Monitoring of blood transfusion operations in EU-countries

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Abstract

The monitoring of blood transfusion operations in EU countries is a vital step in the EU’s Life+ programme’s PVCfreeBloodBag project. The information gathered will be helpful in communication about the project and in trying to increase the demand for a PVC-free blood bag in the EU. A questionnaire was put together with questions about blood transfusion and different aspects of the field, such as procurement, environmental requirements and transfusion statistics. The questions were emailed and communicated via phone to hospital employees, consultants, bioengineers, medical directors, etc., in the EU countries. The answers gathered, alongside complementary information found online, show differences in operational structure, i.e. regional in contrast to national. Furthermore, the study shows a lack of awareness amongst the participants about environmental requirements regarding blood bags, and shows differences in the amount of transfusions carried out nationally and in the blood bags procured; differences that more or less follow the number of inhabitants in each country.
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1 Introduction

On behalf of the EU’s Life+ programme’s PVCfreeBloodBag project, this report will describe how blood transfusion is organized in nine EU-countries: Norway, Denmark, England, France, Finland, Italy, Poland, Spain and Germany. A questionnaire was emailed and communicated via phone to employees in different branches of blood transfusion operations in these countries. This information, alongside complementary information gathered online, is presented and organized nation-wise in the results below. The results section for each country is structured by using the seven questions of the questionnaire as headlines:

1. How are blood transfusion operations organized?
2. Who collects the blood, stores, handles, distributes and transports it between regions?
3. Who is in charge of purchasing/procurement of blood bags?
4. Who sets environmental requirements for blood bags?
5. Deciding what type/model of blood bags – do people who work with the bags have any say?
6. How many blood transfusions are done per year?
7. How many blood bags are procured per year?
8. What publications are suitable for communication about this project?

The references for each country are at the end of each results section. The Introduction, Method and Results are followed by a brief conclusion with tables that summarize and highlight the most significant findings of the report.

2 Method

The questionnaire was put together in order to fully survey the study’s topics of interest regarding blood transfusion. The questions were mainly emailed to the participants because they preferred to have the questions in written form, partly due to language barriers. The nine EU countries were selected based on their significance and market size in the EU and the participants were chosen using prior work in the project and by googling relevant search phrases and words. Hospital employees, consultants, bioengineers, medical directors, etc., comprise the group of participants in the study. Answers to the questionnaire were gathered successively and since many answers were delayed and even missing, complementary information was gathered online.
3 Results

3.1 Norway

How are blood transfusion operations organized?

There are currently 60 blood banks in Norwegian hospitals (2015). The four major blood banks are located in the four major Norwegian cities - Oslo, Bergen, Trondheim and Stavanger (Haugnæss 2015). In Norway, the transfusion service is a part of specialized healthcare, owned by the regional health authorities and administered by each health company. Every healthcare region organizes production for its own use (Nissen-Meyer 2015).

In 2013, there were 73 facilities where blood donors could give blood, in addition to blood buses located in Hordaland and Oslo/Akershus. Pheresis (“breroappning”) is performed by 20 blood banks. Certification or accreditation of blood banks is common and 67% of donations occur at blood banks that are certified or accredited. All blood banks are integrated with hospitals and are owned by regional health trusts. This explains the high number of blood centres. 75% of blood is collected by 14 blood banks. Plasma is provided by the 14 larger blood banks and fractionated by a commercial company (European Blood Alliance nd).

Who collects the blood, stores, handles, distributes and transports it between regions?

Nurses and bioengineers collect the blood and it is then stored in the blood banks. They take care of the blood and distribute it amongst regions (Haugnæss 2015). Each "health company" has its own donor pool, production unit(s) and blood typing/extradition laboratories. There is no permanent cooperation/coordination unit. Transport between regions is largely ad hoc and performed by commercial companies, or organized between two "health companies" that make an agreement (Nissen-Meyer 2015).

Who’s in charge of purchasing/procurement of blood bags?

Norway has a national tender system; the same type/model of blood bags are used nationwide. This tender started in 2015 and was a national decision (Haugnæss 2015). Each blood bank/"health company" purchases blood bags from the supplier that won the biannual procurement. The tenders are mainly national, but the Blood Bank of Oslo ran their own tender for blood bags last year (Nissen-Meyer 2015).
Who sets environmental requirements for blood bags?

This general rule has been mentioned in the tender texts:

*It is a requirement that the provider meets the requirements in the regulations relating to systematic health, safety and environmental standards in business.*

Apart from that, there are no environmental requirements for blood bags. The choice is based on quality properties (tendency to haemolysis, breakage and so on) and price (Nissen-Meyer 2015).

The Environment Department of Immunology and Transfusion Medicine at St. Olavs Hospital are interested in PVC-free blood bags. They follow “Blodförskrift”, which is a regulation that includes medical products. Lene Haugnæss at St. Olavs Hospital says that they can use PVC-free blood bags but it depends on how good they are. Price is a significant factor. They tested one model not so long ago, but it smelled strange so they went back to a conventional blood bag. Lene highlights France and Denmark, countries that are at the forefront of PVC-free blood bags. She believes they work actively with this, without knowing further details (Haugnæss 2015).

Deciding what type/model of blood bags – do people who work with the bags have any say?

