2019 UK Transfusion Laboratories Culture Survey Report

Report from the 2019 survey of culture prevalent in transfusion laboratories across UK undertaken as a joint venture by Medicines and Healthcare products Regulatory Authority (MHRA), UK Transfusion Laboratory Collaborative (UKTLC), Serious Hazards of transfusion (SHOT) and the Transfusion Laboratory Managers Working Group of the National Blood Transfusion Committee (TLM)

MHRA

SHOT Serious Hazards of Transfusion

The Royal College of Pathologists
Pathology: the science behind the cure

NHS
National Blood Transfusion Committee

Transfusion Laboratory Managers Working Group

UKTLC
UK Transfusion Laboratory Collaborative

IS AN OPEN AND LEARNING CULTURE STILL PART OF PATHOLOGY CULTURE

INTRODUCTION

This study has been undertaken because of recent anecdotal reports received by Medicines and Healthcare products Regulatory Authority (MHRA), UK Transfusion Laboratory Collaborative (UKTLC), Serious Hazards of transfusion (SHOT) and the Transfusion Laboratory Managers Working Group of the National Blood Transfusion Committee (TLM). This anecdotal evidence includes:

a. Staff resigning their posts or taking early retirement as they feel that their position has been made untenable by their senior management not providing enough support in carrying out their duties in accordance with best practice and the regulatory standards i.e. the introduction of a policy to discipline staff if found responsible for a SHOT and/or a SABRE reportable event

b. Submitted reports to SABRE that have led to disciplinary action against an individual where the reporter has not included a full and inclusive root cause.

c. Audit and change data that have been manipulated, such as, removing specific turnaround time (TAT) figures and closing adverse incidents before a full investigation has been concluded and prior to inspections.

d. BMS staff suggesting to managers an appropriate course of action, in accordance with their Quality Management System (QMS), but being ignored and, in the opinion of the BMS, the managers then carried out a process that contrasted with safe practice standards e.g. moving a laboratory before an appropriate change control and validation process, for the move, had been performed.

e. Staff being verbally criticised, being labelled as a 'problem child', for actions that they have taken or have suggested, in front of colleagues, that has left them distressed and upset.

f. Lack of management support for the maintenance and development of an effective QMS, as laid out in the Good practice Guide (EU 2016), such as refusing additional staff requests despite staff numbers being below the designated capacity plan.

These reports have been received from 33 different sites and therefore may provide an early signal that reflects a concerning rise in a non-learning as opposed to a learning culture and therefore detrimental to patient safety in accordance with the Berwick Report (Berwick 2013).

AIMS AND OBJECTIVES

The study aims are

a. To see If the learning culture is being eroded in organisations where the focus is on individuals responsible for errors instead of investigating the processes and environment that they work within to identify why the error occurred.

b. To identify if data is being manipulated inappropriately to create a positive picture of QMS function.

c. To ascertain if Pathology staff feel adequately supported or empowered to voice their concerns to senior managers about shortfalls within their QMS.

d. To ascertain if staff feel that insufficient resources are being made available for them to effectively manage and develop an effective safe transfusion service and QMS.

e. To identify If difficulty in retention and recruitment of appropriately qualified and experienced staff is a direct result of the culture employed by a site.

SURVEY SCOPE

As a direct response to the anecdotal evidence representatives from the MHRA, UKTLC. Royal College of Pathologists (RCPath), SHOT and the TLM designed the following questions and distributed them via an electronic survey using SurveyMonkey®. The link was distributed to the SABRE reporters E Mail list, who are responsible for reporting adverse incidents to SHOT and the MHRA.

Sample Size = 202 SABRE reporters across the UK

Replies = 94

Questions

	Question
1	Have you or a colleague been disciplined as a direct result of a single quality incident such as a SABRE/SHOT event?
2	Do you have sufficient resource to provide both a quality management system in line with the good practice guide and a safe transfusion service?
3	Have you ever felt under pressure from line managers or above to present an unrealistic impression of the laboratory's compliance with the good practice guide (e.g. state of audits, training, BCR submission)?
4	Have you or a colleague been affected by behaviour changes from either Pathology or Trust management towards you following an adverse external inspection?
5	Have any staff left or taken early retirement citing the pressure in delivering both a safe transfusion service and fulfilling regulatory requirements?
6	Do you (and the staff in your laboratory) feel empowered and safe to voice your concerns?
7	Are staff reluctant to work in the transfusion laboratory citing additional pressure over and above that of haematology?

