
LIFE FLOWS

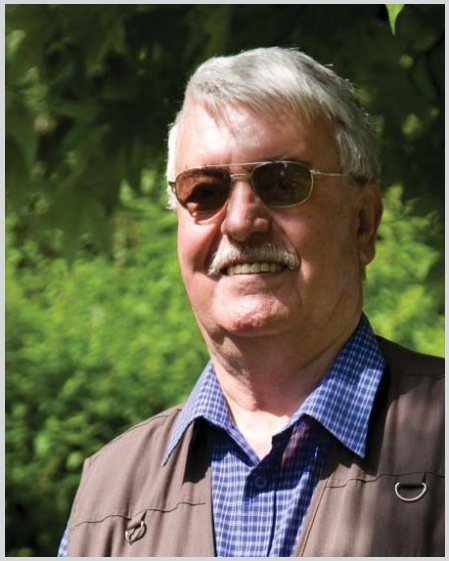
# 2008 ANNUAL REPORT OF THE SLOVENIAN BLOOD TRANSFUSION SERVICE

L I F E  F L O W S

**Today, we offer help,**
**tomorrow, we might need help.**

**Donating blood is one of the noblest ways to help another person.**
**Blood is a medicine allowing doctors to treat and perform demanding procedures**
**and a medicine preserving patients' health and life.**

**Donated blood has changed many sad stories into happy ones,**
**and those involved in these stories are well aware of the invaluable gift they have received.**



**Simo Lajić Dermota**

*“I am a blood donor with all my heart and soul. As a war child, I was aware of how vital it is to receive help when you need it. That is the reason I am proud to have donated blood for more than 30 years every three months, thereby helping other people.«*

**Jan Vogler**

*»It seems to me it is the right thing to do to donate blood. Therefore, I do what I feel is right and I do not leave things that I can do myself to others. My friends from the Silverhawks American football club agree with me and we donate blood together on a regular basis before and after the season.«*

# INDEX

# 2008 IN NUMBERS

| | |
|---|---|
| 93,193 | blood collections |
| 68,136 | blood donors |
| 10,589 | new blood donors |
| 1,152 | blood donation sessions |
| 191,227 | prepared blood components |
| more than 1.5 million | laboratory tests |
| 11,112 | registered bone marrow donors |
| 321 | healthcare professionals |

# BLOOD TRANSFUSION SERVICE IN SLOVENIA

Transfusion medicine provides individuals who need help with sufficient amounts of quality and safe blood and blood products. Symbolically, the activity of transfusion medicine extends from the blood donor's vein to the blood recipient's vein. This encompasses all activities enabling blood therapy, from blood collection, testing, processing and storage to examinations related to blood transfusion, thereby enabling making blood available when needed.

The preparation and processing of donated blood is both a great social and ethical responsibility. The Transfusion Service was organised with a view to performing transfusion medicine activities in Slovenia, the Transfusion Service; its is comprised of the Blood Transfusion Centre of Slovenia (hereinafter referred to as BTCS), with the associated Novo mesto, Trbovlje and Slovenj Gradec Departments of Transfusion Medicine; the Centre of Transfusion Medicine Maribor with an associated unit in Ptuj; the Centre of Transfusion Medicine Celje and Departments of Transfusion Medicine in hospitals in Izola, Jesenice and Nova Gorica (currently in the phase of introduction into the organisational structure of BTCS), and the Department of Transfusion Medicine in Murska Sobota (in the process of incorporation into the Centre of Transfusion Medicine Maribor).

The Transfusion Service network in Slovenia also comprises hospital blood banks in the General Hospital Brežice, the Hospital of Obstetrics and Gynaecology Kranj, and the Hospital for Gynaecology and Obstetrics Postojna. Hospital blood banks have a so-called depot of blood components and mainly perform pre-transfusion testing and some immunohaematology tests during pregnancy and after birth.

The whole transfusion service is responsible for collecting blood (except for blood banks). Blood processing is performed in the BTCS, the Centre of Transfusion Medicine Maribor, the Centre of Transfusion Medicine Celje, and the Department of Transfusion Medicine Izola. Blood collected in Nova Gorica, Trbovlje, Jesenice, Novo mesto and Slovenj Gradec is processed in the BTCS. Processing for Murska Sobota and Ptuj is performed in the Centre of Transfusion Medicine Maribor. The processed blood is then returned to the hospitals according to needs and the plan.

## Transfusion Service reorganisation

The Supply of Blood Act (conforming to European directives) lays down three types of transfusion activity: transfusion institute, transfusion centre and hospital blood bank. Acquiring one of these statuses is conditional on meeting the requirements provided for by the implementing regulations. The conditions for a transfusion institute are fulfilled only by the Blood Transfusion Centre of Slovenia, which conducts blood collection, testing and processing, maintenance of central blood depots, transfusion testing, activities of clinical transfusion medicine and the quality system administration and management. The BTCS also coordinates professional principles, manages education and research and development activity, and provides information technology and expert counselling with surveillance. Hence, the BTCS is responsible for the professional level of blood and blood components supply and connection of transfusion medicine and hospital activity at the national level. So far, the status of a centre for transfusion medicine has been acquired by the transfusion units in Maribor University Medical Centre and Celje General Hospital. Within the transfusion service reorganisation, some hospital transfusion departments were combined with the BTCS Ljubljana or the CTM Maribor, thereby transferring their transfusion activities. In practice, separate units of the BTCS Ljubljana and CTM Maribor were established.

# BLOOD SUPPLY

## Blood collection

Blood donation is an important part of the healthcare system. By their unselfish blood donation, blood donors make an important contribution to realising the principle of self-sufficiency of our country in the field of blood supply. Attaining self-sufficiency means that sufficient amounts of blood are provided to us. This classifies us not only among the well-organised, but also among the unselfish, altruistic nations.

Since 1953, the main organiser responsible for a sufficient number of blood donors has been the Red Cross of Slovenia. Today, this task is performed through a network of 56 regional associations of the Red Cross throughout Slovenia.

The basic form of organised blood donation is regular blood donation sessions. These are conducted in the premises of the transfusion service or in the field. So-called field blood donation sessions are performed by special mobile units throughout Slovenia, mostly in the premises of schools, cultural centres, fire stations, local communities, health centres etc Field collection rooms have to fulfil minimum conditions for blood collection in compliance with the valid legislation.

If there are brief periods of blood shortage or a lack of certain blood types, blood donors are invited to additional blood donation sessions or to individual blood collections. Blood component exchange also occurs within the transfusion service. Thus stock does not depend only on the number of blood donors and blood collections, but also on consumption and the needs.

