

## **An Active Haemovigilance Programme to Assess the Safety Outcome for 18,641 Platelet Components Transfused in Multiple European Clinical Sites**

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**Background:** Inactivation of pathogens and leukocytes in platelet components using INTERCEPT Blood System™ continues to expand in routine use across many European blood centres. To capture safety data related to transfusion outcome for INTERCEPT platelets (I-PLT) products in clinical use, we established an active haemovigilance (HV) programme that has now been in use for more than 5 years.

**Aims:** To summarize transfusion outcomes with respect to safety for 18,641 I-PLT transfusions administered to 3,851 patients at 21 different sites in 11 European countries under routine clinical practice.

**Methods:** To capture safety data comprehensively, investigators using I-PLT components completed a standardized web-based data form following each transfusion regardless of outcome. The transfused products consisted of either apheresis or pooled buffy-coat platelet components treated with the INTERCEPT Blood System, and stored for up to 7 days. The primary outcome measures were the occurrence of acute transfusion reactions (ATR) within the 24 hour period after each I-PLT transfusion or serious adverse events (SAE) within 7 days of each I-PLT transfusion. An ATR was defined as an AE possibly related, probably related, or related to the transfusion. Investigators recorded: patient demographics, primary diagnosis and therapy, and type of platelet product. For AEs, the following data were collected: time of event following transfusion, clinical description, objective clinical parameters (vital signs), results from clinical and laboratory tests (radiographs, bacterial cultures), severity (grade 0-4), serious or non-serious nature, and causal relationship (unrelated, probably unrelated, possibly related, probably related, or related).

**Results:** To date, 18,641 I-PLT transfusions (66% apheresis, 34% pooled buffy-coat) administered to 3,851 patients have been reported. Sixty percent of the patients were male. Approximately 51% (1,979 /3,851) received I-PLT transfusion for haematological disorders, 18% (699/3,851) for surgery, and remaining 31% (1,184/3,851) for general medical indications. The majority of transfusions were administered in non-intensive in-patient care, 28% were administered in an intensive care unit and 6% in out-patient care. The mean number of platelet transfusions per patient was 5.5 (range 1-156).

A total of 181 AEs in 136 patients were reported: 19 AEs occurring in 18 patients were classified as an SAE. Among the 181 total AEs reported, 125 events in 94 patients were classified as ATRs, representing a per-transfusion ATR rate of 0.67% (125 of 18,641) and a per-patient ATR rate of 3.5% (94 of 3,851). Most reactions were of grade 1 severity and representative of the events expected with conventional PLT transfusion. The most frequently reported events were chills, itching, and urticaria. No cases of TRALI, TA-GVHD, transfusion-related sepsis, or death due to an I-PLT transfusion were reported. One SAE (transient hypotension) was judged by the transfusing physician to be possibly related to I-PLT transfusion.

**Conclusions:** Adverse events following I-PLT transfusions were infrequent, mild in severity, and typical of the events expected with conventional PLT transfusion. The use of a comprehensive web-based active HV programme to capture ongoing safety outcome information for each transfusion is a valuable tool to characterize the clinical experience and safety profile of platelet transfusion.