# Participation in United Kingdom (UK) Haemovigilance

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# **Key SHOT messages**

- · Complete and accurate reporting is essential to ensure good quality haemovigilance
- Reporters are encouraged to report all relevant events to SHOT to help promote a shared learning culture so as to improve patient safety



ANTID	Anti-D Ig administration errors	NM
BSQR	Blood Safety and Quality Regulations	SABRE
FFP	Fresh frozen plasma	SAE
lg	Immunoglobulin	SAR
МВ	Methylene-blue treated	SD
MHRA	Medicines and Healthcare products Regulatory Agency	UK
NHS	National Health Service	

Л	Near miss
BRE	Serious adverse blood reactions and events
E	Serious adverse events
R	Serious adverse reactions
)	Solvent detergent-treated
(	United Kingdom

# Recommendation

• SHOT participation benchmarking data should be regularly reviewed to identify areas of potential under-reporting

Action: Hospital transfusion committees

# Introduction

Haemovigilance reporting in the UK continues to increase year on year. In the calendar year 2019, a total of 4248 reports were received by the SHOT on-line reporting system (Dendrite) via the Medicines and Healthcare products Regulatory Agency (MHRA) serious adverse blood reactions and events (SABRE) system. For full details of all MHRA data, see Chapter 26 of the 2019 Annual SHOT Report on the SHOT website (https://www.shotuk.org/shot-reports/).

Not all the reports submitted are SHOT-reportable or are included in the analysis for this SHOT Annual Report. Figure 2.1 details the fate of all submitted reports during 2019. Of the 679 withdrawn reports, 137 were submitted from the four Blood Services, and so are not reportable to SHOT (only to the MHRA). The remaining withdrawn cases are those that were either reported in error or were determined to be not SHOT-reportable. Some of these would still have been included by the MHRA as they would be reportable under the Blood Safety and Quality Regulations (BSQR). The 461 incomplete reports are those that are awaiting completion by the reporters. Reasons for non-completion could be that they are awaiting the outcome of investigations or were reported later in the year. Once complete, these reports will be reviewed for inclusion in the next Annual SHOT Report.



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Figure 2.1: Status of reports submitted to SHOT in the calendar year 2019



Note: 2 reports are not included on this figure as they were reported to Public Health England (PHE) and discussed in the 2018 SHOT Annual Report, but not reported to SHOT until 2019

The outputs from a haemovigilance reporting system are dependent on the quality of the data submitted. It is imperative that the information provided is as complete and accurate as possible for the SHOT Working Expert Group to make a valid assessment. To help with this, feedback will be communicated to reporters where there has been a change to the reported category or imputability of an event or reaction.

While reporting levels are rising, the total number of blood components issued each year continues to decrease. This is reflected in Figure 2.2 by the increasing number of submitted reports per 10,000 components issued.



Figure 2.2: Number of reports submitted to SHOT, and per 10,000 components issued 2010-2019 Figure 2.3 shows the flow of information from the submission of a report to the publication of the Annual SHOT Report.

Haemovigilance refers to the systematic surveillance of adverse reactions and adverse events related to transfusion with the aim of improving transfusion safety. The infographic below captures the flow of haemovigilance data and the process of gathering intelligence from the submitted reports to make recommendations to improve patient safety in transfusion

Figure 2.3: Flow of SHOT haemovigilance data



MHRA=Medicines and Healthcare products Regulatory Agency; SABRE=serious adverse blood reactions and events; SAR=serious adverse reactions; BSQR=Blood Standards and Quality Regulations; SG=steering group

### **Reporting organisations in 2019**

All but three UK National Health Service (NHS) Trusts/Health Boards submitted reports during 2019. Of the three non-reporting organisations, two were indirect users and the third was a low user of blood components.

There were 26 non-NHS organisations that submitted reports in 2019.

MHRA data demonstrates that most SABRE reporters are actively engaged in the UK haemovigilance reporting process with most active reporters reporting in the previous month. The few that have never reported or haven't reported in the last year are either facilities, care homes, private hospitals and very small NHS organisations with fewer than 200 units issued per year. The figure also includes those reporters who have an account for SHOT-only reporting purposes.



### **Participation levels 2019**

Analysis of the reporting levels by organisation and usage level has been carried out again for 2019 data. Although participation is generally high, and the number of reports submitted is increasing each year, there are very variable levels of reporting by organisations of similar size based on blood component usage.

Figure 2.5 emphasises these large differences, and at one end of the scale, a very high usage organisation submitted 5 or fewer reports, while at the other end, another high user submitted in excess of 100 reports.

Table 2.1: SHOT participation benchmarking usage levels 2018

Usage level	Total components per annum
Very low	<1,000
Low	1,001–6,000
Medium	6,001–10,000
High	10,001–19,000
Very high	>19,001

Figure 2.4: The last time a report was received on SABRE from an active

SABRE account



Figure 2.5: Number of 2019 reports by reporting organisation and component usage level

Additional analysis has been undertaken to review the variety of report types submitted by each NHS Trust/Health Board.

Serious adverse events (SAE), serious adverse reactions (SAR), near miss (NM) and anti-D immunoglobulin (Ig) administration errors (ANTID) reports have been included in the analysis to determine how many of these four main reporting categories were reported by each NHS organisation.

