Participation in United Kingdom (UK) Haemovigilance 2

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Abbreviations used in this chapter

ACE	Acknowledging continuing excellence in transfusion
FFP	Fresh frozen plasma
MB-FFP	Methylene-blue treated FFP
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
SABRE	Serious adverse blood reactions and events
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SD-FFP	Solvent-detergent FFP
UK	United Kingdom

Key SHOT messages

- High levels of participation in haemovigilance reporting to SHOT continues despite challenges faced by staff
- Variations exist in the patterns and frequency of reports received across the UK

Recommendation

- Participation benchmarking data should be reviewed to inform local improvements. These discussions should be included in local and regional transfusion meetings

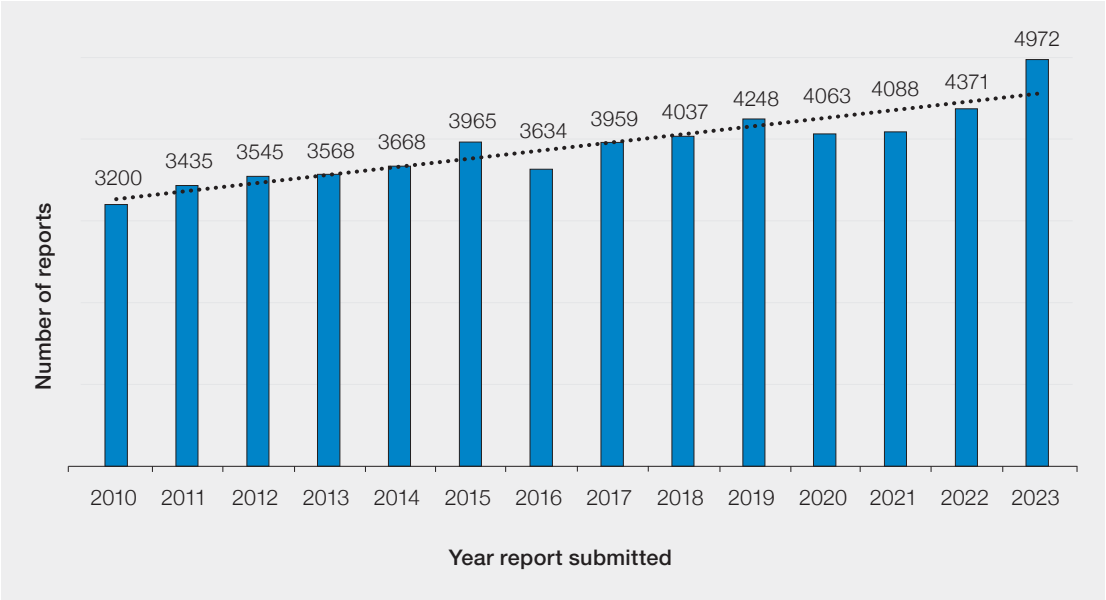
Action: Haemovigilance reporters and local governance teams

Introduction

Haemovigilance reporting and benchmarking play a vital role in promoting transparency, accountability, and continuous improvement in blood transfusion practices. This ultimately benefits patients, donors and staff with improved experiences and outcomes. Participating healthcare organisations contribute valuable data that can be analysed to identify trends, patterns, and areas for improvements in transfusion practices.

