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The use of historical platelet counts from blood donors to program apheresis platelet donation: An Australian perspective

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ABSTRACT

Background: For Australian apheresis platelet donations, in-centre haematology analysers provided the platelet count used to program the platelet collection machines. When the haematology analysers were not functional, historical platelet counts from previous donations were used. This study aimed to confirm that the routine use of historical platelet counts for programming apheresis collection machines would maintain platelet yields within the donated units and that haematology analysers could be removed.

Study design: A staggered implementation for the routine use of mean historical platelet counts to program apheresis platelet collection machines was conducted. The donors' full blood counts following donation were tested centrally for comparison to the historical mean. The component yields when using on-the-day platelet counts to program platelet collection were compared with those collected using historical platelet counts. For historical platelet counts to be deemed successful, the target was for 90% of the mean historical donor platelet counts to have less than 20% variance from the on-the-day platelet count.

Results: Over 96% of the mean historical platelet counts were within 20% variance of the platelet count on the day of donation. The component yield (platelet count $x10^9$ cell/unit) before analyser removal was 273.3 ± 32.0 (n = 2639) and post-removal was 282.8 ± 38.8 (n = 2689).

Conclusion: The removal of haematology analysers from donor centres and replacement with mean historical platelet counts was successful in maintaining platelet yields. Replacement of the haematology analysers with historical platelet counts simplified regulatory compliance, reduced staff workload and costs associated with analyser registration.

1. Introduction

Platelets, also called thrombocytes, are non-nucleated cell elements which function (along with the coagulation factors) to stop bleeding by clotting blood vessel injuries [1]. Platelet units derived from blood donors can be used therapeutically for patients with bleeding disorders (e.g. thrombocytopenia) or prophylactically to prevent bleeding (e.g. during invasive procedures or chemotherapy) [2]. Based on the platelet count and total blood volume of a donor, a donation can consist of a single, double or triple platelet collection with the product stored in a volume of the donors' plasma and an anticoagulant [3]. The Australian Red Cross Blood Service (Blood Service) collects both single and double dose apheresis platelet donations using a sterile closed system automated cell separating machine [4]. There are approximately 33,000 collections per year across 42 blood donation centres.

The donors' platelet count and haematocrit or haemoglobin values are used for programming the apheresis platelet collection instruments. These values are obtained from a full blood count (FBC) test performed using haematology analysers within collection centres. However, at times when the in-centre haematology analysers were out of commission, the donors previously recorded platelet count and haematocrit values were used as an alternative. This process of using previous donor records for programming the apheresis collection machine as an alternative to using in-centre haematology analysers provided evidence that the platelet yields within the donated units were maintained. It seemed that performing platelet counts in the donor centre may not be needed and this became an area of formal investigation for process improvement.

This study was designed to assess whether using the mean of up to three historical platelet counts from a donor coupled with the capillary haemoglobin obtained on the day of donation could be used to program the platelet apheresis collection machines and maintain platelet unit specifications and yields. The acceptable target for implementation was determined to be where at least 90% of the mean historical platelet

Abbreviations: NMBS, national blood management system; FBC, full blood count

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counts had less than 20% variance from the donor's platelet count on the day of donation. This variance target was set to avoid components where there may be a reduced number of platelets to form an adequate clot. The use of historical platelet counts for programming the apheresis collection machines has been used routinely within some blood collection agencies but no previous reports on the maintenance of platelet unit yields where in site analysers were de-commissioned and replaced with the use of historical values have been published to our knowledge. Since the Blood Service has many more platelet collection donor centres than manufacturing and testing sites, centralised FBC analysis for donor samples without requiring in-centre haematology analysers was of significant value.

2. Method

2.1. Platelet component details

Platelet units are available in all ABO Rh (D) blood types and can be stored at room temperature (20–24 °C) for 5 days after collection with gentle agitation (Guide to the preparation, use and quality assurance of blood components, Council of Europe version 14, 2008). Apheresis platelet units are leucodepleted during collection and all platelets units issued by the Blood Service are irradiated. The platelet units have a 5 day shelf life after collection and can be irradiated at any stage during their storage period. Complete irradiation of all issued platelet units is conducted to remove the risk of transfusion graft versus host disease and also avoids the requirement of the hospital or pathology sites to have their own in-house irradiators.

