PATHOGEN INACTIVATION OF PLASMA WITH THE INTERCEPT BLOOD SYSTEM – EXPERIENCES FROM ROUTINE PRODUCTION –

Blood Transfusion Service Zurich, Swiss Red Cross, Switzerland

Introduction
Blood Transfusion Service Zurich is the first Swiss centre that established the INTERCEPT® Blood System to manufacture pathogen inactivated plasma (Pi-FFP). We introduced Pi-FFP in 2014 because of its safety profile and the possibility to cease quarantine storage. This work investigates how well the 2 main challenges in routine production were handled: freezing in time and minimizing plasma loss. To fulfil Swiss regulations, Pi-FFP must be frozen within 20h after donation. This de facto means, Pi-FFP should be ready for freezing within 18.5h since loading the freezer takes up to 0.5h and freezing another 1h. Concerning plasma loss, the challenge is that plasma for INTERCEPT treatment should meet the narrow range of 630-650 mL. At least 630 mL are necessary to use full production capacity of the INTERCEPT set (i.e. 3 Pi-FFPs). Hence, recovered plasma has to be pooled. On the other hand, 650 mL are the set’s upper limit. Excess plasma is discarded (Fig. 1). Therefore, proper pooling of recovered plasma is important (Fig. 2). In case of source plasma, units with optimal volumes can be generated by plasmapheresis.

Methods
Data from December 2016 to May 2017 were analysed. Pi-FFPs were produced from recovered plasma or from source plasma (Blood groups AB and B only). Leukodepleted source plasma was directly sterile connected to the INTERCEPT processing set. In case of recovered plasma, 5 or 6 unfiltered units were manually pooled, filtered and split with a dedicated set (Fig. 2). Each split was then connected to an INTERCEPT set. If only 3 units were available, they were pooled and filtered but not split. Usually, whole blood was either separated on the day of collection (day 0) and plasma was stored overnight (o/n) for pooling and pathogen inactivation on day 1 or WB was stored o/n and separation, pooling and inactivation were done on day 1 (Tab. 1). Following parameters were assessed: Time until ready for freezing, plasma loss because of exceeding the 18.5h limit or missing the 630-650 mL range, and Factor VIII content based on routine QC data.

Results
3,300 Pi-FFPs were successfully made from recovered plasma (86% pools of 5) and 327 from source plasma. 5 failed meeting the 18.5h limit. Range of time to freezing was 3.1-11.7 h for source plasma frozen on day 0 (54% of source plasma) and 13.9-18.3 h if frozen on day 1 (Fig. 3). Range of time for recovered plasma frozen on day 0 (1%) was 7.4-13.1 h and 14.4-18.5 h if frozen on day 1 (99%, Fig. 4). No plasma was lost because of coming under 630 mL. Loss due to exceeding 650 mL was 1.6% of total plasma pooled (pools of 3: 12.8% loss; pools of 5: 0.5%; pools of 6: 11.3%); filtration loss not included). Factor VIII specification (≥ 0.5 IU/mL) was met at 100%.

Conclusions
Meeting the limit of 20h from donation until end of freezing is not a problem in routine. Hence, INTERCEPT allows reducing manufacturing time of FFP from ≥4 months to <1 day compared to quarantine storage. This tremendously increases the possibility to react on fluctuations in demand. Plasma loss can be minimized by generating as many pools of 5 as possible since their splits are closest to 650 mL.