normally form part of a Root Cause Analysis investigation report produced for learning purposes. Staff may wish to write factual reflective notes, but if these are shared with the organisation, they can become discoverable.**

**Formal, signed witness statements are more relevant and appropriate to disciplinary or criminal investigations (see 'Investigative interview guidance': [www.npsa.nhs.uk/rca](http://www.npsa.nhs.uk/rca)).**

**Witnesses should be made aware that documents referred to in any interview or multidisciplinary review meeting may be disclosed in future (this may include reflective practice documents, personal and professional diaries, etc).**

Whilst staff directly involved in an investigation should have the chance to correct factual inaccuracies or comment on recommendations before a report is finalised, it should be clear they do not have a right of veto. Rather than risk situations where the lead investigator/ investigating team might be pressured or influenced, this discussion may require support by an impartial third party.

### 3.12 Chronology of events leading up to the incident

The report should include a summary of the key points of the mapped chronology, so that the reader can gain a clear understanding of the events leading up to the incident. This is ideally presented in visual format, for example a summary timeline, 'tabular timeline', or as part of a 'cause and effect chart' (see 'RCA toolkit' at [www.npsa.nhs.uk/rcatoolkit](http://www.npsa.nhs.uk/rcatoolkit))

The chronology or tabular timeline included in the report should be derived and summarised from the final document, rather than including the entire or working document which, during analysis, will have more detailed notes identifying gaps in information and distinguishing between different types of evidence. For example:

- the source of the information (first-hand, based on memory, contemporaneous);
- attribution or acknowledgement (who said what or provided the information);
- foundation or basis of the information (fact, evidence,

- professional assessment, opinion);
- derivation or background to the data (corroborated or in line with best practice guidance).

This full working document should be saved within the master investigation file and any final, full mapped chronology of events should be included as an appendix to the report.

### 3.13 Detection of incident

It is useful to identify at what stage in the patient's treatment the error was detected. This gives important information on how far the problem progressed without identification, indicating how effective existing controls/barriers were. It may also add insight into where best to invest effort and resources to generate the most effective solutions. Examples may include:

- at risk assessment of new or changed service;
- at pre-treatment patient assessment;
- error recognition pre-care/ treatment;
- error recognition post-care/ treatment;
- by machine/system/environment change/alarm;
- by a count/audit/query/review;
- by change in patient's condition.

### 3.14 Notable practice within the case

It is important to record, with appropriate sensitivity, points in the incident or patient journey where care and/or practice had an important positive impact and may provide valuable learning opportunities.

Use this section to comment on the co-operation and openness of staff during the investigation.

### 3.15 Care and service delivery problems

The report should detail how care delivery problems (CDPs) and service delivery problems (SDPs) were found and which RCA analytical tools were used to identify them.

CDPs and SDPs are points in the timeline at which:

- something happened that **shouldn't** have happened;
- OR
- something that **should** have happened didn't.

The CDPs and SDPs should then be prioritised for analysis.

**Help box:**

Issue	Wrong	Right
Wording of CDPs and SDPs needs to be specific	'communication failure'	'paramedic did not inform A&E that patient was confused'
CDPs and SDPs must describe <b>what</b> happened, not <b>why</b> it happened	'not enough training on hand hygiene'	'staff members rarely washed their hands'

### 3.16 Contributory factors

The contributory factors identified for each prioritised care and service delivery problem should be listed.

This analysis should highlight contributory factors taken from the NPSA contributory factors classification/framework (see [www.msnpsa.nhs.uk/rcatoolkit/resources/word\\_docs/Guidance/Guidance\\_Factors\\_Framework\\_Checklist.doc](http://www.msnpsa.nhs.uk/rcatoolkit/resources/word_docs/Guidance/Guidance_Factors_Framework_Checklist.doc)) and should not include negative descriptors, e.g. poor/inadequate/ careless/complacent.

Clearly explain how these were identified and which tools were used to carry out the analysis.

Although fishbone diagrams are often used to identify contributory factors, you may choose to analyse and display these in a full report using a 'contributory factors grid' (available at [www.npsa.nhs.uk/rca](http://www.npsa.nhs.uk/rca)).

