

# Serious Adverse Blood Reactions and Events 2010

## Mandatory reporting under the UK Blood Safety and Quality Regulations

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### Background

In 2005 the Medicines and Healthcare products Regulatory Agency (MHRA), an existing independent regulator already responsible for the safety, quality and effectiveness of medicines and medical devices, was designated as the UK Competent Authority for Blood Safety & Quality by the Secretary of State for Health. Since then, reports of serious adverse events and reactions have been notified and confirmed to the MHRA by blood establishments and hospital blood banks. All reports made to the MHRA have been submitted via the Serious Adverse Blood Reactions & Events (SABRE) online reporting system, and the content analysed by the MHRA Haemovigilance team. Reporting to Serious Hazards of Transfusion (SHOT) remains voluntary, but is required for compliance with HSC/2004/009 'Better Blood Transfusion' and is a standard for the Clinical Negligence Scheme for Trusts in England.

SABRE continues to facilitate SHOT reporting by providing an electronic link to the SHOT Dendrite database.

This concise overview of the MHRA's role in UK haemovigilance is supported by summary data that can assist reporters in their appreciation of the range of reportable serious adverse events and reactions. It can also support them in enhancing their quality systems, reducing the frequency of errors, and improving the overall safety of transfusion practice. The graphs displayed allow reporters to review reporting patterns within the United Kingdom, and to note the most commonly recurring serious adverse blood reactions and events.

### The reporting cycle

**1 SABRE registration**  
The total number of reports has increased year by year as reporters have become more familiar with the regulatory requirements. There are, however, noticeable regional variations and a small number of low usage sites that have not yet reported at all. These data comprise part of the background information provided to the MHRA inspectors to support their compliance deliberations and inspection planning activities.

Country	Number of registrations	Number of reports (cumulative since 2005)
England	228	5,652
Scotland	38	530
Wales	14	625
Northern Ireland	9	301

Table 1 Registrations and reports by country 2010

**2 Notification report**  
In 2010 a total of 1,762 SABRE reports were received. 1,139 of these were serious adverse events (SAEs), 623 were serious adverse reactions (SARs). 248 reports were subsequently excluded from the annual summary report as they did not meet EU Commission reporting guidelines. The chart below demonstrates the total number of reports received each year and the proportion of SAEs to SARs.

