

Developing an adverse event reporting system for cell salvage incidents

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This work has been undertaken as a joint initiative between the UK Cell Salvage Action Group and the UK Haemovigilance Serious Hazards of Transfusion (SHOT)

SERIOUS HAZARDS OF TRANSFUSION

SHOT

Background (1)

UK Cell Salvage Action Group

- Group convened in 2006
- Deliver a UK approach to cell salvage
- Providing “tools” to assist hospitals to develop a quality service
- Educational and practical materials developed

www.transfusionguidelines.org.uk

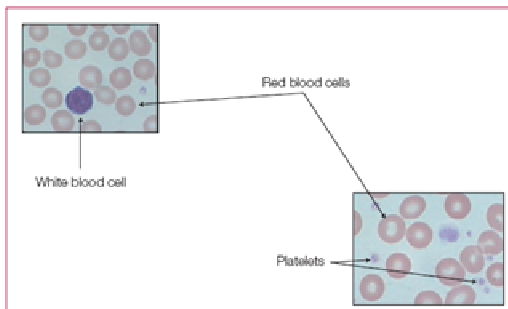
Background (2)

- Subgroups developed
 - Practical documentation
 - Education
 - Audit
 - Quality
 - Incident reporting

Education workbook

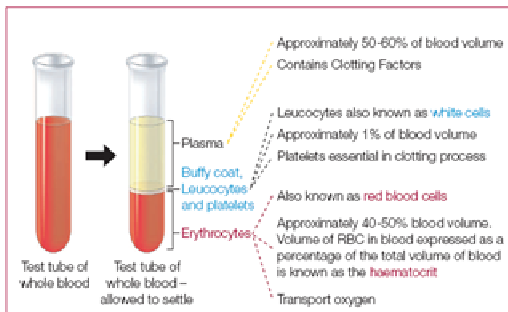
Section 3 Basic Blood Facts

Figure 1. Red Blood Cells, White Blood Cells and Platelets



Because the components of blood have different densities, if they are allowed to settle in a test tube or spun in a centrifuge, they will separate according to their densities (Figure 2).

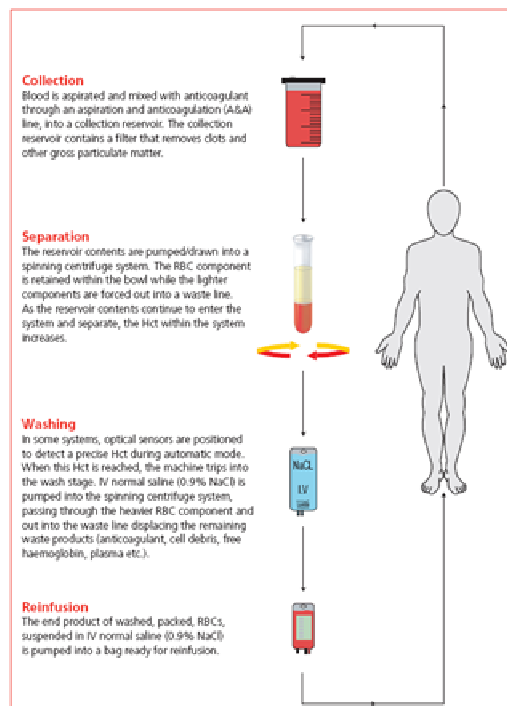
Figure 2. Blood Separated into its Constituent Parts



15

Section 6 Principles of Intraoperative Cell Salvage

Figure 10. Stages of the Process



41

Haemovigilance in the UK

- SHOT – well established, professionally led
- Allogeneic components – well developed
- Autologous components
 - Inconsistent reporting
 - Increasing use

Cell salvage Incident reporting

AIM

To develop and pilot a comprehensive adverse event reporting system for intra and postoperative cell salvage as a joint initiative between the UK Cell Salvage Action Group and SHOT.

Pilot (1)

Define what to collect

- Abandoned procedures due to operator error (incorrect assembly, non intravenous solutions, incorrect anticoagulant, collection time exceeded)
- Abandoned procedures due to machine failure (clotted lines/reservoirs,)
- Adverse clinical events (thromboembolism, coagulopathy etc)

Pilot (2)

Tools developed to support the pilot scheme

- Incident reporting form
- Guidance for completing the form
- Database
- Completion of pilot (delineator data)
 - The total number of Intraoperative cell salvage procedures undertaken
 - The total number of Postoperative cell salvage procedures undertaken

Incident form

- No patient identifiers
- Age and gender
- Specialty / Procedure
- Machine / system
- Operator
- Incident
- Outcome

Pilot (3)

