

## **Quadruple Paediatric Blood Packs - Reducing Donor Exposure**

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Neonatal blood transfusion is currently "routinely " required for sick and pre-term infants in order to maintain Hb levels lost during repeated blood sampling and/or because of immaturity and poor bone marrow response to anaemia.

Prior to 1997 in WA the shelf life of paediatric multiple blood packs was limited by rising potassium levels to 14 days. New technology, including the addition of adenosine, has enabled 4 paediatric packs to be safely produced on demand in our hospital Blood Bank from single donor packs up to 7 days from collection. These quadruple packs have a markedly extended shelf life of 35 days. Once a paediatric pack is crossmatched for a neonate the packs are held for that patient's sole use.

Three years on with the new packs we reviewed our transfusion practices in relation to neonatal exposure to donor red cells:

- a. neonatal exposure to donor red cells
- b. discarded out of date units

	No. Paediatric Packs	Average Blood Donations/Month	Not X-matched and Discarded	X-matched No. Used				
				0	1	2	3	4
1996	156	52 x 3*	62	62	32	0	0	NA
2000	128	32 x 4*	49	32	14	12	9	12

\* no of paediatric packs per adult pack

Prior to 1997 it was rare for a neonate to receive a second top-up transfusion from the same donation due to the short expiry time and only 20% of packs were transfused. An audit of the first six months of 2000 showed that on average 38% of the paediatric packs were used. This may reflect in part more judicious use of blood products. However on closer inspection of the data 25% of the paediatric packs were assigned to neonates and none of the packs was utilised. This highlights a significant wastage and to review medical practice.

The effectiveness of the new paediatric packs in reducing donor exposure is confirmed by the observation that 46% of babies requiring transfusion in 2000 were spared additional donor exposure by using multiples of the original donor pack.

Prior to May 2001, all < 30 weeks gestation infants were crossmatched at birth but less than 40% were transfused with these units.

A change in transfusion policy to a group and antibody screen protocol rather than mandatory crossmatch for pre-term infants at birth has recently been implemented. We now expect to increase the paediatric pack usage rate well above the 2000 figure of 38%. This would result in a saving of approximately 8 adult donor blood units per month from this hospital alone.

# Implementation of an automated component extraction process in the processing area in ARCBS-SA

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## Introduction

A directive was given to develop a process for the implementation of an automated component extraction system into the Processing area of ARCBS-SA. This new technology would standardise processes giving a consistent product for our end users and optimising plasma yields.

The stakeholders involved were consulted and an appropriate strategy for assessing the suitability of an automated component extraction system was devised. The stakeholders decided to evaluate and validate the Terumo Automated Component Extractor system (T-ACE) for use in the processing area of ARCBS-SA.

## Method

The Production Manager after consultation with all stakeholders developed a project plan that addressed the critical elements of the evaluation and implementation process.

Evaluation commenced in January 2001.

The evaluation process involved two elements:

- Investigating the impact of introducing automation on the Processing area's workflow and productivity by consultation and structured review.
- Development of a technique to produce components meeting Council of Europe Product specifications.

## Results

- 1 Impact analysis on introducing T-ACE into Processing meant dynamic changes to the Processing work area and the workflow were needed for success of the project. This resulted in modification of the current facility to accommodate changes accompanying the introduction of automation to the workflow in the processing area. This was introduced concurrently with a comprehensive training program for staff.
- 2 Through a process of structured review a technique was developed to yield components that met Council of Europe specifications while optimising plasma yields

## Conclusion

Implementation of new technology for automated processing involved careful consideration of stakeholder's needs. Development of a detailed project plan and careful review of outcomes allowed major change to occur in Processing with minimal impact on productivity.

Implementation of T-ACE provided the following benefits;

- A more consistent component
- Optimisation of plasma yields
- Reduction in processing time
- Decrease in handling of components
- Work area modifications provide better work environment

# Evaluation of Haemonetics MCS+ Leuco-depleted Platelet Revision C.2 software at ARCBS-SA

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ARCBS-SA performed the Australian evaluation of the MCS+ Leucodepleted Platelet (LDP) Revision C.2 software incorporating the 994CF-E kits with integrated Pall filters and CPP platelet storage bags to produce leucodepleted apheresis platelets. This evaluation was in line with ARCBS National strategies of leucodepletion to provide improved customer service and to satisfy the existing clinical demand by ARCBS-SA end users. Leucodepletion provides benefits to the patient by reducing the potential for non haemolytic febrile transfusion reactions, decreasing cytokine levels, lowering the risk of infection and reducing immune suppressive effects.