Respondents were also asked for additional anonymised comments that they would like to make.

RESULTS

1. **Have you or a colleague been disciplined as a direct result of a single quality incident such as a SABRE/SHOT event?**

Yes	6
No	88
No reply	0

Table 1. Disciplinary action as a result of a SABRE/SHOT reportable event

Table 1 shows that 6 respondents reported that staff have been disciplined as a direct result of a mistake. Considering best practice literature and the relevant regulations, disciplinary action must be the very last option and only undertaken when investigations prove unequivocally that the individual is to blame and not the processes and the environment that they work within. Disciplinary action, taken outside of best practice advice and the regulatory framework is a barrier to incident reporting and transparency. Disciplinary action also influences staff confidence and therefore can be a barrier to effective management and morale. It can also have a detrimental effect on convincing non specialised transfusion staff, despite being trained and deemed competent in transfusion, from working within the transfusion speciality.

Sites must have reassured themselves 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. MHRA 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.

2. **Do you have sufficient resource to provide both a quality management system in line with the good practice guide and a safe transfusion service?**

Yes	64
No	30
No reply	0

Table 2. Resourcing and effective QMS

A total of 30 respondents, see Table 2, stated that insufficient resource was available to maintain an effective and safe service whilst managing and developing an effective QMS. The situation coupled with the findings of the UKTLC Survey 2017, where it states that 47.8% (UKTLC Survey 2019) of respondents reported that they had vacancies, suggests that laboratories are having their available resource seriously stretched affecting their ability to deliver a safe an effective transfusion service. The outcome of an inspection that identifies these issues can lead to a 'cease and desist' notice, post inspection, from the MHRA.

These findings also suggest that laboratory capacity planning may not be set at an appropriate level. In the event of significant capability and performance concerns an individual site must have the means to take necessary actions to ensure patient safety. If actions to mitigate the capacity and resource

issues were insufficient this would be considered a significant risk factor and would be investigated in detail at inspection to ensure the system complies with the Good Practice requirements. Any failure to meet these requirements is likely to be reported as a significant deficiency.

3. **Have you ever felt under pressure from line managers or above to present an unrealistic impression of the laboratory's compliance with the good practice guide (e.g. state of audits, training, BCR submission)?**

Yes	20
No	74
No reply	0

Table 3. Pressure from line managers to manipulate QMS data

4. **Have you or a colleague been affected by behaviour changes from either Pathology or Trust management towards you following an adverse external inspection?**

Yes	20
No	73
No reply	1

Table 4. Senior Management response to a poor inspection

Tables 3 and 4 shows that 20 respondents have been under pressure to change audits and have been adversely affected by the behaviour of management post inspection. Correct data are essential to regulatory compliance and therefore manipulating these data can produce an unrealistic image of an organisation's regulatory state.

Management must take a strong supportive lead in all aspects of securing data, making these transparent and thus a true reflection of the issues that a site is facing. Risks can only be mitigated if they are identified and accepted and organisations can only do that by being open and honest. Pressure to falsify data, either by fear of reprisal after failing to meet expectations or giving 'bad news' or rewarding failure, will only exacerbate a culture of poor performance. This is likely to create an environment which discourages reporting from staff.

Data critical sources in the reflection of a good or poor performing system/process and therefore data integrity has a fundamental bearing on the health of an organisations QMS. Data integrity must be commensurate with the level of its criticality and should be viewed in an open and transparent way. Poor data integrity is an indicative sign of a poor-quality culture.

5. **Have any staff left or taken early retirement citing the pressure in delivering both a safe transfusion service and fulfilling regulatory requirements?**

Yes	35
No	59
No reply	0

Table 5. Staff taking early retirement

Table 5 shows that 35 respondents have reported that due to the increased pressure on managers to maintain a safe and compliant service, staff are leaving. The result of this is exacerbation of capacity pressures and knowledge loss. It is important for organisations to identify the exact triggers for these retirements/ departures to try and understand what organisations can do to try and support, and therefore retain them within the workplace. These measures could include introduction of new technologies and/or employment of additional personnel to avoid the loss of such experienced and valued personnel. Organisations must also ensure that when staff take retirement that they have an effective succession and business continuity plan in place, so the loss of this resource and knowledge is effectively managed.