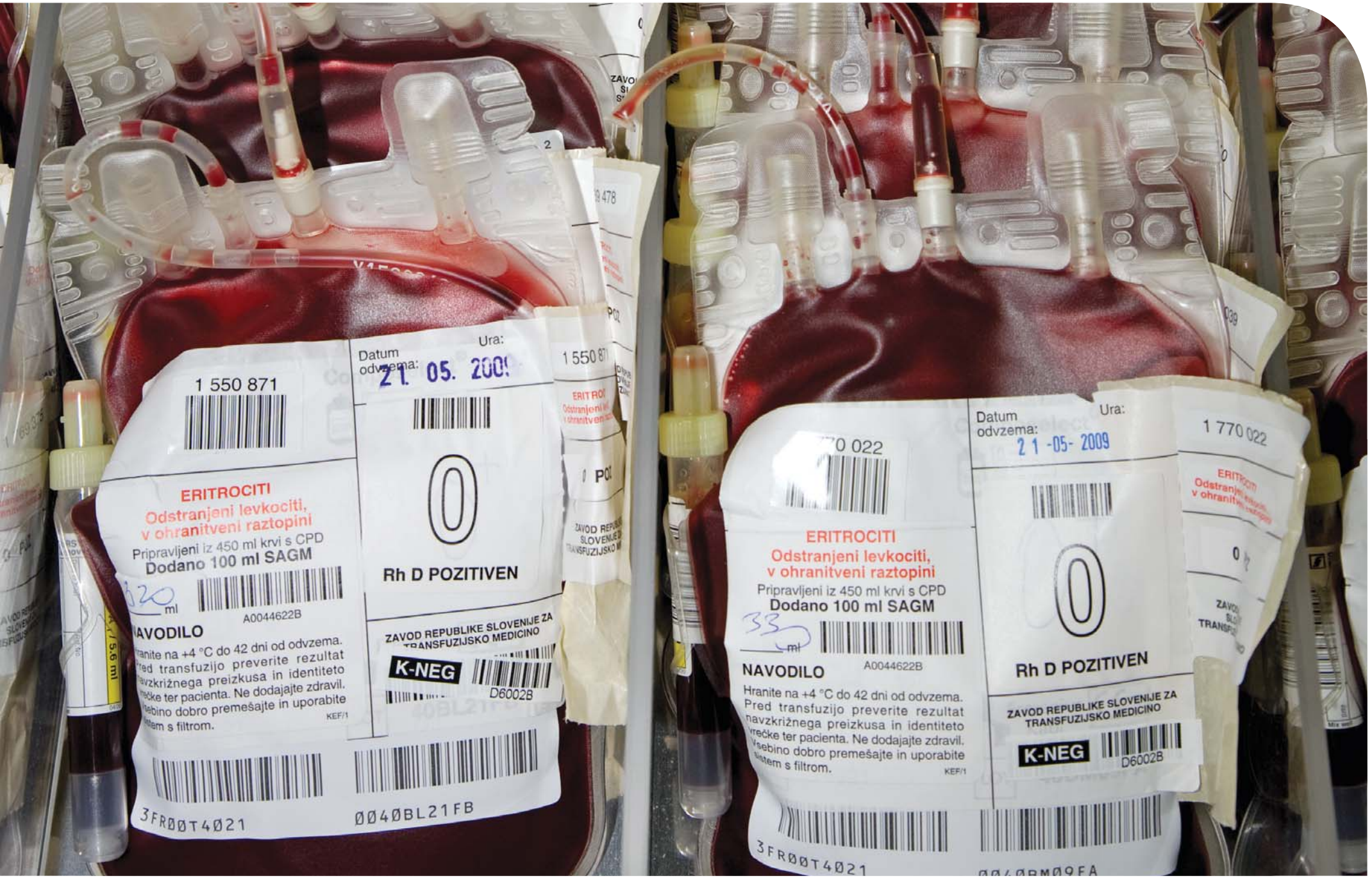
Blood stock adjustment is a highly complex and responsible task requiring the coordinated action of blood donation sessions organisers, transfusion service and users.

**Number of registered blood donors, collections and deferrals by transfusion service in 2008**

| Transfusion service | No. of registered donors | No. of collections | No. of deferrals |
|---|---|---|---|
| Celje | 10,711 | 10,055 | 656 |
| Izola | 5,377 | 5,054 | 323 |
| Jesenice | 3,419 | 3,218 | 201 |
| Maribor | 13,600 | 11,943 | 1,657 |
| Murska Sobota | 4,929 | 4,563 | 366 |
| Nova Gorica | 3,752 | 3,476 | 276 |
| Novo mesto | 4,746 | 4,140 | 606 |
| Ptuj | 3,535 | 3,319 | 216 |
| Slovenj Gradec | 2,840 | 2,769 | 71 |
| Trbovlje | 1,477 | 1,411 | 66 |
| BTCS Ljubljana | 49,788 | 43,245 | 6,543 |
| **Slovenia** | **104,174** | **93,193** | **10,981** |

**Number of performed collections of whole blood, plasmaphereses and thrombocytaphereses by transfusion service in 2008**

| Transfusion service | No. of whole blood collections | No. of performed plasmaphereses | No. of performed thrombocytaphereses |
|---|---|---|---|
| Celje | 10,055 | 0 | 0 |
| Izola | 5,054 | 0 | 0 |
| Jesenice | 3,218 | 0 | 0 |
| Maribor | 11,807 | 7 | 129 |
| Murska Sobota | 4,563 | 0 | 0 |
| Nova Gorica | 3,476 | 0 | 0 |
| Novo mesto | 4,140 | 0 | 0 |
| Ptuj | 3,316 | 0 | 0 |
| Slovenj Gradec | 2,769 | 0 | 0 |
| Trbovlje | 1,411 | 0 | 0 |
| BTCS Ljubljana | 41,470 | 430 | 1,345 |
| **Slovenia** | **91,279** | **437** | **1,474** |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ERITROCITI
Odstranjeni levkociti, v ohranitveni raztopini
Pripravljeni iz 450 ml krvi s CPD
Dodano 100 ml SAGM
320 ml
A0044622B
NAVODILO
Hranite na +4 °C do 42 dni od odvzema. Pred transfuzijo preverite rezultat navzkrižnega preizkusa in identiteto prejemnika ter pacienta. Ne dodajajte zdravil. Vsebino dobro premešajte in uporabite sistem s filtrom.
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ERITROCITI
Odstranjeni levkociti, v ohranitveni raztopini
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# Blood processing

So-called blood components are prepared from whole blood – concentrated erythrocytes, concentrated platelets and fresh frozen plasma. From blood, specifically plasma, medical products are also derived.

