Hungarian National Blood Transfusion Service

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Key Words

Blood bank · GMP · Blood product

Summary

The aim of this article is to present the work of the Hungarian National Blood Transfusion Service (HNBTS). In 1998, the service was based on 64 blood centers, all belonging to hospitals. At present, there are 6 regional blood centers and 17 local blood banks with different functions. 13 blood banks primarily deal with the collection of whole blood. 25 hospital blood banks are in contract with the HNBTS regarding the collection of whole blood, but clinical transfusiological examinations are carried out by only the blood banks. Hospital blood banks operate as clinical transfusiological departments of the respective hospital. Since 1959, the donor population has consisted of voluntary, non-remunerated blood donors from low-risk populations. In 2001, the pharmaceutical GMP (Good Manufacturing Practice) regulatory network was integrated into the HNBTS. Due to strict rules and special software, the percentage of out-of-date blood products in Hungary is less than 3%. The HNBTS Headquarters direct and coordinate the blood supply, the distribution and transportation of blood products, the connection between blood banks and hospitals, as well as quality, educational and financial logistics. In the future, we would like to continue the consolidation of the HNBTS to reduce costs and use space and special equipment more effectively.

Schlüsselwörter

Blutbank · GMP · Blutprodukt

Zusammenfassung

Ziel dieses Artikels ist es, die Tätigkeit des ungarischen nationalen Bluttransfusionsdienstes (Hungarian National Blood Transfusion Service, HNBTS) vorzustellen. 1998 bestand der HNBTS aus 64 an Krankenhäuser angeschlossenen Transfusionszentren. Gegenwärtig gibt es 6 regionale Transfusionszentren sowie 17 lokale Blutbanken, welche jeweils unterschiedliche Funktionen erfüllen. 13 Blutbanken befassen sich hauptsächlich mit Vollblutspenden. Diesbezüglich arbeiten 25 Krankenhaus-Blutbanken mit dem HNBTS zusammen. Transfusionsbezogene klinische Untersuchungen werden dagegen von den Blutbanken selbst durchgeführt. Krankenhaus-Blutbanken arbeiten als klinische Transfusionsabteilungen des jeweiligen Krankenhauses. Die Spenderpopulation besteht seit 1959 aus freiwilligen, unbezahlten Blutspendern aus Niedrigrisiko-Bevölkerungsschichten. 2001 wurde das pharmazeutische GMP (Good Manufacturing Practice)-Regelnetzwerk in das HNBTS eingeführt. Auf Grund von strikten Regeln und spezieller Software beträgt der Anteil verfallener Blutprodukte in Ungarn weniger als 3%. Die HNBTS-Zentrale lenkt und koordiniert die Bereitstellung von Blutkonserven, die Verteilung und den Transport von Blutprodukten, die Zusammenarbeit von Blutbanken und Krankenhäusern, sowie Fragen der Qualitätssicherung, Aus- und Weiterbildung und Finanzierung. Zukünftig wird die Festigung des HNBTS angestrebt, um so Kosten zu reduzieren sowie Räumlichkeiten und Spezialgeräte effizienter zu nutzen.

Fig. 1. Organizational structure of the Hungarian National Blood Transfusion Service.

Fig. 2. Blood donation in Hungary (population approximately 10,100,000).

Fig. 3. The national register is responsible for blood supply, distribution of blood products, and organization of transportation (approximately 8,000 events).

General Information about Blood Organizations and Activities

With the exception of the National Hematology and Blood Transfusion Institute, the Hungarian National Blood Transfusion Service (HN BTS) used to be based on 64 blood centers, all belonging to hospitals. These blood centers were reorganized in 1998, and a government-funded HN BTS was established based on the principles of centralization and independence from hospitals [1–6]. At present, there are 6 regional blood centers [7] and 17 local blood banks with different functions. The HN BTS Headquarters direct and coordinate the blood supply, the distribution and transportation of blood products, the connection between blood banks and hospitals, as well as quality, educational and financial logistics (fig. 1). The HN BTS collaborates with the Hungarian Red Cross in the organization of a voluntary, non-remunerated whole-blood donor system, but approximately 10% of blood donors

are organized by the staff of the national blood establishments. To cover the needs of 10.1 million Hungarians, approximately 450,000 blood donations take place annually, which means that, on average, each donor gives blood 1.6 times a year (fig. 2).

