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## HAEMOVIGILANCE IN FRANCE: CONTRIBUTION TO THE IMPROVEMENT OF TRANSFUSION PROCESS AND PRACTICE

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**Background:** Since haemovigilance has been implemented in France, ten years ago, more than 80 000 notifications of transfusion incidents were recorded in a national database managed by the French Agency for the Safety of Health Products (Afssaps). The overall traceability of the 2.5 millions of labile blood products (LBP) annually produced reached 80% in 1997 and more than 99% since 2004. The aim of this communication is to demonstrate how haemovigilance data are used in France to propose and evaluate corrective and preventive measures.

**Aims:** Three transfusion related events were identified by the French haemovigilance network as major concerns in term of life-threatening incidents: ABO incompatible transfusion, transfusion transmitted bacterial infection (TTI) and excessive volume overload. Workshops and peer-to-peer reviews were conducted and guidelines or ministerial instructions were published. Effectiveness of the measures taken was assessed through the mandatory notification of all transfusion incidents.

**Methods:** ABO reports are related to incorrect blood component transfused (IBCT) incidents where a patient receives blood intended for someone else. Cumulative errors within hospital wards are constantly observed. The Ministry of Health published in December 2003 instructions for carrying out pre-transfusion checks in hospitals, as well as specific recommendations for the assessment of bedside test devices. Hospitals haemovigilance officers investigate all ABO incidents and promote corrective measures such as evaluation of transfusion practices, training of nurses and physicians, reorganization of LBP flow, etc. Moreover, notification of IBCT events without adverse effect on the recipient is mandatory since October 2002. In order to prevent transmission of bacteria, all blood products are leucodepleted since 1998; diversion of the first 30 ml of the donation and modification of cleansing of donors' arm were introduced in the French blood transfusion service (EFS) guidelines in 2000. In 2003, a ministerial order modified the instructions for clinical and biological exploration of TTI. Excessive volume overload is a consequence of bad practices in hospitals and represents in France the first cause of transfusion related deaths. Appropriate training of all clinical staff was promoted.

**Results:** Notifications of ABO incompatible transfusions decrease regularly (36 case reports in 1999, 10 in 2004). Transfusion transmitted bacterial infection case reports also decrease: 57 in 1996, 20 in 2000 and 10 in 2004. On the other hand, no significant effect is perceived on the excessive volume overload events. The haemovigilance network notified 16 deaths since 2000 and 183 incidents per year (1 for 13580 LBP, CI95% [11588.7; 15336.3]).

**Conclusions:** These results confirm the role of haemovigilance and allow Afssaps to define new objectives for improving blood transfusion safety. Special attention should be aimed at promoting training and respect of clinical good practices by physicians and nurses in order to avoid excessive volume overload. Individualization of TRALI as incident to be notified is recently set up in France (2002) and a guideline will be published soon. Concerning TTI prevention, methods of bacterial inactivation of LBP are introduced in the production process. The French haemovigilance network must maintain a high level of efficiency to evaluate these new measures.