INTRAOPERATIVE CELL SALVAGE IN OBSTETRICS: A discussion of current practice, guidelines and research.

Submission for the Alison Holloway Award

By

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Glossary:
NZ = Aotearoa New Zealand
UK = United Kingdom (England, Scotland, Wales and Northern Ireland)
Lead anaesthetic technician = nominated lead cell salvage coordinator for that hospital
AT, ATs = anaesthetic technician, anaesthetic technicians
IOCS = intra-operative cell salvage
AFE = amniotic fluid embolism
LDF = leucodepletion filter
RBCs = red blood cells
JW's = Jehovah's Witnesses

Intraoperative cell salvage (IOCS) has been used as a blood management tool in surgery since the first documented autotransfusion in 1818 (Roets et al., 2019). More than a hundred years later, modern cell salvage technology allowed for the removal of clotting factors and platelets from salvaged blood before it was reinfused back into the patient, which was documented in the first case report of IOCS in obstetric surgery published in 1988 (McDonnell et al., 2010). Concerns regarding transmission of novel blood borne viruses such as HIV and hepatitis led to IOCS becoming more popular and more frequently used in the late 1990s, as an alternative to allogeneic (donated) blood transfusion. According to the 2023 audit of anaesthetic technicians (ATs) in Te Whatu Ora- MidCentral (health district in Aotearoa New Zealand), IOCS use in obstetrics has increased by 20% compared to the previous year of 2022 (J. Barbridge, personal communication, February 2, 2024).

Why should we use cell salvage in obstetrics?

Returning blood via IOCS to the obstetric patient has a number of benefits compared to other forms of blood management, such as allogeneic blood transfusion. Salvaged red blood cells (RBCs) are more viable, able to maintain their flexibility and have similar pH and ATP levels compared to those found in maternal circulation, which means they can become more immediately active when reinfused back into the patient (Willington & Roets, 2017; Australian National Blood Authority, 2014). The Australian National Blood Authority's 2014 guideline states that when used in surgical cases associated with an estimated 20% blood loss, IOCS carries no risk of transfusion reactions or blood borne infections. As the salvaged blood remains with the patient the whole time, the risk of clerical/human errors regarding administration of 'the wrong blood' is greatly reduced compared to allogeneic transfusion. The preservation of allogeneic blood stocks is also an important advantage afforded by IOCS. Key studies such as McDonnell's et al. (2010) Australian study of 27 obstetric cases, Sullivan & Ralph's (2019) United Kingdom (UK) study of 1,170 cases and Iyer's et al. (2024) meta-analysis of 3,361 cases have demonstrated that IOCS decreases the volume of allogeneic blood transfused and the number of obstetric patients receiving allogeneic blood overall. McDonnell et al. also suggested that IOCS could reduce the pressure on blood transfusion services in cases of difficult cross matches.

Research has also attempted to quantify the value of IOCS in obstetrics by comparing health outcomes and costs resulting from IOCS versus standard care. McDonnell et al. (2010) claim that IOCS can reduce the length of hospital stay while more recent analyses of larger groups of data show that IOCS does not affect length of hospital stay (Iyer et al., 2024). The UK Association of Anaesthetists' 2018 guideline states that IOCS helps maintain a stable postoperative haemoglobin concentration, which is reflected in Katz's et al. (2024) American analysis of 99 obstetric patients who received IOCS versus standard care. Researchers have also identified that IOCS increases the risk of fetomaternal haemorrhage (fetal blood cells entering the maternal circulation which can occur during obstetric procedures) resulting in increased alloimmunisation events in Rhesus-incompatible cases. However, the same research has also shown that this risk can be managed with a clear anti-D prophylaxis guideline (Klein et al., 2018; Khan et al., 2018; Smith & Shippam, 2018). Adverse outcomes of IOCS in general surgery are rare and include infection e.g. septicaemia, heart failure & atrial fibrillation, and complications resulting from 'salvaged blood syndrome' which can lead to transfusion-related lung injury, and renal failure (Robson & Leung, 2015; Willington & Roets, 2017). There appear to be no current studies that are monitoring future pregnancy complications from obstetric patients who previously received IOCS.

The cost effectiveness of using IOCS in obstetrics has also been debated. In Grainger & Catling's 2018 review of existing literature and practice in the UK, it was identified that financial arguments for and against IOCS are varied because blood loss in obstetric surgery is not always predictable. The Association of Anaesthetists UK (2018) has noted that cost effectiveness is more apparent in cases where larger volumes of blood are lost, and several UK guidelines and research have identified ways in which unnecessary costs of using IOCS in obstetrics can be avoided, e.g. only setting up equipment for blood 'collection only' (McDonnell et al., 2010; Norfolk, Norwich & James Paget University Hospitals, 2021). A number of pieces of research have questioned the cost effectiveness of IOCS in obstetrics, such as the SALVO trial (Khan et al., 2018), however, Wong & Toledo (2019) note that SALVO and similar studies have only accounted for direct costs for the health provider, and have not considered other costs to society that can result from serious adverse outcomes and maternal death. The cost of an allogeneic blood donation versus the cost of equipment required to process and reinfuse blood in NZ is dependent on the hospital and machine used.

The use of IOCS in obstetric surgery has been endorsed and encouraged by a number of international organisations. The National Institute for Health and Clinical Excellence (NICE), American College of Obstetricians and Gynecologists, UK Royal College of Obstetricians & Gynaecologists, the Association of Anaesthetists of Great Britain and Ireland, the National Blood Authority Australia and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists all support the use of IOCS in obstetrics (Esper & Waters, 2011; Norfolk, Norwich & James Paget University Hospitals, 2021). Despite this endorsement from UK organisations, the use of IOCS in obstetrics in the UK is variable. Skeldon's et al. (2012) UK review of IOCS in obstetric units showed that it was perhaps inappropriately used in obstetrics, which is echoed by a more recent UK review by Kumar et al. (2024) which identified that the use of IOCS in obstetric surgery was inconsistent across services. This issue of inconsistency may be complicated by misconceptions about using IOCS in obstetric surgery, such as the belief that IOCS is inappropriate for some clinical situations, is too expensive, and is ineffective (Esper & Waters, 2011).

In NZ, death by obstetric haemorrhage accounted for 3% of maternal deaths between 2006 and 2018 (PMMRC, 2021). In 2021 within Auckland's Te Toka Tumai district, 19.4% of patients who had an emergency caesarean section and 9.1% that had an elective C-section suffered post-partum haemorrhage of greater than 1000ml (Te Toka Tumai Auckland, 2024). In order for ATs to safely operate IOCS machines and improve treatment outcomes for patients undergoing obstetric procedures in Aotearoa New Zealand (NZ), we require a national standard that outlines best practice in terms of patient selection, correct use of equipment and reinfusion of salvaged blood. This standard would ideally also describe the training and recertification requirements needed to ensure ATs operate the machine in a consistent manner, with the appropriate degree of collegial support (National Blood Authority, 2015). At the time of writing, there is no current national standard in NZ for the safe provision of IOCS in obstetric surgery.

