

Incident Reporting

- getting the balance right

Tony Davies

Patient Blood Management Practitioner

SHOT / NHSBT PBM Team

Drivers for Reporting

- DH 'Never Events'
- Better Blood Transfusion
- The law ! (BSQR)
- GMC encourage reporting as part of good practice for medical staff
- Report / Feedback / Learn

Haemovigilance in the UK

MHRA

Medicines & Healthcare products
Regulatory Agency

SHOT

Serious Hazards of Transfusion

- Competent Authority' for the BSQR 2005
 - **QMS** in blood establishments and hospital blood banks.
- Competent Authority for the Medicines Act 1968
- Competent Authority for the Medical Devices Regulations 2008 (and others)
- **MANDATORY** reporting

- Confidential enquiry
- Serious adverse reactions/events AND near misses all of which occur in **BOTH** a laboratory and CLINICAL environment.
- Reporting is **PROFESSIONALLY MANDATED**

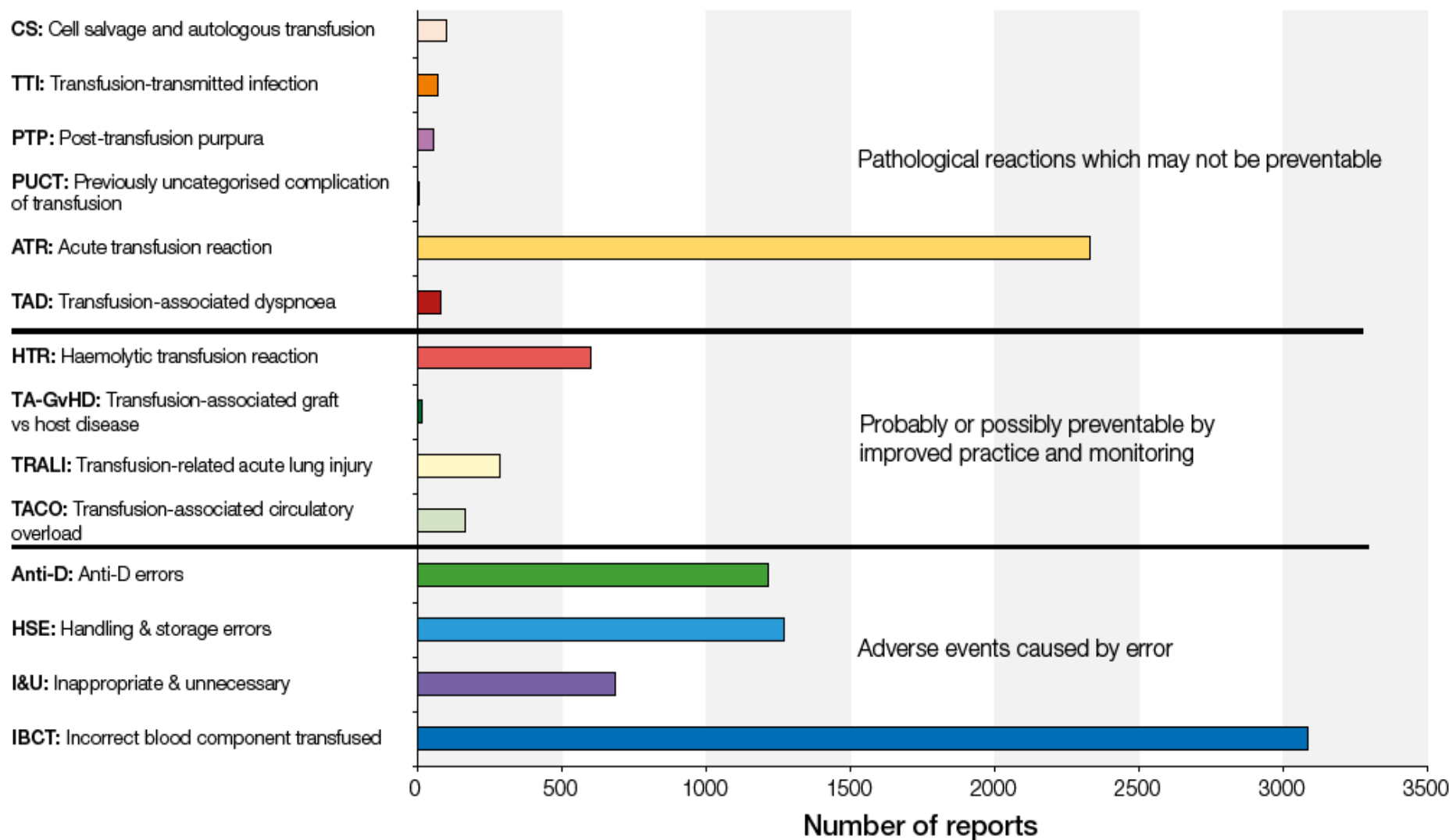
Overlap of critical points in the process between SHOT and MHRA

