Working alone, saving lives: a focus on transfusion laboratory safety

Nicola Swarbrick, Debbi Poles & Shruthi Narayan

Serious Hazards of Transfusion (SHOT), UK

SUMMARY

Serious Hazards of Transfusion (SHOT) is the UK's independent, professionally led haemovigilance system, collecting and analysing anonymised information on adverse events and reactions in blood transfusion. Where risks and problems are identified, SHOT produces annual recommendations to improve patient safety. Transfusion laboratory errors reported to SHOT help highlight gaps in practices and policies paving the way for improvement actions to enhance safety. SHOT data shows that transfusion laboratory errors occur at a disproportionate rate when staff are lone working. A detailed analysis was undertaken of all laboratory errors reported to SHOT between 2020-2023 where staff working alone in laboratories was identified as a contributory factor (Narayan, 2023).

KEYWORDS

Lone working, human factors, blood transfusion

About SHOT

Since 1996, SHOT has been collecting and analysing anonymised information on adverse events, reactions and near misses occurring during the blood transfusion pathway, from donation through to hospital laboratory testing and administration in clinical areas. The SHOT team work closely with the MHRA as the regulatory body and other key transfusion stakeholders to enhance transfusion safety.

SHOT receives reports from all health organisations in the United Kingdom (UK) that are involved in the transfusion of blood and blood components. These events are submitted via a confidential electronic reporting system where a detailed questionnaire relating specifically to the reporting category is completed by the reporter, to ensure all relevant information is submitted including contributory factors and patient impact. Categories include serious adverse errors, serious adverse reactions and near miss events. Each case submitted is reviewed by SHOT incident specialists and working experts to identify trends and patterns, contributory factors, areas for improvement and implemented preventative measures. These findings are contained within the Annual SHOT Report (ASR) which is freely available online via the SHOT website and is widely shared within the transfusion community and to all relevant stakeholders.

Reporting to SHOT is professionally mandated, as SHOT is not a regulatory body. Through SHOT, organisations can monitor their haemovigilance reporting and benchmark themselves against organisations of similar size or blood usage to promote transparency, accountability and continuous improvement in blood transfusion practices. SHOT also receives reports of exceptional practice and innovative solutions to promote the learning both locally and nationally.

Haemovigilance reporting to SHOT is passive and reporting is limited to certain categories; not all transfusion related incidents are reportable to SHOT. It is also important to note that reporting levels varies between organisations and can be impacted on by local staffing issues and safety culture. SHOT is aware that there may be underreporting in certain categories, particularly in near miss events, so this data should be taken as indicative rather than complete. SHOT do not get involved in any local investigations and are dependent upon SHOT reporters submitting all relevant information via the reporting questionnaire or supplementary data. Reporters are encouraged to submit causal and contributory factors based on local incident investigations and applying human factors principles. It can be difficult to access complete data about the number of blood components transfused, the number of transfusions occurring out of hours and the number of laboratory tests performed within certain time frames.

Transfusion laboratory errors reported to SHOT help highlight gaps in practices and policies, paving the way for improvement actions to enhance safety. The SHOT questionnaire asks reporters to identify additional human factors which may have contributed to the error via the SHOT Human Factors Investigation Tool (HFIT). These questions cover the contributory factors regarding communication and culture, situational factors, organisational factors, external factors and lone working conditions. A detailed analysis was undertaken of all laboratory errors reported to SHOT between 2020-2023 where staff working alone in laboratories was identified as a contributory factor to understand common themes and inform improvement actions.

What is lone working?

Lone working can be defined as any situation in which someone works without close or direct supervision; without a colleague nearby or is out of sight or earshot of another colleague. Lone working can inherently pose a greater risk of errors as the worker is isolated, without colleagues available for advice or to assist in tasks. There are unique challenges lone workers face including high pressure decision making, increased responsibility, limited access to support through peers and senior staff, isolation and stress, confidence and competence issues, and communication and contact issues especially when dealing with emergencies in the laboratory where one staff member may cover several pathology disciplines during their lone working shift. Lone working is standard practice in UK laboratories, especially at night and during weekends. Prior to commencing lone working staff need to be trained and competency assessed, with risk assessment and support structures in place.

Blood transfusion laboratories – national regulations, standards, guidelines and recommendations

Detailed quality management system requirements for UK blood transfusion laboratories are outlined in the Blood Safety Quality Regulations (BSQR), governed by the Medicines and Healthcare products Regulatory Agency (MHRA), the competent authority overseeing the quality of the UK blood supply. MHRA has the responsibility to check that organisations adhere to these regulations via annual compliance reports and inspections.

