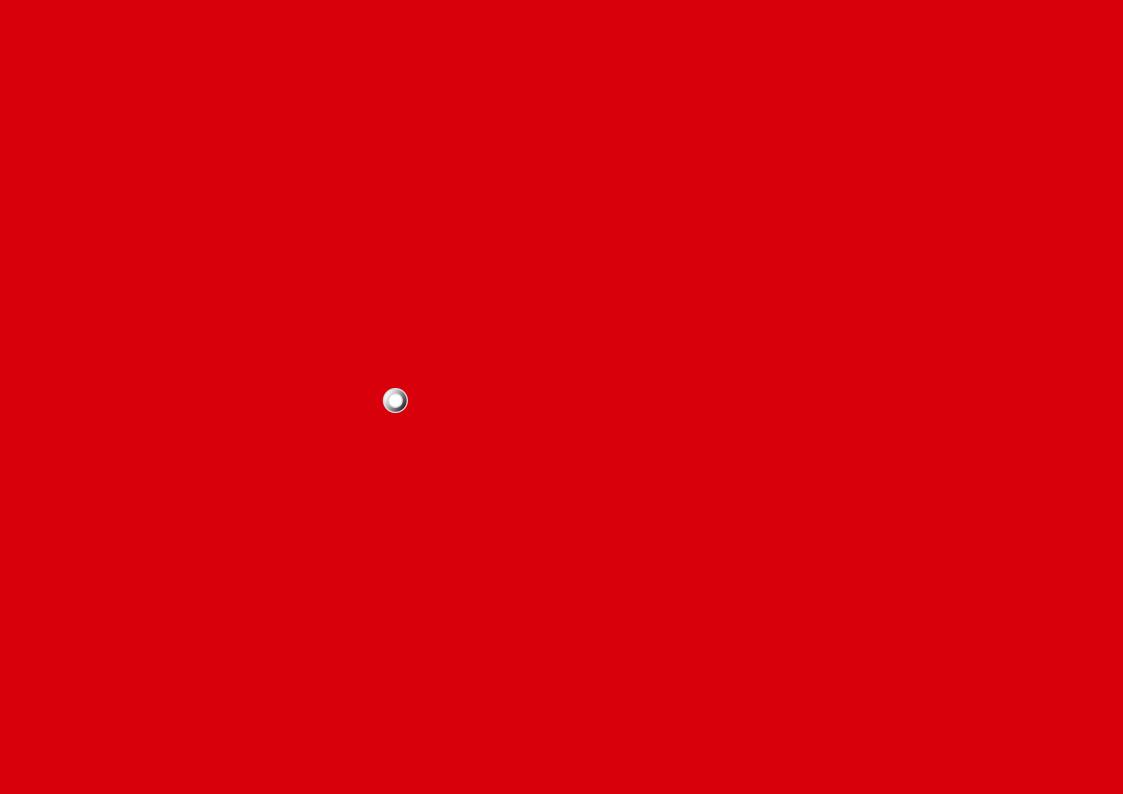


# LIFE FLOWS



# LIFE FLOWS

2006 Annual Report of the Slovenian Blood Transfusion Service

Giving a part of one's own body to someone who urgently needs it is certainly one of the noblest forms of help to a fellow human being. The preparation and processing of donated blood components confers great social and also ethical responsibility. Blood is donated every day by individuals who decide to participate in this type of humanitarian help by joining blood donation sessions, and it is also collected from invited blood donors and groups organised by citizen initiatives.

Groups that regularly participate in blood donation sessions include drivers of the Ljubljanski Potniški Promet public transport company, students, athletes (basketball players, the Ljubljana American football team, the Ljubljana Rugby Team and other sports teams, motorbike enthusiasts, secretaries and groups of employees from various other institutions and companies (SV, Tax Administration of the Republic of Slovenia (DURS), etc.).

We are grateful to each and every one of them.

# INDEX

05	LIFE ALSO FLOWS IN INSTITUTIONS
06	BLOOD TRANSFUSION SERVICE IN SLOVENIA
09	SAFE BLOOD IS A COUNTRY'S GREATEST NATURAL RESOURCE
10	RESPONSIBLE AND HIGH-QUALITY WORK
12	COMPLIANCE WITH APPLICABLE SAFETY MEASURES AND ADDING NEW MEASURES
15	MONITORING AND IMPROVEMENT OF OUR WORK
16	DEVELOPMENTS IN THE YEAR 2006
16	SAFETY AND QUALITY IN LEGAL PROVISIONS
17	QUALITY CONTROL FOR TRANSFUSION ACTIVITIES IN SLOVENIA
17	IRRADIATION OF BLOOD AND BLOOD COMPONENTS
18	NAT TESTING
20	DIAGNOSTIC AND THERAPEUTIC SERVICES
20	DIAGNOSTIC SERVICES
21	THERAPEUTIC SERVICES
21	BONE MARROW REGISTRY
22	INVESTING IN KNOWLEDGE AND INNOVATION
23	EDUCATION
24	INDIVIDUALS WHO HAVE MADE A MARK ON THE DEVELOPMENT OF TRANSFUSION
	MEDICINE IN SLOVENIA
27	LEGISLATION
28	PUBLICATIONS
31	CONTACT PERSONS





## LIFE ALSO FLOWS IN INSTITUTIONS

For over fifty years, the basic duties of the blood transfusion service in Slovenia have included the provision of an adequate blood supply in cooperation with the Red Cross of Slovenia, ensuring the high quality and safety of all blood products along with procedures for their preparation, as well as education in the field of transfusion medicine, research and development, and many other activities. This was also the case in 2006.

Nevertheless, this year was also different in a way. The quick professional and technological development in this field and Slovenia's membership in the European Union (EU), along with the related obligations have led to increased activity in individual areas of our work.

Therefore, two improvements were introduced within the framework of our activities to ensure safe blood transfusion. For preventing the transmission of blood-borne diseases, additional testing of every donated blood unit was introduced to detect viral infection markers for hepatitis B and HIV using the most sensitive test procedure called NAT (at the level of the pathogens' genetic code). In addition, pretransfusion irradiation of blood components was introduced in order to prevent one of the most severe complications of transplantation, i.e. graft versus host disease, which may occur primarily in the most difficult cases involving severely immune-deficient patients.

Among other achievements, research and development activities at the Blood Transfusion Centre of Slovenia (BTCS) have also led to the introduction of the following new blood products in clinical practice: allogenic platelet gel for the treatment of traumatological injuries of bone tissue and autologous peripheral stem cells for the treatment of damaged heart muscle in patients following myocardial infarction.

Slovenia is obliged to harmonise its legislation with that of the EU. The preparation and adoption of a new Blood Supply Act was an important step towards ensuring equal blood transfusion safety in all EU member states. The next task to this end will be to introduce new measures which will enable new legal provisions to be fully implemented in practice. Reorganisation of the transfusion service is certainly a crucial part of this process.

Among the conditions needed for ensuring safe blood transfusions, regular quality assurance ranks first. In previous years, all employees of the BTCS have invested much knowledge and energy to accomplish progress in this respect. The result of these activities, which makes us extremely proud, was the acquisition of the ISO 9001:2000 certificate in 2004. In 2006, a few further improvements of the system were also added and the SIQ audit was successfully passed again. At the end of last year, an additional sign of BTCS' international recognition was its appointment among members of the WHO Collaborative Centre for the area of quality management related to transfusion activities. Furthermore, the BTCS was also assessed very highly by auditors of the European Federation of Immunogenetics (EFI), and as in past years (since 2000) the BTCS has been awarded its annual accreditation for this field.

It should also be mentioned that the BTCS was granted the title of a Teaching Institution, which additionally confirms the high level of pedagogic proficiency and quality of our experts, lecturers and other members of the teaching staff at each and every educational level and level of difficulty.

The provision of blood for transfusion to sick and injured people, in the right amounts and whenever needed, is possible only because of the generosity and altruism of many anonymous blood donors and because of their continual willingness to respond to invitations for blood donation sessions with enthusiasm and without reservation. On the other hand, the dedicated work of everyone who makes sure that patients receive timely, correct and safe blood transfusions also contributes to this. Through our mutual efforts, we will ensure that safe blood will remain available to all patients in the future.