In this paper, I will discuss what the current practice and guidelines are in NZ for IOCS, then international guidelines and academic research on several points of contention/issues that need clarification in order to provide safe patient care. I have consulted a wide array of relevant literature, guidelines and policies; along with references to the Haemonetics Elite® literature which is the machine used at Palmerston North Hospital (MidCentral) theatres; and responses from a nationwide NZ survey of lead ATs from NZ hospitals that provide IOSC and/or obstetric services. Searches on free-access internet platforms e.g. Google Scholar were used as well as access to online journals and databases that were afforded by Te Whatu Ora-MidCentral. I also requested to be supplied with electronic copies of relevant guidelines and policies from other health districts in NZ- these are not accessible to the public but have been included in the list of references. The vast majority of the articles I reviewed were originally written in English.

Note: extensive searching and reading was completed to identify different standards and criteria relating to the medical indications and contraindications for IOCS in obstetrics. The issue and debate around priming leucodepletion filters with saline, and technical aspects of suction were also examined. Although these topics will not be discussed in this paper, they may be useful for inclusion in the development of a national standard.

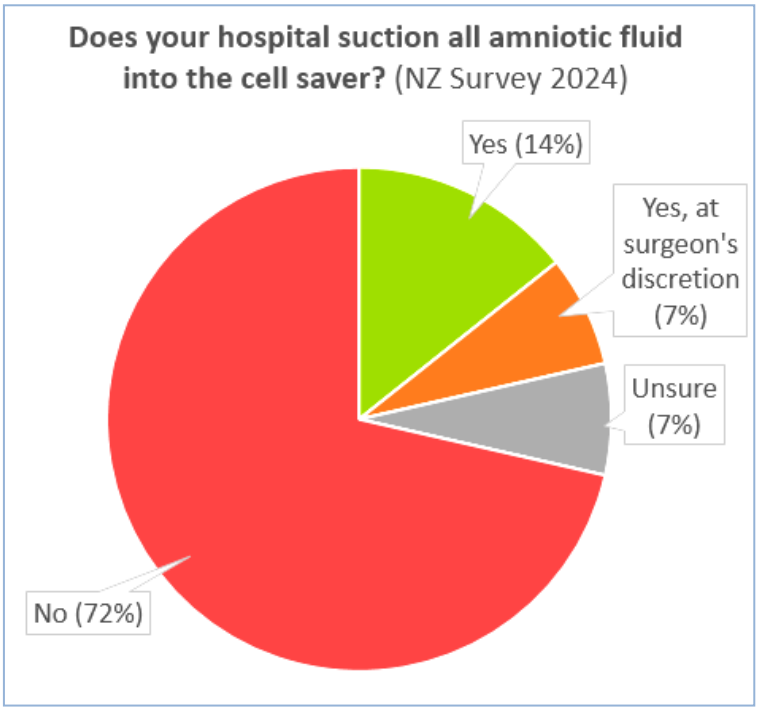
1. Amniotic fluid- use it or lose it?

Should amniotic fluid be aspirated into the cell salvage machine to be processed, or suctioned for disposal?

Amniotic fluid can contain a number of solute and debris substances, including fetal cells, vernix, meconium and tissue factor (McDonnell et al., 2010; Potter et al., 1999). This has caused concern amongst cell salvage operators and manufacturers that this debris could cause amniotic fluid embolism (AFE) (Roets et al., 2019). Amniotic fluid and blood can be aspirated via single suction into the cell salvage ('single suction') or amniotic fluid can be suctioned with a separate suction line to be disposed of as medical waste ('double suction').

What is currently happening in NZ?

In the NZ survey of lead ATs from 14 hospitals that provide obstetric services, three (3) reported that their hospital suctions all amniotic fluid into the cell salvage machine (with one (1) of these three hospitals reporting that this was dependent on the discretion of the surgeon). Ten (10) reported amniotic fluid was not suctioned into the cell salvage, and one (1) reported unsure (K. Bennett, personal communication, August 12, 2024).



What do NZ policies/guidelines say about suctioning amniotic fluid for cell salvage?

There are currently no nationwide NZ guidelines published by NZ government entities, e.g. the New Zealand Blood Service, which dictate how to safely perform IOCS in obstetric surgery and whether to suction amniotic fluid for cell salvage or dispose of it as medical waste.

The autotransfusion course provided by the Australian and New Zealand College of Perfusionists (ANZCP) is completed by many ATs in NZ and often is a requirement for ATs to be able to fully process and reinfuse blood. The 2024 autotransfusion course material states that a separate suction device should ideally be used to aspirate amniotic fluid from the surgical site before starting IOCS (K. Bennett, personal communication, August 20, 2024).

In the trainer workbook for the Haemonetics Cell Saver Elite® (which is the machine used at Palmerston North Hospital) the Haemonetics Corporation declares that due to various clinical factors, the company cannot recommend specific practices such as where to aspirate (Haemonetics Corporation, 2023, p. 43).

Te Toka Tumai Auckland district has shared their guideline, "Intra-Operative Cell Salvage (IOCS) in Obstetrics" (2024). This guideline recommends that a single suction system is used in obstetrics- thereby implying that all amniotic fluid and blood is aspirated into the cell salvage machine. It also mentions that the cell salvage operator may consider using a separate suction in patients with polyhydramnios (an excessive amount of amniotic fluid) to avoid filling the cell salvage machine with amniotic fluid; and that a second wall suction should be available in the event of extreme bleeding or blockage of the cell salvage suction. Waitemata district does not have a specific obstetric IOCS guideline, only a general IOCS guideline that recommends not to suction amniotic fluid for cell salvage. However, in their general IOCS guideline they have noted that in obstetric procedures, the volume of amniotic fluid in the salvaged blood can be greatly reduced if the machine processes the salvaged blood with a "high quality wash" (usually involving an increased volume of 0.9% sodium chloride) (Waitemata, 2023). Middlemore Hospital (Counties-Manukau district) will discuss the use of suction in obstetrics in their local guideline which is currently in the drafting stage. As per email communications with one of the lead ATs, the Counties-Manukau district guideline states that the previous practice of removal of amniotic fluid via separate suction reduced the volume of blood collected. The guideline will ultimately recommend using a single suction device (A. Rolls, personal communication, August 12, 2024). The Canterbury district guideline for IOCS lists amniotic fluid as a 'contaminant' and instructs cell salvage operators to suction amniotic fluid for disposal; and that cell salvage can resume after delivery of the foetus and "copious" irrigation of the surgical site with 0.9% sodium chloride (Canterbury, 2021).

