Handling and Storage Errors (HSE) n=306

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Definition:

All reported episodes in which a patient was transfused with a blood component or plasma product intended for the patient, but in which, during the transfusion process, the handling and storage may have rendered the component less safe for transfusion.



Key SHOT messages

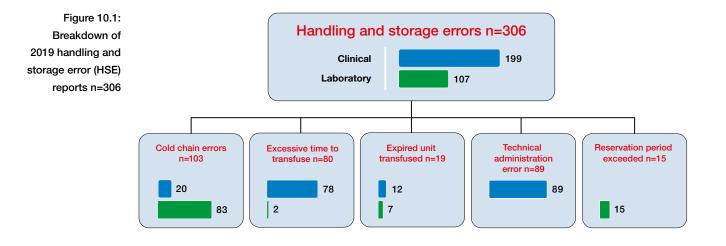
- Key SHOT messages from 2017 remain pertinent on **communication** and **do not assume**, **verify** (Bolton-Maggs et al. 2018)
- Routine processes such as daily checks are prone to inattention bias when staff assume no action will be needed. The potential impact of inaccurately recording laboratory data should be included during training

Abbreviations used in this chapter

AP	Associate practitioner	HSE	Handling and storage error
BMS	Biomedical scientist	SOP	Standard operating procedure

Introduction

There were 306 cases reported in 2019 with an increase of 15.9% from the 2018 Annual SHOT Report which contained 264 errors (Narayan et al. 2019). Clinical errors accounted for 199/306 (65.0%) and laboratory errors for 107/306 (35.0%). The variation between clinical and laboratory errors are illustrated in Figure 10.1.



Death n=0

There were no deaths reported that related to errors associated with HSE in 2019.

Major morbidity n=0

There were no HSE cases reported in 2019 that resulted in major morbidity.

Clinical errors

The number of clinical errors remains consistent with previous years, however there has been an increase in technical administration errors (89/199 (44.7%) in 2019 and 69/195 (35.4%) in 2018) and a reduction in excessive time to transfuse errors (78/199 in 2019 and 96/195 in 2018). Technical administration errors have been further categorised below in Table 10.1.

Technical administration error	Number of cases	
Administration pump error	30	
Incorrect giving set used	24	
Transfusion details not recorded	21	
Unit damaged/clotted	6	
Drug added to unit	1	
Excessively rapid rate	5	
Miscellaneous	2	
Total	89	

Table 10.1: Clinical technical administration errors n=89

Laboratory errors

In most HSE categories the numbers remain consistent with previous annual reports; however, there has been a significant increase in the number of laboratory HSE errors from the 2018 Annual SHOT Report. The increase equates to 55.1%, with 107 errors compared to 69 in 2018. The overall number of laboratory errors has decreased slightly in 2019, therefore the increase in HSE is disproportionate to the overall level of laboratory incidents and signifies an area which requires improvement. A proportion of these cases were due to a single refrigerator failure effecting 23 patients. Despite this, the overall trend raises concern and may be reflective of the challenges within the laboratory setting. Two cases of excessive time to transfuse were attributed to laboratory practice, 1 case where the laboratory released a unit to clinical staff which had insufficient time to complete the transfusion after removal from cold chain storage, and a 2nd case where the laboratory provided incorrect guidance to clinical staff about the amount of time a unit had been outside of cold chain storage.

The greatest overall increase in laboratory HSE errors was seen within cold chain errors, 64/69 (92.8%) reports in 2018 has increased to 83/107 (77.6%) in 2019. The largest cause of cold chain errors identified was equipment failure 65/83 (78.3%), followed by inappropriate return to stock 8/83 (9.6%), inappropriate storage 5/83 (6.0%) and transport and delivery 5/83 (6.0%). Many equipment failures were not detected until days after the incident, indicating that quality management and daily checks are not universally embedded within laboratory culture. The SHOT laboratory learning point from 2018 remains pertinent, 'alerts must be dealt with immediately' and 'must be included in protocol/procedure'.