Medical Director of the BTCS Head Physician Marjeta Potočnik, MD, Transf. Med. Spec. BTCS Director Asst. Prof. Matjaž Jeras, BA Pharm. (Spec.)



# **BLOOD TRANSFUSION SERVICE IN SLOVENIA**

A blood transfusion service has been organized for the performance of transfusion medicine activities in Slovenia. This consists of the Blood Transfusion Centre of Slovenia (hereinafter the BTCS), Department of Transfusiology and Immunohematology of the Maribor General Hospital, and transfusion departments (hereinafter: TD) operating at hospitals in Celje, Izola, Jesenice, Ptuj, Murska Sobota, Nova Gorica, Novo Mesto, Slovenj Gradec and Trbovlje.

All transfusion departments are in charge of blood collection. Processing of blood to blood products is done at the BTCS, the Department of Transfusiology and Immunohematology in Maribor, and TDs in Celje, Izola and Slovenj Gradec. Blood collected at the Nova Gorica, Trbovlje, Jesenice and Novo Mesto TDs is processed by the BTCS in Ljubljana, while the Department of Transfusiology and Immunohematology in Maribor processes blood for Murska Sobota and Ptuj TDs. Processed blood is returned back to the respective TDs in accordance with their needs and plans. The testing of blood is performed in Ljubljana and Maribor, while NAT testing is done only in Ljubljana.





# SAFE BLOOD IS A COUNTRY'S GREATEST NATURAL RESOURCE

Every second of every day, people throughout the world, of all ages and walks of life, need blood transfusions to get well or even just to survive. The need for blood is universal, but sadly, access to blood is not equal for all who need it. Lack of blood is especially marked in developing countries where the majority of the world's population lives.

In order to ensure safe blood for its citizens, every country needs a sufficient number of voluntary, non-remunerated blood donors giving blood on a regular basis. In Slovenia, we can be proud and grateful that our blood donors provide a sufficient amount of blood for our health care, so it has never happened that a patient has not received blood when he/she needed it.

In 2006, the Red Cross of Slovenia organised 1,100 blood donation sessions throughout Slovenia through its regional associations. The Transfusion Service conducted these sessions in the premises of transfusion services and in the field. Field blood donation sessions are performed by field teams from the Blood Transfusion Centre of the Republic of Slovenia (BTCS), the Department of Transfusiology and Immunohematology of the Maribor General Hospital and the Celje Transfusion Department with their field teams. A total of 320 blood donation sessions were conducted in the field.

In most cases, blood donors attend blood donation sessions on the invitation of the Red Cross of Slovenia (hereinafter the Red Cross). To maintain stocks of individual blood types and also in the case of a shortage of blood, the Red Cross organises additional blood donation sessions, while the blood transfusion service also issues so-called personal invitations to blood donors. The percentage of blood donors who come on their own initiative to have their blood collected has been increasing in recent years. Organised attendance of blood donation sessions within certain professional, educational or interest groups of blood donors is also on an increase. Blood donation sessions are attended in an organised manner by university and secondary school students, members of the Secretaries' Society, motorbike enthusiasts, Ljubljana city bus drivers, American football players, rugby players, teachers, etc. In 2006, there were 96,367 registered blood donors in Slovenia, regardless of their form of organisation. In general, the trend of movement in the number of blood donors has been uniform in recent years.

In the year 2006, 11,870 persons donated blood for the first time, i.e. 12% of all registered blood donors.

96,367 people reported for blood donation, among whom 33% were female and 67% male.

A total of 86,074 blood collections were performed, including 1,104 plasmaphereses and 1,244 platelet aphereses.

Among 56,670 blood donors,

63% donated blood once.

27% twice.

8% three times and

2% four times in 2006.

Number of registered blood donors, collections and deferrals by location in 2006			
Transfusion	No. of	No. of	No. of
site	registered donors	collections	deferrals
Celje	9,625	9,141	484
Izola	5,409	5,008	401
Jesenice	2,372	2,214	158
Maribor	12,578	10,874	1,704
Murska Sobota	4,741	4,432	309
Nova Gorica	3,815	3,605	210
Novo Mesto	4,285	3,798	487
Ptuj	3,296	3,113	183
Slovenj Gradec	3,018	2,816	202
Trbovlje	1,458	1,420	38
BTCS Ljubljana	45,770	39,653	6,117
Slovenia	96,367	86,074	10,293

# RESPONSIBLE AND HIGH-QUALITY WORK

We are well aware that blood donors are giving blood voluntarily and receive no payment for it, therefore all employees involved in blood donation sessions strive to make sure that collected blood is used in the best way, and as efficiently and safely as possible.

Transfusions are justified and effective only if the blood component transfused to the recipient is the one he/she needs during treatment, in the amount and form that will provide the best results. This can only be achieved by transfusion of safe blood.

Whole blood collected from blood donors is used to prepare blood products – blood components and medical products derived from blood.

Collected whole blood units are separated into their ingredients, i.e. to individual blood components. This is done using physical methods, for example centrifugation, filtering and other similar methods. In this way, the same number of blood cells, e.g. erythrocytes as is contained in the entire bag of whole blood is obtained in a smaller volume of each individual blood component. Treatment with blood components is more effective and also safer, as patients receive only those blood components which they actually need.

Blood transfusions are done to replace only the deficient blood component. Concentrated erythrocytes are administered to anemic patients, and platelets are used to stop bleeding, while blood coagulation disorders are treated with plasma and medical products derived from blood.

The largest consumers of blood and blood components are hematological, surgical and oncologic patients, as well as accident victims.

Approximately 6 units of blood are required for a single heart operation and one blood donor can provide only one unit at a time. Such surgery therefore requires blood from six donors, and for some operations blood requirements may be significantly higher. For example, surgery for malignant tumours requires over 20 units of blood and the same amount is needed for liver transplantation, while injured patients sometimes need up to 30 units of blood.

Blood component units prepared from whole blood by location in 2006			
	No. of units	No. of units	No. of units fresh
Transfusion site	conc. erythrocytes	conc. platelets	frozen plasma
Celje	9,107	3,646	9,069
Izola	4,957	324	4,829
Maribor	18,113	7,337	18,007
Novo Mesto	3,704	156	3,693
Slovenj Gradec	2,739	187	2,729
BTCS Ljubljana	43,268	24,826	43,308
Slovenia	81,888	36,476	81,635

No. of blood components from whole blood issued to patients in 2006:

Concentrated erythrocytes 76.277
 Concentrated platelets 25.987
 Fresh frozen plasma 30.267



# COMPLIANCE WITH APPLICABLE SAFETY MEASURES AND ADDING NEW MEASURES

The purpose of blood supply is to provide safe blood for transfusion. Blood safety means that there are no adverse consequences for the recipient. Above all, blood for transfusion must not contain viruses or bacteria that cause AIDS, hepatitis B and C, or syphilis. Hepatitis B, hepatitis C and AIDS are chronic infectious diseases. Modern medicine enables treatment of these diseases, but it is expensive and problematic and also very difficult for patients because it has many adverse effects and health consequences which require new interventions and treatment. The effectiveness of treating chronic viral diseases is very limited and usually fails to cure them, but above all such infections are a source of stigma for infected people. It is also socially unacceptable to permit blood to be a possible source of infection.

Patients and the general public expect a safe blood supply. Therefore, they also appreciate all of the effort and measures for risk reduction. One of the main measures for achieving the highest possible blood safety is through so-called screening of collected blood units.

Screening tests are done to find out whether blood units intended for transfusion might be potential sources of infection. These tests enable direct detection of the viral content (or the content of other microorganisms) in blood, although they sometimes provide only indirect detection of markers of infection.

Although modern methods of transfusion provide a safe form of therapy, there is still a risk of transmitting hepatitis B and C viruses as well as HIV via blood. This is due to the so-called diagnostic window, i.e. the time which elapses between the occurrence of infection and the appearance of antibodies which can be detected by serological tests. During this period, the risk of transmitting viruses is still present and can be prevented only by additional testing for nucleic acids of the above-mentioned viruses using the so-called nucleic acid testing (NAT method).