In 2008, we completely renovated and automated the platelet preparation procedure. Four to six units of whole blood are required to prepare a therapeutic dose of platelets. First, buffy coat (platelet – leucocyte layer) is extracted from whole blood, and platelets are prepared in a completely automated procedure by means of special devices. Here, five buffy coat units are poured together, the appropriate conservation solution is added, and upon centrifugation, the separated platelets are then poured through a filter, retaining most of the leucocytes in the final bag used for storage. The procedure is performed in a closed system, thereby minimising bacterial contamination. As most of the leucocytes are removed during the process, there are fewer leukocyte-related adverse reactions in transfusion.

As a result of using a special conservation solution, there is from 60 to 65% less plasma in the new platelet preparation, which considerably reduces the incidence of adverse reactions after transfusion associated with plasma components. An important advantage of the new platelet preparation is the fact that it can be further processed in the psoralene inactivation procedure. By adding amotosalen to the preparation and using UV-A radiation, irreversible cross-linking within DNA and RNA occurs, which means that viruses, bacteria, parasites and leucocytes present in the preparation are rendered permanently inactive. Such an approach additionally reduces the probability of the cross-contamination and septic reactions that occur due to bacterial reproduction during the storage of platelet components. Since the remaining leucocytes have thus been eliminated too, additional ionising radiation to prevent transfusion-related graft-versus-host disease is no longer necessary.

**Number of units prepared from whole blood by transfusion service in 2008**

| Transfusion service | No. of conc. erythrocyte units | No. of *conc. platelet units | No. of fresh frozen plasma units |
|---|---|---|---|
| Celje | 9,856 | 694 | 9,839 |
| Izola | 5,090 | 83 | 5,043 |
| Maribor | 21,263 | 2,482 | 21,594 |
| BTCS Ljubljana | 54,039 | 4,440 | 54,218 |
| **Slovenia** | **90,248** | **7,699** | **90,694** |

** pooled unit (fused blood from 5 to 6 blood donors)*

# Patient care

There is no adequate substitute for blood so far. Health- or life-threatening diseases and haemorrhages causing lack of blood and its components can be treated with transfusions. Blood can only be used as a medicine when appropriately collected and examined, adequately processed and given to the patient in an appropriate manner. Otherwise, blood can provoke dangerous conditions, disease or even the death of the recipient.

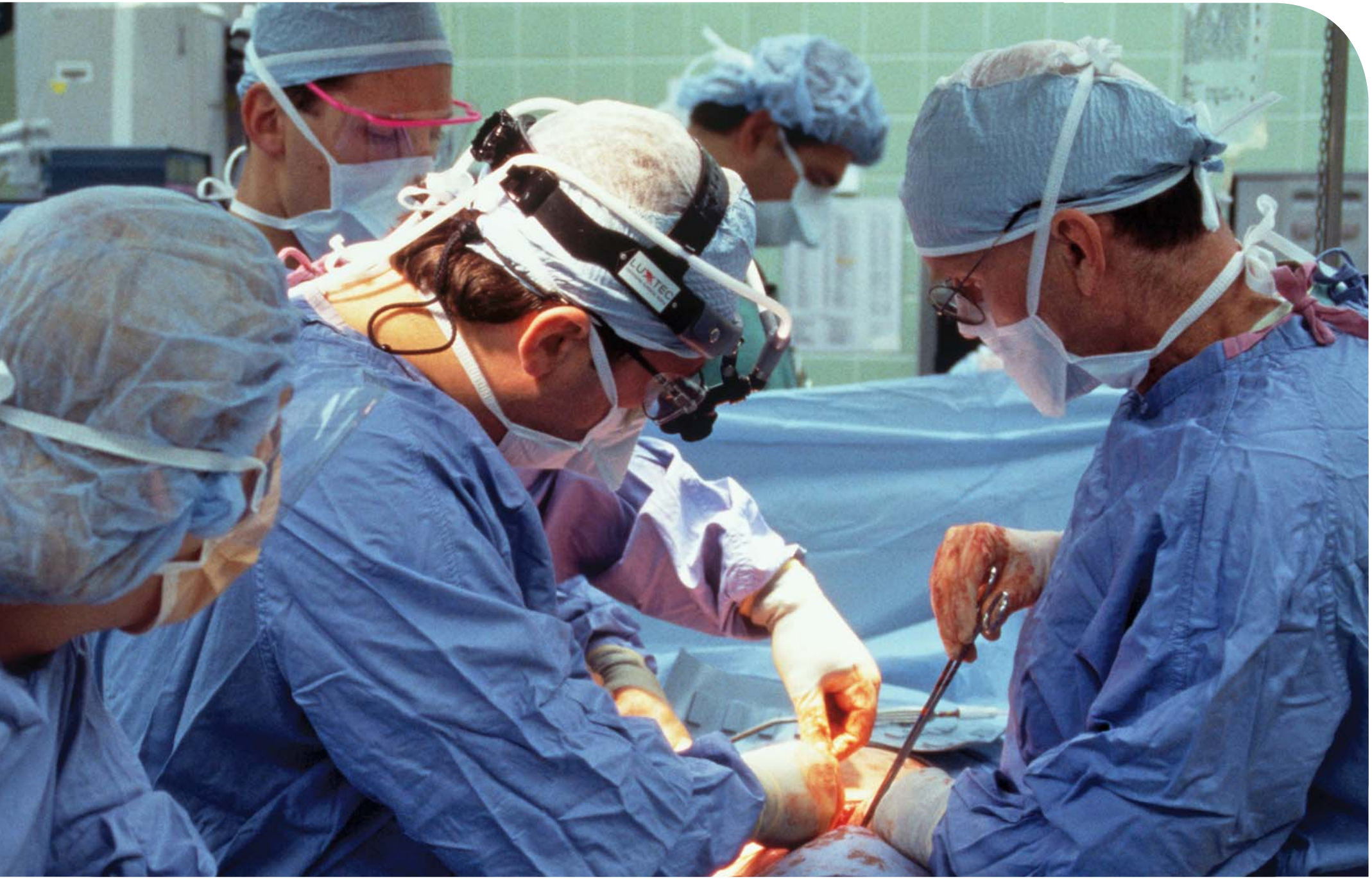
The largest consumers of blood are patients with various haemathological, oncological diseases. A lot of blood is also used for patients undergoing heart operations, organ transplants, and for accident victims etc

