Participation in United Kingdom (UK) Haemovigilance

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Authors: Debbi Poles and Chris Robbie

Abbreviations used in this chapter

ADU	Avoidable, delayed and under/overtransfusion
CCP	COVID-19 convalescent plasma
CHM	Commission on Human Medicines
ED	Emergency department
FFP	Fresh frozen plasma
HBB	Hospital blood bank
MB	Methylene-blue treated
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NHSEI	NHS England and Improvement
SABRE	Serious adverse blood reactions and events
SaBTO	The Advisory Committee on the Safety of Blood, Tissues and Organs
SD	Solvent detergent-treated
UK	United Kingdom
vCJD	Variant Creutzfeldt Jakob Disease

Key SHOT messages

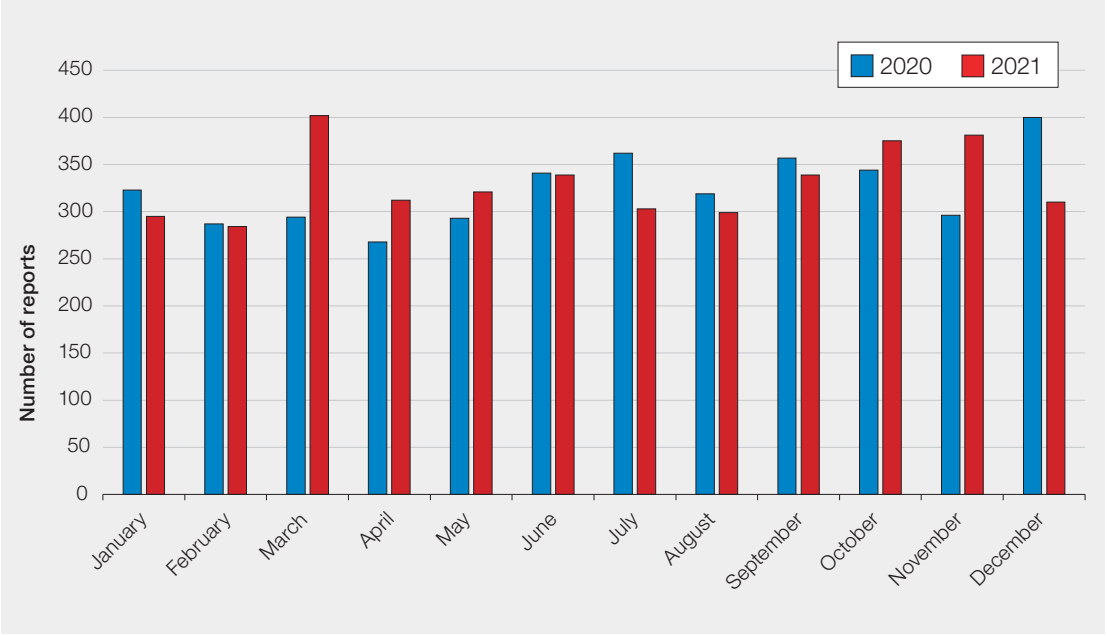
- 2021 was the first year that at least 1 report was submitted by every NHS Trust/Health Board in the UK
- High levels of reporting indicate a good reporting culture with an openness to share the learning when incidents occur. Timely submission and completion of reports enables identification of trends in errors, facilitating early shared learning
- Reporters are encouraged to review their participation benchmarking data on an annual basis, to ensure all appropriate reporting is captured

Introduction

In the first year of SHOT reporting in 1996, 169 initial reports were submitted from 94 different hospitals. Now, 25 years later, in the calendar year 2021, a total of 4088 reports were received from all NHS Trusts/Health Boards in the UK and some non-NHS organisations. In 1996 reporting was voluntary but is now professionally mandated. Increased participation is thought to be due to the confidential anonymised data, and acknowledgement that reporting to haemovigilance schemes helps to support improvements in patient safety.