### 3.17 Root causes

This section of the report should demonstrate a direct link between cause and effect.

These descriptions of root causes (conclusions) should:

- be numbered;
- be clearly linked by analysis to the evidence found;
- avoid blame and not include inflammatory statements or negative descriptors (e.g. poor/ careless/inadequate/reckless).

In essence, the report should show a clear thread connecting:

1. the root cause(s) (in organisational processes);
2. how these directly resulted in the specific care and service delivery problems;
3. how these led to the documented actual or potential effect on the patient.

### 3.18 Lessons learned

(see also 3.7)

There may be occasions when nothing could have prevented the incident and no root cause(s) are identified.

There are always lessons to learn and key safer practice issues may be identified which did not materially contribute to the incident.

Lessons learned from the incident and the investigation should be identified, numbered and addressed by the recommendations, alongside any root causes.

### 3.19 Recommendations

Recommendations and solutions should be designed to address the root causes (conclusions). For shorter, less complex investigations, recommendations and solutions may be developed at the same time. For more detailed investigations, recommendations may inform action planning and solutions development carried out at a later date by a different or reconstituted team.

#### Designing recommendations and solutions to address the root causes

**Recommendations should:**

- be clearly linked to identified root cause(s) or key learning point(s) (to address the problems rather than the symptoms);
- address all of the root causes and key learning points;
- be designed to significantly reduce the likelihood of recurrence and/or severity of outcome;
- be clear and concise and kept to a minimum wherever possible;
- be Specific, Measurable, Achievable, Realistic and Timed (SMART) so that changes and improvements can be evaluated;
- be prioritised wherever possible;
- be categorised as:
  - o those **specific** to the area where the incident happened;
  - o those that are **common** only to the organisation involved;
  - o those that are **universal** to all and, as such, have national significance.

**Recommendations might also include:**

- provision of ongoing support of patients and staff affected by the incident.

Clearly explain in the investigation report how recommendations were developed, which tools were used (for example, barrier analysis to assess effectiveness of controls in place), and who was invited to help (for example, system designers, or those involved in the incident).

**What to consider when developing recommendations**

- o understand that retraining is not always the right solution;
- o intelligent use of checklists, policies and protocols;
- o minimal dependency on short-term memory and attention span;
- o simplification of tasks and processes;
- o standardisation of tasks and processes;
- o avoidance of fatigue (review of working hours/patterns);
- o alignment with evidence-based practice;
- o alignment with organisational priorities and risk registers.

**3.20 Arrangements for shared learning**

Record in this section the degree to which sharing is required (see guide below).

**Guide to sharing learning**

Learning potential	Significance	Sharing
Specific	Local	Shared within the area where the incident happened.
Common	Organisational	Shared across the organisation involved.
Broad / universal	National	Shared across organisation involved and with other organisations/specific services/specialties/directorates – via patient safety networks, Patient Safety Action Teams, NPSA etc.

Note that it is common to assume incidents are unique or only relevant to your own organisation. In reality, patterns recur. If in doubt, it is always wise to share.

It is important to detail the *mechanisms* by which lessons have been or will be:

1. learned/implemented;
2. shared/disseminated.

Lessons learned are most effectively captured by completing a lessons learned log during the investigation and action plan implementation stages. Key findings can then be shared locally, with Patient Safety Action Teams and/or the NPSA as part of future investigation reporting processes.

**3.21 Distribution list**

A discussion should have taken place with the commissioners of the investigation to agree who the audience of the final report is. That list should be included in this section.

**Help box**

**North East Yorkshire and North Lincolnshire Trusts have identified a useful list of other potential stakeholders (Appendix 2) who may routinely or exceptionally request or require sight of investigation reports.**

The process of sharing investigation findings and reports with the patient and/or family should comply with ‘Being Open’ principles ([www.npsa.nhs.uk/nrls/alerts-and-directives/notices/disclosure/](http://www.npsa.nhs.uk/nrls/alerts-and-directives/notices/disclosure/))

Unless there are specific exceptions, the patient/family of a patient have a right to the full investigation report under the requirements of the Data Protection Act. (available at [www.ico.gov.uk](http://www.ico.gov.uk)).

