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Editorial

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Hemovigilance

Behrouz Mansouri Taleghani[a] Hans-Gert Heuft[b]

[a] Institut für Klinische Immunologie und Transfusionsmedizin, Zentrum für Transfusionsmedizin und Hämotherapie, Universitätsklinikum Gießen und Marburg, Gießen,
[b] Institut für Transfusionsmedizin, Medizinische Hochschule Hannover, Germany

According to the International Haemovigilance Network, the definition of hemovigilance may be 'a set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence' [1].

Triggered by the tragic experience with transfusion-transmitted AIDS more than 30 years ago, historically the national hemovigilance programs were primarily driven by and focused on blood product safety and normally included infectious and other major hazards of transfusion. Meanwhile many national laws often mandatorily require a standardized reporting to a competent authority – e.g. in Germany to the 'Paul-Ehrlich-Institute' and in Switzerland to the 'Swissmedic'. The Swiss 'Federal Law on Therapeutic Products' was set in force in 2002 and further requires that 'institutions transfusing blood components implement a quality assurance system for their application'. The latter aspect opens to an even broader scope and reflects the current movement from the initial emphasis on product safety towards 'optimal blood use' overlapping with a smooth transition to the concept of 'patient blood management' which will be in focus in one of our next issues. Hemovigilance may be interpreted as the 'check' step of the PDCA cycle (plan – do – check – act or plan – do – check – adjust), which is an iterative four-step management method used for the control and continuous improvement of processes and products [2]. With this additional angle of view particularly clinical studies in the context of safety, quality, and efficiency of blood transfusion may be seen as an integration and translation of hemovigilance, blood transfusion, and PDCA cycles in scientific concepts of clinical studies in order to improve 'processes and products'.

The present issue of Transfusion Medicine and Hemotherapy includes some examples, how this concept was used for different links of the transfusion chain. Jimenez-Marco et al. [3] for example report about a promising approach to improve reliable and quick availability of male fresh frozen plasma (FFP) by treating the donated plasma with a pathogen reduction method instead of using quarantine storage of FFP. They particularly describe an improved procurement with male FFP as prerequisite for the maximized implementation of their TRALI prevention strategy. Two further groups have focused on transfusion efficacy of gamma-irradiated platelet concentrates (PCs) [4, 5]. The authors of the smaller but prospectively conducted study summarize that, within the two groups (2 × 20 transfusions / 40 patients), they found that 'hemostatic function, transfusion efficacy, bleeding, and safety of single-donor apheresis PCs treated with gamma irradiation versus untreated control PCs are comparable' [4]. This may be due to the small size of the study, because they describe an observed difference of corrected count increment at 1 and 24 h in the order of 10% and also since the second paper looking at 1,000 platelet transfusions to 144 children strongly supports that apheresis platelet concentrates 'should not be irradiated in advance, i.e. ≥24 h before transfusion' [5]. Finally there is a report about the effects of the introduction of a guideline on red blood cell transfusion for elective orthopedic surgery. The authors conclude that the 'introduction of a simple transfusion guideline reduces and standardizes the use of RBCs by decreasing the hemoglobin transfusion trigger, without negative effects on the patient outcome' [6].

Taken together these publications nicely show the facets of the holistic concept of hemovigilance starting from improving product safety and quality to product effectiveness up to optimal blood use as a part of patient blood management.

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Dr. Behrouz Mansouri Taleghani
Klinik und Poliklinik für Hämatologie und Hämatologisches Zentrallabor
Inselspital
3010 Bern, Switzerland
Behrouz.MansouriTaleghani@insel.ch

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