Patient Safety:
How can we find out what went wrong?

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The European Association of Hospital Pharmacists (EAHP) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education
UPN 475-000-09-017-L04-P

Schedule

- 9:00 to 10:30 principles and methodology of risk management
- 11:00 to 12:30 risk analysis: tools and how to use
- 14:00 to 15:30 medication errors
- 16:00 to 18:00 workshop, presentation and discussion of results

why, why, why do we need RCA

- RCA is a structured investigation that aims to identify the true cause(s) of a problem, and the actions necessary to eliminate it

- The main objectives are learning, and system improvement for the organisation and others

Details in RCA Report

- Evidence based practice – evidence based RCA's
  - Details of aims and objectives
  - Details of investigators
  - Investigation methods
  - Investigation finding
  - Recommendations
  - Action plan
  - Evaluation plan
- Enable independent review and validation of RCA report

JCI Template for RCA and Action Plan

A Framework for a Root Cause Analysis and Action Plan
In Response to a Sentinel Event

Level of Analysis		Questions	Findings	Root Cause?	Ask "Why?"	Take Action
What happened?	Sentinel Event	What are the details of the event? (Brief description)				
		When did the event occur? (Date, day of week, time)				
		What area/service was impacted?				
Why did it happen?	The process or activity in which the event occurred	What are the steps in the process, as designed? (A flow diagram may be helpful here)				

Root Cause Analysis Investigation Tools

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

www.npsa.nhs.uk/nrls

Root Cause Analysis Investigation Tools

Three levels of RCA investigation – guidance

Level 1 – Concise investigation

Level 2 – Comprehensive investigation

Level 3 – Independent investigation

Level 1 – Concise investigation

- Most commonly used for incidents, claims, complaints or concerns that resulted in no, low or moderate harm[1] to the patient.
- Also useful as an executive summary to communicate findings from full, comprehensive or independent investigation reports, following actual or potential 'severe harm or death' outcomes.
- Commonly involves completion of a summary or one page structured template.
- Includes the essentials of a thorough and credible investigation,[2] conducted in the briefest terms.
- Involves a select number of RCA tools (e.g. timeline, 5 why's, contributory

Level 2 – Comprehensive investigation

- Commonly conducted for actual or potential 'severe harm or death'[1] outcomes from incidents, claims, complaints or concerns.
- Conducted to a high level of detail, including all elements of a thorough and credible investigation.[2]
- Includes use of appropriate analytical tools (e.g. tabular timeline, contributory factors framework, change analysis, barrier analysis).
- Normally conducted by a multidisciplinary team, or involves experts/expert opinion/independent advice or specialist investigator(s).
- Conducted by staff not involved in the incident, locality or directorate in which it occurred.

Level 3 – Independent investigation

As per Level 2, but in addition:

- Must be *commissioned and conducted* by those independent to the provider service and organisation involved.
- Commonly considered for incidents, claims, complaints or concerns of high public interest or attracting media attention.
- Conducted for mental health homicides which meet Department of Health guidance.[3]
- Should be conducted where Article 2 of the European Convention on Human Rights is, or is likely to be, engaged.

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Comprehensive and Independent Investigation Report Template

- See associated NPSA quick ref. guide, or the more detailed 'RCA investigation report writing guidance'
- Save the document with the chosen file name. Always include a version number in the filename.
- On completion ensure all guidance (in green) is deleted

[Add trust logo]

Root Cause Analysis Investigation Report

Terms of reference

Purpose

To identify the root causes and key learning from an incident and use this information to significantly reduce the likelihood of future harm to patients

Objectives

To establish the facts i.e. **what** happened (*effect*), to **whom**, **when, where**, **how** and **why** (*root causes*)

To establish whether failings occurred in care or treatment

To look for improvements rather than to apportion blame

To establish how recurrence may be reduced or eliminated

To formulate *recommendations and an action plan*

To provide a *report and* record of the investigation process & outcome

To provide a means of *sharing learning* from the incident

To identify routes of *sharing learning* from the incident

Key questions/issues to be addressed

...specific to this incident or incident type

Key Deliverables

Investigation Report, Action Plan, Implementation of Actions

Pre-investigation risk assessment

A Potential Severity (1-5)	B Likelihood of recurrence at that severity (1-5)	C Risk Rating (C = A x B)

Post-investigation risk assessment

A Potential Severity (1-5)	B Likelihood of recurrence at that severity (1-5)	C Risk Rating (C = A x B)

The RCA 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

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

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RCA Investigation Training: Guidance, Tools and Templates – A User Guide

Why things go wrong

Human factors

- those elements that influence the performance of people operating equipment or systems; they include behavioural, medical, operational, task-load, machine interface and work environment factors

- human factors (also known as Ergonomics) the environmental, organisational, job factors, human and individual characteristics which influence behaviour at work

Systems view

- Human errors are induced by system failures.
- Evidence from other ‘high reliability’ industries suggests that systematic investigation of adverse incidents is effective.

Causal factors

Understanding the causal factors of incidents

Person centred approach

- Individuals who make errors are ‘careless, at fault, reckless’
- Blame and punish
- Remove individual = improve safety

Systems approach

- Poor organisational design sets people up to fail
- Focus on the system rather than the individual
- Change the system = improve safety

HUMAN FACTORS ENGINEERING

Human factors engineering design demonstrations can enlighten your RCA team

J Gosbee, T Anderson

Qual Saf Health Care 2003;12:119–121

A case study is presented, based on the experience of the US Veterans Affairs health system, which shows the benefits of healthcare personnel understanding human factors engineering (HFE) and how it relates to patient safety. After HFE training, personnel are better able to use a systems-oriented approach during adverse event analysis. Without some appreciation of HFE, the focus of adverse event analyses (e.g. root cause analysis (RCA)) is often misguided towards policies or an individual's shortcomings, leading to ineffective solutions. The case study followed the investigation by an RCA team of a retained sponge following cardiac surgery. The team began with a focus on the specific failings of the surgical nurse and outdated policies. HFE design demonstrations were used to redirect the team's focus to more systems-oriented issues, which could be uncovered even when events appeared to be related to policy or training, and to point them towards examining the design of systems that contributed to the event. The team was thus able to identify design flaws and make improvements to the design of the forms and computer systems that were key to preventing such events from recurring.