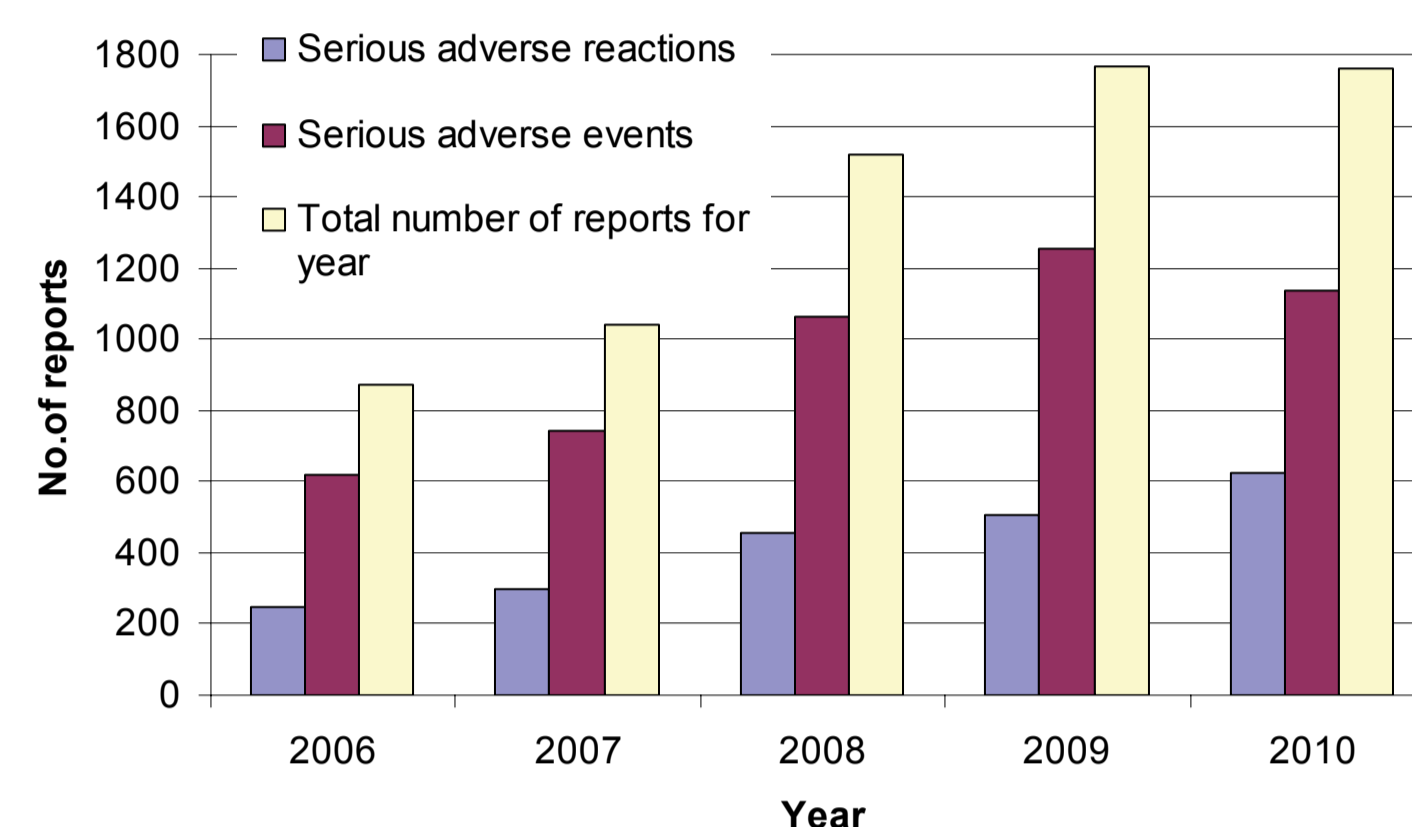


Figure 1 Verified SABRE reports by year

**3 Preliminary review on Haemovigilance Information Tracking System (HITS)**  
All submitted SABRE notification reports undergo preliminary review on HITS, (Lotus Notes database linked to SABRE), within one week of receipt. This ensures that the MHRA's Inspection, Enforcement and Standards Division (IE&S) are rapidly alerted to any significant incidents.

