Medicines & Healthcare products Regulatory Agency

Root cause analysis / incident reporting training

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- Why do we investigate?
- Investigation/reporting process
- Categorisation
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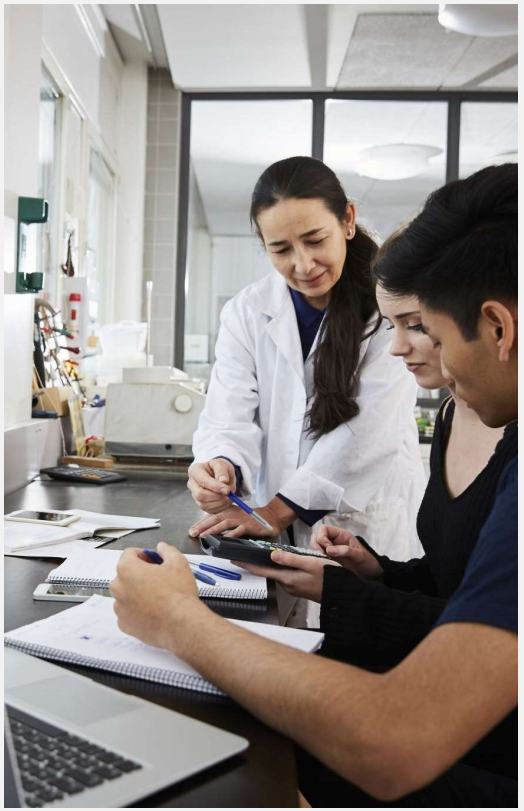
Background

- Blood Safety and Quality Regulations (BSQR) (2005) requirement
  - All Serious adverse events and serious adverse reactions to the Competent Authority (MHRA)
- Reporting to Serious Hazards of Transfusion (SHOT)
- Requirement of any total Quality Management System (QMS)
- Reporting to Trust
  - Not just statutory and mandated incident reports
  - Local (less serious?) reports
  - Good Practice Guide https://www.edqm.eu/en/good-practice-guidelines-blood-establishments



Why do we investigate?

- Correct mistakes and error
- Identify weaknesses in processes (Root cause (RC))
- Make improvements to processes (Corrective action)
- Learn from mistakes
- Manage outcomes
- Build future improvements to the QMS (Preventive action (PA))
- Ensure patient safety from a robust QMS and safe component

- It is NOT to BLAME individuals for the errors made

Common MHRA Inspection findings

The Management of deviations was deficient in that:

2.2 The assessment of Incident Root Cause and CAPA did not adequately reflect potential harm.

2.3 The incidents reviewed showed insufficient evidence of an appropriate level of investigation of root cause and implementation of CAPA.

2.4 There was no justification for the late closure of incidents.

2.5 There was no formal process for requesting investigation extensions and associated impact risk assessments.

2.6 There was no justification for the allocation of incident investigation and close out times.

2.7 SABRE reports were not made "as soon as known"

2.8 There was no detailed trending of incidents.

Reference: CoE GPG 9.4.2, 9.4.3, 9.4.4. 9.4.5, 9.4.6, 9.4.7, 9.4.8

Terms used

Correction is to correct and put right the error/event identified

Corrective action is to ensure the same mistake doesn't happen again

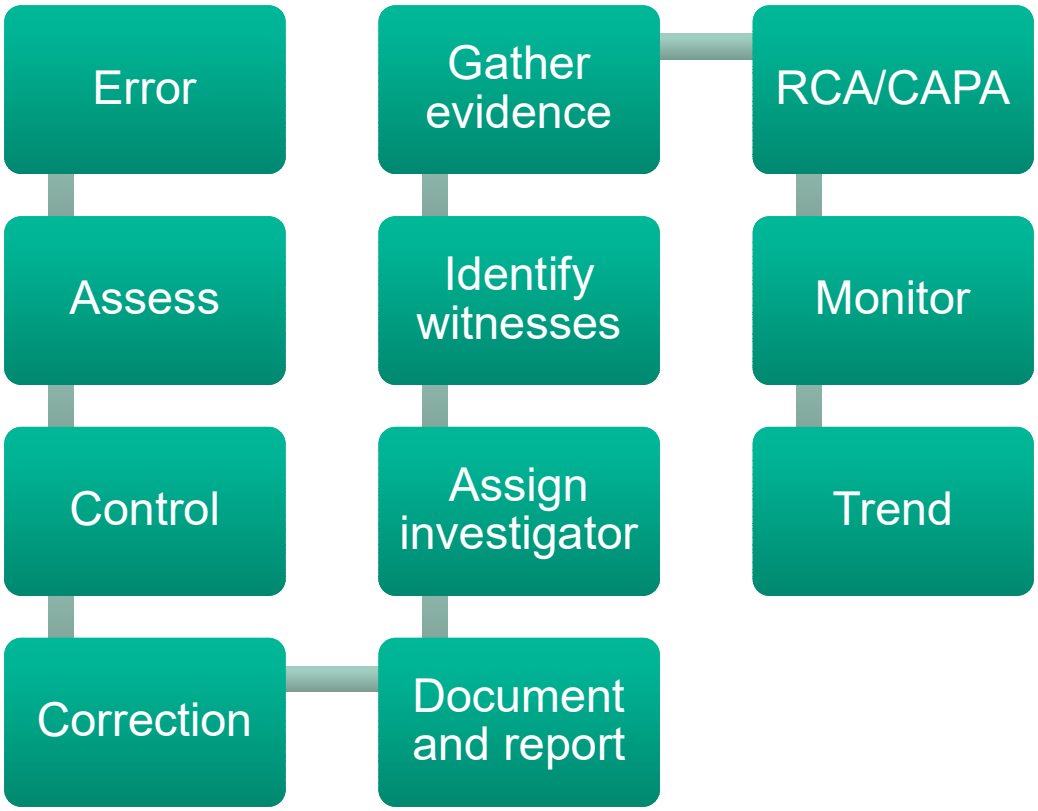
Preventive action is to prevent future, unknown errors yet to be

E.g. A locum issues non-irradiated red cells to a patient
The locum hadn't been trained in the process.

Correction – recall the units and issue correct units
Corrective action – train the locum in the correct procedure and identify training gaps
Preventive action – create an induction programme to manage the training of all new members of staff

Investigation & reporting process

Investigation/reporting process



Investigation/reporting process

- Must have an incident reporting process
  - Must be **documented** in an Standard operating procedure (SOP)
  - Must include methods of investigation, reporting and use of investigation and reporting tools, e.g. forms
  - Must meet **regulatory requirements**

Good practice guide

1.2.13. "A formal system for the handling of deviations and non-conformances must be in place. An appropriate level of root-cause analysis should be applied during the investigation of deviations, suspected product defects, and other problems. This strategy can be determined using Quality Risk Management principles. **If the true root cause(s) of the issue cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing them."**

Section 9, Non-conformance and recall, covers this in detail

What should go in a report? Regulation 12 B

(3) A person responsible for management of a reporting establishment shall ensure that the reporting establishment notifies the Secretary of State as soon as is known, using the notification formats set out in Section A of Part 8 of the Schedule, of all relevant information about serious adverse events which may put in danger donors or recipients other than those directly involved in the event concerned.

(4) A person responsible for management of a reporting establishment shall ensure that the reporting establishment—

(a)as soon as is reasonably practicable after each serious adverse event, evaluates that serious adverse event to identify preventable causes within the process;

(b)upon completion of the investigation, completes the serious adverse event notification, using the format set out in Section B of Part 8 of the Schedule; (i.e. the Confirmation report)

Good Practice Guide

Good Practice Guide Blood Guide - European Directorate for the Quality of Medicines & HealthCare (edqm.eu)

Section 9, Non-conformance and recall, covers this in detail (selected highlights below)

- "There should be systems in place to ensure that deviations, adverse events, adverse reactions and non-conformances are documented, carefully investigated for causative factors of any defect and, where necessary, followed up by the implementation of corrective actions to prevent recurrence."
- *Note: Not just "serious" but all "incidents" even those not reportable to SABRE/ SHOT (Serious Hazards of Transfusion)*
- "The corrective and preventive action (CAPA) system should ensure that existing component nonconformity or quality problems are corrected and that recurrence of the problem is prevented."