- Decision to transfuse
- Prescription/request
- Sampling for pre-transfusion testing
- **Laboratory testing**
- **Collection of blood from issue fridge**
- Bedside administration
- **Monitoring the patient**

SHOT Reports 2011

- 3435 reports made to the scheme
 - 2768 analysed
 - 204 in an inappropriate category, moved
 - 667 withdrawn (20%)
- + 270 reports made in 2010, but only completed in 2011
- 3038 cases including 'near miss' and 'right blood right patient'

SHOT Categories 1996 - 2011

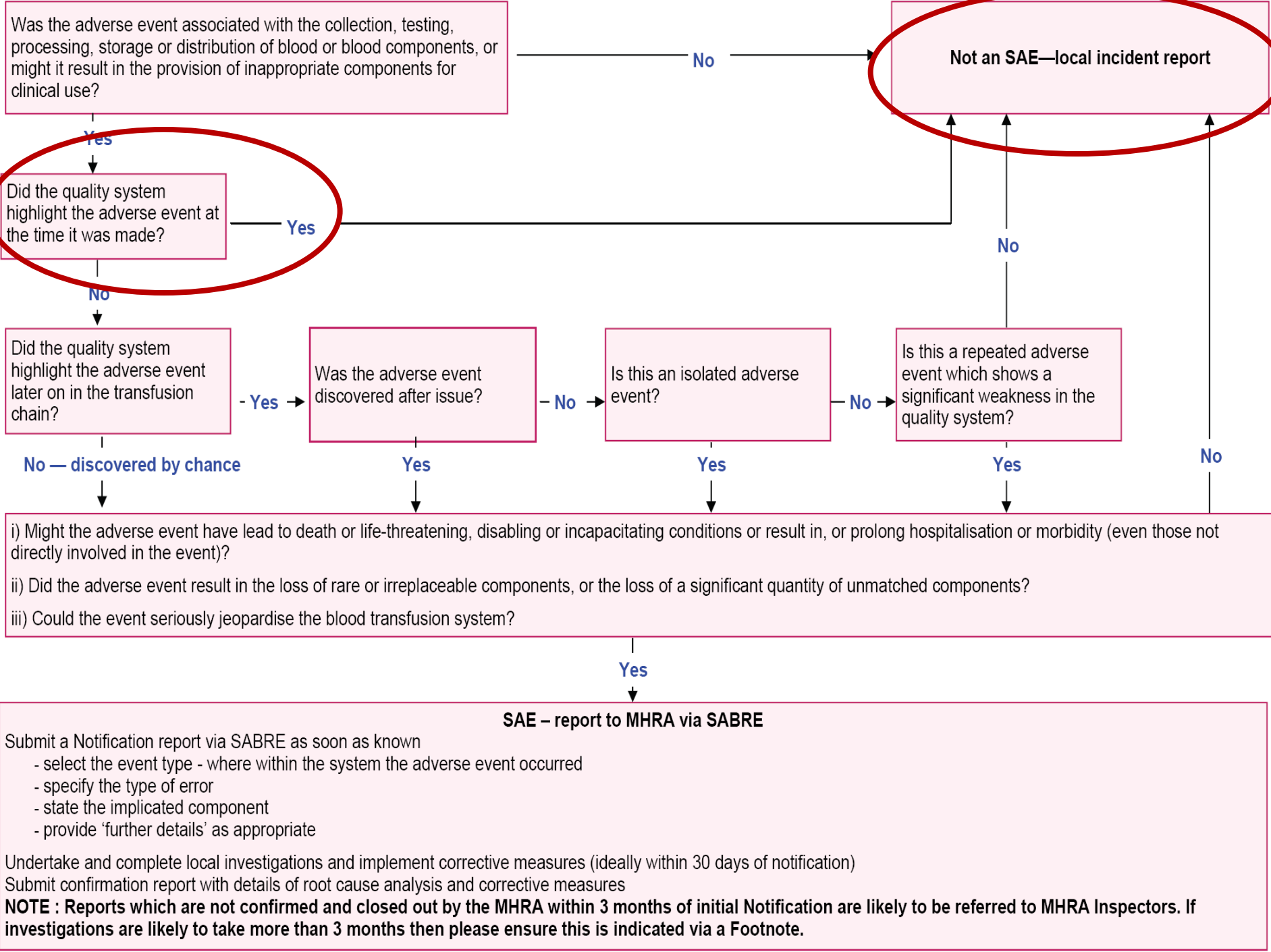


Withdrawn SHOT Reports

- Using reporting to SHOT as a 'stick' to beat people with
 - Unhappy with current lab IT system
 - Unhappy with portering / bleep system
 - Unhappy with compliance with paperwork
- Using SHOT to challenge reasoned decisions by experienced clinicians
- Reporting to SHOT where there is no patient involved
- Reporting BSQR quality incidents to SHOT

Withdrawn from MHRA

- Can be by reporter or MHRA
- Blood product incidents eg anti-D
- Remember to downgrade imputability on SABRE if investigation shows the blood component was not implicated (eg the patient got Hep-C from other sources)



Cold Chain & Traceability *(NOT the same thing!)*

- Issues around cold chain and traceability are dealt with by the MHRA unless 'inappropriate' units are actually transfused, then it should be reported to SHOT.
- If blood that is expired / OTCOL / past dereservation date is *available* in an issue / satellite fridge / cold box then that is MHRA reportable as an SAE, but not reportable to SHOT
- If blood is *collected for transfusion*, but the error is spotted at the bedside, then that is a SHOT near miss
- If blood is *transfused* then that becomes a full-blown HSE / IBCT / SRNM SHOT report

MHRA Quality Error or SHOT Near Miss ?Discuss !

- Screening cells on analyser out of date for half a day's workload and groups reported ?
- Issue fridge out of temperature control for 6 hours with 35 units in it, none collected ?
- Sample labelling error detected at booking in ?
