UK CELL SALVAGE ACTION GROUP

SERIOUS HAZARDS OF TRANSFUSION SHOT

Reporting adverse events and reactions relating to Cell Salvage to SHOT

Guide for staff involved in the use of perioperative and postoperative cell salvage equipment

Introduction

In the first instance, any adverse events or reactions relating to cell salvage must be reported via your organisation's incident reporting system with notification to the Hospital Transfusion Team. A Serious Hazards of Transfusion (SHOT) report should then be made by the appropriate person (e.g. Transfusion Practitioner). If Medical Device failure is implicated, a further report to the Medicine and Healthcare Products Regulatory Agency (MHRA) should also be made through the Yellow Card Scheme (or Equivalent in Scotland and Northern Ireland).

What to report to SHOT

Any adverse events or reactions associated with intraoperative (ICS) and postoperative (PCS) cell salvage (washed or unwashed). Please note that adverse events and reactions associated with acute normovolaemic haemodilution and PAD (preoperative autologous donation) can also be reported to SHOT but not via the cell salvage pathway. They must be reported to the hospital transfusion team in the same way as adverse events are reported for donor blood. In the table below is the list of trigger events to report and the categories that they fall into.

Category	What to report
Operator error	Equipment not assembled correctly to include both collection and processing equipment
	Incorrect preparation of heparinised saline anticoagulant
	Inadequate delivery of anticoagulant leading to clotting of reservoir, lines or other parts of disposable
	Contraindicated substances aspirated into the collection reservoir or washed from soiled swabs
	Non IV grade saline used for wash e.g. use of saline for irrigation
	Time exceeded for collection for either ICS or PCS according to local guidelines
	Reinfusion bag not labelled for the patient or incorrectly labelled - either ICS or PCS
Machine/System failure	Any malfunction of the device that prevents the reinfusion of autologous red cells by effecting the quality, safety or timeliness of the product
	Any manufacturing fault that effects the functionality of the disposable e.g. faulty seals or connections, missing parts etc.
Clinical events	Patient Identification error - Incorrect blood component transfused (IBCT)
	Time exceeded for reinfusion (ICS or PCS) according to local guidelines
	Incorrect reinfusion of product resulting in potential harm, e.g. Fat embolism, air embolism
	Signs of acute transfusion reaction, e.g. pyrexia, rigors, anaphylaxis or other allergic reaction
	Hypotensive episode on reinfusion of processed red cells - not related to hypovolaemia
	Failure of provision of cell salvage which results in transfusion of allogeneic blood that could have been avoided (e.g. availability of staff, technical issues etc)
	Other - please state