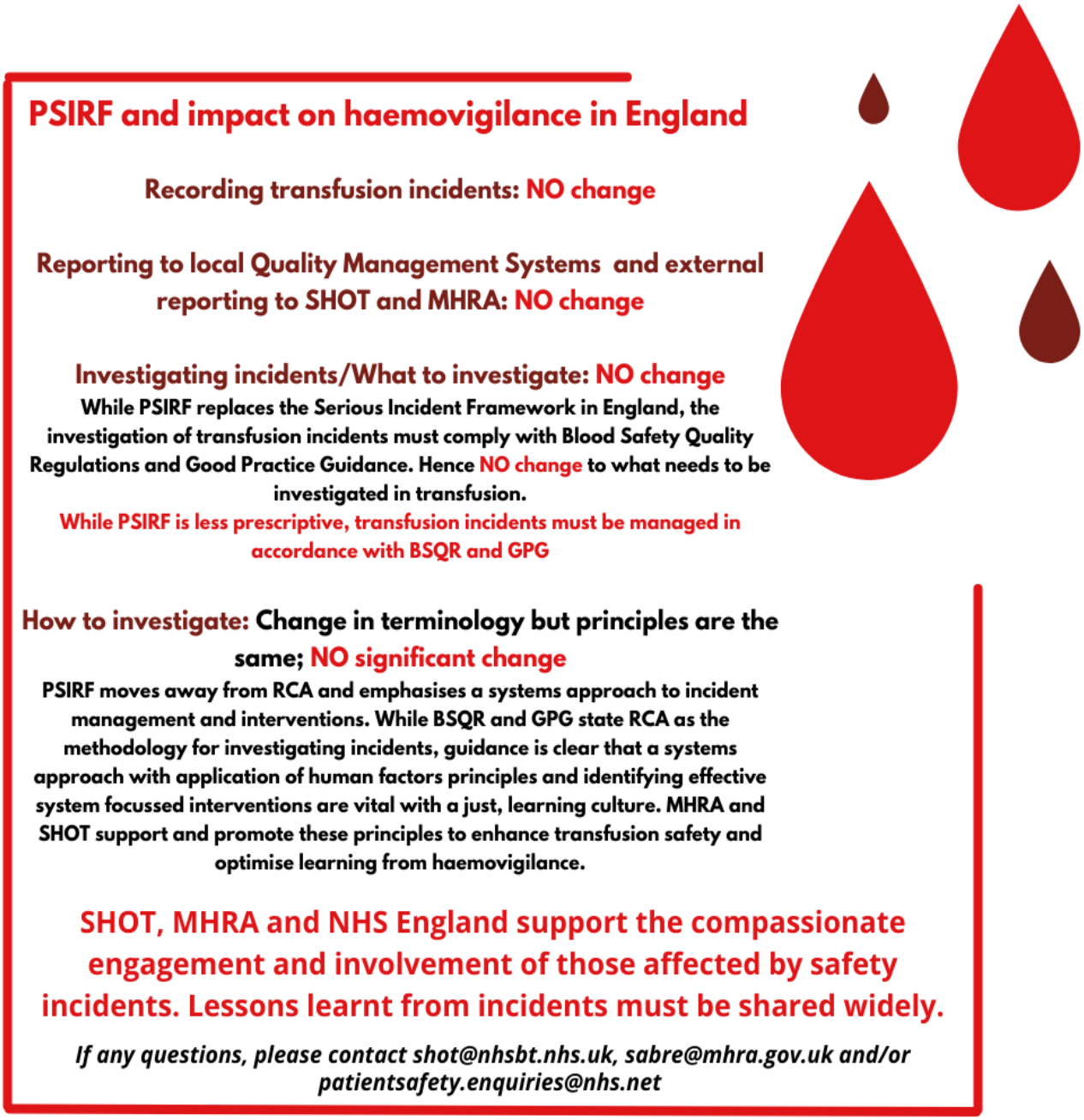
PSIRF and impact on haemovigilance reporting and investigation of transfusion incidents in England, UK

Summary infographic:



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Purpose of this document:

This document aims to answer questions regarding the recording, reporting and investigation of transfusion related adverse incidents in England following the introduction of PSIRF.

What is PSIRF?

NHS England published the Patient Safety Incident Response Framework (PSIRF) in August 2022 as a core element of the NHS Patient Safety Strategy in England. The Framework sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety.

The PSIRF is a contractual requirement under the NHS Standard Contract and is mandatory for providers of NHS-funded care in England. The PSIRF will replace the Serious Incident Framework and makes no distinction between 'patient safety incidents' and 'Serious Incidents'. As such it removes the 'Serious Incidents' classification and the threshold for it. Instead, the PSIRF promotes a proportionate approach to responding to patient safety incident, prioritises compassionate engagement with those affected, and embeds patient safety incident response within a wider system of improvement.

All NHS trusts in England began implementing PSIRF in September 2022 with an expectation for transition to PSIRF by Autumn 2023.

What is haemovigilance?

- Haemovigilance is the surveillance covering the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients, and including their follow-up is essential to improving transfusion safety

Who maintains haemovigilance surveillance?

