Participation in United Kingdom (UK) Haemovigilance

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Key SHOT messages

- Reporting levels have increased again after the slight reduction during the COVID-19 pandemic
- Analysis shows potential under-reporting from some NHS organisations. It is important that healthcare organisations submit reports across all types of reporting categories i.e., errors, reactions and near misses
- Reports where the error occurred in the ED have almost doubled since 2020

Recommendation

- Participation data from each NHS Trust/Health Board should be reviewed and analysed to identify any areas of concern and/or under-reporting to focus improvement efforts

Action: Hospital transfusion teams and hospital transfusion committees

Abbreviations used in this chapter

ED	Emergency department	**NHS**	National Health Service
MHRA	Medicines and Healthcare products Regulatory Agency	**SABRE**	Serious adverse blood reactions and events
		UK	United Kingdom

Introduction

Participation in haemovigilance reporting is on the increase again after a slight dip during 2020 and 2021, likely due to COVID-19 pressures. There were 4371 reports submitted via SABRE in 2022, which is an increase of 283 (6.9%) compared to 4088 in 2021.

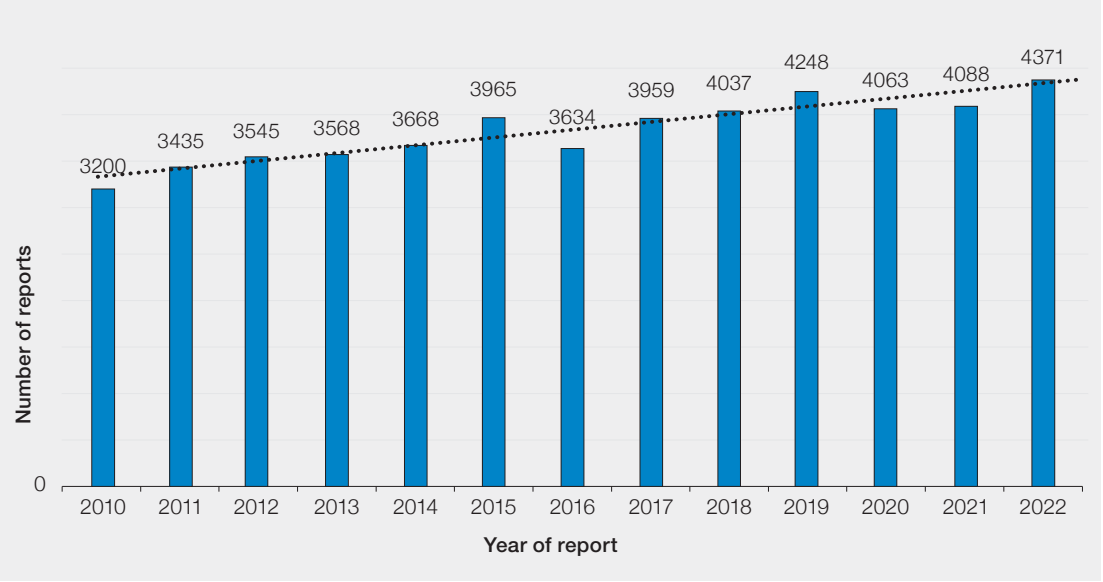


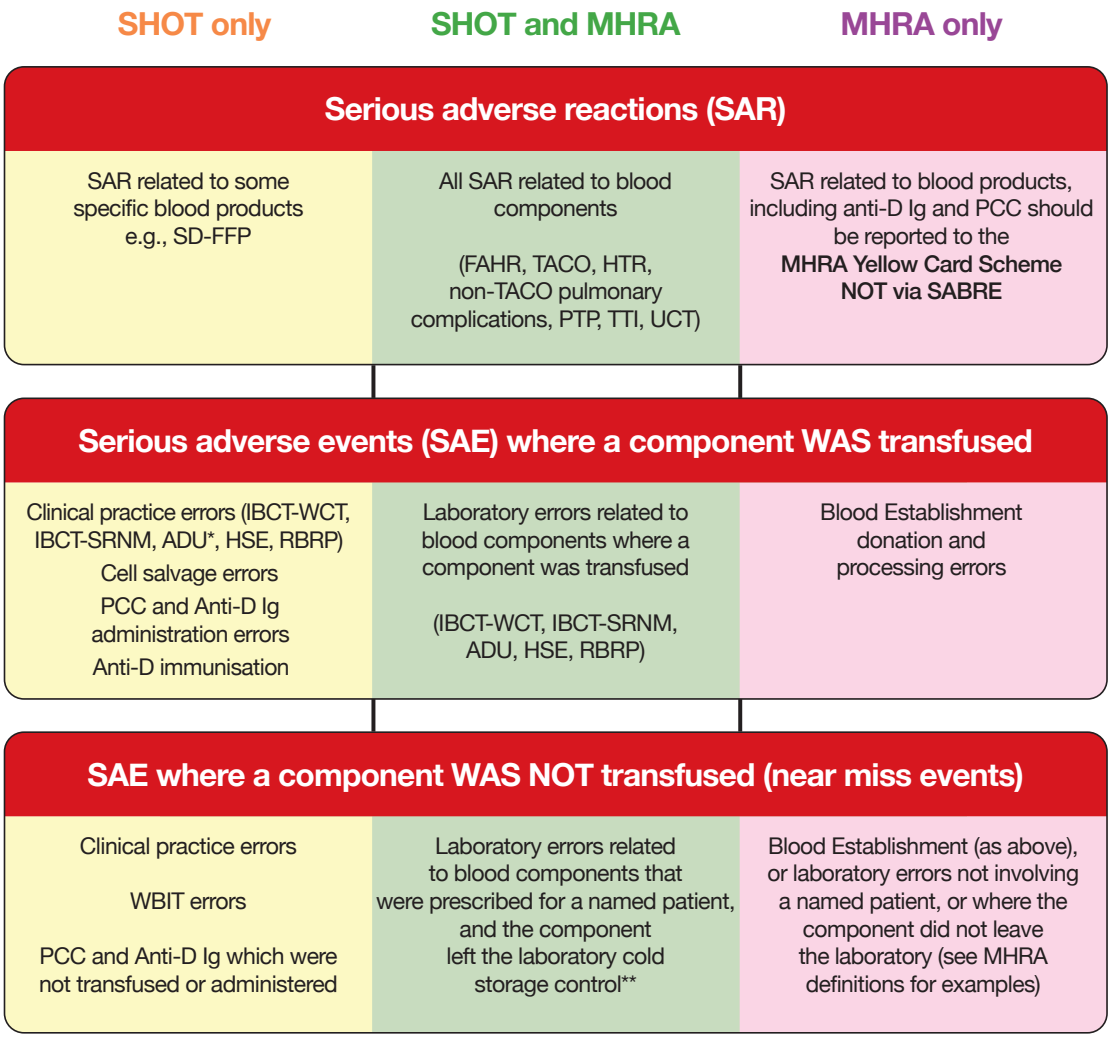
Figure 2.1: Haemovigilance reports submitted by year 2010-2022

Reporting to SHOT and the MHRA

The 4371 reports submitted via the SABRE reporting portal are not always at the same stage of completion or included in the same way by both SHOT and the MHRA. There are differences in reporting criteria for both organisations. Figure 2.2 highlights the main differences and commonalities in reporting criteria between the two organisations.

These differences account for the large numbers of reports that were withdrawn or excluded by each organisation. There were only 314/4371 (7.2%) reports that were withdrawn by both SHOT and the MHRA as not fulfilling either organisation's reporting criteria. Of these 314 reports, 33 were mild reactions, which are not reportable to either SHOT or the MHRA, and 29 were duplicate reports submitted in error.