Reporting levels are similar to the previous year, with only 25 more reports received compared to 2020 (n=4063). Reporting has again fluctuated by month during 2021, with a large spike submitted in March 2021, which could be due to reporters catching up after the winter pressures. However fewer reports were submitted during December 2021, which was the month that most reports were submitted during 2020.

Figure 2.1: SHOT reporting by month during 2020 and 2021



The 4088 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 details how the 4088 reports were included by each organisation. Only 1045/4088 (25.6%) of reports were accepted for inclusion in the 2021 analysis by both SHOT and the MHRA, and this demonstrates the differences in reporting criteria between the two organisations. The main differences in reporting criteria are that the MHRA does not accept reports related to clinical errors, which account for a large proportion of SHOT-reportable incidents. SHOT only accept reports that involve a named patient for whom a blood product or component has been prescribed and collected. The MHRA accepts reports from UK Blood Services, and laboratory errors which don't involve a named patient.

These differences account for the large numbers of reports that were withdrawn or excluded by each organisation. There were only 294/4088 (7.2%) reports that were withdrawn by both SHOT and the MHRA as not fulfilling either organisation's reporting criteria. Of these 294 reports, 49 were mild reactions, which are not reportable to either SHOT or the MHRA, and 23 were duplicate reports submitted in error.

There were 465 reports to SHOT that were submitted during 2021, but still incomplete at the end of December 2021. Whilst there will always be incomplete cases, especially for those reports that were not submitted until towards the end of the calendar year, this is a 17.7% increase from 2020, where there were 395 incomplete reports. This could be due to worsening workload and staffing pressure on haemovigilance reporters impacting their ability to gather all the necessary information in a timely manner. In 2021 there were less reports submitted during December than in 2020.