**Number of issued blood components by transfusion service in 2008**

| Transfusion service | No. of conc. erythrocyte units | No. of conc. platelet units from whole blood | No. of conc. platelet units thrombocytophereses | No. r of fresh frozen plasma units |
|---|---|---|---|---|
| Celje | 7,554 | 306 | 1 | 2.892 |
| Izola | 5,115 | 160 | 0 | 545 |
| Jesenice | 1,941 | 8 | 22 | 725 |
| Maribor | 14,186 | 1,480 | 111 | 8,113 |
| Murska Sobota | 3,705 | 215 | 131 | 805 |
| Nova Gorica | 3,379 | 329 | 17 | 735 |
| Novo mesto | 3,784 | 453 | 0 | 812 |
| Ptuj | 1,643 | 90 | 1 | 658 |
| Slovenj Gradec | 2,535 | 120 | 14 | 372 |
| Trbovlje | 1,463 | 75 | 2 | 346 |
| BTCS Ljubljana | 37,425 | 2,080 | 2,441 | 13,507 |
| **Slovenia** | **82,730** | **5,316** | **2,740** | **29,510** |

In most transfusions, there are no complications, but they sometimes still occur. In order to recognise such complications and prevent them by introducing measures to increase transfusion safety, data on adverse reactions and events in the entire chain, from the donor to the recipient, are collected. A uniform haemovigilance system operates throughout the country to provide efficient work in this field.

| **Number and type of reported adverse reactions in blood transfusions in Slovenia in 2008** | |
|---|---|
| Haemolysis | 3 |
| Graft-versus-host reaction disease | 0 |
| Transfusion-related lung injury/pulmonary edema | 1/11 |
| Post-transfusion purpura | 0 |
| Allergy/anaphylaxis | 82/8 |
| Non-haemolytical febrile reaction | 91 |
| Bacterial or viral infection | 0 |
| Hypotension | 1 |
| Dyspnea | 2 |
| Other | 8 |
| **Total** | **204** |



# Safe blood supply

Blood should contain no viruses or bacteria, which is provided through the consistent implementation of several types of measure:

– rationalisation of transfusion treatment,
– selecting 'safe' blood donors (without risk factors for infection),
– screening for the purpose of eliminating inappropriate blood units,
– quality assurance in blood collection and processing,
– eliminating and inactivating viruses in blood components,
– retrograde studies of reported suspect blood-borne infections and
– blockade of use of blood products with a suspect infection.

**Testing for infective agents**

Blood for transfusion should not contain agents that cause AIDS, hepatitis B and C, and syphilis. In Slovenia, each collected unit is subject to testing. Each unit is tested on the day of collection. We use state-of-the-art screening methods licensed according to the strictest international criteria and completely automated, allowing for the greatest safety at all times.

The diagnostic window is a barrier preventing perfect safety. This is the time which elapses between the occurrence of infection and the appearance of markers detected by a specific test.

One of the most recent and most important measures to achieve maximum safety in blood supply is the screening of collected blood units for transfusion using methods for direct viral detection (Nucleic Acid Techniques - NAT). NAT is used to detect the presence of viral nucleic acids in different biologic samples. NAT is based on the amplification and detection of small quantities of genetic material, including viruses, if present.

The diagnostic window is significantly reduced by using such methods, as an infection can be detected considerably before indirect serologic infection markers appear. Blood tested using NAT is also safer, because the method is extremely sensitive and enables the detection of infections with a low viral load.

In order to provide the maximum safety of blood in Slovenia, the range of mandatory blood donor testing was expanded by introducing screening for HIV, HBV and HCV using NAT in 2007.

Due to its geographic location and level of healthcare, Slovenia is classified as a low-risk country, with a low infection prevalence from blood-borne agents. One unsuitable blood donor per 2,142 is detected per year (for all markers of interest) and one blood unit per 3,276 collected, respectively.

**Frequency of detecting inappropriate blood units due to infection markers content**

| | | No. of detected blood donors: | Incidence per 100,000 collected units | Prevalence in the collected units |
|---|---|---|---|---|
| Hepatitis B | HBsAg | 11 | $12/10^5$ | 1 : 8,339 |
| | HBV DNA | 7 | $7.6/10^5$ | 1 : 13,105 |
| Hepatitis C | Anti HCV | 4 | $4.3/10^5$ | 1 : 22,934 |
| | HCV RNA | 1 | $1.1/10^5$ | 1 : 91,737 |
| HIV | Anti HIV 1/2/0 and p24 | 0 | / | / |
| | HIV RNA | 0 | / | / |
| Syphilis | Anti Treponema pallidum | 6 | $6.5/10^5$ | 1 : 15,289 |

Reports on contaminations or suspect contaminations and their analyses indicate that transfusion is a safe treatment method today. In 2008, there were no reported contaminations from a blood donor to a recipient.

**Chronology of introduction of individual tests:**

– syphilis: anti-Treponema Pallidum (from 1960);
– hepatitis B: HBsAg (from 1970) and HBV DNA (from 2007);
– AIDS: anti-HIV1/2/0 p24Ag (from 1986) and HIV 1 RNA (from 2007);
– hepatitis C: anti-HCV (from 1993), HCV RNA (from 2000).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DO NOT OPEN DOORS
After Beginning THGRID Program

### Immunohaematologic testing

There are genetic markers on the surface of cells which are typical of each individual, distinguishing them from others. Genetic markers called antigents are also located on red blood cells (erythrocytes). Clusters of antigen types appear on erythrocytes representing blood group types.

In addition to the blood group system AB0, antigens of several other blood group systems are also of immune and clinical importance. These are antigens of Rh (D, C, c, E, e), Kell, Duffy, Kidd, MNS and other blood group systems.

With a view to providing safe and efficient blood therapy, all antigens of immune significance should match completely and potentially immunogenic antigens should match as closely as possible.

