Section 5
Haemovigilance

Aim

- To introduce the learner to the basic concepts of haemovigilance

Learning Outcomes

- Demonstrate an understanding of the principles of haemovigilance
- Identify the risks associated with administration of allogeneic (donor) blood

Introduction

Haemovigilance comprises organised surveillance procedures relating to serious adverse or unexpected events or reactions in blood donors and recipients.

5.1 Serious Hazards of Transfusion (SHOT)

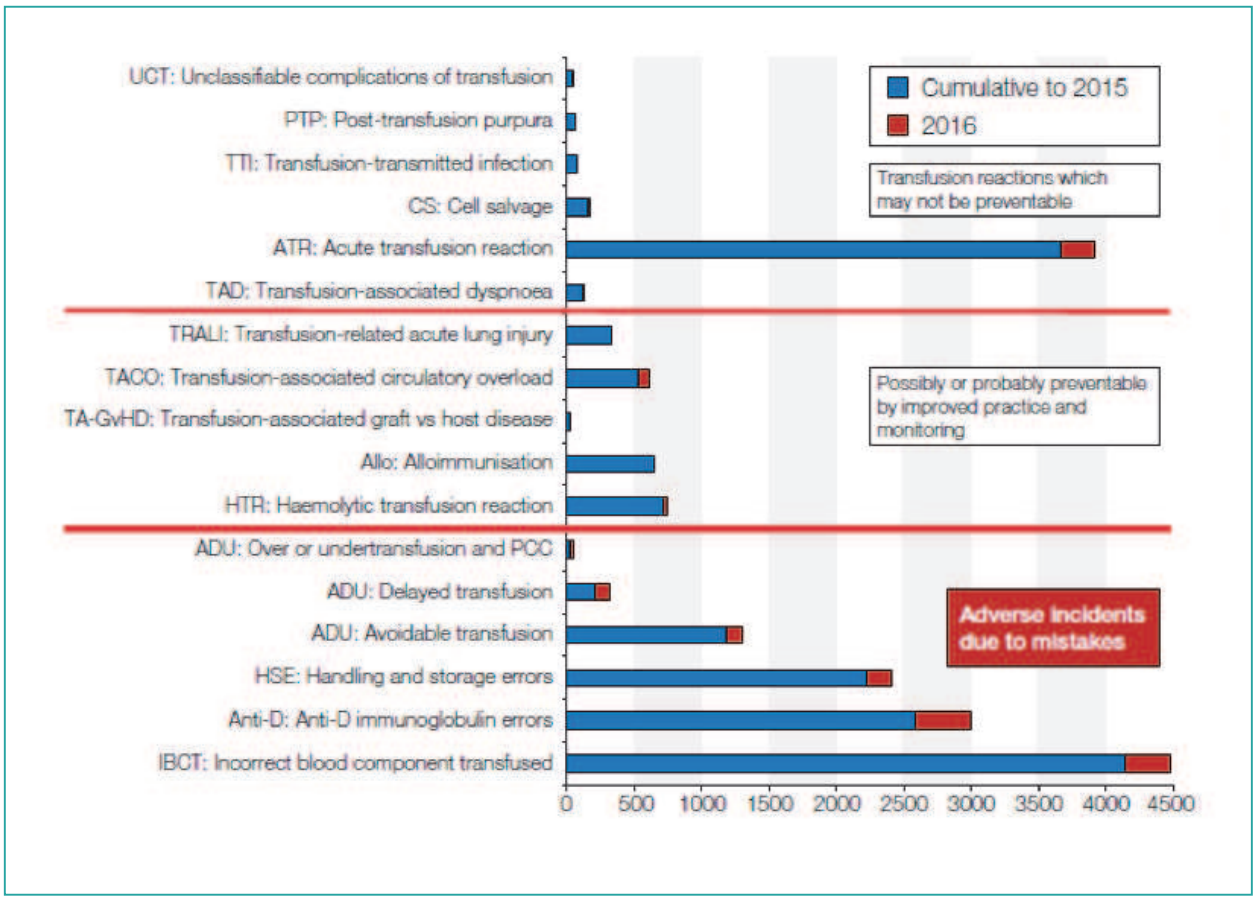
SHOT is the United Kingdom's independent, professionally-led haemovigilance scheme. Since 1996 SHOT has been collecting and analysing anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations that are involved in the transfusion of blood and blood components in the United Kingdom. Where risks and problems are identified, SHOT produces recommendations to improve patient safety. The recommendations are put into its annual report which is then circulated to all the relevant organisations including the four UK Blood Services, the Departments of Health in England, Wales, Scotland and Northern Ireland and all the relevant professional bodies as well as circulating it to all of the reporting hospitals. As haemovigilance is an ongoing exercise, SHOT can also monitor the effect of the implementation of its recommendations.