The RCA Investigation Process

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Getting started

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Which incidents To RCA

- Classify according to
  - the degree of harm or damage caused at the time
  - its realistic future potential for harm if it occurred again

RCA investigation team
(Deaths and Severe harm)

Select People for the RCA Investigation Team

Multidisciplinary group of 3-4 persons

One of which should be fully trained in incident investigation and analysis

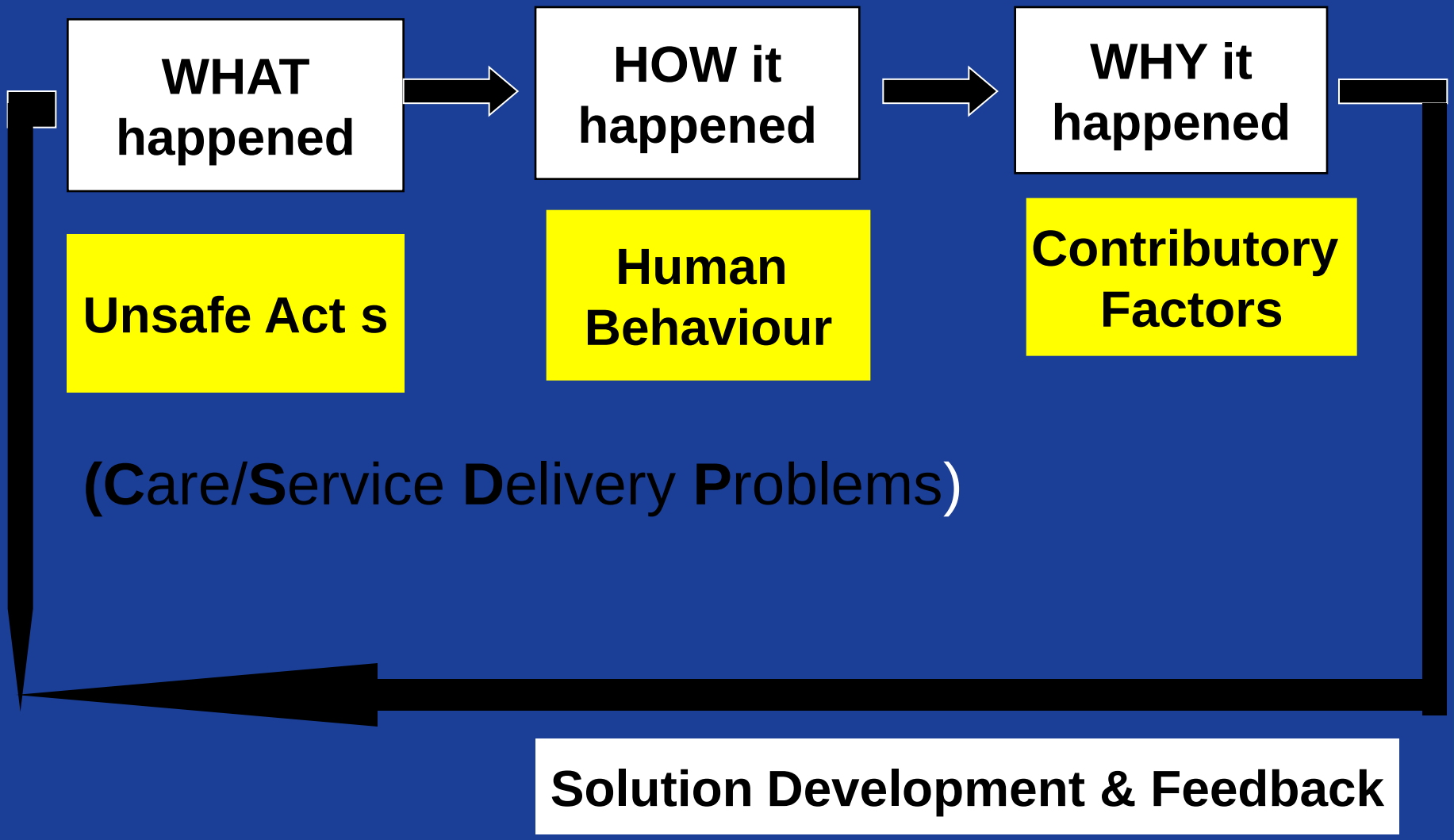
Objective attitude

Good organisational skills

Use of experts

Of course its MEDICINES and we are the experts in medicines, we should/must be there!