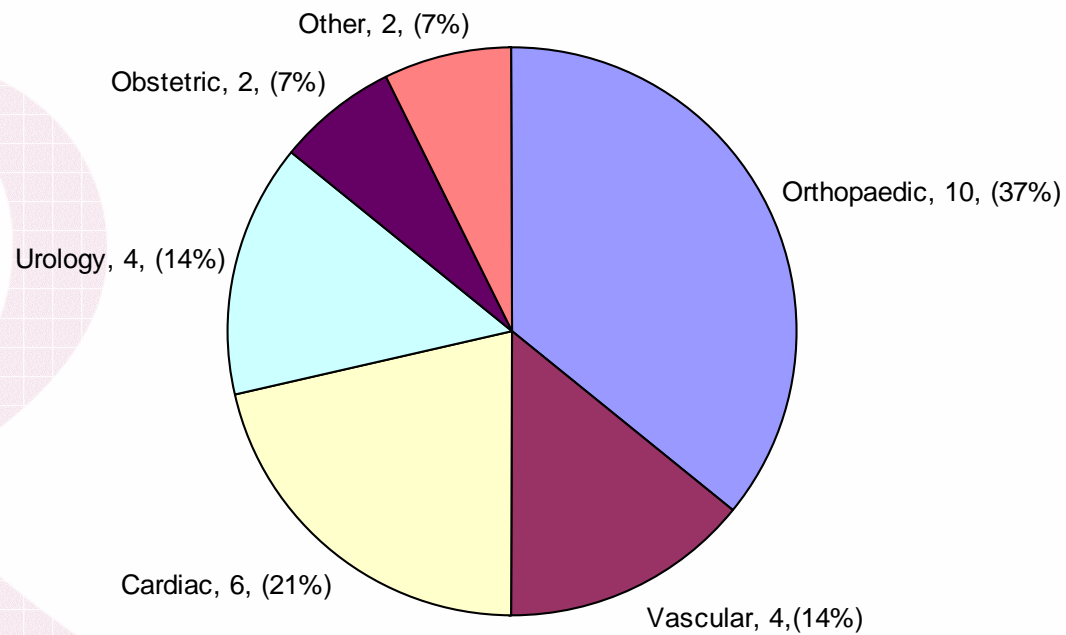
- Hospitals were invited to participate
- Cell salvage manufacturers were briefed

Results

- 62 hospitals participated
- 28 reports from 15 participants
 - 24 Intraoperative (washed)
 - 3 Postoperative (unwashed)
 - 0 combined (washed)
- 24 elective and 4 emergency procedures

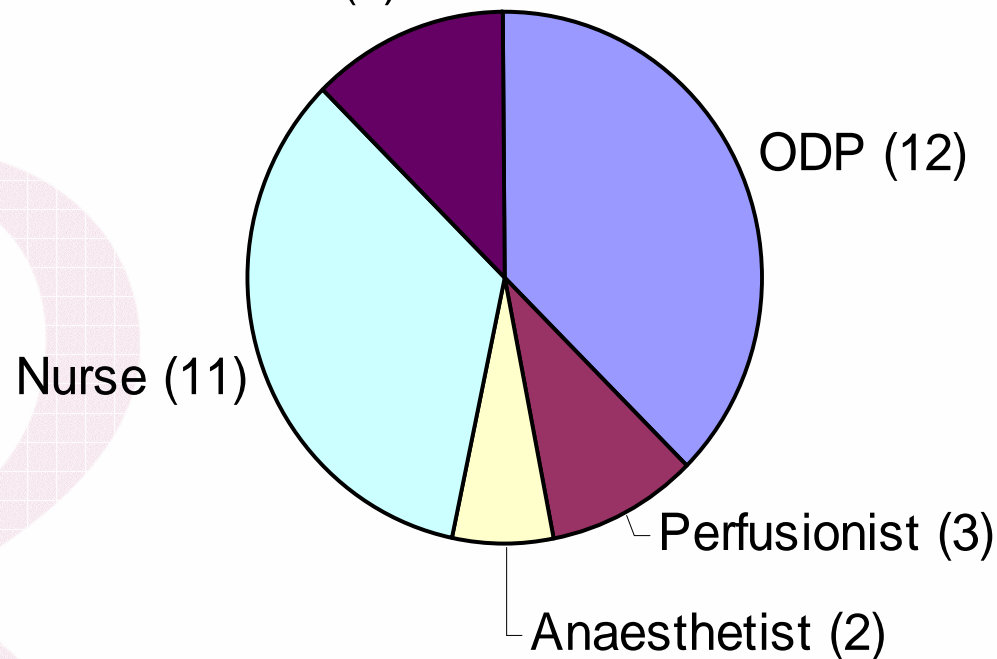
Results (1)

Adverse Events by Specialty



Results (2)

Adverse events by Operator
Commercial (4)



(*In 4 procedures dual operators were nurse + manufacturer/commercial and in 1, ODP + Perfusionist)

Results (3)

By location

- Theatre / ITU 25
- Wards 3

Results (4)

ICS Machines (n=25)

- Fresenius C.A.T.S (1)
- Haemonetics Cell Saver® 5 (14)
- Haemonetics OrthoPAT® (3)
- Sorin Electa (7)

Postoperative systems(n=3)

- Bellovac™ ABT,
- Astratech (2)
- Donor™ Van Straten Medical (1)

Results (5)

- Operator errors
- Clotting – lines/reservoir
- Machine failures
- “Hypotensive” episodes

Results (6)

Operator errors (PCS)

- Bag fell off (? system fault)
- Bag not labelled
- **Could these be a training issue?**

Results (7)

Operator errors (ICS)

- Equipment not assembled correctly
- Non IV Saline used
- Surgeon dropped sucker
- **Could these be a training issue?**

Results (8)

- Clotting of lines/filters
- Is clotting due to a lack of anticoagulant?
- ?Operator error
- ? Training issue

Results (9)

- Hypotensive events
- Ongoing investigations
- Some features identified
 - ACD as the anticoagulant
 - Leucodepletion filter
- **What is happening – we do not know**

Conclusion

- Pilot was a success
- Amend the form
- Difficulty in provision of denominator data
- NO major morbidity / deaths

Lessons learnt

- Form requires amendment
- May require reclassification of events
 - ie clotting in lines – currently machine failure
- Follow up forms have been developed specifically for the hypotensive episodes

Future

- Substantive participation in SHOT
- Online reporting
- Develop a “What to report” trigger list
- UK data base to collect information on intraoperative cell salvage this will link to adverse event reporting

PLEASE REPORT

Acknowledgements

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- **All those who participated in the pilot**