Over an twenty year period, from 1996 to 2016, 18,258 reported incidents have been analysed.

The cumulative incidents, reported to SHOT, within each category from 1996 to 2016 are shown in Figure 5.

Annual reports can be downloaded from: *http://www.shotuk.org/shot-reports/*

Figure 5. Cumulative SHOT Data from 1996 – 2016; n=18,258



Reporting adverse events and reactions relating to Cell Salvage to SHOT

In addition to reporting to the hospital transfusion team, any adverse events or reactions associated with intraoperative (ICS) and postoperative (PCS) cell salvage (washed or unwashed) should be reported to SHOT.

A list of trigger events to report and the categories they fall into is given below:

Category	What to report
Operator error	Patient Identification error - Incorrect blood component transfused (IBCT)
	Equipment not assembled correctly to include both collection and processing equipment
	Incorrect dilution of heparinised saline
	Inadequate anticoagulation - clotting reservoir
	Non IV saline used for wash
	Contraindicated substances aspirated into the collection reservoir
	Reinfusion bag not labelled for the patient - either ICS or post-operative cell salvage (PCS)
	Time exceeded for collection and/or reinfusion for wither ICS or PCS
	PCS system not assembled correctly
	Incorrect swab washing
	Contraindicated procedure e.g. infected hip
Machine/System failure	Any stoppage of the machine where the operator has not made the decision to halt the procedure
	Reinfusion bag falls off (PCS)
Clinical events	Air embolism
	Fat embolism
	Signs of acute haemolytic transfusion reaction - pyrexia, rigors etc.
	Hypotensive episode on reinfusion of processed red cells - not related to hypovolaemia
	Bacterial contamination
	Anaphylaxis or other allergic reaction
	Other - please state