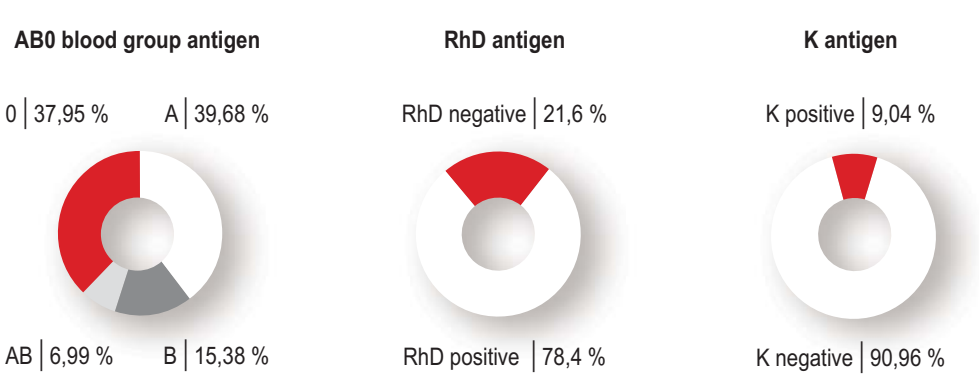
Antigens of AB0 and RhD blood groups are thus determined for each collected blood unit. In the first two blood collections in every blood donor, other antigens of Rh (C,c, E, e) and Kell systems are also determined.
In order to prevent the transmission and harmful action of unexpected erythrocyte antibodies from the donor plasma to the recipient, all units are tested with the indirect Coombs test for the unexpected erythrocyte antibodies. If they are detected, the unit will not be used for transfusion.

### Final control of blood components

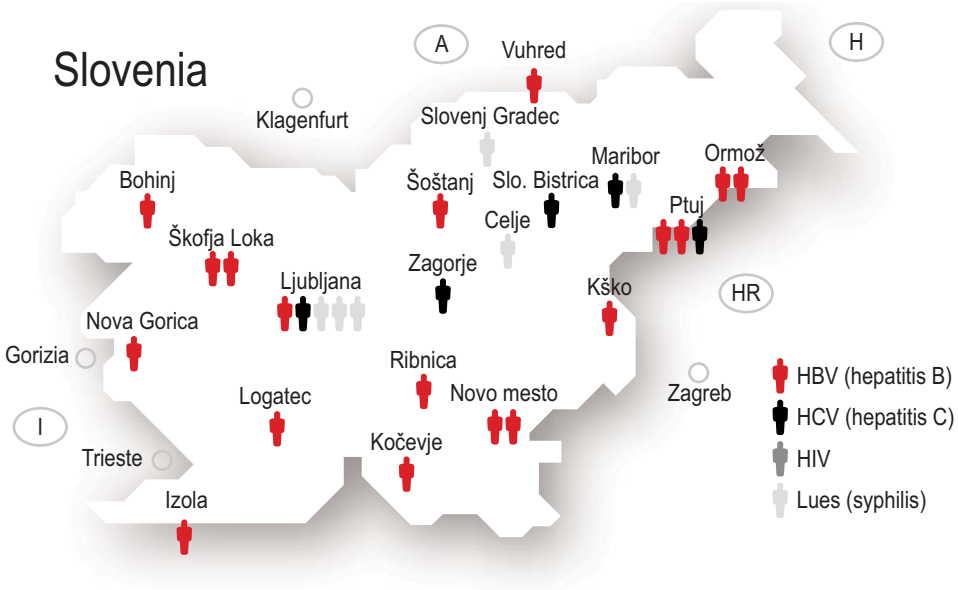
With a view to providing blood safety and efficiency, attention should be devoted to all quality aspects of the prepared blood components. The products are derived from a biological raw input material. The quality and efficiency of the products thus depend on various factors at all levels of collection, preparation, storage, transportation and use.

In order to verify the expected requirements, the testing of a chosen number of components is performed to determine whether they comply with the criteria and target values, and whether the procedures comply with the envisaged specifications. Biochemical and haematological testing of various types is performed in order to establish compliance (considering the values of haemoglobin and haematocrit, the number of unwanted cells, the content of proteins and blood-clotting factors, pH, the presence of bacteria etc.).

**Distribution of blood group types among Slovenian blood donors (data for 37,000 specimens tested by BTCS in 2007)**




**Detected infections among blood donors in Slovenia in 2008**



# THERAPEUTIC AND DIAGNOSTIC SERVICES

## Therapeutic services

Therapeutic blood and blood component collection is involved in treatment of some diseases. In relation to the nature of the disease, whole blood, cells or plasma may be withdrawn from the patient by means of the apheretic procedure.

Preoperative autotransfusions are an alternative to transfusion therapy. The patient's - autologous - blood is collected, properly stored and transfused to the patient peri- or postoperatively. Such collections may only be performed in patients in good psychophysical condition fulfilling the requirements for blood collection. They are mostly patients scheduled for orthopaedic interventions.

By means of therapeutic collection of whole blood, the excess iron accumulated in red blood cells is removed from patients suffering from hereditary haemochromatosis.

In some diseases of haematopoietic tissue, haematologists opt for treatment with stem cell (bone marrow) transplants. Bone marrow can be autologous or allogenic, from a related or unrelated donor. Stem cells can be collected from the donor’s pelvis bone marrow or blood. By transplanting allogenic or autologous stem cells, we actively participate in the treatment of disease.

Therapeutic plasmaphereses are used to remove undesired blood components from the patient’s blood, such as immune complexes, pathological proteins, tumour cells, antibodies, etc

| For therapeutic services, we performed: | |
|---|---|
| 1,502 | autologous blood collections (autotransfusions) |
| 1,327 | therapeutic whole blood collections |
| 112 | autologous haematopoietic stem cell collections |
| 12 | allogenic haematopoietic stem cell collections |
| 26 | granulocytophereses |
| 4 | lymphocytophereses |
| 9 | therapeutic aphereses |

## Diagnostic services

Immunohaematologic tests, certain microbiological tests and tests related to tissue matching are performed as part of diagnostic services.

| For immunohaematologic tests, we performed: | |
|---|---|
| 127,974 | compatibility tests |
| 89,955 | AB0 and RhD blood typing tests |
| 50,974 | indirect Coombs tests |
| 11,171 | direct Coombs tests |
| 2,599 | specifications of erythrocyte antibodies |
| 5,949 | tests preceding Ig anti-D injection |
| 1,134 | platelet tests |
| 65 | granulocyte tests |
| 176 | molecular biology tests |

| For microbiological tests, we performed the following for patients and other subjects: | |
|---|---|
| 7,002 | tests for hepatitis A virus |
| 59,696 | tests for hepatitis B virus |
| 18,367 | tests for hepatitis C virus |
| 18,794 | tests for HIV infection |
| 15,464 | tests for antibodies against Treponema pallidum |
| 366 | tests for antibodies against CMV |

| Services related to tissue matching: | |
|---|---|
| 8,714 | services supporting organ transplantation |
| 3,214 | services supporting haematopoietic stem cell transplantation |
| 322 | services for diagnostics of autoimmune diseases |
| 1,545 | services for the Slovenia Donor Registry |

Most **immunohematologic** tests related to red blood cells are **pre-transfusion** (patient's blood testing prior to receiving a blood component) and **prenatal tests**.