The Environment Department of Immunology and Transfusion Medicine at St. Olavs Hospital discusses PVC-free blood bags, but there is currently no good option. There is a model from the company Nakofarma, but she is not sure why this is not being tested. They are mainly waiting for more suppliers and more competition between them, so that prices can be driven down. The next national tender will be in three years (Haugnæss 2015).

The bags considered in the tender are tested and validated in the blood bank routines before the decision is made. Therefore, hands-on experience was vital for the decision in Oslo. In a national tender, input from hands-on experience will be more remote, as all participating blood banks will have to loyally follow the decision. In recent years, blood bags have become less expensive, but Lise Sofie H. Nissen-Meyer at The Blood Central in Oslo have experienced worse quality, as old reliable products have been discontinued (Nissen-Meyer 2015).
How many blood transfusions are done per year?

In 2013, 184,257 erythrocyte, 48,130 units Octaplas and 26,039 platelets were transfused nationwide (Nissen-Meyer 2015). In 2013, 208,383 donations were carried out, of which 14,571 were pheresis. The number of donations has been relatively stable over the past six years. Because the population in Norway is rising rapidly, the number of donations per 1,000 inhabitants is decreasing. Erythrocytes are produced using pheresis in 14 blood banks. The number of procedures varies between 50 and 504. All in all, 3,220 erythrocyte pheresis were performed. Eight blood banks performed a total of 5,228 plasmapheresis. The number of procedures varies between 21 and 3,442. The blood bank with the most plasmapheresis procedures performs 66% of them. 501 combined apheresis are performed at seven different locations (Blodtransfusionstjenesten I Norge 2014). For platelets, there is an increase in consumption, while for erythrocyte and Octaplas there is a reduction. 365 HLA compatible platelets were transfused and four that were HPA compatible. 96 units of whole blood were transfused at one hospital (Blodtransfusionstjenesten I Norge 2014).

How many blood bags are purchased/procured per year?

Nissen-Meyer estimates a purchase of slightly fewer than 35,000 blood bags per year in Oslo. For all of Norway there are approx. 205,000 donations carried out annually (Nissen-Meyer 2015).

What publications are suitable for communication about this project?

- Bioingenioren – https://www.bioingenioren.no
- Magazine for the Norwegian society for doctors (Norske legeforening) - http://tidsskriftet.no

References


Haugnæss, Lene (2015 ) Department head bioengineer at Unit for blood donation. Section blodbank Department of Immunology and Transfusion Medicine St.Olavs Hospital Trondheim, Phone: 72573107, Questionnaire on blood transfusion, (email), 30 July 2015 [17 September 2015]

3.2 Denmark

How are blood transfusion operations organized?

Denmark is divided into five regions: “Hovedstaden”, “Sjælland”, “Syddanmark”, “Midtjylland” and “Nordjylland”. Each region has its own blood bank organization that is responsible for the complete blood chain in that region (Wantzin 2015). By law, healthcare in Denmark is the responsibility of the five regions. Also by law, only publicly-owned hospitals are allowed to collect blood. Denmark is represented in the European Blood Alliance by the Organization of Transfusion Centres (OTCD) in Denmark. The OTCD was established in 2001 to coordinate countrywide responsibility for the blood transfusion services and to represent the interests of blood programme in the country. The members of the OTCD represent 100% of blood collection in Denmark (European Blood Alliance nd).

The Danish blood transfusion service is a hospital-based service with 65 blood banks located in hospitals as hospital departments. The size of the blood banks depends on the needs for transfusions in the hospitals. Eleven blood banks are situated in larger regional hospitals and function as regional blood transfusion centres, varying in size from 6,000 to 85,000 donations per year. More formal coordination between the blood banks in a region has been established in three of the Danish counties and in the Copenhagen area. These four larger blood banks together carry out approximately 230,000 collections per year. The director has usually full responsibility for the organization and for coordination of the transfusion service in the region. The regional blood bank directors are medical doctors and qualified medical specialists in transfusion medicine. The smaller blood banks are normally part of a department of clinical chemistry or anaesthesiology. The chief physician of these departments has full responsibility for the service, but normally gets advice from the regional centre (The International Haemovigilance Network 2011).

To ensure uniform national performance, the Danish Society for Clinical Immunology has published national guidelines on all aspects of transfusion medicine. Blood components are regarded as medicinal products. Therefore, in accordance with legal requirements, the Danish Medicinal Agency issues an authorization for each blood bank and biannually inspects all the blood banks to ensure good manufacturing practice. Each blood bank has one named person approved by the Danish Medicinal Agency, who is responsible for the production according to the Medicinal products law (ibid 2011).

There is nobody that administers and coordinates the Blood Transfusion Service at the national level. The National Board of Health has established an Advisory Committee on Transfusion Medicine. The regional blood transfusion centre directors meet regularly on a voluntary basis to try to coordinate their efforts (ibid 2011).
A national law on the "Production and use of human blood and blood derivatives" was issued in 1997. The National Board of Health has issued a number of regulations and recommendations concerning blood transfusion and blood donors. Concerning electronic data processing, most blood banks have EDP systems (ibid 2011).