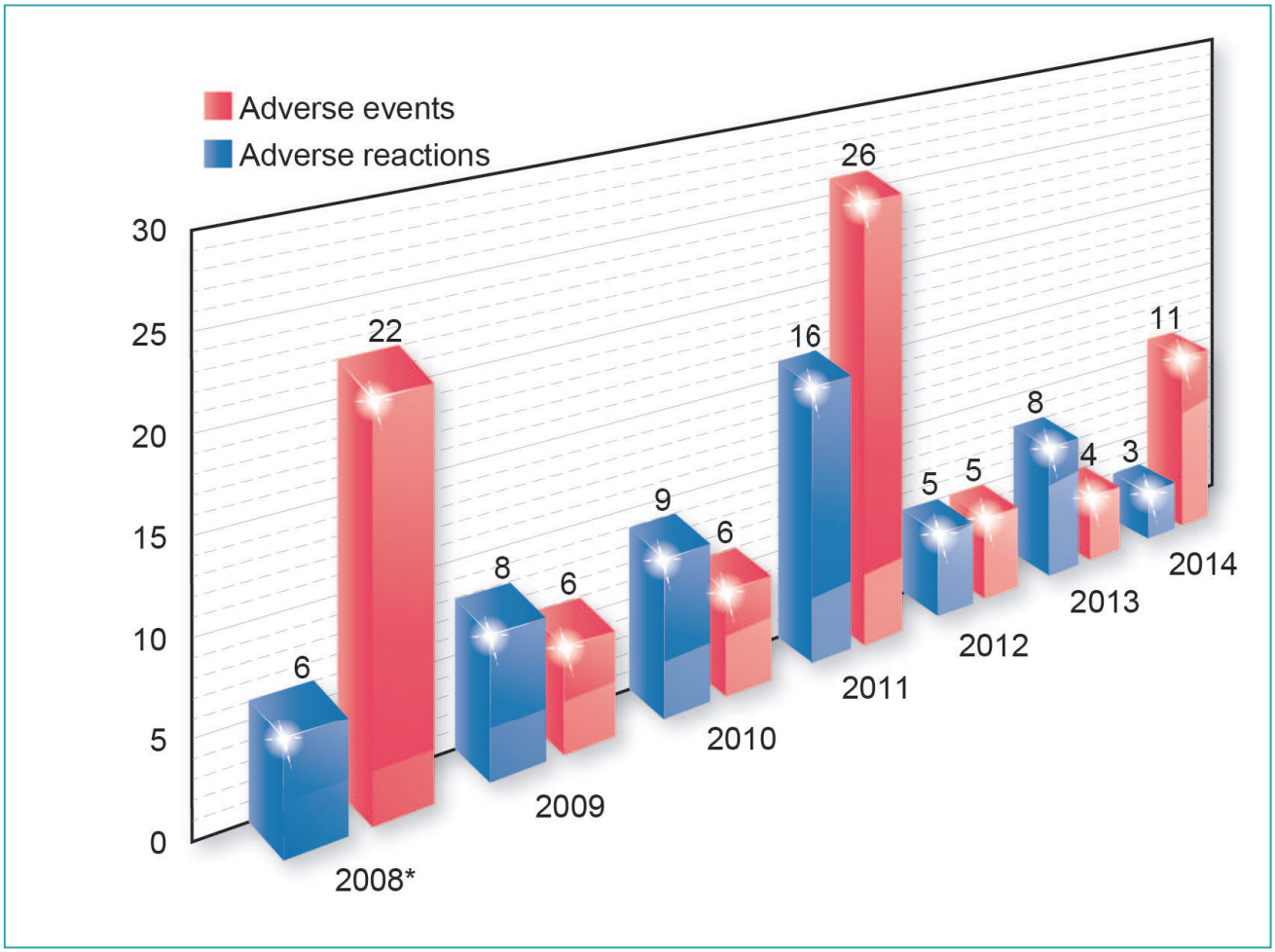
A data collection form to collate the data required to make a report on an adverse event or reaction associated with cell salvage can be downloaded from the SHOT website:

http://www.shotuk.org/wp-content/uploads/2010/03/Cell-salvage-dataset-Jan2010.pdf

Reporting of cell salvage incidents has been ongoing since a pilot scheme was launched in 2008. Reports are generally categorized as adverse events (operator error, machine or equipment failure) or adverse reactions (clinical events). The total number of reports received for cell salvage (both ICS and PCS) between 2008 and 2014 are shown in figure 6.

The most common adverse reaction reported was hypotension following reinfusion of intraoperatively salvaged blood with 27 reports between 2008-2014.

Figure 6. SHOT reporting of cell salvage incidents, 2008-2014 (*2008 pilot data gathered over a 6 month period)



5.2 Serious Adverse Blood Reactions and Events (SABRE)

The European Union (EU) Blood Safety Directive[2] introduced a legal requirement for the reporting of *serious adverse reactions* and *serious adverse events* occurring within EU Member States to the relevant *Competent Authority.* The Department of Health has designated the Medicine and Healthcare products Regulatory Agency (MHRA) as the UK Competent Authority. To facilitate reporting, in 2005 the MHRA developed an online reporting system: *SABRE* (Serious Adverse Blood Reactions and Events).

Serious Adverse Events

Definition *"any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity."*

Serious Adverse Reactions

Definition *"an unintended response in a donor or in a patient that is associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity."*

Key points

- All staff involved in the transfusion process are responsible for haemovigilance and the reporting of adverse events and reactions.

References

1. SHOT Annual reports/Annual summaries available at *www.shotuk.org/home.htm*
2. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 (2003) Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components and Amending Directive 2001/83/EC. *Official Journal of the European Union,* V46: L33/30-40 *http://eur-lex.europa.eu/JOIndex.do*

Self Directed Learning

Can you identify any events which may occur in your area of practice which would be reportable to SHOT/SABRE?

What is the most frequently reported risk from having a blood transfusion?

a) Transfusion transmitted infection?

b) Administration of blood intended for another patient?