6. **Do you (and the staff in your laboratory) feel empowered and safe to voice your concerns?**

Yes	81
No	13
No reply	0

Figure 6. Staff Empowerment

Table 6 shows that 81 respondents feel empowered to voice their concerns. However, the comments submitted suggests that they are rarely listened to. Empowerment of staff has been shown to improve the quality of work, employee satisfaction, and collaboration throughout the whole organisation. In addition, employee productivity increases, and organisational costs decrease (The Kings Fund 2014). If staff feel that they are not heard these positive effects have the opposite effect.

7. **Are staff reluctant to work in the transfusion laboratory citing additional pressure over and above that of haematology?**

Yes	37
No	56
No reply	1

Table 7. Staff reluctance to work in Blood Transfusion

Figure 7 shows that 37 respondents have experienced reluctance of staff to work in blood transfusion as they feel that the additional pressures and responsibilities are too great. This situation only exacerbates the capacity and capability issues that transfusion staff are voicing.

Shift patterns, according to agenda for change guidelines, have nearly all replaced the old on call service and therefore laboratories staffing these shifts must ensure that the transfusion function is covered appropriately with the appropriate experienced and qualified staff. These results suggest that staff who would have usually be expected to work just within one discipline i.e. haematology, do not feel comfortable working in transfusion due to the nature of the work they are expected to do. The reasons for this include:

a. Fear of a mistake leading to a catastrophic event

b. Lack of confidence due to poor or insufficient training

c. Lack of support from experienced transfusion trained staff when lone working

This list is not exhaustive but all of these can be managed effectively with the introduction and availability of the appropriate processes and resource. It is only when this is done can staff, reluctant to work in transfusion, be managed effectively to ensure a safe transfusion service and maintain patient safety.

8. If you have any further comments you would like to make, please add them here.

A summary of 22 comments received highlighted the following:

a. Increasing pressures on resource to deliver a safe and high-quality service

b. Genuine quality concerns raised to higher management are not always taken seriously

c. Higher trust management failing to understand that the available resource is not sufficient to manage and develop an effective QMS.

d. A realistic fear of making mistakes in transfusion leading to a catastrophic event

e. Comments from 3 respondents that blood bank managers are expressing their intention to retire at the earliest opportunity due to the pressures that they are facing in managing a transfusion service safely and effectively.

f. Although staff feel empowered to raise concerns management do not act on them once raised.

g. The lack of concessionary measures within a process blocking the flexibility in allowing staff to exert their professional judgments i.e. Sample acceptance criteria not allowing for cases where patients are difficult to bleed or have a low blood circulation.

h. The implementation of laboratory networks is not adequately supported, by managers and IT staff, which is having a detrimental effect on quality.

i. Failure to consider the maintenance of QMS as part of the workload (in other words only test numbers count) means increasing pressure on transfusion staff particularly senior staff

j. A lack of understanding by executive management about the requirements of the MHRA.

REGULATIONS AND BEST PRCTICE PRINCIPLES

Regulatory framework

The Good Practice Guide was developed to provide the regulatory guidance, and within a learning culture environment, for Hospital Blood Banks (HBB) and Blood Establishments to develop, manage and maintain an effective Quality Management System in accordance with EU regulations 2005/62/EC and the UK Blood Safety and Quality Regulations (BSQR 2006).

The relevant references to the regulatory framework (Good Practice Guide EUC 2016) pertinent to this survey, but not limited to, are as follows:

a. Section 1.2.5. states that executive management has the ultimate responsibility to ensure that an effective Quality System is in place and resourced adequately, and that roles and responsibilities, are defined, communicated and implemented throughout the organisation.

b. Section 1.2.13 states that 'A formal system for the handling of deviations and non-conformances must be in place and 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'.

c. Section 5.1.3 insists that documentation used to manage and record good practice compliance: instructions (directions, requirements) and records/reports must be controlled. Controls should be implemented to ensure the accuracy, integrity, availability and legibility of documents.

d. Section 2.2 states that the organisation should have an adequate number of personnel with the necessary qualifications and experience. Management has the ultimate responsibility to determine and provide adequate and appropriate resources to maintain the Quality Management System.

Best Practice Principles

A learning culture is fully supported and encouraged across the health service authorities. The NHS and other health governance organisations and commissions have highlighted the importance of an open reporting culture in creating and maintaining patient safety.

The following information has been taken from the relevant references in support, and highlighting the importance, of creating an open and just culture within a health care setting.

