BUILDING UP HAEMOVIGILANCE IN SOUTH-EASTERN EUROPE

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Blood is a complex tissue and, in spite of centuries of investigation, we still do not completely understand its function. It has been used in routine therapy of different illnesses for more than a hundred years and has become a mainstay of hospital practice. Transfusion of blood products, however, should be regarded as only a part of the overall patient management. The indications for the use of blood product are not always clear-cut. There is no doubt that transfusion therapy is successful in treatment of many conditions and diseases. But in many cases the usefulness and success of transfusion therapy is not so clear. There are doubts about the role of a number of blood products in the treatment of some diseases. The way blood products are administered differs from hospital to hospital. Transfusion therapy carries some risks. Those risks have also been known for many years. The focus upon transfusion safety or its risks has waxed and waned over the last 50 years, depending on how the society perceived the needs for transfusion therapy and the gravity of adverse effects caused by transfusions.

Minor and major adverse reactions or incidents happen, in spite of the understanding of physiology and pathophysiology on which transfusion therapy is based. It is impossible to prepare blood products and administer transfusion therapy without any risk for the patient. Transfusion medicine specialists are considering transfusion therapy safer than ever. They consider the risks associated with transfusion therapy comparable to risks of adverse reactions to other medical procedures and interventions. Medical specialists in different fields, regulatory bodies and laymen do not share this opinion.

To understand the cause of the adverse reactions it is necessary to gain knowledge of the critical steps for the quality of the blood component production and transfusion treatment. That is achieved by documenting, collecting and analysing all relevant data for the safety and efficacy of transfusion therapy through organized surveillance of donor selection/qualification, laboratory testing, blood processing, release of blood products, their storage and transportation and administration of blood products (transfusion therapy). That is the basis of traceability and haemovigilance in which the whole chain of production and transfusion treatment, from the donor's vein to the patient's vein, has to be put under surveillance. Without that it is impossible to recognize critical parts for the quality of transfusion therapy and find out what went wrong and caused the adverse event. The surveillance strategy makes it possible to analyse and interpret the relevant data, to observe tendencies in transfusion therapy and to have time to institute corrective and preventive actions. Successful surveillance is only possible if all subjects involved in transfusion therapy are adequately motivated.

It does not mean that nothing has been done for quality and safety in the country without a formal organization of the haemovigilance. For many years in every step of blood component production or transfusion therapy some sort of quality control has been applied. The basic disadvantage of that "system" was that it was not done in an organized and systematic way.

Today, one can hardly be satisfied with the state of safety of transfusion therapy in any country and of the way human blood is used in many areas of the world. The public, the patients and the medical profession expect an optimal use of the resources of human blood and the lowest possible risks of transfusion therapy.

Most countries in the European Union have a functioning national haemovigilance system. They have joined into a European Haemovigilance Network (EHN). Some other countries from Europe and outside Europe have also joined the EHN. Even

some Southeast European countries (mostly those that will very soon become members of the EU) have become official or nonofficial members of EHN.

In the majority of Southeast European countries, national systems of haemovigilance or the network of national organizations of haemovigilance corresponding to the organization in the member countries of the EU do not exist. In some Southeast European countries the haemovigilance system is in the early stages of its development. In the majority of these countries health care workers from transfusion service understand the importance of haemovigilance for the safety of transfusion therapy and are starting with the basic preparations for the development of haemovigilance; that is the education and change in culture of those who administer transfusion therapy. A formal organization of haemovigilance system exist only in one South European country.

The prerequisite for the building up of national haemovigilance organisation is the understanding of its importance for the safety of transfusion therapy by the doctors in the clinical departments who administer transfusion therapy, as well as by the health care personnel from transfusion service. From the reports obtained from all Southeast European countries during the ESTM course "Basic Clinical and organizational requirements for en effective haemovigilance", held in Sofia from 27 November to 1 December 2002, it was obvious that transfusion medicine specialists understand the significance of haemovigilance for the safety of transfusion therapy in their countries. From the same reports it was not possible to get a clear view of the position of governments and the clinical health care personnel in relation to haemovigilance in those countries.

The participation of government in the organization of haemovigilance is of major importance. It is universally accepted that government must take responsibility for the organisation of transfusion service and the efficacy and safety of transfusion therapy. The importance of government responsibility for transfusion service in the less developed countries is even greater, because only by the government, or by its help, it is possible to obtain the necessary economic or financial recourses for the functioning of transfusion service and haemovigilance.

Transfusion medicine specialists started the building up of all national haemovigilance organisations in Europe. They are the main promoters of the quality in transfusion therapy. Blood safety is only a part of transfusion safety. Therefore, the other health care personnel who administer transfusion therapy or assist in production and patients treatment with blood products must join them in their efforts to make blood transfusion a safer procedure.

The clinicians have the basic and the important role in the functioning of the haemovigilance system. They have to administer transfusion therapy in the required way, to report the outcome of transfusion therapy and to report the observed adverse reactions. Without them it is impossible to organize the haemovigilance system. The general feeling of the participants of the previously mentioned ESTM course has been that the education of clinicians and the change of transfusion medicine culture in hospitals is a prerequisite for obtaining the participation of all health care personnel in a functioning haemovigilance. The education and the change of culture take time in every country regardless of its culture, civilization or the economics.

