7 Human Factors in SHOT Error Incidents n=2569

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Definition

Human factors and ergonomics (HFE) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system.

Key SHOT messages

- The term 'human factors' is not interchangeable with 'human error'. It broadly denotes the opposite because it refers to the factors that influence humans in their execution of tasks. It means the same as ergonomics, which incorporates how system and organisational factors, as well as design aspects, can affect human performance

- System and organisational factors – this phrase is used extensively and the simplest way to explain the meaning is to consider all the questions asked in the SHOT HFIT, particularly in conjunction with the tooltips on the website as they cover most of the system and organisational factors that are likely to contribute to adverse incidents

Recommendations

- The term 'human error' should no longer be used as a conclusion in any incident report and investigators should focus on finding the system and organisational factors that contributed to the incident

- Incidents should be investigated by staff trained in this process and protected time should be allocated for staff to receive training for incident investigation techniques and to carry out comprehensive incident investigations

- A tried and tested human factors-based framework should be applied to incident investigations. The SHOT HFIT questions may be used in addition, so that answers to the questions can be discovered during the investigation

- Human factors and ergonomics training should be provided to all staff, clinical and laboratory, to ensure a holistic approach to building safe systems and work towards error reduction

Action: Hospital risk departments, hospital transfusion committees, hospital transfusion teams

Abbreviations used in this chapter

AI	Artificial intelligence	**HSIB**	Healthcare Safety Investigation Branch
BMS	Biomedical scientist	**IT**	Information technology
BSQR	Blood Safety and Quality Regulations	**MHRA**	Medicines and Healthcare products Regulatory Agency
CCP	COVID-19 convalescent plasma	**NHSEI**	NHS England and NHS Improvement
FFP	Fresh frozen plasma	**PSIRF**	Patient Safety Incident Response Framework
GPG	Good practice guidelines	**SAE**	SAE Serious adverse event
HFE	Human factors and ergonomics	**SEIPS**	Systems Engineering Initiative for Patient Safety
HFIT	Human factors investigation tool	**SOP**	Standard operating procedure
		YCFF	Yorkshire Contributory Factors Framework

Introduction

SHOT would like to emphasise the importance of recognising that the term 'human factors' does not equate to 'human error'. In fact, it means the opposite, as the discipline is related to understanding how humans interact with systems and processes. Ergonomics is the science applied to study the relationship between workers and their environments and means exactly the same as human factors and these principles must guide incident investigations. Investigators should look beyond the actions of the human to examine in more depth what system and organisational factors affected the decisions taken by the person or people involved in the event.

The new SHOT HFIT, introduced in 2021, is designed to encourage reporters to recognise that 'human error' is not an appropriate conclusion for an incident investigation. It has long been argued that the phrase 'human error' is a misnomer because it cannot exist as something that is observable in an incident or accident (Hollnagel 1983) and the activity leading to an error would usually be more accurately defined as a failure to achieve the intended outcome. SHOT is aware that the BSQR specification category of 'human error' exists, but reporters to the MHRA are also directed by the regulations to investigate incidents thoroughly to identify system or process improvements. The BSQR 2005 (as amended) mandates that reporters evaluate SAE to 'identify preventable causes within the process' (Regulation 12B (4a)). The Good Practice Guidelines for blood (GPG 2018) state '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 preventative actions (CAPA) should be identified and taken in response to investigations.' (1.2.13). (Chapter 25, Medicines and Healthcare products Regulatory Agency (MHRA) Report).

In other words, even if it is concluded that an error is a result of a slip, or lapse in concentration in an individual human, it is likely that there is a process or system problem that contributed to the error, which can be identified and addressed. Attributing error to the actions of one person or team is not objective (Woods et al. 1994) so the use of the phrase 'human error' is likely to be misleading and best avoided (Hollnagel and Amalberti, 2001). SHOT recommends that the term 'human error' should no longer be used as a conclusion in any incident report and investigators should instead concentrate on finding the system and organisational factors that contributed to the incident.

