Medicines & Healthcare products Regulatory Agency

Eroding the ‘No Blame’ Incident Reporting Culture

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Are we finding people to blame for their errors instead of blaming the processes and the environment that they work within?

Current Situation – MHRA reports submitted include:

- Submitted reports to SABRE that have led to disciplinary action appearing to target the individual rather than looking at the processes involved.
- QMS data that has been manipulated to show an inaccurate picture of the true situation
- BMS staff suggestion being ignored by senior management and forcing them into an action that they feel is contrary to the GPG forcing staff to carry out processes that they believe was in contrast to safe practice standards.
- Staff being verbally ostracised for actions that they have taken in front of colleagues that has left them distressed and upset.
- Staff either resigning their posts and/or taking early retirement as they feel that their position has been made untenable.
- Lack of management support for the maintenance and development of an effective QMS as laid out in the Good practice Guide:

Good Practice Guide Reference

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. **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.

Good Practice Guide References Continued

1.2.2. The Quality System encompasses quality management, quality assurance, continuous quality improvement, **personnel,** premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance and self-inspection (Directive 2005/62/EC/Annex 1.1.2). (everything must be considered)

9.1.4. 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.

9.1.5. The corrective and preventive actions (CAPAs) system should ensure that existing component non-conformity or quality problems are corrected, and that recurrence of the problem is prevented.

9.1.6. Deviations from established procedures should be avoided as much as possible and should be documented and explained. Any errors, accidents or significant deviations that may affect the quality or safety of blood and blood components should be fully recorded and investigated in order to identify systematic problems that require corrective action. Appropriate corrective and preventive actions should be defined and implemented.

9.1.7. Investigations relating to serious deficiencies, significant deviations and serious component defects should include an assessment of component impact, including a review and evaluation of relevant operational documentation and an assessment of deviations from specified procedures.

THIS IS THE LAW NOT A CHOICE

What the MHRA are doing

We have set up a study collecting data relevant to the current situation.

Representatives from the UKTLC, Royal College of Pathology, UKTM and SHOT.

If you are uncomfortable talking to the MHRA talk to the other but please talk.

Please read this: **Achieving an Open, Ethical and Just Culture in the NHS that Learns and Improves -** Professor Christopher Hodges

Aims and Objective of a Study into the reports received:

That the ‘no blame’ culture is being eroded - Disciplinary measures are taken against an individual instead of adequately looking at the processes to identify a relevant root cause (Scrutiny of SABRE reports for detail including failure to provide additional information when requested by the Haemovigilance Specialist)

Gather pertinent information that reports and QMS data are being manipulated to make HBB and BE QMS look appropriate - Hiding audit data and manipulating records such as training and document reviews

Transfusion staff not being supported in their CPD and training activities in accordance with their state registration requirements – Blocking attendance at internal and external events.

Transfusion Staff morale – Sickness levels, loss of good will.

Staff Turnover and use of locums – Find out why.

Effective management support in the maintenance and development of the QMS – This support includes requests for, changes in staffing levels, application for new technologies i.e. only funding half of a system such as only buying the Kiosks and not the safe Tx elements of the Bloodtrack System despite advice to the contrary by laboratory staff

MHRA guidance

The use of staff disciplinary procedures in response to laboratory staff errors is likely to discourage an open reporting culture amongst staff, and as a result could lead to serious errors going unreported with a resulting increased risk to patient safety. It should be noted that the Guide to Good Practice is clear that where human error is suspected or identified as the cause of a deviation or non-conformance, this should be justified in the investigation report having taken care to ensure that process, procedural or system-based errors or problems have not been overlooked, if present (section 1.2.13).

The Hospital Blood Bank should therefore have reassured itself through a thorough investigation of all potential causes that the only cause is human error, and ensured that the investigation report includes clear evidence for why other potential causes have been excluded. Inspectors are likely to review this at inspection. In the experience of the Inspectorate, many investigations listing the root cause as human error have failed to identify other problems, for example the clarity and accuracy of procedures and records; the logic, design and validation of processes; system faults and/or inadequate resources creating workload pressures. In these instances recording the cause as human error means that the site has missed the opportunity to improve operations and genuinely reduce the risk of reoccurrence.

Whilst it is accepted that in the event of significant capability and performance concerns with an individual the Hospital Blood Bank should have the means to take necessary actions to ensure patient safety, use of these processes as part of the routine response to all deviations and non-conformances would be considered a risk factor and would be investigated in detail at inspection to ensure the system complies with the Good Practice requirements above. Any failure to meet these requirements is likely to be reported as a significant deficiency.”

Summary of current situation – Is this true?

RCA may not be ID flaws in a process

Staff are feeling undervalued

Lack of understanding of the regulatory process

A blame instead of a learning culture is being employed

Retention of staff with the correct skill mix and experience is becoming difficult

QMS are being eroded and therefore less effective.