HOW TO IMPROVE THE QUALITY OF THE TRANSFUSION CHAIN: FACTSHEETS AND "GUIDELINES" AVAILABLE AND USED BY THE FRENCH HAEMOVIGILANCE NETWORK

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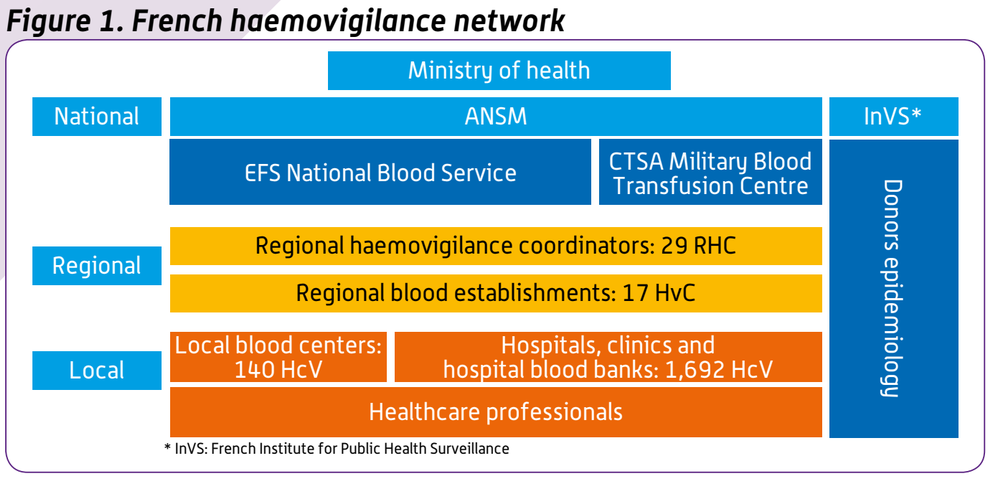
BACKGROUND

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).

Figure 1. French haemovigilance network



From 1994 to 1998, reporting was made in paper form sent by fax. And in a 2nd time *via* the 1st generation of national HV database, called GIFIT.

In 2003, the ANSM has developed an IT system for reporting, called e-FIT to improve collection, supervision and evaluation of the HV reports. This system was available for the HV network in 2004 and it was accompanied by successive factsheets and guidelines.

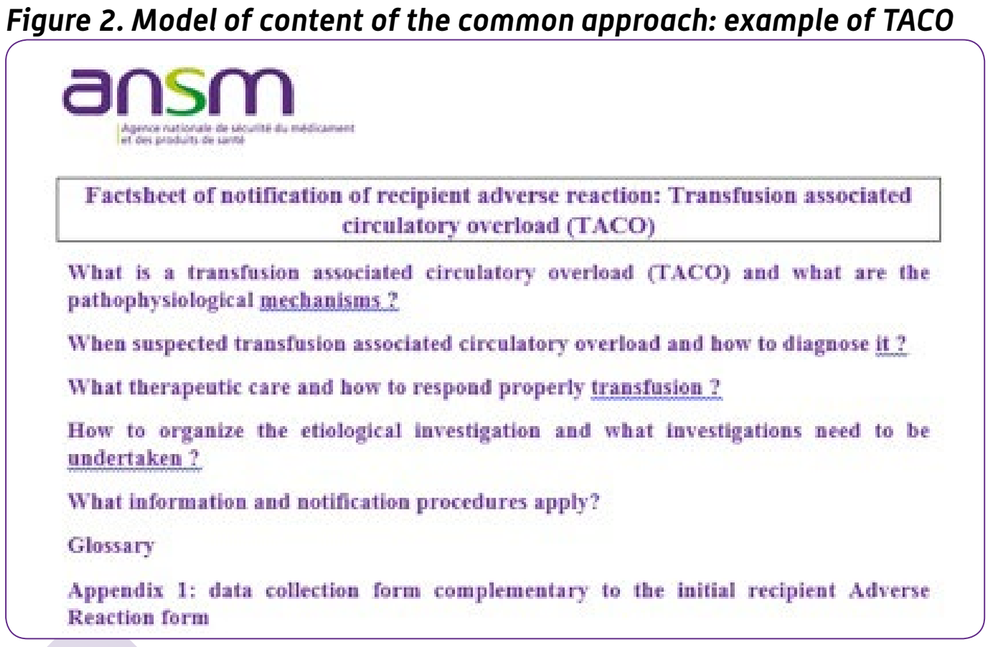
PURPOSE

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.