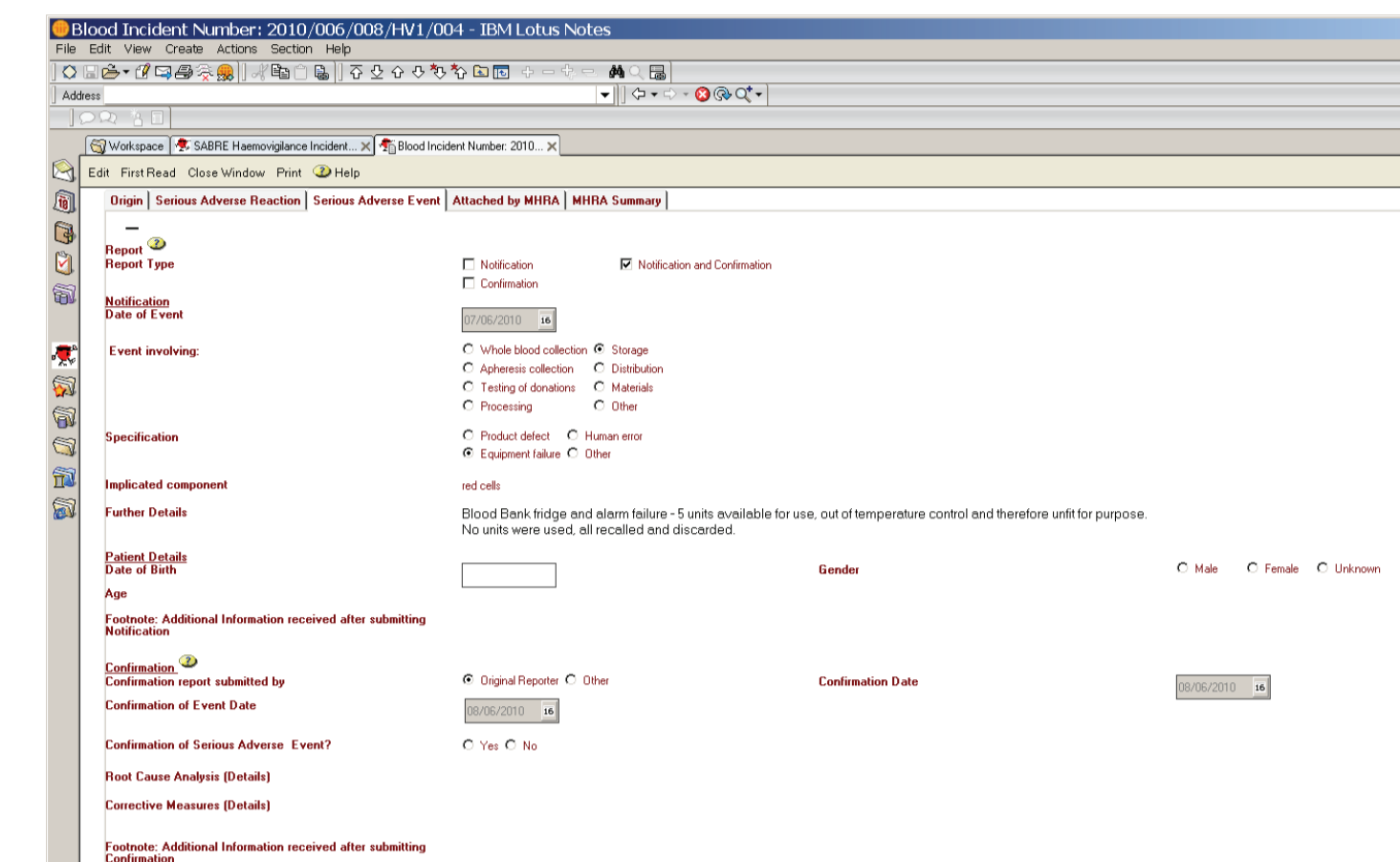


Figure 2 Example of a notification view on HITS

**6 Excluded reports 2010**  
The majority of excluded reports are related to clinical errors and anti-D events which are not reportable to SABRE. These are, however, reportable to SHOT.

