Safeguarding public health

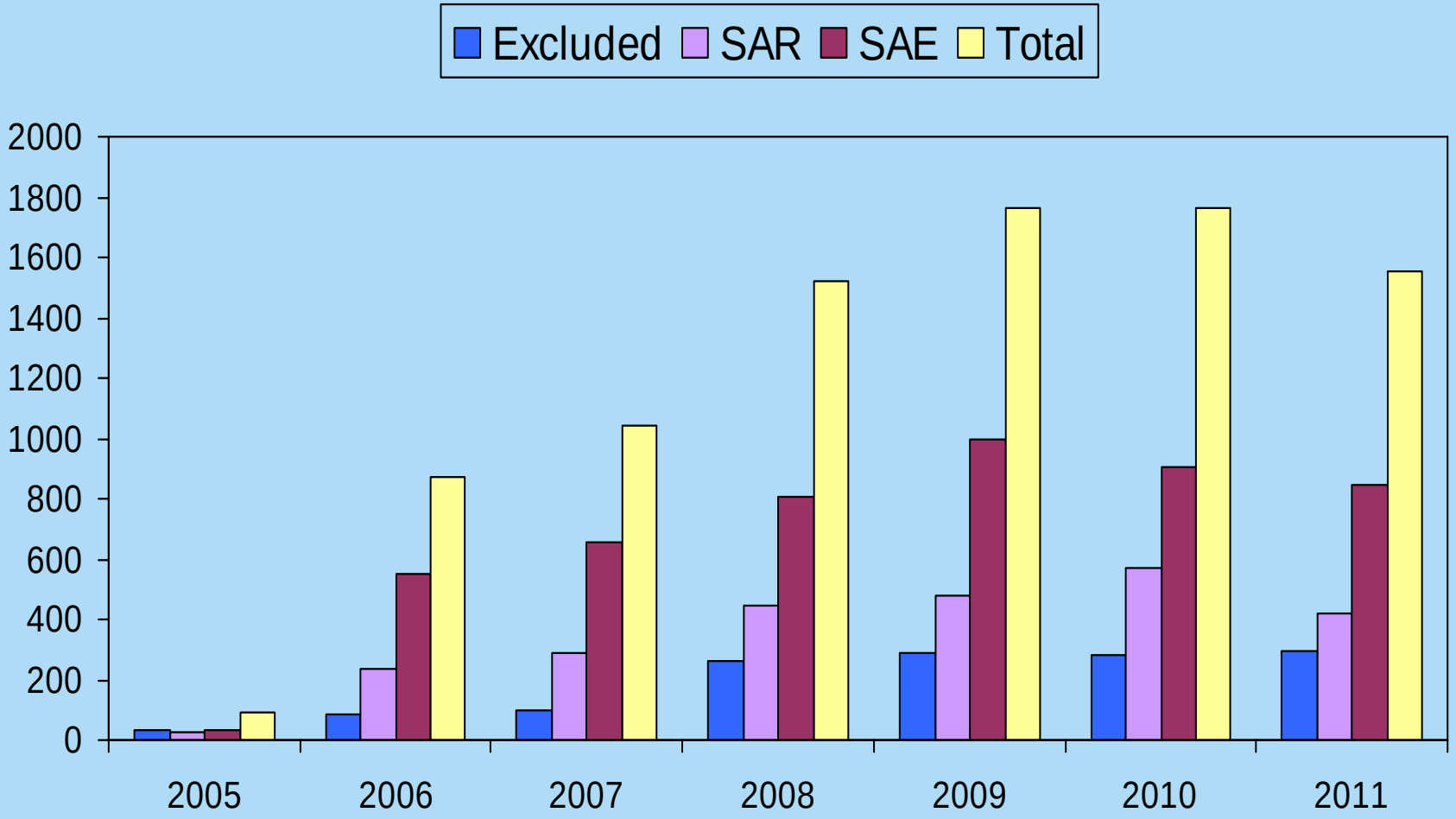
SABRE UPDATE

October 2012

Judy Langham
Principal Haemovigilance Specialist

- SABRE statistics 2012 (unverified)
- Reporting trends
- Educational activity
- Haemovigilance project MHRA/ SHOT

All UK SABRE reports by year



SABRE reports 2012 (unverified)

01.01.12 – 30.09.12

Incident Type	Notification	Confirmation	Exclusion	Total
Serious Adverse Event	130	582	98	810
Serious adverse Reaction	34	248	35	317
Grand Total	164	830	133	1127

NON- REPORTERS AND LOW VOLUME REPORTERS

No. of Organisations who have yet to report to SABRE = 26

NB. All of these sites issue < 1000 units of blood components per year

A further 42 Organisations have not submitted any reports to SABRE since September 2011

MHRA

Unverified UK SAR reports - 01.01.2012 – 30.09.2012 (n = 248)

REACTION TYPE	No. of reports (all imputability levels)	No of reports where imputability ≥ 2
Anaphylaxis / hypersensitivity	88	52
Other (FNHTR/ TACO/ TAD)	85	27
Immunological haemolysis due to other allo-antibody	31	24
TRALI	21	8
Transfusion transmitted bacterial infection	15	1
Immunological haemolysis due to ABO incompatibility	2	2
Transfusion transmitted viral infection (HBV)	4	3
Non-immunological haemolysis	1	1
Post- transfusion purpura	1	1

Unverified SAE reports 01.01.12 – 31.08.12 (n = 582)