Each hospital has its own donor organization, which is run on a totally voluntary basis, and which has the responsibility to provide the blood bank with donors. All the blood donor organizations are members of one national donor organization called "The Blood Donors in Denmark" (ibid 2011).

The Blood Donors in Denmark is a non-profit association that works independently of governmental authorities and without association to the Red Cross. The main aim of the association is to secure a sufficient number of blood donors anywhere in the country at any time. Out of a total population of 5.3 million, more than 260,000 are registered blood donors, i.e. about 10% of the population aged between 18 and 60. All Danish blood donors are voluntary and non-remunerated (ibid 2011).

**Who collects the blood, stores, handles, distributes and transports it between regions?**

The regional blood bank organization provides these services (Wantzin 2015). In Denmark, blood banks almost have a monopoly on blood collection, and are responsible for the testing, processing, storage and supply of blood and blood components for transfusion. The blood banks are part of clinical immunological departments, or in a few cases part of clinical biochemical departments, in public hospitals. Whole blood is collected either at mobile or fixed sites (hospital-based blood banks), whereas plasmapheresis, platelethpheresis and leukapheresis are only performed at fixed sites. About 75% of the collected plasma is sold to CSL Behring for fractionation. Storing, handling, preparation and distribution is done primarily by the staff (technicians, nurses etc.) at the blood banks. In some procedures, employees from a transportation company or from CSL Behring are also involved. Blood Bags are transported in different ways (e.g. by drivers from different transportation companies or by drivers employed by the clinical immunological departments) (Larsen 2015).

**Who is in charge of purchasing/procurement of blood bags?**

Each of the five regional authorities in Denmark has a central “procurement department”, which conduct the purchasing/tendering process. The procurement department collaborates with the blood bank director and a user group (consisting typically of medical doctors specialized in immunology, head technicians and/or nurses, etc.) (Larsen & Wantzin 2015).
Who sets environmental requirements for blood bags?

General environmental requirements are described in the following Danish regulations:

- LBK nr. 879 dated 26-06-2010. Bekendtgørelse af lov om miljøbeskyttelse (Miljøbeskyttelsesloven) - Guidance on environmental protection

Denmark, as a member of the EU, has to comply with EU legislation, and as far as Rune Larsen at Copenhagen University Hospital knows, the EU principle of “free movement of goods” and the regulation of medical devices prevents Denmark from setting national environmental standards for CE-marked medical devices (Larsen 2015).

Deciding what type/model of blood bags – do people who work with the bags have any say?

They may have the opportunity to state their opinion during the testing/evaluation/validation of new blood bags and to participate in user groups, when there is some kind of tendering process (often a as part of a public procurement) (Larsen 2015). The type/model of bags used is based on a regional procurement, usually for a three-year period (Wantzin 2015).

How many blood transfusions are done per year?

There has been a significant decline in the use of red cells in Denmark in the last 5-10 years. Last year a total of about 330,000 units (red cells, platelets and plasma) was transfused (Larsen 2015). (Red blood cell units 246,000, plasma units 52,000, platelet-pools (each consisting of four platelet units) 32,000 = 330,000 units (Wantzin 2015)).
Figure 1. Number of transfusions per region for the years 2007 and 2008 (Dansk Transfusionsdatabase 2009)

How many blood bags are purchased/procured per year?

Per Wantzin’s (Herlev Hospital) best guess is that the number of “blood bag systems” (each consisting of more than one bag) should be around the same as the total number of collections (whole blood, plasmapheresis, plateletapheresis), which was about 290,000 in 2014 (Wantzin 2015).

What publications are suitable for communication about this project?


References


Larsen, Rune (2015) MD Department of Clinical Immunology Rigshospitalet, Copenhagen University Hospital Blegdamsvej 9 DK-2100 Copenhagen Denmark Phone: + 45 48 29 41 85 Mobile: + 45 24 27 93 26, Questionnaire on blood transfusion, (rune.larsen@regionh.dk), 30 July 2015 [17 September 2015]


Wantzin, Per (2015 Area Responsible Consultant Plan Area midst Herlev / Gentofte Department of Clinical Immunology Capital Region Blood Bank 54K6 Herlev Hospital Herlev Ringvej 75 2730 Herlev Kontor: 38 68 47 00 Mobil: 23 38 38 60, Questionnaire on blood transfusion, (Per.Wantzin@regionh.dk), 30 July 2015 [17 September 2015]
3.3 France

How are blood transfusion operations organized?

Since 2000, EFS (Etablissement Français du Sang) has been the only blood transfusion operator in France and is in charge of the whole transfusion chain for the French territory. It is placed under the authority of the Ministry of Health and is present throughout the country (Etablissement Français du Sang 2013).