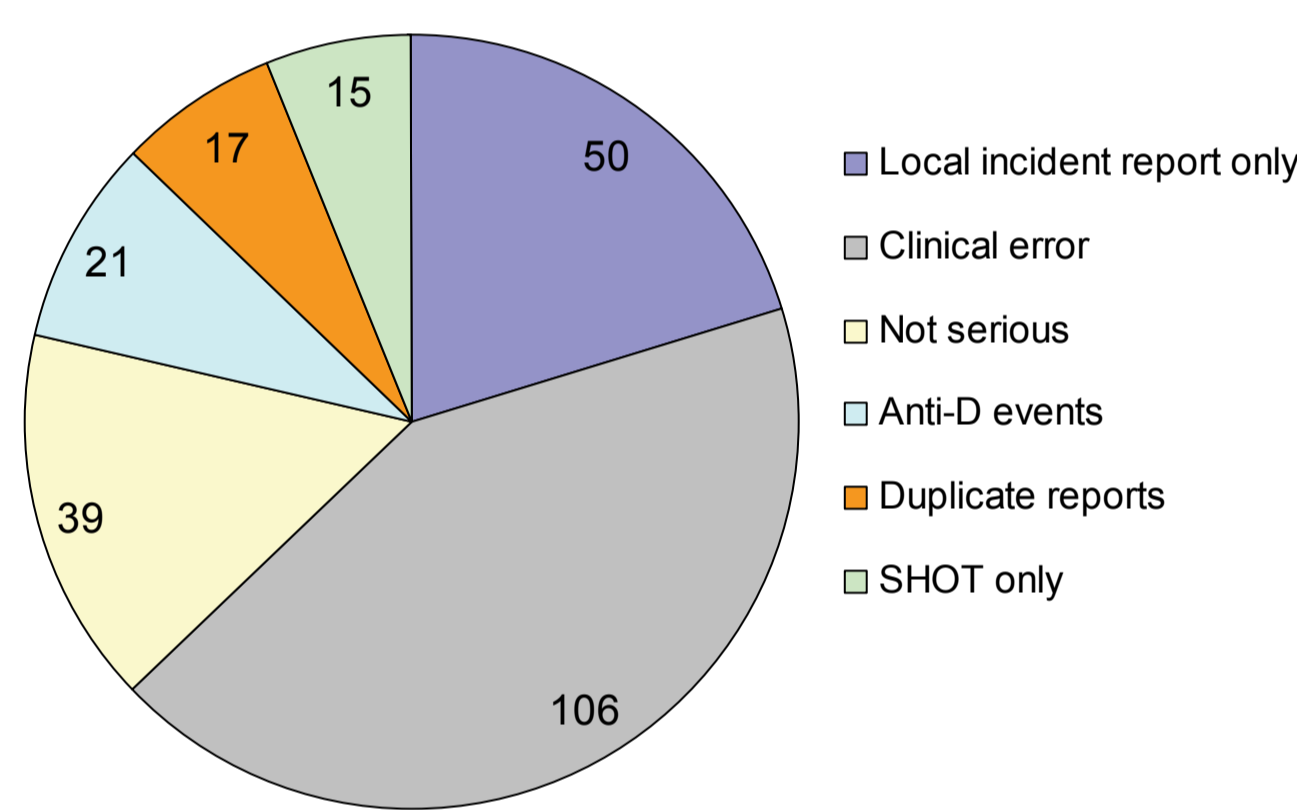


Figure 3 Excluded reports 2010

**5 Serious adverse reactions (SAR) 2010**  
Of the SARs, the majority of reports are febrile non-haemolytic transfusion reactions and anaphylactic/hypersensitivity reactions. In 2010 there were 4 deaths attributable to the blood component transfused, which caused TACO, anaphylaxis and hyperhaemolysis syndrome. None of these reactions were caused by laboratory error.

Anaphylaxis/hypersensitivity	300
Febrile non-haemolytic transfusion reaction	115
Immunological haemolysis due to other alloantibody	45
TRALI	36
TACO	30
Other	26
TTBI	20
Non-immunological haemolysis	5
TTVI	4
PTP	2
ABO incompatibility	1

Table 3 Serious adverse reactions 2010 (n= 584), minus excluded reports

**4 Serious adverse events (SAE) 2010**  
Of the SAEs, the most commonly occurring errors relate to the storage and handling of blood and blood components. This includes the issue and availability of expired units. Other frequent reports include the issue and transfusion of incorrect blood components (usually non-irradiated/non-CMV Neg units) and laboratory sample and component labelling errors.

Other	486
Storage	274
Distribution	63
Whole blood collection	58
Processing	33
Testing of donations	12
Materials	3
Apheresis collection	1

Table 2 Serious adverse events 2010 (n=930), minus excluded reports

**7 Monthly follow-up of overdue reports**  
If a confirmation report is not received within one month of the initial SABRE notification, regular email reminders will be sent to the reporter. The Haemovigilance team will also telephone to check reasons for delays.