<u>What do international guidelines say?</u>

In the UK, The National Institute for Health and Care Excellence (NICE) (2005) published "Intraoperative blood salvage in obstetrics" guidance. This report stated that after analysis of the available evidence (in particular research regarding concerns about AFE) the use of IOCS in obstetrics was considered adequately safe. Whether amniotic fluid should be suctioned from the surgical field and disposed of or used for cell salvage was not addressed in this guideline and could not be found in NICE's more recent blood transfusion guideline (NICE, 2015). The UK Cell Salvage Action Group (UKCSAG) has published a number of helpful guidelines which state that the cell salvage operator should not aspirate amniotic fluid into the cell salvage, but remove it by separate suction prior to starting cell salvage (UKCSAG, 2014). This is reflected in several other UK local guidelines that also recommend suctioning amniotic fluid for disposal (NHS Norfolk, Norwich & James Paget University Hospitals, 2021; NHS Peterborough & Stamford Hospitals, 2016; NHS Sherwood Forest, 2023; NHS Tayside, 2023; NHS Wales, 2023) with NHS Tayside mentioning that suctioning amniotic fluid for cell salvage may be used at the discretion of the obstetrician and consultant anaesthetist. Tanqueray's et al. (2010) article published by the Association of Anaesthetists of Great Britain & Ireland supports not only suctioning and disposing amniotic fluid, but recommends that cell salvage does not commence until complete delivery of the foetus and placenta.

In Australia, recommendations for suctioning amniotic fluid are detailed in the National Blood Authority's "Guideline for the provision of intraoperative cell salvage" (2014) which is endorsed by the Australian & New Zealand College of Anaesthetists. These guidelines report that suctioning of amniotic fluid for disposal is recommended prior to cell salvage and note that this continues to be common practice, and that more evidence would be required to recommend a single suction set up where amniotic fluid and blood were suctioned into cell salvage. Interestingly, this contrasts with an article in the 2017 version of the "Blue Book" which is published by the aforementioned Australian & New Zealand College of Anaesthetists. This article by Willington & Roets makes reference to one hospital in Australia- "In our institution it is routine to use a single suction system. All amniotic fluid is collected in the reservoir." (2017, p. 141).

What does the research say is best practice?

Recommendations in the research have been based on the incidence of adverse effects, primarily AFE. AFE is thought to contribute toward maternal fatality and multi-organ failure (Khan et al., 2018). Though key research and reviews by Catling et al. (1999), Grainger & Catling (2018) and Kuppuaro & Wee (2010) recommend that removing amniotic fluid through a double suction technique is "intuitively reasonable" because of historical concerns of AFE and to reduce the load of fluid that is processed through the cell salvage machine; the research has appeared to have shown that the incidence of AFE is extremely low, regardless of whether amniotic fluid was aspirated via single suction into the cell salvage machine or double suctioned to be disposed of.

Earlier pieces of research on this topic included Rebarber's et al. (1998) cohort study which compared 139 obstetric patients who received IOCS to 87 general surgical patients who did not receive IOCS. While this study did not clearly specify the type of suction set up used, no cases of AFE or acute respiratory distress syndrome were observed. Allam's et al. (2008) review of existing literature on cell salvage in obstetrics revealed "no single serious complication leading to poor maternal outcome has been directly attributed to its use" (p. 42). Sullivan's et al. (2008) study was one of the first pieces of research to compare a single suction setup (where amniotic fluid was drawn into the cell salvage machine) to a double suction setup (where amniotic fluid was removed by a second device). They found that there were no incidences of AFE, however in both groups a leucodepletion filter (LDF) was used. McDonnell's et al. (2010) Australian study reviewed 27 patients who received IOCS after amniotic fluid was suctioned and removed from the surgical field (theatre staff used "visual confirmation" to determine when AF was removed). Again, a LDF was used and no incidences of AFE occurred; however the authors noted that more research was needed in order to recommend a single suction technique. In Smith & Shippam's (2018) Canadian education resource, IOCS is not considered to increase the risk of AFE, based on the theory that the levels of foetal squamous cells in processed salvaged blood are the same seen in the maternal circulation when the foetus is delivered, hence no reactions should occur when the salvaged blood is re-transfused.

Recent research includes the SALVO (cell SALVage in Obstetrics) trial by Khan et al. (2018) which was a comprehensive study of 3,028 patients in UK obstetric units. In SALVO, patients who were at risk of haemorrhage received IOCS or "routine care" in a randomised controlled trial. The data shows that in

patients who received IOCS, a single suction was used in 58% of cases and double suction in 42% of cases; the trial allowed each hospital to decide whether to use a LDF, and no incidents of AFE were observed. Sullivan & Ralph (2019) also completed a study of observational data in 1,170 obstetric patients who received IOCS with a single suction system, with an undisclosed number of cases also using a LDF. This study consistently used a single suction system and reported no incidences of AFE, however, these conclusions are based on observational data, which are weaker than conclusions from randomised controlled trials such as SALVO (Wong & Toledo, 2019). Iyer's et al. (2024) analysis of five (5) randomised controlled trials (1,685 patients who received IOCS) found no incidences of AFE occurring when a mixture of single and double suction systems was used- which mirrors the results of the SALVO study, because the SALVO study accounted for more than 90% of the patients in Iyer's et al. review. Leeson's et al. (2023) cohort study of 436 obstetric patients who received reinfusion of salvaged blood did not specify the type of suction set up, and concluded that the risk of AFE occurring is extremely low even when used without a LDF. It also identified another potential complication of IOCS using a single or double suction technique: risk of foetal cell alloimmunisation occurring in a future pregnancy, which is estimated as one in 436. It is important to note that none of these studies have completely ruled out the risk of AFE occurring in a single or double suction type set up, though according to Grainger & Catling (2018) a randomised controlled trial with 265,000 patients would be needed to completely rule out this risk.

SUMMARY STATEMENT:

The recommendations in NZ and international guidelines clash when it comes to suctioning amniotic fluid for removal or for use in cell salvage. Most NZ hospitals report that they do not suction amniotic fluid for cell salvage ('single suction'). Te Toka Tumai Auckland district have highlighted that a separate suction could be considered in patients with polyhydramnios, and that a second wall suction should be available in the event of extreme bleeding or blockage of the cell salvage suction.

