

# HAEMAPHERESIS VIGILANCE: DEVELOPMENT OF A NATION-WIDE, INTERNET-BASED SYSTEM TO ASSESS DONOR AND APHERESIS COMPLICATIONS DURING OR AFTER CELL SEPARATOR PROCEDURES

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## Purpose

To assess donor- and/or apheresis-complications related to preparative cell separation procedures: a simple, safe, and effective nation-wide Internet-based system is being developed: <http://haemovigilance.de>

## Methods

All complications (e. g. venous access and circulation problems, citrate toxicity, donor compliance and some technical complications), shall be assessed with respect to preparative plasmapheresis, platelet apheresis, leukapheresis (blood stem cells, granulocytes, monocytes), red cell apheresis and multicomponent apheresis from healthy donors. The complications will be graded according to the European Haemovigilance Network Standards. To avoid operator-specific interindividual variability the grading will be based on the operator's interventions rather than on the operator's subjective estimation of the severity of the complication. An automatic evaluation program will allow comparing the centre-specific complication rate with corresponding rates of other centres from the same institution as well as with a national benchmark.

## Results and Discussion

Currently, a system is planned that mainly consists of two Internet assessment masks: one page for entering donor, procedure and cell separator-related data (Fig. 1). In particular, this mask offers clickable submenus (e.g. for preparative plasmapheresis, plateletpheresis, stem cell apheresis, granulocyte apheresis etc) to assess technical characteristics that are typical for a specific apheresis procedure.

The second page is designed for collecting specific information about the complication and its severity (Fig. 2a / 2b). The upper part of this mask records discontinuations and the consequences of this event for the donor (e.g. red cell losses), the set and product logistics (e. g. available products despite discontinuation; Fig. 2a). The middle and lower part of this page include clickable submenus that summarize specific complications (e. g. venous access problems, citrate toxicity, circulation reactions, donor compliance) and assess the severity of the complication by an underlying automatic algorithm that combines donor symptoms and medical staff interventions to control the complication (Fig. 2b).

These masks are supported by an entry-control and by an automated evaluation system that is visible for center related authorized personell only. All complication data are evaluated on a center specific base and against institution specific or nation-wide benchmarks.

Two modes are available to enter the data: a "draft" mode to record and modify data as long as data need control, are unclear or incomplete, and a "final" mode to control and confirm the data by an authorised person after clarification or completion of the draft data. The system is aimed to admit each complication within less than two minutes in the "draft" mode. Final data can only be modified by persons with an institution-specific administrator status. The system is likely to start as a test system by November, 2010 and will probably be in full operation by March, 2011. The system is supported by a grant from the German Society for Transfusion Medicine and Immunohaematology (DGTI).

## Conclusions

This Internet based platform provides a simple, safe and useful tool to assess and to evaluate all relevant complications associated with preparative haemapheresis procedures on a center-specific, institution-specific, nation-wide or even European base.

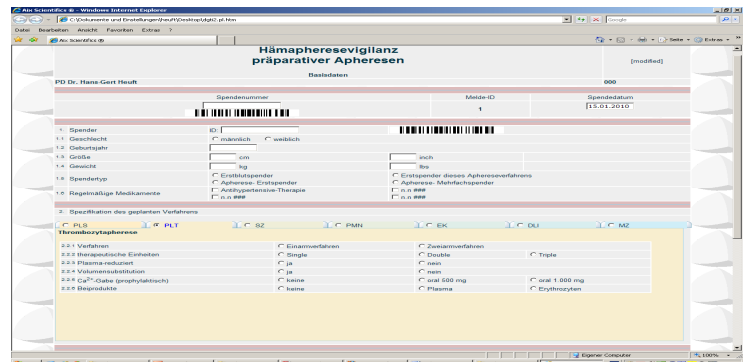


Figure 1 Donor and Procedure related Data (e.g. Plateletapheresis)

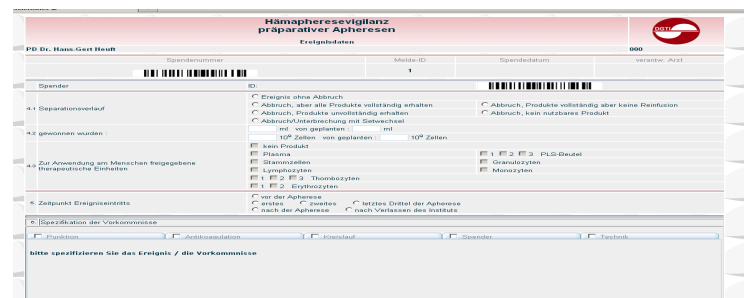


Figure 2a Complication related Data (Discontinuations)

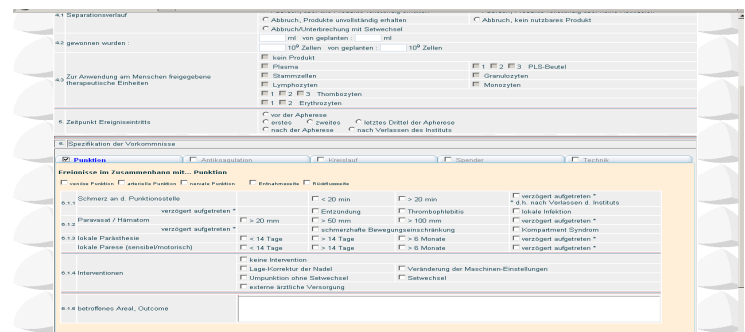


Figure 2b Assessment of specific Complications (e.g. Venous Access Problems)