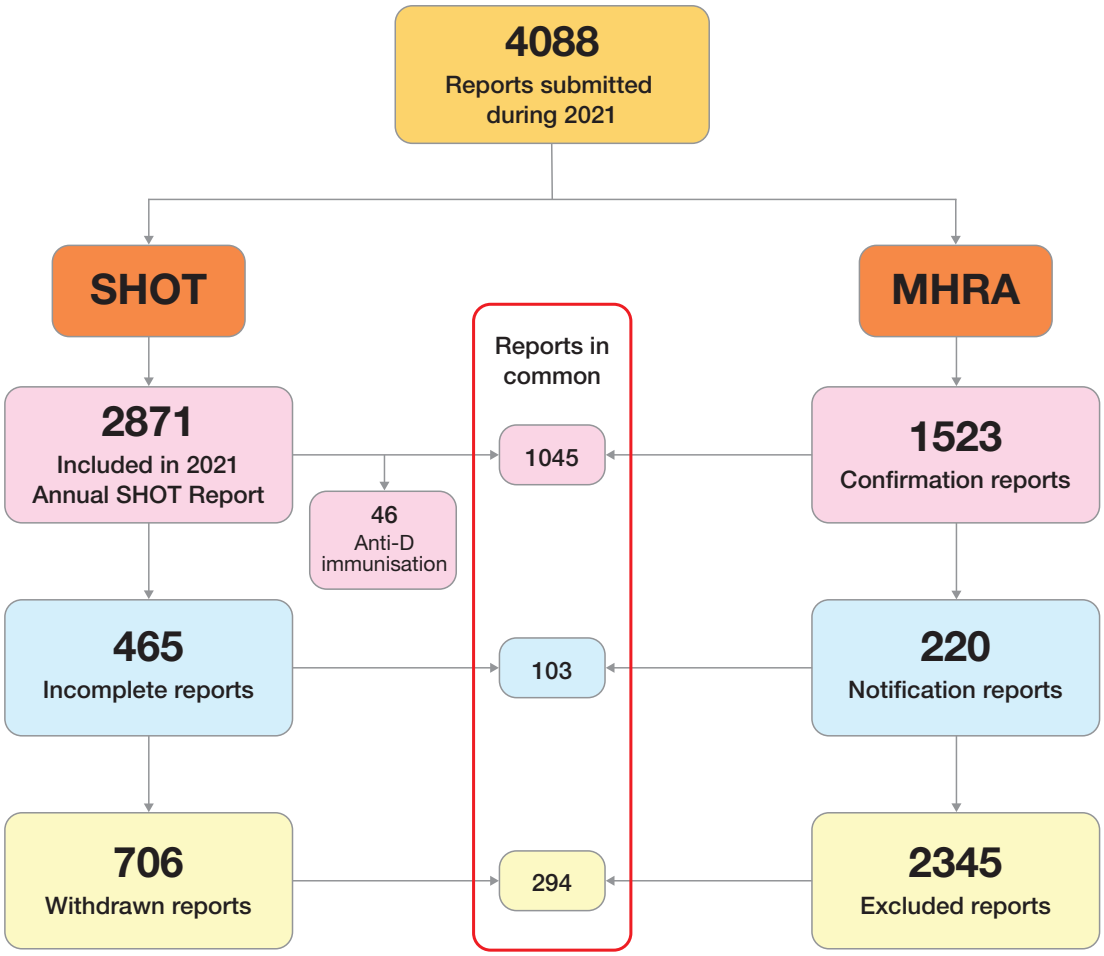


Figure 2.2: Reports submitted to SHOT and the MHRA in the calendar year 2021 (n=4088)

Reporting organisations in 2021

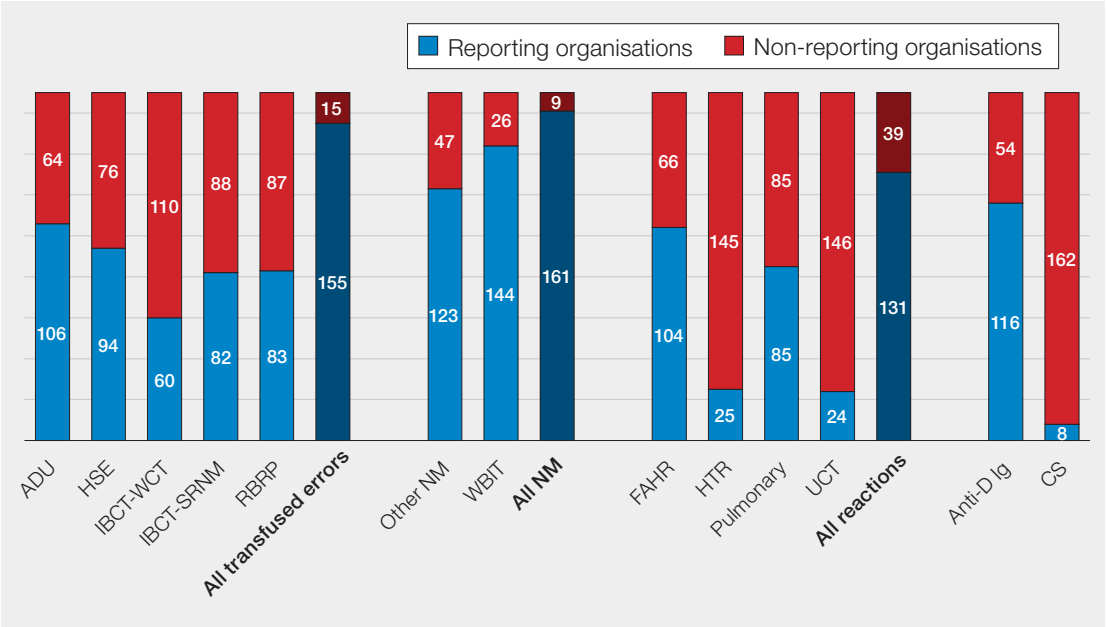
During 2021, 100% of UK NHS Trusts/Health Boards involved in transfusions submitted reports. This is the first year that there have been reports received from all registered Trusts/Health Boards since participation was first analysed in the Annual SHOT Report. This is commendable in what has been another difficult year for NHS staff. Whilst there may have been 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 49 reports in 2021.