Organisations need to support investigators to ensure this does not inhibit them from identifying areas of concern. It is important to discuss preferences with patients or relatives, however, as many may prefer to receive a shorter executive summary or just a copy of the recommendations from the report.

Staff should not disclose in the report any health or personal issues of a patient that the patient may have previously chosen not to disclose to their family or others.

If an organisation takes varying approaches on how much of the investigation report they share, the justification for this needs to be clear, explicit and in line with the patient’s wishes.

**3.22 Investigation report appendices**

The appendices should include key explanatory documents including:

- full terms of reference (where applicable);
- list of literature reviewed;
- summary list of evidence gathered (if this is too lengthy to be included in the report);
- copies of key documents, site plans, photographs etc (all others in archived master);
- final chronology or timeline;
- templates used for analysis, for example fishbones, run charts, change/ barrier analyses;
- lessons learned log;
- acknowledgements (if part of NHS organisation style and format).

# Section 4: Next steps

The following actions are not normally included as part of the RCA investigation report itself, but must be conducted as essential next steps once the report and its recommendations have been approved by the overseeing committee.

## 4.1 Action planning and solutions development

Action plans should set out how each recommendation will be implemented, with named leads responsible for each action point or solution. To ensure solutions are realistic, accepted, and owned by the service, it is essential that frontline staff and those with appropriate local knowledge are heavily involved in, or consulted on this process.

### Actions taken following a patient safety incident

Action	Explanation
<b>Immediate response and recovery actions</b>	Taken to prevent or moderate the progression (severity or likelihood of impact) of an incident; or to treat/compensate for harm after an incident. These are often recorded as part of the incident report, but may also be included in an action plan.
<b>Preventative or risk-reducing actions or solutions</b>	Taken to address the cause(s) of the incident and robustly reduce, manage or control future risk of harm. These should be logged in the action plan.

Clearly explain in the investigation report how action plans and solutions were developed, which tools were used, if any, (for example, barrier analysis to assess effectiveness of controls in place and to design new or more robust controls/solutions), and who was invited to help (for example, system designers, those involved in the incident).

Development of solutions might usefully include consideration of the following:

- understanding that retraining is not always the right solution;
- wise use of checklists, policies and protocols;
- minimised dependency on short term memory and attention span;
- simplification of tasks and processes;
- standardisation of tasks and processes;

- avoidance of fatigue (review of working hours);
- cost benefit analysis and risk assessment;
- alignment with evidence-based practice;
- alignment with organisational priorities and risk registers.

As with recommendations, action points and/or solutions should:

- be clearly linked to identified root cause(s) or key learning point(s); (addressing the problems rather than the symptoms);
- address all of the root causes and key learning points;
- be designed to significantly reduce the likelihood of recurrence and/or severity of outcome;
- be clear and concise and kept to a minimum wherever possible;
- be Specific, Measurable, Achievable, Realistic and Timed (SMART) so that changes and improvements can be evaluated;
- be assessed for resource needs, risks and impact;<sup>8</sup>
- be prioritised wherever possible (for example following risk/cost benefit analysis);
- be categorised as:
  - o those **specific** to the area where the incident happened;
  - o those that are **common** only to the organisation involved;
  - o those that are **universal** to all and, as such, have national significance.

Solutions might also include:

- provision of ongoing support of patients and staff effected by the incident.

The action plan should be in a format that can be presented to the Board and attached to an executive summary for internal circulation following approval of recommendations.<sup>9</sup>

## 4.2 Action plan - risk/impact assessment

Risk assessments (using your organisation risk assessment processes) conducted during the recommendation or action planning process should be included in the report. Even positive changes have

the potential to produce adverse effects elsewhere in a system as complex as healthcare. The risk assessment should:

- identify and address any material downsides to recommendations or solutions;
- demonstrate the expected impact of solutions, or decisions not to act;<sup>8</sup>
- identify any priority in terms of expected effectiveness and ease of implementation.

## 4.3 Implementation, monitoring and evaluation arrangements

This section should demonstrate clearly the arrangements in place to successfully deliver the action plan.

