

## **Retrospective Study on the Quality Monitoring Procedure of Blood Components in Newly Established Manufacturing Facility at the Department of Transfusion Medicine, University Hospital, General Sir John Kotelawala Defence University**

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### **Abstract**

Transfusion service must adhere to the strict quality assurance program to ensure minimal to zero risk to the recipient and optimal therapeutic efficacy. Study is planned to assess a selected internal quality monitoring parameters of blood components produced at University Hospital, Kotelawala Defence University . The samples from all components collected and processed from March 2022 to April 2023 were tested and analyzed for Transfusion Transmitted Infection (TTI) markers. According to international standards four units of each component were selected by simple random sampling for internal quality parameters. The samples were obtained from each unit according to standard procedure and tested for specific quality parameters. Number of discard units was calculated according to the component type. 1477 Red Cell Concentrates (RCC), 1291 fresh frozen plasma and 1036 platelet concentrates have been produced. Thirteen (0.88%) unit samples were TTI screening reactive. Mean packed red cell volume was 291 ml and haemoglobin per unit was 65 g/unit. Mean haematocrit was 68% and pH was 6.9. Mean volume and count in platelet concentrates were 69 ml and  $74 \times 10^9$ /unit respectively. White cell contamination was  $0.02 \times 10^9$  /unit. Swirling was present in all units. Produced components met  $\geq 75\%$  of minimum standards according to the international guidelines. 27.9% of RCC supply deficit was detected. Total RCC discard was 1.28%. Implementation of standard operating procedures and validation of the instruments and techniques have been successful according to the findings. The study ensures the quality and safety of blood components as a therapeutic product.

**Keywords:** *Blood components, Internal quality control, Quality assurance*