Transfusion Medicine in Austria

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Key Words

Transfusion medicine · Legislation ·
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Summary

This article describes the field of transfusion medicine in Austria. It refers to national legislation, the organisation and areas of responsibility of the Austrian blood establishments. Information is provided about the mandatory qualification and the duties of the staff, including specialists, medical assistant technicians and nurses. In the last years topics of special interest were the implementation and validation of the IT systems, the introduction and maintenance of quality management systems – almost all blood banks are ISO 9001:2000 certified – and the mandatory haemovigilance network established in 2004. A short preview gives a summary of scientific and future considerations.

Schlüsselwörter

Transfusionsmedizin · Gesetzgebung ·
Blutspendeeinrichtungen · Blutdepot

Zusammenfassung

In diesem Artikel wird das Transfusionswesen in Österreich beschrieben. Dabei wird Bezug genommen auf die gesetzlichen Grundlagen, organisatorische Besonderheiten und Aufgaben der Blutspendeeinrichtungen. Ein Kapitel widmet sich den Aufgabenbereichen und geforderten Qualifikationen bei den unterschiedlichen Mitarbeitern dieser Organisationen. In den letzten Jahren wurden vor allem Anstrengungen in Bezug auf eine validierbare Informationstechnologie, die Etablierung von Qualitätsmanagementsystemen – fast alle großen Blutbanken sind ISO 9001:2000-zertifiziert – und die Implementierung eines verpflichtenden Hämovigilanzsystems im Jahr 2004 unternommen. Eine kurze Vorschau beschäftigt sich zum Schluss mit den künftigen Hauptthemen im österreichischen Transfusionswesen.

National Laws and Organisation

Austria has nine federal states and 8,067,300 inhabitants (census 2002). The population of the states determines also the size of the 10 regional blood centres (table 1). As indicated in the table, 95% of blood donations are carried out by the Red Cross and to a minor degree by other institutions. This ratio is unchanged since 1950, when the Red Cross started its first blood donation service. However, 64% of the annually

450,000–500,000 whole blood units are further prepared by and a slightly higher amount of screening tests are performed in Red Cross blood centres. The remaining 36% are produced in hospitals, of which two sites are university institutes and one site a hospital-based institute in close relationship to a medical university.

Hospitals without donation, production and screening facilities run a hospital blood bank, so-called 'Blutdepots' (depositories), with the main emphasis to serve as a local blood trans-

Table 1. Blood establishments in the federal states of Austria: location, donor recruitment, blood collection, component processing, donor laboratory and percentage of the whole blood units

Nr.	Provincial districts	Inhabitants 2002	Location of blood establishment	Donor recruitment	Blood collection	Whole blood units, % (1998–2002)	Component processing	Donor laboratory
<i>Red Cross blood establishments</i>								
1	Vienna ^a	1,550,874	Vienna 1	RC	RC	42.51	RC	RC
2	Lower Austria ^a	1,550,940	Vienna 1					
3	Burgenland ^a	277,260	Vienna 1					
4	Upper Austria	1,381,592	Linz	RC	RC	13.39	RC	RC
5	Styria	1,183,250	Graz (U)	RC	RC	12.1	H	H
6	Tyrol	679,720	Innsbruck (U)	RC	RC	10.44	H	H
7	Salzburg	517,510	Salzburg (U)	RC	RC	7.13	H	H
8	Carinthia	353,670	Klagenfurt	RC	RC	4.97	RC	RC
9	Voralberg	353,670	Feldkirch	RC	RC	2.6	RC	OA
<i>Hospital blood establishments</i>								
1	Lower Austria	1,550,940	St. Pölten	OA	OA / H	2.94	H	H
2	Lower Austria	1,550,940	Mistelbach	OA	OA / H	1.96	H	H
3	Upper Austria	1,381,592	Wels	RC	RC / H	1.96	H	H

RC = Red Cross; H = hospital; OA = other associations; U = university.

^aBlood establishment for Vienna, Lower Austria and Burgenland in Vienna.

fusion storage and immunohaematology laboratory. The production and storage of allogeneic and autologous blood products as well as the provision of services in transfusion medicine are based on regulations released by legal authorities and the Austrian ministry of health (i.e. the Federal Ministry of Health and Women, which often has changed its denotation). Some of them have been developed in close collaboration with the Austrian Health Institute (Österreichisches Bundesinstitut für Gesundheitswesen; ÖBIG), some have been driven by the European Commission directives. The regulations are described in the following.