The research appears to show that the incidence of AFE is extremely low, regardless of whether amniotic fluid was suctioned for cell salvage ('single suction'), or suctioned away from the surgical field and then disposed of ('double suction').

The risk of AFE may be minimised by the concurrent use of a LDF, though the research is not clear on this.

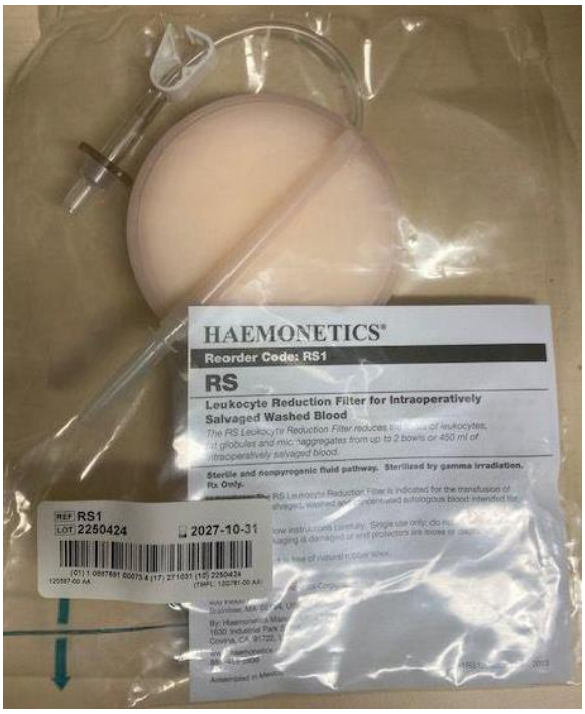
The risk of foetal cell alloimmunisation occurring in future pregnancies of patients who received IOCS (one study estimates this risk to be one in 436) appears to be higher than the risk of AFE in IOCS received by obstetric patients, however this can be avoided with an anti-D prophylaxis guideline.

NOTE: The NZ annual maternity mortality report for 2006-2018 lists AFE as the second leading cause of maternal death (PMMRC, 2021), however a recent review of international figures by Fitzpatrick et al (2019) suggests that these incidents were not a result of use of intraoperative cell salvage and re-transfused blood, rather, it was dependent on having an obstetrician and/or anaesthetist present at the time of the event and whether blood clotting abnormalities were appropriately addressed.

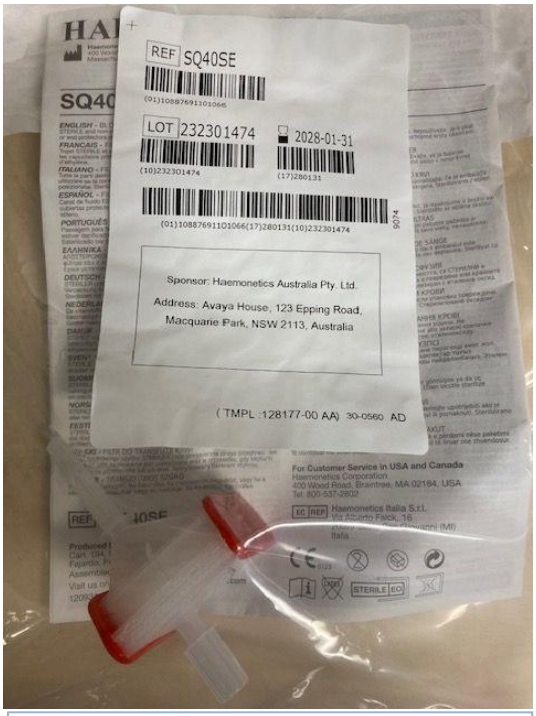
2. Leucodepletion filters- put them in or pull them out?

Should leucodepletion filters be used in every obstetric IOCS case? What are the risks?

Leucodepletion filters (LDF) (also called leucocyte reduction filters with regional variations in spelling) are an optional component used in modern cell salvage. LDFs further filter reinfusion blood after it has been washed and processed through the main unit of the machine, then the reinfusion blood is returned intravenously to the patient. LDFs are thought to work by binding DNA containing cellular material to the negatively charged small pore polyethylene surface. This increases the removal of contaminants, plasma and clotting factors after the machine washing process (McDonnell et al., 2010; Smith & Shippam, 2018; Waters et al., 2000).



Haemonetics Leukocyte Reduction Filter RS1 (8 microns)



Haemonetics SQ40SE microaggregate filter (40 microns)

What is currently happening in NZ?

In the NZ survey, lead ATs from 13 hospitals that provide obstetric services reported what key actions they performed for obstetric patients. Six (6) reported that an LDF is used for all obstetric patients, four (4) reported that no specific measures were taken, two (2) reported that key actions were taken but did not specify what actions and one (1) reported unsure (K. Bennett, personal communication, August 12, 2024).

What do NZ policies/guidelines say about using LDFs in obstetric IOCS?

At the time of writing, there are no nationwide NZ guidelines published by NZ government entities, e.g. the NZ Blood Service regarding the use of LDFs in obstetrics. In the trainer workbook for the Haemonetics Cell Saver Elite®, no recommendations or references to LDFs are made (Haemonetics Corporation, 2023).

The 2024 autotransfusion course material from the Australian & New Zealand College of Perfusionists comments on the use of LDFs. It states that in obstetric patients, a LeukoGuard RS Pall medical filter should be used; and in cases of life threatening haemorrhage, a clinical decision can be made to remove the LDF when reinfusing blood. It also notes that all LDFs and their use should comply with local, national and manufacturer guidelines (K. Bennett, personal communication, August 20, 2024).

Te Tokai Tumai Auckland health district clearly outlines its position on use of LDFs in its obstetric IOCS policy. It recommends that a LDF is not routinely used for obstetric IOCS, and instead salvaged RBCs should be filtered through a 40-micron filter and administered via a standard blood administration set; except for cases such as malignancy, sepsis or infection when a LDF should be used (Te Toka Tumai Auckland, 2024). This contrasts with Waitemata health districts' general IOCS guideline, which does not clearly state that a LDF should be used in all obstetric cases. It does note that use of a LDF makes fast infusion "impossible", and the attending obstetrician and anaesthetist can decide whether the LDF should be removed to speed up reinfusion (Waitemata, 2023). Counties-Manukau health district (Middlemore Hospital) will discuss LDF use in their local guideline which is currently in drafting stages. As per email communications with one of the lead ATs, LDFs are not routinely used in obstetric IOCS unless the patient has malignancy, sepsis or infection. Instead, a 40 micron microaggregate SQ40SE Haemonetics filter is used (see above picture) (A. Rolls, personal communication, August 12, 2024).

What do international guidelines say?