**8 Confirmation report**  
Once local investigations of SAEs and SARs have been completed a Confirmation report should be submitted. SAE confirmations should detail the root causes of the incident and all corrective and preventative measures taken. SAR confirmations should detail any further tests undertaken to establish the reaction type and give reasons for the reported imputability level.

**9 Referral to Inspection, Enforcement & Standards Division or expert panel**  
Some reports may be referred to the IE&S Division for further action where there is a clear increase in risk to patient safety e.g. death due to transfusion of incompatible blood, multiple pre-transfusion testing errors, or recurrent failures of the quality management system. Complex reports may be referred to the Haemovigilance Expert Panel for their consideration and advice.

#### Incident closure on HITS

When the report has been satisfactorily completed it will be marked as Closed by the Haemovigilance team.

**12 Submission of annual summary report to the EU Commission**  
EU and UK regulations require each EU member state to submit annually a summary of all SAE and SAR reports received during the preceding calendar year. The health directorate of the EU Commission uses this information to help develop new blood policies, manage global health threats and promote public health protection and disease prevention.



**11 Reconciliation of data with SHOT**  
Each year (usually in May) SABRE and SHOT representatives meet to compare data and review differences in report numbers received. This reconciliation helps to ensure consistency and full understanding of both UK sources of haemovigilance data.



**10 Verification of annual summary reports and submission of blood component usage data by reporter**  
By the end of January of every year, each reporter is presented with a summary of the reports they have submitted in the previous twelve months. In addition to verifying the summary data, reporters are asked to provide details of the number of units of blood issued, the number of units transfused and the number of patients transfused. Verified reports and transfusion data must be returned to the MHRA by the end of March each year.

Serious adverse events, affecting quality and safety of blood component due to a deviation in:	Total number	Product defect	Equipment failure	Human error	Total	Other	Other specification detail
Whole blood collection	51	0	0	30	1	20	Arm cleaning system.
Apheresis collection	3	0	0	1	2	1	Harness 'fault' not spotted at time.
Testing of donations	6	0	0	2	4	2	Test kits weak D variant missed on Human error and poor process design.
Processing	37	2	1	26	8	7	Regular maintenance missed. Under investigation under investigation regular maintenance overdue. Unclear procedure.
Storage	267	1	42	220	24	19	Fridge door left open. Local protocol inadequate. Procedural violation Inadequate policy for titration.
Distribution	56	0	0	48	8	8	Lack of formalised arrangements and training. Stocks not maintained. Software reference table access denied storage temperature out of specification in delivery van.
Materials	2	1	0	1	0	0	
Other	551	0	14	509	28	28	Bedside transfusion. Procedural error. Communication error. System failure. Human error and resource issues.
Overall total	973	4	57	837	75	75	

Figure 4 Example of an annual summary report

### Future direction

Since the beginning of 2010, the MHRA Haemovigilance team have expanded the number of informal visits to hospital blood banks and blood establishments. These visits are not only a valuable means of helping to ensure that reporters have a good understanding of the relevant regulatory requirements, but also provide an opportunity to give practical assistance and guidance in the use of SABRE. This is particularly useful as local reporting responsibilities have changed considerably since the initial round of SABRE training seminars. The MHRA Haemovigilance team remains available to provide support and advice to those who request assistance.

In accordance with the EU Commission's latest guidance on the Blood Safety and Quality Directives the MHRA has recently published its own revised guidance document. This is being supported by a series of workshops for blood establishment and blood bank staff around the UK. Haemovigilance data has now been collected on the SABRE system for 5 years and this is being collated into the first MHRA Haemovigilance Annual Report. It is hoped that by including common inspection findings in this report, blood establishments and hospital blood banks will gain a clearer picture of the progress being made in the field of blood transfusion safety in the UK.