Blood Safety Act 1999 (Blutsicherheitsgesetz 1999 – BSG 1999 (BGBl. Nr. I 44/199 i.d.g.F.))

This law [1, 2] regulates generally blood donation, including also all forms of preparative apheresis. It provides specific articles on the management, licensing, minimal setting of donation sites, quality assurance and documentation. Additional requirements were added concerning donor acceptance, donor selection, donor safety and identification.

Blood Donor Ordinance (Blutspenderverordnung 1999 – BSV (BGBl. Nr. II 100/1999 i.d.g.F.))

This ordinance [3] and its amendment in 2005 [4] derive from the blood safety act 1999 and were published by the ministry of health. Donor acceptance and examination, medical history, deferral policy (temporarily, permanently), donation volumes, donation frequency and pre-donation testing as well as screening tests and post-donation care are regulated in detail.

Pharmaceutical Act 1983 (Arzneimittelgesetz 1983 – AMG (BGBl. Nr. 185/1983 i.d.g.F.))

Blood, blood components and derivatives are pharmaceuticals if they are used for medical purposes, and therefore nearly all products for transfusion are subject to the pharmaceutical act 1983 [5] and corresponding ordinances [6, 7]. This law relates to principles of good manufacturing practice (GMP) and sets quality requirements on the production and release of pharmaceuticals. It also covers pharmacovigilance and the mandatory reporting of serious adverse events and reactions (see also ‘Haemovigilance’ below). In 1998 by decree [6] unique criteria for donor selection and identification based on international standards and for HIV-testing of each blood donation were defined. In 2005 the ministry of health regulated the plasma master file [7], the obligation to obtain a permit for all blood products, and fixed a date for the implementation of the ISBT 128 barcode system with the year 2007.

Pharmaceutical Manufacturing Ordinance (Arzneimittelbetriebsordnung 2005 – AMBO (BGBl. Nr. 518/1986 i.d.g.F.))

More detailed in specifications, especially a thorough interpretation of GMP, are depicted in this legal ordinance which was published in 2005 [8]. It is nowadays the major legal document in regard to inspections and the licensing procedures.

Standards for Hospital Blood Banks 2002 (Mindeststandards für Blutdepots – 2002, Bundesministerium für Soziale Sicherheit und Generationen)

Hospital blood banks (depositories) are organized within hospitals or, when adjacent to a hospital, in the blood centre. These

store, test and distribute blood products and serve the wards with laboratory services. Management responsibilities, staffing, space and technical resources are defined in this standard [9] which requires a quality assurance system. Officers of hospital blood banks are responsible to maintain maximum blood order schedules and to report serious adverse reactions and serious events to the haemovigilance registry. Their major task is to perform compatibility testing and immunohaematology services.

Guideline for Mobile Donor Sessions and Fixed Sites with Blood, Platelet and Plasma Donations – 2001 (Leitlinien für mobile Blutspendeaktionen sowie stationäre Blut-, Thrombozyten- und Plasmaabnahmen – 2001, BMSG (GZ 22,313– VIII/D/21/1))

This guideline [10] is an addendum to a checklist for health departments which inspect staffing, space, specifications, technical issues and hygiene at donor sites with a standardized checklist.

Guidelines for Blood Group Serology and Transfusion Medicine – 1996 (Richtlinien in der Blutgruppenserologie und Transfusionsmedizin – 1996, Mitteilungen der Österreichischen Sanitätsverwaltung, Sonderdruck aus 97. Jahrgang, 1996, Heft 3)

Major issues covered by these guidelines [11], which have been developed by experts of the Austrian Society for Blood Group Serology and Transfusion Medicine (Österreichische Gesellschaft für Blutgruppenserologie und Transfusionsmedizin; ÖGBT) and published by the ministry of health as a legal decree, are standards for the production, storage and transfusion of blood products and components. Additional attention is focused on autologous blood donation, blood salvage and the use of autologous blood and plasma. These guidelines adhere to guidelines from the Council of Europe, which specify quality control of cellular and plasma products and set standards for transfusion, pre- and post-transfusion procedures. Furthermore, immunohaematological pathways for pregnancy surveillance testing and minimal requirements for blood grouping and compatibility testing are incorporated in these standards, which were amended in 2001.