Table 1. EFS Organization structure (Etablissement Français du Sang 2013)

<table>
<thead>
<tr>
<th>One institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 regional establishments including 3 in overseas territories</td>
</tr>
<tr>
<td>152 permanent sites</td>
</tr>
<tr>
<td>2,750 voluntary, not for profit associations</td>
</tr>
<tr>
<td>1,900 hospitals and clinics supplied with labile blood products</td>
</tr>
<tr>
<td>91 health centres</td>
</tr>
<tr>
<td>1 medical biology laboratory in France</td>
</tr>
</tbody>
</table>

The 17 regional centres of the EFS (14 in the metropolitan area) are headed by directors appointed by the President of the EFS and act on his delegation as regards management and operations. Centralized services cover medical and scientific matters (the Responsible Person is also the Scientific Director of EFS), quality management, human resources, purchasing, finances, communication, information technology, legal affairs and technical services. The major points of the national quality policy of EFS deal with: 1. self-sufficiency and quality and safety of labile blood products and services for the patients, 2. staff skilling and 3. efficiency. Great efforts are constantly dedicated to harmonizing practices between establishments and reducing the cost of products and services (Etablissement Français du Sang 2013).

Who collects the blood, stores, handles, distributes and transports it between regions?

The French Blood Institute is responsible for:

- Blood collection
- Biological evaluation of samples
- Preparation and distribution of blood samples (Billod-Mulalic 2015)

The French National Blood Service (EFS) is a public organization that was established in January 2000. EFS has a monopoly on collection, testing, preparation and distribution of labile blood products to some 1,900 health care facilities (these activities can only be
performed by blood transfusion establishments approved by the competent authority). Voluntary and unpaid donations, self-sufficiency and safety for patients are first basic principles governing blood transfusion in France and are registered as such in French legislation. Issuing of the majority of blood components is carried out by the blood transfusion establishments directly to patients in hospitals from orders received from the prescribers. The plasma for fractionation prepared by EFS is fully fractionated by the Laboratoire Français du Fractionnement et des Biotechnologies (LFB), which imports limited volumes of plasma from abroad (collected from voluntary non-remunerated donors). Aside from the core activities, EFS carries out the following associated activities: immune-haematology and HLA laboratories, tissue and cell engineering, reagent manufacturing, research, training and education (European Blood Alliance nd).

Who is in charge of purchasing/procurement of blood bags?

Who sets environmental requirements for blood bags?

Deciding what type/model of blood bags – do people who work with the bags have any say?

How many blood transfusions are done per year?

France performs about 2.5 million blood transfusions per year (Billod-Mulalic 2015).

<table>
<thead>
<tr>
<th>Mobilization of donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,625,735 donors</td>
</tr>
<tr>
<td>347,530 new donors</td>
</tr>
<tr>
<td>2,833,351 blood donations (whole blood, plasma and platelets)</td>
</tr>
<tr>
<td>40,000 mobile blood drives organized</td>
</tr>
</tbody>
</table>

Table 2. Donor statistics (Etablissement Français du Sang 2013)

How many blood bags are purchased/procured per year?

What publications are suitable for communication about this project?
Comments

Not much information available online and hard to find contact persons.

References

Billod-Mulalic, Rachel (2015) C2DS international, Questionnaire on blood transfusion, rachel.billod-mulalic@c2ds.eu [17 September 2015]


3.4 England

How are blood transfusion operations organized?

See next question.

Who collects the blood, stores, handles, distributes and transports it between regions?

There are four UK Blood Services:

- NHS Blood and Transplant for England
- SNBTS for Scotland
- WBS for Wales
- NIBTS for Northern Ireland

The blood services collect, test, manufacture and distribute blood components collected as whole blood or by aphaeresis. Blood is supplied to UK hospital transfusion departments and issued from there to patients for transfusion. Each hospital or hospital Trust has a Transfusion Committee and each region in England has a Regional Transfusion Committee and there is a National Transfusion Committee\(^1\) (Rowley 2015).

Who is in charge of purchasing/procurement of blood bags?

The blood bags used by NHS are procured through the Eurobloodpack initiative under the aegis of the European Blood Alliance\(^2\) (Smith 2015).

Who sets environmental requirements for blood bags?

Guidelines for all the materials produced by the United Kingdom Blood Transfusion Service for therapeutic and diagnostic use are defined in The ‘Red’ Book (Transfusion guidelines nd) (Rowley 2015).

NHS follow EU guidance on environmental requirements (Smith 2015).

\(^1\) details can be found here [http://www.transfusionguidelines.org/uk-transfusion-committees](http://www.transfusionguidelines.org/uk-transfusion-committees)

Deciding what type/model of blood bags – do people who work with the bags have any say?

How many blood transfusions are done per year?

The most recent data Caroline Smith at NHS has seen is in the annual blood stocks management scheme report: (Smith 2015).

<table>
<thead>
<tr>
<th>Data for 2013/14</th>
<th>NHSBT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size of Region (square miles)</td>
<td>50,000</td>
</tr>
<tr>
<td>Population (million) (2011 Census)</td>
<td>53m</td>
</tr>
<tr>
<td>Red Cell Issues</td>
<td>1,691,868</td>
</tr>
<tr>
<td>Platelet Issues</td>
<td>268,344</td>
</tr>
<tr>
<td>No. of hospitals</td>
<td>235</td>
</tr>
<tr>
<td>No. of issuing blood sites</td>
<td>10</td>
</tr>
</tbody>
</table>

Figure 2. Donation statistics (blood stocks 2012)

The table shows that in 2013/2014 England issued:
1,691,868 red blood cells
and 268,344 platelets (Bloodstocks 2014).

How many blood bags are purchased/procured per year?

What publications are suitable for communication about this project?

