VALIDATION AND IMPLEMENTATION OF THE INTERCEPT BLOOD SYSTEM FOR PLATELETS FOR PATHOGEN INACTIVATION OF APHERESIS AND BUFFY-COAT PRODUCTS AT ONE OF THE BIGGEST REGIONAL BLOOD-CENTERS OF SWITZERLAND

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Background: The INTERCEPT^{TM} Blood System for platelets (plts) is CE marked since 2002 and has been approved by Swissmedic in 2009. The Swiss Red Cross has decided to introduce pathogen inactivation with the INTERCEPT System in its centers. The blood transfusion service Zurich is one of the first centers in Switzerland to validate the technology for introducing it into routine production. To ensure highest degree of effectiveness of the pathogen inactivation process the input products have to meet certain guard bands. Also, a platelet product has to fulfill additional pre-conditions to meet Swiss regulations.

Aims: The objective of this validation program was to study existing production steps and potentially required optimizations for platelet concentrates (PC) from Buffy-Coats (BC) or apheresis in order to meet both sets of requirements. It included also the thorough analysis of the end-products in terms of volume, platelet dose and amount of contaminating cells.

Methods: Buffy Coats were produced from whole blood (450mL) using MacoPress Classic Separators. To get 1 PCBC, 5 ABO/Rh-matched BCs were pooled with SSP^{+} as additive solution (PAS). Apheresis PCs were produced using the Amicus or Trima device with InterSol as PAS. 13 PC were evaluated before and after INTERCEPT treatment with either the small volume (SV) or the large volume (LV) disposable set. Volume, platelet content and loss, residual white blood cells (WBC), erythrocytes (RBC) as well as residual amotosalen were determined.

Results: For PCBC (n=7) the mean platelet dose before INTERCEPT was $4.0x10^{11}$ (range 2.9-5.0) in 327mL (range 297-347) of 37-39% plasma with SSP^{+}. Residual RBC were $0.9\text{-}2.6x10^{6}$/mL and residual WBC at $0.044\text{-}0.099\ x10^{6}$/unit. After treatment mean platelet dose was $3.7x10^{11}$ (range 2.7-4.5) in 315mL (range 286-333) and residual RBC were at $0.30\text{-}0.73x10^{9}$/unit and WBC at $0.016\text{-}0.137x10^{6}$/unit. Average production-losses were 12mL (range 7-17mL) and the mean plts loss was 7.8% (range 4.2 -10.7%).

For apheresis products (n=6), the mean platelet dose was $3.1x10^{11}$ (range 2.6-3.8) in 284mL (range 277-289) of 33-38% plasma with InterSol. RBC were at $0.4\text{-}1.0x10^{6}$/mL and WBC at $0.014\text{-}0.210x10^{6}$/unit. After treatment the mean platelet dose was $2.9x10^{11}$ (range 2.4-3.3) in 268mL (range 257-279) with $0.07\text{-}0.23x10^{9}$/unit of residual RBC and $0.000\text{-}0.154x10^{6}$/unit WBC. Production-losses were 9-20mL with a mean plt loss of 9.2% (range 6.3-14.0).

Values for residual amotosalen after adsorption in the compound adsorption device (CAD) were in the range of 0.19-0.52µM, independent of the disposable set used (SV with a CAD time of 4 -16 hours, LV disposable set with a CAD time of 6-16 hours).

Summary/Conclusions: All BC and apheresis products met the guard bands for the INTERCEPT process with the SV or the LV disposable set. All pathogen inactivated products (apheresis and BC) were in compliance with the Swiss specifications ($\geq 2.4x10^{11}$plts/unit, $<5x10^{9}$ RBC/unit and $<1x10^{6}$ WBC/unit). Residual amotosalen was quite below the threshold of 2µM. Production-losses were within the expected range. Implementation of the INTERCEPT technology was easy and our validation study was positive for all parameters measured. Production for routine use started successfully in January 2011.