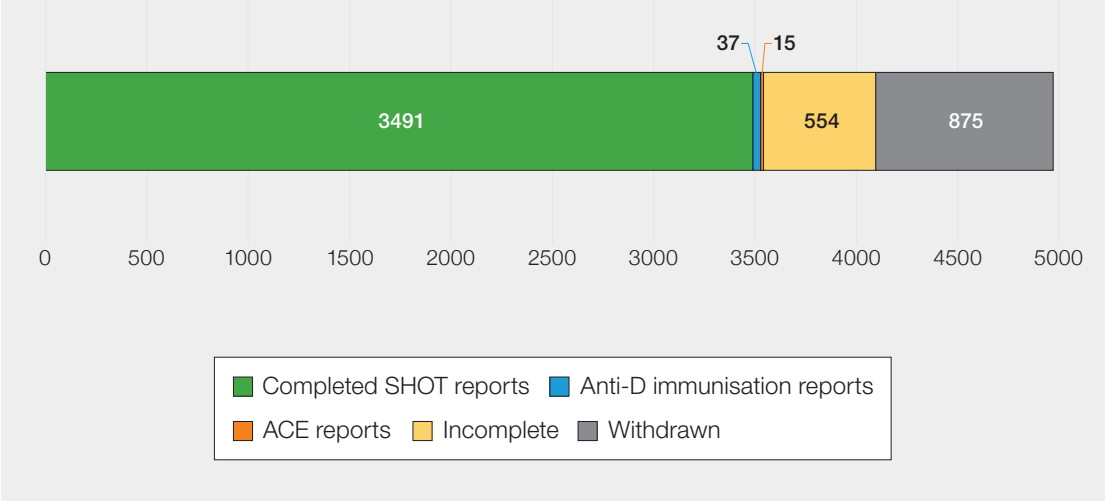
Participation in UK haemovigilance reporting has risen in 2023. There were 4972 reports submitted via the SABRE online reporting system in 2023, which is an increase of 601 (13.7%) compared to 4371 in 2022. This is the largest annual increase since 2017, however, given the relative dip in reporting seen in 2020 and 2021, this is more likely to reflect a restoration of the previous upward trajectory that was suppressed during the pressures of the COVID-19 pandemic.

Figure 2.1: Haemovigilance reports submitted by year 2010-2023



Of these 4972 reports, 3491 (70.2%) were completed by the reporter and have been analysed and included in this 2023 Annual SHOT Report. Additionally, there were 37 completed anti-D immunisation reports, and 15 completed ACE reports. The remaining 1429 reports were either withdrawn (875) or incomplete at the cut-off date for inclusion (554). Common reasons for withdrawal of reports from the SHOT analysis are reactions that were assessed to be mild or more likely related to underlying condition, or errors that were MHRA-reportable only (Ryan, et al., 2022).

Figure 2.2: The status of reports submitted to SHOT during 2023 (n=4972)



ACE=acknowledging continuing excellence

Reporting to SHOT and the MHRA

There are differences in reporting criteria for both organisations, and the 4972 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. Figure 2.3 highlights the main differences and commonalities in reporting criteria between the two organisations.

Further information regarding the numbers of reports accepted by SHOT and the MHRA can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

