Safeguarding public health

REGULATORY HAEMOVIGILANCE:

The root causes of ‘human error’

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Serious adverse blood reactions and events (SABRE)

- SABRE data 2005 - 2012
- Serious adverse events - EU Directive ‘ Deviations and Specifications’
- Outcomes versus root causes
- Why do root cause analysis?
- Case study

Why undertake haemovigilance?

What is haemovigilance?

- a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients (of blood and blood components) and the epidemiological follow-up of donors

Why do we do it?

- to discharge our legal obligations
- to inform the European Commission
- to inform the Department of Health, National Transfusion Committee and SaBTO
- to advise on improvements to the safety of transfusion practice based on the data supplied by reporters

Why have an incident management system?

- to prompt any follow-up action necessary to protect other patients from suspected hazards e.g bacterial contamination

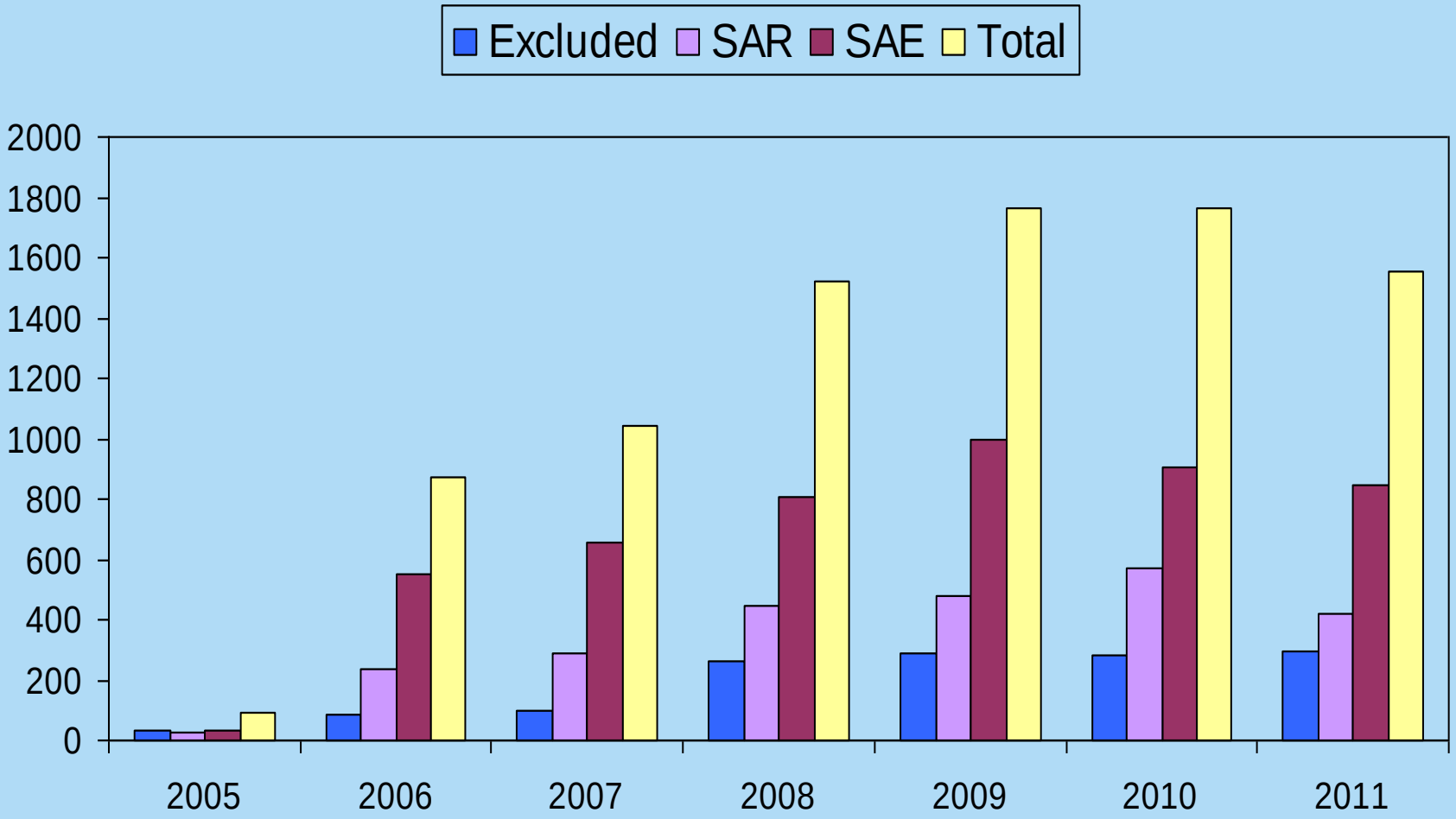
- to support the development of clinical guidelines for hospitals in relation to the use of blood and blood components

