

EBA Europheresis Group Report

Background

In September 2009 a donor death occurred in France during a plasmapheresis procedure. The cause of the death was due to the incorrect connection of anticoagulant solution to the saline line when connected to the apheresis disposable set. During the last few months, regulators, medical device suppliers and blood services have been discussing measures to be taken to reduce and, if possible, eliminate the risk of this very unfortunate incident occurring in the future.

Proposal

The safest proposal would be NOT to give replacement fluid (this does not include fluids necessary to prime the apheresis system) unless absolutely necessary for the type of procedure and clinical indication. It is recommended that all users are aware of ALL the potential risks for replacement fluids. It is critical that all users are appropriately trained and competent in the safe operation of this technology. IF replacement fluids are recommended and necessary a safe system has to be implemented which will not allow wrong and dangerous fluids to be infused instead of replacement fluids within the apheresis system during routine procedures.

The potential to cause harm to the donor/patient through infusing the wrong fluid has to be mitigated against. Consideration must also be given to ensure that the right additive fluid is added to the products (platelet additive, red cell additive). The concept of harmonization between suppliers was discussed with the conclusion reached that this may lead to organisations using devices/solutions from different companies (which is often the case), but they should not be exposed to a possibly confusing situation of having different connectors for the same fluid or the same connector for different fluids. Harmonization may also bring about cost savings in production, validation and training of staff. The idea to colour code was deemed as not being an ideal solution and can cause problems for operators and manufacturers, so other possibilities were discussed. A safe system can be achieved by using various unique connection systems, i.e. specific for AC, specific for storage solutions etc., and, naturally, the storage bags for these solutions will need to be adapted so that these bags cannot be spiked. However, in this way it will be ensured that operators cannot make any changes. Incorrect connections can be harmful for donors, but much less so for patients. The majority of misconnections, (e.g. use of saline, SAG-M, PAS in stead of AC), will be detected during the procedure by failures/alarms caused by pressure problems and the collected component will be clotted.

Since there is only one line which may be used for donor fluid replacement (this is common to all apheresis procedures) it is recommended that this line should always (and only) have a spike. It is recommended that all other solutions used (anticoagulant, additive solutions) should have an alternative form of connection (e.g. Luer) so that a spike may not be used. Pre-connected infusion/solutions may be an option, however, there are production problems associated with these and also with the procedure, e.g. if more fluid is required.

Proposal for further improvements beyond the initial changes:

While the above will ensure that solutions may only be infused into a donor/patient through a spike (and all solutions which may be infused having a corresponding port are easily available in the market), it does not solve the issue that other solutions used in the procedure may be wrongly connected. While this does not pose any risk to the donor it may affect the product.

Currently the connections available are:

1. Spike
2. Luer lock male to female and
3. Luer lock female to male.

The need for more possibilities for connecting solutions and devices is evident. This is not without problems, including the challenge to find acceptable simple alternatives and the time frame required to achieve appropriate licensing and standardization.

A suggestion to have anticlockwise Luer locks was presented, this will, however, require time to license but no specific training. It also two other connecting possibilities (M to F and F to M).

Another possibility may be to develop a software solution, but this, though interesting, may take a considerable time to implement.

Summary

1. Only give replacement fluid if strictly necessary
2. Spike to be used only for replacement fluid line, all other solutions that may be used in an apheresis procedure are connected with Luer lock (risk analysis to be submitted)
3. New connection devices to be considered
4. Other possible solutions including software enhancements to be considered.

Report prepared by the EBA Europheresis Group

15th June 2010

Johan Aerts	Fenwal
Dr Alex Aquilina (Chair)	National Blood Service of Malta
Isabelle Bartier	Haemonetics
Ruth Clayton	CaridianBCT
Christian Coffe	EFS
Catherine Howell	NHSBT
Jean Marc Payrat	Fenwal
Jane Pearson	NHSBT
Janet Sampson (Co-chair)	Welsh Blood Service
Hans Vrielink	Sanquin
Roger Wilson	CaridianBCT