- The Medicines and Healthcare products Regulatory Agency (MHRA) is the designated UK Competent Authority for blood safety and quality with a legal obligation under the Blood Safety and Quality Regulations (BSQR)(2005) (as amended) to monitor all serious adverse event and reactions related to blood and blood components
- Serious Hazards of Transfusion (SHOT) is the UK's professionally led, independent haemovigilance scheme collecting and analysing anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations that are involved in the transfusion of blood and blood components in the United Kingdom

What are the *reporting* requirements for haemovigilance?

- It is a regulatory and legal requirement to report all serious adverse events (SAEs) and serious adverse reactions (SARs) to the MHRA as soon as known
    - An SAE, as per BSQR, means any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that ***might or could potentially*** lead to death or life-threatening, disabling, or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity
    - An SAR, as per BSQR, means an unintended response in a patient that is associated with the transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating or which results in or prolongs hospitalisation or morbidity

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- Reporting to SHOT is professionally mandated and SHOT work collaboratively with MHRA to cover haemovigilance in the UK. SHOT collect reports on serious adverse events, serious adverse reactions, near misses and more recently, excellence reports promoting a holistic approach to safety
- Further information on reporting to MHRA and SHOT can be found here: https://www.shotuk.org/reporting/

What are the *investigation* requirements for haemovigilance?

It is a **regulatory and legal** requirement for organisations to investigate all SAEs and SARs related to the quality and safety of blood and blood components.

The Good Practice Guidance (GPG) states:

> '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.'
>
> '9.2.1. All complaints and other information, including serious adverse reactions and serious adverse events that may suggest that defective blood components have been issued, must be documented, carefully investigated for causative factors of the defect and, where necessary, followed up by recall and the implementation of corrective actions to prevent recurrence. Procedures must be in place to ensure that the competent authorities are notified, as appropriate, of serious adverse reactions or serious adverse events in accordance with regulatory requirements (Directive 2005/62/ EC Annex 9.2).'

How does PSIRF affect haemovigilance?

- **Recording and reporting of transfusion incidents**
  PSIRF does not impact on the recording or reporting of transfusion related incidents. Current processes within organisations for reporting to Serious Hazards of Transfusion (SHOT) and The Medicines Healthcare products Regulatory Agency (MHRA) remain unchanged.
  https://www.shotuk.org/reporting/

- **Incidents that need investigating**
  The investigation of transfusion incidents must comply with BSQR 2005 and Good Practice Guidance (GPG).
  PSIRF does not impact on the requirement to investigate SAEs and SARs. Incident investigations must not be limited to incidents that resulted in patient harm. Near miss incidents such as wrong blood in tube incidents, are valuable learning opportunities and have the potential to cause serious patient harm. Investigations must consider the potential risk for future patient harm.

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- **Methodology for incident investigations**
  PSIRF supports a system-based approach that involves examination of the components of a system - including a person(s), tasks, tools and technology, the environment, and the wider organisation – to gain a deeper understanding of how their interdependencies might impact patient safety. A framework based on the well-established SEIPS (Systems Engineering Initiative for Patient Safety) replaces the contributory factors classification framework, a guide for which can be found in the patient safety learning response toolkit.
  A thorough system-based patient safety incident investigation that thoroughly examines systemic contributory factors using the PSIRF tools and templates meets the GPG requirements for Root Cause Analysis.
  It is not appropriate to search for a single root cause and evaluation of systemic factors is vital. One of the key recommendations from the human factors and ergonomics chapter in the 2021 Annual SHOT Report is to avoid using the term 'human error' as a conclusion in any incident report and that investigators should focus on finding the system and organisational factors that contributed to the incident.

  SHOT, MHRA and NHS England are clear that thorough incident investigations using human factors principles will help identify contributory factors; and will inform the development of corrective and preventive actions to improve patient safety. One of the main SHOT recommendations in the 2020 Annual SHOT Report was relating to incident investigations: *'Effective investigation of all incidents and near miss events, application of effective corrective and preventive actions, and closing the loop by measuring the effectiveness of interventions should be carried out to optimise learning from incidents'*. Incidents should be investigated by staff trained in this process.

  SHOT, MHRA and NHS England are clear that protected time should be allocated for staff to receive training for incident investigation techniques and to carry out comprehensive incident investigations.

In summary, incidents reviewed at MHRA inspections and reported to MHRA and SHOT must show sufficient evidence of an appropriate level of investigation of underlying contributory factors with application of human factors principles and a systems approach with effective implementation of CAPA. The failure to explore systemic contributory factors with poor implementation of effective CAPA or inappropriate CAPA will inevitably mean lack of learning from incidents and recurrence of such safety incidents.

Common themes between PSIRF, SHOT and MHRA

SHOT, MHRA and NHS England support and have, for a long time, been promoting compassionate engagement and involvement of those affected; a system-based approach to learning; and a just, learning culture. MHRA, SHOT and NHS England support that staff involved in leading or conducting incident investigations should have an adequate level of knowledge and experience to ensure that investigations lead to learning and improvement. Lessons learnt from incident investigations must be shared widely.

Contact details:

If you require any additional clarification with regards to haemovigilance reporting, please do not hesitate to email shot@nhsbt.nhs.uk, sabre@mhra.gov.uk and/or patientsafety.enquiries@nhs.net.