- British Journal of Haematology (The official journal of the British Society for Haematology)
- Transfusion Medicine (The official journal of the British Blood Transfusion Society)

References


Rowley, Dr Megan (2015) Consultant in Haematology and Transfusion Medicine Imperial
Smith, Caroline J, (2015) Joint UKBTS Professional Advisory Committee (JPAC) Manager NHS Blood and Transplant Longley Lane SHEFFIELD S5 7JN Tel: +44 (0) 114 358 4903 Fax: +44 (0) 114 358 4994 E-mail: caroline.smith@nhsbt.nhs.uk, Questionnaire on blood transfusion, (email) [17 September 2015]

3.5 Finland

How are blood transfusion operations organized?

The Finnish Blood Service is the nationwide blood service operator in Finland and is a financially and operationally independent organization within the Finnish Red Cross. It provides Finnish hospitals with all the blood products they need. It is a non-profit organization and focuses on the patients. Hospitals pay the Blood Service for ordered products and services and with these charges; the Blood Service fund their operational and investment costs. Sales at the Blood Service amounted to 66 million Euros in 2010 (European Blood Alliance nd).

The Blood Service’s activities are governed by Finnish law on blood services, as well as the European Union's Directive on the safety of whole blood and blood components, among other legislation. Blood Service activities are supervised by the Medical Products Agency (The Red Cross nd).

The Blood Service also offers hospitals a range of laboratory and specialist services, including laboratory tests relating to blood transfusion, stem cell and organ transplantation and homeostasis, and the distribution of many plasma derived and recombinant pharmaceuticals. Many functions of the Blood Service, such as testing, quality control and administrative support functions are centralized to the Helsinki Blood Centre. This is also the venue for research and product development. In addition to the Helsinki Blood Centre operations are carried out in four regional centres and 12 collection centres (European Blood Alliance nd).

Who collects the blood, stores, handles, distributes and transports it between regions?

The Blood Service’s tasks include organizing blood donations and collecting blood as well as testing donated blood, manufacturing blood products and distributing them to hospitals. They provide healthcare sector services such as blood cross-matching, tests needed for organ, tissue and stem cell transplants, and coagulation factor and thrombocyte assays. The Blood Service performs blood group and blood group antibody tests for all pregnant women in Finland (Hurttia 2015).

The Finnish Red Cross Blood Service organizes blood-donor sessions in public places. They also specify what type of blood bag they require from manufacturers. They buy/purchase/procure the blood bags from abroad, according to Jouni Vikman from Wipak (Packaging manufacturer and participant in the PVCfreeBloodFree project). There are no blood bag manufacturers in Finland (Vikman 2015).
**Who is in charge of purchasing/procurement of blood bags?**

The Finnish Red Cross Blood Service is the provider of the blood products in Finland; there is no other operator for collecting, producing and delivering blood. They take care of the purchasing and they choose the blood bags, too (Hurtti & Vikman 2015).

**Who sets environmental requirements for blood bags?**


**Deciding what type/model of blood bags – do people who work with the bags have any say?**

They don’t have this possibility, or at least it’s not emphasised in the procurement process. The Blood Service defines the specifications (Vikman 2015).

**How many blood transfusions are done per year?**

![Blood product sales to hospitals](image)

Figure 3. Blood product numbers from The Blood Service (Hurttia 2015)

During 2014, The Blood Service collected a sufficient and constant number of blood donations throughout the year, including the summer, despite the fact that the use of blood products at hospitals exceeded their predictions in the summer months. The number of whole blood donations was about 216,000, in addition to over 4,000 plasma and platelet donations. The number of whole blood donations fell by about 3%, which corresponded to the decrease

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³ European Community rules on blood services available on the EU website ([http://europa.eu.int/comm/health/horiz_legal.htm](http://europa.eu.int/comm/health/horiz_legal.htm))
in red blood cell use at hospitals (The Red Cross nd).

**How many blood bags are purchased/procured per year?**

In 2014, as mentioned above, the number of whole blood donations was about 216,000, in addition to over 4,000 plasma and platelet donations. So, one can say, they need at least 220,000 blood bags per year. The bag package used for donation follows all the way to the transfusion (Hurttia 2015).

**What publications are suitable for communication about this project?**

**References**


3.6 Italy

How is blood transfusion operations organized?

The National Blood Centre (Centro Nazionale Sangue – CNS) is the national coordinating organization in Italy. It is one of the national technical centres of the Ministry of Health and it operates at the National Institute of Health in autonomous position. It is responsible for coordination as well as scientific and technical control of the national blood system. It also provides blood inspectors’ education and qualification and manages a national register of qualified blood inspectors, as well as the periodic assessment of their activities and skills. CNS also coordinates the Italian Cord Blood Network (ITCBN) with the support of the National Transplant Centre and collaborates with the National Medicines Agency as concerns the evaluation of plasma for fractionation and plasma-derived medicinal products (European Blood Alliance nd).

National healthcare delivery is delegated to the 21 regional health authorities; blood activities are provided by the regional health authorities through regional networks of public blood establishments; each of these networks is coordinated by the SRC (Regional Coordinating Centres). Voluntary blood donor associations and federations play a key role in the national blood system (Pupella 2015).