In ideal circumstances, a patient receives blood identical to their own in all erythrocyte antigens. Due to the large number of these antigens and their possible combinations, we strive to transfuse blood units that match as closely as possible. Compatibility is examined for each unit with a **compatibility test**. The donor's erythrocytes (antigens) are 'mixed' with the recipient's plasma (antibodies against antigens). If there is no reaction, the patient has no antibodies and may receive the blood. This is the testing outcome in the majority of cases (estimated to around 98 %). However, in a small percentage of patients, so-called unexpected erythrocyte antibodies are detected, which can develop after blood component transfusion, during pregnancy or after stem cell or organ transplantations from foreign donors, when an individual comes into contact with foreign antigens he or she does not have. When screening tests indicate presence of such antibodies, their specificity is further established, which means the determination of the antigen they are directed against. It is concluded from the specificity of the antibodies whether the detected antibody is clinically important and should be taken into account in further procedures, or if it is clinically unimportant and its presence can be neglected. Clinically important antibodies are those antibodies that could cause the destruction of erythrocytes (haemolysis) or haemolytical disease in foetus or newborn babies after the transfusion of incompatible erythrocytes (carrying antigens against which the antibodies are directed). If clinically important antibodies are detected in a patient, they should be considered until the end of life, and the patient can receive only erythrocytes from donors who do not have the antigen against which the antibody is directed. Only such transfusion is efficient and safe, which means that the haemoglobin level in the patient increases and no haemolytical transfusion reaction occurs.

**Number of newly detected erythrocyte antibodies (sensibilisations) in patients and pregnant women in 2008**

| Subjects | patients | pregnant women | **Total** |
|---|---|---|---|
| Number of sensibilisations | 212 | 53 | **265** |

**Prenatal testing** during and after pregnancy enables the identification of pregnant women and mothers with a certain type of erythrocyte antibody which could cause so-called haemolytical disease in the foetus and newborn baby. Our task is to identify such pregnant women and, together with the obstetrician, monitor them and provide proper treatment if necessary. Prenatal testing and measures are also used to prevent the formation of anti-D antibodies, which are one of the most dangerous antibodies in the development of haemolytical disease. The formation of other antibodies during pregnancy and after birth cannot be prevented; therefore, early detection and proper control are of the utmost importance.

A large proportion of diagnostic services comprises **testing for infection markers,** notably for agents causing hepatitis B, C and A, AIDS, syphilis and toxoplasmosis. Most of these tests are performed for pregnant women (in compliance with the valid legislation), dialysis patients, patients scheduled for organ transplantation, persons punctured with an infected needle etc.

The third element of diagnostic testing is **tissue matching testing prior to transplanting organs, tissues or cells, and also assisting in diagnostics of autoimmune diseases**. In the 1930s and 1940s, after the first experiments on tissue transplantation in animals, it was recognised that rejection or successful transplantation depends on markers present in the transplanted tissues, called tissue

antigens. The discovery of tissue antigens in humans was different. Its roots lie in haematology and transfusiology. In the 1950s, in a patient suffering from leukaemia and neutropenia, antibodies were detected which agglutinated leucocytes foreign to the patient. Nobel Prize winner Jean Dausset showed that the appearance of such leukoagglutinising antibodies was caused by blood transfusions. Antibodies were directed against tissue antigens, which vary between individuals. They are found in almost every cell of the human body. Since they were discovered on leucocytes, they were called Human Leukocyte Antigens (HLA). If a representative sample of at least one hundred persons of the same nationality is taken and HLA tissue antigens determined, a number of different HLA antigens are found on the cell surfaces. Genes that code for them differ even more. Research of tissue antigen diversity between individuals, ethnic groups and races is further conducted in modern centres for tissue typing. Some of the key reasons for such research are the desire and need to know more about the influence of compatibility in relation to tissue antigens (tissue compatibility) between the donor and recipient of an organ, tissue or cells on the outcome of transplantation.

Most of the work conducted in the Centre for Tissue Typing within the framework of the Blood Transfusion Centre of Slovenia is devoted to:

– tissue compatibility testing prior to kidney transplantations;
– tissue compatibility testing in stem cell transplantation;
– tissue antigen determination in volunteer stem cell donors, in members of the Slovenia Donor Registry and for the umbilical cord blood storage unit;
– HLA typing as support in the diagnostics of autoimmune diseases.

With a view to expanding the potential choice of donors, strictly controlled non-profit international organisations were established to coordinate donor or recipient selection at the international level. The participating laboratories must be accredited by an appropriate organisation. Therefore, the Centre for Tissue typing has been accredited by the EFI (the European Federation for Immunogenetics) since 2000.

# BONE MARROW REGISTRY - SLOVENIA DONOR

We were successful in this area also in 2008, enlisting 2,042 new donors to the registry. At the end of the year, 11,112 donors were thus enlisted to the Slovenia Donor (SD) Registry. In 2008, 15 transplants of non-related haematopoietic stem cells (HSC) were performed in Slovenia. Suitable HSC were found for 11 Slovenian patients among foreign registry members and for four patients among our registry members. Transplants were provided for four patients from abroad, for whom SD Registry members donated their HSC. A target search for 52 patients from abroad was performed, and non-related HSC donors were found for four of them; 162 preliminary searches were also performed.

Thereby, we would like to thank the members for their philanthropy and noble contribution, which they voluntarily made when they registered with the SD Registry. There are quite a lot of us now, but we are glad of every new member who joins us.

The support of patients' relatives who find themselves in a difficult situation when confronted with a severe disease in a close relative is especially precious and admirable, when they unselfishly organise help for others, despite their own distress.

So thank you all, you very special people who help by donating the most precious thing you have, a part of yourselves, thereby saving other people's lives.

# UMBILICAL CORD BLOOD STORAGE UNIT

In April 2008, within the Blood Transfusion Centre of Slovenia, the Umbilical Cord Blood Storage Unit was established for the storage of umbilical cord blood for public purposes. Non-related umbilical cord blood which serves as a source of haematopoietic stem cells is stored in the public bank. Umbilical cord blood can be used to treat children and adults who need haematopoietic stem cell transplantation treatment. Currently, this method is used to treat some blood cancer diseases and hereditary metabolic and immune system disorders.

