

SABRE reporting - 2007 statistics and future plans

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Introduction

Annual summary data

- Key figures
- Lessons learnt

- Ongoing MHRA activities
 - EU reporting workshop
 - Senior Haemovigilance Specialist
 - SABRE redevelopment

- Reporting reminders

Participation rates

- Reports received from 216/308 in 2007
- 66 registrants have never reported

Annual summary data

- Submitted to the EU Commission 16/06/08
- Reconciled with SHOT
- Differences with SHOT Report findings

Reasons for differences

- Reporting requirements
- Low imputability
- Reporting period
- Categories

SABRE reports submitted in 2007

- **MHRA** 1012
 - *Confirmed within the reporting year*

- **SHOT only** 427
 - Received within the reporting year

- *Note: These figures do not assume that reports sent to SHOT have been included in the SHOT report*

SABRE reports submitted in 2007

- Serious Adverse Reactions 264
- Serious Adverse Events 659
- Excluded 89

Comparison with previous year's data – numbers of reports

Year	SAR	SAE	Exclusion	Total
2006	237	507	84	828
2007	264	659	89	1012

Comparison with previous year's data – numbers of units issued

Number of units issued	Red Cells	Platelets	Plasma	Other	Whole Blood
HBB 2006	2,381,800	260,036	358,989	29,149	35
BE 2006	2,267,927	260,435	438,207	29	200
HBB 2007	2,315,846	252,329	332,467	13,420	45
BE 2007	2,264,814	267,113	345,778	468	2

Summaries Received

- 8 out of 308 registrants were late
 - 1 was not in a readable format and re-submitted
 - 1 was sent to the wrong email address
 - 2 due to personal reasons
 - 4 no adequate excuse

Serious Adverse Events, affecting quality and safety of blood component due to a deviation in



	Total Number	Product Defect	Equipment Failure	Human Error	Other
Whole blood collection	11	1	0	9	1
Apheresis collection	1	1	0	0	0
Testing of donations	7	1	0	2	4
Processing	20	2	0	16	2
Storage	133	0	26	98	9
Distribution	20	0	0	15	5
Materials	2	0	1	0	1
Other	465	3	4	426	32
Total	659	8	31	566	54

Serious Adverse Events

- **Mostly “other”**
- **Next highest category “storage”**
- **Biggest root cause is human error**

Adverse Reactions Relating to Red Cells



Type of Reaction		Not Assessable	Level 0	Level 1	Level 2	Level 3
Immunological haemolysis due to ABO incompatibility	Total: 7 Deaths: 0	0	0	0	0	7
Immunological haemolysis due to other allo-antibody	Total: 24 Deaths: 1	1	0	1	8	14
Transfusion-transmitted bacterial infection	Total: 8 Deaths: 1	1	5	2	0	0
Anaphylaxis / hypersensitivity	Total: 31 Deaths: 1	0	2	18	10	1
TRALI	Total: 11 Deaths: 1	2	3	2	1	3
Transfusion-transmitted viral infection (HBV)	Total: 1 Deaths: 0	0	1	0	0	0
Transfusion-transmitted viral infection (HCV)	Total: 1 Deaths: 0	0	1	0	0	0
Post-transfusion purpura	Total: 4 Deaths: 0	0	1	1	1	1
Other	Total: 67 Deaths: 5	5	21	25	13	3
Total	Total: 154 Deaths: 9	9	34	49	33	29

Adverse Reactions Relating to Platelets

Type of Reaction		Not Assessable	Level 0	Level 1	Level 2	Level 3
Immunological haemolysis due to ABO incompatibility	Total: 1 Deaths: 0	0	0	0	0	1
Immunological haemolysis due to other allo-antibody	Total: 1 Deaths: 0	0	1	0	0	0
Transfusion-transmitted bacterial infection	Total: 4 Deaths: 0	0	2	1	1	0
Anaphylaxis / hypersensitivity	Total: 29 Deaths: 1	0	0	12	13	4
Transfusion related acute lung injury	Total: 7 Deaths: 1	0	4	1	0	2
Transfusion-transmitted viral infection (HBV)	Total: 1 Deaths: 1	0	0	1	0	0
Post-transfusion purpura	Total: 0 Deaths: 0	0	0	0	0	0
Other	Total: 19 Deaths: 2	1	3	8	7	0
Total	Total: 62 Deaths: 5	1 0	10 2	23 2	21 1	7 0

Adverse Reactions related To Plasma



Type of Reaction		Not Assessable	Level 0	Level 1	Level 2	Level 3
Transfusion-transmitted bacterial infection	Total: 1 Deaths: 0	0 0	1 0	0 0	0 0	0 0
Anaphylaxis / hypersensitivity	Total: 22 Deaths: 1	0 0	0 0	5 0	16 1	1 0
Transfusion related acute lung injury	Total: 7 Deaths: 3	1 0	5 3	1 0	0 0	0 0
Other	Total: 8 Deaths: 1	2 1	1 0	3 0	2 0	0 0
Total	Total: 38 Deaths: 5	3 1	7 3	9 0	18 1	1 0

Adverse Reactions Related to Other (other component types and multiple components involved)

Type of Reaction		Not Assessable	Level 0	Level 1	Level 2	Level 3
Anaphylaxis / hypersensitivity	Total: 1 Deaths: 0	0 0	0 0	0 0	1 0	0 0
Transfusion related acute lung injury	Total: 5 Deaths: 0	0 0	2 0	2 0	0 0	1 0
Transfusion-transmitted viral infection (HBV)	Total: 1 Deaths: 0	0 0	1 0	0 0	0 0	0 0
Other	Total: 2 Deaths: 0	1 0	0 0	1 0	0 0	0 0
Total	Total: 9 Deaths: 0	1 0	3 0	3 0	1 0	1 0

Lessons learnt

- Confusion between Annual Summary and BCR
- Terminology used
- LIMS systems not capable
- Emails
 - Blocked by firewalls
 - Accounts not monitored
 - Accounts not active
 - Tables not received/returned in a readable format
 - Not returned to the correct email address
 - Ignored/not actioned

Ongoing MHRA Activities

- EU Reporting Workshop
 - Selection of representatives from CAs and non-regulatory haemovigilance bodies
 - Common interpretation of current EU Directives
 - Guidance for users
 - Current MHRA guidance still stands

Ongoing MHRA Activities

- Senior Haemovigilance Specialist
 - Interviews planned
 - Expert panel

Ongoing MHRA Activities

- MHRA Website Accessibility Projects
 - Redesign SABRE to become RNIB compliant
 - The way SABRE works will stay the same
 - But navigation will be different
 - Assessed by RNIB
 - Further update prior to launch in September/October

Reporting Reminders

- Only report “serious” adverse events and reactions as soon as known
- Choose the right category
- Write reports using clear language so that someone unconnected to the incident will understand what occurred
- Do not report clinical events
- Do not report events involving blood products
- Always submit a Confirmation report
- Emailed reminders are only reminders, not demands that a confirmation is required regardless of whether the SAE/SAR is completed