# 22 Cell Salvage (CS) n=23

*Author: Sarah Haynes*

## Definition:

**Any adverse events or reactions associated with cell salvage (autologous) transfusion methods, including intraoperative and postoperative cell salvage (washed or unwashed).**

## Key SHOT messages

- All cell salvage related incidents should be reported to SHOT
- All staff members involved in the cell salvage process should have a level of knowledge and understanding consistent with their role

## Abbreviations used in this chapter

| | |
|---|---|
| **CS** | Cell salvage |
| **EPR** | Electronic patient record |
| **ICS** | Intraoperative cell salvage |
| **ICU** | Intensive care unit |
| **LIMS** | Laboratory information management system |
| **MHRA** | Medicines and Healthcare products Regulatory Agency |
| **IV** | Intravenous |

## Recommendations

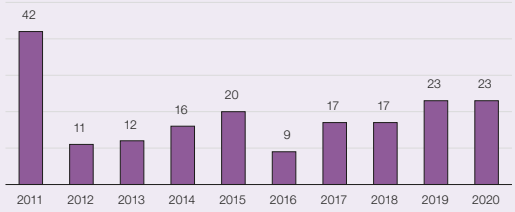
- Organisations should ensure that the provision of cell salvage is recorded within the patient record in an auditable format that includes the volume of red cells transfused. Consideration should be given as to how this data might be shared electronically (e.g. within the electronic patient record (EPR) or laboratory information management system (LIMS))
- All organisations should develop a robust system for reporting all adverse incidents/reactions related to cell salvage, preferably reporting to the hospital transfusion committee and onward to SHOT
- Healthcare organisations should ensure that adequate and appropriate training is delivered to all staff groups involved in the cell salvage process
- Devices should be checked after servicing to verify that everything is as expected before the device is put back into use. Operators should go through a basic system check before starting a procedure which includes programming parameters

**Action: Cell salvage leads, theatre leads, hospital transfusion teams, hospital transfusion committees**

### Headline data 2020

Number of reports n=23
Deaths n=0
Major morbidity n=0

### CS reports by year




### Demographic data

Male n=9
Female n=14
Adults n=23
Paediatric n=0

### Blood component data

Red cells n=23
Platelets n=0
Plasma n=0
Multiple Components n=0
Other n=0

## Introduction

Twenty-three cases were reported from eight reporting Trusts/Health Boards; on review none were withdrawn or transferred from other reporting categories. All 23 cases related to the use of ICS. There were no reported adverse reactions, deaths or morbidities attributed to cell salvage.

All reported incidents were categorised as adverse events. Of these, 12 were attributed to failures of machine or disposables, the majority of these being related to a field safety notice published by the MHRA in October 2019 (MHRA 2019).

As with previous years, incidents were probably under-reported. Without robust denominator data however, it is difficult to know how this reporting rate compares to previous years. It is highly likely that the use of cell salvage in elective surgery was reduced as surgical activity itself was impacted by COVID-19.

## Deaths n=0

## Major morbidity n=0

## Cell salvage adverse events n=23

All 23 incidents were in adult patients, with an age range of 18 to 85 years old. Fourteen patients were women, 9 were men.

| Speciality | Elective | Emergency | Total |
|---|---|---|---|
| Gynaecology | 1 | - | **1** |
| Obstetrics | 2 | 7 | **9** |
| Orthopaedic | 2 | 1 | **3** |
| Spinal | 3 | - | **3** |
| Trauma | - | 2 | **2** |
| Urology | 2 | - | **2** |
| Vascular | 3 | - | **3** |
| **Total** | **13** | **10** | **23** |

**Table 22.1: Specialty for cell salvage reports**

## Equipment failure n=12

In October 2019, a field safety notice (MHRA 2019) identified a potential issue with one manufacturer's bowl sets (single use disposables) used to process red cells. The issue related to radial cracks developing in the inner core of some bowl sets, leading to fluid leaking into the core. The user is alerted to this issue by the device displaying a 'Long Empty' error message as the expected volume on emptying is exceeded as the fluid draining from the core is added to the processed red cells. The risks of this are that the fluid retained in the core is not washed and may contain haemolysed red cells and free haemoglobin which could be reinfused to the patient. Suggested corrective actions included changing the bowl set and rewashing any processed blood.