Act for Medical Goods 1996 (Medizinproduktegesetz – 1996 (BGBl. Nr. 657/1996 i.d.g.F.))

The above mentioned guidelines and ordinances require safe medical goods and devices. In the act for medical goods [12] all aspects of quality assurance related to the production and maintenance of medical devices as well as in vitro diagnostics and the reporting of incidents are defined. Blood bags and sterilisation procedures are subject to quality assurance based in a broad view on the best available technology. The same notion refers to the safety and quality of devices which are used in transfusion medicine.

Quality and safety standards in transfusion medicine originate from the Directive 2002/98/EC of the European Parliament

and of the Council [13] and the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended by Directive 2002/98/EC, Directive 2004/24/EC and Directive 2004/27/EC. The use of the standards published by the Council of Europe and guidelines of the German medical board (Leitlinien zur Therapie mit Blutkomponenten und Plasmaderivaten i.d.g.F.) [14] was common until the legal regulations were published [15]. International, especially English and American, publications were often accepted as common medical practice.

Guidelines on Transplantation of Stem Cells ('Richtlinien zur Transplantation von Stammzellen (Teil I, II, III)', herausgegeben 01.03.04, von der 'Kommission für die Weiterentwicklung des österreichischen Stammzellspende- und Transplantationswesens' vom Bundesministeriums für Soziale Sicherheit und Generationen unter der Geschäftsführung des ÖBIG)

These guidelines [16] relate to organisational responsibilities, donation, preparation, transplantation and quality assurance of autologous and allogeneic adult stem cells and cord blood. The guidelines were a result of a cooperation between transfusion medicine specialists, haematologists, immunogeneticists and the Austrian Bone Marrow and Stem Cell Registry ('Geben für Leben').

Plasmapheresis Act 1975 and Plasmapheresis Ordinance 1978 (Bundesgesetz über die Vornahme der Plasmapherese – 1975 (BGBl 427, RV 1580, AB 1659/XIII.GP) und die Verordnung des Bundesministeriums zur Durchführung der Plasmapherese – 1978 (BGBl 231))

In the end of 2004 Austria had 13 apheresis sites for commercial plasma production in 10 cities organized by 5 different companies. 4 centres had to be closed recently due to an oversupply of the world plasma market. Commercial plasmapheresis was regulated since 1975 in a plasmapheresis law [17] and a legal ordinance [18] which are replaced in 1999 by the blood safety act with its legal ordinance.

Licensing, Certification and Accreditation

Nowadays blood centres, hospital blood banks and commercial plasmapheresis centres require a license on the basis of the pharmaceutical law. Bi-annual inspections are a substantial element. Inspections were performed until December 31, 2005 by the third section of the ministry of health and have been transferred to the Agency for Health and Food Safety (AGES). Inspections according to the blood safety act are performed by the local health department and reported to the ministry of health. Amendments of various laws were the reason to implement the Austrian Federal Agency for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswe-

sen; BASG) and the section for Medicaments and Medical Devices in the AGES (AGES PharmMed). The BASG is the competent authority for all operative tasks in the field of medicaments and medical devices previously performed by the ministry of health or the Federal Institute for Pharmaceutical Safety. Now the ministry of health is acting as supervisory authority of the BASG and as the regulatory authority. The AGES PharmMed is the operative agency of the BASG.

The main duties of the BASG in relation to transfusion medicine are: assessing the quality, efficacy, and safety of drugs, and authorizing their sale or supply in Austria; assessing and authorizing manufacturers of pharmaceuticals for human and veterinary use; monitoring and ensuring compliance with GMP inspections of manufacturers and taking enforcement action where necessary; clinical investigations of medical devices; performance of evaluation studies of in vitro diagnostics. These activities are carried out by six units.