Results of screening tests of collected blood units in Slovenia for 2006						
(N = first-time b	(N = first-time blood donor - first donated blood unit; R = regular blood donor)					
Year 2006	No. of tested	New				
	blood units	blood donors	HBsAg	ANTI-HCV	ANTI-HIV	ANTI-TP
Slovenia total	84.882	9.371	15 (12N,3R)	6 (4N, 2R)	0	7 (1N, 6R)
Test site						
LJUBLJANA	54,851	5,097	8 (6N, 2R)	5 (4N,1R)	0	5 (1N, 4R)
Test site						
MARIBOR	30,031	4,220	7 (6N, 1R)	1 (0N, 1R)	0	2 (0N, 2R)

In 2005, screening tests began to be performed only in Ljubljana and Maribor.

In Slovenia, about 90,000 units of donated blood are tested each year. The number of blood donors is lower than the number of actually donated blood units, as some blood donors donate blood 3 to 4 times a year. The greatest number of viral infections is found among first-time blood donors, i.e. those giving blood for the first time, and only 7 to 12 % of newly diagnosed infections are found among regular blood donors.

Results of screening tests for HCV RNA using the PCR method in Slovene blood donors for 2006				
No. of tested	Anti-HCV neg.	Anti-HCV pos.	Anti-HCV pos.	Total No. of detected
persons	HCV RNA pos.	HCV RNA pos.	HCV RNA neg.	anti-HCV pos.
84,500	0	5	1	6

A total of 424,028 tests were performed to ensure blood safety.





# MONITORING AND IMPROVEMENT OF OUR WORK

The use of any medicine is associated with a risk of adverse effects, and blood transfusions are no exception to this.

Along with the numerous above-mentioned activities for the provision of high-quality and safe blood supply, the Blood Transfusion Service also runs a hemovigilance system to monitor the adverse effects of transfusions.

All information passed within the framework of hemovigilance improves the safety of transfusion therapy and explains the risks of occurrence of adverse effects of transfusion therapy and how to reduce this risk by implementing additional measures.

An important goal of hemovigilance is to warn users and contractors that even if an incident has occurred, timely recognition of an adverse effect may prevent even greater damage.

Number and type of reported adverse reactions from blood transfusions in Slovenia in 2006	
Hemolysis	3
Graft versus host disease	0
Transfusion related lung injury/pulmonary edema	13
Post-transfusion purpura	0
Allergy/Anaphylaxis	69
Non-hemolytic febrile reaction	92
Bacterial or viral infection	2
Other	12
Total	191

# DEVELOPMENTS IN THE YEAR 2006

#### SAFETY AND QUALITY IN LEGAL PROVISIONS

With Slovenia's accession to the EU, the entirety of European legislation, including laws relating to the field of transfusion medicine, became binding for Slovenia as well. This meant that even before entry in the EU, Slovenia had to initiate procedures for the adjustment of Slovene laws and regulations to meet European legislation. Four European directives have been published in the field of transfusion medicine. The most important among them is the basic directive from 2002 (called colloquially the 'mother directive'), which regulates and prescribes the quality and safety standards for collection, testing, processing, storing and distribution of human blood and blood components. The previous Slovene Blood Supply Act, which had been in force since June 2000, needed to be adjusted and completely harmonised with this directive. In October 2006, Slovenia thus passed an updated Blood Supply Act (ZPKrv–1) which regulates the basic areas of our activity.

The European Commission continued issuing additional directives to regulate individual fields of transfusion medicine in greater detail and to set concrete requirements for all activities within the blood supply system. In March 2004, a so-called 'daughter' directive on technical requirements for blood and blood components was published. In September 2005, it was followed by two binding amending directives which prescribe EU standards and specifications related to the quality system for transfusion institutions and the requirements for traceability of blood and information collection regarding severe adverse reactions and events. In accordance with the instructions of European legislative bodies, the respective provisions from all of the above-mentioned three documents had to be included in Slovenian legislation in the form of regulations and rules for the field of transfusion medicine. In February 2007, the Minister of Health adopted seven new or updated rules which prescribe: the professional/medical conditions for blood collection, the types of compulsory testing of blood and blood components, the methods for collecting, preparing, storing, distributing and transporting blood and blood components, the types of pretransfusion tests and procedures with transfusion, the standards and technical requirements of the quality system for transfusion activities, the methods and types of access to documentation related to blood transfusion, and the national hemovigilance system.

Before its laws were harmonised with EU legislation, Slovenia already had its own Act and some rules applicable to the field of transfusion medicine, but their harmonisation with European directives significantly contributed to a more detailed regulation and definition of many procedures in both the professional and organisational sense. The most important changes and developments brought about by the updated legislation have been: the implementation of a unified quality assurance system, development of the hemovigilance system, compulsory issuance of licenses for work of transfusion institutions (inspections are performed and licences issued by a newly formed Blood Unit that is part of the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia-JAZMP), reporting methods within Slovenia and internationally, clinical procedures related to treatment with blood etc.

Among the most important changes and news resulting from the adjustment to European legislation is certainly a provision relating to the organisational composition of transfusion organisations. The law authorises units which perform transfusion activities to be organised as any of the following 3 possible entities: transfusion institute, transfusion centre or hospital blood bank.

**TRANSFUSION ESTABLISHMENT I** (i.e. the Blood Transfusion Centre, Ljubljana, Slovenia) is responsible at the national level for professional supply of blood and blood products and for linking the field of transfusion medicine with hospital activities. This institute harmonises all activities related to donor selection and collection, testing, processing, storage and distribution of blood and blood components, clinical use of blood, and control of severe adverse events and reactions related to blood transfusions. The Blood Transfusion Centre of Slovenia harmonises and connects the network of hospital transfusion establishments and hospital blood banks, manages a unified information system, educational and research and development activities at the national level, and cooperates with related international organisations, associations and institutions in other countries.

**TRANSFUSION ESTABLISHMENTS II** are organisational units of hospitals which are in charge of collecting and testing blood, processing collected blood to blood components, and their storage. They perform pretransfusion testing and hospital transfusion activities and supply blood and blood components to hospitals and other users.

**HOSPITAL BLOOD BANKS** are hospital units which store and distribute blood and blood components.

They also conduct pretransfusion testing and hospital transfusion activities, but are not authorised to collect blood.

Strict and detailed criteria are prescribed in respect of each of these three organisational forms, and they must be fulfilled.

The procedure for implementing all legislative provisions in practice is not expected to be simple and easy. However, the providers of transfusion activities would like to ensure consistent implementation of legal provisions through our joint efforts and in cooperation with the relevant ministry in the shortest possible time, which will further increase the already high level of safety and the quality of treatment with blood and blood components in Slovenia.

#### QUALITY SYSTEM FOR TRANSFUSION ACTIVITIES IN SLOVENIA

Since the certification audit, two ISO 9001:2000 certificates have been granted to date: one to the Blood Transfusion Centre of Slovenia in December 2004 by the Slovenian Institute of Quality and Metrology, and the other to the Department of Transfusiology and Immunohematology in Maribor in September 2005 by the BVQI, an independent certification agency which is part of Bureau Veritas.

The acquisition of this certificate proves that the two institutions have achieved such a level of organisation and transparency in their work that they comply with all requirements of the ISO 9001:2000 standard. All of the employees have contributed to this. The setting up and maintenance of the quality system in the field of transfusion medicine is one of our high-priority tasks aimed at achieving the highest quality of work in all transfusion departments.

In 2006, the Blood Transfusion Centre in Ljubljana and the Department of Transfusiology and Immunohematology in Maribor successfully passed regular audits of their quality management systems in line with ISO 9001:2000 requirements. This confirms the dedication of their employees' to ensure continual improvement of their work, which is also evident from active involvement of those employees who have completed a course for internal auditors in the performance of internal audits.

Among other regulations, the Blood Supply Act (Official Gazette of the Republic of Slovenia (RS), No. 104/2006) which was adopted in October 2006, also prescribes the Rules on standards and technical requirements for the quality system for transfusion activities, which states the requirements related to these activities.