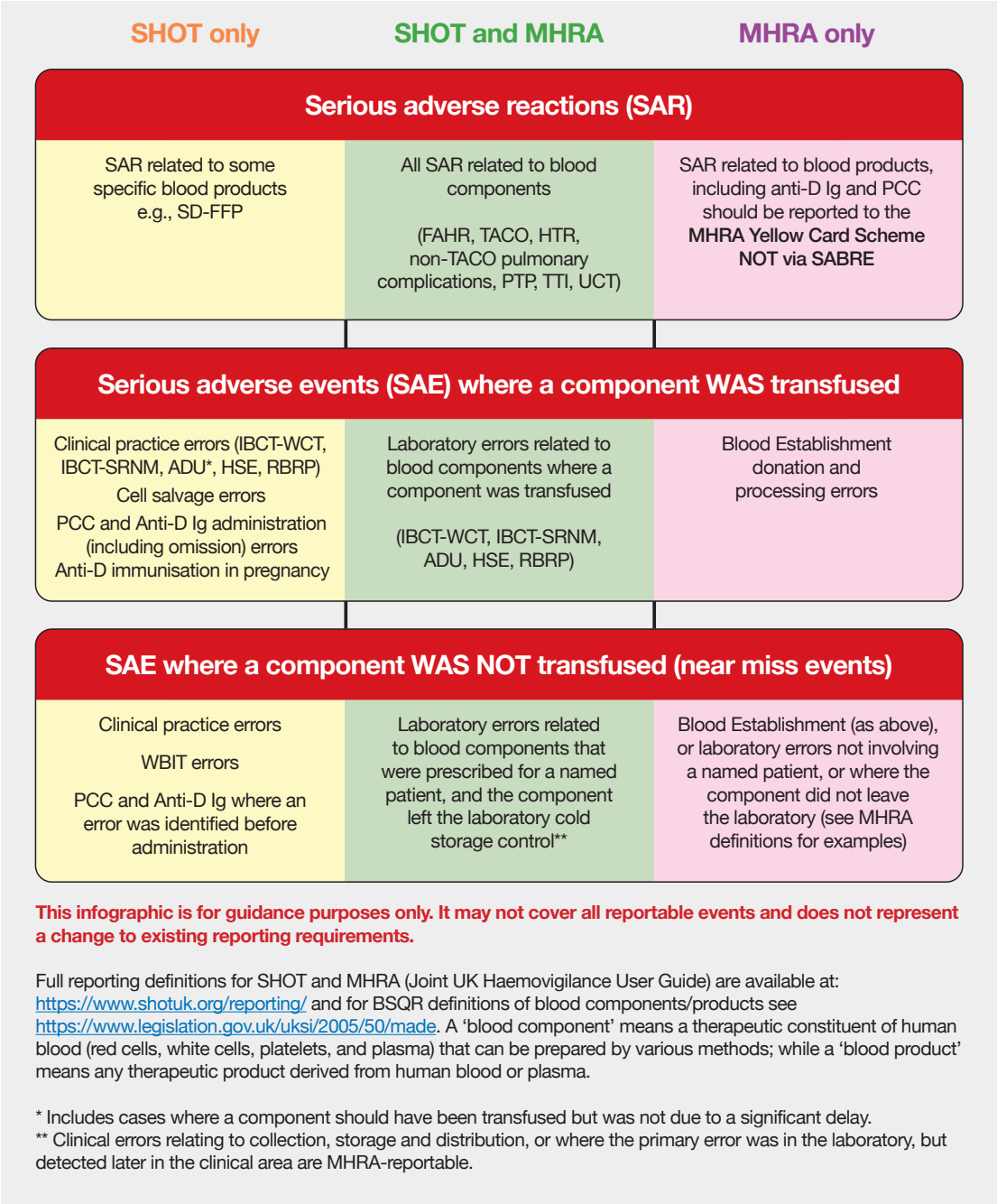


Figure 2.3: SHOT and the MHRA reporting criteria

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=immunoglobulin; 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

Blood component issue data 2023

Table 2.1 lists the total number of blood components issued from the UK Blood Services in 2023, and the number of SD-FFP (Octaplas®) units issued in each country.

Table 2.1: Blood components and SD-FFP issue data for the calendar year 2023 in the UK

	Red cells	Platelets	FFP	SD-FFP	Cryoprecipitate	Totals
NHS Blood and Transplant	1,351,959	250,530	169,875	53,710	40,739	**1,866,813**
Northern Ireland Blood Transfusion Service	42,238	8,886	4,523	772	934	**57,353**
Scottish National Blood Transfusion Service	138,372	23,890	14,588	3,490	3,208	**183,548**
Welsh Blood Service	72,932	8,248	7,628	1,490	258	**90,556**
Totals	**1,605,501**	**291,554**	**196,614**	**59,462**	**45,139**	**2,198,270**