Figure 2.2: SHOT and the MHRA reporting criteria



This infographic is for guidance purposes only. It may not cover all reportable events and does not represent a change to existing reporting requirements.

Full reporting definitions for SHOT and MHRA (Joint UK Haemovigilance User Guide) are available at: https://www.shotuk.org/reporting/ and for BSQR definitions of blood components/products see https://www.legislation.gov.uk/uksi/2005/50/made. A 'blood component' means a therapeutic constituent of human blood (red cells, white cells, platelets, and plasma) that can be prepared by various methods; while a 'blood product' means any therapeutic product derived from human blood or plasma.

* Includes cases where a component should have been transfused but was not due to a significant delay.
** Clinical errors relating to collection, storage and distribution, or where the primary error was in the laboratory, but detected later in the clinical area are MHRA-reportable.

ADU=avoidable, delayed and under/overtransfusion; FAHR=febrile, allergic and hypotensive reactions; HSE=handling and storage errors; HTR=haemolytic transfusion reactions; IBCT-SRNM=incorrect blood component transfused-specific requirements not met; IBCT-WCT=IBCT-wrong component transfused; Ig=immunoglobulian; MHRA=Medicines and Healthcare products Regulatory Agency; PCC=prothrombin complex concentrates; PTP=post-transfusion purpura; RBRP=right blood right patient; SABRE=Serious Adverse Blood Reactions and Events; SD-FFP=solvent-detergent fresh frozen plasma; TACO=transfusion-associated circulatory overload; TTI=transfusion transmitted infections; UCT=uncommon complications of transfusion; WBIT=wrong blood in tube

Figure 2.3 details how the 4371 reports were included by each organisation. Only 1171/4371 (26.8%) of reports were accepted for inclusion in the 2022 analysis by both SHOT and the MHRA, and this demonstrates the differences in reporting criteria between the two organisations.