At the same time, the Blood Supply Act set up the legislative framework for the implementation of regular supervisory inspections in transfusion institutions for the issuance of permits for performing transfusion-related activities. The tasks of the competent body will be performed by the Agency of the Republic of Slovenia for Medicinal Products and Medical Devices.

#### **IRRADIATION OF BLOOD AND BLOOD COMPONENTS**

The irradiation of blood products with ionising radiation contributes to the destruction of T lymphocytes and prevention of the graft versus host disease. With the acquisition of a new irradiation device, a great step has been made at the BTCS Ljubljana towards helping patients who need irradiated blood and blood products. This helps us avoid rare, but most often fatal complications of transfusion.

The graft versus host disease may occur primarily after the transplantation of hematopoietic stem cells or solid organs and other tissues or during treatment of aplastic anemia with immunosuppressant drugs and treatment of certain lymphoproliferative diseases. Transfused T lymphocytes react to the recipient's antigens, which makes them activated and triggers the destruction of target cells in tissues of the transfusion recipient. The two reasons for inadequate responses of the recipient's immune cells may be immature immune system (intrauterine transfusion) or a deficient immune response (hereditary diseases, transplantation of hematopoietic stem cells). The only effective prevention of the graft versus host post-transfusion reaction is irradiation of blood components with ionising radiation.

The BTCS performs irradiation of blood products using the Gammacell 1000 Elite irradiation device, which enables controlled and validated dosing of the necessary amount of radiation. It is also important that the irradiation device is safe for the environment and for medical personnel who operate it. Irradiation is performed by senior and graduate nurses and graduate medical technicians who have completed training in the field of protection from ionising radiation.

The irradiation device consists of the following four assemblies: the protective container, the source of irradiation and a sample changer and control unit. In addition, it also includes a keyboard, optical scanner, metal container for samples and a printer.

The protective container is made of lead, cast within a steel casing. The thickness of lead throughout the container is at least 20 cm. The source of irradiation is the isotope Cs-137 with an initial activity of 49.2 TBq and a half-life of 30 years. The protective container also contains a sample changer which rotates to move samples to the correct position for irradiation. The container into which a sample to be irradiated is placed, rotates during irradiation to ensure homogenous irradiation. The mean irradiation dose for blood products is 30 Gy.

Due to its design, the irradiation device can be used in normal laboratory environment or in rooms without special additional protection. The use of personal dosimeters is compulsory, along with their monthly controls. The source of radiation which is sealed into the irradiation device is closed-type, therefore no radioactive waste or radioactive emissions to the environment are generated during work. Cs-137 irradiates beta and gamma rays. The protective lead and steel casing prevents beta rays from reaching the sample, while highly penetrating gamma rays which consist of electromagnetic waves (such as light or microwaves) do reach the samples.

Irradiated products do not emit radiation themselves. Erythrocytes can be irradiated up to 14 days from the date of their collection and preparation, and they can be used for up to 28 days after irradiation or until the end of their shelf life. In the case of newborns, irradiated blood products are transfused within 48 hours of their irradiation. Platelets can be irradiated at any time within the shelf life and the shelf life remains unchanged after irradiation. It is a major advantage for patients and clinics that irradiated products can now be obtained 24 hours a day throughout the year.

#### NAT TESTING

NAT methods are used to demonstrate the presence of viral nucleic acids (RNA, DNA) in various biological samples and thus to prove viral presence directly and reliably, and thus confirm that blood is in fact infectious. Such units are naturally not used for transfusion. These techniques are used also for screening of blood units to prevent infections via transfused blood.

The principle of NAT methods is to multiply and detect small amounts of genetic material.

The target sequences of new particles of nucleic acids (from 10 to 100 NA, so-called amplicons) in the DNA and RNA helix are multiplied so many times (several 100,000 times to several million times) by using the enzymes which are involved in biochemical reactions, that they can be detected with biochemical reactions. The target amplicons are highly specific. Only those NA particles are selected that are specific for an individual organism and do not appear in the genomes of other organisms.

Above all, the efficiency of NAT testing is expressed as the pathogen detection power during the so-called 'seronegative window'. Using NAT methods, for example, HIV can be detected up to 10 days before its antibodies are confirmed by anti-HIV serological tests. For HCV, the diagnostic window is shortened by 2 months and for HBV by 25 days.

NAT has such capabilities that it also enables the detection of those infections which involve a low viral load. This is especially important in the case of hepatitis B viral infection when the viral particles have already disappeared from the bloodstream, but the virus is still present in traces in liver cells or the bloodstream. This is so-called latent or silent hepatitis.

In 1999, Slovenia was among the first countries to introduce NAT screening. Only testing for the hepatitis C virus was implemented at that time, as the calculated advantage of searching for infection with this virus was the highest. Due to the complexity of this technology, testing was done on several pooled blood samples. However, further studies and the development of this technology have enabled simplifications of these procedures. At the end of 2006, we therefore started introducing a new technology which concurrently searches for three viruses: hepatitis B, C and HIV. Modern technologies enable quick and simple performance of tests on individual blood samples, which additionally increases the efficiency and reliability of searching for and eliminating infectious blood units. Our experience to date has revealed a small number of persons with a silent hepatitis B viral infection, and the possibility of spreading the infection to recipients in these cases has fortunately been prevented.



# DIAGNOSTIC AND THERAPEUTIC SERVICES

#### DIAGNOSTIC SERVICES

Immunohematologic tests enable safe blood transfusions and organ/tissue transplantation, and they also prevent certain undesirable immune phenomena following transfusion or transplantation and during pregnancy.

Whenever a patient is expected to require a blood transfusion, his/her AB0, Rh and Kell (K) blood types need to be determined and the so-called cross-matching test needs to be done which ensures that no adverse reactions will occur after transfusion due to erythrocyte antibodies following a transfusion. Patients always receive blood of their own AB0, Rh and Kell (K) types, and only in exceptional cases is it permissible to transfuse blood of other blood types.

In a certain percentage of patients, the cross-matching test shows the presence of erythrocyte antibodies, and this necessitates additional tests, specifications of erythrocyte antibodies. Then, on the basis of the determined specificities of erythrocyte antibodies, the patient can receive a transfusion of properly matched erythrocyte components.

In certain groups of patients, primarily those with hemolytic anemia, two other tests - the direct and indirect Coombs' test - need to be done as part of diagnostic procedure in order to ensure successful treatment.

By performing immunohematologic and immunogenetic tests, the BTCS also participates in the preparation of patients for transplantation of various organs and tissues. In 2006, 48 kidneys, 7 hearts and 8 livers were transplanted in Slovenia, along with 85 transplantations of hematopoietic stem cells, 67 of which were autologous, 11 were from a related donor and 7 from an unrelated donor.

Tests are also conducted to detect potential incompatibility of fetal erythrocyte antigens with those of the mother, which causes so-called fetomaternal incompatibility and hemolytic disease of the fetus and newborn.

The BTCS' immunohematologic activities also include the detection of platelet antibodies, which develop as a result of an immune response to platelet antigens and lead to a decrease in the platelet count.

The presence of platelet antibodies is determined in the serum as well as on platelets, along with the specificity of the detected antibodies.

Tests of the granulocyte species constitute an important part of the BTCS' activities, including granulocyte serology and molecular biology tests. Granulocyte antibodies cause alloimmune neutropenia in newborns, autoimmune neutropenia, drug-related neutropenia and certain transfusion reactions, such as the TRALI syndrome and non-hemolytic febrile reactions.

Granulocyte antibodies may develop during pregnancy or after blood transfusions due to potential incompatibility of granulocyte antigens between the mother and fetus or in the blood recipient and after transfusions. Granulocyte autoantibodies are most commonly found in children during the first years of their life, but later they disappear spontaneously in most cases. In elderly patients, they are mostly found by coincidence and appear as part of other autoimmune and malignant diseases.

The BTCS also conducts certain special activities in the field of cellular engineering and molecular biology tests. For example, fetal genes can be are determined from a sample of the amniotic fluid and hematopoietic and other stem cells are prepared as starting points for various applications in neurology, cardiology (treatment of myocardial infarction), and gynecology (treatment of infertility). Technology is also being developed for the use of platelets in the treatment of bone fractures.

