Ensuring the trail in blood supply,

0018/NA/2006-1/ÖP/5

2011. March

Supported by a grant from Norway through the
Norwegian Financial Mechanism

Operative Project Management:
Dr. Miskovits Eszter,
Pájer Péter
Dr. Baróti-Tóth Klára,
Dr. Nagy Sándor,
Szász Gergely,

Tartalomjegyzék

1. Introduction

A safe blood transfusion (treatment with blood) primary application of the principle not to harm the patient! In practice, the XX. beginning of the century there was not applied any transfusion, because many adverse events, complications, death was occured several times during or after the transfusion.

At present the physicians know a lot of parameters and (immuno-hematology, microbiology, pathophysiology, etc), they have got good experience on the details of the transfusion (pharmaceutical, process control, quality control, etc), despite of it the risk of transfusion is a real problem. A well-designed and operated surveillance system can monitor the experience, the collection data, analyze and draw conclusions, investigate serious adverse effects, and all known unexpected events, in the reaction of blood donors and in the transfused patients, and it makes also possible the epidemiological follow-up of blood donors. The most important prevention action is to analyze the serious adverse effects.

2. History of the hemovigilance

The hemovigilance term has come from Pharmacovigilance. The latter system is designed well for the effects of drugs, adverse events monitoring.

During the 70's the FDA has launched the development of data collection for the events of transfusion. Almost at the same time in Europe, many countries such as Hungary, in 1972, the Health Policy was issued as Transfusion Rules. It required to issue the transfusion document and the use of blood products, but the paper-based data collection process, the evaluation of statistical methods were required.

The establishment of the hemovigilance system has become reality, in some countries the reason was a large number of documented viral transmission (HIV, HCV, HBV). In 1993, European law defined the stable plasma products such as albumin, clotting factors, immunoglobulins, etc, of human origin that are considered as medicinal products, including pharmaceutical preparations for the Pharmacovigilance system.

3. Regulation

The 2002/98/EC Directive (so-called "mother Directive") in the second (15 and 29) article also deals with serious adverse events (accidents and errors) with the concept of the collection, investigation, production, storage and distribution process, if this event affects the blood product quality and safety. The event will be reported to the Competent Authority. These processes are happen in the blood establishments. The second article is closely matched to the 28 article, during the transfusion or after detect and document of the reactions, too. The Rapid Alert System (RAS), namely the rapid reporting is the fastest possible exchange of information (such as manufacturing defective blood bags, filters, apheresis, tubing, screening test, seasonal-related infections, monitoring, etc) that prevented further adverse events and possible complications. The 2005/61/EK directive defines the details of hemovigilance. In February 2005, the 3 / 2005. (II.10) Health Decree of human blood and blood collection, testing, processing, storage and distribution of quality and safety standards, as well as

their specific technical requirements, incorporated into the domestic legal system of so-called "Mother Directive" (2002/98/EC; 33/2004/EC) and later follow-traceability of blood supplies and mandatory aspects of the quality system.

In 2008 the next milestone was the emergence of a new Transfusion Rule in the OVSz edition. The Rule provides, the standardization and uniformization of the process in blood demand, the using of the transfusion report card, and the investigation of complications.

In 2008 a new, single IT (eProgesa) blood supply system was implemented by the Országos Vérellátó Szolgálat (OVSz).

4. The aim of the project

The nation-wide system will connect the blood service IT system (eProgresa) used in 23 blood centres with the IT systems at 4 university policlinics and 19 county hospitals in Hungary. The single IT system for the creation of a national donor registry, which is the basis for donor OVSz hemovigilance system. In this way we

will be able to replace virtually the collecting data on paper for years, and instead of a paper-based test and / or blood product claim, the adverse events and follow-up will have received by an electronic signal. The connection through our country can meet the intra-EU exchange of information.

Realizing the most important directive means the same aspects of a tracing system in blood and blood products, the look back mechanism from „vein to vein" and the uniform documentation saving for 30 years.

5. Activities

29 Hospital and University clinics have been involved in the project with their different type of HIS by the experts. We have chosen the company for the public procurement procedure chosen who created the databases, and collaboration with colleagues in the hospital IT departments who implemented the work that has been started for the validation of parallel systems of education.

6. Results

Management of blood products: Inventory, transportation, cross-matching, follow-up, product recall, reporting transfusion.

Patient Documentation mobile devices: blood products and manufacturing products for patient documentation, including electronic cross-matching (for mobile computers, mobile barcode, mobile patient's identification, etc). Patients with laboratory tests (blood transfusion before, after): AB0 group identification, cross matching, antibody screening tests and other immuno-hematology, virology, coagulation.

Follow-up transfusions: Incomings and blood products used for registration, records of tests carried out, recorded complications and side effects, indications for transfusions.

Immune-hematology tests, respectively: blood products and demand - consumption records: Qualify for access to be linked to specific data. Direct data connection options

for laboratory instruments and systems (LIMS, HIS), billing, laboratory devices.

7. Publicity

According to the project plan: Workshop 2008. April 10.

Konzultation 2010. June 17.

2011. March 04,

Planned Closing Workshop 2011. April 06, International Conference, 2011. April 14.

1. Picture Introduction Workshop

2. Picture Consultation