As a result of failings found within the Mid Staffordshire NHS Trust the Berwick Report was published whose recommendations centred on placing the quality of patient care, especially patient safety, above all other aims. Engagement, empowerment, and listening to patients and carers is key. The NHS must foster whole-heartedly the growth and development of all staff, including their ability and support to improve the processes in which they work. Embrace transparency unequivocally and everywhere, in the service of accountability, trust, and the growth of knowledge (The Berwick Report 2013).

In 2014 the Kings Fund published a paper that stated,' it is now accepted that healthy cultures in NHS organisations are crucial to ensuring the delivery of high-quality patient care'.

Sustaining cultures of high-quality care involves all staff focusing on continual learning and improvement of patient care. Learning and quality improvement are dependent on continual patient input – innovation is most likely where patients' views and feedback play a strong role. A focus on improvement should ensure that:

- teams at all levels collectively take time to review and improve their performance
- quality and patient safety practices are an ongoing priority for all
- there are high levels of dialogue, debate and discussion across the organisation to achieve shared understanding about quality problems and solutions.

All staff should encourage, welcome and explore feedback and treat complaints and errors as opportunities for learning across the system rather than as a prompt for blame. This encourages collective openness to and learning from errors, near misses and incidents (The Kings Fund 2014).

NHS Improvement (NHSI) produced a Just Culture Guide focusing on the fair treatment of staff and the importance of supporting a culture of fairness, openness and learning in the NHS by making staff feel confident to speak up when things go wrong, rather than fearing blame.

Supporting staff to be open about mistakes allows valuable lessons to be learnt so the same errors can be prevented from being repeated. In any organisations or teams where a blame culture is still prevalent, this guide will be a powerful tool in promoting cultural change (NHSI 2018).

The evidence collected here is worrying. It does raise a significant concern that there is a lack of management support in developing and maintaining an attitude of learning from incidents and errors, contrary to all recent recommendations.

SUMMARY AND RECOMMENDATIONS

The purpose of this survey was to find out if transfusion laboratory staff were being disciplined or inhibited from their essential reporting of transfusion incidents and what the impact of this is. The number, although small, shows evidence that a just and learning culture is not being effectively employed within the NHS transfusion service based on:

a. 6 respondents have known of disciplinary action against an individual after an error

b. 30 respondents feel that there is insufficient capacity to resource an effective QMS

c. The combined results from questions 3 and 4 show that 40 respondents feel that management are allowing a manipulation of data to portray an inaccurate picture of regulatory and best practice compliance and when they voice their concerns have experienced a negative response from managers.

d. 35 respondents have experienced staff taking early retirement to relieve the pressures of running a safe transfusion service

e. 81 replies show that respondents feel empowered but not necessarily supported by management action on the concerns raised. 13 respondents did not feel empowered.

f. 37 respondents stated that staff have a fear of working in transfusion by staff who are worried about disciplinary action as a result of a mistake and a lack of dedicated transfusion training.

The findings of this survey strongly suggest a need for further investigation. This could be a larger project, either by site visits of Pathology laboratories commissioned by a nominated independent body, and/or carry out a more detailed investigation. This would examine the issues found to see if a case can be made for the following recommendations to be actioned:

a. Install a program of education directed at higher management on the use of an adverse incident system as a tool for improvement rather than looking at it as a tool for disciplinary measures being taken against individuals who make mistakes.

b. Install an education program for staff and management on the requirements for developing and maintaining an effective QMS and how it links with good patient safety practices.

c. Carry out a larger and more targeted survey on transfusion departments capacity issues and educate staff and managers on effective capacity and resource management measures.

d. Introduce tools to allow pathology staff to feel more empowered and supported, to raise pathology concerns regarding issues unique to pathology such as UKAS accreditation and MHRA regulatory compliance.

e. Understand the issues facing transfusion departments concerning the retention and employment of appropriately trained and qualified staff.

Currently Pathology services are undergoing significant changes due to the NHS Improvements (NHSI) initiative to create 29 regional networks for Pathology service delivery (Wells 2018). This is intended to drive costs down but must not result in unsafe practice.

Organisations, at every level of the hierarchical structure, should feel free to voice concerns about issues, such as poor performance and lack of capacity, without repercussion from regulatory bodies or the organisation. Errors must be managed as a learning tool and not as a weapon to punish. Commissioning a more detailed survey targeted specifically at identifying the cultural pressures on management and staff may lead to a series of effective educational and management measures to create an effective culture of learning where staff and management feel valued and work together in systems that compliments each other and across the organisation.

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