Concerning licensing, the site master file is the basic document which is checked with scrutiny. A license is issued once and can be revoked any time when a major complaint is found. All blood centres are inspected every 2 years, and in most cases the license is renewed without any major complaint. Blood donation sites and fixed locations are inspected by the local health departments which use as basic legal document a checklist according to the Guideline for Mobile Blood Donor Sessions and Fixed Sites with Blood, Platelet and Plasma Donations – 2001.

Most immunogenetic laboratories are based in blood establishments and are accredited by the European Federation of Immunogenetics (EFI).

The Directive 2004/23/EC of the European Parliament and of the Council [19], introduced in March 31, 2004, sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. According to the directive, licensing and inspections of the blood establishments working in this field will be arranged by the AGES PharmMed in the future. At the moment inspections and accreditation are performed by the Joint Accreditation Committee – International Society for Cellular Therapy (ISCT) and the European Group for Blood and Marrow Transplantation (EBMT).

Role of Blood Establishments

The major purpose of blood establishments is the recruitment of donors and the production of sufficient amounts of blood products for patient care in hospitals. The service profile of blood establishments is complex. They deal with donors, donations, the preparation process and screening tests of blood donations. However, many blood establishments are responsible for additional tasks such as immunogenetics, genetics, immunology, prenatal testing, infectious disease testing and more recently tissue banking and tissue engineering. Most

blood establishments serve for the region or federal state, and there is a close relation to the political responsibility in health care which is in the hands of state governments and central medical institutions such as blood establishments. The Austrian blood centres serve for 183 hospitals, either directly – if blood establishments are adjacent to hospitals – or indirectly by hospital blood banks. The decentralization of the blood establishments – encouraged by the Austrian health policy – assures a well timed, individualized and patient-oriented blood supply.

Product-Oriented Tasks: Donors, Donations and Preparation

A blood donor association does not exist in Austria. The promotion for voluntary non-remunerated blood donation and the safety of blood donors are the centre zone of the Red Cross blood donation services. Approximately 3–4% of the population are regular blood donors who donate in average 1.5 times a year. About 10% of all donors are first-time donors. 40–60 donations/1,000 inhabitants are needed for a sufficient supply [20]. The steps of donor questioning, medical examination, blood donation, component preparation, storage and distribution are performed in concordance with the blood safety act and blood donor ordinance. Screening of donations includes blood grouping and tests for viral markers as well as an unspecific marker for immune activation (which is the neopterin assay). Molecular screening is performed on HIV, HBV, and HCV and particularly for plasma on parvovirus B19 and HAV, mainly in two laboratories in Germany (85%) and to a greater extent in one blood centre in Austria. Although there is no regulation, 100% of all whole blood donations are processed to leucocyte-depleted red cells. Platelets are produced in some sites prior to component filtration out of buffy coats and pooled by 4–6 units. These products are leucocyte-depleted as it is the case for platelets procured by apheresis. All products may be washed, plasma-reduced or irradiated. Testing for bacterial contamination is mostly performed by automated blood culture systems and more recently also by PCR, and implemented on nearly all platelet products. Plasma may be transfused either as quarantine plasma (6 months minimum storage period) or virus-inactivated plasma (SD plasma). Both types are equally used in Austria. Frozen erythrocytes and platelets are stored in two centres only. Quality control is determined by law and guidelines, and the logistics of products is closely monitored.

Clinical Tasks: Donors and Outpatient Care

Compatibility testing between products and recipients as well as antibody determinations have a great importance. Still most of prenatal immunohaematological care is covered by clinical chemistry laboratories. Most blood centres and greater hospital blood banks are also immunohaematological reference laboratories serving for hospitals in the region and other laboratories. Two thirds of the blood centres have integrated immunogenetics laboratories which are approached by oncologi-

cal departments or needed for organ transplantation which is organized in cooperation with Eurotransplant. Most blood centres perform also elementary platelet antibody determinations and molecular tests for platelet antigens.

Coagulation tests are established in all blood centres for quality control but rarely used to test patients. Therapeutical apheresis, immune absorption and photopheresis are common in nearly all blood centres as part of the out-patient care or service to neurological and oncological departments. Stem cells are procured by apheresis and – in reduced dimensions – by bone marrow aspiration. One blood centre stores allogeneic cord blood. Other fields of experience are autologous blood donation, blood salvage, medical advice in massive bleeding and immunohaematology.