Good Practice Guide (1/3)

"The **potential impact** of the source of the deviation on other components or results should also be considered and preventive action should be taken to eliminate the root cause of the deviation and thereby avoid recurrences"

"An appropriate level of **root cause (RC) analysis** work should be applied during the investigation of deviations. In cases where the true root cause(s) cannot be determined, consideration should be given to identifying the **most likely root cause(s)** and to addressing those."

"Any errors, accidents or significant deviations …should be fully recorded and investigated in order to identify **systematic problems** that require corrective action. Appropriate CAPAs should be defined and implemented."

Good Practice Guide (2/3)

"Where **human error** is suspected or identified as the cause of the deviation, this should be formally justified and care should be exercised so as to ensure that **process, procedural or system-based errors or problems are not overlooked**, if present."

"Senior management and the Responsible Person should be notified in a timely manner of serious deficiencies, significant deviations and serious component or product defects, and **adequate resources** should be made available for their **timely resolution**."

"A **regular review** of all incidents …should be conducted, … to verify the effectiveness of the CAPAs taken"

"The decisions …should reflect the **level of risk** …as well as the **seriousness** ... Such decisions should be **timely** to ensure that **patient safety** is maintained"

Good Practice guide (3/3)

Remember..

These are ***highlights*** and not the full requirements of the GPG

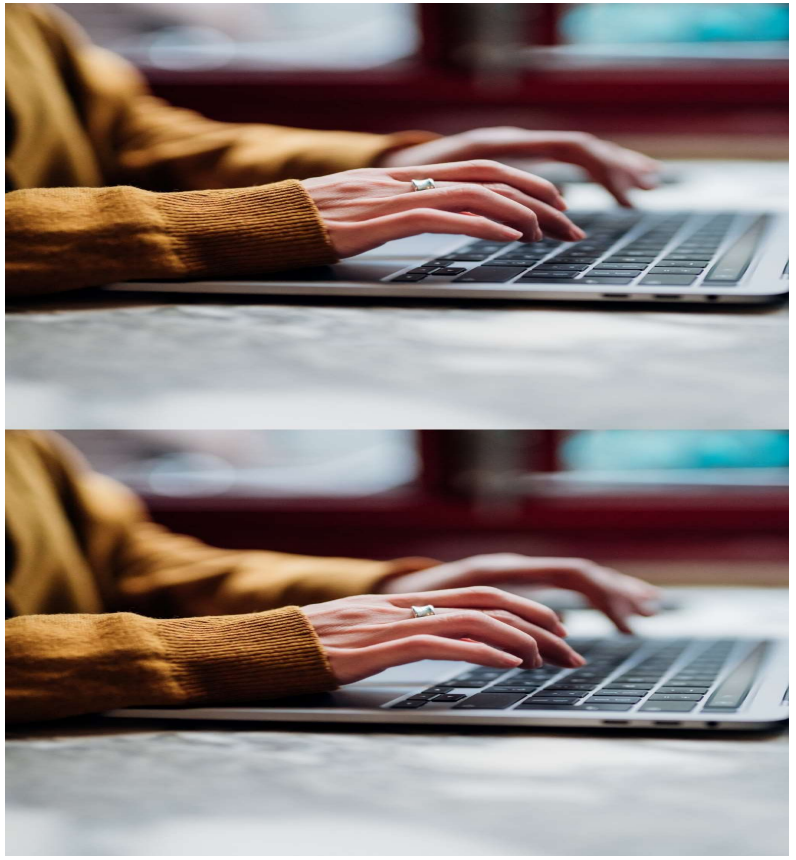
Reporting requirements

In summary;

- Report as soon as known (within 48 hours)
- All relevant information
- Identifies preventable causes in the process

- Note: Many terms used such as Root cause, causative factors, preventable causes.

None of these terms prescribes a method of investigation, only to find out why something went wrong



What does that mean in practice?

Quite Simply

Who?

What?

Where?

When?

How?

Why?

What does the report need to cover (1/3)

Who?

Staff involved including roles, patients (actual harm), potential patients (potential harm), third parties. It is NOT to identify *who* to blame

What?

What went wrong?

Distinguish between the Outcome(s) and the Error(s)

Patient may have been transfused an incorrect component (outcome) but how did it get there? What was/ were the error/s?

Managing risk – Error vs outcome – Potential harm

- (Consider only BSQR errors and not clinical in this example)

- Consider two similar examples

1. Group A patient was mistakenly transfused with group O blood?
2. Group A patient was mistakenly issued with group O blood, but identified at the bedside?

What's the error?

Managing risk – Error vs outcome

Considering the BSQR error (not any clinical error)

The error is the same

- Selected and issued the wrong group

Only the outcome is different

1. Transfused incorrect group
2. Error detected at bedside

Actual harm - none

What is the potential harm?

Of the **outcome** – none

Of the **error –** potentially fatal

Remember the error was not transfusing the wrong group but **selecting and issuing** the wrong group

The same error might have resulted in group B to group O

What does the report need to cover (2/3)

Where?

For clarity, helps build the timeline

Can also describe the environment (staffing levels, workload, skill mix, capacity)

How?

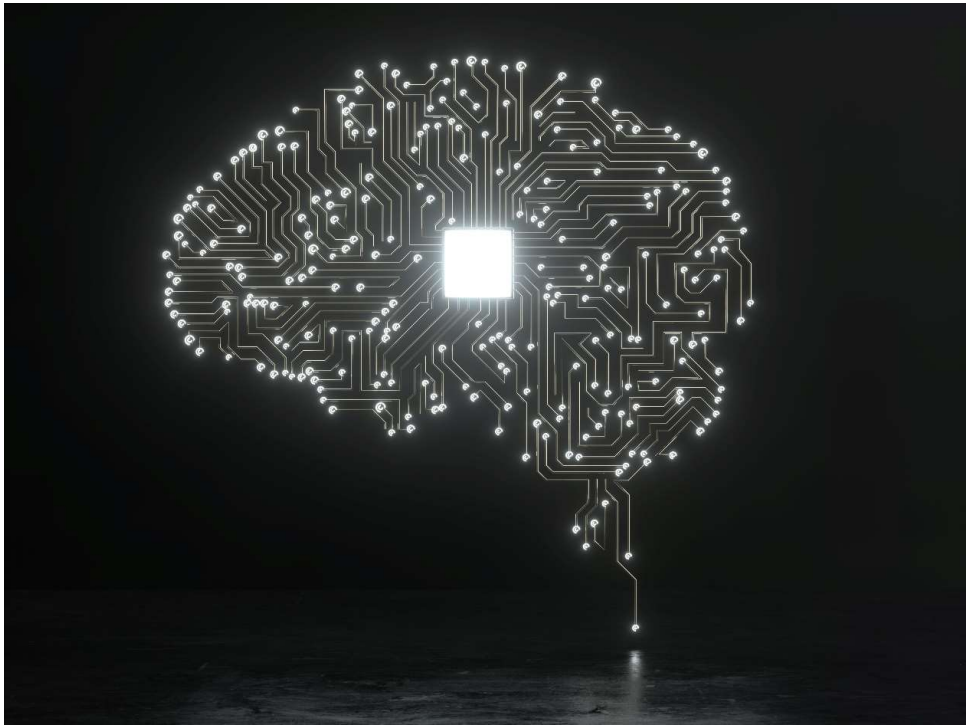
Build timeline. What should have happened? What did happen instead? Identify the human factors relating to the organisation, the process/ procedure and the individual(s)

What does the report need to cover (3/3)

Why?

Why did the staff involved act or behave the way they did? What human factors influenced their decision making and actions?

Remember human factors are not just down to a human’s personality.