- to support the training of medical, nursing and technical staff

- to provide summary data over a period of time which may highlight emerging trends

- to use as evidence to drive process improvements

All UK SABRE reports by year



All UK Serious Adverse Events 2011

Deviation /specification	Total Number	Product Defect	Equipment Failure	Human Error	Other
Whole blood collection	**36**	0	0	36	0
Apheresis collection	**1**	0	0	1	0
Testing of donations	**8**	0	0	8	0
Processing	**37**	3	1	32	1
Storage	**228**	1	3	224	0
Distribution	**52**	0	0	51	1
Materials	**0**	0	0	0	0
Other	**449**	3	10	436	0
Overall Total:	**811**	**7**	**14**	**788**	**2**

SABRE data 2012:

Closed reports (unverified) to Oct 31st

Total	**=**	**1238**
Excluded	=	153
SAR	=	306
SAE	=	779

All UK Serious Adverse Events 2012

Deviation /specification	Total Number	Product Defect	Equipment Failure	Human Error	Other
Whole blood collection	**47**	23	0	23	1
Apheresis collection	**11**	8	0	3	0
Testing of donations	**8**	0	2	5	1
Processing	**20**	0	0	19	1
Storage	**182**	1	5	171	5
Distribution	**40**	0	0	38	2
Materials	**3**	0	1	2	0
Other	**468**	2	4	457	5
Overall Total:	**779**	**34**	**12**	**718**	**15**

Serious Adverse Events 2012:

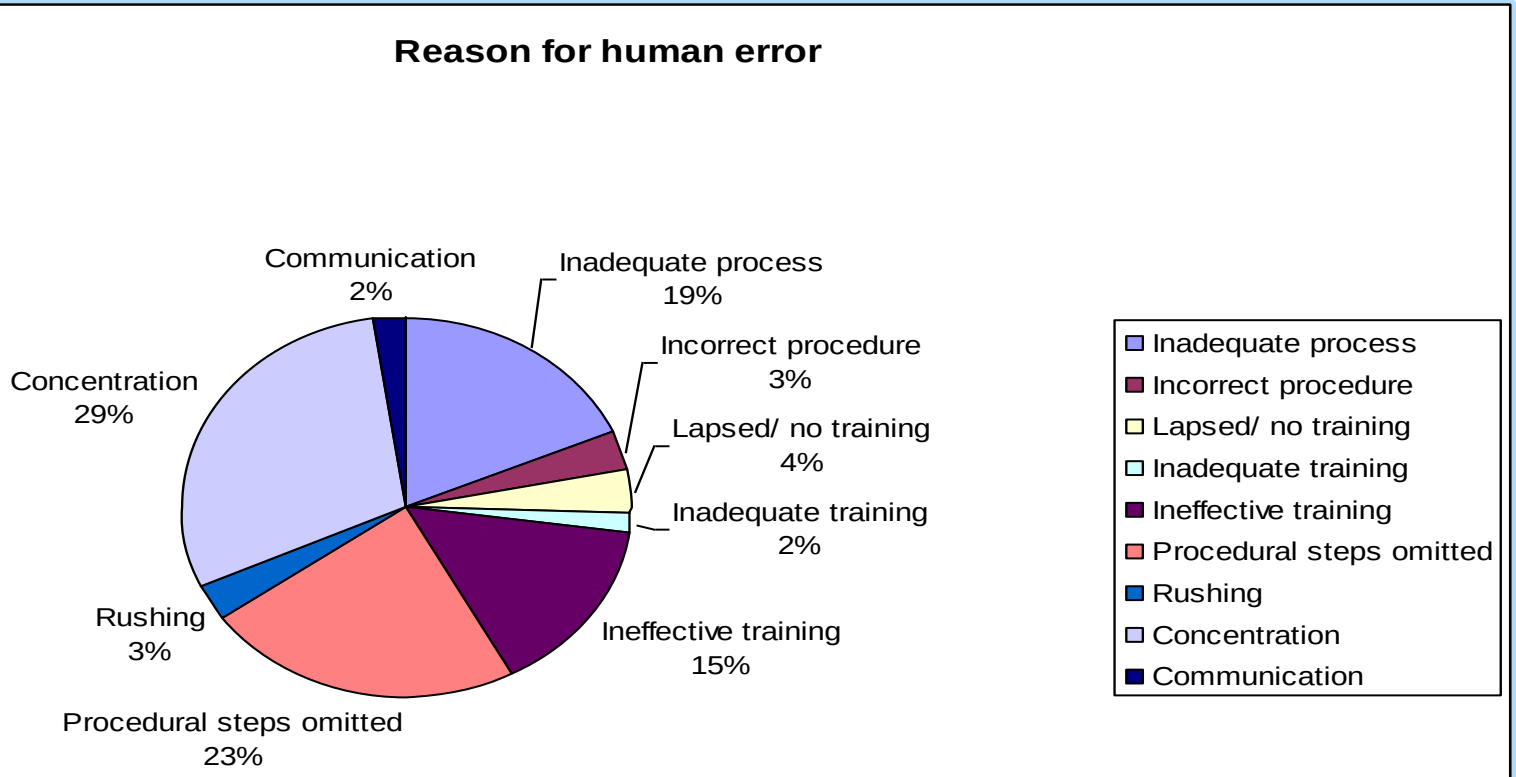
Other/Human Error Outcomes (unverified)