Other Tasks

The regular duty is accompanied by training and educational activities for officers of hospital blood banks, medical assistant technicians, nurses and students. In comparison to other medical specialities much time is spent doing regulatory work in abundant meetings and lobbying activities.

Staff, Qualification and Continuous Medical Education

Physicians

Until 1994 medical directors of blood centres and officers of hospital blood banks were specialists of quite different medical specialities, mainly internal medicine, clinical chemistry or anaesthesiology, holding accessory microbiology certifications. Then an amendment of the Austrian law for general practitioners and specialities [21] introduced an own speciality for transfusion medicine and blood group serology [22].

1992 marked the year when a new scientific and medical society, the ÖGBT, was founded. Its first task was to develop standards for the medical education of transfusion medicine specialists and guidelines for transfusion medicine in which the production of blood products is the sole competence of transfusion medicine specialists (Facharzt für Blutgruppenserologie und Transfusionsmedizin). These recommendations were the basic framework of the newly defined medical speciality for blood group serology and transfusion medicine. The definition was taken into the legal ordinance for the education and qualification of physicians and specialists. The articles cover the goals, length, composition and content of training. It also frames the qualification of medical institutions to educate specialists and the transition periods. Additionally medical qualifications in mobile and fixed blood donation sites are declared in the guidelines issued in 1996 and renewed in 2001 by the ÖGBT. Due to the new legal ordinance for pharmaceutical manufacturing (AMBO 2005) some issues which may be restricted to pharmaceutical companies are not transferable to blood centres or hospital blood banks. A new amendment is on the way to clarify the medical positions in a blood centre.

However, a solution for the situation of officers and medical staff in hospital blood banks is not found yet; a concept of the ÖGBT seems to resemble resistance. In the meantime this unregulated situation enables a flexible management of different organizations involved in the transfusion chain. Today all blood centres are managed by certified specialists in transfusion medicine and blood group serology. 14 blood centres and hospital blood banks offer 30 full and 4 partial educational and training positions for residents. Hospital blood banks are operated mainly by anaesthesiologists, clinical chemists and specialists for internal medicine.

The supervision of a mobile donor session or fixed donation site requires the qualification of a licensed physician with an experience in blood collection of more than 2 years. A comprehensive curriculum was developed by the ÖGBT for physicians at blood donation sites, specialists in transfusion medicine and officers of hospital blood banks. The training of specialists in transfusion medicine takes at least 6 years and ends with a board certified examination. In general all physicians may attend the voluntary continuous medical education (CME) program [23]. It was introduced by the Austrian Medical Board (Ärztetikammer) in collaboration with various scientific societies. Educational sessions are classified with educational points. The minimum of 150 points in attendance is needed to obtain the CME certification which is valid for 3 years.

Medical Assistant Technicians

The educational pathway of medical technical assistants takes 3 years after general qualification for university entrance and is also regulated in the professional act for medical assistant technicians (Bundesgesetz über die Regelung der gehobenen medizinisch-technischen Dienste (MTD-Gesetz), BGBl 460/1992 i.d.g.F.) [24]. The education in immunohaematology includes 38 theoretical and 30 practical lessons. Additional experience has to be gained in a 6-week internship. A new legal ordinance (FH-MTD-Ausbildungsprogramm(FH-MTD-AV), vom 05.01.2006 über die Fachhochschul-Bakkalaureatsstudiengänge für die Ausbildung in den gehobenen medizinisch-technischen Diensten) [25] prepares the way for the education of medical technical assistants in a technical college in convergence to European standards. Lifelong learning and a higher personal responsibility is also mentioned in this law.

Nurses

This profession works in the field of blood donation and apheresis, in mobile blood donor sessions and in fixed sites. The out-patient workload, especially therapeutical apheresis procedures, transfusions, autologous and blood salvage procedures are performed mainly by nurses. Some blood centres have nurses in the staff for blood component preparation. Nurses have to complete a 3-year training and education in a hospital according to their specific professional law (Bundesgesetz über Gesundheits- und Krankenpflegeberufe (GuKG),

BGBI 108/1997 i.d.g.F.) [26]. A curriculum for nurses in apheresis units is now in discussion, and a course for apheresis nurses will be opened soon by the university institute for transfusion medicine in Graz. Continuous training for medical professions is in the responsibility of the medical director and often organised in the own institution. Seminars in immuno-haematology are organised 3–4 times a year in different sites in Austria by the blood centre of Innsbruck.

