Top 5 laboratory SAEs

BBTS – Quality Improvement

Chris Robbie

MHRA, UKTLC and SHOT Working Expert and Steering groups

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Introduction

The Brief

- Top 5 lab SAEs
- Common themes
- Types of CAPA
- Is lab training a major problem around lab incidents

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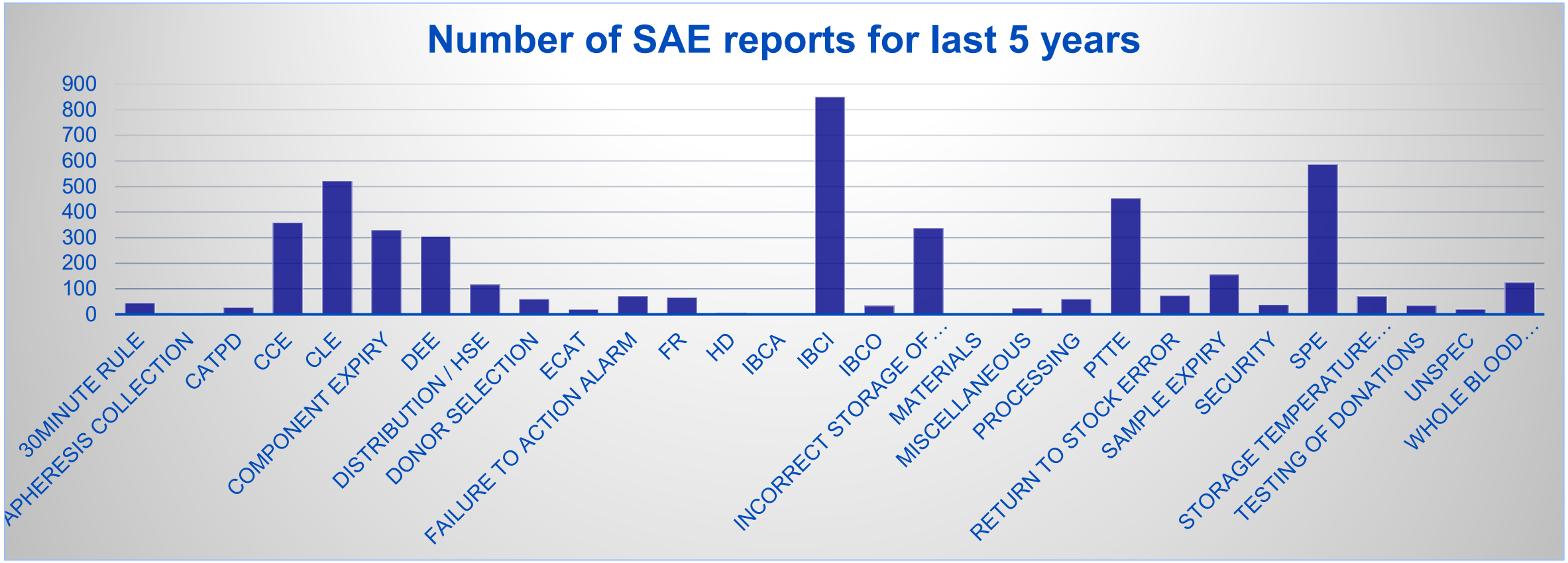
All SABRE incidents by Deviation



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Top 5 “lab” SAEs + *2 outside lab*

Type	Description	Root cause
Incorrect blood component issued	Issue of blood with missing or incorrect specific requirements	Procedure performed incorrectly
Sample processing error	Acceptance of sample against policy	Procedure performed incorrectly
Component labelling error	Typically transposition of labels	Procedure performed incorrectly
Pre-transfusion testing error	Patient sample screening and interpretation of results	Inadequate process
Component collection error	*Errors in collecting components for transfusion*	*Procedural steps omitted/ wrong procedure performed*
Incorrect storage of component	*Storage of components in wrong or unmonitored conditions*	*Ineffective training*
Component expiry	Expired components not removed from	Inadequate process

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Top 5 “lab” SAEs

“Conclusions”

Most errors in the laboratory are due to slips and lapses of concentration by individual members of staff

Really?

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Top 5 “lab” SAEs

MHRA Inspection findings relating to incidents and CAPA is the most commonly occurring “Major” non-conformance

- Investigations and root cause analysis lacked adequate depth, detail and scope
- Data from investigations and incidents were not routinely analysed to identify unfavourable trends that may require preventative action
- Where root cause analysis had been performed, the determined root causes were typically human error without adequate justification. This approach failed to ensure that other causes such as system, process and environmental issues were adequately reviewed.

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Top 5 “lab” SAEs

Many “procedural” errors may be “genuine” slips or lapses but how many of those SABRE reports have not been investigated thoroughly, or identified the root cause adequately?