Basic elements of RCA

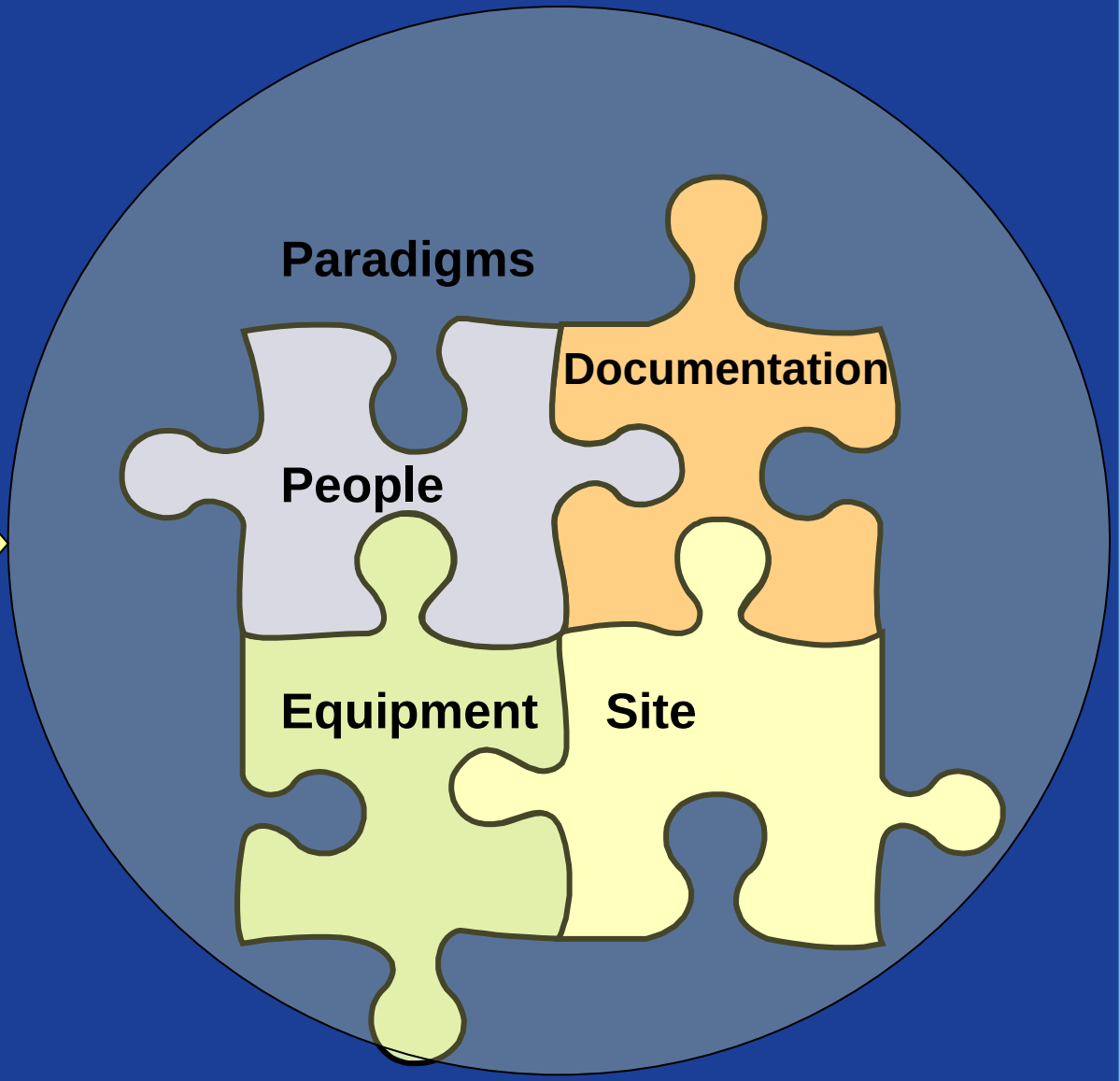


Gathering and mapping information

Gathering information

- Information is the lifeblood of investigation
- 60% of your investigation time should be spent on data gathering

What Information to collect?



People

- Personnel directly involved in the incident & Other witnesses
  - Clinical staff
  - Patient/family
  - Porters
  - Health care assistants
  - Ward clerks
  - members of the public, etc

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).

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).

Documentation

- Incident report(s)
- Prescription, dispensing and administration record
- Medical record
- Guidelines, policy and procedures (in operation at the time of the incident)
- Relevant audit data (clinical, risk management, H&S)
- Staff rota's
- Training and supervision records
- Medical equipment maintenance records
- ... and more

Equipment

Any equipment involved in the incident

- Medicine pack, ampoules, pack information
- Infusion bag and administration set
- Infusion pump

Site

Consider the following

- Securing the site
- Take some photographs
- Sketch the layout
- What was the position of the equipment/ people?
- Reconstruction

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.

3.9 Involvement and support of the patient, relatives or carers

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.

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Analysing Information

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Identifying the root causes

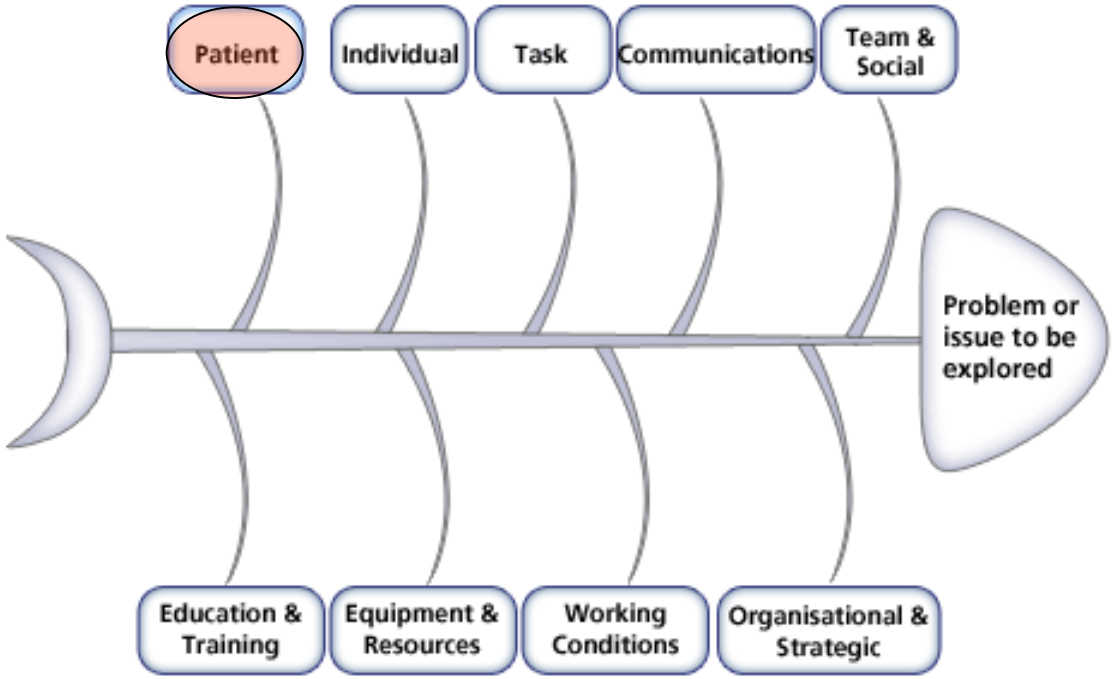
- Identify the contributory factors having the biggest impact on system failure = ROOT CAUSEs
- A Root Cause is a fundamental cause which if resolved will eradicate, or significantly contribute to the resolution, of the identified problem to which it is attached both within the local department and more widely across the organisation

Contributory factor taxonomy

- Patient Factors
- Individual Factors
- Task Factors
- Communication Factors
- Team and Social Factors
- Education and Training Factors
- Equipment and Resource Factors
- Working Conditions Factors
- Organisational & Strategic Factors

Contributory factors - NPSA framework

The key part of the analysis is to identify the contributory factors lying behind each problem. The NPSA's CFF has categories and components relating to exploring incidents. Click each category to find out more.



Patient factors

Patient factors are grouped into five types:

- Clinical condition
- **Social factors**
- Physical factors
- Mental and psychological factors
- Interpersonal relationships

Example: The patient did not understand the risks of treatment due to his poor understanding of the English language and no interpreters were available.