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


Factsheet of notification of recipient adverse reaction: Transfusion associated circulatory overload (TACO)

What is a transfusion associated circulatory overload (TACO) and what are the pathophysiological mechanisms ?

When suspected transfusion associated circulatory overload and how to diagnose it ?

What therapeutic care and how to respond properly transfusion ?

How to organize the etiological investigation and what investigations need to be undertaken ?

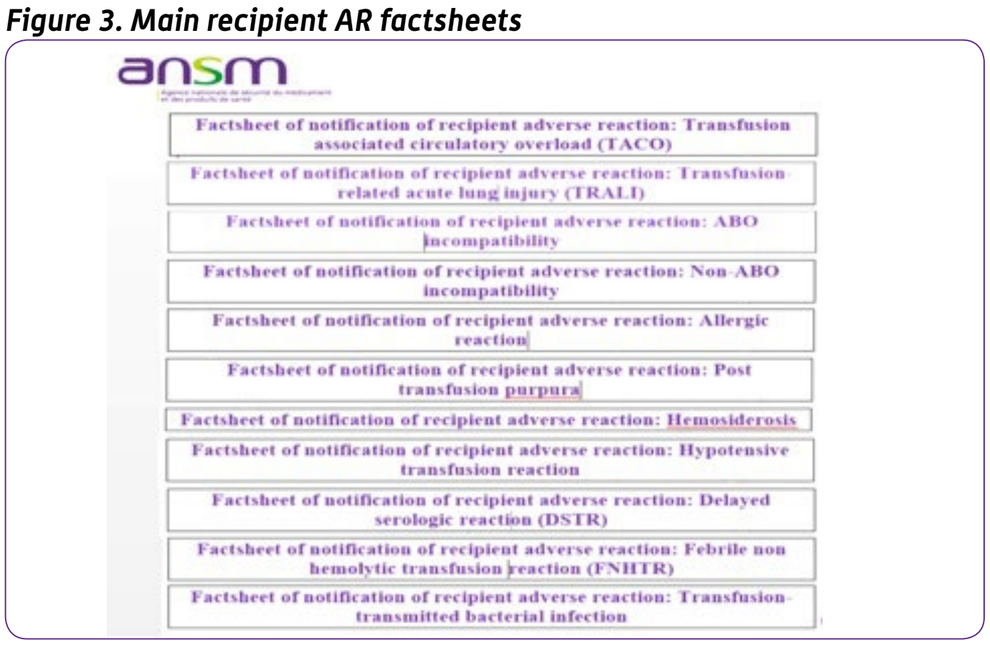
What information and notification procedures apply?

Glossary

Appendix 1: data collection form complementary to the initial recipient Adverse Reaction form

The main Factsheets are related to recipient ARs (Figure 3). Transfusion-transmitted bacterial infection (TTBI) which was the first implemented permitting the TTBI surveillance to reduce the TTBI's occurency.

Figure 3. Main recipient AR factsheets


Factsheet of notification of recipient adverse reaction: Transfusion associated circulatory overload (TACO)

Factsheet of notification of recipient adverse reaction: Transfusion related acute lung injury (TRALI)

Factsheet of notification of recipient adverse reaction: ABO incompatibility

Factsheet of notification of recipient adverse reaction: Non-ABO incompatibility

Factsheet of notification of recipient adverse reaction: Allergic reaction

Factsheet of notification of recipient adverse reaction: Post transfusion purpura

Factsheet of notification of recipient adverse reaction: Hemosiderosis

Factsheet of notification of recipient adverse reaction: Hypotensive transfusion reaction