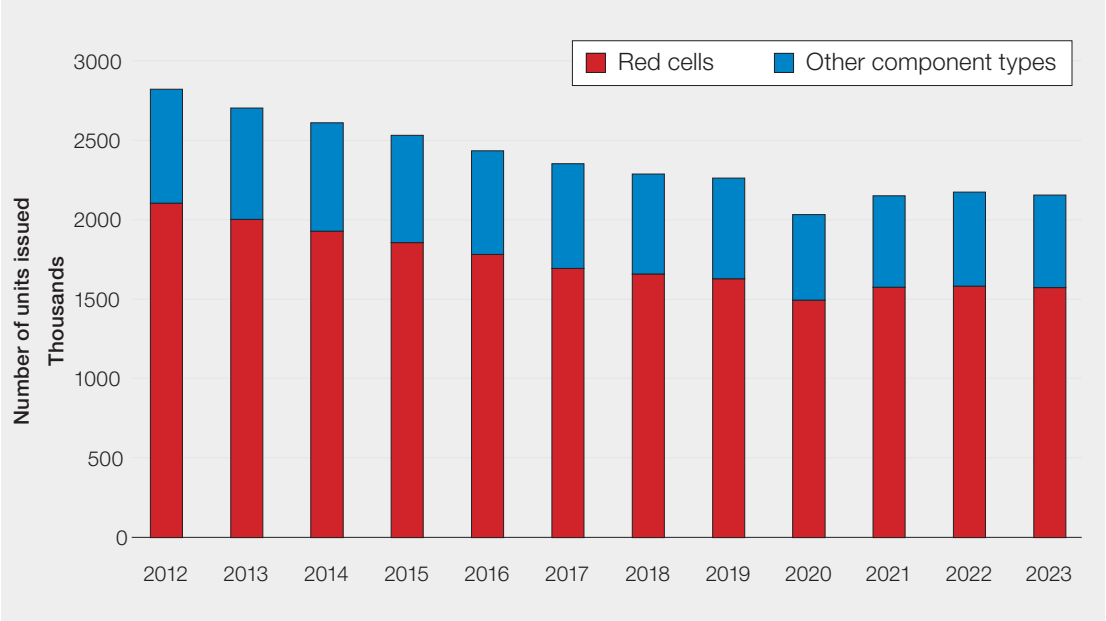
SD=solvent-detergent; FFP=fresh frozen plasma

Cryoprecipitate numbers are expressed as pools and single donations as issued; all other components are adult equivalent doses

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

There were no MB-FFP units issued in any of the UK Blood Services in 2023. This follows the SaBTO report where the requirement for MB-FFP was withdrawn in 2019 (Thomas, et al., 2022), so this has been removed from Table 2.1.

Figure 2.4a: Blood component issue data in the UK 2012-2023



Includes solvent-detergent fresh frozen plasma

While this provides the issue data for the various blood components, it is important to note that there continues to be a differential demand for some of the blood components. For example, the demand for O D-negative red cells as a percentage (of the overall demand) continues to rise and demand may exceed supply, thus putting additional pressure on Blood Services.

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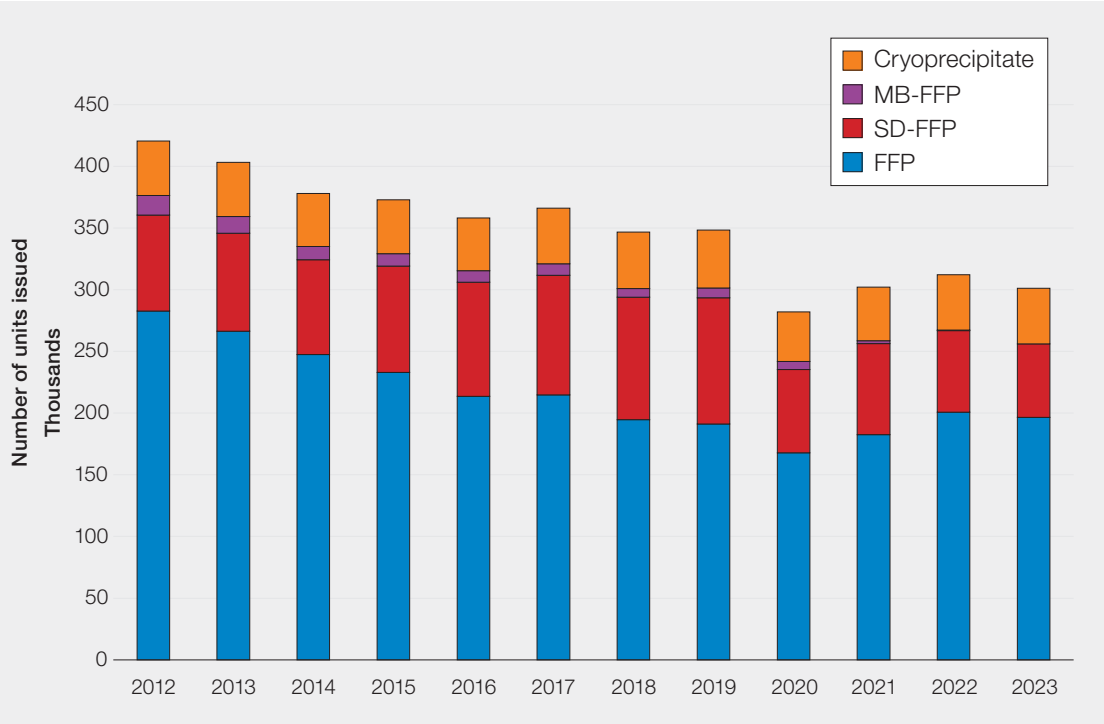