Ideally, overseeing committees should plan and request final review or risk assessment to be conducted at around one year post-implementation, to ensure recommendations and solutions have been adopted and that changes designed to reduce risk have been successful.

### Activities for the action plan

Activity	Associated actions
<b>Implement</b>	For example, piloted, roll-out, phased, championed). <sup>10</sup>
<b>Monitor</b>	For example, monthly monitoring by the organisation governance committee or progress report compiled by risk manager.
<b>Evaluate</b>	For example, assessing the impact of changes/solutions introduced (this could include conducting an impact analysis, <sup>8</sup> reviewing incidence/severity of recurrence).

<sup>8</sup> See 4.2 and the 'Solutions option appraisal and impact analysis template' at [www.npsa.nhs.uk/rca](http://www.npsa.nhs.uk/rca)

<sup>9</sup> See 'Action plan template' at [www.npsa.nhs.uk/rca](http://www.npsa.nhs.uk/rca)

<sup>10</sup> NHS Sustainability Model and Guide 2002' at: [www.institute.nhs.uk](http://www.institute.nhs.uk)

# Section 5: Appendices

## Appendix 1: Prompts for terms of reference

The following are thoughts which may prompt or inspire development of standard or individual terms of reference for investigations. They have been provided to allow you to make notes of your own thoughts next to them.

Prompt	Notes
Accountability	
Agreeing recommendations and action plan	
Assurance frameworks	
Awareness	
Building confidence in organisation	
Closure	
Communication	
Encouraging reporting	
Explanation	
Identifying system failures	
Identifying trends	
Improving practice	
Informing patients/carers/families	
Issuing an apology	
Learning and sharing	
Litigation	
Ongoing review – audit/monitoring	
Ownership	
Prevention	
Promoting an open and fair culture	
Quality assurance	
Referral on, if potential disciplinary or performance issues are flagged	
Remedial action	
Resolving complaints	
Support staff	
Transparency	
Valuing staff	

## Appendix 2: Prompts for investigation report distribution list

This list will help with ideas when developing an investigation report distribution list.

Action plan implementers	Monitor
Care Standards Improvement Partnership	National Clinical Assessment Service
Clinical Governance and Complaints Committees	National Confidential Enquiry into Patient Outcome and
Clinical Risk Group	National Confidential Inquiry into Suicide and Homicide by People with Mental Illness
Clinical team members involved	National Institute for Health and Clinical Excellence
Commissioners	National Institute for Mental Health Executive
Confidential Enquiry into Maternal and Child Health	NHS Litigation Authority (CNST & RNST)
Commissioning Primary Care Organisation	NPSA & National Reporting and Learning System
Coroner	Overview and Scrutiny Committees
Counter Fraud and Security Management Service	PALS and PPI Forums
Department of Health Investigations Unit	Patient Experience Committee
Environmental Health agencies	Patient/carers/family
Executive Directors	Police
General Medical Council	Prison Service
Legal services – claims	Protection of Vulnerable Adults
Nursing Midwifery Council	Regional Office (Wales)
Health & Safety Executive Reporting of Injuries, Diseases & Dangerous Occurrences Regulation	Risk Management Team
Health Protection Agency	Royal Colleges and professional bodies
Health Service Ombudsman	Service Directors/Managers
Healthcare Commission	Social Services (Child Protection/Mental Health)
Commissioning Primary Care Organisation	Staff newsletter
Local Authority	Staff
Local Supervisory Authority (Midwifery Officer)	Strategic Health Authority/Patient Safety Action Team
Media	Trade Unions representing staff (NB: issues of confidentiality)
Medical Director/accountable Director for Risk	Trust/Local Health Board
Medicines and Healthcare products Regulatory Agency	Mental Health Act Commission

Good practice principles from North and East Yorkshire and Northern Lincolnshire Trusts (NEYNL)

## Section 6: Bibliography

National Patient Safety Agency. *Being open when patients are harmed*: [www.npsa.nhs.uk/patientsafety/alerts-and-directives/notices/disclosure/](http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/notices/disclosure/)

*Canadian root cause analysis framework – A tool for identifying and addressing the root causes of critical incidents in healthcare*. Canadian Patient Safety Institute, Institute For Safe Medication Practices Canada, and Saskatchewan Health. ISBN 0-9739270-1-1