Molecular biology methods are also extremely important in cases of unclear or inconsistent serological results.

#### As part of immunohematologic tests, the Blood Transfusion Service performed:

118.831	compatibility tests.

77,607 AB0 and RhD blood typing tests.

33.027 indirect Coombs tests.

9.205 direct Coombs tests.

2,204 specifications of erythrocyte antibodies,

4,370 tests for HDN prevention,

833 tests for detecting platelet antibodies.

66 granulocyte tests, and

95 molecular biology tests.

## As part of microbiological tests, the Blood Transfusion Service performed the following ones for patients and other subjects:

5,538	tests for hepatitis A virus,
52,688	tests for hepatitis B virus,
17,696	tests for hepatitis C virus,
96	tests for hepatitis D virus,
15,243	tests for HIV infection,
13,312	tests for antibodies against Treponema pallidum,
273	tests for antibodies against CMV.

#### THERAPEUTIC SERVICES

Transfusion medicine is not intended only for substitution treatment of patients with blood components and medicinal products prepared from blood and plasma – it also includes a number of other therapeutic procedures.

Therapeutic collection of blood and blood components is part of the palliative treatment of certain diseases. Depending on the nature of the disease, whole blood can be taken from patients, or only cells or plasma with the use of an apheresis procedure.

Preoperative autotransfusion is an alternative method of transfusion treatment in which the patient's own, autologous blood is taken and appropriately stored, and is later transfused back to the same patient during or after a planned surgery. Autotransfusion is the option used primarily in patients scheduled for orthopedic surgical procedures or in those with confirmed erythrocyte antibodies when compatible allogenic blood cannot be provided. In most cases, one to two units of blood are taken 7 to 14 days prior to the planned surgical procedure.

#### The following therapeutic services were performed:

- 1,798 collections of autologous blood,
- 1,228 therapeutic collections of whole blood,
  - 1 leukapheresis,
- 141 collections of hematopoietic stem cells ,
- 85 transfusions of hematopoietic stem cells,
- 3 procedures for concentrating bone marrow using a cell separator,
- 1 procedures for collecting and storing umbilical blood,
- 12 therapeutic plasmaphereses.

## **BONE MARROW REGISTRY**

In 2006, 2,875 new donors were obtained, so that at the end of 2006 the Slovenia-Donor Registry contained 7,694 registered donors.

# INVESTING IN KNOWLEDGE AND INNOVATION

The BTCS houses three research groups which comply with the criteria and requirements of the Slovenian Research Agency (ARRS) for managing national projects and performance of research activities.

The BTCS is also a member of the Biotechnology and Pharmacy excellence centre. Within the framework of this centre, it participates as a partner in the research and development project entitled Development of New Medicines and Biochips.

(Duration: from 15 July 2004 to 14 June 2007)

In addition, BTCS researchers are also involved in the national research programme P4-0176 (D):

Molecular Biotechnology: From Dynamics of Biological Systems to Applications.

(Duration: from 1 January 2004 to 31 December 2008)

A list of all other scientific-research and developmental activities is shown below under the relevant categories:

#### INTERNATIONAL RESEARCH PROJECTS

Bilateral Slovenian-German project entitled 'System Biology Tools Development for Cell Therapy and Drug Development', short name SYSTHER. It is conducted within the framework of the BTCS.

(Duration: from 1 November 2006 to 30 October 2011)

#### **NATIONAL RESEARCH PROJECTS**

More detailed data on national research projects coordinated by the BTCS and those in which the BTCS is a participating partner can be found at the web site: http://sicris.izum.si/

#### PROJECTS MANAGED BY THE BTCS

ARRS Code / Duration / Project Title

L4-6325 / from 1 February 2004 to 30 January 2007

Development of tissue engineering bone substitutes for use in parodontology, traumatology and orthopedics

L3-6006 / from 1 July 2004 to 30 June 2007

Prionic diseases and their diagnosis

L3-6011 / from 1 July 2004 to 30 June 2007

Isolation, characterization and differentiation of human stem cells as the basis for cell therapy

L1-6295 / from 1 July 2004 to 30 June 2007

Dendritic cells prepared from human monocytes – activators and modulators of specific immune responses

L7-7457 / from 1 September 2005 to 31 August 2008

Use of cultured skin substitutes for the treatment of chronic and acute wounds

#### PROJECTS MANAGED BY OTHER RESEARCH INSTITUTIONS

ARRS Code / Duration / Project Title

J3-6072 / from 1 July 2004 to 30 June 2007

Genetic background of chronic diseases in children and adolescents II

J3-6290 / from 1 July 2004 to 30 June 2007

Treatment of unhealed and poorly healed fractures of long bones using platelet enriched plasma

L3-6265 / from 1 February 2004 to 30 January 2007

Use of cultured autologous cartilage cells for the treatment of vesicourethral reflux

J1-6001 / from 1 February 2004 to 30 January 2007

Chemical and biological tracing of neonicotinoids and their effects on the environment

# **EDUCATION**

The following forms of education are performed as part of the Blood Transfusion Service's activities:

#### 1. SECONDARY SCHOOL EDUCATION at the:

- Secondary School of Pharmacy, Cosmetology and Health Care,
- Medical Secondary School.

#### 2. UNDERGRADUATE EDUCATION in transfusion medicine at the:

- Medical Faculty,
- Faculty of Pharmacy,
- Faculty of Chemistry and Chemical Engineering,
- University College of Health Care.

#### 3. POSTGRADUATE EDUCATION:

- internship for bachelors of science in pharmacy,
- specialization in clinical pharmacy and drug design,
- specialization in transfusion medicine,
- specializations in other clinical specialties, such as surgery, orthopedics, gynecology and obstetrics, anesthesiology, clinical
- microbiology, internal medicine and pediatrics,
- course in transfusion medicine for health-care professionals with secondary, high, higher professional and higher education
- levels working in the field of transfusion activity at transfusion institutions and hospitals.

During the school year, all transfusion departments are visited by primary school students, primarily third and seventh grade students, as well as secondary school and university students, to be informed of blood collection activities and the activities of transfusion departments, as they are related to their school curricula.

Moreover, transfusion departments also perform educational courses for organizers of blood collection sessions with the Red Cross of Slovenia, and for bone marrow donors who are included in the register of unrelated donors.

#### In 2006, the BTCS organised the following trainings:

- · Donors with HIC (Health Insurance Card),
- · ScanSystem for detecting bacteria in platelet components,
- · Working safely with liquid nitrogen,
- · Occupational and fire safety,
- · Storing samples at low temperatures.
- Mentor training,
- CETTERM 2006 Symposium Cellular therapy, regenerative medicine and tissue engineering,
- · Working safely with hazardous chemicals,
- · Public procurement,
- · Resuscitation course.
- National professional qualifications possibilities in the field of transfusion medicine.

#### The BTCS employees also participated in numerous external training courses in 2006:

- Professional seminars organized by the Association of Transfusion Medicine, in Podčetrtek in April and October.
- 1st professional meeting of the Slovenian Association of Transplantation Medicine in Čatež,
- · Laboratory management how to use good practices according to ISO 9001, in Ljubljana,
- Professional seminars organized by the Association of Laboratory Technicians in Podčetrtek,
- Validation and good practices, in Ljubljana,
- · Seminar on flow cytometry, in Ljubljana,
- · Challenges of laboratory medicine, in Ljubljana,
- Internal audits and quality management systems in medical laboratories, Ljubljana,
- Ensuring correct operation of medical equipment and safe work environment, Liubliana,
- Professional seminars organized by the Section of Nurses and Medical Technicians (NMT) for Anesthesiology, Intensive Care and Transfusion Medicine, in Rogla,
- Professional seminars organized by the Association of Hematology Nurses and Medical Technicians (NMT) in Podčetrtek.
- 13th Symposium of Emergency Medicine in Portorož,
- The life-threatened patient. NMT Section in Emergency Care, in Čatež,
- · Strategy of development in modern medicine is a bridge to basic research, in Portorož,
- Working in health care teams, in Ljubljana.