Figure 2.4b: Non-cellular component issue data in the UK 2012-2023

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

SHOT reporting by UK country

Full tables containing the breakdown of data from 2023 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-2023/).

Cases included in the 2023 Annual SHOT Report n=3833

The total number of reports analysed and included in the 2023 Annual SHOT Report is 3833. This is an increase of 334 from the 3499 reports analysed in the 2022 Annual SHOT Report (Narayan, et al., 2023). In addition to these 3833 reports, there were 42 reports of immunisation against the D-antigen during pregnancy. These are counted separately as part of a stand-alone study.

The number of reports with potential for patient harm (excluding 'near miss' and 'right blood right patient') is 2154, an increase of 285 from 2022 (n=1869).

Analysis has been carried out on the reports included in the 2023 Annual SHOT Report to look at the number of reports per region/country in each main reporting category, plus cell salvage. Figure 2.5 demonstrates that there is some variability between regions in the percentage of reports across different report types, with near miss reports accounting for between 29.0% and 47.4% of reports in each geographical area.

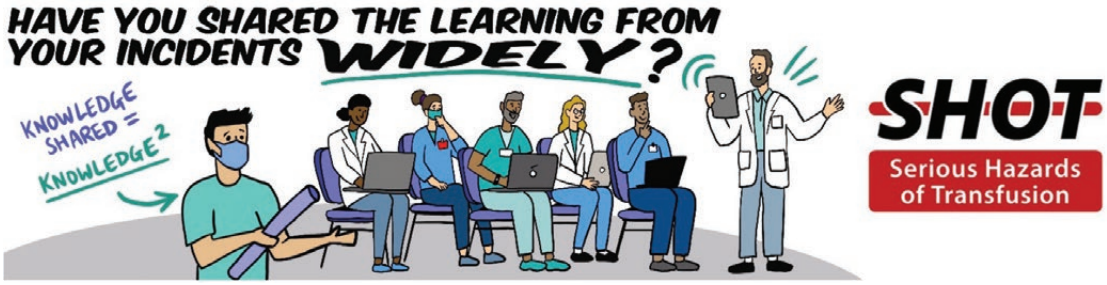
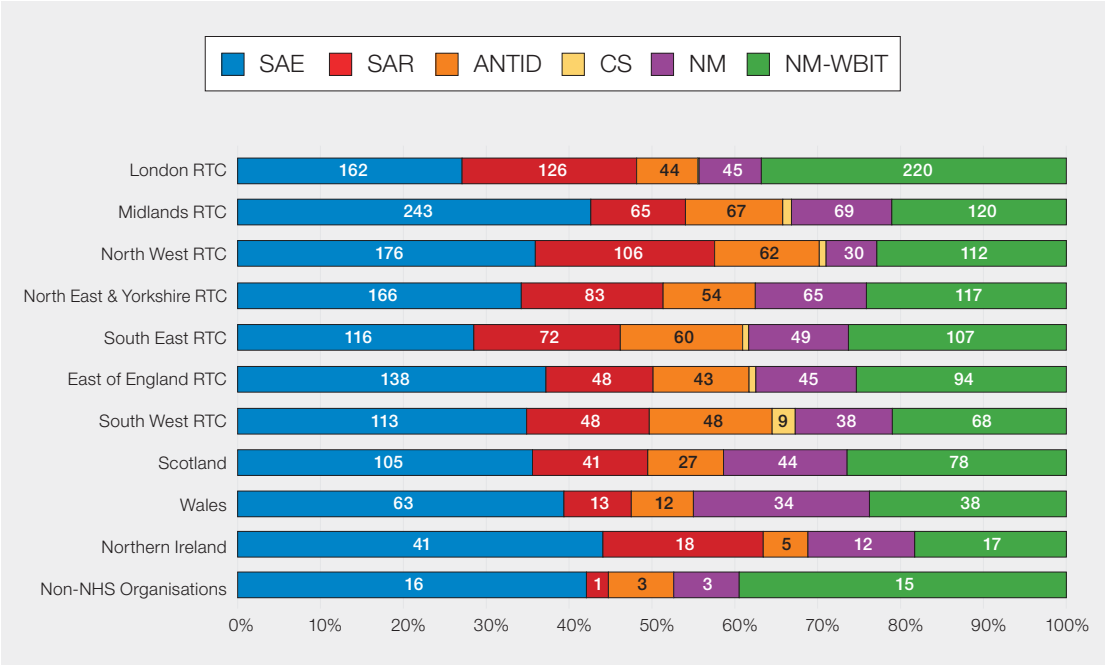


