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UK CELL SALVAGE ACTION GROUP
NEWSLETTER

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SHOT Special Edition

This is the eighth in a series of newsletters to update cell salvage users with the activities of the UK Cell Salvage Action Group.

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We would welcome any feedback on the content of this newsletter.

Serious Hazards Of Transfusion (SHOT) Reports

In 2007, SHOT published its first Annual Report with a chapter dedicated solely to Autologous Transfusion. Prior to this there had been occasional, unsolicited reports to SHOT, however, the aim from this point forward was to ensure active reporting of autologous incidents.

What to report

Adverse events and reactions associated with intraoperative (ICS) and postoperative (PCS) cell salvage (washed or unwashed). Adverse events and reactions associated with acute normovolaemic haemodilution and pre-operative autologous donation can also be reported to SHOT but not via the cell salvage pathway.

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 in reservoir
	Non IV Saline used for the 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 either ICS or PCS
	PCS system not assembled correctly
	Incorrect swab washing
	Contraindicated procedure eg 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)
Category	What to report
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

Cell Salvage incidents should be reported to the hospital transfusion team in the same way as adverse events are reported for donor blood. The table above lists trigger events for reporting and the categories that they fall into. In addition, incidents that result in cell salvage not being available or in a significant delay in the patient receiving their blood back, should also be reported to the hospital transfusion team. All staff involved in the cell salvage process should be made aware of the cell salvage reporting data set so that they can retain the necessary information for reporting should an incident occur. This information can be found on the SHOT website: www.shotuk.org/home/ via the link for reporting to SHOT and the MHRA.

Incidents to Date

The level of reporting has remained low, with a peak in 2011 of 42 reports. In 2012 only 24 incidents were submitted to SHOT. Without denominator data regarding the level of use of cell salvage in the UK it is difficult to determine whether or not under-reporting may be occurring. SHOT recommend that all adverse events involving ICS or PCS are reported.

Reports of hypotension have been included year on year in the SHOT reports since the Autologous Transfusion chapter was first published in 2007. The majority of these incidents involved reinfusion of washed intraoperative cell salvage blood via a Leucodepletion filter (LDF), where ACD-A was the anticoagulant used*.

Other incidents include transfusion of PCS blood above the manufacturerôs maximum recommended volume and a possible air embolus resulting from the pressurisation of the reinfusion bag during reinfusion. In addition, an incident in the 2010 report related to two patients receiving reinfusions of PCS blood at the same time. Both patients had reactions soon after the reinfusions commenced. On investigation, a lack of patient identifiers on PCS units meant that it could not be ruled out that the units were transposed resulting in the patients receiving the wrong blood back.

*Exceptions to this are one case reported in 2007 where the type of filter is not recorded, one case in 2010 using an unwashed ICS system, one case in 2011 where the anticoagulant was heparin and one case in 2012 where there was no LDF, however the patient was on ACE inhibitors.

SHOT Recommendations and Learning Points

The yearly SHOT reports include recommendations and learning points aimed at reducing future occurrences of similar incidents. Recommendations for autologous transfusion include:

Training

- Adequate knowledge and training is required for all involved in the use of both ICS and PCS systems.
- Training and competency assessment for cell salvage operators should be in place in all organisations where cell salvage is undertaken.
- All cell salvage operators must undertake initial and regular update training and be assessed as competent. There should be documented evidence of competence in the form of a training record. Competency assessment workbooks are available for both ICS and PCS at www.transfusionguidelines.org.uk

Incident Reporting

- All ICS and PCS related adverse events and reactions should be reported to SHOT. Hospital transfusion teams should develop a process to ensure all these events are reported to SHOT.
- Cell salvage machines are classified as Medical Devices, so all adverse events attributable to machine errors and failures should be reported to the MHRA (medical devices section) as well as SHOT.

Clinical Practice

- Monitoring of patients is as important for the reinfusion of red cells collected by ICS or PCS as it is for allogeneic red cells.
- Regardless of the component being transfused staff need to be vigilant to avoid air in the giving set.
- All cell salvage units should be labelled with the patient core identifiers to reduce the risk of error on reinfusion. The autologous transfusion label has been designed by the UK Cell Salvage Action Group and supplied by the manufacturers to allow these criteria to be met.

Investigating and Reporting

Hospital transfusion teams (HTT) should develop a process to ensure all incidents related to cell salvage are thoroughly investigated and reported to SHOT. All staff involved in cell salvage should be made aware of the procedure for reporting incidents. Actions to be undertaken will depend on the type of incident, but may include:

- Documentation of incident by relevant personnel e.g. surgeon, anaesthetist, scrub nurse, cell salvage operator, recovery/ward nurse
- Quarantining the cell salvage blood and removing the equipment/batch of disposables from use
- Informing the relevant staff/departments e.g. theatre and clinical cell salvage leads, HTT, clinical engineering
- Analysis of cell salvage blood by a Consultant Haematologist and analysis of cell salvage disposables by a Surgical Materials Testing Laboratory
- Reporting the incident to the relevant bodies such as the SHOT and MHRA
- Implementing Corrective and Preventative Action (CAPA) such as staff retraining

Message from SHOT - Dr. Paula Bolton-Maggs, Medical Director

The core objective of reporting to SHOT is to improve patient safety by learning from any incidents where there was an adverse clinical outcome, or an error, and also from ónear missôevents. Sharing such data from across the UK has resulted in changes in transfusion practice, and recognition of associations that would otherwise not emerge. Reporting is anonymous and is mandated now by professional organisations. Learning from your mishaps may prevent them occurring in other centres, so SHOT encourages you to share these, in particular the local root cause analysis, for the benefit of all. See the annual reports at www.shotuk.org

The UK Cell Salvage Action Group are continuously developing resources to help support cell salvage in the UK. If you feel there is an area of cell salvage in need of support, please contact the UK Cell Salvage Action Group with your suggestions.

The work from the UK Cell Salvage Action Group and contact details for group members are available on the Better Blood Transfusion Toolkit website - www.transfusionguidelines.org.uk