#### The BTCS hosted:

The 1st Regional consultation on tissue and organ transplantation for NIS and CAR, organised by the World Health Organisation from 31 August to 2 September,

Regular annual meeting of the European Blood Alliance (EBA), which took place in October.

#### The BTCS also cooperates with the following international professional organisations:

- with the WHO, in the organization of workshops on implementing a high-quality and safe blood supply in Central and Eastern European countries,
- with the Sarajevo Institute of Transfusion Medicine, the BTCS traditionally cooperates in the education of their professionals on the introduction of cytaphereses and bone marrow transplantations,
- · with the Blood Bank and Institute for Production of Biological Products in Chengdu, China,
- with the Tissue Typing Laboratory, Dept. of Blood Group Serology, AKH in Vienna, Austria, in the field of sequencing and external quality controls (EFI),
- with the Immunogenetics & Transplantation Immunology Department of Immunohematology & Blood
  Bank in Leiden, the Netherlands (Eurotransplant reference laboratory), in the field of determining antibody
  allosensitisation and external controls (EFI),
- with the Tissue Typing Laboratory, University Hospital in Maastricht, the Netherlands, in the field of external quality controls (EFI).
- with the HLA Laboratory, BRK Blutspendedienst, Klinikum der Ludwig Maximilians Universität in Munich, Germany, in the field of HLA typing of unrelated HSC donors,
- with the UCLA Immunogenetics Center, Los Angeles, USA, in the field of external quality controls for serological HLA typing,
- with the AVIS Veneto Treviso, Italy, in the field of promotion of HSC donation,
- with the Treviso Cord Blood Bank, Italy, in the field of research of mesenchymal stem cells,
- with the CDC, Atlanta, USA, in the field of external quality controls for determination of HIV antibodies,
- with the VQC EQAS a part of WHO, in the field of external controls for serological and NAT testing for viral markers.
- through cooperation in various programs of external controls for infection markers (UK NEQAS Great Britain, Labquality Finland),
- with the CLB in Amsterdam, the Netherlands, in the field of prenatal testing.
- with the Blutspendedienst SRK in Bern, Switzerland, in the field of external quality controls for immunohematologic testing,
- with the UK National Blood Service in Manchester, Great Britain, in the field of external quality controls for anti-D quantitation,
- with the IBGRL, Red Cell Reference Department in Bristol, Great Britain, in the field of immunohematology.

# INDIVIDUALS WHO HAVE MADE A MARK ON THE DEVELOPMENT OF TRANSFUSION MEDICINE IN SLOVENIA

#### Prof. Dr. Mateja Bohinjec, BA Biol., Senior Councillor

Prof. Mateja Bohinjec, PhD, was born on 13 July 1932 in Trbovlje, Slovenia, to parents Robert Plavšak, a mining company employee, and Franja Plavšak, a teacher. She completed primary and secondary school in Trbovlje. In 1959, she graduated from the Biology Department of the Faculty of Natural Sciences and Engineering in Ljubljana. During her studies, she worked as junior assistant at the Institute of Anthropology for several years. During this time, she also participated in research work and in 1958 received the Prešeren Student Award.

After completing her studies, she was employed at the Blood Transfusion Centre of Slovenia (BTCS) and in 1960 passed the professional examination in Clinical Biology. During the period from 1961 to 1962, she undertook further studies with scholarship from the British Council at the Immunology Department of the Wright-Fleming Institute in London.

In 1964 and 1965, she participated as a Red Cross scholar in a study of procedures for obtaining gamma globulins for intravenous administration, which was conducted at the Theodor Kocher Institute for protein studies in Berne, Switzerland.

In 1966, she was awarded the title of Doctor of Science in the field of Biochemistry at the Medical Faculty of Ljubljana. Her doctoral thesis was entitled Metabolism of Normal and Pathological Gamma Globulins.

During her employment at the BTCS, Prof. Mateja Bohinjec first founded the Laboratory of Biochemistry, which was later renamed Laboratory of Immunology. She also introduced many important laboratory tests in the field

of clinical immunology. In 1970, she became involved primarily in the study of immunogenetics of the HLA system of tissue antigens and determination of histocompatibility (tissue compatibility) for the needs of clinical transplantation. In 1983, she accomplished a pioneering effort in founding the Tissue Typing Centre. She undertook further training in the field of immunogenetics and histocompatibility at several reputable researched centres, e.g. in Houston, London, Oxford, Cambridge, Lyon, Paris and Vienna.

The Ljubljana Medical Faculty Council confirmed her election to the position of assistant professor in May 1979, and in February 1985 she was awarded the title of associate professor in the field of immunology. In 1986, the Association of Medical Societies of the then SFR Yugoslavia bestowed upon her the prestigious title of allergologist and clinical immunologist.

At the Medical Faculty of Ljubljana, she occasionally participated in the undergraduate studies programme and regularly participated in the postgraduate studies programme. In addition, she also worked within the postgraduate studies programme of the Faculty of Natural Sciences and Technology, Pharmacy UTO. She passed her extensive knowledge and many insightful ideas on to young professionals, as she was a mentor to many undergraduate, masters and doctoral students in preparing their theses. She is also a sworn court expert for disputed paternity testing. Furthermore, she initiated the founding of a knowledge centre in the field of transfusion medicine at the BTCS.

Up until her retirement, she was actively involved in the highest managerial and professional bodies of the BTCS and was also a member of the specialist board for the field of transfusion medicine. With her exceptional spirit and enthusiasm, she founded the Slovene registry of unrelated bone marrow donors called Slovenia-Donor at the end of 1991, together with her closest associates. The next year, this registry became a full member of the world register Bone Marrow Donors Worldwide (BMDW). She significantly contributed to the fact that Slovenia was the only country among new EU member states to be a full member of Eurotransplant, a non-profit international organisation for exchanging organs from unrelated cadaveric donors, upon its accession to the EU. Her efforts for founding an RS institute for tissue and organ transplantation entitled Slovenia-Transplant were also successful. This institute now serves as an umbrella organisation, which coordinates and supervises the implementation of national transplantation programmes.

With her exceptional professionalism and wide-ranging knowledge, Prof. Bohinjec put Slovenia on the world map in the field of immunogenetics and histocompatibility. Among her other accomplishments during the past six years since her retirement, she also organised three reputable international postgraduate schools within the framework of the BTCS and under the patronage of many reputable international institutions, including the European Federation of Immunogenetics (EFI) and the World Health Organisation (WHO).

As a guest editor of the reputable professional journal Transplant Immunology, she also ensured that all lectures were published in this journal in the form of review articles.

On 22 June 2006, Dr. Janez Drnovšek, President of the Republic of Slovenia, awarded her the Gold Order of Merit for life achievement in the field of transfusion medicine, in particular for her contributions to the development of immunogenetics and histocompatibility testing.

As a leader of many research projects and author of major professional articles, she has made an indelible mark in Slovene medicine. She set the foundations for immunochemistry, immunogenetics and histocompatibility in Slovenia and has had an important influence on the development of national transplantation programmes.

Prof. Mateja Bohinjec, PhD, is an exceptional individual who always successfully represented Slovene knowledge in the wider world and passed it on to younger generations unreservedly and with great enthusiasm. She weaved her whole life into the development of immunochemistry, immunogenetics and histocompatibility and thus became a synonym for professionalism of the highest order in these fields.

# HEAD PHYSICIAN PROF. EDVARD GLASER, PhD, TRANSF. MEDICINE SPEC. (1922-2007)

(Sources: www. mariborcan.com and vestnik.szd.si.)

Head Physician Prof. Edvard Glaser, PhD, was born on 5 February 1922 in Maribor. His parents were also from Maribor; his mother was a homemaker and his father a railway company clerk. He completed primary and secondary schools in Maribor.

As a young man, he witnessed the horrors of World War II, and immediately after the war enrolled in the Zagreb Medical Faculty. He was also prompted to choose the medical profession because of his mother's illness, which led him to think about the importance of medical studies. After completing his studies, his hardships were not over: on a compulsory administrative order, he was dispatched to a place that is heavily involved with blood, a transfusion station, and unfortunately, the mere sight of blood made him sick. Nevertheless, he was to become one of the most reputable transfusion specialists in the country.