There were 412 reports to SHOT that were submitted during 2022, but still incomplete at the end of December 2022. This equates to 9.4% of all submitted cases, which is marginally better than in 2021 where there were 465/4088 (11.4%) cases that were still incomplete at the end of the calendar year. Once completed, these reports will be included in subsequent Annual SHOT Reports.

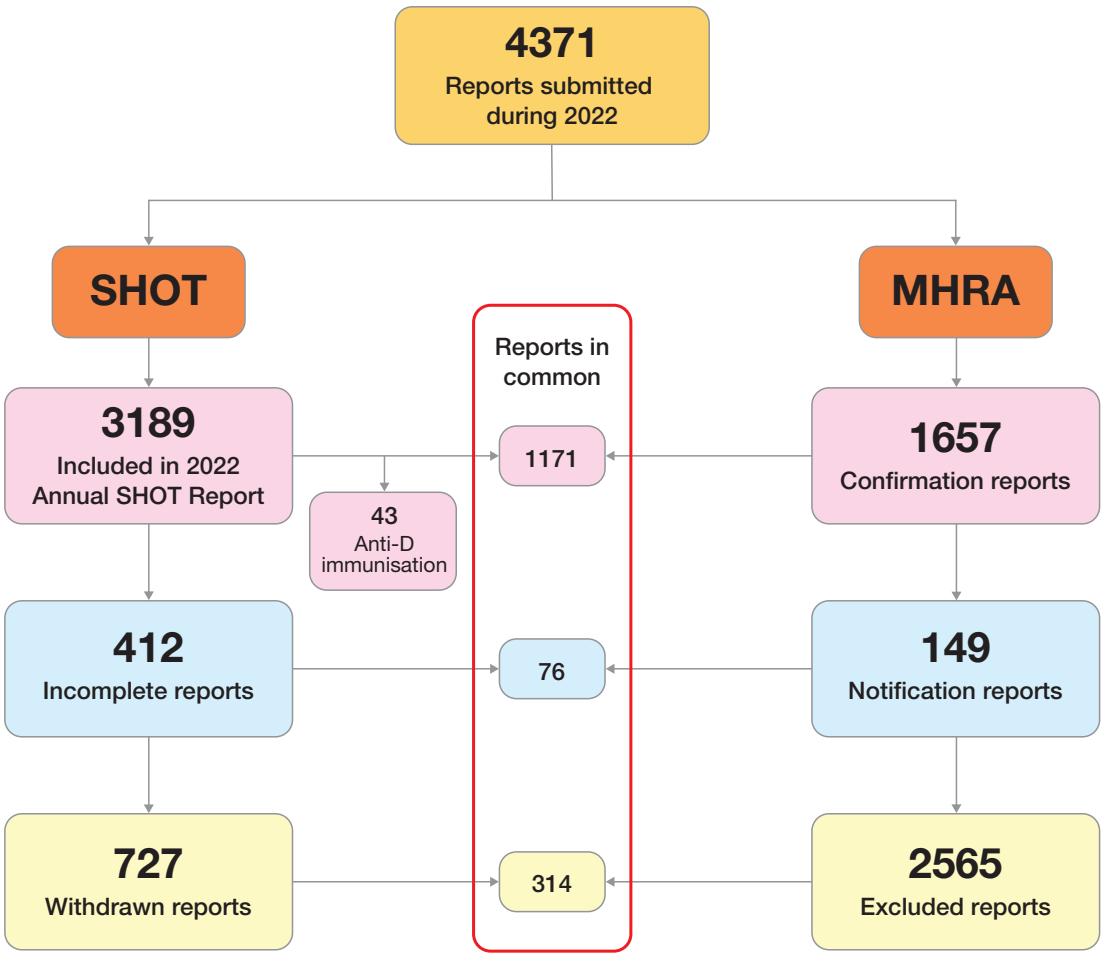


Figure 2.3: Reports submitted to SHOT and the MHRA in the calendar year 2022 (n=4371)

Withdrawn reports consist of reports that do not fit the SHOT reporting criteria but may still be MHRA-reportable (321), reports from Blood Services (127), reactions that were determined to be due to the underlying condition or unrelated to the transfusion (97), mild reactions (57) or duplicate reports (37). The remainder were due to various reasons, which included patient non-compliance, clinical decisions, no error following review etc.