SAE Deviation	Total Number	Product Defect	Equipment Failure	Human Error	Other
Whole blood collection	**39**	23	0	16	0
Apheresis collection	**10**	8	0	2	0
Testing of donations	**2**	0	1	1	0
Processing	**12**	0	0	12	0
Storage	**140**	0	2	136	2
Distribution	**28**	0	0	28	0
Materials	**2**	0	2	0	0
Other	**349**	2	2	340	5
Overall Total:	**582**	**33**	**7**	**535**	**7**

Safeguarding public health

Serious Adverse Events:

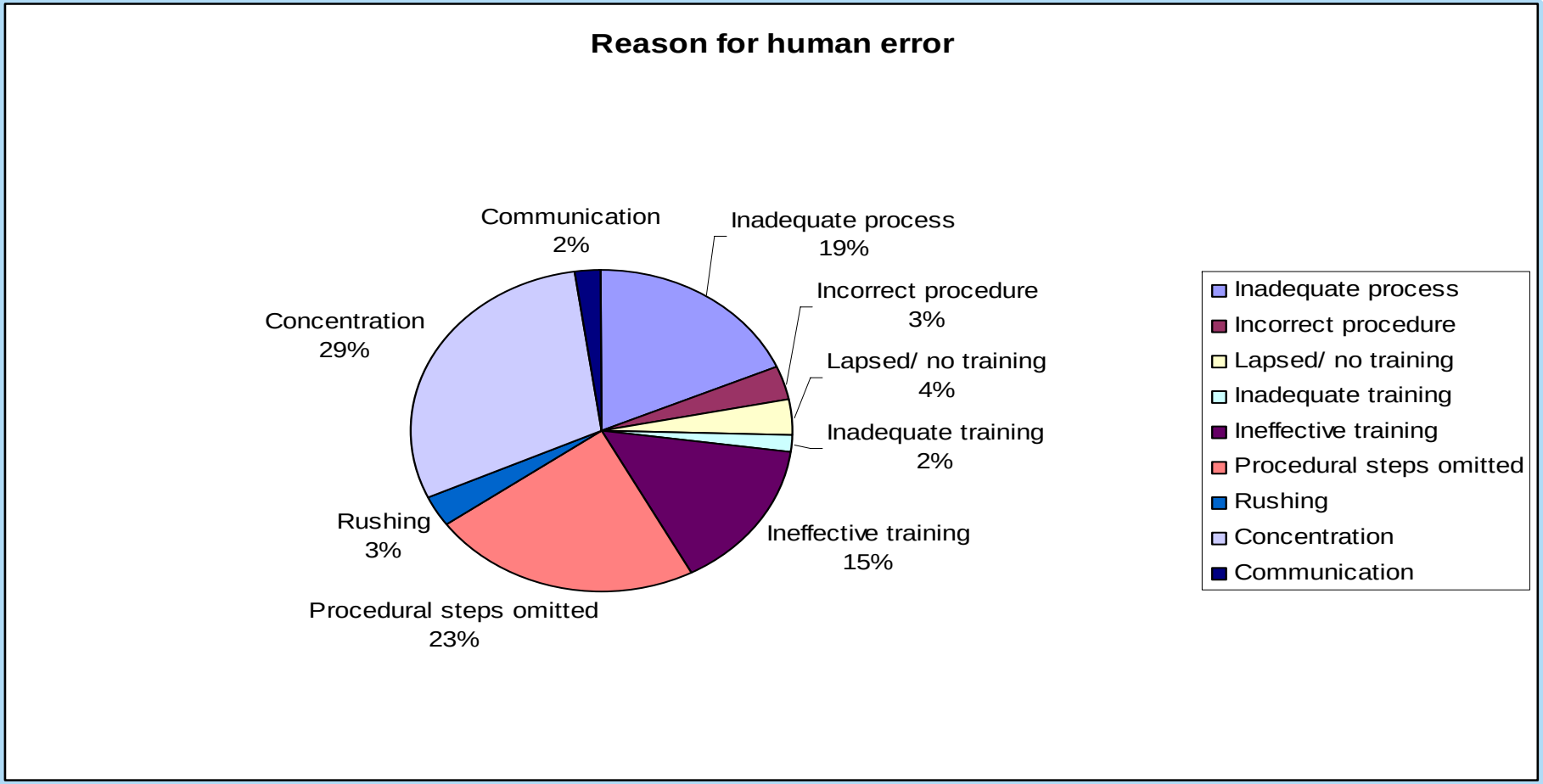
Other/Human Error Top Ten

• Incorrect blood component issued (missing special requirements)	80
• Component labelling errors (at point of issue from lab)	53
• Sample processing errors	46
• Data entry errors (lab IT)	36
• Pre transfusion testing errors	36
• Component available past dereservation date	33
• Component collection error	20
• Expired component available for collection	8
• Failed recall	5
• Incorrect blood component ordered/ accepted	5

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)



Additional haemovigilance activity 2012

SABRE presentations and workshops:

- RTC meetings x 3
- TP and BMS workshops x 8
- IT User group meeting x 1
- Junior doctors introduction to haemovigilance x 1
- UK haemovigilance presentation to Turkish delegation
- BBTS x 1

Publications:

- MHRA chapter published in 2012 SHOT report

Single haemovigilance reporting system:

- Progress continues with the development of a single reporting system, draft workflows under review by group extended to include members of the SHOT working expert group
- Interim improvement to increase shared data between SABRE and Dendrite undergoing UAT – expect implementation in November/December