In NICE's guideline "Intraoperative blood salvage in obstetrics" published in 2005, it is stated that a LDF is "nearly always used" to reduce amniotic fluid contamination to a level similar to those found in maternal blood (NICE, 2005, p. 3). NICE's more recent blood transfusion guideline published in 2015 does not reference LDFs in its discussion of cell salvage as an alternative to allogeneic blood transfusion. The UKCSAG (Cell Salvage Action Group) has also published material regarding the use of LDFs. In 2015, out of 73 hospitals that used IOCS in obstetrics, 66% used a LDF, 22% reported using a LDF sometimes, and 12% reported that they did not routinely use a LDF (UKCSAG, 2015). The LeukoGuard RS Leukocyte Removal Filter for Salvaged blood is recommended to reinfuse salvaged blood as according to the Group, it is the only filter that has been proven to remove residual elements of amniotic fluid (UKCSAG, 2012; UKCSAG, 2014); while the UK Medicines and Healthcare Products Regulatory Agency (2011) state that the use of LDF in IOCS is not validated and that hypotension can be a rare side effect. Local NHS guidelines also recommend that this type of LDF is used in IOCS in obstetrics (NHS Norfolk, Norwich & James Paget University Hospitals, 2021; NHS Peterborough & Stamford Hospitals, 2016; NHS Tayside, 2023; NHS Wales, 2023) with NHS Tayside, Swansea Anaesthetic Consultants (2020) and NHS Peterborough & Stamford Hospitals (2016) additionally recommending that in cases of life threatening haemorrhage, a clinical

decision should be made to remove the LDF to allow salvaged blood to be reinfused faster. NHS Norfolk, Norwich & James Paget University Hospitals (2021) is the only local guideline that advises on the course of action if hypotension occurs during reinfusion of salvaged blood. Reinfusion of salvaged blood should be paused if hypotension occurs and then resumed when the hypotension resolves; if the hypotension recurs, then removal of the LDF should be considered. The Association of Anaesthetists of Great Britain & Ireland (AAGBI) has also commented on the use of LDFs in obstetrics. In Tanqueray's et al. (2010) article, the use of a LDF when reinfusing salvaged blood from obstetric patients is recommended, which conflicts with later guidelines published by the AAGBI in 2018 which report that there is mixed evidence to support the use of LDF in obstetrics (Klein et al., 2018). Lastly, the 2023 UK Serious Hazards of Transfusion report recommends that local guidelines mention the risk of hypotension resulting from LDFs. It also advises that if LDF-induced hypotension occurs, the reinfusion should be stopped, the hypotension corrected with vasopressors and fluid, and consideration be given to removing the LDF.

In Australia, the National Blood Authority (2014) discusses use of LDF in their Guideline for the provision of intraoperative cell salvage. Echoing NICE's (2005) guideline, the NBA states that LDFs are "nearly always used" in obstetrics to reduce contamination by amniotic fluid. The Australian & New Zealand College of Anaesthetists' 2017 issue of the "Blue Book" features an article by Willington & Roets (2017) which states that in standard practice, blood is usually reinfused via a LDF to aid removal of amniotic fluid.

What does the research say is best practice?

The research varies on the benefits of using LDFs in IOCS for obstetric patients. One argument in favour of the routine use of LDFs is that they are essential in removing cellular debris that can enter the cell salvage machine when blood and possibly amniotic fluid is suctioned from the surgical field. Earlier studies by Catling et al. (1999) and Waters et al. (2000) appeared to demonstrate that the Pall RC and Pall RS filters completely removed cellular debris such as trophoblastic tissue and leucocytes. Esper & Waters (2011) also found that combining the normal cell salvage washing process with a filter such as a LDF, would produce a product that was similar to maternal blood. Sullivan's et al. (2008) study of 34 caesarean section patients who received IOCS even goes as far to claim that an LDF is "essential" for the removal of amniotic fluid contamination. As mentioned earlier in the paper, there is a possibility that leucodepletion filters reduce the incidence of AFE in studies that used both single/double suction systems; however studies that did not consistently use a LDF appeared able to replicate the same results of no reported AFE events. It is also important to note that at the time of writing, it appears that no cell salvage manufacturers have endorsed the use of a specific LDF for use in obstetric surgery.

One common argument against the use of LDFs is that they slow reinfusion rates, which could compromise a patient's physiological stability in cases of severe life threatening haemorrhage. Larger studies such as the SALVO study (Khan et al., 2018) and Sullivan & Ralph's study (2019) have identified that LDFs slow re-infusion rates. There are currently no pieces of research that examine exactly how much longer it takes to reinfuse blood through an LDF compared to a standard blood giving set; and no guidance on exactly what point the surgical team should remove the LDF to speed up the reinfusion rate. As discussed earlier,

this concern about slower reinfusion rate through an LDF was also reflected in the NZ local policies, with the recommendation that the obstetric surgeon and anaesthetist use their clinical judgement to decide whether to remove the LDF or keep it insitu. Another common criticism of LDFs is their association with a higher rate of adverse effects (Smith & Shippam, 2018) specifically cases of hypotension which can occur during reinfusion of the salvaged blood. This is thought to be due to cytokines and vasoactive substances such as bradykinin that can be produced by leucocytes as they pass through the LDF (Khan et al., 2018; Kuppurao & Wee, 2010). However, the incidence of LDF-induced hypotension and other adverse effects appears to be low. McDonnell's et al. (2010) Australian study where 27 obstetric patients had IOCS with a Pall RS1 LDF reported one case of unexplained hypotension, which was resolved with IV phenylephrine. In their 2018 review of existing literature and practice, Grainger & Catling consider LDF-induced hypotension to be a "rare possibility" (p. 55). In the SALVO study, out of 1,498 obstetric patients who received IOCS, two cases of hypotension were observed with use of LDF, with one these cases considered to be life-threatening. The LDF was thought to cause a transfusion type reaction in one case (tachycardia, facial flushing, difficulty breathing) which was also considered to be life threatening (Khan et al., 2018). Sullivan & Ralph's (2019) study of observational data from 1,170 patients who received IOCS did not identify any hypotension events or maternal collapse, with or without an LDF. The UK Serious Hazards of Transfusion report identified 20 hypotensive episodes with use of a LDF between 2010 and 2017, and one incident of hypotension in 2023 which required intensive postoperative care (SHOT, 2023). In terms of recommending treatment options to resolve LDF-induced hypotension, Hussain & Clyburn (2010) recommend that the LDF is removed until the hypotension resolves; while Grainger & Catling (2018) recommend ceasing reinfusion and administering fluids and vasopressors.