Investigation/reporting process

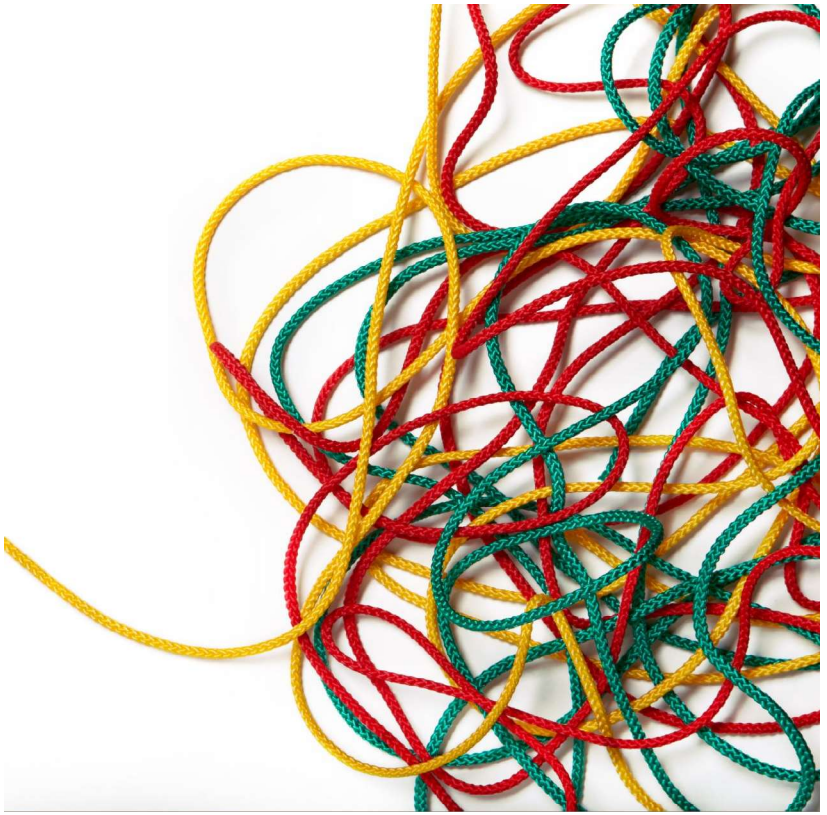
Error

- Any error, not just Serious adverse events and reactions (SAE/SAR)

Assess

- Effect on “the four Ps”
  - **P**eople, **p**lant, **p**remises and **p**rocedures
    - Patient, staff, people not yet involved, LIMS, storage equipment, lab, escalate and cascade, contingency plans and concessionary processes, etc

- Impact
  - (minor, serious, critical)
  - Assess POTENTIAL as well as ACTUAL harm
  - Prioritise



Risk Assessment

Actual harm

Consider a unit with the wrong specific requirements

- Might be a one off or rare event
- Might have been spotted before administration
- Or may not have resulted in harm

Risk assessment

Potential harm

- BSQR and GPG require us to consider potential impact on other donors and patients and not just the one in the event
- It has already happened at least once so likelihood is increased
- Potential harm could be serious or even catastrophic

RISK MATRIX

RISK RATING KEY	LOW	MEDIUM	HIGH	EXTREME
	0 – ACCEPTABLE	1 – ALARP as low as reasonably practicable	2 – GENERALLY UNACCEPTABLE	3 – INTOLERABLE
	OK TO PROCEED	TAKE MITIGATION EFFORTS	SEEK SUPPORT	PLACE EVENT ON HOLD

LIKELIHOOD ↓ / SEVERITY →	ACCEPTABLE LITTLE TO NO EFFECT ON EVENT	TOLERABLE EFFECTS ARE FELT, BUT NOT CRITICAL TO OUTCOME	UNDESIRABLE SERIOUS IMPACT TO THE COURSE OF ACTION AND OUTCOME	INTOLERABLE COULD RESULT IN DISASTER
IMPROBABLE RISK IS UNLIKELY TO OCCUR	LOW – 1 –	MEDIUM – 4 –	MEDIUM – 6 –	HIGH – 10 –
POSSIBLE RISK WILL LIKELY OCCUR	LOW – 2 –	MEDIUM – 5 –	HIGH – 8 –	EXTREME – 11 –
PROBABLE RISK WILL OCCUR	MEDIUM – 3 –	HIGH – 7 –	HIGH – 9 –	EXTREME – 12 –

Investigation/ reporting process

Control

- Limit the effects of the error
- Prevent further errors
  - E.g., recall non-irradiated red cells, investigate if other components issued and recall

Correction

- Put the immediate error right
  - E.g., issue components that replace those recalled

Investigation/ reporting process

Document and report

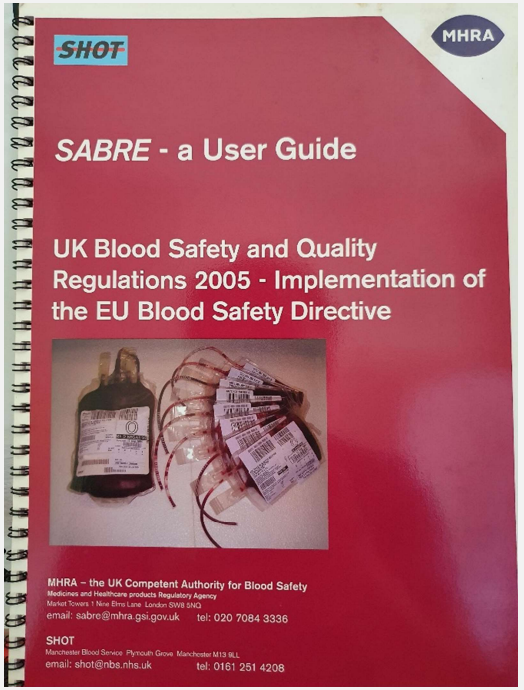
- Locally
  - As soon as possible
    - Fresh recall of events
    - As much detail as possible

- If possible, evidence should be gathered **before** the end of shift as directed by the documented incident SOP
- Many investigations are **weak** because evidence is not gathered while it is fresh i.e., after annual leave, sick leave, rest days

Investigation/ reporting process

Document and report

- Externally
  - SHOT/SABRE/Other
    - SABRE (BSQR 2006)– “As Soon as known” (within 48hrs)…”all relevant information….”
    - In other words, **full details**, not just a few sentences



Investigation/reporting process

Assign an investigator

- Relevant authority
  - Consider investigations may cover lab, clinical area, third parties
- Relevant experience
  - Of investigation, not necessarily in the process that went wrong
  - Independent
  - Objective
- Assess level of investigation

CAPA evaluation via a Severity Index Score (one method)

The time periods stated in the table below are only an example and NOT a definitive figure mandated by the MHRA. Base your timescales on your Quality Management Policies

SEVERITY INDEX	RCA Type	Immediate Action	Target Period for Completion of RCA by type	Comment
MAJOR/CRITICAL • **Serious Harm to Patient/Donor** • **Failure of service provision which indicates a breakdown in supply chain** • **Significant loss of product in one event** • **An event that has a significant effect on laboratory operations**	**Full RCA**	Assess the ACTUAL and POTENTIAL risk using Quality Risk Management Principles immediately. Introduce immediate mitigation based on the initial investigation so further risk is reduced	Optimum of 30 days but with a maximum of 8 weeks. Extension, with justification may be required i.e. when several departments are involved.	Justify and evidence all extensions if required i.e. Police involvement and ONLY when the immediate risks have been reduced.
MINIMAL • **Noncritical event caused by a significant failure in the QMS** • **Recurrent failure**	**RCA** Full or minimal dependant on actual and potential risks. Can be upgraded.	Assess the ACTUAL and POTENTIAL risk using Quality Risk Management Principles immediately. Introduce mitigation based on the initial investigation	2-4 weeks	If necessary, upgrade to Major based on initial findings
OBSERVATION • **All other events not covered by the above** • **Any failure on the QMS that has no direct effect on function but requires action**	**Minimal RCA** May upgrade to a more detailed RCA based on findings	Assess the ACTUAL and POTENTIAL risk using Quality Risk Management Principles. Introduce mitigation based on the initial investigation	1-2 Weeks	A one-off failure i.e. IQC/EQA failure (upgrade where required

Investigation/reporting process

Identify witnesses

- Clinical, lab, 3rd party etc
- Consider experience of staff working similar shifts

Gather evidence/ facts

- Consider all forms of evidence

  Verbal accounts

  Records
  - Paper
  - Electronic

  Establish time-line

Investigation/ reporting process

Step	Example
Identify the outcome	Patient transfused non-irradiated blood
Identify the error	Non-irradiated blood was issued
Identify the first mistake	Selecting the wrong component
Map the steps between the first mistake and the error	Request form and LIMS should have been checked for requirements, correct blood should have been selected, LIMS should have detected error.
Map the steps between the error and the outcome	Error not picked up after issue, when blood taken to fridge, at collection, at administration
List all the factors involved	Next slide
Determine how to fix the problems	Next section

Investigation/ reporting process

What	How
LIMS and form wasn't checked	The checks were omitted
Correct blood wasn't selected	The BMS didn't realise irradiated blood was required so selected non-irradiated
LIMS didn't detect the error	There was no flag placed on the LIMS
Checks on the issued blood were not successful when placing unit in fridge	The checks were omitted
The porter didn't detect the error	The porter did not check for special requirements at collection
The error wasn't detected at administration	The checks at administration weren't thorough

Root cause – Procedures not followed, right?