Reporting organisations in 2022

For the first time in 2021, all UK NHS Trusts/Health Boards involved in transfusions submitted reports. This has not been repeated in 2022, as there were two NHS Trusts/Health Boards that did not submit any reports. Both these organisations were low blood users (1 issued with less than 1,500 components, and 1 less than 500 in 2022). Whilst there may have been other individual hospitals that did not submit reports, for participation purposes, SHOT consolidates reporting accounts into their respective Trust/ Health Board as a whole.

There were 19 non-NHS organisations that submitted 48 reports in 2022. This includes healthcare organisations situated in the Channel Islands who are not considered to be a part of the UK and therefore

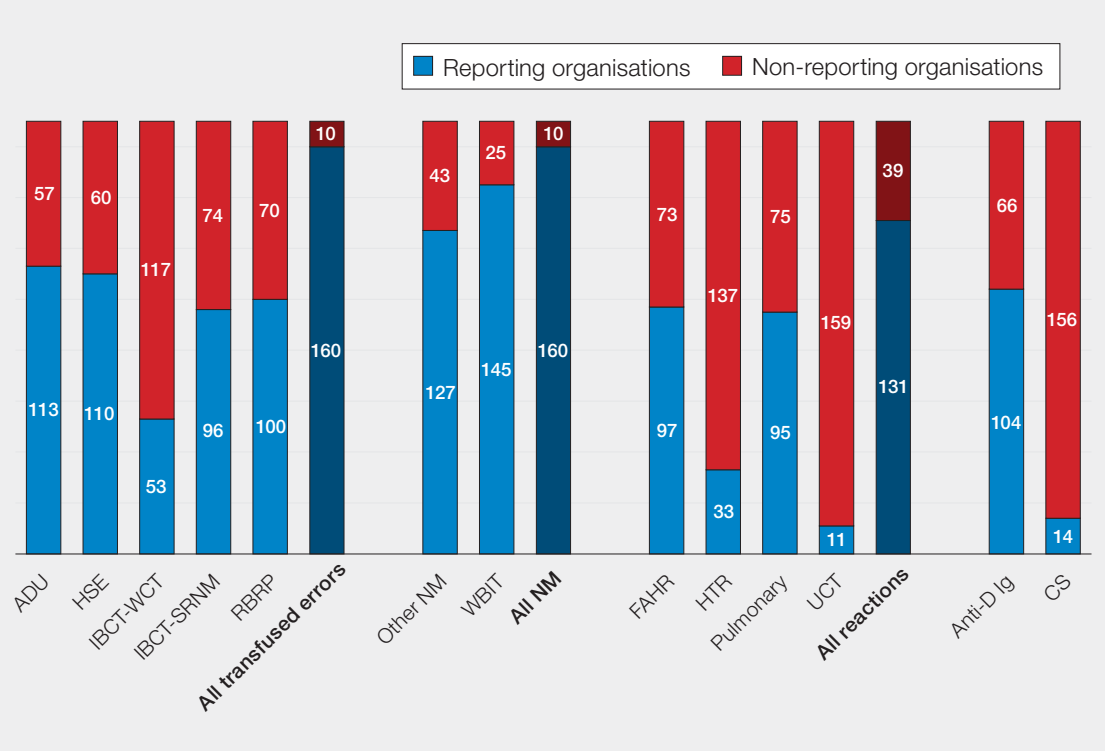
are not regulated by the MHRA. However, they still report to SHOT and incidents submitted are included in this Annual SHOT Report.

Further analysis has been carried out on the reports included in this year's Annual SHOT Report to determine how many NHS Trusts/Health Boards contributed to each reporting category, and overall type of report (Figure 2.4).

There was a slight increase in the proportion of NHS organisations that submitted error reports where a component was transfused,160/170 (94.1%). Of the 10 organisations that did not submit error reports, 1 was a very high user of blood, and 2 were medium users (according to the blood usage levels used for the 2021 participation benchmarking data https://www.shotuk.org/reporting/shot-participation-benchmarking/). Of the 10 reporting organisations that did not submit any type of near miss report, 1 was a high blood user, and 2 were medium users. There were a higher number of organisations that did not report any reaction reports, and 17/39 (43.6%) of these were medium, high, or very high usage organisations.

These data suggest that although in general participation is extremely good, there are still a small number of organisations that are likely to be under-reporting in certain areas. It is recommended that the participation data is reviewed by the hospital transfusion committee and appropriate actions taken if any concerns in trends or on comparison with similar organisations.

