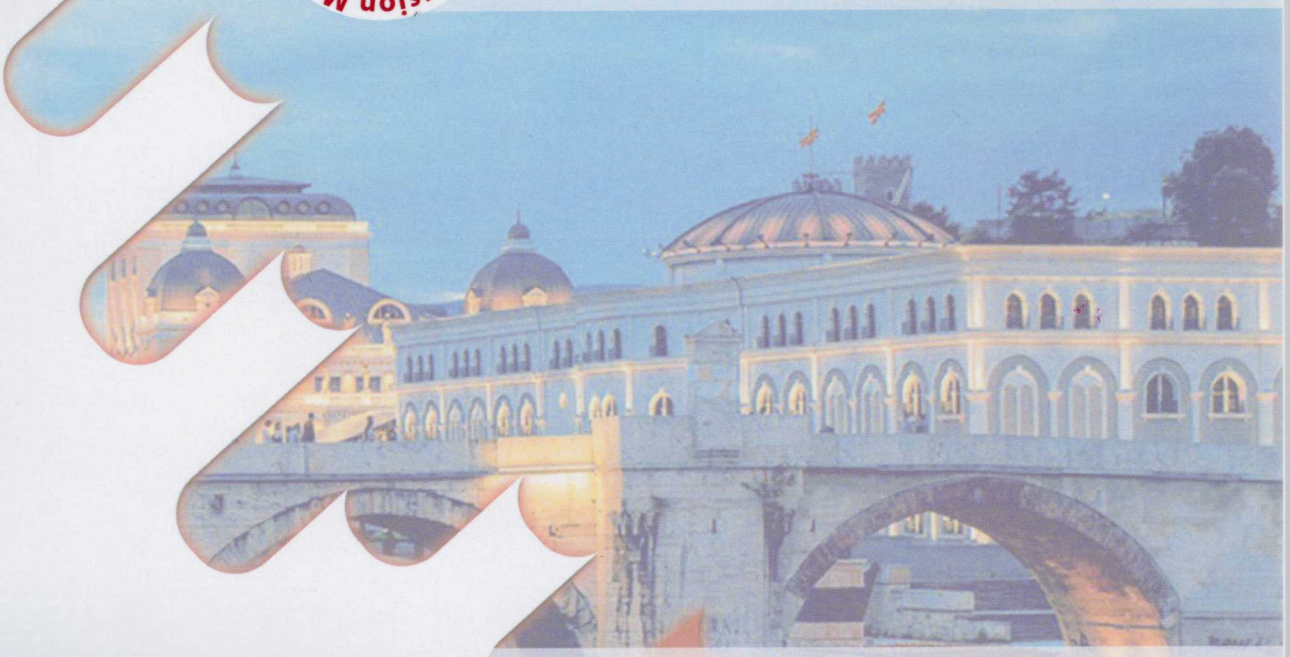
ISBT

6th Congress of Macedonian Society
for Transfusion Medicine
with international participants
1 - 4 November, 2023



# MACEDONIAN MEDICAL REVIEW
# Plenary Lectures and Book of Abstracts

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# HAEMOVIGILANCE IN MACEDONIA – CURRENT SITUATION AND FUTURE DEVELOPMENTS

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Blood transfusion is critical element of medical and surgical therapies. Although blood transfusion is safe and effective treatment when used appropriately, it can be associated with a few adverse effects either immediate or delayed. The concept of haemovigilance has existed much earlier, but the first haemovigilance program was established in Japan in 1993, following by France in 1994 and afterward by other countries (1). Haemovigilance is a surveillance system and is dealing with the safety of the blood transfusion chain, from vein to vein. There are different definitions of haemovigilance, but each one of them emphasizes recognition, reporting, analyzing and taking actions on undesirable consequences of blood donation and transfusion in order to improve quality of the whole transfusion chain.

The International Haemovigilance Network (IHN) has defined haemovigilance as "a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence"(2). The World Health Organization (WHO) has described the goal of haemovigilance as "The continuous quality improvement of the transfusion chain through corrective and preventive actions to improve donor and patient safety, improve transfusion appropriateness and reduce wastage"(3). Directive 2002/98/EC defines haemovigilance as "a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors"(4). It is a continuous process of data collection and analysis of adverse events and reactions in blood donors related to donation or in recipients related to transfusion. Transfusion as well as haemovigilance is a complex process and requires a multidisciplinary team: transfusion nurses/ practitioners, doctors, laboratory scientists, data managers; the donors and recipients with their experience; the quality managers and the management representatives who are establishing and implementing the haemovigilance system.

International Society of Blood Transfusion Working Party on Haemovigilance (ISBT WP HV) in partnership with other professional associations has developed definitions for adverse reactions in recipients and in donors and also has set standards for the surveillance of complications related to blood donation. Analysis of reports of adverse reactions in donors will assist in the development of approaches to improve the overall safety of blood collection. An adverse event is defined as any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that may lead to an adverse reaction in blood recipients or blood donors. Adverse events related to donation may also have consequences for the safety and quality of the derived blood components and include incorrect, inappropriate or unsuitable blood component transfusions, even if they did not lead to harm to the recipient.