UK blood transfusion laboratories must also adhere to quality requirements outlined by the United Kingdom Accreditation Service (UKAS) to gain accreditation to detailed standards through annual assessment visits.

Laboratory staff should follow all relevant guidelines and good practice guides outlined by the British Society for Haematology (BSH) in relation to transfusion practice to ensure provision of safe and effective blood components.

The UK Transfusion Laboratory Collaborative (UKTLC) is a collaborative group of transfusion laboratory representatives from across the UK, including SHOT, regulatory and accreditation bodies, external assessment schemes, and institutes and societies of biomedical science and blood transfusion. UKTLC produce standards for transfusion laboratories to develop staff knowledge and skills and improve transfusion safety. Compliance with UKTLC standards has been accepted by the MHRA, and UKAS as evidence to support their inspections for laboratories. UKTLC also conduct surveys to address gaps in practices, improve safety culture and promotion of best practice.

The Infected Blood Inquiry (IBI) report released in May 2024 highlighted the importance of laboratory safety and that laboratory teams can function optimally only if adequately staffed and resourced. The Inquiry reiterated the importance of staff receiving sufficient transfusion knowledge and training to reduce risks to patient safety by adherence to the regulations and standards provided by MHRA, UKAS and UKTLC. Reporting to SHOT and actioning SHOT recommendations was also outlined as essential in improving patient safety.

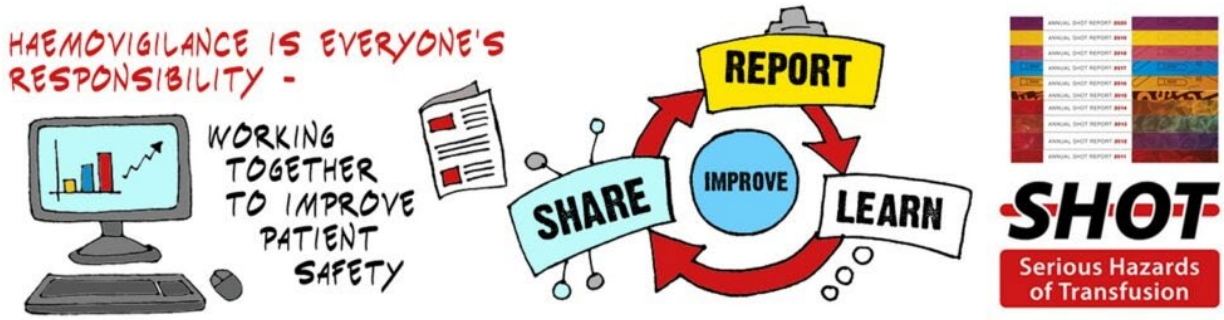

Figure 1. SHOT email signature highlighting the importance of haemovigilance in patient safety

Transfusion laboratory errors reported to SHOT between 2020-2023 with lone working identified as a contributory factor

There were a total of 1794 laboratory errors between 2020-2023, of which 540 (30.1%) occurred when the staff were lone working.

Most questions on the SHOT reporting questionnaire are non-mandatory, and therefore the denominator may vary due to non-responders.

There were 540 reports involving lone working laboratory staff, and these were analysed for contributory factors. Reports were assessed for the event time of errors, with 493 reporters submitting a response. Of these 263/493 (53.3%) errors occurred over a night shift between 8pm–8am, and 230/493 (46.7%) over a day shift between 8am–8pm. More specifically reporters were asked about the classification of working hours when lone working errors occurred and, of the 470 responses, 337/470 (71.7%) stated outside, and 133/470 (28.3%) within normal working hours.

Transfusion laboratory errors occurring during lone working resulted in:

- 171/540 (31.7%) blood transfusions which did not meet the patient's specific requirements
- 109/540 (20.2%) handling and storage issues of the blood components
- 86/540 (15.4%) laboratory-based patient identification errors
- 75/540 (13.9%) wrong component being transfused
- 61/540 (11.3%) transfusion delays which impacted on patient wellbeing
- 41/540 (7.6%) errors relating to anti-D Ig administration

These errors resulted in 2 patient deaths (1 possible, 1 probable) due to transfusion delays, and 11 cases of major morbidity due to development of anti-K in patients of childbearing potential due to laboratory errors. Of the errors 492/540 (91.1%) involved adult patients and 48/540 (8.9%) paediatric patients.

Many of these errors were compounded by lone working situations such single point of failure without a second member of staff to check or confirm correct procedure, gaps in knowledge, tiredness, difficulties in communication, dealing with emergency situations, multitasking and managing multiple laboratory areas as a single member of staff.