In Hungary, stocks are held in 3 different places – blood banks (approximately 70%), hospital blood banks (approximately 20%) and hospital departments (approximately 10%). There is a national administration registering the amounts of stock at the different locations. Remaining blood products are sent to the centers, because of the ratio of blood donations is higher in the countryside (fig. 3). The national register is responsible for controlling the quality and quantity of the national stocks, coordinating blood supply-related logistics and information exchange, distributing blood products, and organizing transportation (approximately 8,000 events), as well as for the collaboration between blood banks and hospitals. The HN BTS has a special contingency plan for extraordinary situation, in-

volving a special project team which, in conjunction with the Ministry of Health, will coordinate exceptional events.

National Transfusion Guidelines/Laws

Blood transfusion in Hungary is regulated at 3 different levels:

1. Laws concerning the HNBTS, donor selection, blood collection (including apheresis), red blood cell (RBC) stocks and contracts, and the Clinical Transfusion Committee. The complete EU Blood Directive was expected to come into effect by February 2005 (3/2005, II.10., Decree of the Ministry of Health according to Commission Directive 2004/33/EC of 22nd 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).

2. Guidelines – principles set in the Council of Europe Recommendation 95 ‘Guide to the Preparation, Use and Quality Assurance of Blood Components’ have been applied since 1993.

3. The Council of Transfusiology and Hematology (e.g. transfusion practice) – 2 institutions are responsible for the authorization and control of blood supply activities in Hungary. The license for the operation of blood collection institutes is issued by the Executive Office of the Chief Medical Officer, while the manufacturing authorization for the processing of blood products is issued by the National Institute of Pharmacy.

Quality System

Blood transfusion is a key part of modern health care. It is the responsibility of the Hungarian National Blood Program to provide an adequate supply of blood for all patients requiring transfusion and to ensure the quality of blood products for clinical use. All products must be safe, clinically effective, appropriate and of consistent quality. Since 1959, the donor population has consisted of voluntary, non-remunerated blood donors from low-risk populations.

In 1995, the Quality System was established as a voluntary self-regulation network. The main goal was to provide blood and blood components according to the principles of GMP and Standard Operating Procedures (SOPs). Strategies for achieving this have included: i) setting of standards for quality systems, ii) establishment of a regulatory or legislative framework, including a quality manual and standards, iii) appropriate and comprehensive documents, including a quality manual, SOPs, records and a system for controlling documents, iv) introduction of a training policy and plan that covers the training of all staff in quality control and other health care sectors involved in blood transfusion, v) assurance that the quality system covers all aspects of its activities and is traceable from the recruitment and selection of blood donors to the transfusion of blood products to patients. In 2001, the

Fig. 4. Structure of quality management.

pharmaceutical GMP regulatory network was introduced to the HNBTS, and a nationwide quality management system was established by the HNBTS Headquarters (fig. 4). 2 years later, a validation system (plan) was implemented. The Quality System is based on GMP in our transfusion service and involves all activities, such as policies, responsibilities, quality planning, quality control, quality assurance and quality improvement. Quality manuals have been prepared for processing and examination steps in blood banks. An authorized person is responsible for good quality of products and results in the whole country.

Audit protocols are issued to control the work at all levels, and there is a special program of regular internal and external audits of the Quality System reporting and analyzing errors and providing effective corrective and preventive action. Our screening and reference laboratories have actively participated in appropriate external quality assessment schemes to improve laboratory performance. Furthermore, all laboratories participate in national and international quality control systems. The quality policy of the HNBTS is determined by the HNBTS Headquarters. Confirmatory virus tests, immunohematology and quality control of blood products are controlled by special reference laboratories in the Headquarters, which are independent from the regular screening laboratories.

The HNBTS collaborates with the hospital transfusion committees. The minimum requirements for Transfusion Departments in hospitals have been set by the Ministry of Health. There are regular consultations and strict collaboration between the HNBTS transfusiologist and hospital doctors (fig. 5) based on the Hungarian Hemovigilance System.