"Near-miss" events are a subgroup of adverse events can be any error which, if undetected, could result in determination of a wrong blood group or failure to detect a red cell antibody, or the issuance, collection or administration of an incorrect, inappropriate or unsuitable component, but where the mistake was recognised before transfusion took place. Notification of adverse events that do not cause an adverse reaction may help to identify weaknesses in the transfusion process and thereby reduce risk.
Haemovigilance system as a shared responsibility of the professionals in the field and the competent authorities there should be a strong cooperation between the blood establishments, hospital blood banks, hospitals/clinical departments and national authorities (5).

In Europe, the key to haemovigilance is ensured through the legislative framework for blood products through four guidelines: Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 (Standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components)(4), Directive 2004/33/EC of the European Parliament and of the Council 22 March 2004 (Certain technical requirements for blood and blood components)(6), Directive 2005/61/EC of the European Parliament and of the Council 30 September 2005 (Traceability requirements and notification of serious adverse reactions and events)(7), Directive 2005/62/EC of the European Parliament and of the Council 30 September 2005 (Community standards and specifications relating to a quality system for blood establishments)(8). The Directive 2005/61/EC refers to the traceability system and imputability where possible assessment of association of adverse reaction and transfusion of blood products: Not assessable- NA, Excluded/ Unlikely-0, Possible-1, Likely/ Probable-2, Certain-3. This is a very important parameter in the analysis of the association between the adverse reaction and blood transfusion. For better assessment the French agency (AFSSAPS) and ISBT Proposals (9) introduced the term severity reactions: Labile products are not related to the reaction (Level 0), Absence of immediate or long-term vital treatments (Level 1), Long-term illness (Level 2), Urgent vital treatment (Level 3) and Death (4).

The Institute for Transfusion Medicine of Republic of North Macedonia (ITM) is working according the actual national legislative, the Law for safety in blood supply (Official Gazette, No 110 from September 2007) (10), which is harmonized with the First European Blood Directive ("mother" Directive) 2002/98/EC for safe and quality collection, processing and testing of blood, storage and distribution of the blood components and its consequent by-laws harmonized with the rest three "daughter" European Blood Directives. The form and content of the documentation in the process of the use of blood, written forms and procedure for reporting of serious adverse events and reactions from used blood and blood components is prescribed in the Rulebook (Official Gazette, No 87 from July 2010) which is harmonized with the Directive 2005/61/EC. In accordance with this Rulebook, there are forms for reporting serious transfusion reactions that are partially filled out by a small number of hospitals. ITM has appointed authorized persons, doctors specialists in transfusion medicine, as external members in the hospital transfusion committees. The process of introducing the legally existing forms into the electronic healthcare system "mojtermin" has begun, which must be filled out by clinical doctors who order blood and blood component transfusions for

their patients, with precise data on how many units and which blood components have been transfused and if there was serious adverse reactions and events.

Although many elements exist, haemovigilance as a national and functional system does not exist completely in R.N. Macedonia. There is no Competent authority as part of the Ministry of Health of R.N. Macedonia as a key element to verify the consistency and clarity of the collected information related to Serious adverse reactions and events.

Adverse transfusion reactions that were reported to the Quality Assurance and Quality Control (QAQC) Department of the Institute for Transfusion Medicine of Republic of North Macedonia – Skopje in the period 2007-2022 were as following. The most frequent adverse reactions that were reported were mild allergic and febrile non-haemolytical transfusion reactions with urticaria, rash, fever and vomiting; just a few of them were moderate and severe with dyspnoea, headache, hypotension and tachycardia. There was no mortality associated with blood transfusion in the last 16 years.

**Conclusion:** As blood transfusion professionals we recognize the need for national haemovigilance system as an overall goal is to improve donor and patient safety as well as to improve the efficacy and efficiency of blood transfusion. More work, support and cooperation with the healthcare authorities and policy-makers in our country is needed in order to finish the implementation of the haemovigilance with by-law for Haemovigilance as part of the Law for safety in blood supply; Clinical use of blood and blood components with mandatory registration and practical notification of the blood establishment on the outcome of each individual transfusion of blood and blood component and the appropriate subsequent functioning of the inspection system in the sphere of clinical use of blood.

In conclusion, there is continuous need to work on establishing and maintaining fully functional haemovigilance system, that should involve all relevant stakeholders and should be coordinated between the Institute for Transfusion Medicine, hospital staff, hospital transfusion committees and the national health authorities by establishing competent authority in R.N. Macedonia; and the following prerequisites are necessary: legal framework, national guide for haemovigilance, agreed definitions, use of standardized reports, guaranteed continuous funding of the haemovigilance program, functional hospital transfusion committees, introduced system of corrective and preventive actions, established culture of professionalism, anticipated international cooperation.and establishing correct awareness and alert system to ensure that the transfusion policies, standards and guidelines will be followed.

The hospital transfusion committees and an active surveillance program have a key role in enhancing patient safety by making changes to prevent reoccurrence and management of adverse reactions to blood transfusion. Improving the reporting of transfusion related adverse reactions, analysis of the reports for the blood components use and adverse transfusion reactions will help us to focus on safe transfusion. The information from a good functioning haemovigilance system can be used as a quality indicator for blood transfusion safety and can contribute significantly to evidence-based transfusion medicine.

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