Figure 2.5: Number and percentage of reports in each region/country by category in 2023



ANTID=anti-D immunoglobulin errors; CS=cell salvage; NM=near miss; RTC=regional transfusion committee; SAE=serious adverse event; SAR=serious adverse reaction; WBIT=wrong blood in tube

Note: numbers for CS are too small to be displayed on the figure for most RTC areas

Understanding the contributory factors associated with variations can help identify best practices, areas for improvement, and potential risks, leading to enhanced patient safety and quality of care. Additionally, benchmarking fosters collaboration and knowledge sharing among healthcare professionals resulting in advancements in transfusion medicine.

Reporting organisations in 2023

To calculate participation data by reporting organisations, SHOT combines data from individual hospitals into their parent NHS Trust or Health Board. This is because there are varying reporting arrangements between different organisations. Some NHS Trusts/Health Boards submit from only one reporting account, whereas others may have one reporting account per hospital.

In 2023 there were two NHS Trusts/Health Boards that did not submit any reports. One of these organisations was a medium level blood user (issued with less than 7,000 components in 2022), and the other was a low blood user (issued with less than 1,500 components in 2022).

There were 26 non-NHS organisations that submitted 65 reports in 2023 which is an increase from 2022 (48 reports from 19 non-NHS organisations). 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.

SHOT participation benchmarking data

SHOT first began publishing participation benchmarking data in 2011, with the aim of promoting awareness of reporting levels and breadth of reporting (i.e., reporting across a wide range of different categories). Reporters are encouraged to review their individual reports to understand how many reports they submit in each of the 4 main categories of reporting (SAE, SAR, NM, and anti-D), and to benchmark their overall reporting levels against other similar sized organisations.

In 2011 there were 21/188 (11.2%) organisations that submitted reports in less than 2 of the 4 main categories and only 60/188 (31.9%) reported across all 4 categories. This suggested that some

organisations were not fully participating across all areas of haemovigilance. In 2022, there was a reduction in organisations submitting in fewer than 2 reporting categories, 6/173 (3.5%) and a move towards more comprehensive participation, with 83/173 (48.0%) reporting in all 4 main categories (Poles & Narayan, 2024).