Regional health authorities inspect, authorize and accredit Blood Establishments (BE) and Blood Collection Units (BCU), according to regional, national and European regulations. Each regional inspection team must include at least one nationally qualified blood inspector from the CNS register. In Italy there are four main blood donor organizations (AVIS, FIDAS, FRATRES, and CRI) that are greatly involved in blood donor management. By law, they can run BCUs upon specific regional authorization and accreditation, under the technical control of BEs and regional blood centres (European Blood Alliance nd).

Who collects the blood, stores, handles, distributes and transports it between regions?

The collection is entrusted to public hospital-based blood establishments and blood collection units managed by blood donor associations, which also conduct most donor promotion and recruitment and participate in regional and national blood planning sessions (all donors are voluntary and non-remunerated). There is also a small blood establishment operated by the armed forces. Testing is performed in regional BEs (Pupella 2015).

In Italy, the blood system is part of the National Health Service. Healthcare services, including blood and blood component collection, processing, testing, storage and distribution,
as well as all transfusion medicine activities, are delivered by the regional health services within a federalist legislative framework which defines the functions of the Ministry of Health (legislation, coordination, supervision) (European Blood Alliance nd).

**Who is in charge of purchasing/procurement of blood bags?**

Purchasing/procurement of blood bags is the responsibility of either administrative regional bodies or BEs. Regional blood coordination centres operate on global budgets and blood is free to individual hospitals, although a fee would apply to transfers to other regions according to the logic of cost recovery. By law, regions should be self-sufficient but there are many blood exchanges through the CNS; about 75,000 annually [national and regional quantitative and qualitative self-sufficiency of blood and blood products is guaranteed by law (article 14 of the above-mentioned Law n. 219/2005), which envisages that every year the Ministry of Health must issue a national blood and blood products self-sufficiency Plan, upon advice from the CNS and the SRC] (Pupella 2015).

In Davide Sgarzi’s (Regione Emilia Romagna) Region, most of the hospitals are public ones, so public procurement (PP) is done by hospitals themselves (a small amount), regional PP agency (a large amount), or the national PP agency (a smaller amount): things can be quite different in other regions. For instance, in Lombardy region, most of the hospitals are private, so they purchase by themselves (Sgarzi 2015).

**Who sets environmental requirements for blood bags?**

In Regione Emilia Romagna, Sgarzi says they have very little experience. In a procurement carried out by the regional PP agency, a quality score was given to PVC-free and DEHP-free MD or to solutions that reduced the amount of packaging and improved plastic and paper recycling from MDpackaging (Sgarzi 2015). According to national law, all disposables used by BEs and collecting units must be CE marked (Pupella 2015).

**Deciding what type/model of blood bags – do people who work with the bags have any say?**

Regional or local tenders are carried out in order to choose the type/model of blood bags(Pupella 2015).
How many blood transfusions are done per year?

In 2013 and 2014, respectively 3,195,077 and 3,131,416 units of blood components were transfused (Pupella 2015).

Verlicchi et al carried out a nationwide survey of Italian blood transfusion practices. Out of the 278 blood centres that received a questionnaire, 179 (64.4%) returned it: 80 of these centres were in the north of Italy, 46 in the centre and 53 in the south of Italy. Two of the centres did not release blood products and their data were excluded from the analysis. Altogether these services collect about 1,900,000 whole blood units/year, which is about 70% of the number of units collected annually in Italy. The mean number of units collected at each centre, an indirect measure of the organisations capacity, was 10,984 (range, 476–58,604), with differences between geographic areas (mean number of units in the north 14,502; in the centre 9,342 and in the south 6,826: p=0.000) (Verlicchi et al 2011).

How many blood bags are purchased/procured per year?

In 2013, 3,144,724 collection procedures were carried out, while in 2014 the number was 3,083,694 (Pupella 2015).
What publications are suitable for communication about this project?

Blood Transfusion – [https://www.bloodtransfusion.it](https://www.bloodtransfusion.it)

References


Sgarzi, Davide (2015) DS *Questionnaire on blood transfusion*, (garzi@regione.emiliaromagna.it), 30 July 2015 [17 September 2015]

3.7 Poland

How are blood transfusion operations organized?

Daniel Jaworski, Technical Manager at Primo (plastic manufacturing company and participant in the PVCfreeBloodBag project), describes the Polish blood transfusion structure by listing bodies which the Ministry of Health/Minister of Health supervises:

- NCK – National Centre of Blood. NCK are responsible for coordination and creation of blood transfusions.
- Regional Blood Donation and Blood Treatment Centre. These centres are responsible for blood collecting, storing, distribution etc.
- Hospitals – Dialysis stations. They are responsible for blood transfusion and blood donation (Jaworski 2015).

There are 21 regional blood centres (RBC) as well as the Military Blood Transfusion Centre and the Blood Transfusion Centre of the Ministry of Internal Affairs. The latter two are supervised by their respective ministries. The Institute of Haematology and Transfusion Medicine (IHTM) supervises the activity of all centres. In 2006, a new organization was established – the National Blood Centre – responsible for financial economy of the Polish Blood Transfusion Service (BTS). All BTCs must have an accreditation from the Ministry of Health. Poland has a national system of haemovigilance (Letowska & Antoniewicz-Papis 2007).