In this year's incidents, 9 equipment failures related to 'Long Empty' error messages. On all occasions the problem was identified mid procedure after a number of processing cycles had been completed. This resulted in interruption (whilst disposables were replaced) or curtailment of the cell salvage process. All of these incidents were reported to the MHRA under the yellow card scheme.

The remaining 3 equipment failures related to manufacturing flaws in the collection reservoir in 2 cases and a bowl set in 1 case. Only 1 of these incidents was notified to the MHRA.

Over the same reporting period the MHRA yellow card scheme had 24 incident reports relating to cell salvage devices and disposables, suggesting a further 14 cases not reported to SHOT.

## Technical errors n=6

There were 4 incidents involving incorrect selection of the appropriate administration set for infusion. In 3 incidents a standard fluid giving set as opposed to a blood administration set was set up or used. All 3 cases occurred in the obstetric setting following emergency caesarean section and involved handover to another member of staff. In 1 of these cases, the administration set was changed, but infusion was subsequently abandoned as a pressure cuff was inappropriately and unsuccessfully employed. In the 4$^{th}$ case a standard blood giving set was used where a leucocyte depletion filter was indicated for a malignant urology case.

In another incident non-IV saline was used for the swab wash which resulted in the cell salvage collection being abandoned. The patient in his 80s was undergoing an open reduction internal fixation of a left distal femur periprosthetic fracture. He subsequently received a unit of allogeneic blood 4 days postoperatively which may have been avoided if the cell salvage process had not been contaminated. Contraindicated substances were aspirated into the blood collection in another incident resulting in abandonment of the cell salvage process.

### Learning points

- Cell salvage involves the collection, processing, and reinfusion of blood. Several staff may be involved in that chain of events and they should have sufficient knowledge and training to understand their responsibilities to ensure the safety of the procedure
- Reinfusion of salvaged red cells should be undertaken using an administration set designed to filter particles that are potentially harmful to the patient. The use of a more specialised filter, such as a leucocyte depletion filter, should be considered in relation to clinical need and policy

## Other adverse events n=5

As seen in previous years, there were 3 further cases of unidentified black particles seen in the salvaged red cell reinfusion bag. Two of these incidents were in obstetric cases and 1 in orthopaedic surgery. All were from the same reporting centre and the reporter states that there have now been 11 such cases since January 2019. Further investigations are underway in collaboration with the manufacturer to assess practice, environment, and any other contributory factors.

**Case 22.1: Massive obstetric haemorrhage patient unable to receive reinfusion of red cells due to suspected machine failure**

*In an emergency caesarean section, 3L of blood was collected and was being processed. The cell salvage operator became concerned that the quality of the reinfusion product was suboptimal as the device was not showing the washing efficiency as it normally would. The machine was swapped for a second device and the same issue occurred. After discussion with the anaesthetist, the cell salvage process was abandoned and a decision to use allogeneic blood made. Subsequent investigation revealed that the cell salvage devices had been serviced by a third-party engineer. The programming was changed to factory default settings with the wash quality settings routinely used in the hospital turned off. This had not been communicated to the cell salvage lead and the devices were assumed to be working as normal after servicing.*

This case demonstrates the importance of a process for device acceptance testing post service or repair. Any issues should be identified at this point and rectified to prevent adverse patient impact.

