SHOT Bite No.1(b):

Investigating Incidents: effective interventions

SHOT Serious Hazards of Transfusion

March 2021

Investigating incidents is integral to maintaining the quality and safety of blood and blood components, and preventing patient harm. The quality and safety risk in the context of the patient should be central to all investigations. This also applies to near miss events.

SHOT Bite No.1 Investigating incidents: a systems-based approach released February 2021 explored methods for investigating incidents. This SHOT Bite follows on with a review of corrective and preventive actions and how to ensure they are effective.

The Good Practice Guide states that an appropriate level of root cause 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. 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.

Improvement actions and interventions will only prevent recurrence of error if they are effective and sustainable. Identifying and implementing appropriate actions are the most important aspect of incident investigations.

SMARTER closed loop feedback: SMART actions can be improved to SMARTER

Specific – articulate and understandable

Measurable – verified that is solving the problem, reviewing the effectiveness of the action

Achievable – can be achieved within the resources and time frame

Relevant – related to the cause(s) of the incident

Time bound – specified time to complete the actions

Evaluated – have the actions had the desired effect, has the risk reduced or been eliminated

Readjust– do further changes need to be made

The CAPA process: following the identification of a risk relating to the quality and safety of blood

Remedial actions: actions taken immediately following the event to ensure the risk to patient is minimised. Incident reported as appropriate to clinical area, laboratory, management or raising a report on an electronic system. Work suspended if appropriate.

Corrective actions: actions taken after the event to prevent recurrence; these address the root causes. May include interim measures to mitigate problems until a more comprehensive solution is found.

Preventive actions: planned activity with the aim of preventing error. May include review of other processes to ensure similar problems do not present elsewhere.

Review of effectiveness: closing the loop between identifying the problem and completing the resolution actions, may include trend analysis, periodic checks, audits. Some checks may be completed soon after the action has been completed, others may be done much later. Identify any re-adjustments required.

Example: Red cells released with incomplete antibody identification

Remedial
- Inform clinical team of error and risk
- Recall implicated red cell units
- Complete all tests and issue compatible red cells

Corrective
- Checklist for red cell release with positive antibody
- SOP update to include checklist requirement
- Staff reminder to ensure all tests complete

Preventive
- LIMS warning for incomplete tests with override
- LIMS block if tests incomplete
- Review other similar processes for failure potential

Review
- Audit of complicance with checklist completion
- Trend analysis to determine if problem has occurred again
- Periodic checks of LIMS override usage

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The Intervention Hierarchy: The system should be designed so that it is easier to do the task right and harder to do it wrong. Any intervention actions applied should support this, but some interventions are more effective than others and this is called the hierarchy for intervention effectiveness.

BEST

Forcing functions: robust process that include barriers and fail-safes, automation, and computerisation. These are the most effective barriers but are usually the hardest to implement. Reliance on systems to ensure safe practice, but can be subject to technology complacency, flag fatigue and short cuts if not set up correctly.

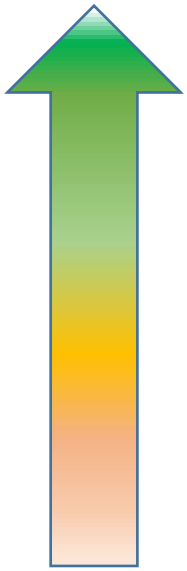
GOOD

System focussed: standardisation, protocols and procedures, warnings, alerts, reminders, checklists, and robust checking. Partial reliance on humans and partial reliance on systems. Can be used as interim measures whilst more effective forcing functions are being explored.

LIMITED

People focussed: education and training, rules, and policies, even if applied to teams rather than individuals these are known to be ineffective. They are easy to implement and often used as the first line of defence. Reliant on humans to remember safe practice.

More effective



Less effective

Making the most of your interventions: The following guide can help ensure that the interventions identified are effective and fit for purpose:

Process

- As simple as possible, as complex as necessary
- fail-safes and barriers (visual and physical) to error
- Check points for safety
- Reviewed for fitness for purpose

LIMS & Automation

- Functionality utilised to its full potential
- Appropriate rules and meaningful alerts
- Alerts not easily overrriden with audit trail of overrride reasons

SOPs

- Clear and concise instructions for methodology
- Clear escalation pathways and instructions for discrepancies
- Regular review and updates

Training

- Planned and delivered to all relevant staff
- Clear learning outcomes
- Follow up for learning assurance/ regular sessions

Checklist

- Clear purpose for design
- Utilise best practice
- Succinct reminder not an explanation of process
- Clear pause points for use

Warning signs of an ineffective investigation process: If any one or more of the following factors are true, then the incident investigation process and interventions need to be reviewed and improved:

- One or more individuals are identified as causing the event; causal factors point to human error or blame. Human errors must have a preceding cause and system issues need to be identified
- No corrective actions are identified, or the corrective actions do not appear to address the system vulnerabilities identified by the contributing factor
- There are no causal and contributing factors identified, or the contributing factors lack supporting data or information
- The incident investigation is not done in a timely manner and no clear ownership of actions identified or action follow-up is assigned to a group or committee and not to an individual

Beware of attribution bias: Incident investigators should analyse all evidence as impartially as possible