CNST standards and assessment: [www.nhs.uk/RiskManagement/CnstStandards/](http://www.nhs.uk/RiskManagement/CnstStandards/)

Data Protection Act: [www.ico.gov.uk/what\\_we\\_cover/data\\_protection.aspx](http://www.ico.gov.uk/what_we_cover/data_protection.aspx)

Department of Health. *Independent investigation of adverse events in mental health services*. June 2005 [www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH\\_076535](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_076535)

Good practice principles from North and East Yorkshire and Northern Lincolnshire Trusts (NEYNL)

HSG (94)27: Guidance on the discharge of mentally disordered people and their continuing care in the community and Investigation of adverse events in mental health services (June 05 - amends paras 33-36 of circular) [www.dh.gov.uk](http://www.dh.gov.uk)

Incident Decision Tree [www.npsa.nhs.uk/idt](http://www.npsa.nhs.uk/idt)

Independent investigations of serious patient safety incidents in mental health services: Good practice guide. [www.npsa.nhs.uk/nrls/alerts-and-directives/directives-guidance/mental-health/](http://www.npsa.nhs.uk/nrls/alerts-and-directives/directives-guidance/mental-health/)

International Classification of Patient Safety Events (ICPSE) - World Health Organization [www.who.int](http://www.who.int)

Learning through action to reduce infection. [www.npsa.nhs.uk/nrls/improvingpatientsafety/humanfactors/infection-control](http://www.npsa.nhs.uk/nrls/improvingpatientsafety/humanfactors/infection-control)

Memorandum of understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm. [www.dh.gov.uk/en/Consultations/Closedconsultations/DH\\_409017](http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_409017)

Modernisation Agency's NHS Sustainability model and guide 2002 NHS Institute for Innovation and Improvement [www.institute.nhs.uk](http://www.institute.nhs.uk)

National Institute for Health and Clinical Excellence. How to change practice: understand, identify and overcome barriers to change. Available at: [www.nice.org.uk/usingguidance/implementationtools/howtoguide/barrierstochange.jsp](http://www.nice.org.uk/usingguidance/implementationtools/howtoguide/barrierstochange.jsp)

RCA Toolkit. [www.npsa.nhs.uk/rcatoolkit/](http://www.npsa.nhs.uk/rcatoolkit/)

Risk assessment made easy. [www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/risk-assessment-guides/](http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/risk-assessment-guides/)

Risk matrix for risk managers [www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/risk-assessment-guides/risk-matrix-for-risk-managers/](http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/risk-assessment-guides/risk-matrix-for-risk-managers/)

Safer care [www.institute.nhs.uk/safer\\_care](http://www.institute.nhs.uk/safer_care)

National Patient Safety Agency. *Seven steps to patient safety*. [www.npsa.nhs.uk/sevensteps/](http://www.npsa.nhs.uk/sevensteps/)

The Joint Commission Sentinel events policy [www.jointcommission.org](http://www.jointcommission.org)

# Section 7: Acknowledgements

This report was compiled with valuable information, help and advice provided by:

- Donna Forsyth, Head of Reporting and Local Improvement, National Patient Safety Agency
- Alison Prizeman, Patient Safety Consultant, NHS South East Coast
- Bridget James, Patient Safety Manager, NHS South West
- John Morrison, Patient Safety Manager, NHS East of England
- North and East Yorkshire and Northern Lincolnshire Trusts (NEYNL)
- Dr Christine Jorm, Senior Medical Advisor, Australian Commission on Safety and Quality in Health Care
- Bryce Cassin, Manager Clinical Safety and Quality Projects, Australian Commission on Safety and Quality in Health Care
- Colin Phillips, Head of Investigations, Department of Health
- Peter Walsh, Chief Executive, Action against Medical Accidents (AvMA)
- Malcolm Alexander, National Association of LINKs Members
- Katherine Murphy, Director of Communications, The Patients Association
- Sue Line, National Association for Patient Participation
- Brian Toft, Professor of Patient Safety, Applied Research Centre, Coventry University
- Chris Brougham, Training Consultant, Verita