The LDP Revision C.2 software and the 994CF-E kits offered the following advantages:

- reduced red cell spillage
- improved platelet count
- platelets continually filtered as they are collected
- reduced filtration rate thereby reducing white cell contamination
- air removed from the final product via an air bag
- optional control of the maximum platelet concentration and the citrate re-infusion rate (to prevent citrate toxicity reactions)
- improved bowl optics algorithm for handling lipaemic plasma to prevent red cell and buffy coat spillage
- information provided about the amount of anticoagulant in final platelet or plasma collections

Thirty platelet units are in the process of being tested for platelet concentration, leucocyte count, pH, platelet activation, presence of platelet swirling and microbial contamination. To date all results are meeting both the National ARCBS Quality Control specifications and the Council of Europe specifications. In addition, these platelet collection procedures are being evaluated for elapsed collection time and comparison between expected and actual platelet yields.

## **Automated pre-transfusion testing using the Autovue**

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Automation has an important contribution to make towards increased safety and efficiency in diagnostic laboratories. It offers increased standardization of test performance and objectivity of test results, faster specimen processing, decreased hands-on operation time, and maximizes laboratory resources.

Pre-transfusion testing was fully automated in June 2000. The Autovue system is a fully computerized, automated instrument. It is designed to perform ABO/Rh typing, antibody screens, direct antiglobulin tests, Rh phenotyping and crossmatching using column agglutination technique (CAT). Since introduction, the Autovue has improved workflow, and turn around times. Hands-on technical time to process a type and screen has been reduced by 79% when compared to tube method (9.3 minutes to 1.95 minutes). Although workloads have increased by 36% and staff is reduced by 1.5 FTE, productivity has increased by 31%. Test result reliability has been maintained along with improved test reproducibility.

The Autovue offers a greater level of sensitivity and standardization of pre-transfusion testing. There have been significant improvements in productivity and processing times, as well as reduced biohazard waste and dangers associated with handling of specimens.

## **Plasma Optimisation Strategies**

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Objectives:

The demand for plasma-derived products continues to increase, in particular, Factor VIII concentrate (AHF) and Intravenous Immunoglobulin (Intragam). Optimisation of Plasma for fractionation can be achieved either by increasing collections or maximising the plasma harvest from existing collections.

Production strategies must meet current end user demand but also form the basis for potential new initiatives such as leucodepletion and pathogen inactivation.

Methodology:

The impact of two strategies employed to increase plasma by ARCBS-NSW were analysed for their impact on plasma collection - increased plasmapheresis collections and implementation of Buffy Coat Processing using Optisystem..

Results:

Increase in plasmapheresis collections from 26 000 to 37 000 collections yielded an extra 7700 Kilograms of plasma for fractionation. Implementation of Optisystem at the main Clarence Street site for four days per week released a further 4. 660 Kilograms of plasma to the system in the first six months of operation (an increase of 8% over 1999/2000). Buffy Coat processing of Whole Blood Collections allowed production of Buffy Coat Poor Red Blood Cells and Pooled Platelets whilst permitting an average increase of 0.1 Kgs plasma to be harvested per platelet produced.

Conclusion:

Two separate plasma optimisation strategies provided increased plasma for plasma derived products. The backlog of elective surgery for patients with bleeding disorders has been completed and all requests authorised by the HAC are being supported. There is also a marked increase in Intragam available for issue - all AHMAC Category 1 indications were supported. Optisystem technology also results in standardised volumes of RBCs, Platelet Pools and Fresh Frozen Plasma.

Fresh product and plasma product drivers must be considered in tandem as well as emerging technologies when planning to meet current and future customer needs.

# The Baxter Amicus Cell Separator: The South Australian Experience

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## Introduction

The aim of this study was to evaluate the process and product quality achieved using the Baxter Amicus Cell Separator for the collection of platelets. This study was performed over 2 Phases. The aim of Phase 1 of the study was to maximise double unit collection whilst minimising collection duration. On completion of this Phase, changes to both the process and software were implemented and evaluated in Phase 2 of the study.

## Method

70 platelets were collected with the Amicus Separator in Phase 1 with a view to optimising double unit collection within a 90-minute interval. Phase 2 targeted single unit donations only, with a reduction in cycle volume from 300ml to 150ml. Apheresis staff assessed process efficiency and donor acceptance. All platelets were evaluated according to standard quality parameters, which included platelet aggregometry and activation status.