![Diagram of blood transfusion actory](https://example.com/diagram.png)

**Figure 2.** Organization of the BTS in Poland. *The IHTM is obliged to supervise the Polish BTS and therefore to control the regional centers in various fields of their activity.*

**Figure 5.** Map of blood transfusion actors (Transfusion medicine and hemotherapy 2006)
Who collects the blood, stores, handles, distributes and transports it between regions?

The 21 RBCs have a uniform organizational structure and uniform quality assurance system and act according to uniform guidelines referring to the collection, testing, processing, storage, and distribution of blood and blood components. The IHTM is responsible for issuing guidelines. Such guidelines are currently updated to fulfil the demands of international regulations and adaptation to national standards. (Letowska & Antoniewicz-Papis 2007 & Jaworski 2015) The RBCs have satellite collection sites, the number of which decreases every year in favour of mobile blood collection units (Table 3). Apheresis is performed in 81 establishments including RBCs and satellite blood banks.

<table>
<thead>
<tr>
<th>Changes in the structure of blood collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year</td>
</tr>
<tr>
<td>No. of collection sites</td>
</tr>
<tr>
<td>No. of mobile collections</td>
</tr>
</tbody>
</table>

Table 3. Collection site numbers (Letowska & Antoniewicz-Papis 2007)

The task of RBC centres is to supply hospital patients with safe blood and blood components. Blood safety is guaranteed by careful donor and donor–candidate selection according to Directive recommendations and the Ministry of Health regulations. Three hundred and forty-five hospital blood banks are exclusively responsible for the distribution of blood in hospitals. (Letowska & Antoniewicz-Papis 2007)

Who is in charge of purchasing/procurement of blood bags?

The Regional Blood Donation and Blood Treatment Centres (Jaworski 2015).

Who sets environmental requirements for blood bags?

The Quality Department of IHT (Institute of Haematology and Transfusiology4) is responsible for environmental requirements of blood bags (Jaworski 2015).

Deciding what type/model of blood bags – do people who work with the bags have any say?

4 http://www.ihit.waw.pl/strona-glowna.html
How many blood transfusions are done per year?

1.2 million blood donations are carried out in Poland annually (Jaworski 2015). In 2014, the regional centres of blood donation and blood treatment sold:

- 285 units of blood
- 1,127,076 units of red blood cells
- 340,297 units of erythrocyte/plasma
- 113,154 units of thrombocyte concentrate (Jaworski 2015)

Since 1991, blood in Poland has been collected in disposable plastic bags, and recently additive solutions are used in about 50% of all cases. The country is self-sufficient in red blood cell concentrates, platelets and fresh frozen plasma ‘for clinical use’. Between 900,000 and 1 million units of blood and plasma are collected every year in Poland, which is statistically over 24 donations per 1000 inhabitants (Table 4) (Letowska & Antoniewicz-Papis 2007).

<table>
<thead>
<tr>
<th>Blood and plasma donations in Poland</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Year</strong></td>
</tr>
<tr>
<td>Number of donations</td>
</tr>
</tbody>
</table>

*Table 4. Donation statistics (Letowska & Antoniewicz-Papis 2007)*

There is consistent improvement in blood handling from 18% losses in 1990 to less than 3% in 2006. Red blood cell concentrate is prepared from 99.5% of collected blood (Fig. 8) (ibid 2007).
How many blood bags are purchased/procured per year?

What publications are suitable for communication about this project?

References


3.8 Spain

How are blood transfusion operations organized?

Despite their autonomous operations management, each of Spain's 17 Regional Blood Transfusion Services is fully incorporated into a unique and common Public National Health System, supplying a cohesive blood transfusion care to all citizens, residents, and visitors in Spain based on 100% voluntary and non-remunerated blood donation (European Blood Alliance nd). Antolin Denizot at Centro de Hemoterapia y Hemodonación de CyL refers to these 17 services as communities. Each community has a blood transfusion centre and works on their own but under the European Laws (Antolin Denizot 2015).

The Public Health Directorate of the Ministry of Health was designated as the general Spanish authority to coordinate and guarantee the safety and the sufficiency of the Spanish blood supply through the Spanish Blood Transfusion Committee (it works like a real cohesion body for the 17 Blood Transfusion Services), and the Scientific Committee for Blood Safety, whose six members, named by the scientific societies involved in blood transfusion issues and the Ministry of Health, are currently working at Spanish blood centres or at hospital blood transfusion units. This committee makes proposals to the authorities about safety issues and disseminates/publishes their own studies, reports, and recommendations etc. to the Spanish blood transfusion organization (European Blood Alliance nd).

In summary, a blood transfusion network established by 24 public blood transfusion centres licensed and authorized by 17 regional governments supply all the blood components, and a big part of plasma derivatives needed by any public or private hospital blood transfusion unit (ibid nd).
The Blood Transfusion Network in Spain (2012)

Figure 7. Map of 20 blood centres (ISBT nd)

Blood and blood components main stakeholders in Spain

Figure 8. Chain of blood and blood component stakeholders (IHS 2014)
**Figure 1.** Spanish blood regulation (IHS 2014)

**Figure 9.** Organization overview (IHS 2014)

**BLOOD ESTABLISHMENT:** Health establishment where each activity related to collection, qualification, processing, storage and distribution of blood and blood components is carried out no matter their final destination. The Director of a BE has to be a doctor specialist in Haematology and Blood Transfusion and a minimum experience of two years in a BE or Hospital Transfusion Unit is required.