Contributory factors to errors

There were multiple contributory factors identified which compounded errors occurring during lone working. Most questions on the SHOT reporting questionnaire are non-mandatory, and therefore the denominator may vary due to non-responders.

Staff knowledge and training

In 350/540 cases reporters were asked if the member of staff had been competency assessed for the task where the error occurred. This question did not apply to all SHOT reporting categories until 2023. Of the 318/350 responses, 307/318 (96.5%) stated staff were competency assessed for the task, yet the error still occurred. In 370/540 cases reporters responded to the question 'were there issues or gaps with staff skill or knowledge', of which 128/370 stated yes there were gaps. Some reported cases mentioned that staff received accelerated training to expedite staff onto shift patterns due to staff shortages.

Information technology

Reports were assessed and 326/540 (60.4%) errors were deemed to involve information technology (IT). Common themes reported included overriding IT alerts, staff not heeding information available in IT systems, staff not adding IT alerts where available, lack of functionality in IT systems, patients having multiple records on hospital electronic patient records, lack of interoperability between systems and unplanned IT downtime. Use of IT to alleviate pressures from lone working staff has long been recommended, but staff must be sufficiently trained and IT systems implemented correctly considering human factors.

Task and team function

Reporters were asked to assess further contributory human factors in lone working errors:

- 159 of the 372 (42.7%) responders stated that task features impacted on the likelihood of the error
- 72 of the 369 (19.5%) responders stated there were failures in team function in relation to leadership, supervision, and roles

These errors are similar in other transfusion incidents occurring during routine hours but are compounded in lone working situations.

Specific lone working factors

Additional contributory factors stated in the reports included staff being physically and mental tired, lack of knowledge and experience, insufficient training, multitasking and distractions, insufficient staffing levels, high workloads, pressured emergency situations and sequential night shift working. Poor communication, poor handover, and IT issues compounded these errors. Local working conditions and situational factors contributed to the errors and included lack of out of hours support,

poor delegation of tasks and staff being unprepared to deal with uncommon and/or emergency situations and complex cases. An illustrative case resulted in the wrong ABO group red cells being issued and transfused to a transplant patient. The lone working laboratory staff was under increased pressure due to a backlog of work remaining from the day shift and was rushing to complete all work before the end of their shift. IT alerts were not heeded, and training was deemed to have been insufficient.

The 2024 UKTLC culture survey identified that laboratory staff felt that work pressures impacted on their personal and home life, including negative impacts on their mental and physical wellbeing. A poor safety culture impacted on staff's ability to confidently and competently do their day-to-day role. Some staff also felt that they had been pressured to present an inaccurate assessment of the severity of an incident or been discouraged from reporting both internally within the organisation or to external bodies such as SHOT or MHRA.

Figure 2. SHOT email signature to highlight human factors contributory with blood transfusion errors

Mitigating strategies

SHOT

As part of the 2023 Annual SHOT Report, analysis of the laboratory errors highlighted several challenging areas of concern including abbreviated and accelerated training of laboratory staff to expedite staff onto continue processing patterns, and lone working laboratory staff. As such SHOT made several laboratory recommendations in 2023:

- Patients should not die or suffer harm from avoidable delays in transfusion. Where transfusion needs are complex, laboratory staff should have access to and follow specialist advice to provide the most suitable component available. Hospital policies and processes must reflect this.
- Staff must have protected time for training and education to provide a safe service.
- Policies for lone working should be reviewed to identify when extra support or reallocation of tasks are required.
- A just and learning safety culture should be implemented to improve the safety of patients and staff members, and to ease the existing recruitment and retention pressures in the laboratory.

These recommendations reinforced the need for staff working alone to be sufficiently trained, competent and confident in their tasks, with access to and follow specialist advice when required. Reallocation of tasks from lone working periods will alleviate additional pressures, allowing lone working staff to focus on the necessary tasks. Having a just safety culture where staff are well supported and confident to bring forward concerns and issues will lead to improved practices and enhanced service provision.