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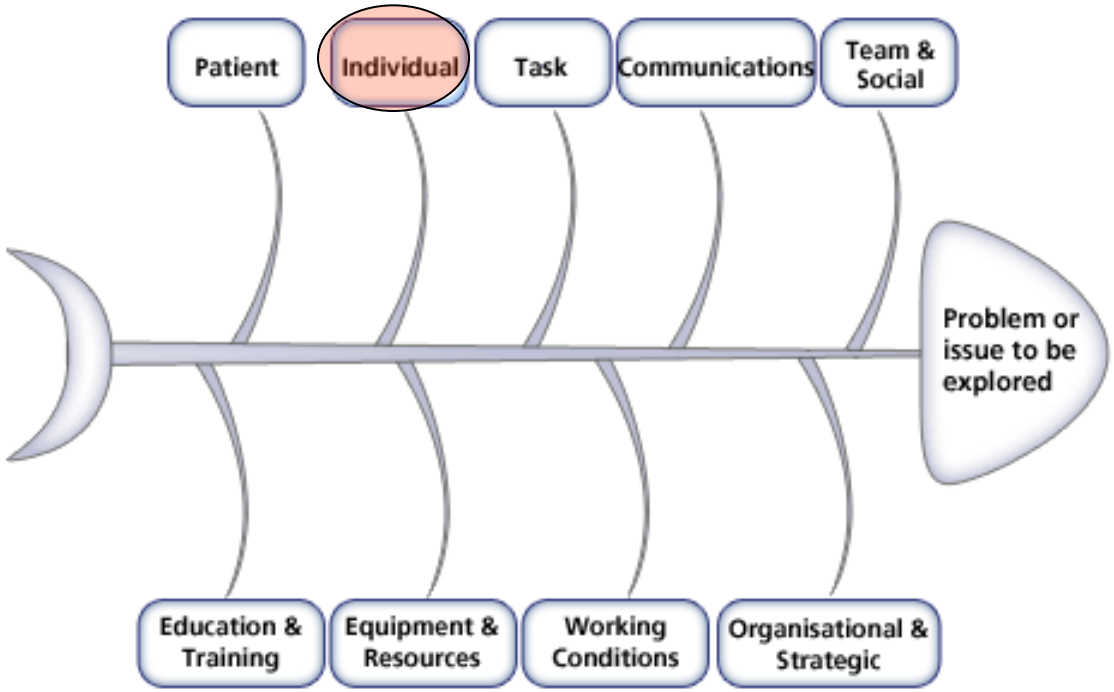

Individual factors

Individual factors are grouped into three types:

- **Physical Issues**
- Psychological Issues
- Personality.

Example: A staff nurse experiencing problems with hearing and misheard handover instructions to patient.

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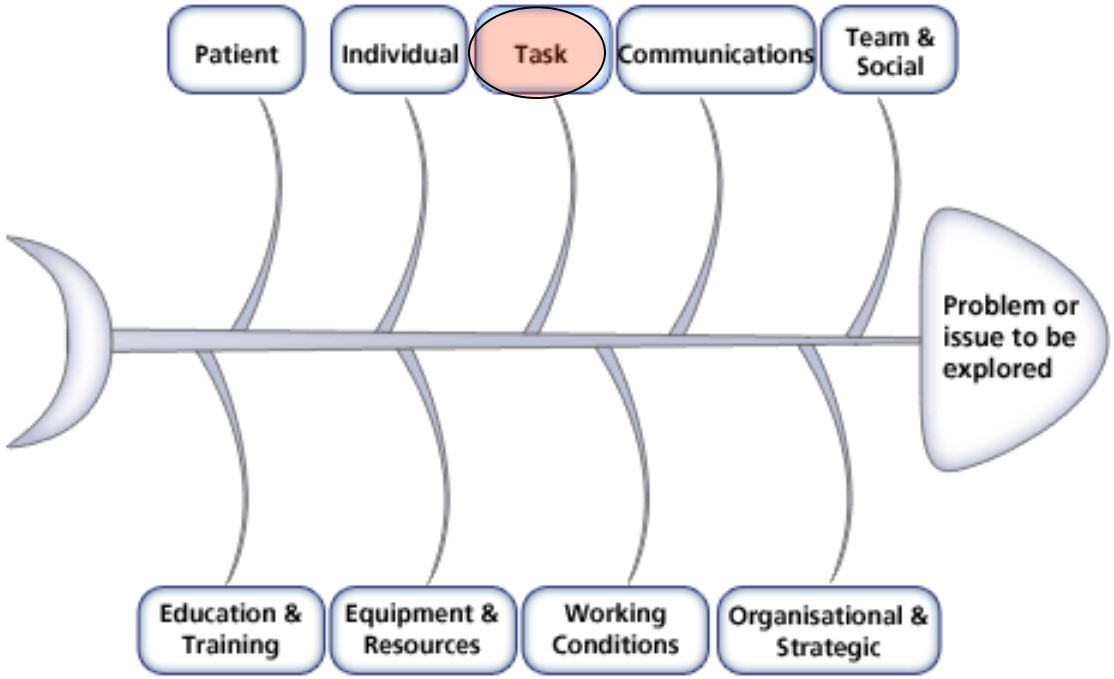

Task factors

Task factors are grouped into three types:

- Guidelines and Policies
- **Decision making aids**
- Task design

Example: The algorithm for managing respiratory arrest had a vital component missing.

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Communication factors

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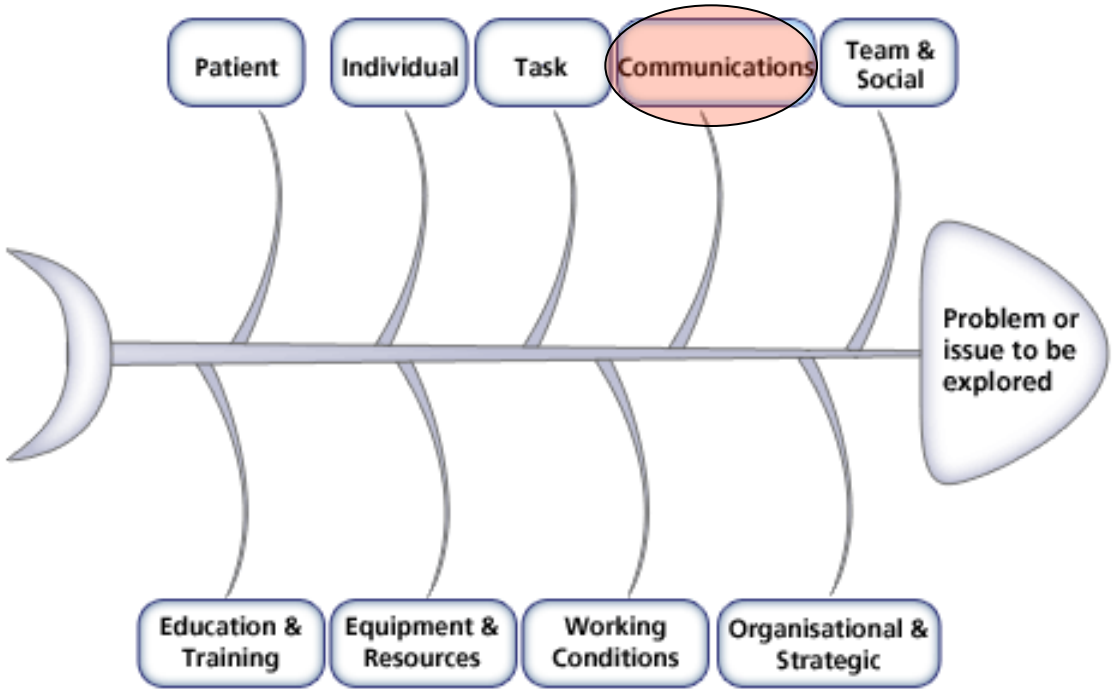

Communications factors are grouped into three types:

- **Verbal**
- Written
- Non-verbal.