He started working at a transfusion station in his home town, as transfusion medicine was still in its early stages in Slovenia. In those times, Dr. Glaser and his then superior, Dr. Gorišek, did pioneering work in this field, including the introduction of blood donation sessions. He later undertook residency at the Military Medical Academy in Belgrade, Serbia, and the Belgrade Institute of Blood Transfusion, and in 1964 became the first Slovene specialist of transfusion medicine. In the same year, he also specialised in internal medicine. He founded the Department of Transfusiology and Immunohematology in Maribor and initiated many new

laboratory activities. For a time, he was also head of this department.

He underwent further training at reputable world clinics and participated in many congresses. He received a doctorate from the Ljubljana Medical Faculty in 1976. He was elected assistant professor in 1977 and became associate professor in 1982. As a pedagogue, he trained many future transfusion specialists. Prof. Glaser wrote numerous professional articles and published independent professional brochures. He participated in the production of a film on intrauterine fetal transfusion. He also organised, led and hosted many symposia and seminars, as he was a splendid organiser. He lectured in both Slovenia and abroad. He became chairman of the Association of Hematologists and Transfusiologists of Yugoslavia and also chairman of the Transfusiology Section, which is part of the Slovene Medical Association. He was particularly active in the organisation of fundraising for the construction of the Maribor General Hospital as chairman of its fund, since blood donors were effective promoters of such fundraising and it always proved successful in Maribor. He was an honorary chairman of the Dr. Milan Černelč Fund's committee and also participated in activities of the Red Cross for several years. Moreover, he was a member of various international organisations, including the German Association of Transfusiologists and Hematologists and the International Association of Hemogenetics. He made significant contributions to the research of the history of medicine in Slovenia and was therefore also the chairman of the History of Medicine Section within the Slovene Medical Association, and the Maribor chapter of the Scientific Society for the History of Health Culture in Slovenia, as well as the Maribor Society for the Fight against Cancer.

The research work of Prof. Glaser was focused on transfusiology, immunohematology and hemostasiology.

Prof. Glaser was also active in various other fields outside of his medical practice. He introduced a visiting nurses service in the Maribor area. In 1961, he was elected chairman of the administrative board of the Fund for the Construction of the Maribor General Hospital. He was also a member of the Maribor University professors' Executive committee.

His broad range of interests and activities even included football; he was the cofounder of the Maribor Football Club and a member of its supervisory board.

In spite of his great enthusiasm for his work, which did not exclusively involve transfusion medicine, he never neglected his family. They showed considerable understanding for his work obligations, since his wife was also a doctor and his daughter dedicated her life to medicine as well.

Throughout his prosperous life, Prof. Glaser received many awards, for example:

 On 14 February 2002, he was awarded Maribor's Bronze Coat-of-Arms by Boris Sovič, Mayor of the City Municipality of Maribor,

- On 15 November 2002, he received a national medal for his selfless medical and humanitarian work, which was presented to him by Milan Kučan, President of the Republic of Slovenia,
- On 19 October 2004, he was also awarded the title of honorary townsman of the City of Maribor.

Based on all of the above, Head Physician Prof. Edvard Glaser has made significant contributions to the development of health care in Slovenia, especially in the field of blood donation in the Maribor region, as well as throughout Slovenia.

#### Prof. Ljerka Glonar, Transf. Medicine Spec., Senior Councillor

Prof. Ljerka Glonar, PhD, was born in 1926 in Celje, in a doctor's family. During World War II, her family was deported to Križevci, Croatia, where she completed secondary school in 1945. A year later, she enrolled in the Zagreb Medical Faculty, from which she graduated in 1952. She later also nostrified her medical diploma with the Medical Faculty of the University of Graz.

In September 1953, immediately after completing her internship, she was employed by the then transfusion station of the Ljubljana Medical Faculty, which later developed into the Blood Transfusion Centre of the People's Republic of Slovenia in 1955 and is presently called the Blood Transfusion Centre of the Republic of Slovenia. In 1965, she completed her specialisation in transfusion medicine at the Medical Faculty of Zagreb and in 1976 successfully defended her doctoral dissertation entitled Study of Rh Sensitisation in Slovenia at the University of Ljubljana. Her mentor was Prof. Trampuž, a reputable gynecologist.

Prof. Glonar was dedicated to her work at the Blood Transfusion Centre of the Republic of Slovenia and transfusion medicine in general throughout her life. At the beginning of her professional path, she worked at the Department for Blood Collection and Preservation, but later became increasingly interested in immunohematology, as well as the development and introduction of new laboratory tests to determine various characteristics of blood, which would serve as the basis for safer blood transfusion treatments.

The main subject of her professional interest was the detection and prevention of hemolytic disease of the newborn. Her objective was to ensure timely detection and elimination of risks to newborns and their mothers arising from incompatibilities in rhesus (Rh D) antigens. The essential measure introduced by Dr. Glonar, which was based on the latest medical advances in the world, was the compulsory protection of all RhD-negative pregnant women and women in labour with immunoglobulin anti-D injections. In addition, she established the national register of Rh sensitised women and introduced a programme for collecting plasma from sensitised

women to produce protective serum for preventing sensitisation in other pregnant women.

Owing to the professional dedication, determination and endless energy of Dr. Glonar, Slovenia has been implementing systematic control and protection of all pregnant women for decades.

Another part of her professional activities involved the detection of blood-transmissible diseases. She strived for the enactment of compulsory testing of all collected blood units for pathogens causing infectious diseases. As a result of her efforts, the Blood Transfusion Centre of Slovenia has been testing all collected blood for the hepatitis B antigen since 1970, and for antibodies against the HIV virus since 1986. Since 1993, all collected blood has also been tested for the hepatitis C virus.

Prof. Glonar made a major professional and organisational contribution to the systematic treatment of Slovene patients with hemophilia. She was also a cofounder of the Hemophilia Patients Society, which serves as a professional link between patients and practitioners in this field and has a crucial influence on decision-making concerning appropriate treatment for this patient population. On her initiative, the BTCS began producing a cryoprecipitate for regular treatment of hemophilia as early as 1967.

She continuously strived for mutual linking and collaboration between practitioners from different clinical disciplines, knowing that this was in the best interest of patients and would also promote the development of individual medicinal disciplines. In 1985, she became an associate professor and in 1990 a full professor at the Medical Faculty of Ljubljana. In addition, she also lectured at the Junior College for Nurses and Medical Technicians. She passed her immense professional experience and knowledge to generations of students, young doctors and nurses, as well as laboratory technicians and other professionals. In this way, Prof. Glonar made an important mark on Slovene medicine through her work.

Owing to the commitment of Prof. Glonar, Slovene transfusion medicine became better known in Slovenia and abroad. She always tried to make sure that Slovene medical professionals had the best knowledge and technology available in this field at their disposal, and that they were able to use the latest professional advances in their work.

After her retirement, she remained active as a consultant for the BTCS and also dedicated her time to writing. Her book Doctors' Memories is a resounding testimony of Slovene medical practice and contains stories from one hundred Slovene doctors from all generations, providing insights into the lives and work of physicians from various medical specialties. She also published many articles in the well-known Slovene medical journal ISIS.

On 22 June 2006, Dr. Janez Drnovšek, President of the Republic of Slovenia, presented her with a Golden Order of Merit for life achievement in Slovene transfusion medicine, in particular for her contributions to the detection and prevention of hemolytic disease of the newborn in Slovenia.