Learning points

- Think beyond the person - human error is an outdated term and cannot be considered as a causal factor. Errors are unintended while deliberate acts of sabotage are not errors, they are deliberate harm events. Factors that led the human to make an error are the underlying causes of any incident, so every effort should be made to identify and resolve these system and organisational factors to prevent future problems

- The HFIT questions are designed to identify system and organisational factors that have contributed to an incident, so it may be beneficial to refer to these when trying to detect and understand causes beyond 'human error'

NHS organisations should develop systems that recognise and deal with people in a 'just' way, acknowledging through learning to support the changes required when people make errors. The fair treatment of staff supports 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. The framework of a just culture ensures balanced accountability for both individuals and the organisation responsible for designing and improving systems in the workplace. The NHS Improvement's 'A Just Culture guide' provides a powerful tool to help promote cultural change in organisations or teams where a blame culture is still prevalent (NHSEI 2021). Such a culture will help empower employees to proactively monitor practices at the workplace and ensure safety. Risk reduction will be achieved by focusing on human behaviours and redesigning systems. Promoting a just and learning culture was one of the main SHOT recommendations in the 2018 Annual SHOT Report (Narayan et al. 2019).

When examining adverse events, it is recommended that investigators should be fully trained in techniques for incident investigations and that appropriate time and resources are allocated to facilitate this training. In addition, a tried and tested human factors-based framework should be used. The SHOT HFIT questions may be used alongside that framework, so that answers to the questions can be discovered during the investigation. NHS England and NHS Improvement (NHSEI) are in the process of introducing a new Patient Safety Incident Response Framework (PSIRF) (NHSEI 2022).
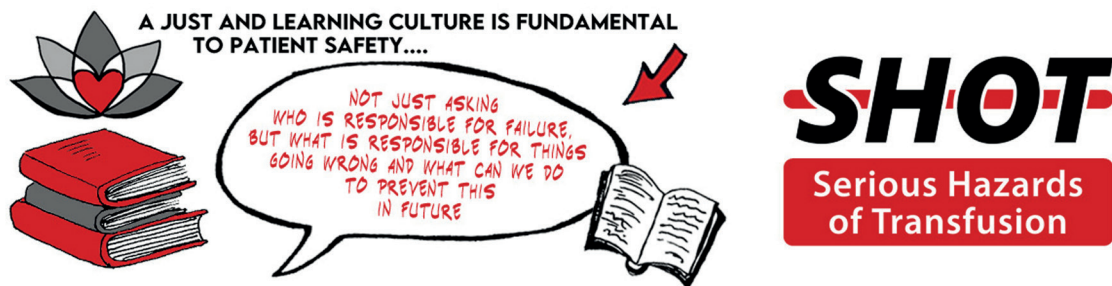
Patient Safety Incident Response Framework (PSIRF) (NHSEI 2022)

Contributed by Tracey Herlihey, Head of Patient Safety Incident Response Policy, NHS England and NHS Improvement

The PSIRF is supporting NHS providers to take a systematic, compassionate, and proportionate response to patient safety incidents, to achieve better learning and support continuous improvement.

PSIRF encompasses all patient safety incidents and supports development of an effective patient safety incident response system that integrates:

- Compassionate engagement and involvement of those affected by patient safety incidents

- Application of a range of system-based approaches to learning from patient safety incidents

- Considered and proportionate responses to patient safety incidents

- Supportive oversight focused on strengthening response system functioning and improvement

The framework is expected to be published by NHS England in June 2022, when NHS Trusts in England will begin preparing to transition from the Serious Incident Framework to PSIRF. Find out more on the PSIRF webpage (see 'Recommended resources').

Analysis of the SHOT HFIT

The number of error cases included in 2021 was 2569, which is comparable to 2020 (n=2623). Therefore, 81.3% of the total cases analysed in this Annual SHOT Report result from preventable error, rather than unforeseeable transfusion reactions, which is consistent with the 2020 error figure (81.6%).

These data represent the first year of the new SHOT HFIT which was based on the YCFF (Lawton et al. 2012). The YCFF was the first evidence-based framework of accident causation in hospitals developed following a systematic review of 83 research studies about the causes of patient safety incidents (Improvement Academy 2022). It is important to note that the SHOT HFIT is not a validated incident investigation tool, although it is adapted from the YCFF which is an evidence-based framework. SHOT suggests investigators have access to the SHOT HFIT questions when examining incidents, so that answers to the questions can be determined during the investigation, but it is recommended that this is done alongside a tried and tested incident investigation framework.