Figure 2.4: Number of NHS Trusts/Health Boards submitting reports by reporting category included in the 2022 Annual SHOT Report



ADU=avoidable, delayed and under/overtransfusion; HSE=handling and storage errors; IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; RBRP=right blood right patient; NM=near miss; WBIT=wrong blood in tube; FAHR=febrile, allergic and hypotensive reactions; HTR=haemolytic transfusion reactions; UCT=uncommon complications of transfusion; Ig=immunoglobulin; CS=cell salvage

Figure 2.5 demonstrates that reporting levels are extremely variable between different sized NHS organisations. There were 6 very high users (>19,000 components issued) that submitted fewer than 25 reports (1 only submitted 7 reports), compared to some low users (<6,000 components issues) that submitted more than 25 reports. The reasons for this are unknown but could indicate a poor reporting culture or staffing issues in some of the large organisations. These must be reviewed and addressed within each organisation to ensure learning from all patient safety incidents including near misses.

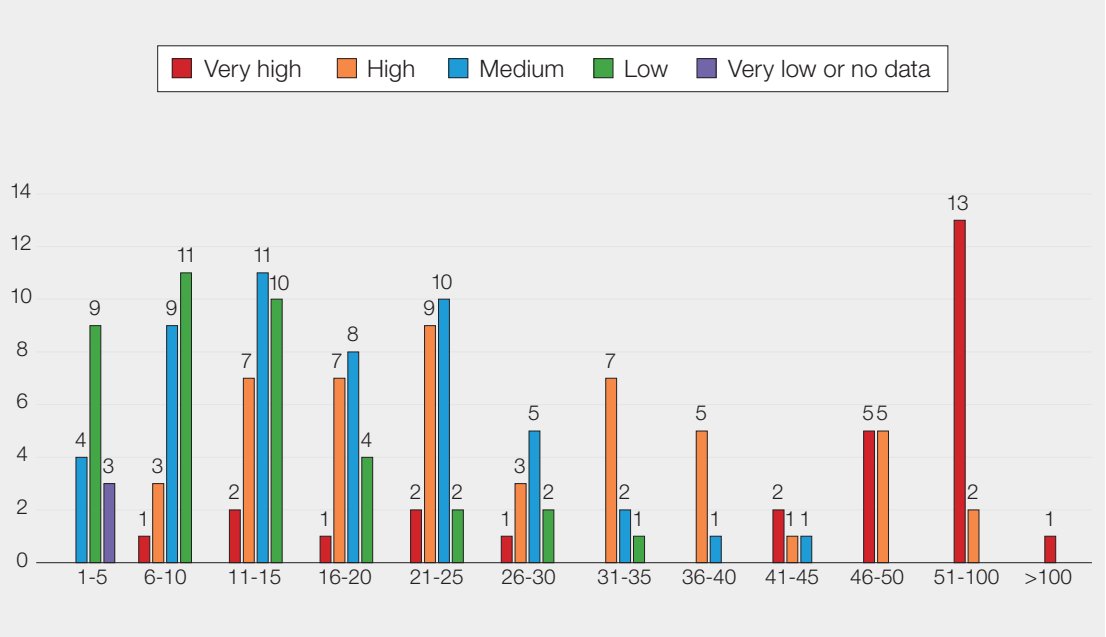


Figure 2.5: Number of reports by NHS reporting organisation and component usage level in 2022

Blood component issue data 2022

Table 2.1 lists the total number of blood components issued from the UK Blood Services in 2022.

	Red cells	Platelets	FFP	SD-FFP	MB-FFP	Cryo	Totals
NHS Blood and Transplant	1,361,676	248,360	173,134	66,400	404	40,166	**1,890,140**
Northern Ireland Blood Transfusion Service	41,622	8,108	4,305	3,120	1	882	**58,038**
Scottish National Blood Transfusion Service	136,633	24,313	15,350	2,450	0	3,384	**182,130**
Welsh Blood Service	74,840	9,426	7,930	1,865	-	465	**94,526**
Totals	**1,614,771**	**290,207**	**200,719**	**73,835**	**405**	**44,897**	**2,224,834**

FFP=fresh frozen plasma; SD=solvent detergent-sterilised; MB=methylene blue-treated; Cryo=cryoprecipitate

SD-FFP data is supplied by Octapharma; in England, hospitals order directly from Octapharma and in other countries, the process is via the Blood Services

Paediatric/neonatal MB-FFP are expressed as single units; cryoprecipitate numbers are expressed as pools and single donations as issued; all other components are adult equivalent doses

Table 2.1: Total issues of blood components from the Blood Services of the UK in the calendar year 2022

Although blood component issues increased in 2022 compared to the previous 2 years, the larger reduction in 2020 was likely due to the pandemic, and Figure 2.6 demonstrates that the overall downward trend in blood component issue data is continuing.