Standards, Quality and Accreditation

There is a common standard for the evaluation of blood donor suitability and for testing infectious markers which are com-

Fig. 5. Dispatch process.

patible with EU standards (98/463/ES, 2002/98/ES, 2004/33/EC). In Hungary, 2 institutions are responsible for the authorization and control of blood supply activities. The license for the operation of blood collection institutes is issued by the Executive Office of the Chief Medical Officer, while the manufacturing authorization for the processing of blood products is issued by the National Institute of Pharmacy. The service is regularly inspected by these authorities, according to Hungarian rules and decrees.

Quality-Related Specifics

In 2004, statistical process control was implemented. The collection of data has been expanded from the output to the product costs to compare cost-effectiveness. Of course, the raw data are analyzed by the controlling department. The Quality Assurance Department estimates the quantity and quality of the blood products, as well as laboratories results. Feedback to the staff on their performance is essential for continuing quality assurance and improvement.

The Hungarian Hemovigilance System was established in 1972. Since then, the HNBTS has been collecting special reports in paper form on each transfused blood product, adverse event etc. In 1998, a new version of the Transfusion Regulations was published, which standardized the documentation of blood transfusion. This version is currently being reviewed. The HNBTS Headquarters collect the completed questionnaires which contain the quantity of produced and transfused blood products, the number of verified virus-positive donor samples, adverse events etc., according to Directive (61/2005/EC).

Fig. 6. Transfusion safety in Hungary.

Specific Topics

Obligatory tests include HBsAg (hepatitis B surface antigen), HCV (hepatitis C virus) and HIV (human immunodeficiency virus) on antibodies, and in Hungary donor samples are also tested for syphilis and anti-HBc (hepatitis B core antigen antibody) (at the first donation). During the past 20 years, 1,018 HIV infections were registered in the whole country. Since 1986, 42 donors have been found to be HIV-positive.

The Headquarters of the Reference Virus Confirmatory Laboratory verify reactive donor samples sent in by the 9 screening laboratories (fig. 6). Polymerase chain reaction (PCR) technique used to be applied for HCV verification only, but since last year, it is used for all virus verification. In our opinion, the Confirmatory Laboratory should be independent from the screening laboratory. Bacterial contamination of blood products and the work environment are also regularly tested.

On average, 76,000 l of plasma are available for fractionation, yielding plasma derivatives in adequate quantities for self-sufficiency. Since 2000, all plasma pools for fractionation are being tested for HCV RNA. Treatment with blood components and plasma derivatives is fully covered by the health insurance system (except factor VIII, 40% import).

In Hungary, approximately 33% of transfused platelet concentrates and 6–8% of RBCs are leukocyte-depleted. These products are indicated for patients with known or suspected leukocyte antibodies, or to prevent alloimmunization to leukocyte antigens and cytomegalovirus (CMV) transmission. Only those patients who suffer from hematological diseases can get frozen platelet concentrates. In 4 regional blood centers, blood products can be irradiated by special devices using a ^{137}Cs source.

Future Challenges

The use of and need for blood and blood products have changed during the past half century. The HNBTS is centralized, which is in accordance with international standards. There is an increased use of expensive testing robots, stricter control measures, and a wider use of computerization (we now use 2 types of software for donor data follow-up). By the end of 2006, the data management software eProgesa (MAK-System, Paris, France) will be introduced to the HNBTS to create a solid donor register. Due to the strict rules and special software, the percentage of out-of-date blood products in Hungary is less than 3%. For reasons of donor motivation it is considered very important that all blood is utilized. In the future,

we aim to continue the harmonization of immunohematological methods, to improve the hemovigilance system, and to discuss the use of blood products with clinical doctors and the hospital transfusion committees established in 2000.

Data collection was instigated in 1972 by the Decree of Health. Since then, written reports on blood transfusion have been sent to the blood banks, and in future, electronic data collection systems will be implemented in the whole country. Having a common set of high standards helps facilitate the cooperation between healthcare systems. Day-to-day quality control and the regulation of institutions collecting, processing and storing blood still takes place at the national and regional level. We plan to continue the consolidation of HNBTS to reduce costs and use space and special equipments more effectively.

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