Although the fact that all NHS organisations submitted reports is extremely positive, it is important to ensure that reporting covers a wide range of categories to minimise under-reporting. 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 2.3).

The error category with the largest amount of reporting organisations was ADU with 106/170 (62.4%) of organisations making reports. The overall number of organisations that submitted error reports where a component was transfused was 155/170 (91.2%). Of the 15 organisations that did not submit error reports, 1 was a high user of blood, and 3 were medium users (according to the blood usage levels used for the 2020 participation benchmarking data https://www.shotuk.org/reporting/shot-participation-benchmarking/). Out of the 9 reporting organisations that did not submit any type of near miss report, 1 was a very high blood user, and 1 was a high user. There were a higher number of organisations that did not report any reaction reports, and 19/39 (48.7%) of these were medium, high or very high usage organisations.

Figure 2.3: Number of NHS Trusts/Health Boards submitting reports by reporting category included in the 2021 Annual SHOT Report

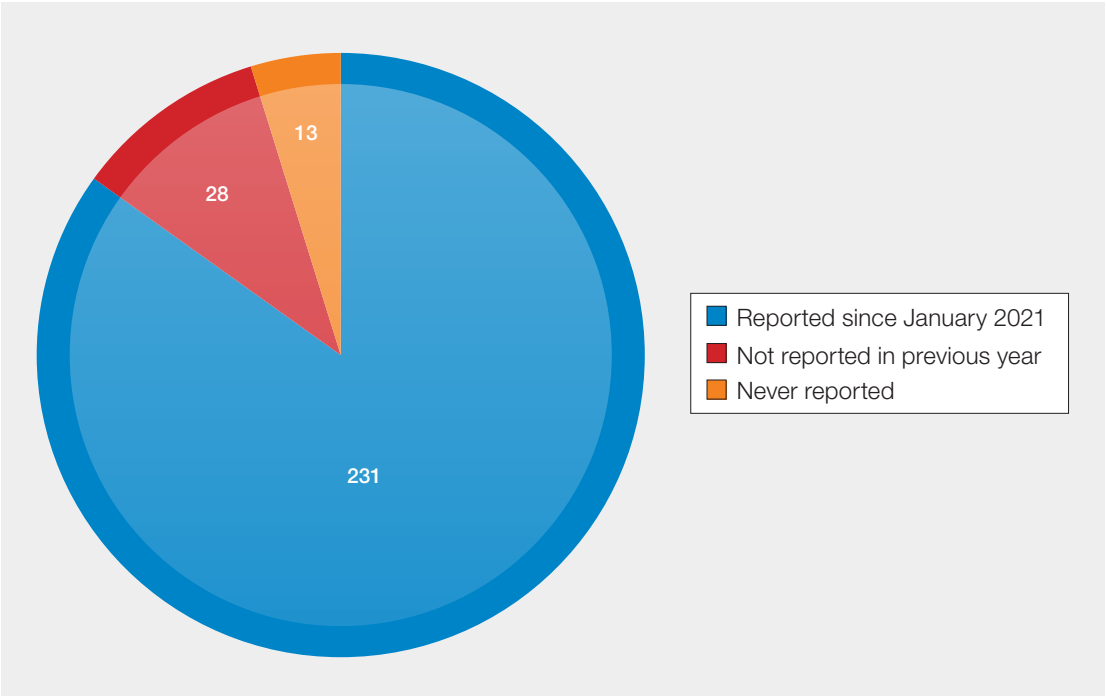


ADU=avoidable, delayed and under/overtransfusion; HSE=handling and storage errors; IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; RBRP=right blood right patient; NM=near miss; WBIT=wrong blood in tube; FAHR=febrile, allergic and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

Analysis from SABRE

Figure 2.4 demonstrates excellent involvement in the SHOT and MHRA haemovigilance systems, with most organisations reporting at least once in the previous few months. There are a small number of reporters who report less frequently. Most of those who have not reported at least once in the past 12 months are hospitals without HBB or small NHS organisations or a private HBB.