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Figure 2.6a: Blood component issue data in the UK 2011-2022

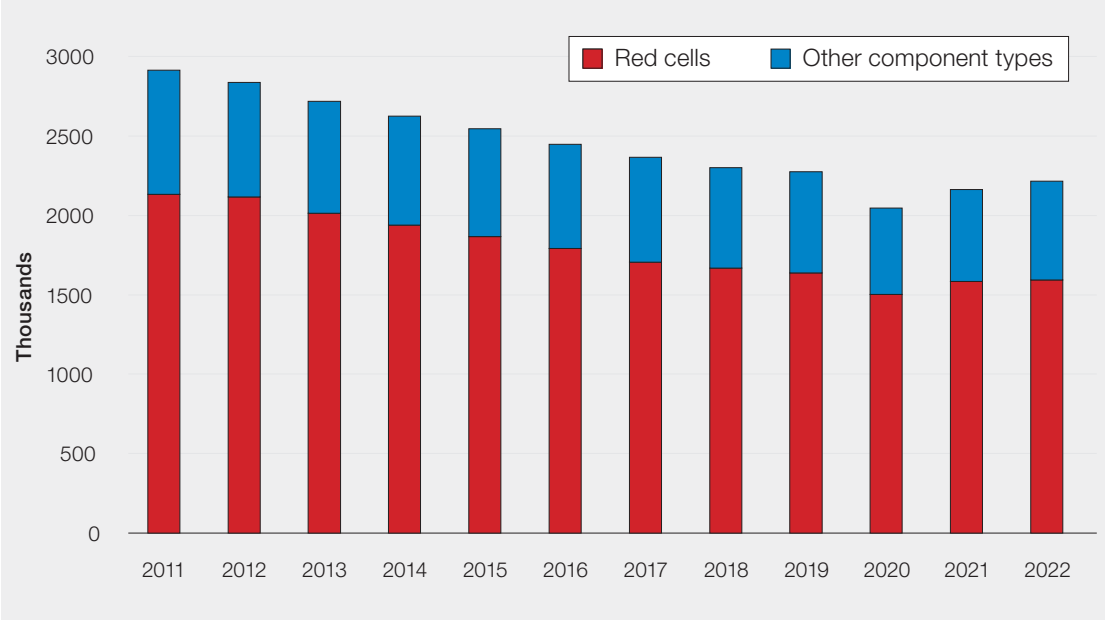
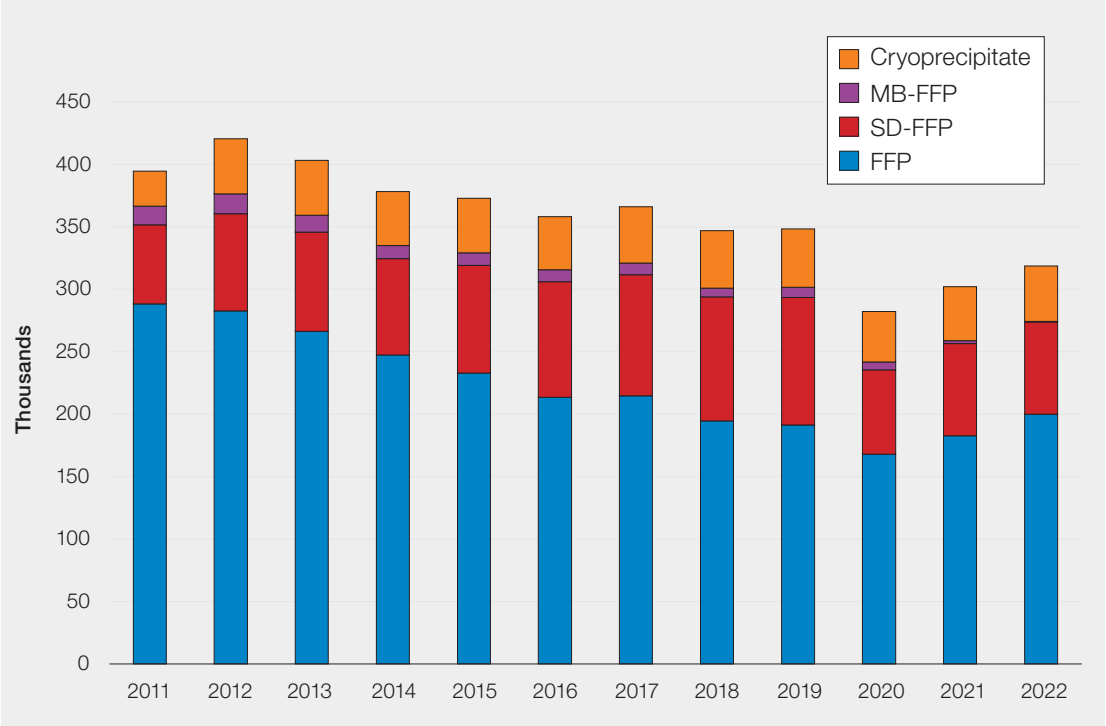