Other Professionals

Blood donations, component preparation and laboratory procedures require high skills in quality management and hygiene. Laboratory assistants with a short certified course have a high knowledge about general aspects and are educated on the job. Many blood centres employ biologists and other academics who work at most on molecular methods for blood group antigens, immunogenetics and infectious diseases. In some rare occasions pharmacists are installed as production officers. Quality management positions may vary in their qualifications. Computer technicians and information managers are common in all blood banks although most of them are assigned to the ruling Red Cross or hospital organization. But recently a big move to the main duty in the blood centre is registered due to the high complexity of the blood bank information system and growing validation requirements.

Hygiene Plan

According to the national hospital act (Krankenanstaltengesetz 2. KAG-Novelle, BGBI. 281/1974) and its amendment in 1993 [27] hospitals must adhere to hygiene criteria which are deduced from a hygiene plan. Due to the out-patient care most blood centres are legally seen as specialized hospitals and require as such a hygiene officer who is a licensed physician with a special training and a qualified nurse with an additional license as hygiene expert. Both are in a staff position to the medical director. However, the blood safety act and the pharmaceutical act additionally require general hygiene standards which must be in place for manufacturing procedures. A unified hygiene standard for blood centres does not exist, but commercial apheresis sites have released a guideline in 2003 in the aftermath of hepatitis C transmissions in some member sites.

The hygiene plan is intended to safeguard donors as well as to ensure occupational safety for the staff of blood donations. This document includes the definition of staff functions, the separation of different areas and relevant procedures as well as the requirements for technical resources as for instance medical devices and facilities. Types of donations and a list of infectious agents which are most likely to occur and the handling of laundry, cleaning and disposal procedures are mentioned. A disinfection plan with approved disinfectants as well as the dosage lists and hand and skin disinfection procedures

are attached to the hygiene plan. If required, it may also include the sterilisation of instruments, sampling and monitoring of heating, ventilating and air-conditioning as well as sanitary facilities. A cleaning and maintenance plan is also necessary in addition to the hygiene plan. All procedures must be documented by continuously educated personnel. At last the hygiene officer and the hygiene nurse must perform regular sampling of critical elements such as water, air and surfaces of exposed spaces.

Information Technology and Documentation

The complete chain between the donor, the blood product and the patient must be kept in records for at least 30 years. Due to the various services which are provided by the blood centres and, more common, their different organisational structure, a uniform information technology (IT) system is not in place, and most blood centres run an IT system adapted to their structure. Commercial systems may be of different quality, and the use of different systems in one blood centre is very common. Due to legal requirements all data of the donors, their form of identification, the donation procedures and all data during production as well as the identification of medical devices must be captured. Hospital blood banks must hold the data of recipients and the testing performed in the patients. Screening laboratories have to collect all data of assay lots, reagents, devices and especially the algorithms to generate results and release specifications. Software must fulfil GMP requirements and is regularly validated. All users have to change their passwords in a defined frequency. The use and manipulation of data is strictly regulated and controlled. Most of the validation procedures are spent for standing data and algorithms and the development process of the software. Statistical work is generally rudimentary in most systems but catches up as the requirements for haemovigilance are emerging. The blood safety act sets also ISBT-128 as the general barcode system mandatory until 2007. Most blood centres are now in transition to ensure the new coding system on time.

Quality Management System

According to the blood safety act, the blood donation services have to run a quality management system. This system has to point out quality goals, the major task, responsibility and competence of personnel, and the organization chart. All steps before and during blood donation are defined in standard operating procedures. The coverage of documentation and quality control are well defined. On top of all documents is the quality manual. Quality management is also required by the pharmaceutical act and in this context regularly audited by the donor plasma-processing pharmaceutical companies as it ad-

Fig. 1. Demonstration of the Austrian haemovigilance system.

heres strictly to GMP. However, the function of the quality management remains quite the same.

