**BACKGROUND**

The French haemovigilance (HV) system is organised by the ANSM (former Afssaps), French Competent Authority for health products, in a network (Figure 1) integrating different levels: national (French national blood service (EFS), Army blood centre (CTSA)), regional (regional coordinators (RHC) and HV correspondents (HvC) of regional blood establishments) and local levels (HV correspondents (HvC) of hospitals and clinics and sites of blood establishments).

The epidemiological follow-up of blood donors is carried out by the French institute for public health surveillance (InVS).

**PURPOSE**

The quality of the data used as indicators is essential. In order to help the harmonization of the HV reports, a common approach was developed at the national level: definitions, "guidelines" and factsheets which have been written by national expert working groups from the ANSM and disseminated following a period of public survey.

HV in France is based on (i) a compulsory and standarized reporting, (ii) a network structure, (iii) a standard reporting form (Figure 2) created to harmonize and facilitate the reporting.

Each notification is classified according to the diagnosis, severity and imputability to transfusion or donation.

**SUMMARY**

The factsheets and guidelines have, since their elaboration, permitted to the reporters to take into account the pathophysiological approach for the transfusion reactions, occurred both in the blood donors and in the recipients of blood components.

The complementary notification forms, included Root cause analysis form, were used to refine the analysis of adverse reactions and also analysis of processes in all the steps of the transfusion chain.

These documents are intended to be updated in the light of scientific and technical progress.

Authors are acknowledging all the members of the HV network for their continuous involvement and their prompt and efficient cooperation.

**Figure 1. French haemovigilance network**

**Figure 2. Model of content of the common approach: example of TACO**

**Figure 3. Main recipient AR factsheets**

**Figure 4. Recipient AR complementary notification form**

**Figure 5. Model of Root cause analysis as complementary notification form**