Investigation/ reporting process

Root Cause analysis and corrective and preventive action

GPG 1.2.13 continued

Where human error is suspected or identified as the cause, **this should be justified having taken care to ensure that process, procedural or system-based errors or problems have not been overlooked**, if present. Appropriate corrective actions and/or preventive actions (CAPAs) should be identified and taken in response to investigations. The effectiveness of such actions should be monitored and assessed in accordance with Quality Risk Management principles.

Reflective practices

- Useful as a part of the **investigation**
- Highlights **human factors** which must be addressed in the CAPA
- **Should not** be used as CAPA
  - **Overlooks** system improvements
  - Places **unnecessary responsibility** on the individual alone

Investigation/ reporting process

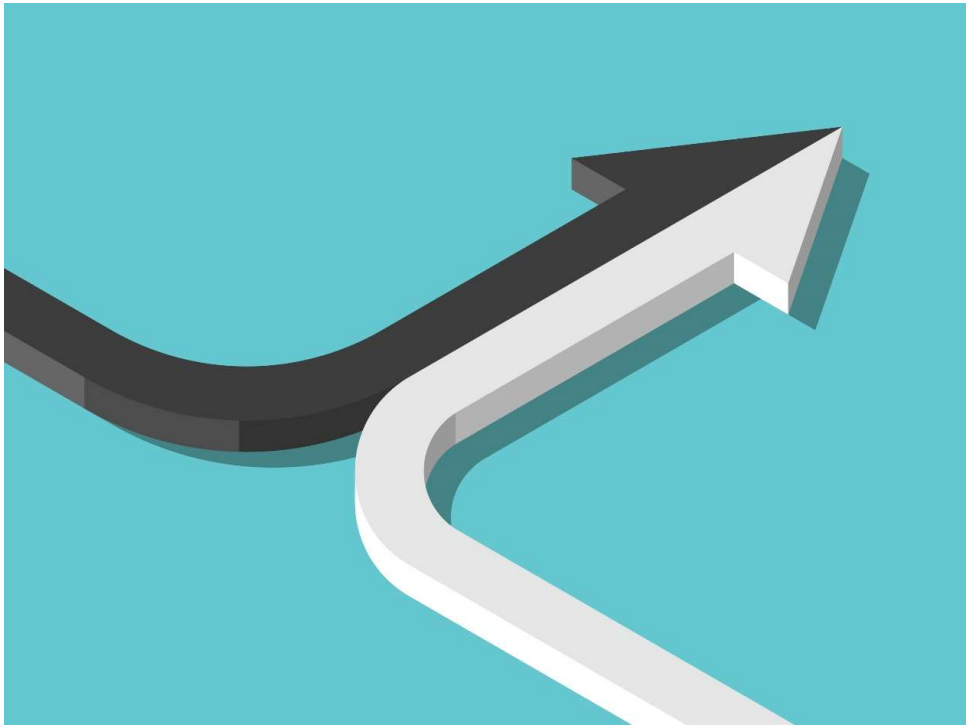
Many different methods and tools available

- 5 whys
- Fish-bone
- Etc

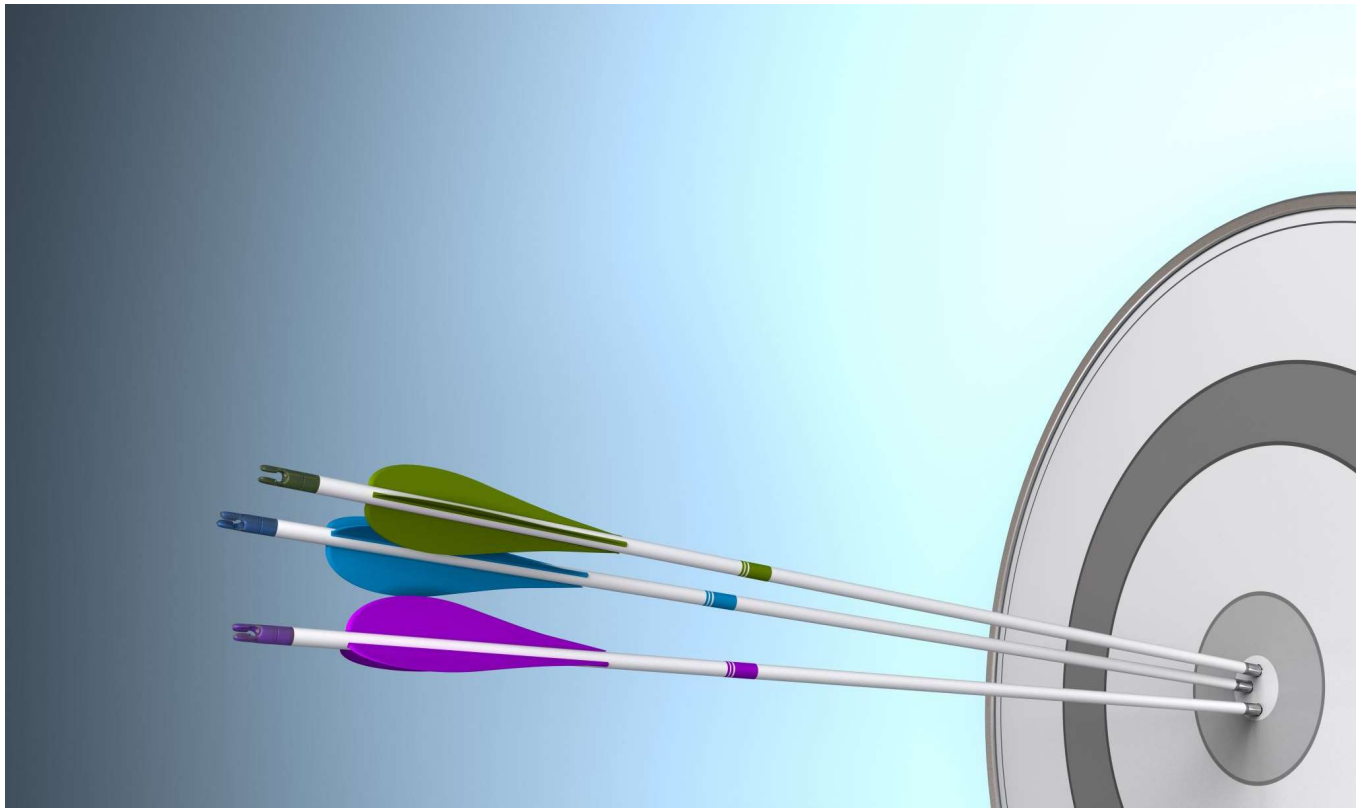
In principal, they want to achieve the same goal

i.e. Identifying

- Causal factors (contributory factors, but not the main RC)
- Communication failures
- Root causes (i.e. something that, if removed, will eliminate the problem)



Investigation/ reporting process



- Not important what method/ tool you use
- Use, any, or a combination
- Not important to establish if they are causal, communication or true root causes
- They all need to be addressed

- If you haven't understood why an error occurred, your RCA has not been successful, because you can't target your CAPA to the problem