**Case 22.2: Cell salvage used outside of guidelines in massive obstetric haemorrhage with successful outcome**

*A parturient in her 20s, with an abnormally invasive placenta, underwent an emergency caesarean section. Massive blood loss ensued, estimated in the region of 10L, and a hysterectomy was required. Cell salvage was utilised and within the urgency of the situation the surgeons made an on the spot decision to salvage blood lost from the vagina as well as the abdomen. This was not communicated to the cell salvage operator or anaesthetist at the time. Blood salvage from vaginal loss was outside of institutional guidelines. All blood collected was processed and 2496mL of salvaged red cells reinfused without the use of a leucocyte reduction filter, along with over 30 units of allogeneic blood components. The patient recovered well without the need for ICU admission. There were no signs of transfusion reaction or bacterial contamination.*

**Commentary:** Salvaging red cells from lower genitourinary tract bleeding has been proposed previously but remains controversial. Teare et al. (2015) published a small study in 50 women where vaginal blood loss was collected and processed, but not reinfused. The quality of the salvaged product was tested and found to be satisfactory. Bacterial contamination was present, but not in significantly high enough concentration to be deemed clinically significant. In 2018, a small series of cases was published (Lim et al. 2018) in which 10 out of 28 women had sufficient salvaged red cells to be reinfused after vaginal delivery. Although there were no instances of postpartum sepsis, wound infection or thromboembolism, there was one suspected amniotic fluid embolism, but symptoms started before the reinfusion of the salvaged red cells. More research is needed in larger clinical trials before the safety and effectiveness of this intervention can be proven if it is to be adopted into routine practice. However, in the case reported above, in extremis, the additional red cells salvaged may have made a difference. The issue here was that not everyone was engaged in making the decision and given the opportunity to consider the relative risks and benefits to the patient.

## Learning point

- A fast-moving emergent scenario may result in decisions that are centred on an individual patient's circumstances and fall outside of current guidance. Care should be taken to ensure that any decisions align within the standard of care provided by a medical practitioner (Hurwitz 2004). These decisions must be clearly documented in the patient's clinical notes including the rationale for the decision

## Conclusion

The safe execution of cell salvage relies on everyone involved in the process understanding their role and responsibilities. There are three distinct phases to cell salvage that cannot be undertaken by a single person. The quality of the collected blood, the correct processing of that blood and the safe reinfusion

of the washed red cells can be influenced by all those involved. It is imperative to provide adequate and appropriate training, including updates, to support all staff involved in the cell salvage process.

## Recommended resources

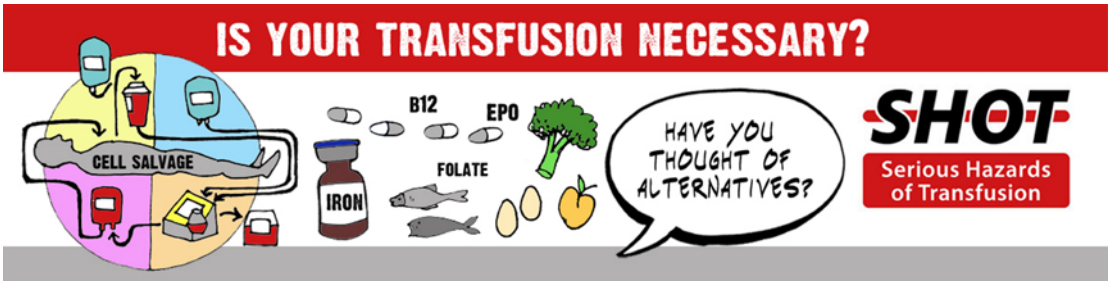
**UKCSAG technical factsheets**

**Staff responsibilities:** https://www.transfusionguidelines.org/document-library/documents/factsheet-10-staff-responsibilities-version-1/download-file/Factsheet%2010%20-%20Staff%20Responsibilities%20%28version%201%29.pdf

**Use of filters:** https://www.transfusionguidelines.org/document-library/documents/factsheet-7-use-of-filters-version-2/download-file/Factsheet%207%20-%20Use%20of%20filters%20%28version%202%29.pdf

**Intraoperative cell salvage education**

https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/intraoperative-cell-salvage-education




## References

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MHRA. Field Safety Notice 2019/011/001/701/025 (2019). https://mhra-gov.filecamp.com/s/AYMLuOqjtldEbwql/d. [accessed 28 April 2021].

Teare KM, Sullivan IJ and Ralph CJ. Is cell salvaged vaginal blood loss suitable for re-infusion? *Int J Obstet Anesth* 2015;**24(2)**:103-10.