- WBIT sample error detected in the laboratory
- Incorrect G&S result reported ?

MHRA Quality Error or SHOT Near Miss ?Discuss !

- Incorrect data entry into LIMS of patient ID – *one off event*
- Incorrect data entry into LIMS of patient ID – *several events*
- Recall failures – but component not transfused to patient

What to report as ?

- Transfusion based on wrongly-labelled Hb sample
- Using adult-specification O Negative red cells to resuscitate a flat baby (*no paedipacks in stock*)
- Consultant obstetrician decides not to give anti-D Ig to a woman with a continuing PVB at 14 weeks of gestation
- Obstetric registrar refuses to write up anti-D Ig in response to a sensitising event at 28 weeks of gestation “because the Kleihauer is negative”

Remember.....

- If a component is transfused, it cannot be a 'Near Miss' anything !
- If a component is connected to the patient, then the transfusion has 'started', even if no blood has actually been transfused, so it is reportable as a 'full' incident rather than a near miss
- Just because something 'turned out OK', it doesn't make it less reportable !

Remember.....

- ‘Right Blood Right Patient’ is for when the component was always intended for the patient, not for when a wrong blood component happens to be compatible in retrospect
- Failure to sign the crossmatch register does not constitute a SHOT report if the patient gets the right blood
- SHOT and MHRA have good guidance and flowcharts as to what to report – if in doubt
ASK !

Participation is the key to successful haemovigilance

- Don't be afraid to report – a certain level is expected

but...

- Don't over-report when you don't need to and can deal with issues 'in-house'
- Don't shift responsibility for dealing with an incident by reporting it externally !

SHOT Annual Symposium

- Weds 10th July 2013
- Royal Society of Medicine, London
- £75 registration fee
- Contact SHOT Office to register
- shot@nhsbt.nhs.uk

Thank you

- The SHOT Team
- Joan Jones, Head of Quality, WBS
- You, for listening.....and reporting !