The HFIT questions were restructured for 2021 as the results from the original five years study of HFIT (2016-2020) showed reporters tended to give high scores to the staff involved. Various system and organisational factors contributing to these incidents may have been missed (Watt 2020). The expanded HFIT questions request more details about the contributory system and organisational factors and the scoring was revised to a five-point scale with guidance suggesting the scores were assigned by calculating the relative contribution thus:

0 – None, 1 – Barely, 2 – A little, 3 – Some, 4 – A lot, 5 – Fully.

The total scores assigned to each factor and the comparative percentages are shown in Figure 7.1. The analysis indicates that the new HFIT is encouraging scoring across a broader range of contributory factors. Where high scores have been attributed across all or several questions, they highlight the various systemic issues that contributed to a single incident.
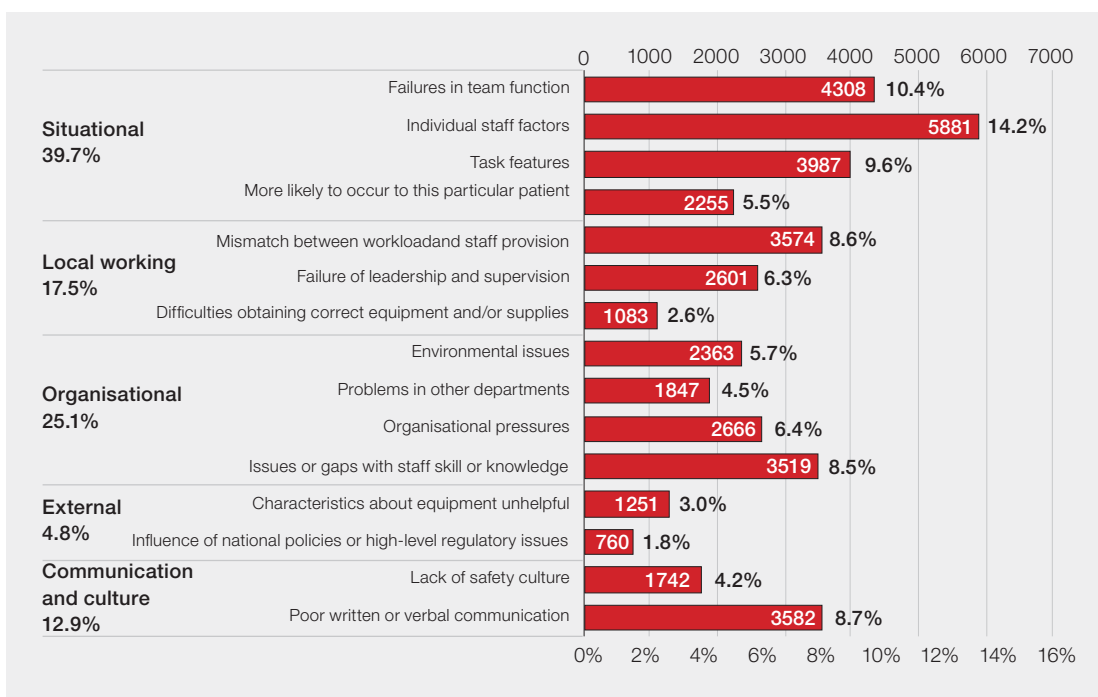

Figure 7.1: Comparative scores assigned for different system factors

The expanded HFIT introduced in 2021 reveals a greater breadth of factors that contribute to adverse incidents, so investigators can identify areas for system and organisational improvement

Figure 7.1 shows the highest scores were assigned to individual staff factors, which may be a sign that reporters are still focussing mainly on staff involvement. This question is designed to analyse specific issues with staff members, such as fatigue, stress, rushing, distraction, or inexperience. This question was amended slightly for 2022. The original question was 'To what extent did individual staff factors make this incident more likely?', this was amended to say, 'To what extent were there any reasons this incident was more likely to occur with the particular staff involved?'. A comparison was made of the scores given for each factor against a simple count of the number of cases assigned any score for the relative factors. A noticeable difference was seen for this question about individual staff factors, showing that reporters tended to assign comparatively higher scores which may indicate reporters are scoring

this question related to staff involvement slightly higher than other questions. SHOT is considering removing the requirement to assign quantitative scores and to simply ask if each factor is considered to have contributed at all.