## LEGISLATION

Health-Care Activities Act

(ZZDej, Official Gazette of the RS (OG RS), No. 9/1992)

Blood Supply Act

(ZPKrv, OG RS, No. 104/2006)

Regulations concerning compulsory testing of blood and blood components

(OG RS, No. 9/2007)

Regulations concerning the storage, issuing, transport and disposal of unused blood and blood products

(OG RS, No. 100/2002)

Regulations concerning the procedure for collecting, storing and using hematopoietic stem cells

(OG RS, No. 104/2003)

Regulations concerning professional medical standards for blood collection

(OG RS, No. 9/2007)

Regulations concerning the conditions for patients obtaining their own blood and collecting individual cells and blood plasma

(OG RS, No. 118/2003)

Regulations concerning the conditions for the organization and implementation of blood donation sessions

(OG RS, No. 92/2003)

Regulations on the work methods of the Medical Council for the supply of blood, blood products and medicines made from blood

(OG RS, No. 39/2002)

Regulations concerning the collection, preparation, storage, issuing and transport of blood and blood components

(OG RS, No. 9/2007)

Regulations concerning transfusion-related tests and procedures

(OG RS, No. 9/2007)

Regulations on pharmacovigilance

(OG RS. No. 9/2007)

Regulations concerning professional standards and technical requirements for quality systems related to transfusion activities (OG RS, No. 9/2007)

Regulations concerning the methods and type of access to documentation

(OG RS, No. 9/2007)

Directive 2002/98/EC of the European Parliament and of the Council (dated 27 January 2003) setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, and the Supplement to Directive 2001/83/EC.

Directive 2005/62/EC of the European Commission (30 September 2005) on the implementation of Directive 2002/98/EC of the European Parliament and of the Council concerning Community standards and specifications relating to a quality system for blood establishments

Directive 2005/61/EC of the European Commission (30 September 2005) implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events

Directive 2004/33/EC of the European Commission (22 March 2004) implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.

Regulations undergoing preparation:

- Regulations concerning staff, premises and equipment for transfusion organisations,
- Regulations concerning pricing methodology for blood and blood components.

# **PUBLICATIONS**

# ARTICLES AND OTHER SCIENTIFIC AND PROFESSIONAL CONTRIBUTIONS

#### 1.01 ORIGINAL SCIENTIFIC ARTICLES

BERGANT, Martina, MEDEN, Luka, REPNIK, Urška, SOJAR, Valentin, STANISAVLJEVIĆ, Dragoje, JERAS, Matjaž. Preparation of native and amplified tumour RNA for dendritic cell transfection and generation of in vitro anti-tumour CTL respones. Immunobiology (1979), 2006, vol. 211, str. 179-189. [COBISS.SI-ID 19737639]

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POKLAR ULRIH, Nataša, SKRT, Mihaela, VERANIČ, Peter, GALVANI, Vesna, VRANAC, Tanja, ČURIN-ŠERBEC, Vladka. Oligomeric forms of peptide fragment PrP (214-226) in solution are preferentially recognized by PrPSc-specific antibody. Biochem. biophys. res. commun., 2006, vol. 344, str. 1320-1326. [COBISS.SI-ID 3163512]

STANTIČ-PAVLINIČ, Mirjana, LEVIČNIK-STEZINAR, Snežna, ZALETEL-KRAGELJ, Lijana, HOSTNIK, Peter. Longevity of lasting specific immunity after primary vaccination against rabies - comparison of ELISA and FAVN tests = Trajanje specifične imunosti po primarnem cepljenju proti steklini - primerjava testov ELISA in FAVN. Slov. vet. res.. [English ed.], 2006, vol. 43, no. 3, str. 119-125. [COBISS.SI-ID 2668922]

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ZAVAŠNIK-BERGANT, Tina, BERGANT, Martina, JERAS, Matjaž, GRIFFITHS, Gareth. Different localisation of cystatin C in immature and mature dendritic cells. Radiol. oncol. (Ljubl.), 2006, letn. 40, št. 3, str. 183-188. [COBISS.SI-ID 20249895]

#### 1.02 REVIEW SCIENTIFIC ARTICLE

VRTOVEC, Bojan, SEVER, Matjaž, DOMANOVIČ, Dragoslav, LEŽAIČ, Luka, ČERNELČ, Peter. Stem cell therapy for advanced chronic heart failure = Zdravljenje napredovalega srčnega popuščanja s presaditvijo matičnih celic. Slov. kardiol., 2006, letn. 3, št. 2, str. 138-142. [COBISS.SI-ID 21964761]

#### 1.04 PROFESSIONAL ARTICLES

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VOLJČ, Božidar. Sodobno javno zdravstvo po spremembah v Evropi in Sloveniji. Isis (Ljubl.), 2006, letn. 15, št. 3, str. 52-54. [COBISS. SI-ID 20722649]

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#### CONTACT PERSONS

#### **BLOOD TRANSFUSION CENTRE OF THE REPUBLIC OF SLOVENIA**

Šlajmerjeva 6, 1000 Ljubljana, Phone: (01) 543 81 00

BTCS Director: Asst. Prof. Matiaž JERAS, BA Pharm., PhD

Acting Medical Director: Head Physician Marjeta POTOČNIK, MD, Transf. Medicine Spec.

Director of the Blood Supply Department: Dragoslav DOMANOVIĆ, MD, PhD, Transf. Medicine Spec.

Director of the Diagnostic Services Department: Snežna LEVIČNIK - STEZINAR, Transf. Medicine Spec.

Head of the Centre for the Development and Production of Diagnostic Reagents; Prof. Vladka ČURIN - ŠERBEC, BA Chem., PhD

Head of the Centre for the Supply and Marketing of Medicinal Products and Medical Devices: Marjana RUS - ISKRA, BA Pharm. (Spec.)

#### DEPARTMENT OF TRANSFUSIOLOGY AND IMMUNOHEMATOLOGY MARIBOR

Maribor General Hospital, Ljubljanska 5, 2000 Maribor, Phone: (02) 321 22 75

Department Head: Lidija LOKAR, MD, Transf. Medicine Spec.

#### CELJE DEPARTMENT OF TRANSFUSION MEDICINE

Celje General Hospital, Oblakova 5, 3000 Celje, Phone: (03) 423 35 92

Department Head: Janja PAJK, Transf. Medicine Spec.

#### IZOLA DEPARTMENT OF TRANSFUSION MEDICINE

Izola General Hospital, Polje 35, 6310 Izola, Phone: (05) 660 62 30

Department Head: Irena KRAMAR, Transf. Medicine Spec.

#### MURSKA SOBOTA DEPARTMENT OF TRANSFUSION MEDICINE

Murska Sobota General Hospital, Rakičan, Ulica Dr. Vrbnjaka 6, 9000 Murska Sobota, Phone: (02) 512 31 00

Department Head: Danijela ULEŽIĆ - PAUČIČ, Transf. Medicine Spec.

(In 2007, the Department of Transfusion Medicine was led by Daniel GRABAR, MD, Spec.)

#### NOVO MESTO DEPARTMENT OF TRANSFUSION MEDICINE

Novo Mesto General Hospital, Šmihelska 1, 8000 Novo Mesto, Phone: (07) 391 65 74

Department Head: Ludvika BARAGA - ŽIBERNA, Transf. Medicine Spec.

#### NOVA GORICA DEPARTMENT OF TRANSFUSION MEDICINE

Nova Gorica General Hospital, Ulica padlih borcev 13, 5290 Šempeter pri Novi Gorici, Phone: (05) 330 11 73

Department Head: Janka ČERNE, Transf. Medicine Spec.

#### PTUJ DEPARTMENT OF TRANSFUSION MEDICINE

Dr. Jože Potrč General Hospital, Potrčeva 23–25, 2250 Ptuj, Phone: (02) 749 14 36 Department Head: Marija ŠERUGA - DOLIŠKA, Transf. Medicine Spec.

#### SLOVENJ GRADEC DEPARTMENT OF TRANSFUSION MEDICINE

Slovenj Gradec General Hospital, Gosposvetska 3, 2380 Slovenj Gradec, Phone: (02) 882 34 82

Department Head: Lidija BOHNEC - STRMČNIK, Transf. Medicine Spec.

#### TRBOVLJE DEPARTMENT OF TRANSFUSION MEDICINE

Trbovlje General Hospital, Rudarska 9, 1420 Trbovlje, Phone: (03) 565 25 89

Department Head: Rudi ZUPAN, MD, Surg. Spec.

#### JESENICE DEPARTMENT OF TRANSFUSION MEDICINE

Jesenice General Hospital, Titova 112, 4270 Jesenice, Phone: (04) 586 83 08

Department Head: Zoja ZALOKAR - SAMBRAILO, Transf. Medicine Spec.



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