Investigation/ reporting process

Don’t just determine how things happened, establish <u>WHY</u>

Helps understanding the weaknesses in the QMS and identifying improvements

Can have many levels and identify a number root causes and factors

Importance of RCA

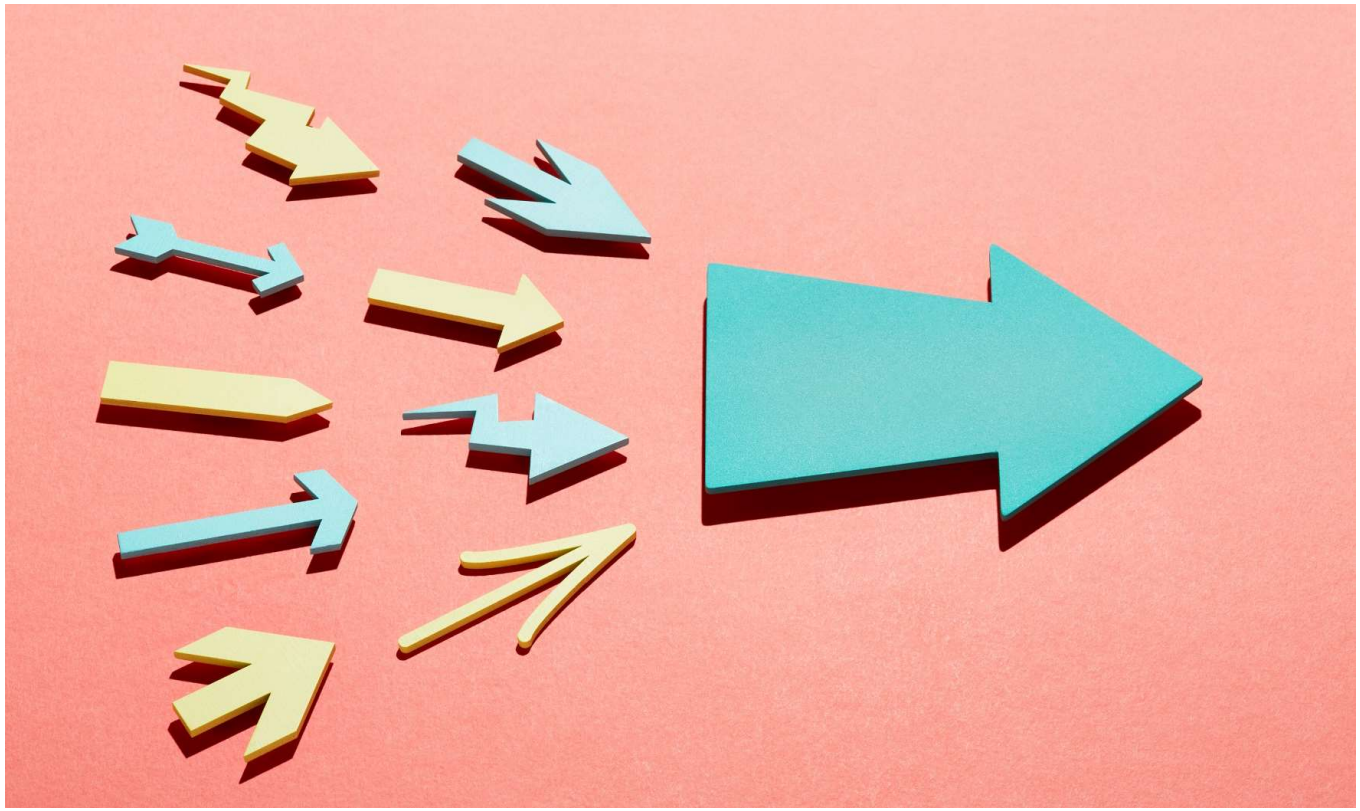
Identify “Human factors”

- Ie. Factors at the involving the individual, task/ process, and organisation

Not just for dealing with “human error”

Determine the important factors that lead to success

Investigation/ reporting process



List the factors involved

- Multiple factors will involve multiple problems to be fixed
- May involve a number of investigations
- May involve a number of CAPAs

Investigation/ reporting process

Wrong

We haven't determined why

Ask the people involved why they didn't perform the tasks as expected

How	Why
The LIMS/form checks were omitted	Checks rushed due to workload
The BMS didn't realise irradiated blood was required so selected non-irradiated	Special requirements not clear
There was no flag placed on the LIMS	There was no formal procedure to update LIMS
Checks of issued blood were omitted	Was rushing to complete order as there was a backlog of outstanding work due to understaffing
The porter did not check for special requirements at collection	Although in the SOP, the training material does not cover checking special requirements
The checks at administration weren't thorough	The nurse involved was unclear what checks were required as there was no SOP with clear instructions

Managing change

Question		Action
Was the error a result of change?	No	Follow the “**Process**” flow diagram
Was the change formally managed by the change control process?	No	Use a formal **change management process**
Were plans robust/adequate?	No	**Improve** change management process and validation plan and re-do
Were the plans followed correctly?	No	**Re-do** change management process
Follow the “**Process**” flow diagram		

Process

Question		Action
Is there a defined process that covers the root cause of the error?	No	**Design** a process that defines all the critical steps
Is the process fully described in all documentation?	No	**Write** SOPs covering all steps with clear instructions that cover all scenarios
Is there training and assessment material that covers the process?	No	Design suitable **training and assessment** material
Has the person involved in the error been trained?	No	**Train and assess** individual
	In training	Was the person supervised? If not review **training** process. If yes, review **Supervision** arrangements
Is further training required?	No	Continue process for **individual**

Individual

Question				Action
Did the individual deliberately deviate from the accepted procedure?	Yes	Did the individual take an unacceptable risk or deliberately ignore the procedure?	Yes	Consider **re-training** initially or formal proceedings if persistent
Did the individual follow an incorrect procedure or miss steps in the process?		Was the deviation made using professional judgement in the best interests of the patient?	Yes	**Update SOP** or ensure that a formal **process deviation** is used in future
		Consider if the process/SOP/ training can be re-designed to improve staff performance		
Did the individual follow the correct procedure but make an incorrect decision?		Consider if staff have access to sufficient support and information to help the decision making process		Follow **environment** flow

Environment

Question		Action
Do you have a capacity plan?	No	Devise a **capacity plan** with minimum staffing levels, skill mix and expected workloads
Was the department sufficiently staffed when the error was made?	No	Address **staffing problems** considering skill-mix, workload, bottlenecks, rotas and breaks
Was the workload above what you'd normally expect?	Yes	Consider **process** and **work flows**
Is the skill-mix of staff appropriate according to your capacity plan?	No	Consider addressing through staff rotas and training plans
Was the staff member distracted?	Yes	Consider all possible distractions and look to eliminate or manage the distraction. Train staff to deal with distraction including starting again and empowering staff to ask for help