Figure 2.6b: Non-cellular component issue data in the UK 2011-2022



FFP=fresh frozen plasma; SD=solvent-detergent; MB=methylene blue

SHOT reporting by UK country

Full tables containing the breakdown of data from 2022 by UK country and previous years can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Cases included in the 2022 Annual SHOT Report n=3499

The total number of reports analysed and included in the 2022 Annual SHOT Report is 3499. This is an increase of 338 from the 3161 reports analysed in the 2021 Annual SHOT Report (Narayan et al. 2022).

In addition to these 3499 reports, there were 52 reports of immunisation against the D-antigen. These are counted separately as part of a stand-alone study.

The total number of 3499 is made up of the 3189 completed reports submitted in 2022 (Figure 2.3) plus 310 reports that were submitted in earlier years, but not finalised until 2022. Some of these reports may be related to historical transfusion incidents but incidentally discovered during audits and reported to SHOT.

The number of reports with potential for patient harm (excluding 'near miss' and 'right blood right patient') is 1869, a small increase of 79 from 2021 (n=1790).

Analysis of transfused errors by location

The number of incidents reported from the ED has increased substantially for the second year in a row and is now almost double the number reported in 2020. The large rise could be due to multiple factors including pandemic pressures, increasing workload, worsening staffing pressures and longer patient stays in the ED due to poor patient flow within organisations. The numbers of reports from other areas do not have such striking increases, and the trends as a percentage of transfused errors are mostly downwards.

Unfortunately, there are no denominator data available with regard to the number of transfusions undertaken in each of these areas, so it is difficult to draw any meaningful conclusions.

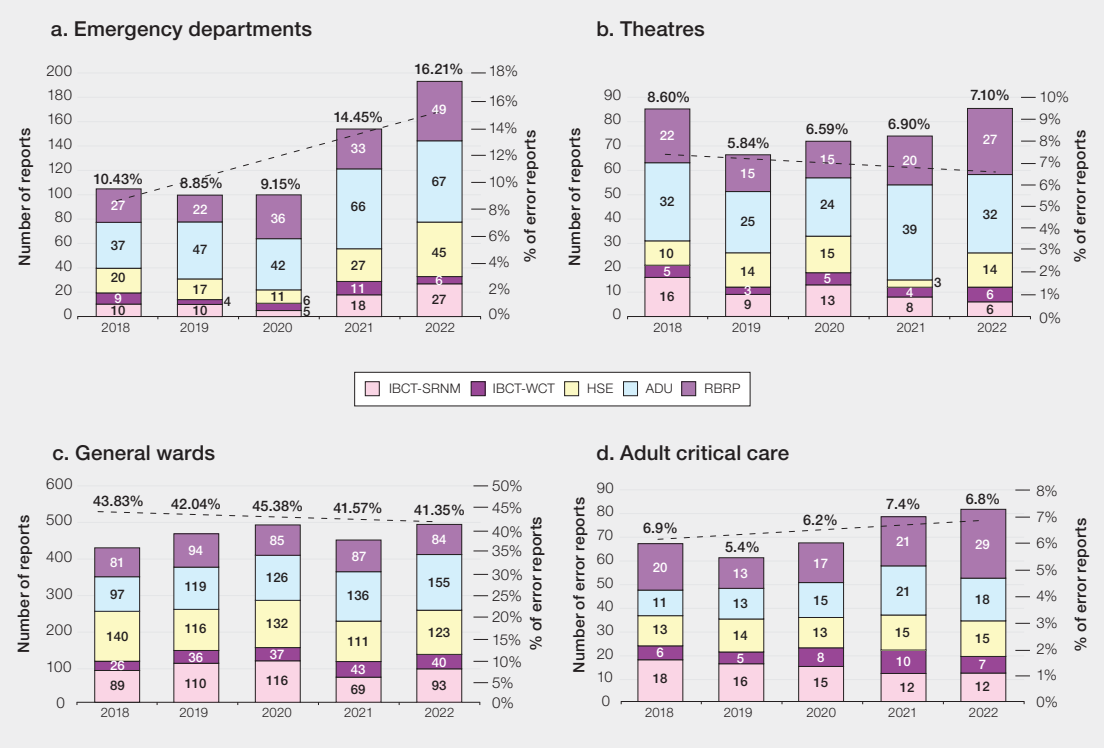


Figure 2.7: Five-year trend of error reports from different departments

ADU=avoidable, delayed and under/overtransfusion; HSE=handling and storage errors; IBCT-SRNM=incorrect blood component transfused-specific requirements not met; IBCT-WCT=IBCT-wrong component transfused; RBRP=right blood right patient

SHOT participation benchmarking data

SHOT participation data provides a useful benchmarking tool which is an integral part of continuous improvement in healthcare. Measuring, comparing to similar users, and identifying opportunities for tangible improvements will help improve patient safety. This supports local governance processes as well.