Although certification of quality management systems is not required by the specified laws and a uniform quality management system does not exist, most blood centres are ISO 9001:2000-certified. In nearly all cases the introduction of the quality management systems necessitated external help. Most quality management systems are nowadays hybrid systems of ISO 9001:2000 and GMP.

All blood centres with their laboratories participate in external quality control schemes. Outsourcing of tests to other institutions is common, and there are strict requirements that a contract has to be signed before testing is given away. All hospital blood banks and depositories have to be registered in the blood centre's distribution list. The quality management system is guided by internal and external audits. There are seminars for internal auditors provided by different institutions which offer a regular audit scheme and a practical introduction. External audits are arranged by accredited institutions and performed by a qualified auditor with knowledge in transfusion medicine. According to the legal requirements the hospital blood banks and depositories have to introduce and maintain a quality management system.

Haemovigilance

Article 75 and following of the pharmaceutical act obliges physicians to notify the ministry of health about serious adverse reactions and events. The haemovigilance system [28] (fig. 1) includes the notification procedure to a central notification registry which is organised by the ÖBIG to identify complaints and errors in the transfusion chain. This registration should provide more knowledge about risks in transfusion and should help to avoid further damage to patients. The main focus is on organizational errors, the indication for transfusions and screening procedures. This registry was installed in January 1, 2003 as a non-obligatory system and is since January 1, 2004 a mandatory system. The registry was switched to the Austrian poisons centre, which is a 24/7 service and also serves as the transplantation objection registry. A structured documentation system sets a standardised way of decision making and notification which may be immediate or annually. Standardised reports are available on internet for all physicians.

Physicians have to report every suspected case to the hospital blood bank which is in charge to find out if the case is really linked to transfusion. Hospital blood banks have an important

Table 2. ÖBIG: Results of the haemovigilance reports 2003 and 2004

Haemovigilance reports, Austria	2003	2004
Voluntarily reported near miss events	68	60
Immediate reports on suspected bacterial contamination	23 (in 4 cases bacteria had been found in the product, no blood culture from the patients had been made)	17 (in no case bacteria had been found in the product)
Immediate reports on product-related defects	9	18
Immediate reports on suspected viral infection	4 (in all cases no viral infection of the product)	6 (in 5 cases no viral infection of the product, in 1 case transmission of HCV seems to be confirmed)
Reports on incorrect blood transfusions	0	25
Annually reportable reactions and events	430 (febrile and non-febrile NHTR and allergic reactions)	518 (febrile and non-febrile NHTR and allergic reactions)

NHTR = Non-haemolytic transfusion reactions.

function to investigate the case and report it further on to the Austrian haemovigilance registry and the inflicted blood centre which produced the blood product. Reports have to be sent in questionable and confirmed transfusion-related cases. The hospital blood bank officer has the responsibility to teach all departments and physicians about the mandatory haemovigilance reporting system. Besides the registration of transfusion reactions and product non-conformities at the bed-side, it will be now also obligatory to report donor reactions, events and reactions during production, storage and distribution. This new reporting scheme is in accordance with the Commission Directive 2005/61/EC and the Austrian Haemovigilance Registry reports to the European Haemovigilance Network (EHN).

The ÖBIG is not only the major notification body in Austria but also collects data about blood products, the produced quantities and transfusions. Blood centres have to report annually the amount of autologous and allogeneic donations as well as specific figures of donors, the preparations produced and disposed products to the ÖBIG. Hospital blood banks are asked in the same way to report transfused and disposed units. Out of these reports, the ÖBIG generates a statistical overview for the health ministry (table 2).

Planning of Resources, Costs

Forecasts in blood donation are highly dependent on the willingness of the population to donate blood. But beside the population density, vacation periods, communications and logistics are quite important. On the supply side the density of hospitals and their consumption of specific blood products is sometimes quite demanding. However, information technologies made it apparent that blood groups are not evenly dis-

persed in Austria, and the donation planning has to mention these differences as well as times with low donor availability such as carnival, the Easter week, the week before summer school vacations and Christmas. The loss of up to 12% of donations must also be taken into account as questionnaires are more complex and this high loss of donations is caused in many cases by a positive anamnesis of diabetes, high blood pressure, dental procedures, vaccinations and travelling. A surplus of 4–5% is required to meet the short rises in demand. Therefore, the exchange of blood products between blood centres is getting more common to avoid heavy losses of expired blood products.