The importance of systems thinking

It is important that a systems-thinking approach is taken when trying to learn from adverse events. Systems thinking is a holistic way to investigate factors and interactions that could contribute to a possible outcome.

Case 7.1: Limited scores assigned, but investigation shows a wider range of contributory factors could have been considered

A request was made for FFP and cryoprecipitate, but when the components were issued the compatibility labels were transposed. This was discovered during pre-transfusion checks on the ward. Only two scores were assigned for factors contributing to the incident: 2/5 for the extent to which the environment hindered work and 1/5 for organisational pressures playing a role in the incident. The most important contributory factors were listed as lack of concentration and distraction from external members of staff, but no scores were assigned to reflect these factors. The investigation report noted other factors that were also not fully reflected in the scoring, such as the staff member was busy and the procedure to issue only one component type at a time was not fully documented.

The incident was attributed mainly due to 'lack of attention to detail by staff member' and the individual was required to complete a reflective learning form. This meant that other system and organisational problems were not considered adequately. Scores in Case 7.1 could have been assigned to a broader range of contributory factors resulting in missed opportunities for learning. These included a mismatch between workload and staff provision, as the BMS was busy; problems with team leadership because colleagues were distracting the BMS who was crossmatching; difficulties caused by other departments, i.e., external staff also distracting the BMS, characteristics of the equipment because they were similar components and poor communication, as the SOP was unclear. Preventative measures that could have been considered included revising policies so that only one type of component is issued at a time, colleagues prohibited from distracting the BMS who is crossmatching and installing a doorbell to stop external distractions. The reflective learning outcome was that the staff member should seek help when busy, but if that has not been seen as a wider system problem related to staff leadership, then it is possible that other staff have not been empowered to seek help when needed. Reflective practice is a suboptimal intervention and can be perceived as punitive following any incident and is not an effective measure to prevent future recurrence of similar incidents. System level interventions including standardisation and IT solutions are sustainable solutions.

In previous Annual SHOT Reports the importance of a combined Safety-I and Safety-II approach has been detailed, and recently the concept of Safety-III as a safety management principle has been introduced (Leveson 2020). Safety-III is based on systems theory, and 'it spans the entire lifecycle but puts particular focus on designing safety in from the very beginning of system concept definition.' The simplest description of Safety-III is freedom from unacceptable losses, which in a transfusion context would equate to freedom from adverse incidents. The goal of Safety-III is to eliminate, mitigate or control hazards, because incidents can result from inadequate control or enforcement of safety-related aspects. Hence the focus is on preventing hazards, but also on learning from events, accidents, incidents, and audits of how the system is performing (Aven 2022).

Table 7.1

Definitions of Safety (Leveson 2020)

Safety-I	Safety-II	Safety-III
As few things as possible go wrong	As many things as possible go right	Freedom from unacceptable losses as identified by the system stakeholders. The goal is to eliminate, mitigate, or control hazards, which are the states that can lead to these losses (i.e., adverse incidents)

Learning point

- To improve safety in healthcare, it is vital to apply human factors and ergonomics principles as well as systems thinking. This will help address organisational and other system issues and help design safer systems so that hazards are eliminated, mitigated, or controlled. NHS Patient Safety Syllabus training programme has recently been introduced that covers these aspects (see link under 'Recommended resources' at the end of this chapter

Effect of the COVID-19 pandemic

A search of terms related to COVID-19 identified 161/2569 (0.6%) cases that had some link to the pandemic. This is a relatively small percentage, and the pandemic was not necessarily identified as a key contributory factor in these incidents, but it could be argued that most of these adverse events would not have occurred if not for the prevalence of COVID-19 in 2021.

Case 7.2: Pressures caused by COVID-19 pandemic contribute to error with CCP

A patient was due to receive a second dose of CCP, but FFP was issued in error and placed in a yellow CCP trial bag. The porter received an electronic request to collect 'plasma'; CCP was not specified. The unit was administered without any of the staff involved noticing that FFP had been issued in error. The hospital was experiencing an overwhelming number of COVID-19 cases and many staff were unfamiliar with the component. Staff in all ward areas were under pressure and overwhelmed physically and emotionally. It was a difficult time to oversee and implement any changes and face-to-face training could not be undertaken, so a training video had been created to help staff, but uptake was likely to have been variable.

