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.

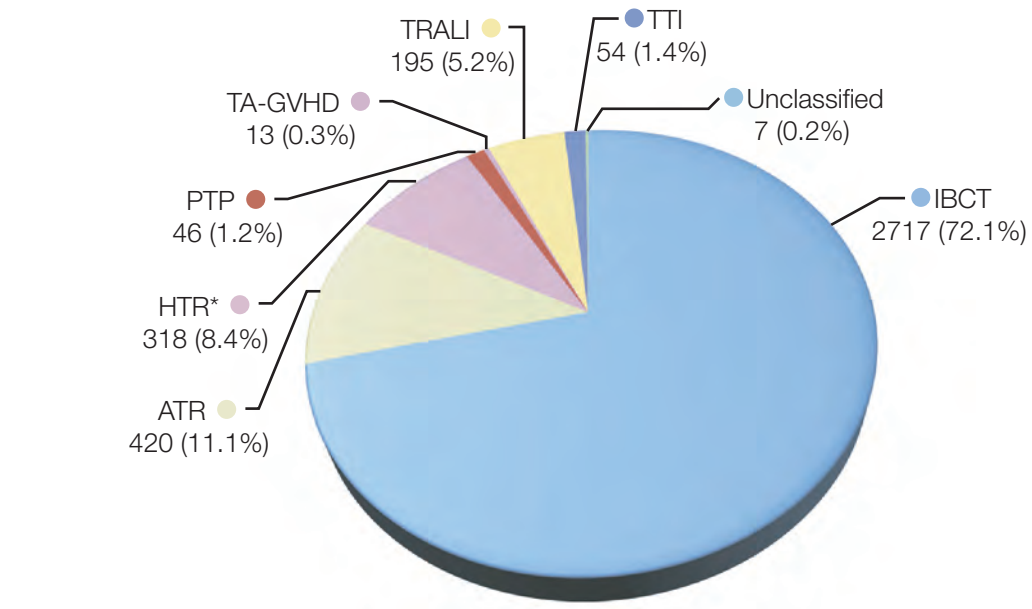
5.1 Serious Hazards of Transfusion (SHOT)

The Serious Hazards of Transfusion scheme (SHOT) provides an analysis of serious transfusion complications in the UK. It was launched in 1996 following growing concern amongst the UK transfusion specialists, haematologists and other clinicians that there was little information available on the safety of the transfusion process (SHOT Report 1996-1997)[1]. SHOT is a confidential, voluntary, anonymised, UK-wide scheme that aims to collect data on adverse events of transfusion of blood and blood components (red cells, platelets, fresh frozen plasma and cryoprecipitate).

Over a ten year period, from 1996 to the end of 2006, 2,626 incidents and more than 3,500 'near miss' events have been analysed.

The cumulative incidents, reported to SHOT, within each category from 1996 to 2006 are shown in Figure 5.

Figure 5. Cumulative SHOT Data from 1996 – 2006



IBCT	–	Incorrect Blood Component Transfused
ATR	–	Acute Transfusion Reaction
HTR	–	Haemolytic Transfusion Reaction
PTP	–	Post Transfusion Purpura
TA-GvHD	–	Transfusion Associated Graft versus Host Disease
TRALI	–	Transfusion Related Acute Lung Injury
TTI	–	Transfusion Transmitted Infection

SHOT findings are used to:

- Inform policy within transfusion services
- Improve standards of hospital transfusion practice
- Aid the production of clinical guidelines for the use of blood
- Educate users on the hazards of transfusion and their prevention

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*