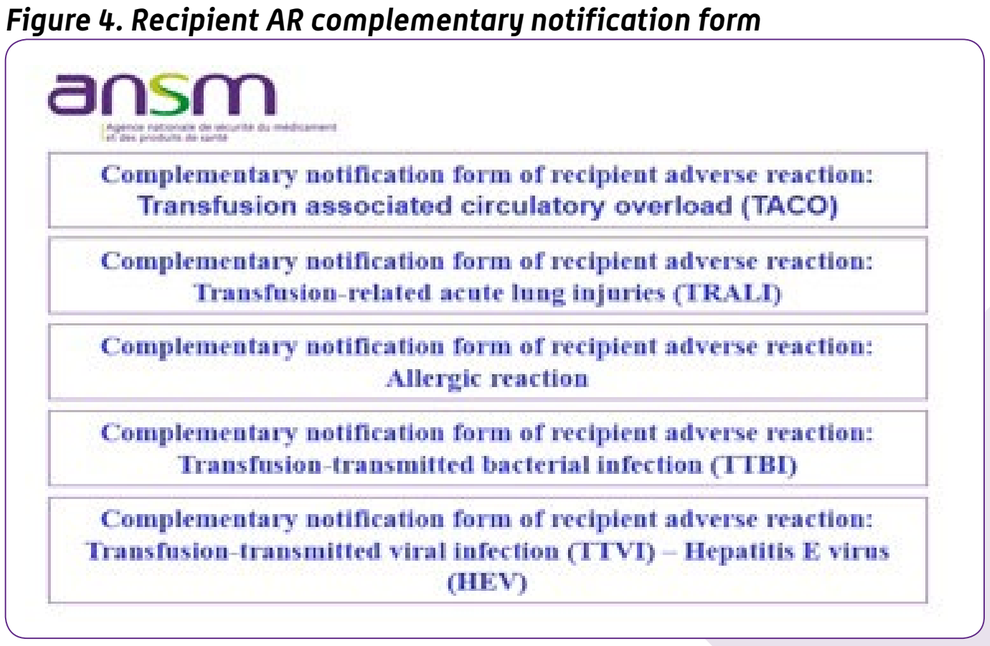
Factsheet of notification of recipient adverse reaction: Delayed serologic reaction (DSTR)

Factsheet of notification of recipient adverse reaction: Febrile non hemolytic transfusion reaction (FNHTR)

Factsheet of notification of recipient adverse reaction: Transfusion-transmitted bacterial infection

Furthermore, specific complementary notification forms are available. The last one elaborated was the form concerning HEV (2014). (Figure 4).

Figure 4. Recipient AR complementary notification form


Complementary notification form of recipient adverse reaction: Transfusion associated circulatory overload (TACO)

Complementary notification form of recipient adverse reaction: Transfusion-related acute lung injuries (TRALI)

Complementary notification form of recipient adverse reaction: Allergic reaction

Complementary notification form of recipient adverse reaction: Transfusion-transmitted bacterial infection (TTBI)

Complementary notification form of recipient adverse reaction: Transfusion-transmitted viral infection (TTVI) – Hepatitis E virus (HEV)

Recently, the documentation concerning Donors HV was developed (Citrate reaction and Major cardiovascular event (MCE)).

Moreover, the root cause analysis document was made available to the network in 2010. (Figure 5).

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


Report ID

ROOT CAUSE ANALYSIS OF EVENTS
INFORMATION DOCUMENT

Cette partie est destinée à expliciter ce qui est attendu de l'analyse systémique d'un événement indésirable grave (ou incident). Elle n'est pas à joindre au document d'analyse si celui-ci est versé au dossier d'une déclaration réglementaire.

Quels événements analyser ?

Les événements à analyser en priorité seront les événements indésirables graves ou potentiellement graves, les incidents ou les accidents évités de justesse (near missed incidents), ou encore les événements à faible pouvoir décisif pouvant servir d'exemple. De même, lorsqu'un événement est fréquent (usuel), il pourra faire l'objet d'une analyse systémique même s'il n'est pas considéré comme grave.

Des défaillances actives :

Le premier objectif de l'analyse approfondie d'un événement est d'étudier le contexte et les conditions de survenue, et à rechercher l'existence de défaillances actives, résultant le plus souvent d'erreurs de professionnels de santé ou d'équipe. Ces erreurs humaines peuvent être intentionnelles ou non. Les plus fréquentes font suite à une omission ou à un acte mal réalisé, sans intention de nuire.

Action non intentionnelle
- Défaillance attentionnelle : intrusion, omission, inversion, désordre, contre - temps
- Défaillance de la mémoire : omission d'actions planifiées, perte de lieu, oubli, oubli d'intention

Action intentionnelle
- Faute : mauvaise application d'une règle, application d'une mauvaise règle, faute basée sur des connaissances déclaratives erronées
- Violation : exceptionnelle ou routinière
- actes de sabotage

Dynamique de survenue d'un incident
Causes (facteurs)

SUMMARY

The factsheets and guidelines have, since their elaboration, permits 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.