• Incorrect blood component issued (missing special requirements)	97
• Component labelling errors (at point of issued from lab)	63
• Sample processing errors	59
• Data entry errors (lab IT)	58
• Pre transfusion testing errors	55
• Components available for transfusion past de-reservation date	40
• Component collection errors	23
• Failed recalls	8
• Expired components available for transfusion	6

Root Causes of SAEs – human error (2011 n = 788)

Error Type	Definition
Incorrect process	Process does not achieve the desired outcome
Incorrect procedure	Written procedure does not reflect the process
Procedural steps omitted	Procedural steps missed out (Intentional or forgotten) -may be a result of rushing/concentration lapse
Lapsed/ no training	Training/competency assessment out of date, not completed
Inadequate training	Training/competency assessment does not cover error made
Ineffective training	Training is adequate, but has been misunderstood
Rushing	Working too quickly, failing to check for accuracy
Concentration	Error when not obviously omitting steps or rushing
Communication	Written/verbal communication not clear/inaccurate

Root causes of SAEs (2011) specification Human Error (n = 788)



Targeted corrective measures

Procedural based errors:

- Inadequate process
  - review existing system for process validation
- Incorrect procedure
  - reassess document control process
- Procedural steps omitted
  - re-emphasise the importance of strict adherence to written protocols (a basic principle of Good Manufacturing Practice)

Targeted corrective measures

Training based errors:

- Lapsed/ no training – review training and induction schedules and ensure these identify re-joiners

- Inadequate training – reassess training material to ensure it covers all essential activities

- Ineffective training – encourage staff to take responsibility for their own learning and to highlight any areas they have not fully understood

Targeted corrective measures

Concentration and Communication:

- Communication – encourage teamwork and the use of clear, unambiguous written and verbal communication protocols

- Rushing – encourage staff to work at an appropriate pace which allows them time to follow procedures precisely, prioritise workload effectively and self-check for accuracy

- Concentration – minimise distractions, advise staff to restart a process when they have been distracted and encourage individual reflective practice to understand what they would do differently in future

Case Study

Notification: SAE/ Storage/ Human error

- Blood was returned from the ward because the expiry date on the accompanying paperwork was incorrect
- Blood was out of the fridge for 33 minutes
- Lab staff amended the expiry date and returned the unit to stock
- This unit was then issued and transfused to another patient – unit was out of the fridge for a total of 49 mins (within the 4hr limit)

Case Study

Confirmation:

- Root cause = not following laboratory procedure

- Corrective measures = lab staff have been retrained in the correct procedures for booking in stock and on the importance of the cold chain. The 30 minute rule is now specifically discussed at GMP updates.

COMMENTS ?

Case Study

Suggestions :

- Report as SAE/ Other / human error (data entry error)
- Investigate WHY laboratory procedures were not followed
  i) why was the expiry date entered incorrectly?
  ii) why was the unit returned to stock?
- Root causes are likely to be
  i) rushing/ cutting corners by not scanning all units into stock individually
  ii) lack of concentration when checking details prior to issue
  iii) distraction when returning unit to stock rather than discarding as out of temperature control

Corrective Measures:

- Check patient receiving the out of temperature unit suffered no consequences
- Check lab staff are aware of the correct procedures – if not then provide training
- Encourage lab staff to consider what they would do differently in similar circumstances