- Review processes and make “lean” and maintain safety
- Identify and eliminate or mitigate against distractions
- Educate staff in dealing with distractions and prioritising workloads
- Stop rushing – slow down – get it right first time
- Consider if staff are having personal issues, not readily apparent

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Top 5 lab SAEs with slips/lapses removed

Type	Root cause
Incorrect blood component issued	Inadequate process
Component expiry	Inadequate process
Pre-transfusion testing error	Inadequate process
Incorrect blood component issued	Ineffective training
Pre-transfusion testing error	Ineffective training

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Top 5 lab SAEs

- Once slips and lapses eliminated “manual”, repetitive, easy-to-lose-focus processes such as labelling and sample acceptance removed
- Most errors would seem to occur due to “inadequate processes”
  - Not robust/not well defined
  - Do not achieve a consistent safe outcome
  - Can be related to poorly designed equipment and/ or LIMS or even SOPs with ambiguous content or missing instructions
  - Evidence of poor change control

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Top 5 lab SAEs

Ineffective training (includes task-based training and education)

- Training has been given
- Covers the error that occurred
- Has been forgotten or incorrectly applied

- Consider more frequent training
- Scenario based training
- Work to transfer knowledge and skills from seniors to juniors so they gain experience

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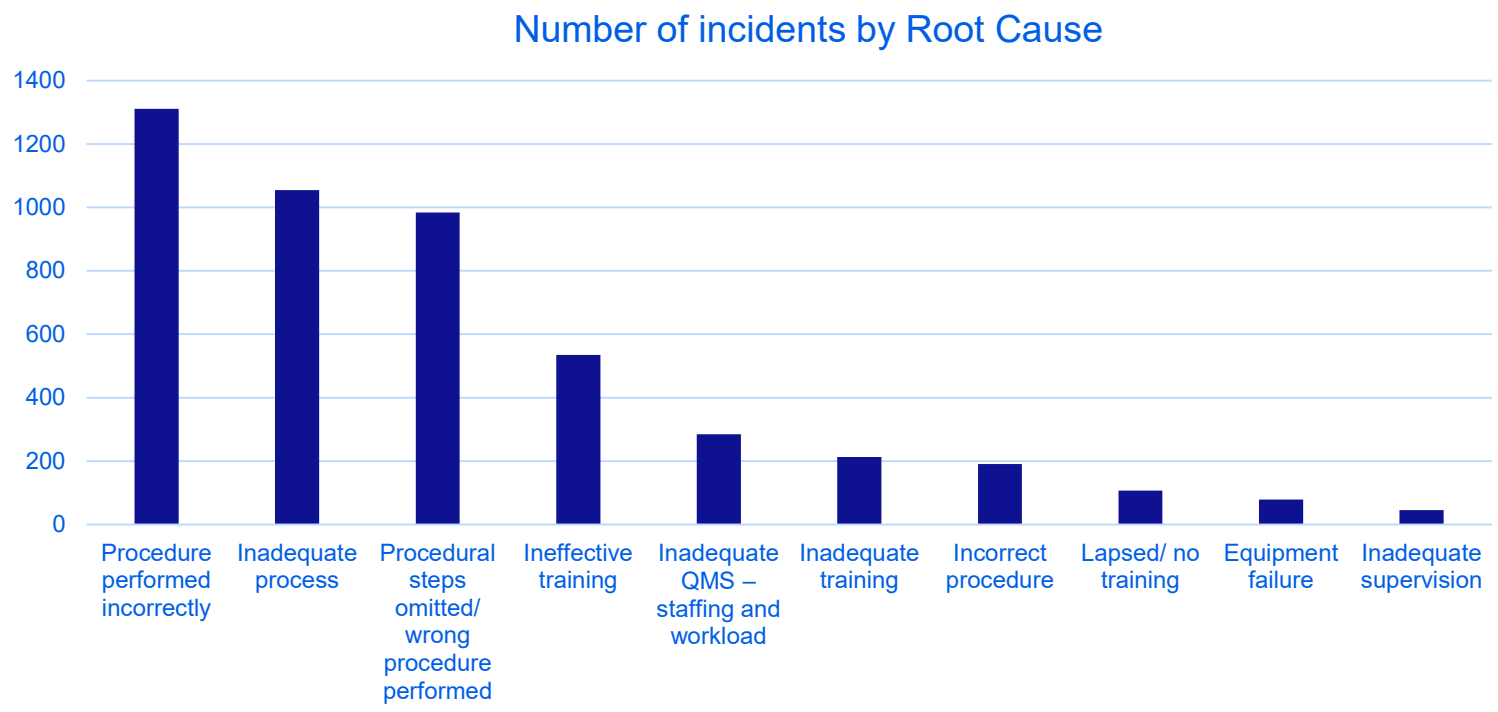
Root causes



Most errors appear to be due to slips/lapses

22% Due to inadequate processes

19% Training issues

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Conclusions

- Errors in manual/repetitive processes likely to be due to slips and lapses
- Errors “Technical” processes likely to be due to weak process design and training and education
- Training errors will also include design of training packages and content, delivery and supervision, not just knowledge of staff

- However, improvements in investigation and reporting may highlight more QMS improvements than at present.

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Blood forum http://forums.mhra.gov.uk/forumdisplay.php?60-Blood-Forum

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