Figure 2.4: Participation in haemovigilance reporting from active SABRE accounts



MHRA participation data reflects SABRE reporting accounts rather than NHS Trusts/Health Boards whilst for SHOT, the individual accounts are amalgamated into the appropriate NHS Trusts/Health Boards, as reporting arrangements can differ widely between different organisations.

Blood component issue data 2021

Table 2.1 lists the total number of blood components issued from the UK Blood Services in 2021 and excludes CCP.

	Red cells	Platelets	FFP	SD-FFP	MB-FFP	Cryo	Totals
NHS Blood and Transplant	1,356,335	245,221	157,831	66,400	1,874	39,111	**1,866,772**
Northern Ireland Blood Transfusion Service	39,886	8,163	4,047	3,120	84	796	**56,096**
Scottish National Blood Transfusion Service	135,054	23,171	14,164	2,450	394	3,028	**178,261**
Welsh Blood Service	75,899	10,502	6,540	1,865	-	410	**95,216**
Totals	**1,607,174**	**287,057**	**182,582**	**73,835**	**2,352**	**43,345**	**2,196,345**

FFP=fresh frozen plasma; SD=solvent detergent-sterilised; 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

Table 2.1: Total issues of blood components from the Blood Services of the UK in the calendar year 2021

Although blood component issues increased in 2021 compared to 2020, the larger reduction in 2020 was likely due to the pandemic, and Figure 2.5 demonstrates that the overall downward trend in blood component issue data is continuing. It is important to note that in 2021, NHSBT started collecting plasma for medicines from blood donors mainly through apheresis but also recovered plasma from whole blood donations. In February 2021, the UK Government lifted a decades old ban on using plasma from UK blood donors for medicinal products such as immunoglobulins. SaBTO evaluated the risk of transmission of vCJD and recommended that the current risk-reduction measures be withdrawn (Thomas et al. 2021). In 2020, the MHRA undertook a comprehensive review of the safety of using UK plasma to make immunoglobulins. The CHM considered the evidence and recommended that UK-sourced plasma can be used for the manufacture of immunoglobulins subject to several risk-mitigation measures. The UK has had to rely on importation of these medicines which are in scarce supply worldwide due to disproportionate demand. The Secretary of State for Health and Social Care directed NHSEI, NHSBT and MHRA to begin preparations to appoint a fractionator(s) through a competitive process with an aim to secure a domestic supply of immunoglobulins. The Welsh and Scottish Governments and the Northern Ireland Executive have also directed their respective Blood Services to take forward work on this (Department of Health and Social Care 2021).

