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DEVELOPMENT OF AN INTERNET-BASED SYSTEM TO ASSESS DONATION-RELATED COMPLICATIONS

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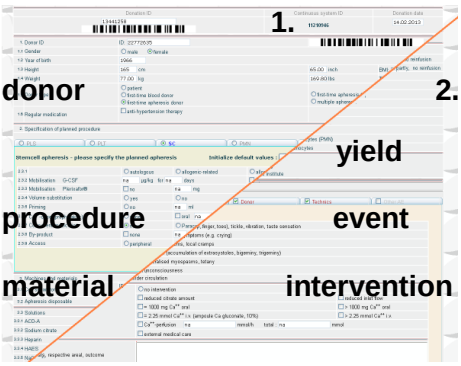
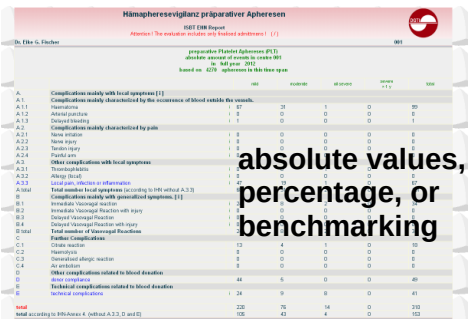
Haemovigilance needs to be based on comparable trustworthy data. To document and evaluate complications related to blood donations, a simple, quick, and safe Internet-based remote data capture system has been established: **http://haemovigilance.eu**



To document an adverse event simply two HTML pages have to be filled in. On the first page, data regarding the donor and the proposed procedure are asked, on the second, data regarding the complication itself and medical interventions performed are asked. As blood donation procedures are usually standardised, corresponding default profiles can be established by the local administrator. The default profiles include establishment of local lists of devices, disposables and solutions to reduce data entry efforts and to minimise errors.

Complications are automatically evaluated according the Standards of the International Haemovigilance Network. To avoid operator-specific variability the severity grading is based on the operator's interventions rather than on the operator's subjective estimation. The program allows benchmarking of local complication rates by comparing to the rates of all other participating centres. The haemovigilance.eu system is multilingual and expandable to future needs.



	22.5.2012	31.12.2012
Puncture	677	2533
Anticoagulation	164	744
Circulation	107	508
Donor	275	727
Technics	165	453
Missing	26	64
total	1414	**5029**
# Admissions	1303	**4630**

(multiple designations possible)
(5029-64)/(4630-64) = 1.087
i.e. about one in eleven

Since February of 2012 donation-related complications are recorded in the scope of a Haemapheresis Vigilance study for a duration of five years [ClinicalTrials.gov : NCT01576237]. Within the first year about 200 operators from 20 centres in three countries reported about 5000 complications. Currently about 20 complications are reported per day. Based on all aphereses performed, the current proportion of serious reactions is 1.8%.

We report here a multilingual Internet-based system that ensures stable, safe and rapid assessment and evaluation of donation-related complications. It guarantees standardised evaluation and thus international comparability.

The haemovigilance.eu system is open for participation of additional transfusion centres in Europe.

The haemovigilance.eu system is based on good experiences with the eCRF.[de] used in various international clinical trials. Within the next few months it will be translated into further languages and apart of haemapheresis procedures it will be used also for full blood donations.

Based on the amount of foreign data it will allow benchmarking to all other participating centres.