Umbilical cord blood is blood derived from the placenta and umbilicus of newborns. A healthy pregnant woman without familial leukaemias or hereditary genetic diseases - which also applies to the biological father - may donate umbilical cord blood for public purposes prior to giving birth. Umbilical cord blood collection is performed immediately after birth, when the umbilicus is cut. For collection, a needle is used to puncture the umbilical cord vein and blood flows into a sterile bag for blood collection. The collection is safe and painless for child and mother. The collected blood is examined, processed, frozen and stored. Only blood containing at least 750 x $10^6$ of leucocytes can be stored, which suffices to treat a child weighing 25 kg. Due to the requirements for the optimum number of leucocytes, only 50 percent of donated umbilical cord blood can be stored.

The acquisition of umbilical cord blood increases the chances of finding a suitable tissue-compatible haematopoietic stem cells for patients and thereby, the chances of treatment.

In 2008, 93 neonatal mothers donated umbilical cord blood. Forty-two units were stored and frozen.

# SCIENTIFIC AND RESEARCH PROJECTS

Scientific and research and development activity are extremely important to the BTCS, as there are three groups meeting the criteria and requirements of the Slovenian Research Agency (SRA) for managing national projects and conducting research activity:
311-01 Tissue Typing Centre; Head Assist. Matjaž Jeras, MS in Pharm. – 8 members;
311-02 Transfusion Medicine; Head Assoc. Prof. Primož Rožman, MD – 21 members;
311-04 Biomedicine, Head Prof. Vladka Čurin-Šerbec, BS in Chem. – 10 members.

**International research project:** Bilateral Slovenian–German project entitled 'System Biology Tools Development for Cell Therapy and Drug Development' (SYSTHER). Conducted within the BTCS, duration: 1. 11. 2006 - 30. 10. 2011.

**European projects financed by the European Union:**
- European Blood Inspection System, duration 2007 - 2010;
- EU Optimal Use of Blood, duration 2007 - 2010.

**National research projects**
More details on the national research projects we manage or participate in are on the website (http://sicris.izum.si/).

| Designation | Name of the programme/project: | Duration (month, year) | |
|---|---|---|---|
| **Nosilec ARRS** | | | |
| | **BTCS is the leading research organisation** | | **Holder** |
| P3-0371 | Human stem cells – advanced cell therapy. | 01. 2009 / 12. 2011 | Assoc. Prof. Primož Rožman |
| J3-9612 | Use of human stem cell for therapy. | 07. 2007 / 06. 2010 | Assoc. Prof. Primož Rožman |
| L3-0206 | Prions in human medicine: from structural studies to applications. | 02. 2008 / 01. 2011 | Prof. Vladka Čurin-Šerbec |
| | **BTCS is the participating research organisation** | | **Holder at the BTCS** |
| P4-0176 | Molecular biotechnology: from the dynamics of biological systems to applications. | 01. 2009 / 02. 2014 | Prof. Vladka Čurin-Šerbec |
| J3-0415 | A new insight into human ovary function: human embryonic stem cells. | 02. 2008 / 01. 2011 | Assoc. Prof. Primož Rožman |
| J3-9663 | Genetic and morphologic background of chronic diseases in children and young people. | 01. 2007 / 12. 2009 | Assist. Blanka Vidan -Jeras |

# EDUCATION

The employees in transfusiology undergo regular professional training both in Slovenia and abroad. The employees are being trained to conduct new procedures and activities, and newly recruited staff and trainees are given job coaching.

At the BTCS, under- and postgraduate education and activities to promote transfusion medicine and blood donation are conducted. The table below indicates the number of hours and participants.

| Type of education | No. of lecture hours | No. of practice hours | No. of participants |
|---|---|---|---|
| Undergraduate education | 101 | 546 | 640 |
| Post-graduate education | 89 | 1,037 | 248 |
| Promotion of transfusion medicine | | 43 | 1,177 |
| **Total** | **190** | **1,626** | **2,065** |

# EVENTS

– Novo mesto Department of Transfusion Medicine (1 March 2008), Trbovlje Department of Transfusion Medicine (1 October 2008) and Slovenj Gradec Department of Transfusion Medicine (1 March 2009) were combined with the Blood Transfusion Centre of Slovenia as separated units.

– Ptuj Department of Transfusion Medicine (1 January 2009) was combined with the Centre of Transfusion Medicine at the Maribor UMC.

– On the basis of verification inspection of 23 - 27 April 2008, on 4 August 2008, the Agency of Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) granted a permit to the Blood Transfusion Centre of Slovenia on performing the activity of supplying blood for the location of the Novo mesto Department of Transfusion Medicine.

- On the basis of verification inspection of 9 - 12 December 2008, on 25 March 2008, JAZMP granted a permit to the BTCS for performing the activity of supplying human tissues and cells.
- On 10 October 2008, JAZMP executed the regular inspection of the activity of supply of blood at the location of the Novo mesto Department of Transfusion medicine.
- On 10 November 2008, the Slovenian Institute for Quality and Metrology performed a regular external assessment of the quality management system by ISO 9001:2000 at the location of Novo mesto Department of Transfusion Medicine.
- Within the BTCS, Octapharma performed an external assessment (22 - 26 September 2008).
- On 7 May 2008, on the basis of a verification inspection JAZMP, granted a permit to the Centre of Transfusion Medicine UMC Maribor to supply blood.
- On 13 October 2008, Bureau Veritas performed a regular external assessment of the quality management system by ISO 9001:2000 at the location of the Centre of Transfusion Medicine UMC Maribor.
- Within the CTM Maribor, Octapharma performed an external assessment (on 24 and 25 September 2008).
- On the basis of a verification inspection of 3 - 5 June 2008, on 5 August 2008, JAZMP granted a permit to CTM Celje to supply with blood. Thereby, Celje transfusion department obtained the status of a centre for transfusion medicine.
- Within the Blood Transfusion Centre of Slovenia, the Umbilical Cord Blood Storage Unit was established (April 2008).
- Under the auspices of the BTCS, a transfusion medicine course for healthcare professionals and collaborators was held between 28 January and 1 February and between 11 and 15 February 2008.
- Presentation of the international study “Blood donation and healthy lifestyle in Romania, Slovenia and Italy”, Ljubljana, Fužine Castle, 28 November 2008.
- Press conference on AIDS day with the topic ‘Safety of blood donors and recipients of blood, blood products and medicinal products deriverd from blood – 25 years of experience of the Republic of Slovenia’, Ljubljana GH Union, 1 December 2008.