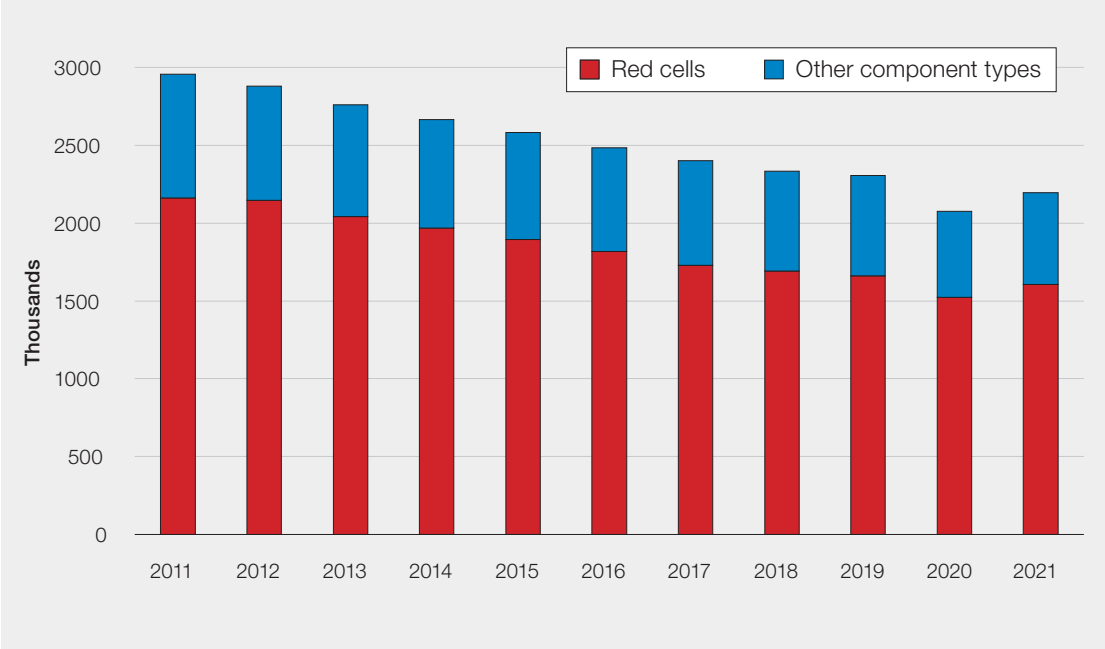
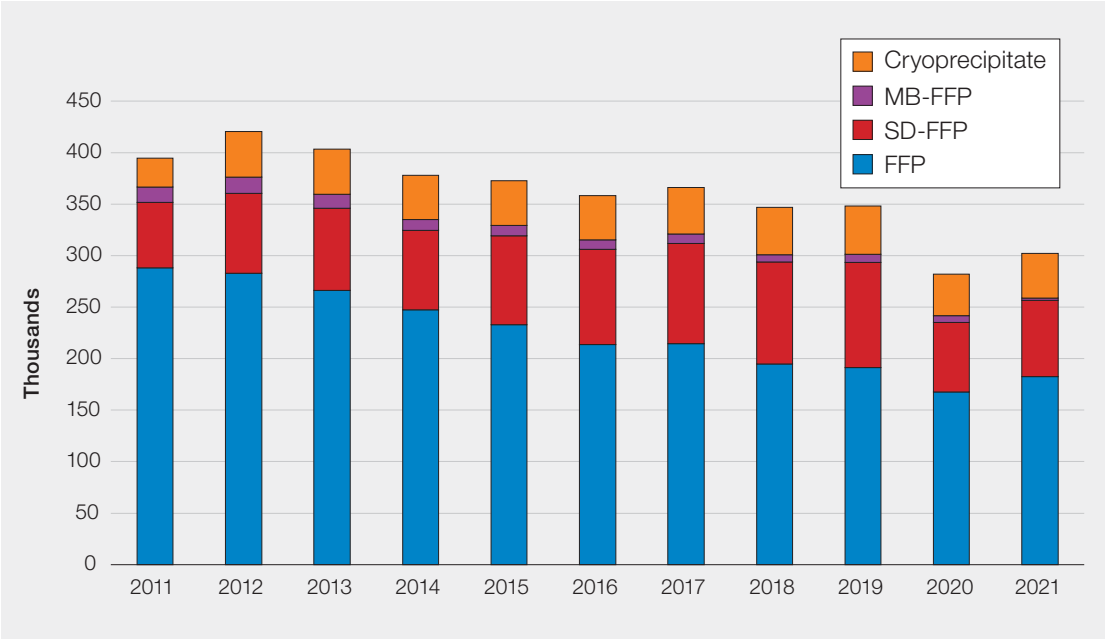


Figure 2.5a: Blood component issue data in the UK 2011-2021

Figure 2.5b: Non-cellular component issue data in the UK 2011-2021



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

SHOT reporting by UK country

Full tables containing the breakdown of data from 2021 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-2021/).