The French government initiated the building up of the first national haemovigilance organisation in Europe. The haemovigilance organisations in other European countries were built up by health care workers from transfusion service. The reporting of the adverse reaction in these countries is voluntary. Our view is that a haemovigilance should start as a voluntary organization. After some years of experience, and after a trust were established between the participants, the voluntary reporting system may be changed to the mandatory one. The mandatory reporting in haemovigilance would make the development of the organization more rapid in the countries where

the financing of the health care system and the transfusion service depends on the government and where it is extremely difficult to organize consistent financing from different sources. Another reason for mandatory reporting is that we need the participation of all hospital doctors. On the other hand the mandatory reporting can be viewed as the intrusion in the doctors independency and it may hinder the development of the haemovigilance. The decision whether the reporting should be mandatory or voluntary depends on the culture and varies from state to state. We have to be aware that no system *per se* would guarantee the reporting of all adverse reactions and success. The commitment of all the people involved, their trust in the system and the quality of their work are the factors that have the greatest impact on the function of any system.

The majority of countries in the Southeast Europe are not big. They do not have a formal organization of the national transfusion service and do not have functioning haemovigilance system on the national level. The reports of serious consequences of transfusion therapy in these countries are sent to different institutions. That shows that some reporting system or at least the reporting system of severe reactions does exist. We may question if it is effective? If all observed reactions are reported? Have the corrective or preventive actions been taken in time? The notification of adverse reactions shows the awareness of the health care personnel and that is a sound base for building up a haemovigilance system.

Haemovigilance depends on the existence of the national transfusion service (NTS). Without the existence of an organized NTS only a notification system of adverse reactions can be built up. The haemovigilance system is more than notification. It is the system in which the data are collected, analysed, digested, the decision about the further action made and disseminated to the relevant parties. It is a two-channel system. First the information is sent from the patient doctor/hospital department through the blood bank (BB/BTC) to a centre where all the data are collected. The second channel transfers the digested information from the centre to the BB/BTC and to the hospitals. The haemovigilance network includes the collection of data on adverse reactions from all hospitals in the country in one centre where they are analysed, digested and from which the information are disseminated and preventive actions started. In such a way the information is disseminated back to the all interested parties. In the majority of countries of the South-East Europe only the first and basic part of haemovigilance exists, that is the liaison hospital department – blood bank/ BTC. That part of vigilance (hospital- blood bank) makes it possible to take corrective measures after an adverse reaction has been observed. Those measures include look back and trace back procedures, quarantine of the non transfused blood product prepared from the implicated donor, the notification of other hospital departments where the other blood products prepared from the implicated donor were sent. The channel hospital-blood bank, makes it almost impossible to observe new adverse reactions, to disseminate information to all parties concerned, to observe trends in transfusion therapy and to get insight into the epidemiology. Therefore, it is imperative to share the experience and the data on the national level.

The concept of the quality of transfusion therapy includes the quality management of all critical processes "from vein to vein". That implies that safety is part of quality and to improve safety we have to improve the quality. Therefore the quality and the safety are inseparable. The majority of BB/BTCs in the countries in Southeast Europe do not satisfy all the requirements of the cGMP. Therefore they have to improve the quality of the blood products. That will also improve the quality of transfusion therapy. The quality of transfusion therapy depends on more elements. The majority of them are located in the hospital and they are relevant for the management and administration of transfusion therapy. Haemovigilance, in the short and long term, influences the quality of transfusion therapy. Therefore, the development of haemovigilance should be taken as part of the improvement of the quality of transfusion therapy.

Haemovigilance may be considered expensive on a higher level (national network), but on the basic hospital level what is needed is mainly good organization, a good documentation system (electronic information system is not a prerequisite, but it is exceedingly helpful) and good management. Because of the general medical knowledge, especially knowledge of the production of blood products and transfusion treatment, and of the experience in the organization of haemovigilance that is being transferred from our colleagues that already have an organized and functioning haemovigilance, the national, professional societies of transfusion medicine specialists and other societies of medical specialist that are involved in transfusion treatment should have the principal role in the building up haemovigilance organization in their countries. At least, they have to put down the basic requirements and define the elements of the system.

The basic requirements for the development of a well functioning haemovigilance in the South-east Europe countries are:

- To establish the national organization of transfusion service,
- To establish the national haemovigilance network (headquarter, define channels, unique reporting form, decide on the data that have to be collected, etc.).
- To foster the improvement of the quality of blood products through the adoption of cGMP, quality system and quality system management in each blood bank or blood transfusion centre that collect, process or test blood or blood products. Their work should be in compliance with the Council of Europe current requirements defined in the Guide to the Preparation, Use and Quality Assurance of Blood Components.
- To organize diffusion of transfusion medicine basic culture at all medical levels from the undergraduate students to the medical and surgical specialists.
- To educate a sufficient number of transfusion medicine specialists to allow for the presence of at least one of them in every hospital.
- To establish a functioning Transfusion Committee in each hospital.
- To educate clinicians to appropriately administer transfusion therapy, and through such measures to increase the effectiveness and to reduce the risks associated with transfusion therapy.
- To establish a well defined set of obligatory minimal rules for the administration of transfusion therapy (a uniform identification system, request forms, the establishment of criteria for the indications of transfusion therapy, the definition of parameters that have to be followed up, the assessment of the effect of transfusion therapy, the return of non-used blood products and empty bags, a unique written report of the outcome of each transfusion event, management of documentation, etc.).
- To establish a uniform information system in blood transfusion service.
- To allow for and organize the exchange of data between countries, its diffusion and comparison.
- To foster the participation of transfusion medicine and public health specialists in educational courses on haemovigilance and in the meetings of the European. Haemovigilance Network.
- National haemovigilance organizations should join the European Haemovigilance network.

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