Investigation/ reporting process

Distraction

If distraction is identified as a causal factor, then it must be addressed

Treat as a risk assessment

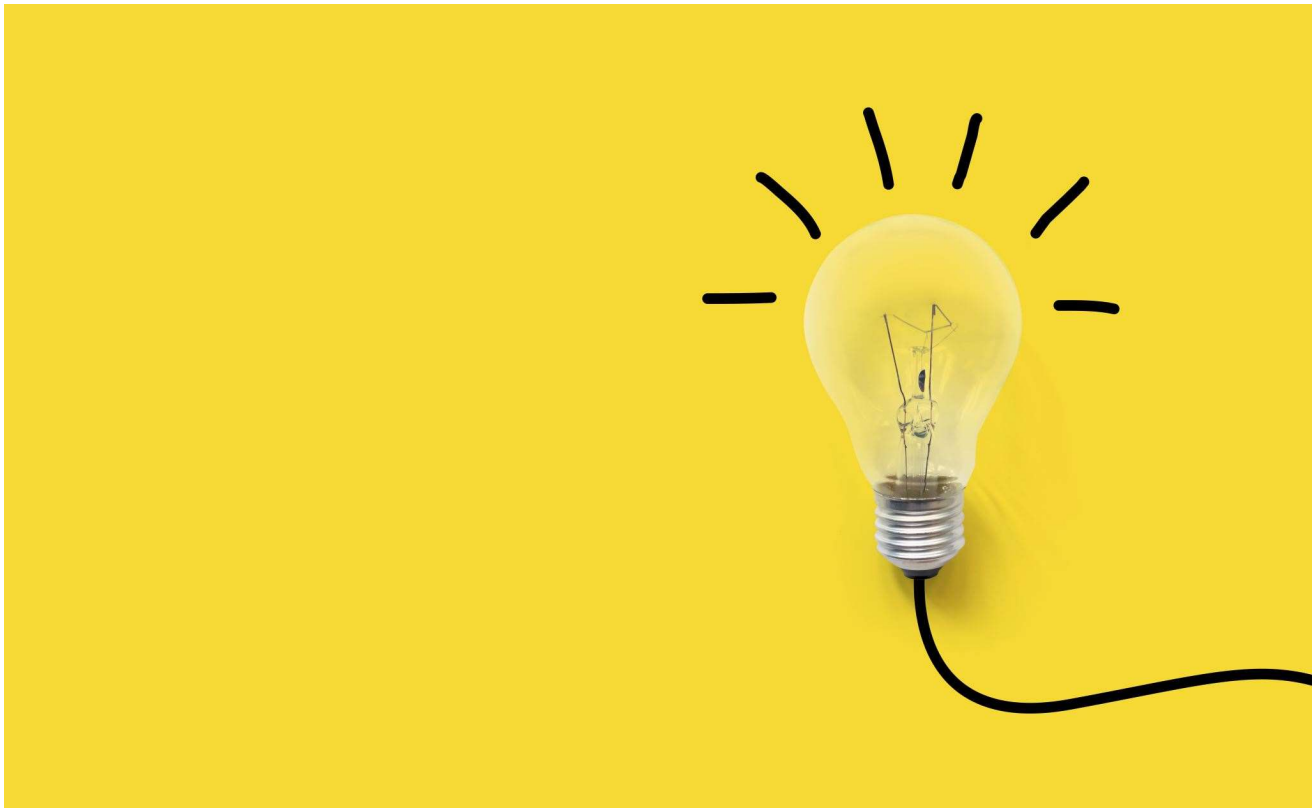
- Eliminate
- Reduce
- Train staff to cope

- E.g Do staff **have** to answer the phone?
- (bleep service, computer systems to check results, location of blood etc?)

Investigation/ reporting process

Problem	Corrective action	Preventive action
Staffing/ workload	Review Capacity plan to determine minimum staffing levels are appropriate and change Make business case for additional staff based on requirements of updated capacity plan	Redesign staff rota so fewer people can take breaks or A/L at same time Examine workflows and balance against staffing levels
Training	Update training of porters to include missing steps in collection process Re-train porters in updated process	Review and update other training material Update Good Practice training to include the effects of rushing, getting it right first time and distraction management
SOP/ Procedures	Redesign request form to make specific requirements more visible Write SOP for administering blood that gives clear step-by-step instructions	Review all processes to ensure they are covered by SOPs
Processes	Design a process to update LIMS with specific requirements from clinical areas	

Investigation/ reporting process



Instead of making staff responsible for their mistakes we have identified a number of areas of improvement to the QMS in

- Staffing and workload
- Training
- SOP/documentation
- Processes and procedures

Investigation/ reporting process

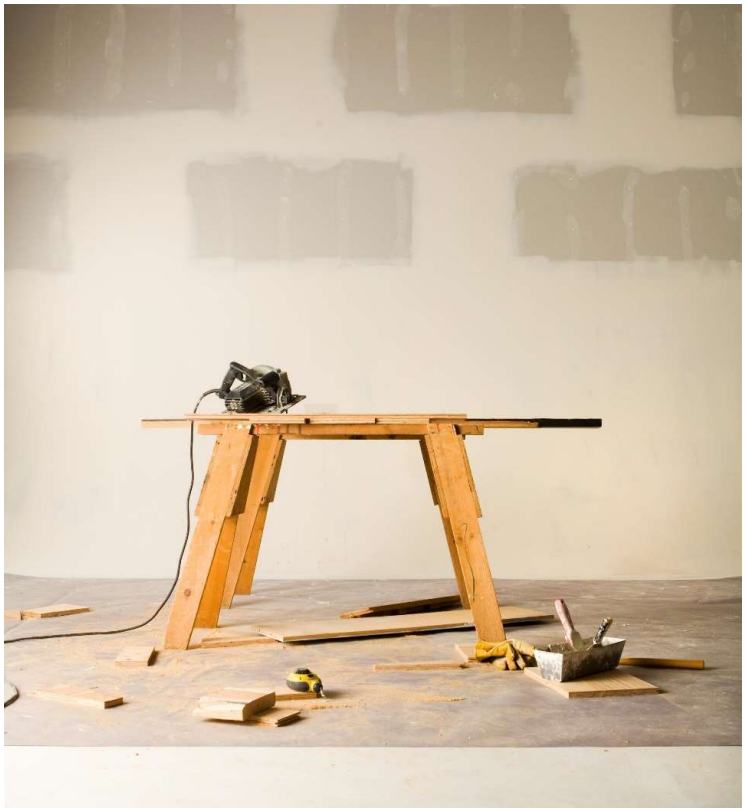
Not one of those actions involved **“re-training”** a member of staff because they “didn’t follow procedure”

Avoid “unfinished” CAPA e.g.

- Ask supplier if possible…
- Review SOP…
- Carry out an audit…

Do not

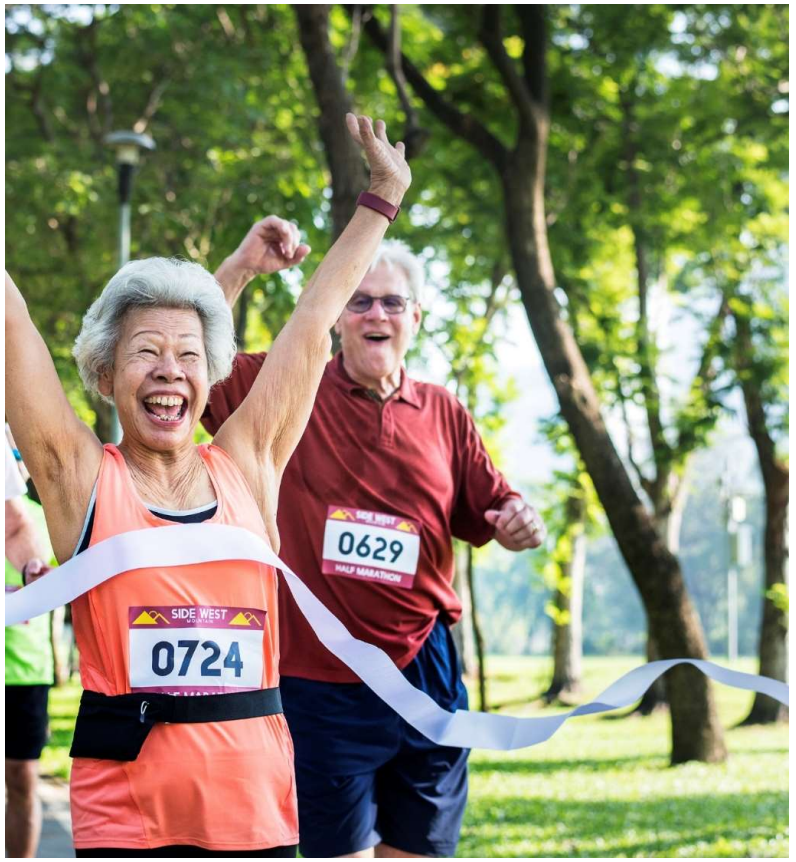
- Introduce unnecessary “second” checks
- remind staff to follow procedures
- confuse recommendations with CAPA
  - A recommendation is not a commitment to CAPA



Investigation/ reporting process

CAPA must be specific to the RC

- Supplier was contacted and a change will be introduced following change control and validation…
- The SOP was reviewed, and the following changes will be implemented…
- An audit was conducted into the process and as a result the following amendments to the process were made…



Monitor and Trend

Monitor the error for effectiveness and **trend** for re-occurrence

Again the GPG

9.1.10

A regular review of all significant deviations or non-conformances should be conducted, including their related investigations, to verify the effectiveness of the corrective and preventive actions taken.