Cases included in the 2021 Annual SHOT Report n=3161

The total number of reports analysed and included in the 2021 Annual SHOT Report is 3161. This is a decrease of 53 from the 3214 reports analysed in the 2020 Annual SHOT Report (Narayan et al. 2021).

In addition to these 3161 reports, there were 56 reports of immunisation against the D-antigen. These are counted separately as part of a stand-alone study.

The total number of 3161 is made up of the 2871 completed reports submitted in 2021 (Figure 2.2) plus 290 reports that were submitted in earlier years, but not finalised until 2021.

The number of reports with potential for patient harm (excluding 'near miss' and 'right blood right patient') is 1790, a small decrease from 2020 (n=1877).

Analysis of errors by location

The number of incidents reported from the emergency department has increased substantially from 2020, and is still on an upward trend. 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 theatres remain consistent with previous years. Reports from general wards and adult critical care continue a downwards trend since this data has been analysed from 2010. Although the number of reports from adult critical care increased slightly in 2021, the percentage of total reports is still lower than 2010.

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.

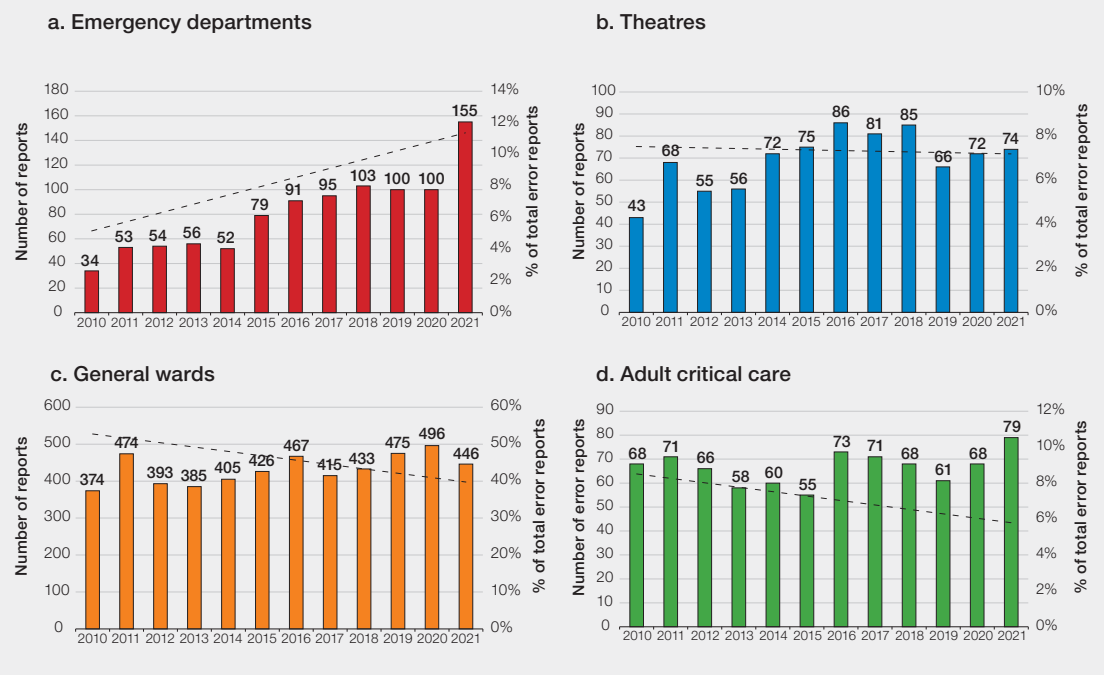


Figure 2.6: Trend of error reports from different departments

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. Figure 2.7 illustrates how the SHOT participation data can be used to benchmark and drive local improvements in practices.

Data are collated and published annually in the autumn, and the 2021 participation data will be available on the SHOT website during October 2022.

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 until they have been reviewed by the SHOT working expert group.

