



MHRA
Regulating Medicines and Medical Devices

SABRE Update – October 2014

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Introduction



- SABRE Stats (as of July 2014)
- Reporting Trends



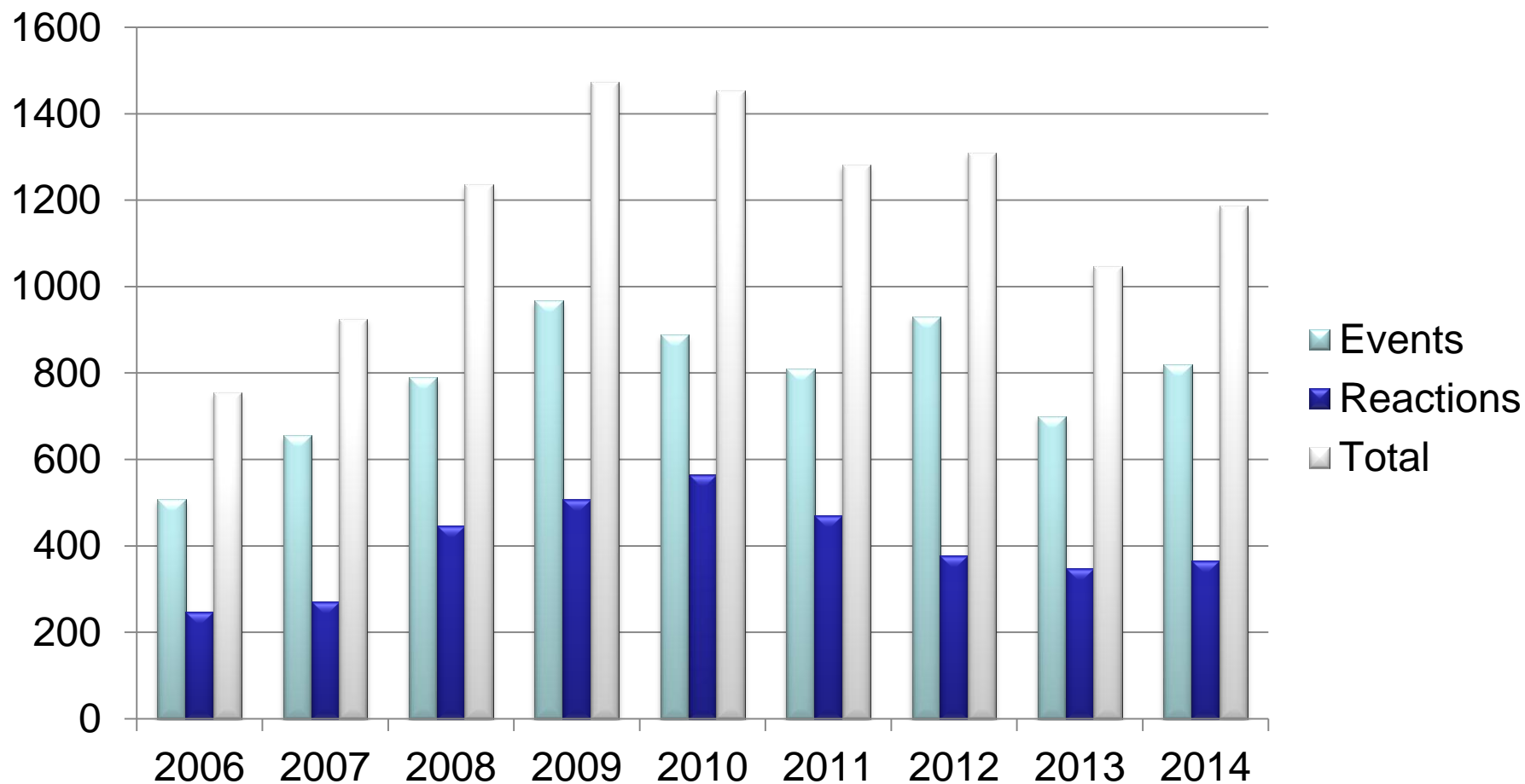
Reporting Activity



Report Type	Reports to Date (2014)	Estimated total (2014)	2013
Serious Adverse Events	567	820	700
Serious Adverse Reactions	253	366	347
Excluded	134	194	230
Total	954	1380	1277



SABRE reports included in Annual Summary by year



Non-reporters/ low volume reporters



- 19 reporters have never submitted a report (Slight drop)
 - Private hospitals and facilities
- 46 reporters have not submitted a report since August 2013
 - Previous BCC 36 since August 2013
 - Majority small trusts and private hospitals
- Low volume and high volume reporters are notified to IE&S yearly



SAR reports received Jan 2014 - Aug 2014 (Confirmed only)



Reaction type	Number of reports	Imp ≥ 2
Anaphylaxis/ Hypersensitivity	100	50
Immunological haemolysis due to ABO Incompatibility	5	5
Immunological haemolysis due to other allo-antibody	16	12
Non-immunological haemolysis	3	2
Other (Febrile, TAD, TACO)	86	40
Post-transfusion Purpura	3	1
TRALI	8	2
Transfusion-Transmitted bacterial infection	13	0
Transfusion-Transmitted Viral Infection (HBV)	3	1
Transfusion-Transmitted Viral Infection (CMV)	1	0



Deaths/ Imputability 2/3



- ABO Incompatibility Imputability 2
 - 85 year old male, group O+ received group AB- red cells.
 - 2 patients in adjacent beds with the same surname
- IH due to other allo-antibody Imputability 3
 - 65 year old female
 - No apparent quality and safety error



SAEs included in annual report Jan 2013- Aug 2013



	Product defect	Equipment failure	Human error	Other	Total
Whole blood Collection	0	0	11	0	11
Apheresis collection	1	0	0	0	1
Testing of donations	0	1	5	1	7
Processing	0	0	7	0	7
Storage	0	3	141	0	144
Distribution	0	1	14	0	15
Materials	1	0	0	0	1
Other	0	1	318	2	321
Total	2	6	496	3	507



Others reports received Jan 2013 – Aug 2013



Description	Code	Total (last year's league position)
Incorrect blood component issued	IBCI	90 (1)
Component labelling error	CLE	67 (2)
Sample processing error	SPE	47 (5)
Pre-transfusion testing error	PTTE	46 (3)
Data entry error	DEE	38 (4)
Component collection error	CCE	14 (6)
Failed recall	FR	9(8)
Component available for transfusion past de-reservation	CATPD	4 (7)
Expired component available for transfusion	ECAT	4 (9)
Incorrect blood component ordered	IBCO	2 (11)
Incorrect blood component acceptable	IBCA	0 (10)