# ADOPTED REGULATIONS

- Rules on conditions for granting permission for performing of activity of supply with human tissues and cells
  Official Gazette of the Republic of Slovenia, No. 70/2008
- Rules on adopting, processing, storing, releasing and distributing human tissues and cells
  Official Gazette of the Republic of Slovenia, No. 70/2008
- Rules on histovigilance
  Official Gazette of the Republic of Slovenia, No. 70/2008
- Rules on traceability of human tissues and cells and products and materials, which are coming in contact with tissues and cells
  Official Gazette of the Republic of Slovenia, No. 70/2008
- Rules on conditions and procedures for import and export and entry and carry out of human tissues and cells
  Official Gazette of the Republic of Slovenia, No. 70/2008
- Rules on donating and production of human tissues and cells
  Official Gazette of the Republic of Slovenia, No. 70/2008

# PUBLICATIONS

## Articles and other scientific and professional contributions

### 1.01 Original scientific articles

AUGST, Alexander, MAROLT, Darja, FREED, Lisa E., VEPARI, Charu, MEINEL, L, FARLEY, Michelle, FAJARDO, Robert, PATEL, Nipun, GRAY, Martha, KAPLAN, David L., VUNJAK-NOVAKOVIC, Gordana. Effects of chondrogenic and osteogenic regulatory factors on composite constructs grown using human mesenchymal stem cells, silk scaffolds and bioreactors. Journal of the Royal Society interface, 2008, letn. 5, št. 25, str. 929–939, doi: 10.1098/rsif.2007.1302. [COBISS.SI-ID 24142041].

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### 1.02 Review scientific articles

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### 1.04 Professional articles

GALVANI, Vesna, MAVER, Slavica, SOLDATOVIĆ, Gordana, KRAMAR, Irena. Prvi primer s transfuzijo povezane akutne poškodbe pljuč (TRALI) v Sloveniji = First report of transfusion-related acute lung injury (TRALI) in Slovenia. Zdrav Vestn (Tisk. izd.). [Tiskana izd.], 2008, letn. 77, št. 4, str. 323–329. [COBISS.SI-ID 24224729]

### 1.08 Published scientific contributions at conferences

BRESKVAR, Marko, BRICL, Irena, ROŽMAN, Primož, MEŽA, Marko, TASIČ, Jurij F. Uvedba telekonzultacij v transfuzijsko službo = Introduction of teleconsultations in the blood transfusion service. V: Številka ob 3. kongresu hematologov in transfuziologov Slovenije z mednarodno udeležbo : Olimje, 11. in 12. april 2008 : Olimje, April 11th - 12th, 2008, (Zdravniški vestnik, letn. 77, supl. 1). [Ljubljana]: Slovensko zdravniško društvo, 2008, 2008, letn. 77, suppl. 1, str. I-177-I-182. [COBISS.SI-ID 24134873]

JOVANOVIČ, Petra, LEVIČNIK-STEZINAR, Snežna. Prevalenca protiteles anti-HTLV-I/II med krvodajalci v Sloveniji ter pomen pripresejalnem testiranju = Prevalence of anti-HTLV-I/II in Slovenian blood donors and the impact on bloodscreening. V: Številka ob 3. kongresu hematologov in transfuziologov Slovenije z mednarodno udeležbo : Olimje, 11. in 12. april 2008 : Olimje, April 11th – 12th, 2008, (Zdravniški vestnik, letn. 77, supl. 1). [Ljubljana]: Slovensko zdravniško društvo, 2008, 2008, letn. 77, suppl. 1, str. I-193-I-197. [COBISS.SI-ID 24135641].

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### 1.09 Published professional contributions at conferences

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# IN MEMORIAM

## We said goodbye to Dr. Sonja Sovdat Banič

We will always stop at her name when looking back on the development of transfusion medicine and blood donation in Slovenia. With the commitment to being a physician in caring for others, together with colleagues in healthcare service and the Red Cross of Slovenia, she carried out numerous demanding tasks and made a great contribution to the fact that Slovenia's developed blood donation and transfusion medicine place it among the most successful countries.

As early as 1945, as a student of medicine, she was given the important task of organising the foundations of the transfusion service in Slovenia. In a few months, she had organised the Department for Transfusion in the Central Military Hospital in Ljubljana, where the first blood doses were collected under her leadership on 4 June 1945.

Thanks to her, payment for blood donations was abolished (1 January 1953). Before that, blood donors had received food as a compensation, but it became obvious that any payment had a bad influence on both the health of the blood donor and the patient receiving blood. With a sufficient stock of blood and with the help of some unselfish blood donors and healthcare professionals who donated blood and thus provided a continuous supply for patients, unpaid, voluntary and anonymous blood donation in Slovenia began. This kind of blood donation is recommended in many parts of the world, but remains an unattained objective.

Along with the development of the healthcare service and the increased need for conserved blood, she obtained the agreement of the Ministry of Health of the Republic of Slovenia to establish transfusion departments in hospitals. Because of the development of transfusion medicine and the expansion of this activity, Dr. Sonja Sovdat Banič was the initiator and founder of the decision of the Executive Council of the People's Assembly to establish an independent Blood Transfusion Centre of the Republic of Slovenia in 1955 and to build a new building in 1958. This enabled improved techniques for blood conservation, the drying of frozen plasma, the preparation of sera to blood typing, the making of plastic transfusion systems, HLA typing, etc.

Throughout her active years, she also dedicated herself to teaching and training healthcare staff to work in the transfusion service. She had an important role in preparing expert instructions for organising the service; she was a source of initiative and support for expert work, both for her first colleagues and the teachers of our generation.

In addition to all her organisational, teaching and routine work, she published professional articles in journals at home and abroad and wrote an extensive chapter on blood collection for what was the main text book on transfusion medicine for Yugoslav physicians for many years. She was the manager of the Blood Transfusion Centre of the Republic of Slovenia until she retired in 1979.

Dr. Sovdat Banič was a person who paved new ways in development. She organised the transfusion service in Slovenia and retained the independence of the Centre in difficult times, as she knew that the transfusion service had to be something special, as is now inscribed in the European Directive. Under her management, the Blood Transfusion Centre of the Republic of Slovenia had a key role in Slovenia and was one of the main transfusion institutes in Yugoslavia. She formed a circle of experts who led the development of the Slovenian transfusion service in such a way that blood transfusion in Slovenia still remains safe and available to every patient in need.

**Marjeta Potočnik**

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za transfuzijsko medicino
Blood Transfusion Centre of Slovenia

Informa Echo