Example: Relatives interpret GP's instructions to patient wrongly due to limited understanding of language.

Click **Next** to continue

Descriptions of verbal communication errors between staff. An analysis of 84 root cause analysis-reports from Danish hospitals

Method: Two independent raters analysed 84 RCARs, conducted in six Danish hospitals between 2004 and 2006, for descriptions and characteristics of verbal communication errors such as handover errors and error during teamwork.

Results: Raters found description of verbal communication errors in 44 reports (52%). These included handover errors (35 (86%)), communication errors between different staff groups (19 (43%)), misunderstandings (13 (30%)), communication errors between junior and senior staff members (11 (25%)), hesitance in speaking up (10 (23%)) and communication errors during teamwork (8 (18%)). The kappa values were 0.44–0.78. Unproceduralized communication and information exchange via telephone, related to transfer between units and consults from other specialties, were particularly vulnerable processes.

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Team & Social factors

Contributory factors - NPSA framework

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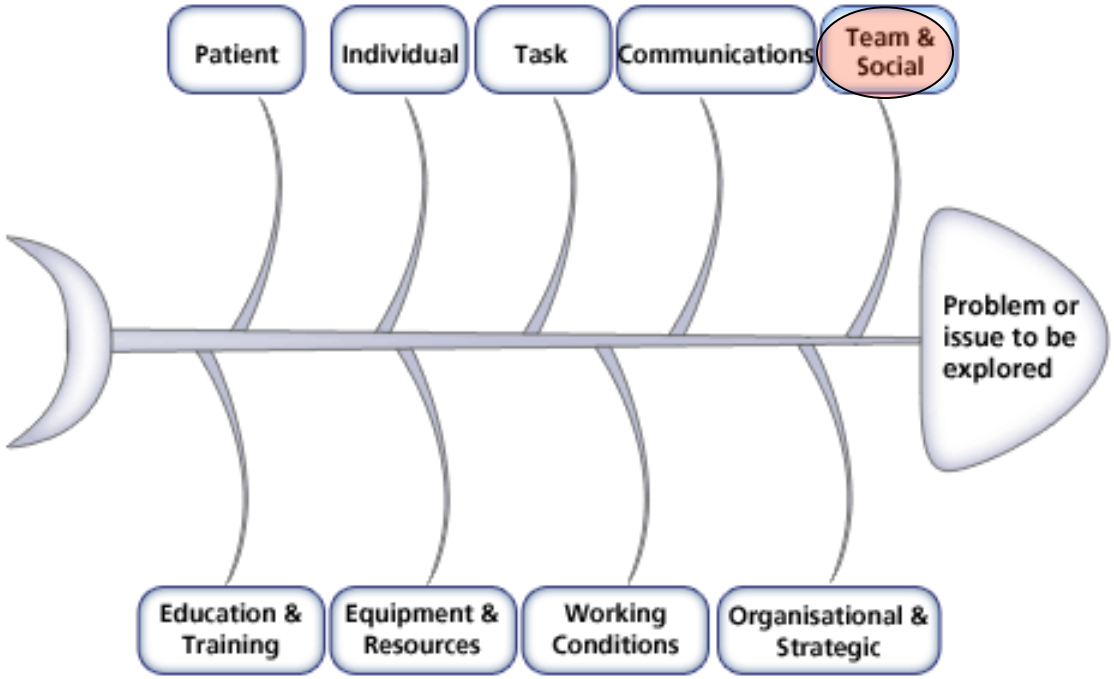

Team and social factors are grouped into three types:

- Role congruence
- Leadership
- **Support and cultural factors.**

Example: Multi-disciplinary team rarely met and the weekly Directorate meeting was for doctors only.

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Exploring Incidents - Improving Safety

Education & Training factors

Contributory factors - NPSA framework

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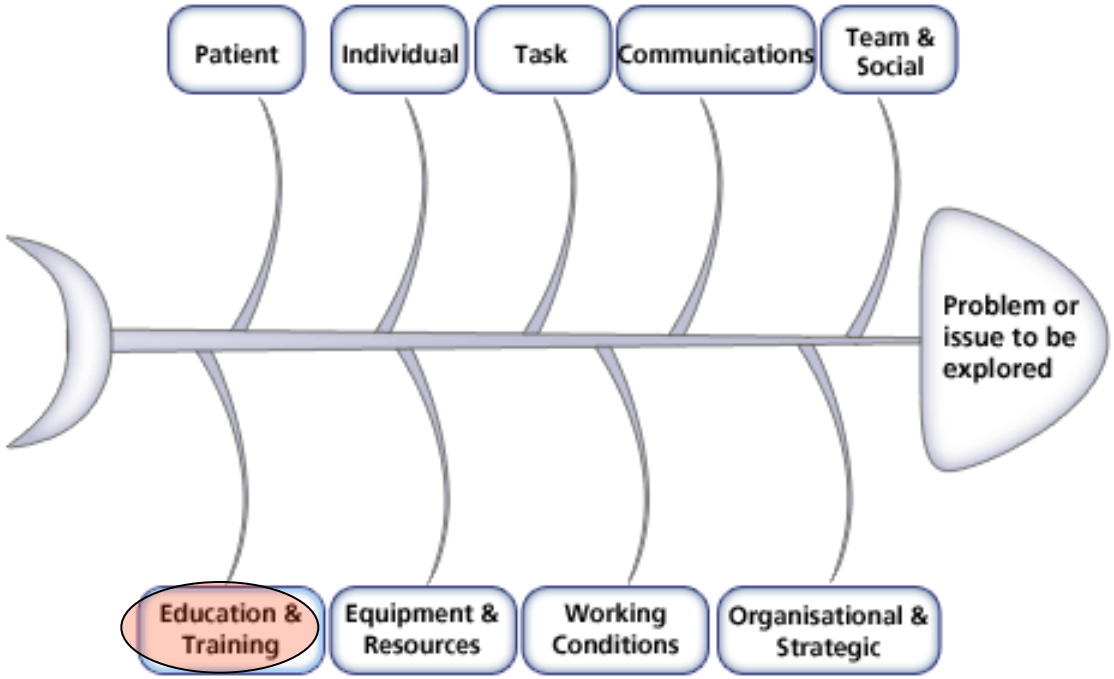


These factors are grouped into four types:

- **Education/training**
- Appropriateness
- Supervision
- Availability

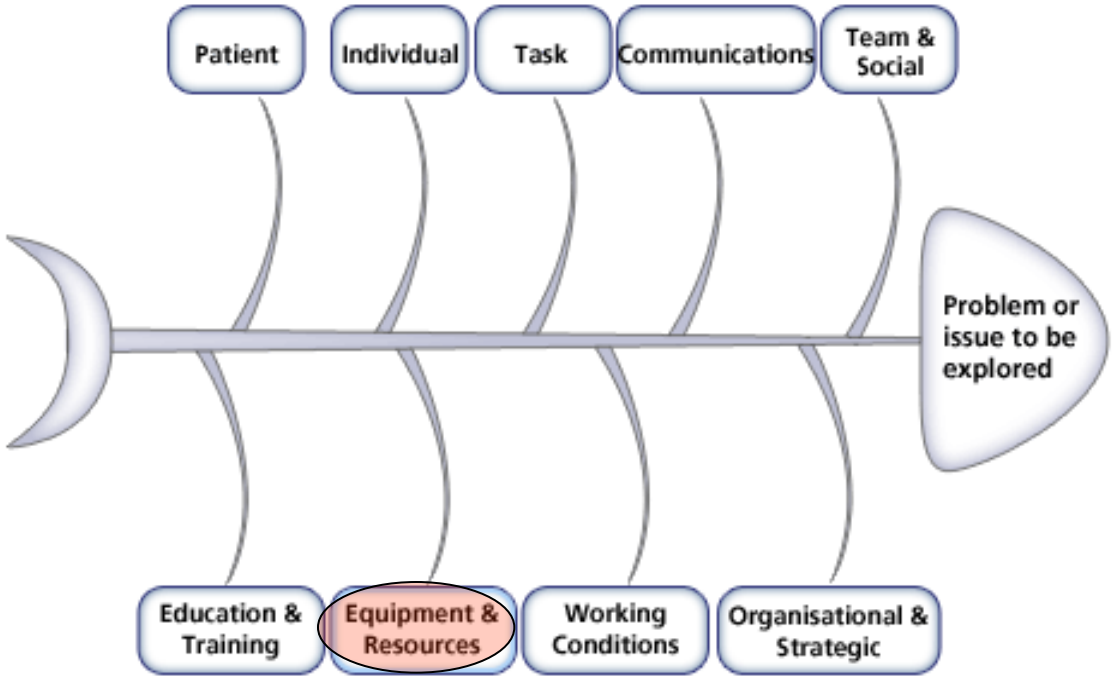
Example: Standards of care were not met as new care assistants at ward level were trained by someone who was competent as a practitioner but had no training expertise or experience.

Click **Next** to continue

Equipment & Resources factors

Contributory factors - NPSA framework

The key part of the analysis is to identify the contributory factors lying behind each problem. The NPSA's CFF has categories and components relating to exploring incidents. Click each category to find out more.



Equipment and resources factors are grouped into five types:

- Equipment and supplies
- Visual Display
- **Integrity**
- Positioning
- Usability

Example: A patient's oxygen levels dropped causing respiratory arrest. The alarm on the monitor was faulty.

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Working Conditions factors

Contributory factors - NPSA framework

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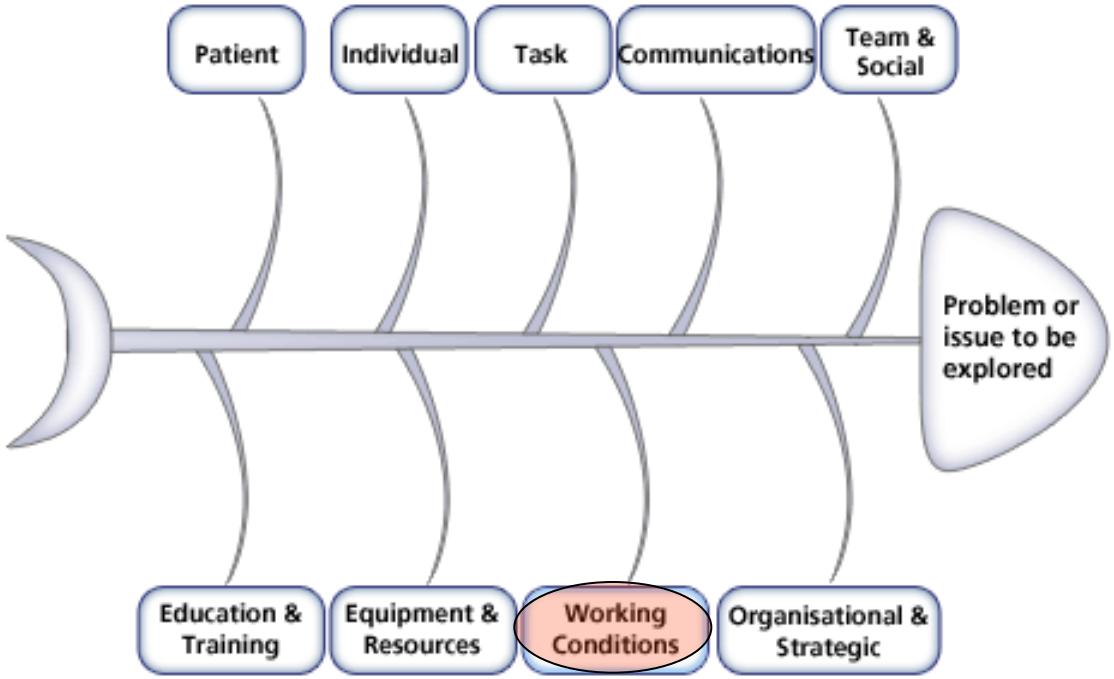

Working conditions factors are grouped into four types:

- **Administrative**
- Design of physical equipment
- Staffing
- Time

Example: Previous medical records were not available for clinical staff to plan treatment and care for an emergency admission, therefore delaying clinical decisions and treatment.

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Organisational & Strategic factors