SUMMARY STATEMENT:

LDFs are currently not routinely used to filter salvaged blood in all cases of obstetric IOCS in NZ, and the local guidelines vary on whether a LDF should be routinely used in all obstetric IOCS patients.

In the UK, guidelines and surveys appear to show that LDF's are more widely used in obstetric patients, but similar to NZ, there are conflicting recommendations in the local and national guidelines.

The research suggests that Pall RC and RS filters can effectively remove cellular debris and amniotic fluid from salvaged blood; however at the time of writing, no cell salvage manufacturers have endorsed any specific LDFs for use in obstetric IOCS.

The concern that reinfusion happens much more slowly through an LDF was also reflected in the NZ local policies, with the recommendation that the obstetric surgeon and anaesthetist use their clinical judgement to decide whether to remove the LDF or keep it insitu. Specific guidance on exactly what point a LDF should be removed to speed up infusion rates could not be found in the literature.

The literature explored the incidence of LDF-induced hypotension and other adverse effects and showed that LDF-induced hypotension is rare and is able to be resolved intraoperatively, by administration of IV fluids/vasopressors, temporary removal of the LDF or ceasing reinfusion altogether. The risk of, and management of LDF induced hypotension should be clarified if a national standard were to be drafted.

3. Swab washing- wash them or 'chuck' them?

Should we wash surgical swabs and salvage the blood from them in obstetric cases? How should we do this?

The issue of whether or not to wash swabs and salvage blood from these in obstetric surgery does not feature in the literature and guidelines as prominently as AFEs and LDFs. The first documented autotranfusion by James Blundell in 1818 involved bloody swabs that were washed in a saline mixture; then the resulting liquid was reinfused (with an unsurprisingly high mortality rate) (Ashworth & Klein, 2010). Historically, there has been some uncertainty towards the safety of this practice. Waters (2005) described early concerns about swab washing for IOCS in general surgery. This included fears that cotton fibres from the swabs may be reinfused into the patient, however some manufacturers claimed that no fibre is shed from their product and that modern cell salvage washing would prevent reinfusion of fibres back into the patient. Concerns that swabs may introduce bacteria into the collected blood were also refuted- although the research showed that the patient would not be harmed as they had already been exposed to that bacteria, the recommendation was that swabs should be discarded if they were thought to be contaminated.

What is currently happening in NZ?

When lead ATs from NZ hospitals with obstetric services were surveyed on their use of cell salvage, only one (1) reported that swab washing took place in order to salvage blood in obstetric cases (K. Bennett, personal communication, August 12, 2024).

The 2024 autotransfusion course material from the ANZCP clearly describes the correct swab washing process, however it does not mention whether this process is endorsed for use in obstetrics or any other specific recommendations that ATs need to be aware of (K. Bennett, personal communication, August 20, 2024).

Blood soaked swabs in sterile bowl

Blood soaked swabs in normal saline 0.9% ready for suctioning into cell salvage machine

What do NZ policies/guidelines say about salvaging blood from swabs in obstetric IOCS?

The Haemonetics Cell Saver Elite® trainer workbook declares that they are unable to give recommendations for certain practices, including whether to conduct swab washes (2023, p. 43). Te Toka Tumai Auckland district states in their obstetric IOCS guideline that any patient who is eligible for cell salvage is eligible for swab washing. It also details the recommended swab washing procedure, which requires the use of 2000ml IV sodium chloride 0.9%, weighing the blood soaked swabs to estimate blood loss and compressing the swabs (not wringing) to express the residual blood (Te Toka Tumai Auckland, 2024). Waitemata district's IOCS guideline describes their swab washing procedure which involves use of heparin and a smaller quantity of normal saline (1000ml) however it does not specify any special precautions for salvaging obstetric patients' blood from swab washing (Waitemata, 2023).

What do international guidelines say?

In the UK, the NICE (2005) guideline "Intraoperative blood cell salvage in obstetrics" does not mention swab washing and swab washing is also absent from their 2015 blood transfusion guideline. The UK Cell Salvage Action Group (2015) have given recommendations on intraoperative swab washing in general, but not specifically for obstetrics. Some local NHS guidelines appear to endorse the use of swab washing in obstetrics, such as NHS Wales- Swansea Bay University (2020) and Norfolk, Norwich & James Paget University Hospitals (2021). The Swansea Bay University guideline states that blood can be salvaged from washed swabs, by first weighing swabs in an aseptic manner to measure blood loss, then soaking swabs in 2000ml IV sodium chloride 0.9% and compressing them to express residual blood before suctioning the fluid into the cell salvage machine. In Australia, swab washing is not mentioned in any professional governing body publications or in guidelines from national bodies e.g. the National Blood Authority. As a

point of comparison, Smith & Shippam's (2018) Canadian educational resource states that bloodied swabs can be "gently washed with isotonic saline in [a] sterile bowl and the fluid processed to optimise red-cell yield" (p. 4).

What does the research say is best practice?

There is a dearth of research on the use of swab washing in obstetric IOCS. The SALVO study of obstetric patients who received IOCS reported that theatre staff at the participating hospitals were "encouraged" to use swab washing, with a total of 802 patients receiving swab washing during IOCS. The use of swab washing appeared to increase the likelihood that salvaged blood was actually returned to the patient- 81.3% of patients who had swab washing had blood returned compared to 16% who did not have swab washing. The SALVO study also did not appear to link any adverse effects or incidents associated with swab washing. As noted earlier in the paper, there were no incidents of AFE observed and the two cases of hypotension that occurred were associated with the use of LDFs (Khan et al., 2018). Ultimately, the SALVO authors report that more research is needed to identify a clear correlation between swab washing and the likelihood that all collected blood is returned via IOCS. The only other large scale study that examined the effects of swab washing is Sullivan & Ralph's (2019) study of observational data from 1,170 obstetric patients over a ten year period. In the study, swab washing with saline to increase RBC return was a routine practice. Adverse effects directly resulting from swab washing in IOCS were not the primary focus of the study, but it was noted that among the 1,170 patients who received IOCS, there was "no evidence of maternal collapse or hypotension" (p. 980). There appears to be no qualitative research exploring why theatre staff may feel reluctant to incorporate swab washing in obstetric IOCS.

SUMMARY STATEMENT:

Swab washing in obstetric IOCS does not appear to be common practice in New Zealand and overseas. As such, there are very few local and international guidelines that describe how to safely wash swabs to increase RBC return in obstetric IOCS.

There appears to be some evidence that swab washing increases the volume of salvaged blood returned to the patient, and that swab washing may increase the chance that salvaged blood is actually reinfused. No specific complications from swab washing have been noted in larger bodies of research. However, more research is needed to clearly link swab washing with these beneficial outcomes and to rule out any potential risks.