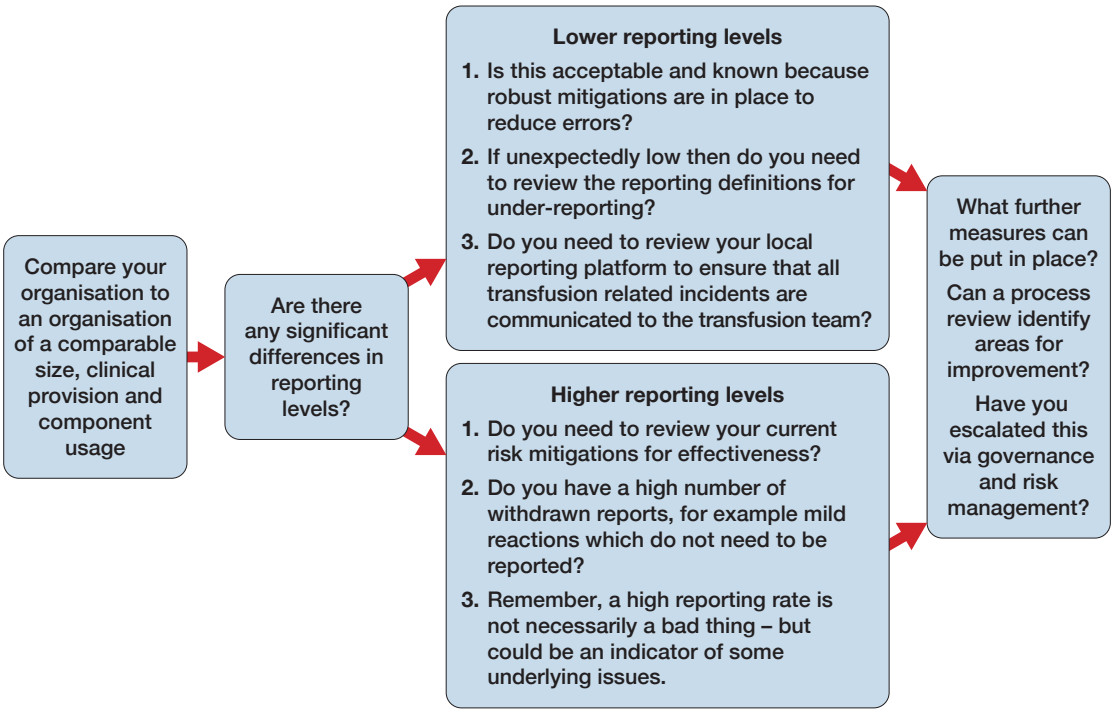


Figure 2.7: Using SHOT participation benchmarking data to drive improvements

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.

Conclusion

A continuing high level of participation in haemovigilance reporting is a sign of good reporting culture and reflects that an open and fair culture largely exists in the NHS where staff learn from things that go wrong. Organisations with a culture of high reporting are more likely to have developed proactive reporting and learning to ensure the services they provide are safe. Participation has continued despite the pandemic-related challenges and benchmarking of this data helps identify areas for improvement. Analysis of submitted data allows identification of risks so that appropriate measures can be initiated to mitigate these risks and improve transfusion safety.

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

Department of Health and Social Care. Ban lifted to allow UK blood plasma to be used for life-saving treatments (2021). https://www.gov.uk/government/news/ban-lifted-to-allow-uk-blood-plasma-to-be-used-for-life-saving-treatments [accessed 04 May 2022].

Narayan S (Ed), Poles D, et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2020 Annual SHOT Report (2021). https://www.shotuk.org/shot-reports/ [accessed 31 March 2022].

Thomas S, Kats M, Slowther AM, et al. Importation of plasma and use of apheresis platelets as risk reduction measures for variant Creutzfeldt-Jakob disease: The SaBTO review. *Transfus Med* 2022;**32(1)**:24-31. https://doi.org/10.1111/tme.12840 [accessed 24 April 2022].