Contributory factors - NPSA framework

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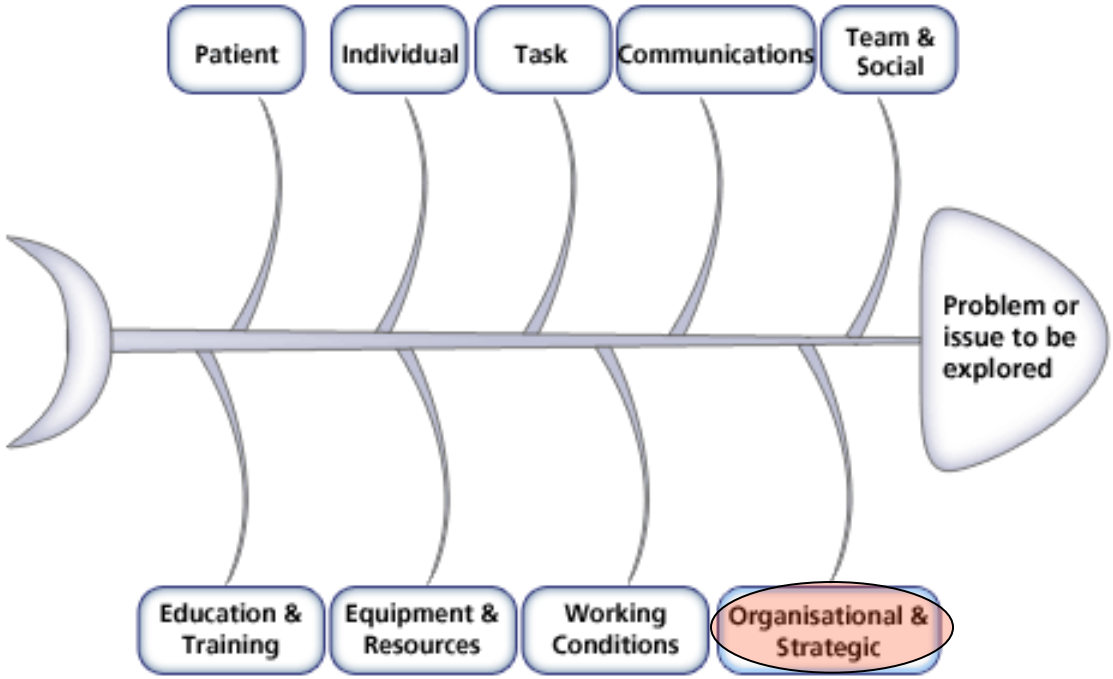


These factors are grouped into five types:

- Organisational structure
- Policy, standards, goals
- Externally imported risks
- **Safety culture**
- Priorities

Example: The ambulance crew would not lift 20 stone cardiac patient as it would put them at risk.

Click **Next** to continue

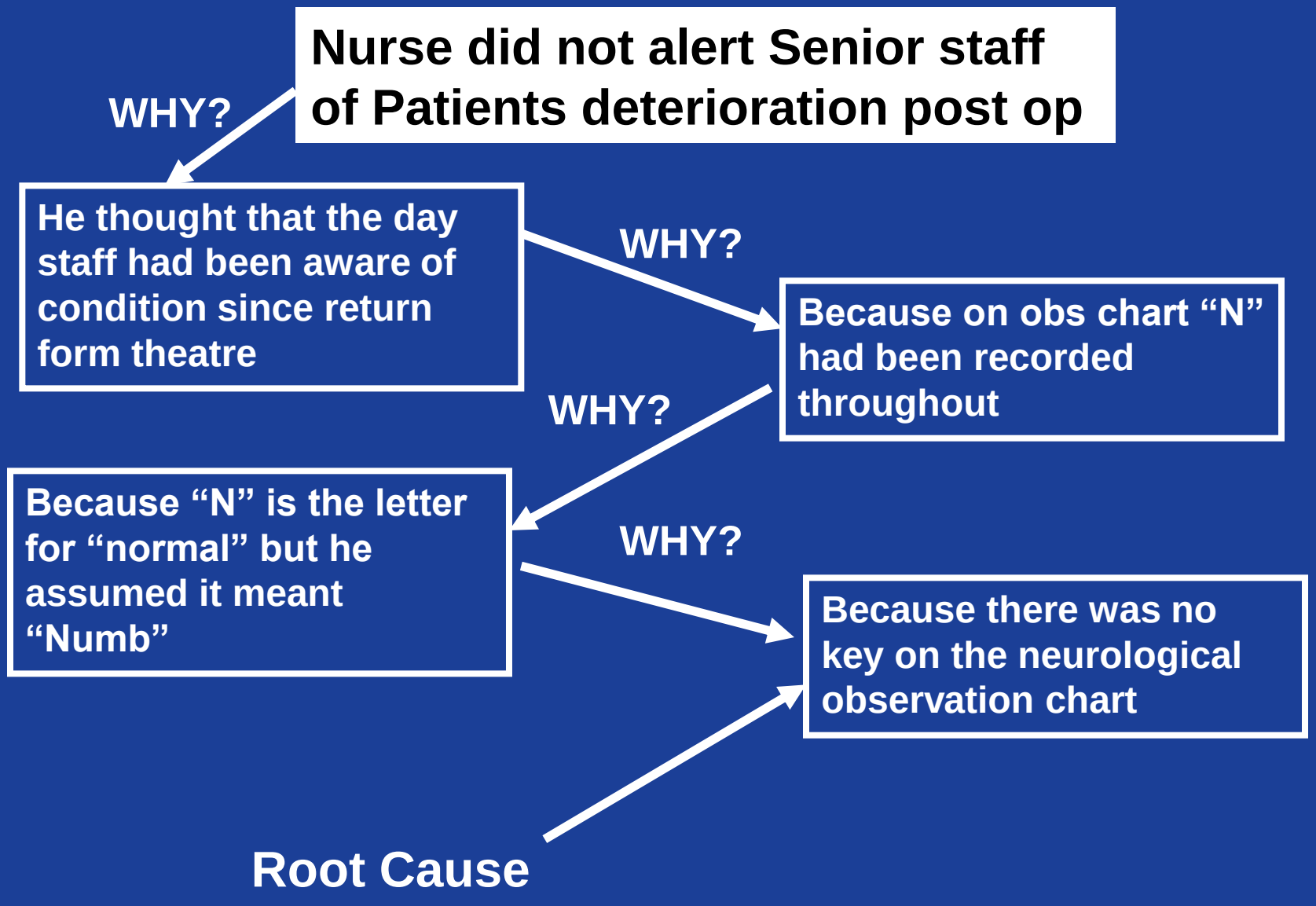
Organisational factors

- Similar medication incidents previously reported
- Culture – volume of medication incidents reported from the clinical area
- Clinical pharmacy input into the clinical area

Five whys

- Tool that enables investigator(s) to identify the causes for each problem.
- Best suited to simple and non-complex problems.
- Quick and easy to teach
- 3 – 5 – 7 whys?

Five why questions



Run charts

Purpose

- To identify trends and patterns in a process, over a specific period of time.

How to Construct Run Charts

- Decide what the chart will measure (what data over what period of time.
- Draw graph

Run charts example

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Generating Solutions

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Generating solutions

- Keep it Simple
- List all recommendations for change and prioritise for effective implementation
- Draw up an Action Plan
- Involve Patients and Staff

Key principles for solution design

- Design tasks and processes to minimise dependency on short-term memory and attention span
- Avoid fatigue: review working hours and workloads
- Retraining is not always the right solution
- Simplify tasks, processes, protocols, equipment
- Standardise processes and equipment
- Use protocols and checklists wisely

What is a barrier

A control measure designed to prevent harm to

- **People**
- **Buildings**
- **Organisations**
- **Products**
- **Communities**

When can barrier analysis be used?