Blood usage of the hospitals is monitored at least twice a year and communicated to the hospital blood bank officers in regular meetings. The general use of blood products was stable in the last 3 years and may be higher in some third-level and university hospitals. However, a trend in the last 3 years shows that the demand of blood group O, RhD-negative blood is rising in the majority of hospitals and exceeds double of the population percentage (approximately 12%), whereas the need for products with type AB and B is declining rapidly to zero. This is an effect of the reporting procedures to the ÖBIG and tighter economical measures in some hospitals. However, the focus should be driven to correct this form of mis-use which is clearly a violation of good medical practices.

Blood products are charged by a fee or cost transfer to the hospitals. There is no subsidisation of blood centres in their regular business, but on rare occasions some regional governments support the regional blood centre with partial grants for investments in new facilities if these facilities are attached to a hospital or meet additional centralised demands like tissue banking or immunogenetics services. The fees are different as the overhead costs coming from services charged by the Red Cross or a hospital fund may differ. Higher expenses may

occur also due to higher requirements in logistics, information technologies and attached laboratory services asked by the hospitals. The calculation methods are not uniform. Some blood centres have contracts with hospitals in which the calculations are disclosed to the customers, some set fees without further notification, some are embedded in the hospital fund and transfer the costs.

Emergency and Disaster Planning

A general emergency and disaster plan for the Austrian blood centres exists as a framework. Most blood establishments have detailed plans to help each other in case of emergency. As the majority of blood establishments is run by the Red Cross, which has huge logistical resources, a flexible and rapid response is guaranteed.

Future and Scientific Considerations

Nearly all specialists and a smaller part of medical assistant technicians are members of the ÖGBT. Many transfusion medicine specialists are also registered in the German Society of Transfusion Medicine and Immunohaematology (Deutsche Gesellschaft für Transfusionsmedizin und Immunhämatologie; DGTI), which traditionally offers one position of a counselling member of the executive board to an Austrian member and selected three presidents from Austria. Few Austrian specialists are also members of the American Association of Blood Banks (AABB) and International Society of Blood Transfusion (ISBT).

Some scientific events are regularly organised for autologous blood donation and blood salvage (Vienna), apheresis (Vomp, Tyrol) and general topics in immunohaematology and blood transfusion (Vienna). *Blut.at* is a periodical publication of the Red Cross with articles on scientific news and reports, which are well accepted by physicians performing transfusions. The

publication and other informations are also available on the internet (www.blut.at).

The coordination of all directors of blood establishments was organised from 1952 to 2005 by the Directors Board for Blood Donor Services of the Austrian Red Cross (Direktorium für das Blutspendewesen des Österreichischen Roten Kreuzes) [29, 30]. This was changed to the Commission of Red Cross Donation Services (Kommission Blutspendewesen), a new board exclusively assigned with medical directors and administrative managers from the Red Cross blood donations services. This was created in response to commercial activities to import blood derived from remunerated donations and to underline the importance of non-remunerated voluntary blood donors. Along with the routine work and the growing regulatory issues which have to be solved, scientific work has always been performed in the Austrian blood centres by academics, assistant medical technicians and physicians. The foundation of three university institutes for transfusion medicine and blood group serology, the promotion of many university professors in the last 3 years and the rising amount and quality of publications is an indicator for the better scientific qualification of the blood centres. The centre of gravity is the development of methods and the discovery of new and variant erythrocyte antigens, especially weak Rh and Rh variants as well as leucocyte and platelet antigens. Many publications in the last decade dealt with the detection of infectious donations by unspecific markers (e.g. neopterin). Bacterial detection and the detection of viruses, especially by NAT, are well followed, but publications are rare. New procurement methods for stem cells and biocompatibility, especially in the filtration of blood products, have been a long time topic in some institutions. Clinical studies responding to the awareness that in the clinical setting transfusion triggers are substantially diverse are now planned. The ÖGBT is still devoted to regulatory work but it stimulates young scientists with the Domanig Award issued every second year. New plans to support scientific networks in Austria and neighbouring countries are on the way.

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