Case 10.1: Poor communication and assumptions lead to a non-compliant component being transfused

Red cells were collected from the laboratory by the correct transportation method at 01:32, and subsequently returned to the laboratory unused at 03:03 which equates to 1 hour and 31 minutes after collection. In accordance with the hospital policy this would deem that the units would not be appropriate for transfusion and consequently they should have been discarded and fated as not suitable for use. The units were entered into quarantine to be checked by a senior member of the team as the biomedical scientist (BMS) on duty was unsure of the appropriate time limits for out of controlled temperature storage for the unit. However, there was no adequate communication

between the staff and the assumption was made by another BMS that the units in quarantine had been assessed and approved as cold chain compliant. They returned the units to stock and in turn issued them to another patient whom they were transfused to. Fortuitously the patient did not come to any harm.

Case 10.2: Ambiguous standard operating procedures (SOP) for temperature excursion puts 23 patients at risk

Red cells which had been stored in a refrigerator with a core temperature between 6°C and 7°C for 4 hours were transfused to 23 patients. The temperature rise began after the refrigerator was shut incorrectly at 22:00 but was able to lock without an airtight seal. A further rise in temperature occurred at 01:35 and prompted a call from the helpdesk to the BMS working within the transfusion laboratory, however this alert was not acted upon. It is also assumed that the refrigerator alerted locally but was muted. The BMS was covering both haematology and transfusion departments and acting on 'autopilot', they were further required to review an urgent malaria screen and were feeling unwell. The temperature excursion was also not acted upon by the associate practitioner (AP) performing daily checks of the paper temperature chart for the next two mornings. The AP expressed confusion over the different temperature ranges for blood and reagent refrigerators, and the difference between air and load temperature displays. Upon investigation, it was found that the information in the SOP regarding recording of refrigerator temperatures was incorrect. A second AP checked the refrigerator on day 3 but did not escalate concerns as the SOP stated to record any deviations which occurred within the past 24 hours. Many units which had exceeded temperature control were returned to stock and re-issued to patients. The temperature increase was discovered 4 days after the excursion, but fortunately no patients came to any harm. The root cause analysis (RCA) from this case listed three causes which were all related to the errors and omissions made by individuals, and none related to the systemic failures highlighted. The hospital has updated their SOP and competency assessments relating to refrigerator temperature monitoring. The hospital is now in the process of implementing an updated temperature monitoring system.

This case illustrated multiple systemic factors which require improvement. It is essential that instructions are clear and unambiguous. Human error should only be considered when all other system factors are excluded.



Learning points

- Staff should be mindful not to make assumptions, especially in busy environments, during the transfusion process and are reminded to communicate at all times to mitigate against errors
- Staff should only take part in the transfusion process if they have been deemed competent to do so. Competency is best gained by training all staff with every relevant standard operating procedure (SOP) or policy, no matter how simple the content may seem. This should provide opportunities for clarifying any confusion and avoiding misunderstandings
- It is essential that instructions are clear and unambiguous
- Human error should only be considered when all other system factors are excluded

Near miss HSE cases n=164

There were 164 near miss HSE cases, 86/164 (52.4%) originated in the clinical area and 78/164 (47.6%) in the laboratory. The near miss HSE cases primarily involved cold chain errors in 123/164 (75.0%) followed by 31/164 (18.9%) cases where expired units were almost transfused to patients, 5/164 (3.1%) cases where the reservation period had been exceeded, 4/164 (2.4%) classified as 'miscellaneous' and 1/164 (0.6%) where a technical administration error was spotted prior to transfusion.

IT-related HSE cases n=76

Further details of the IT-related reports can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2019/).

Conclusion

The findings overall remain consistent with previous years' Annual SHOT Reports. SHOT reinforces the message that all staff who participate in the handling and storage of blood and blood components throughout the transfusion process should adhere to the correct procedures that are outlined in guidelines and their local transfusion policy. Transfusion policies should be based on the most current published guidance available (BSH Robinson et al. 2018).



References

Bolton-Maggs PHB (Ed), Poles D, et al. (2018) on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2017 Annual SHOT Report. https://www.shotuk.org/shot-reports/ [accessed 08 June 2020].

BSH Robinson S, Harris A, Atkinson S, et al. (2018) The administration of blood components: a British Society for Haematology Guideline. *Transfus Med* 2018;**28(1)**:3-21. http://onlinelibrary.wiley.com/doi/10.1111/tme.12481/full [accessed 08 June 2020].

Narayan S (Ed), Poles D, et al. (2019) on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2018 Annual SHOT Report. https://www.shotuk.org/shot-reports/ [accessed 08 June 2020].