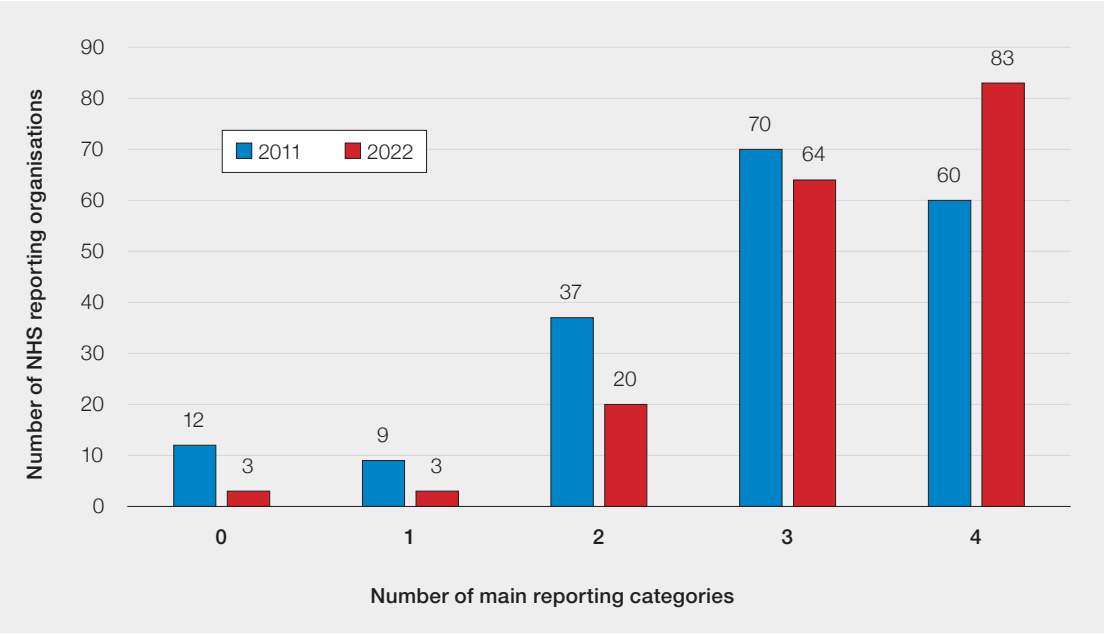


Figure 2.6: Number of NHS organisations submitting in reporting categories 2011 versus 2022

The full 2023 participation benchmarking data for individual organisations will be available to view on the SHOT website in the autumn of 2024. Benchmarking haemovigilance participation data is important for assessing compliance and engagement with haemovigilance reporting, identifying disparities, monitoring progress, potentially informing policy decisions, and promoting accountability. It helps drive quality improvement and ultimately enhances patient safety in blood transfusion practices.

SHOT also provides monthly participation data, 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.

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

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Improvements to the SHOT reporting database

The online SHOT reporting system (supplied by Dendrite Clinical Systems Ltd) was upgraded at the end of 2023 to modernise the user interface and improve the reporting experience. One of the main changes was to colour code the questions for status. Unanswered questions are coloured in red, and completed questions are green. It is hoped that this will encourage more complete reporting and in turn, improve the quality of the data analysed in the Annual SHOT Report.

A user-satisfaction survey to assess reporters opinions on the new interface will be conducted in the second half of 2024.

Planned future developments include implementation of dashboards which will provide real-time visibility of key metrics such as the number of reports submitted by time period, reporting category, location etc. These will enable stakeholders to make informed decisions and readily identify areas where tangible actions are needed. These dashboards may help facilitate local improvements with regard to reporting benchmarking and further actions.

Conclusion

SHOT is grateful for and appreciates the dedication of healthcare staff who contribute towards and participate in haemovigilance reporting and related activities. This speaks volumes about their commitment to patient safety and quality care. It demonstrates their recognition of the importance of monitoring and improving blood transfusion practices amidst challenging circumstances. Their efforts contribute to a culture of vigilance, continuous learning, and improvement in transfusion practice, ultimately benefiting patient outcomes.

Recommended resources

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

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. et al., 2023. *The 2022 Annual SHOT Report,* Manchester: Serious Hazards of Transfusion (SHOT) Steering Group. doi: https://doi.org/10.57911/605r-em59.

Poles, D. & Narayan, S., 2024. *Looking back to plan ahead: Reflections on over a decade of SHOT UK haemovigilance participation benchmarking data.* Athens, International Haemovigilance Network (IHN). Available at: https://ihn-org.com/ihn-symposium/posters/ (Accessed 01 July 2024).

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Thomas, S. et al., 2022. Importation of plasma and use of apheresis platelets as risk reduction measures for variant Creutzfeldt-Jakob disease: The SaBTO review. *Transfusion Medicine,* 32(1), pp. 24-31. doi: https://doi.org/10.1111/tme.12840.