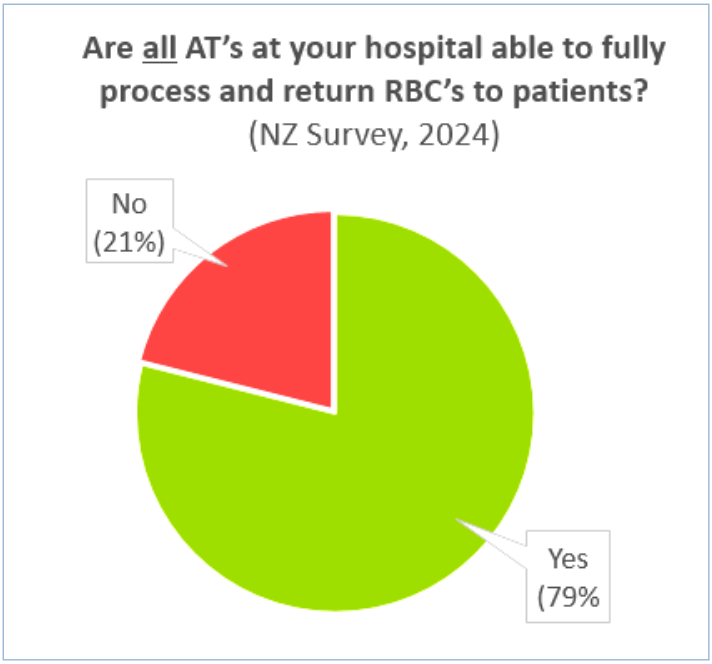
4. Training

How are we training ATs to use IOCS in obstetrics in NZ? How should we be training ATs?

How are ATs trained in NZ?

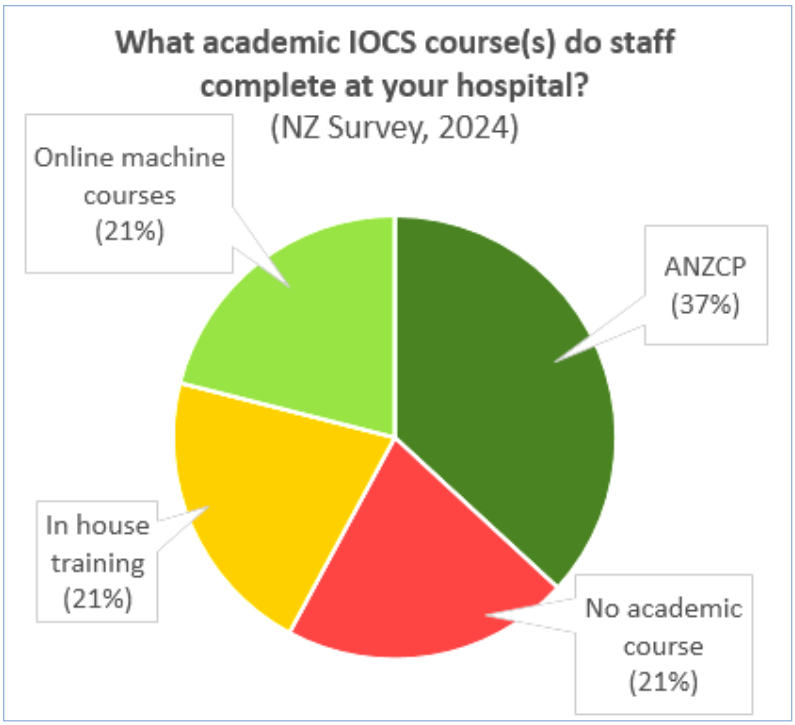
The NZ survey of 19 hospitals that used cell salvage (in all procedures not limited to obstetrics) provided some valuable insight into what is currently happening with training and recertification (K. Bennett, personal communication, August 12, 2024).

Lead ATs reported that in 79% (15) of hospitals, all ATs are able to fully operate the cell salvage machine and reinfuse RBCs, with 21% (4) of hospitals reporting that not all ATs are able to fully operate the cell salvage machine.



In terms of academic courses that ATs can complete, 37% (7) of hospitals offered the ANZCP autotransfusion course, 21% (4) of hospitals offered 'in house' training only, 21% (4) of hospitals provided online training via the machine manufacturer only, and 21% (4) of hospitals did not offer any academic courses for IOCS.

Some hospitals require several IOCS cases to be completed per year per AT to maintain competency. Only 21% of hospitals require ATs to perform a minimum number of cell salvage cases per year, and this varies between a minimum of two (2) to ten cases to be completed per year in order to retain that competency standard.



What do NZ guidelines say about training ATs to use IOCS?

Although the Competence Standards for Anaesthetic Technicians in Aotearoa NZ (2018) require ATs to "identify ongoing professional learning needs and opportunities", there are no NZ guidelines that require ATs to complete specific IOCS training and/or recertification. Recommendations for training ATs to operate cell salvage machines can be found in some manufacturers training manuals. For NZ hospitals that use the Haemonetics Cell Saver Elite®, the Haemonetics Corporation (2023) has a comprehensive checklist of skills that trainees are expected to learn, as well as instructions on how to record trainee's attendance and certify trainee's competence in using the machine. It also recommends that local hospital guidelines be followed throughout the certification process. Te Toka Tumai Auckland health district's (2024) IOCS obstetric guideline appears to be the only NZ guideline that refers to training cell salvage operators. It states that theatre staff need to be specially trained in the use of IOCS in obstetrics, as it is different to 'standard' IOCS.

What do international guidelines & research say about training ATs to use IOCS?

The Australian National Blood Authority guidelines (2012; 2014 & 2015) recommend that all staff using IOCS should be given appropriate training according to local policies. It also recommends that staff who are new to IOCS complete at least 10 IOCS cases (with at least two of these cases being emergency/time critical) under the supervision of a senior staff member experienced in IOCS to ensure the 'trainee' develops competency and familiarity with all aspects of the IOCS process. Willington & Roets (2017) have elaborated on the training process in Australia in the 2017 version of ANZCA's 'Blue Book', stating that the manufacturer of the cell salvage machines usually conducts an initial training, then trainees are required to complete a minimum number of cases to maintain their competency. It also refers to the ANZCP autotransfusion course, which continues to be a mainstay in the IOCS training programme for ATs in Australia.