The donation of apheresis platelets takes 60–80 minutes excluding registration, interview and refreshment time. Apheresis platelet donations can be collected from donors at 14 day intervals. Collection is based on a 13% total blood volume up to the maximum volume of 650 mL including plasma. Platelets are stored in the donors' plasma and the anticoagulant citrate dextrose solution with a final volume of 181 ± 11 mL (specification ranges from 100 to 400 mL). The platelet yield per unit is $280 \times 10^9 \pm 37$ platelets per unit (specification ranges from $> 200 \times 10^9$ to $\leq 510 \times 10^9$), the pH is 6.9 ± 0.2 (specification ranges from 6.4 to 7.4) and leucocyte counts per unit are $0.20 \times 10^6 \pm 0.11$ cells (specification requires count to be $< 1.0 \times 10^6$ cells) (all component specifications are available from www.transfusion.com.au).

The Blood Service routinely analyses a minimum of 10 platelet collections per collection site per month for quality control (QC), which equates to approximately 8% of total collections per year.

2.2. Process of platelet collection before removing haematology analysers

An acceptable haemoglobin level for donation of platelets for males is 125–185 g/L and for females is 115–165 g/L. Haemoglobin levels of the donor are checked at each blood donation via finger-prick capillary testing using the CompoLab TS (Fenwal, Fresenius Kabi, Lake Zurich, IL). The required sample in a full blood count tube for cell count analysis is obtained from the donation diversion pouch. Ethylenediaminetetraacetic acid (EDTA) blood collection tubes are used for this test sample (Becton Dickson, Franklin Lakes, NJ). The counts were tested on the COULTER® A^{c}·T diff™ Analyzer (diff 2 or 5 diff haematology analyser Beckman Coulter, Brea, CA). Apheresis platelet donations at this time were collected using a sterile closed system automated cell separating machine running software version 6.0.6 (Trima Accel®, Terumo BCT, Lakewood, CO).

To begin the apheresis platelet donation process, the previous platelet count or a default platelet count of 220×10^9 platelet/L and the donors' prior haematocrit value was used. As a minimum requirement the machines have been programmed to maintain a predicted post-donation platelet count of 100×10^9 platelets/L. Once the donors' counts were returned from the haematology analyser, the collection machine values were manually reprogrammed for the remainder of the donation procedure. If any donor was found to have aberrant full blood count results, the sample was also sent for testing at a centralised testing facility for confirmation. The platelet count, haematocrit and haemoglobin values of each donor each time they donate is recorded within their blood donation record on the national blood management systems (NBMS) database.

2.3. Process of platelet collection after the removal of the haematology analyser

In times where the in-centre haematology analysers were out of commission, historical platelet counts were used to program the apheresis collection machines. This process did not appear to alter platelet yields within the collected units and therefore in order to determine whether this could become a formally implemented process change, a staggered national implementation process was begun in June and July 2015. For this process, the apheresis collection machine was programmed using the finger-prick haemoglobin level on the day of donation to estimate the haematocrit levels and also the mean of up to three historical platelet counts over the last 2 years from each donor. The historical platelet counts were obtained by an IBM Cognos report run by the donor centre staff that is accessed using NBMS data during the interview process. The cut-off point of two years of prior platelet counts was chosen as a donor is regarded as lapsed after this time.

New donors in Australia have been required to perform one whole blood donation prior to moving into plasmapheresis or apheresis platelet donations. New apheresis donors have their FBC tubes analysed by the centralised testing facility for donor safety requirements and therefore any new platelet donors would have their historical platelet count available.

As part of the process change full blood count tubes collected from donors during each apheresis platelet donation were now being tested at the centralised testing facility using the CellDyn Ruby haematology analyser (Abbott Diagnostics, Abbott Park, IL). Thus these results would be available on NBMS for comparisons. A detailed assessment of the QC data was undertaken to ensure there were no adverse changes to platelet yields per unit by using historical platelet counts instead of on-the-day haematology analyser values.

To maintain safety for this assessment period, donors would be restricted to single platelet donation unless their recent platelet results were available and their calculated blood volume exceeded 4 litres. Any low platelet count results obtained via the centralised full blood count testing would receive urgent follow-up of the donor via a standardised approach.

2.4. Other changes implemented at the same time as the removal of the haematology analysers

The following concurrent strategies were implemented at a similar time where historical platelet counts were used for programming apheresis platelet collection machines. In order to reduce the risk of transfusion related lung injury (TRALI), the Blood Service moved to a male predominant panel. HLA matched donations may still be made by females. Male donors tend to have a larger blood volume and donors with higher platelet counts (greater than 220×10^9 cells/L) are preferred to maximise platelet collection targets.

2.5. Assessment period

The assessment of the QC data was chosen to ensure that it fell outside of the time that the national implementation of the removal of haematology analysers was being conducted. Haematology analysers were removed between June and July 2015 at the donor centres. The intent was to investigate the effect of the change and exclude temporary impacts around the change. QC data on platelet yields for a 6 month