Prospectively to identify possible ‘Hazards’ their ‘Targets’ and potential solutions

Reactively following a patient safety incident to identify the ‘Barriers’ that should have been in place to have prevented or mitigated against an incident

Barrier analysis cont'd

- Evaluate the list of barriers as strong, average or weak - any barrier involving human action is marked down
- Record the findings
- Remember barrier analysis can be used proactively or reactively!

Performing a reactive analysis

Event:

Prevention Barriers in Place	Did the Barrier Fail?	Why?	How Barrier affect the outcome of event?

Performing a pro-active barrier analysis

Activity **Target**

Hazard(s)	Barriers in place?	Failsafe ? S/M/W	Improve by?	Additional barriers required?	Cost Implic.?	Responsib. Lead?

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:
  - those **specific** to the area where the incident happened;
  - those that are **common** only to the organisation involved;
  - 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.

Action plan document

Root Cause	Actions to Address Root Cause	Level of Recommendation	By Whom	By When	Resource Required	Evidence of Completion	Sign

Report writing

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.

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.

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.

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;

Actions taken following a patient safety incident

Action	Explanation
Immediate response and recovery actions	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.
Preventative or risk-reducing actions or solutions	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).

4.3 Implementation, monitoring and evaluation arrangements

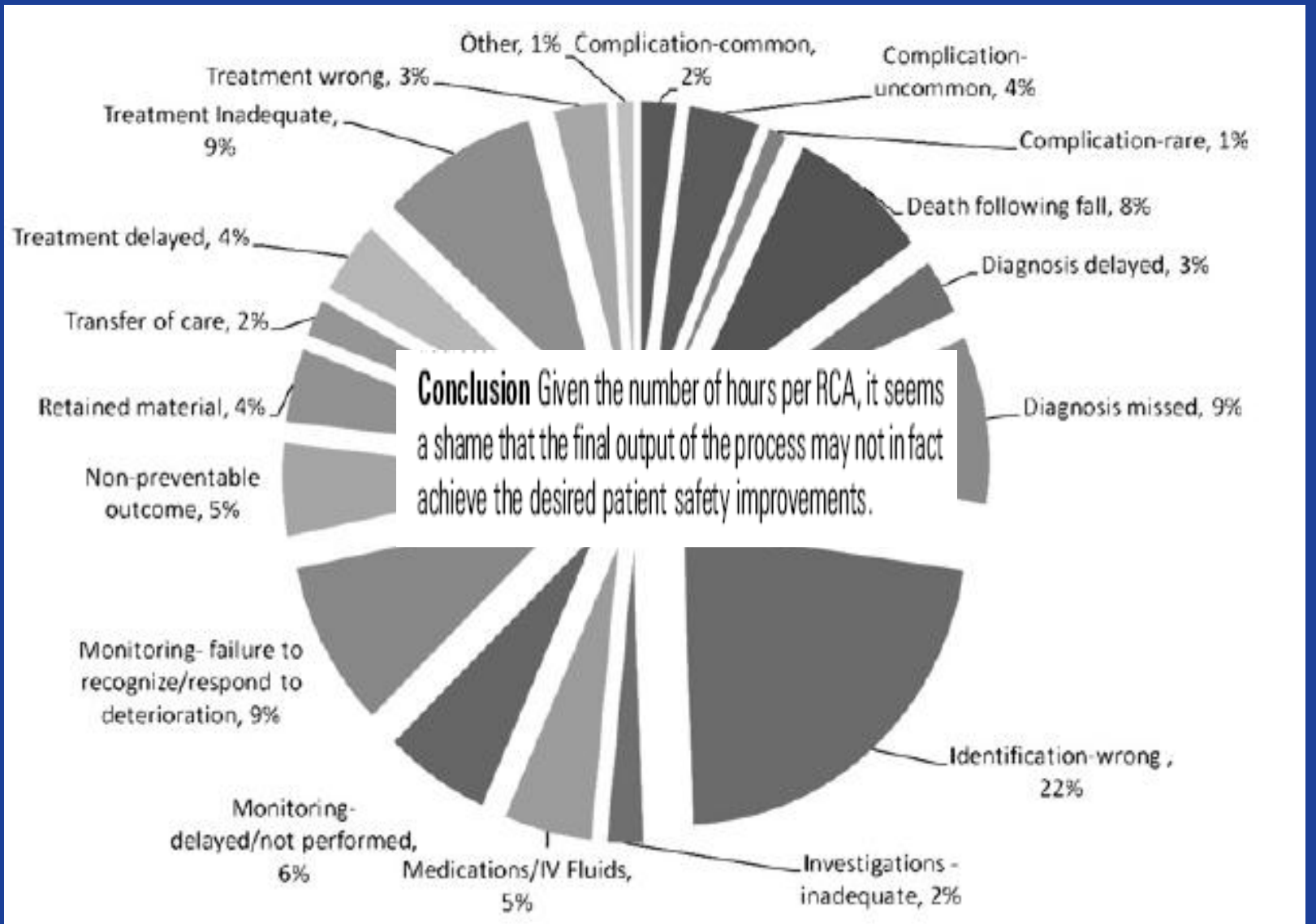
This section should demonstrate clearly the arrangements in place to successfully deliver the action plan.

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

System-wide learning from root cause analysis: a report from the New South Wales Root Cause Analysis Review Committee



Conclusion Given the number of hours per RCA, it seems a shame that the final output of the process may not in fact achieve the desired patient safety improvements.

Recommendation Category	Classification		
	Weak	Medium	Strong
Alerts/warning/labeling	■		
Checklists		■	
Expected practice - no policy	■		
Communication and documentation processes	■	■	
Education - general	■		
Education - targeted		■	
Environmental (modifications/storage)		■	■
Equipment		■	■
Counseling/directive/memo	■		
Organisation/management/rostering		■	
Policies/procedures/guidelines (incl. review)	■		
Staffing numbers or skill mix (incl. review)		■	
Workflow or process redesign			■

Our initial findings highlight the as yet untapped system-wide learning potential of the RCA methodology. It is clear that a single RCA in and of itself may provide little learning beyond the unit and staff involved. However, through aggregation of RCA data and successful dissemination strategies, healthcare workers can learn about adverse events rapidly.

One of the key lessons learnt from our committee is the value of a multidisciplinary governing body accepting responsibility for aggregating incident data and disseminating findings widely in that system or country. Critical to the process would be to review the risks identified, potential solutions and lessons learnt from individual RCAs and develop an evidence-based evaluation tool to gauge whether risks identified have led to improved patient safety on a system-wide scale.[22–24] Thought also needs to be given to the membership of such a body. Time availability, clinical background, regional and rural representation, data

Multi-incident RCA