Categorisation

Helps to group similar incidents based on

- type of incident / error and
- root cause / area of improvement

Can aid trending of similar errors and help focus areas for further improvement

Can help provide early warning signals of more serious errors

Can use any categories, but probably advisable to use SHOT and SABRE categories and categories which reflect non-regulated laboratory activities

Categorisation

Reaction Categories

- Immunological haemolysis due to ABO incompatibility / IBCT
- Immunological haemolysis due to other allo-antibody / HTR
- Non-immunological haemolysis
- Transfusion-transmitted bacterial infection
- Anaphylaxis / hypersensitivity / Allergic / FAHR
- Transfusion related acute lung injury
- Transfusion-transmitted fungal infection
- Transfusion-transmitted viral infection (HBV)
- Transfusion-transmitted viral infection (HCV)
- Transfusion-transmitted viral infection (HIV-1/2)
- Transfusion-transmitted viral infection - Other - Specify in Further Details
- Transfusion-transmitted parasitical infection (Malaria)
- Transfusion-transmitted parasitical infection - Other - Specify in Further Details

Categorisation

- Post-transfusion purpura
- Graft versus host disease
- Other / Febrile FAHR
- Other / Mixed febrile / allergic FAHR
- Other / Hypotensive FAHR
- Other / FAHR
- Other / Hyperhaemolysis
- Other / TACO
- Other / TAD
- Other / UCT
- Other / Cell salvage
- Other / Haemosiderosis
- Other

Categorisation

Event Categories

- Storage / 30minute rule
- Storage / Miscellaneous
- Storage / Component expiry
- Storage / Failure to action alarm
- Storage / Incorrect storage of component
- Storage / Return to stock error
- Storage / Sample expiry
- Storage / Security
- Storage / Storage temperature deviation
- Distribution
- Materials
- Other / Data entry error
- Other / Sample Processing error
- Other / Component labelling error
- Other / Pre-transfusion testing error
- Other / Incorrect blood component issued
- Other / Component collection error
- Other / Expired component available for transfusion
- Other / Component available for transfusion past de-reservation
- Other / Incorrect blood component ordered

Categorisation

- Other / Incorrect blood component accepted
- Other / Handling damage
- Other / Failed recall
- Other / Not known
- Other / ADU
- Other / Anti-D Ig administration
- Other / Anti-D immunisation
- Other / Cell salvage
- Other / HSE
- Other / IBCT – SRNM
- Other / IBCT - WCT
- Other / Near Miss
- Other / Prothrombin Complex Concentrate (PCC) administration
- Other / RBRP
- Other / WBIT
- Other / Miscellaneous

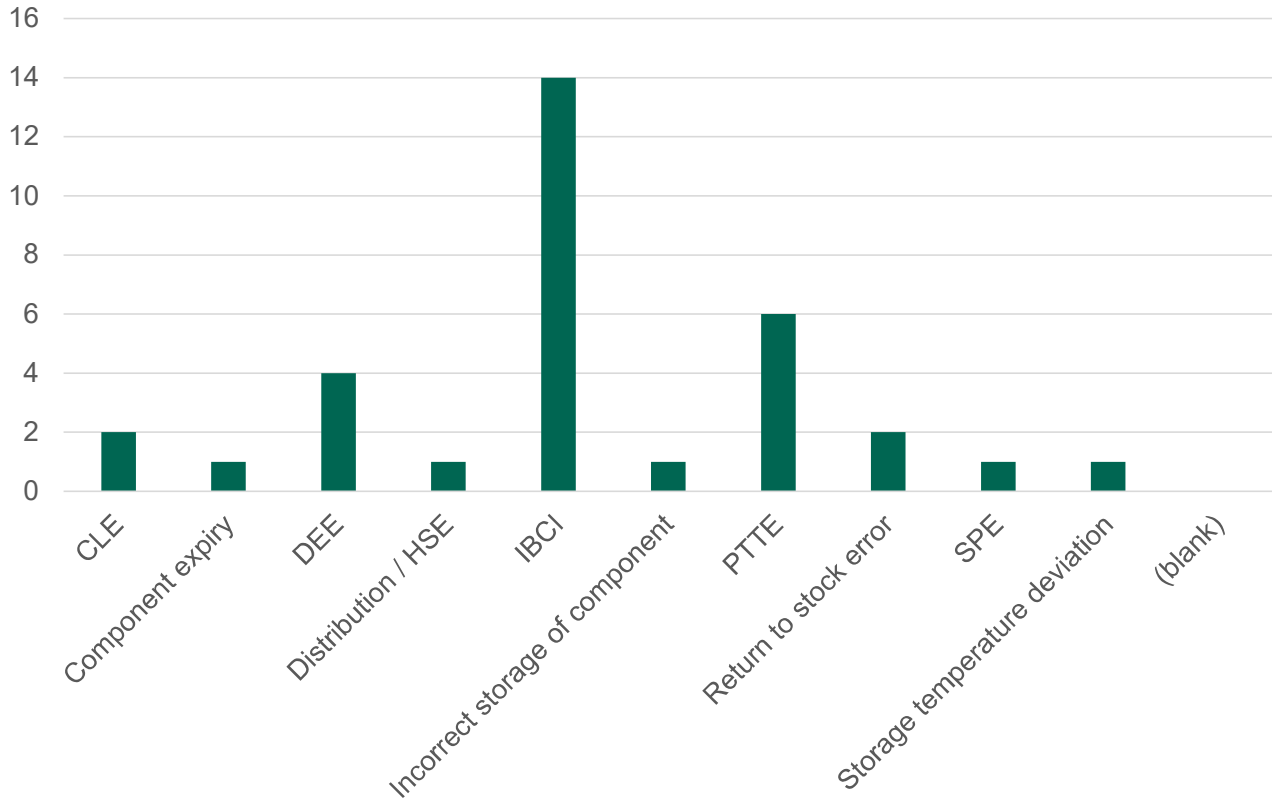
Categorisation

Specification (Root cause) Categories

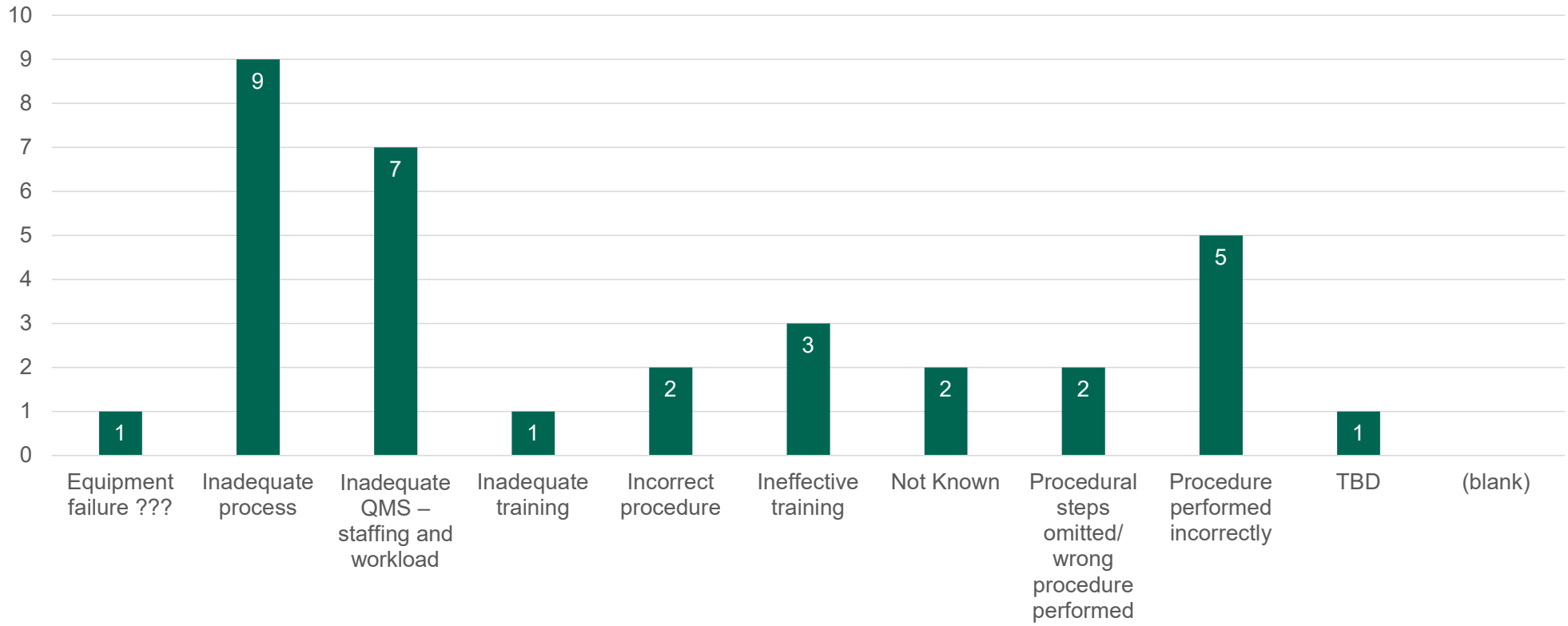
- Equipment failure
- Procedure performed incorrectly
- Procedural steps omitted/ wrong procedure performed
- Ineffective training
- Inadequate training
- Lapsed/ no training
- Incorrect procedure
- Inadequate process
- Inadequate QMS – staffing and workload
- Inadequate supervision

