Canadian Blood Services
Société canadienne du sang

Summary of Validation Study – Project Report

(netCAD-PP2-PS-003 v1.0)

***In vitro* Platelet Quality in Storage Containers Used for Pediatric Transfusions**

BACKGROUND

Pediatric platelet transfusions require smaller volumes of platelet concentrates than what is supplied by current production of CPD Platelets, Pooled LR or Platelets Apheresis, LR. Hospital blood banks remove appropriate volume aliquots from CPD Platelets, Pooled LR or Platelets Apheresis, LR (apheresis platelets) by a variety of means: gas-permeable small volume platelet storage bags, gas impermeable transfer packs or syringes to issue platelets to the ward for transfusion. The quality of the platelets following aliquoting into small volume platelet storage containers has been examined by a number of research groups and found to be a function of the length of storage and the material properties of the container. The transfusion policy in many Canadian hospitals is that aliquoted platelets must be transfused within 4 hours except where a gas permeable transfer bag and a sterile connection device are used.

On October 25th, Canadian Blood Services will standardize production processes across all Centres and discontinue the production of CP2D Platelets LR in Saskatchewan. After this time single doses of CP2D Platelets LR for pediatric use will no longer be available. CPD Platelets, Pooled LR or Platelets Apheresis, LR will be the two products supplied by Canadian Blood Services.

Canadian Blood Services has performed a study to validate the process of aliquoting from Platelets Apheresis, LR into small volume containers and to determine the product quality of the platelet aliquots at the end of storage. This information is being made

available to Canadian Blood Service's hospital customers to assist them in making their own decisions about continuing or altering their practices of preparing small volume platelet concentrates for pediatric transfusions. The full Validation Study – Project Report is available upon request from your local Canadian Blood Services Liaison Specialist.

EXPERIMENTAL METHODS

This study used single apheresis platelet units collected on either the CaridianBCT Trima or the Haemonetics MCS+ instruments using standard CBS procedures. Platelets were aliquoted into each of the following small volume containers: Fenwal 4R2014, Fenwal PL1240 and a 60 mL BD syringe on day 2, 3, 4 or 5 of storage. All apheresis platelet were stored at 20 – 24 °C in the platelet incubator (with agitation) until aliquot removal. Platelets were expressed into sterile docked transfer bag before being drawn into syringes and stored at room temperature on the bench. Platelets drawn into the PL1240 platelet packs and 4R2014 transfer bags were stored at 20 - 24 °C in the platelet incubator (with agitation). Samples aliquoted into syringes or the gas impermeable 4R2014 transfer bags were tested 4 h after aliquoting. Samples drawn into gas-permeable PL1240 transfer bags were tested on day 5 post-collection, or if aliquoted on day 5, a minimum of 4 h after aliquoting. A sample was drawn from each of the parent bags at the time of aliquoting and tested immediately (within 90 min). The effect on platelet quality of storage in the small volume containers was examined for: platelet concentration, mean platelet volume (MPV), blood gas levels and pH. The effect of oxygen availability or the lack of, on platelet metabolism was determined in the context of glucose consumption and lactate production. The sterility of the products was assessed at expiry. The expression of surface CD62 on the platelets was used as an indicator of platelet activation. The **primary endpoint** for the study was the determination whether there was a significant difference in platelet quality between the products stored in the small volume containers that are either gas-impermeable or gas-permeable, as measured at their respective expiry periods of 4 h or 5 d.

SUMMARY OF RESULTS

The data resulting from the validation study indicated the following:

- that platelet concentrations at expiry were not dependent on the age of the apheresis platelet on the day the aliquot was taken or the small volume container that was used.
- the mean platelet volume for MCS+ and Trima platelets in small volume containers were greater than or equal to the mean platelet volume for control apheresis platelet stored for 5 d.
- the CD62 levels in the small volume containers, irrespective of the day of aliquot and manufacturer, were less than or statistically equivalent to the level of CD62 expression on the control 5 d stored apheresis platelet.
- the platelet concentrates in the 4R2014 transfer bags had a higher pH than the platelets in the PL1240 transfer bags and syringes.
- the material of the syringes was gas impermeable resulting in the accumulation of CO_2 in the platelet concentrates during storage compared to the 4R2014, PL1240 and parent bags.
- the bicarbonate concentration in all of the small volume containers at the time of testing was greater than or equivalent to the bicarbonate concentration in 5 d stored apheresis platelet.
- With the exception of the syringes, the pO2 in the small volume containers at 4 h was greater than or equivalent to the pO_2 in the 5 d parent apheresis platelet.
- the glucose concentration decreased as a result of the metabolic activity of the stored platelets.
- there was no growth of bacteria in any of the small volume containers tested.

KEY FINDINGS

For the complete data set and description of the data, please refer to the Validation Study – Project Report (netCAD-PP2-Pr-002 v1.2). Data resulting from the validation study indicates the following:

1) Process of aliquoting is efficient and can maintain sterility of parent and small volume container platelets;
2) Quality of platelets in small volume containers at 4 h (non-permeable) and 5 d (gas permeable) were generally equivalent to conventional 5 d stored platelets;
3) Small volume platelets are consistent with the standards requirements for pH and sterility.

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REPORT APPROVAL RECORD

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ATTACH TO REPORT WHEN READY TO PROCEED TO APPROVAL

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