In the UK, Grainger & Catling's (2018) review of existing literature and practice identified a lack of training as a potential barrier to IOCS being routinely used in obstetrics. They found that 80% of maternity units felt that a lack of training impeded the routine use of IOCS in obstetrics, rather than concerns about the safety of the procedure. The Association of Anaesthetists recommends that to maintain theatre staff competency and consistent IOCS care, only one type of cell salvage machine should be used; and each hospital should have a designated clinical lead and coordinator who supervises trainees and staff experienced in IOCS (Klein et al., 2018). Additionally, the UK Royal College of Obstetricians & Gynaecologists (2015) recommend that for obstetric cases, IOCS should only be performed by multi-disciplinary teams who routinely perform obstetric IOCS. Kuppurao & Wee (2010) also suggested a training infrastructure that would promote consistent use of IOCS and reduce wastage of resources. This would include a lead clinician e.g. a senior theatre manager working in the theatre to support trainees and promote the IOCS service. To ensure regular and continuous auditing of IOCS use, each unit of salvaged blood would require an audit trail and all details of the IOCS procedure should be recorded on a specific collection form.

SUMMARY STATEMENT:

There appears to be inconsistency in the IOCS training programmes within NZ, which could compromise the consistency of IOCS care that ATs provide to obstetric patients. Use of the same machine, identifying lead clinicians and creating a training pathway and recertification program which is enshrined in a national standard could improve and maintain ATs competence in using IOCS for all procedures.

Other discussion points that would be useful for inclusion in a national guideline/standard:

Who makes the clinical decision to use cell salvage?

In NZ, local guidelines appear to emphasise that the decision to perform IOCS is a team decision, and should be discussed in the pre-theatre/surgical "time out" (Te Toka Tumai Auckland, 2024; Waitemata, 2023). The Australian National Blood Authority (2014) states that the decision to use IOCS is at the discretion of the anaesthetist and obstetrician involved; while in McDonnell's et al. (2010) Australian study of 27 obstetric patients who received IOCS, the decision was made in consultation between the anaesthetist, obstetrician and anaesthetic technician. Providing clarity on the role of the AT in this decision could further empower ATs and aid prompt decision making especially in obstetric cases when life-threatening haemorrhage occurs.

What are some important machine dependent variables?

NZ hospitals utilise a variety of different cell salvage machines for each hospital district. The most commonly used cell salvage machines in NZ are as follows: 45% (9) of hospitals use Sorin brand machines 35% (7) use Haemonetics brand, 15% (3) use CATS brand and 5% (1 hospital) use Medtronic Autolog (K. Bennett, personal communication, August 12, 2024). International guidelines and literature recommend that in obstetric cases, 'high quality' or 'double' washes with an increased volume of saline should be used where possible to clear contaminants from amniotic fluid (Haemonetics Corporation, 2023; Sullivan & Ralph, 2019; UKCSAG, 2014; Waitemata, 2023). It is also recommended that machines be run in 'automatic' mode, to reduce operator errors (Klein et al., 2018; McDonnell et al., 2010; Waitemata, 2023).

What are some cultural safety considerations that ATs need to be aware of?

Religious beliefs may influence a patient's decision to consent to IOCS. Patients who identify as Jehovah's Witnesses (JW's) have a set of core beliefs around blood transfusions, which usually results in their refusal of allogeneic blood transfusions. Te Toka Tumai Auckland (2024), Waitemata (2023) and Canterbury (2021) districts all identify this issue in their local IOCS guideline, and state that although JW's typically refuse allogeneic blood transfusion, it is a personal decision; and the patient may accept IOCS if they are reassured by the surgical team that continuity of the circuit will be maintained. This can be achieved by priming the cell salvage machine with saline, thereby maintaining continuous 'contact' between the

patient and their blood (Grainger & Catling, 2018). Waitemata (2023) also states that maintaining a continuous circuit would require the placement of a separate designated IV cannula for cell salvage. Te Toka Tumai Auckland (2024) has identified the need for a clear guideline on establishing a continuous circuit for JW's.

SUMMARY STATEMENTS:

Suctioning amniotic fluid

The recommendations in NZ and international guidelines clash when it comes to suctioning amniotic fluid for removal or for use in cell salvage. Most NZ hospitals report that they do not suction amniotic fluid for cell salvage ('single suction'). Te Toka Tumai Auckland district have highlighted that a separate suction could be considered in patients with polyhydramnios, and that a second wall suction should be available in the event of extreme bleeding or blockage of the cell salvage suction.

The research appears to show that the incidence of AFE is extremely low, regardless of whether amniotic fluid was suctioned for cell salvage ('single suction'), or suctioned away from the surgical field and then disposed of ('double suction').

The risk of AFE may be minimised by the concurrent use of a LDF, though the research is not clear on this. The risk of foetal cell alloimmunisation occurring in future pregnancies of patients who received IOCS (one study estimates this risk to be one in 436) appears to be higher than the risk of AFE in IOCS received by obstetric patients, however this can be avoided with an anti-D prophylaxis guideline.

LDFs

LDFs are currently not routinely used to filter salvaged blood in all cases of obstetric IOCS in NZ, and the local guidelines vary on whether a LDF should be routinely used in all obstetric IOCS patients.

In the UK, guidelines and surveys appear to show that LDF's are more widely used in obstetric patients, but similar to NZ, there are conflicting recommendations in the local and national guidelines.

The research suggests that Pall RC and RS filters can effectively remove cellular debris and amniotic fluid from salvaged blood; however at the time of writing, no cell salvage manufacturers have endorsed any specific LDFs for use in obstetric IOCS.

The concern that reinfusion happens much more slowly through an LDF was also reflected in the NZ local policies, with the recommendation that the obstetric surgeon and anaesthetist use their clinical judgement to decide whether to remove the LDF or keep it insitu. Specific guidance on exactly what point a LDF should be removed to speed up infusion rates could not be found in the literature.

The literature explored the incidence of LDF-induced hypotension and other adverse effects and showed that LDF-induced hypotension is rare and is able to be resolved intraoperatively, by administration of IV fluids/vasopressors, temporary removal of the LDF or ceasing reinfusion altogether. The risk of, and management of LDF induced hypotension should be clarified if a national standard were to be drafted.

Swab washing

Swab washing in obstetric IOCS does not appear to be common practice in New Zealand and overseas. As such, there are very few local and international guidelines that describe how to safely wash swabs to increase RBC return in obstetric IOCS.

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Training

There appears to be inconsistency in the IOCS training programmes within NZ, which could compromise the consistency of IOCS care that ATs provide to obstetric patients. Use of the same machine, identifying lead clinicians and creating a training pathway and recertification program which is enshrined in a national standard could improve and maintain ATs competence in using IOCS for all procedures.

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All included photos were taken by the author of this paper.

I am very happy to answer any queries via my email karen.bennett@mdhb.health.nz regarding the content of this paper and the NZ staff survey.

Karen Bennett 27/08/2024