UKTLC

In 2023, UKTLC produced standards for transfusion laboratories (Dowling 2023) covering four main areas:

- Staffing - including staffing levels, capacity plans to meet workload demands, staff with specialist transfusion knowledge
- Qualifications, knowledge and skills - including minimum qualification requirements for all staff grades, training and competency assessment, and required provision of resources available to provide staff with sufficient knowledge and skills
- Information technology – including blood transfusion analysers, laboratory information management systems, and electronic transfusion systems
- Just culture – including encouraging staff to report errors, near misses, suggested improvements, potential risks that may impact on patient safety, and report examples of excellence, whilst consideration of human factors and system thinking

The UKTLC standards are produced with associated resources such as an example capacity plan and gap analysis self-assessment tools for teams to identify gaps in local processes. UKTLC also outlines the requirement for multi-disciplinary scientific staff and senior transfusion staff who would be expected to work within blood transfusion to complete a minimum of 10 practical working days per annum in a hospital blood transfusion laboratory. These standards are regularly reviewed to meet current workforce needs and requirements.

MHRA

The BSQR regulations include organisations having adequate numbers of personnel with the necessary qualifications and experience, and that management ensure staff are provided with adequate resources for the BSQR to be implemented and the quality management system to be maintained. MHRA state it is essential that laboratories have a capacity plan in place to ensure there is sufficient staffing to cover the workload, including out-of-hours working, and should be reviewed and updated if appropriate. This capacity plan should be available to suit all situations so business continuity can be preserved. Where gaps are identified senior management should take action to ensure sufficient resources will be made available.

Infected Blood Inquiry

The light of all the evidence supplied, the IBI made several recommendations relating to transfusion laboratory safety which included a laboratory and clinical training and education review including undergraduate and postgraduate to ensure they are adequately trained in transfusion, transfusion laboratories must be staff and resources adequately to meet the requirements of their functions, that all NHS organisations have a mechanism for reporting to SHOT and actioning their recommendations, and that a framework be established for recording outcomes for recipients of blood components.

Addressing workforce challenges

In England, based on the foundations of the Better Blood Transfusion initiatives, the 5-year Transfusion 2024 plan was to develop and promote the following key priorities - appropriate blood use, information technology, laboratory safety and research and innovation. The transfusion laboratory safety actions included the review of scientific training pathways and programmes to

strengthen transfusion content and the provision of training resources to all laboratory staff to ensure an appropriately skilled and knowledgeable workforce. This has been realised in the format of the Transfusion Training Hub hosted via the National Blood Transfusion Committee website. This has been specifically created to support education and training for all healthcare professionals working within blood transfusion, providing a wide variety of learning, resources and signposts, each based on the levels of learning required from foundation and intermediate to in-depth and expert level.

Transfusion 2024 project is currently undertaking a review of all Institute of Biomedical Science (IBMS) accredited BSc Biomedical Science undergraduate degrees for blood transfusion course content. A working group of working transfusion experts and representatives from 12 universities has recently been established with the aim to produce standardised content to satisfy both the Quality Assurance Agency (QAA) standards and the IBI recommendations, which universities can access as a support tool to improve the content and delivery of transfusion education

The recent release of the Government's 2025 Mandate to NHS England has set out the vision for NHS reform and has placed biomedical scientists at the heart of these developments through improved efficiency and capacity of diagnostic services. In order to meet these challenges IBMS has called for:

- Expansion of training pathways and career progression opportunities to address workforce issues
- Increased investment in pathology networks and community diagnostic centres
- Greater recognition of biomedical scientists' expertise in strategic NHS workforce planning
- Clear career progressions pathways for biomedical scientists to maximise utilisation of skills and knowledge

The IBMS also outline the importance of widespread interoperability between digital systems to improve patient safety. Long-term investment in skills, technology and capacity rather than a focus on financial savings has been outlined as being key to the Government's plans.

Conclusion

Hospital transfusion laboratories are required to provide a 24/7 diagnostic and blood transfusion service to meet the needs of the hospital and its patients. Service provision requires laboratory staff to work out of routine hours, often lone working. There must be protective measures in place for lone working staff including risk assessments of tasks, regular reviews with feedback loops, availability out of hours advice or support, clearly defined standard operating policies and sufficient training and competency to equip staff to work alone. Policies for lone working should be reviewed to identify when extra support or reallocation of tasks are required.

There should be committment by teams to consider the impact of lone working on staff wellbeing, and the influence this may have on physical and mental health and an individual's home life, and mitigating actions taken where this is identified. Lone working staff require adequate rest breaks, and this must be factored into the laboratory's capacity plan. The capacity plan should demonstrated that the staffing levels are sufficient to cover the workload in all situations so business continuity is preserved, and reviewed and updated when required.

Harnessing the implementation of IT, and maximising of interoperability between IT systems will significantly improve patient safety. IT must be implemented correctly with consideration of human factors and ergonomics, to prevent workarounds or short cuts. Staff must be sufficient trained to use these systems with detailed contingency plans in place for downtime.

Acknowledgements

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