## Results

- Following completion of Phase 1 and prior to commencement of Phase 2 the following changes were implemented:
- Introduction of an automatic restart following process alarms
- Improved installation checkpoints
- Reduction of the cycle volume to maximise donor comfort.
- Resuspension of platelets in 35 ml saline prior to resuspension in plasma
- Introduction of a process tracking feature
- Addition of bar code reader and printer

Apheresis staff reported a high level of donor satisfaction and ease of operation using the Amicus Cell Separator. The availability of a barcode reader and printer significantly reduced additional documentation requirements and improved process efficiency. The citrate infusion rate could be altered independently of return speed which enabled timely response to citrate sensitivity without impact on duration of collection. Addition of saline for platelet resuspension and modification of resuspension technique resulted in easier, efficient resuspension of platelets, which was also reflected in excellent platelet yield and low platelet activation status.

## Conclusion

The Baxter Amicus Cell Separator combines donor comfort with ease of operation for the production of high quality single or double unit platelets.

# Anti-LW associated with T-Cell lymphoma.

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Occasionally, transient weakening or loss of LW antigens together with simultaneous appearance anti-LW has been noted in pregnancy or associated with Hodgkin's disease, leukaemia, sarcomas or other malignancies.

Case Report: In December 2000 a 60-year old O Rh(D) positive male was admitted with malaena and anaemia. Subsequently he developed massive ascites and liver failure. Further investigations showed the presence of a rapidly progressive anaplastic T-cell lymphoma of the duodenum and small bowel that was treated with chemotherapy. His past history included ITP, Guillian Barre Syndrome, myocardial infarct, splenectomy and in 1991 transfusion of red cells, platelets and intravenous immunoglobulins. Previous antibody screens during 1991 and 1996 were negative. Antibodies screens performed at the time of his most recent admission initially showed the presence of 'Anti-D' with a negative direct antiglobulin test (DAT). Antibody screens performed 14 days later identified Anti-LW. The DAT remained negative. His red cells typed as LW<sup>(a-b-)</sup>. The most recent DAT was weakly positive with mixed field reactions and the Anti-LW was still present.

Despite the initial negative DAT and apparent allo-anti-LW, it is more likely that this case presents suppression of the Lwa antigen rather than a genetic LW<sup>(a-b-)</sup>. This is supported by the recent weakly positive DAT.

# **A comparative multi-laboratory assessment of AHF (High Purity), Biostate and Humate factor concentrate and implications for treatment of von Willebrand's disease.**

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Five expert laboratories participated in a cross-laboratory study to co-evaluate and compare factor replacement options for von Willebrand disease (VWD). Nine factor concentrate lots (AHF (High Purity) x 3, Biostate x 3, and Humate x 3) were characterised for factor VIII activity (FVIII:C), von Willebrand factor (VWF) antigen (VWF:Ag), VWF collagen binding activity (VWF:CB), VWF Ristocetin Co-factor activity (VWF:RCo) and VWF multimers. AHF (High Purity) was found to contain approximately 25 U/mL FVIII:C (in line with the stated potency of 25 U/mL), 60-75 U/mL VWF:Ag, 30-40 U/mL VWF:CB and 40-50 U/mL VWF:RCo (thus, VWF:CB/VWF:Ag and VWF:RCo/VWF:Ag ratios of 0.5-0.7). In comparison to normal human plasma, the multimer profile of AHF (High Purity) showed some loss of high molecular weight (HMW) multimers, together with an intense low molecular weight (LMW) VWF band consistent with some reduction or proteolysis of HMW VWF. Humate was found to contain 23-32 U/mL FVIII:C (in line with the stated potencies of 25-33 U/mL), 75-105 U/mL VWF:Ag, as well as 50-90 U/mL VWF:CB and VWF:RCo (VWF:CB/VWF:Ag and VWF:RCo/VWF:Ag ratios of 0.6-1.0). The multimer profile showed some loss of the largest multimers and the intense LMW band observed with AHF (High Purity). Biostate was found to contain 40-60 U/mL FVIII:C (in line with the stated potency of 50 IU/mL), 105-170 U/mL VWF:Ag, 90-150 U/mL VWF:CB and 90-135 U/mL VWF:RCo (VWF:CB/VWF:Ag and VWF:RCo/VWF:Ag ratios of 0.7-1.1). The multimer pattern was similar to that of normal plasma and the intense LMW band observed with AHF (High Purity) and Humate was not observed.

The current study yielded inter-laboratory CVs for VWF:Ag and FVIII:C of approximately 10-15%, and for VWF:CB and VWF:RCo around 20%, significantly lower than those of previous multi-laboratory surveys. Despite the variation in test results, the defined pattern of increasing VWF:CB/VWF:Ag from AHF (High Purity) to Humate and Biostate was consistently observed in study data from each of the five laboratories.

Overall, the findings have significant clinical implications as they suggest that Biostate, which was found to be superior to AHF (High Purity) in terms of quantitative and qualitative VWF parameters, may represent the best option for replacement therapy in VWD.