Encouragingly there were 85/171 (49.7%) of NHS organisations that submitted reports across all four reporting categories and indicates a broad reporting culture in these organisations. However, there were 38 organisations that only submitted reports in one or two different categories. Whilst low use organisations may not submit many reports if they do not perform many transfusions, it is worrying that 10/38 (26.3%) of these were 'high' or 'very high' blood component users. This could either indicate sub-optimal reporting arrangements in those organisations or conversely some hospitals may have robust safety measures in certain areas that considerably reduce risk of error.

There were also 12 'high' or 'very high' usage organisations that submitted no SAR reports in 2019.

Since 2012, SHOT has produced participation benchmarking data at NHS Trust/Health Board level, and for any independent, non-NHS reporting organisations that have reported during the preceding two years. These data are available on the SHOT website (https://www.shotuk.org/reporting/shot-participation-benchmarking/), and reporters are encouraged to review these data when they are published in the autumn each year.

Number of reporting	Number of NHS organisations by usage size						
categories	Very high	High	Medium	Low	Very low	Total	
1	1	2	2	8	2	15	
2	3	4	11	4	1	23	
3	7	15	11	15	-	48	
4	20	30	25	10	-	85	
Total	31	51	49	37	3	171	

Table 2.2: Category of reports submitted by NHS Trusts/Health Boards

3 NHS organisations did not submit any reports

### Blood component issue data 2019

Table 2.3: Total issues of blood components from the Blood Services of the UK in the calendar year 2019

	Red cells	Platelets	FFP	SD-FFP	MB-FFP	Cryo	Totals
NHS Blood and Transplant	1,400,536	254,735	164,505	88,720	7,288	42,073	1,957,857
Northern Ireland Blood Transfusion Service	41,160	8,493	3,819	2,460	264	991	57,187
Scottish National Blood Transfusion Service	137,393	22,749	15,406	7,260	503	3,240	186,551
Welsh Blood Service	82,506	11,111	7,457	3,820	-	494	105,388
Totals	1,661,595	297,088	191,187	102,260	8,055	46,798	2,306,983

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

SD-FFP data supplied by Octapharma

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

# SHOT reporting by UK country

Figure 2.6 shows the numbers of submitted reports and issued blood components across all four UK countries. The number of reports submitted for Northern Ireland in 2018 was artificially inflated as a result of 1 refrigerator failure case that resulted in 106 patients being administered anti-D Ig that was out of controlled temperature (Narayan et al. 2019). For 2019, the numbers for Northern Ireland have reverted to levels more consistent with previous years, which still show the highest level of reporting per 10,000 component of the four countries.

Wales has submitted its lowest number of reports and reports per 10,000 components for a number of years with 165 reports, and 15.7 reports per 10,000 components in 2019 (223, 20.7 in 2016; 189, 16.7 in 2017 and 196, 18.0 in 2018).

Reporting levels for England and Scotland per 10,000 components have continued to increase each year, the largest increases being in Scotland.

It is important that a 'low' reporting rate from an organisation should not be interpreted as a 'safe' organisation, as this may represent under-reporting which could be due to multiple factors including staffing issues, infrastructure and reporting culture. Similarly, a 'high' reporting rate should not be interpreted as an 'unsafe' organisation, as this may actually represent a culture of greater openness. It is well known that as the reporting culture in an organisation matures, staff are more likely to report incidents. Therefore, an increase in incident reporting should not be taken as an indication of worsening patient safety, but rather reflective of an increased awareness of safety issues amongst healthcare professionals and a more open and transparent culture across the organisation. It is also important to note that NHS Trusts/Health Boards are changing constantly with closures, mergers, and restructuring of services with very different risk profiles and these will have to be borne in mind when reviewing haemovigilance data. Regular review of these data by hospital transfusion teams, and shared learning from peers is strongly recommended to help system-wide meaningful changes in transfusion practices to improve patient safety.

Full tables containing the breakdown of data from 2019 and previous years can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2019/).



# Cases included in the 2019 Annual SHOT Report n=3397

The total number of reports analysed and included in the 2019 Annual SHOT Report is 3397. This is an increase of 71 from the 3326 reports analysed in the 2018 Annual SHOT Report (published 2019).

This number does not include 54 reports of immunisation against the D-antigen as these are part of a separate study.

The total number of 3397 is made up of the 3060 completed reports submitted in 2019 (Figure 2.1) plus 337 reports that were submitted in 2017 and 2018, but not finalised until 2019.

The number of reports with potential for patient harm (excluding 'near miss' and 'right blood right patient') is 1867, a 12.5% increase from 1659 in 2018.

### Analysis of errors by location

Following a steady increase in reports from emergency departments in the last few years, 2019 sees a slight drop in numbers for the first time, and although the trendline is still on an upwards trajectory, the actual percentage of total error reports in 2019 has dropped from 10.4% in 2018 to 8.9% in 2019.

The number of reports submitted from theatres is the lowest since 2013.

The downward trends in percentage of error reports continue in general wards and adult critical care, despite an increase in the absolute number of reports from wards in 2019.

Unfortunately, there are no denominator data available with regard to the number of transfusions undertaken in each of these areas.



# Conclusion

Engagement with haemovigilance reporting in the UK is generally very high, however there are wide variations between reporting organisations, and there is likely to be under-reporting in some areas.

SHOT publishes annual participation benchmarking data to assist organisations in understanding their own level of reporting, and how it compares to organisations with a similar level of blood component usage.

Reporters are encouraged to report fully across all types of incident report, SAE, SAR, NM and ANTID, to ensure a full and accurate picture of UK haemovigilance.

#### References

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].