Data are collated and published annually in the autumn, and the 2022 participation data will be available on the SHOT website during October 2023.

SHOT also provides participation data on a monthly basis, which includes the number of reports submitted, and the number of reports completed in each category. However, these numbers are subject to change following review of the completed cases by the SHOT working expert group.

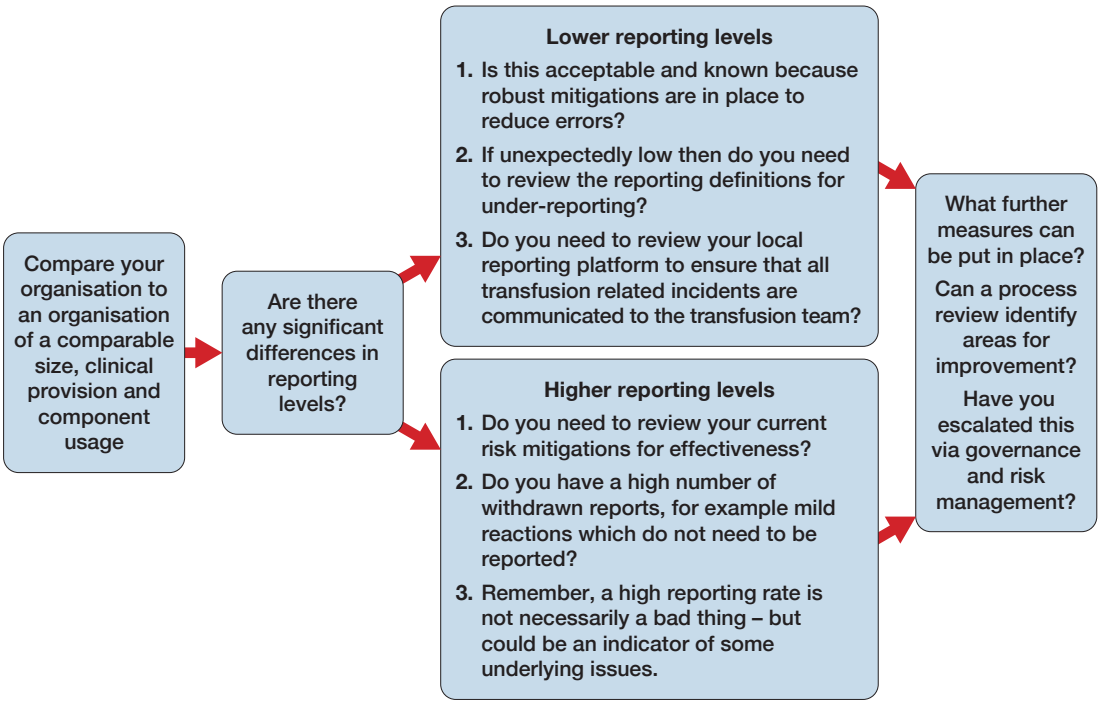
All reporters and local governance teams should access and use this participation data to inform local improvements. These discussions should be included in local and regional transfusion meetings.

Please see the links to the annual and monthly participation data on the SHOT website provided in the 'Recommended resources' section.

Conclusion

Reporting incidents is fundamental to error prevention and improving safety. Participation in UK haemovigilance is well supported, with a high level of engagement throughout the whole country, despite the ongoing pressures across the NHS. Reporting to SHOT and the MHRA across a broad range of reporting categories is essential to continue to learn from these incidents, and to embrace a culture of openness and sharing.

Figure 2.8: Using SHOT participation benchmarking data to drive improvements



Recommended resources

Definitions of current SHOT reporting categories & what to report
https://www.shotuk.org/resources/current-resources/

SHOT Participation Benchmarking Data
https://www.shotuk.org/reporting/shot-participation-benchmarking/

SHOT Monthly Participation Data
https://www.shotuk.org/reporting/monthly-participation-data/

References

Narayan S (Ed), Poles D, et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2021 Annual SHOT Report (2022). https://www.shotuk.org/shot-reports/ [accessed 10 March 2023].