This case reveals how difficult it was for staff to work during the height of the COVID-19 pandemic. It demonstrates challenges faced when implementing new processes which the pandemic itself required, such as the introduction of CCP as a new component. HFE methods can be applied to lessons learned from responses to the COVID-19 pandemic (Wooldridge et al. 2022). Scores for the HFIT questions in this case were given across the full range of contributory factors and highlighted key system and organisational problems, such as the CCP storage drawer being near to the FFP drawer and that the IT systems did not warn against selection or administration of FFP versus CCP. Preventative actions included relocation of CCP to another freezer, plus photographs of both components with an indication of the correct unit to transfuse for incorporation in the training video and circulated directly to staff. IT failings were not addressed, potentially because effecting major IT amendments might be outside the remit of the incident investigators. The BMS was required to complete training and a reflection log, which is unlikely to have been an effective corrective action and may be seen as punishment for an error that was driven by system and organisational problems.

Conclusion

The new format of the revised HFIT has helped SHOT reporters and incident investigators to focus on underlying system failures instead of stopping at the classic outcome of blaming 'human error'. The foreword of a valuable new open access book telling the story of the patient safety movement discusses medical errors and states the causes would not be '…rogue clinicians or even incompetent ones, but rather the very designs of healthcare delivery, itself, in which even the best of the workforce get trapped … the myriad interactions of those delivery system designs and the frailties of unaided human minds and manipulations – the human factors that set up normal people for the familiar 'oops' of daily life.' (Leape 2021).

The patient safety syllabus, launched in 2019 and updated in 2021, was developed for all NHS staff to help identify risks proactively to prevent errors before they occur (HEE 2021) and emphasises the need for all staff to have basic awareness of human factors.

An essential learning outcome within the patient safety syllabus is to understand the hierarchy gradient and its effects. In healthcare, mistakes that are potentially harmful or fatal to patients are often the result

of poor communication between members of a team. This is particularly important in high-risk areas such as operating theatres or during any intervention, and the ability to challenge colleagues who are in authority when something does not seem right or is clearly wrong, is crucial (Green et al. 2017). It is further recognised that patient safety can be compromised where there is failure or reluctance to challenge poor practice or culture. Flattening the hierarchy within teams and organisations, empowering staff to speak out safely with confidence that concerns will be investigated is essential; without this a just culture cannot thrive.

Incident investigations must be systematic and thorough, proportionate to the risk and impact and identify systems-based corrective and preventative actions. Fostering a strong and effective safety culture that is 'just and learning' is vital to ensure a reduction in transfusion incidents and errors, and to improve patient safety. The framework of a just culture ensures balanced accountability for both individuals and the organisation responsible for designing and improving systems in the workplace. The NHS Improvement's 'A Just Culture guide' provides a powerful tool to help promote cultural change in organisations or teams where a blame culture is still prevalent (NHSI 2021). Such a culture will help empower employees to proactively monitor practices at the workplace and ensure safety. Risk reduction will be achieved by focusing on human behaviours and redesigning systems.

Recommended resources

SHOT Videos: Human factors videos
https://www.shotuk.org/resources/current-resources/videos/

SHOT Bite No. 1(a) and 1(b): Incident Investigation
SHOT Bite No. 12: Cognitive Bias
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOTcast: Human Factors
https://www.shotuk.org/resources/current-resources/shot-casts/

SHOT Webinar: Human Factors
https://www.youtube.com/watch?v=ie0UK9R5IbM

Yorkshire Contributory Factors Framework
https://improvementacademy.org/tools-and-resources/the-yorkshire-contributory-factors-framework.html

Human Factors in Healthcare AI
https://ergonomics.org.uk/resource/human-factors-in-healthcare-ai.html

Patient Safety Incident Response Framework (PSIRF)
https://www.england.nhs.uk/patient-safety/incident-response-framework/

NHS HEE Patient Safety Syllabus
https://www.hee.nhs.uk/our-work/patient-safety

NHS Patient Safety Syllabus training programme
https://www.e-lfh.org.uk/programmes/patient-safety-syllabus-training/

NHSEI: A just culture guide
https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS_0932_JC_Poster_A3.pdf

Case Study reworked using updated HFIT and SEIPS framework
https://www.shotuk.org/wp-content/uploads/myimages/HFIT-and-SEIPS-Supplementary-material-2020.pdf

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