Example data

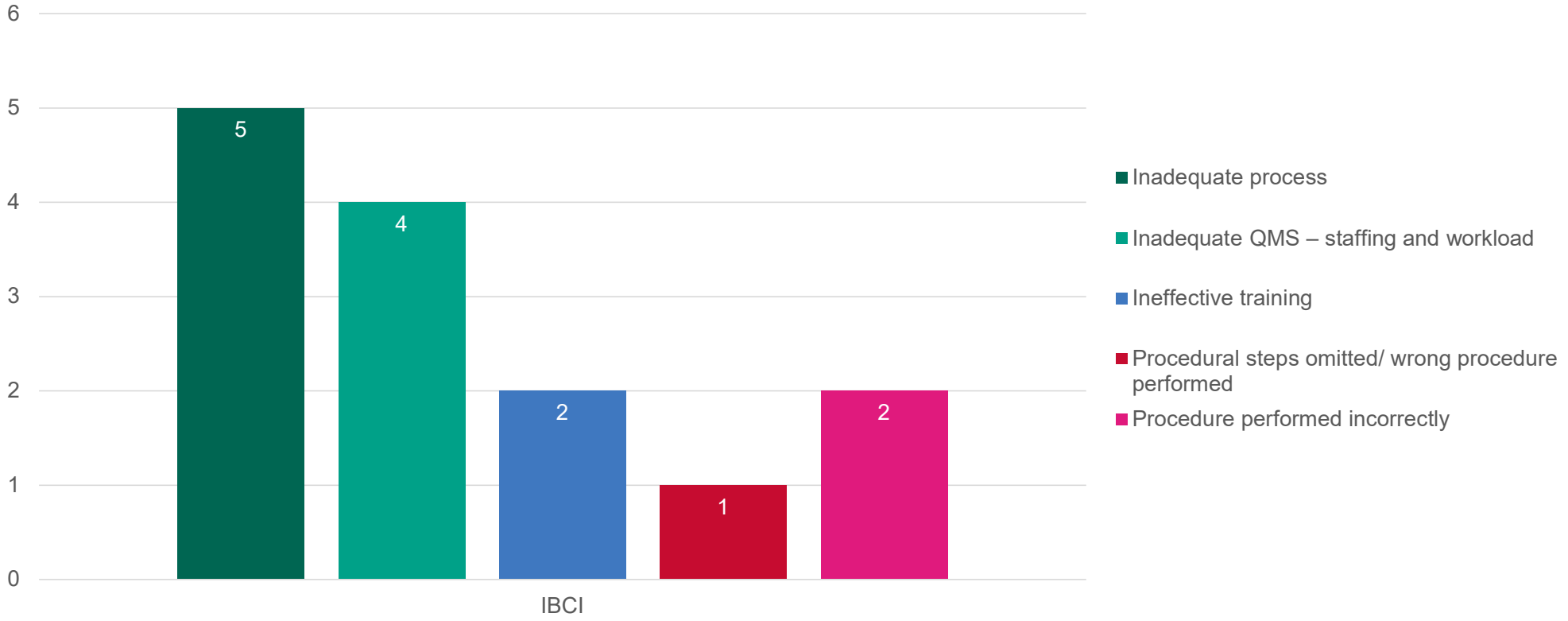
- Data collected for SAEs
- From 2011 (when SABRE categorisation introduced)



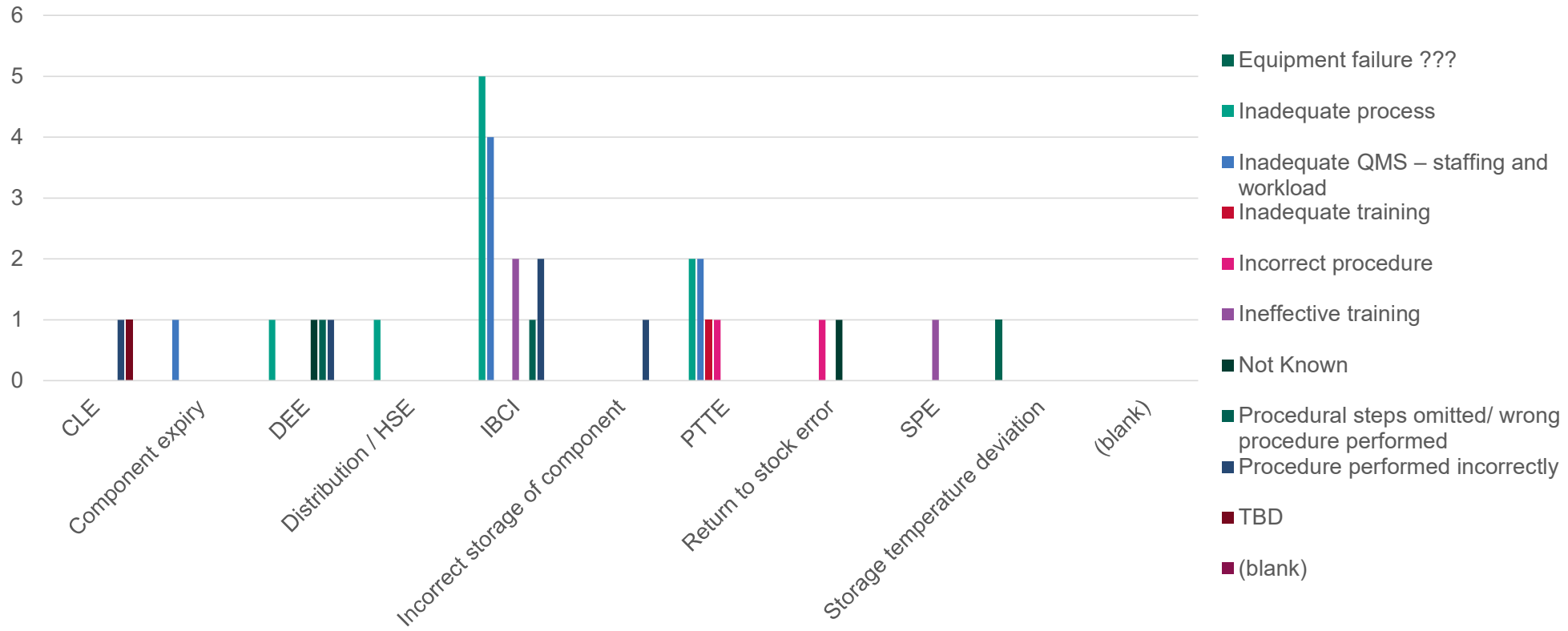
Example data



Example data



Example data



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