**HOSPITAL TRANSFUSION UNIT:** Healthcare unit inside a Hospital Center bonded to a Blood Establishment, where, under the responsibility of a doctor specialist in Haematology and Blood Transfusion, blood components intended for transfusion are stored and hospital transfusion activities are organised and monitored.
Who collects the blood, stores, handles, distributes and transports it between regions?

The transfusion centre of each community collects, analyzes, handles, transports and distributes all the blood necessary for the public and private hospitals in its community only (Antolin Denizot 2015).

The Transfusion Centre of Galicia (CTG), a public foundation, provides blood components 24/7 to all health facilities in the autonomous region. Every day, ten mobile units travel to Galician municipalities to meet people who wish to make a donation. Once collected in the mobile units and in local hospitals, the donations are sent to the CTG for processing, analysis and storage. At the fixed collection points located in the hospitals, one of the most important processes performed is apheresis. Every day, 35 community hospitals, both private and public, request blood components to enable them to conduct their daily work schedule and to deal with emergencies. The decision of the Department of Health to centralize the transfusion of blood components in a single, centralized processing and distribution centre, has ensured that the patients in the community receive blood components with consistent quality, based on the most stringent safety criteria for transfusion. In 1998, the CTG received ISO 9002:1998 certification, which has been revalidated (ISO 9001:2008). It also received European Federation for Immunogenetics (EFI) and other national certifications (Intercept Blood System nd).

Who is in charge of purchasing/procurement of blood bags?

Each transfusion centre is in charge of purchasing the blood bags (Antolin Denizot 2015).

Who sets environmental requirements for blood bags?

As far as Isabel Antolin Denizot at Centro de Hemoterapia y Hemodonación de CyL knows there are no environmental requirements for blood bags in Spain (Antolin Denizot 2015).

Deciding what type/model of blood bags – do people who work with the bags have any say?

The financial manager of each transfusion centre is the one who chooses the bag type/model (depending on the price) (Antolin Denizot 2015).
How many blood transfusions are done per year?

In Castilla y Leon, around 90,000 transfusions are performed per year (Antolin Denizot 2015).

The Spanish Red Cross Transfusion Centre in Madrid produces approximately 6,000 units of platelets and 10,000 units of plasma for transfusion each year (Intercept Blood System nd).

How many blood bags are purchased/procured per year?

In Castilla y Leon, they need around 110,000 bags a year (Antolin Denizot 2015).

<table>
<thead>
<tr>
<th>COMUNIDAD AUTONOMA</th>
<th>DONACIONES AÑO 2013</th>
<th>DONACIONES AÑO 2014</th>
<th>% INCREMENTO</th>
<th>POBLACION INE 1/1/2014</th>
<th>DONACIONES/1000 HABIT.</th>
<th>RANKING %/ INDICE DON.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANDALUCIA/CEUTA</td>
<td>285.864</td>
<td>274.136</td>
<td>-4.04</td>
<td>8.487.268</td>
<td>32.30</td>
<td>15º</td>
</tr>
<tr>
<td>ARAGON</td>
<td>48.354</td>
<td>45.460</td>
<td>-5.99</td>
<td>1.325.395</td>
<td>34.30</td>
<td>12º</td>
</tr>
<tr>
<td>ASTURIAS</td>
<td>40.067</td>
<td>41.104</td>
<td>2.59</td>
<td>1.061.756</td>
<td>38.71</td>
<td>7º</td>
</tr>
<tr>
<td>BALEARES</td>
<td>38.189</td>
<td>38.872</td>
<td>1.81</td>
<td>1.103.442</td>
<td>35.23</td>
<td>9º</td>
</tr>
<tr>
<td>CANARIAS</td>
<td>94.721</td>
<td>92.740</td>
<td>-3.08</td>
<td>2.104.815</td>
<td>29.81</td>
<td>10º</td>
</tr>
<tr>
<td>CANTABRIA</td>
<td>23.468</td>
<td>23.614</td>
<td>0.63</td>
<td>388.855</td>
<td>40.12</td>
<td>5º</td>
</tr>
<tr>
<td>CASTILLA Y LEON</td>
<td>102.466</td>
<td>104.510</td>
<td>2.00</td>
<td>2.494.790</td>
<td>41.89</td>
<td>2º</td>
</tr>
<tr>
<td>CASTILLA-LA MANCHA</td>
<td>77.109</td>
<td>72.521</td>
<td>0.71</td>
<td>2.978.611</td>
<td>34.94</td>
<td>11º</td>
</tr>
<tr>
<td>CATALUNIA</td>
<td>257.918</td>
<td>255.964</td>
<td>-0.41</td>
<td>7.518.993</td>
<td>34.04</td>
<td>13º</td>
</tr>
<tr>
<td>EXTRAMADURA</td>
<td>48.010</td>
<td>47.130</td>
<td>-0.18</td>
<td>1.099.632</td>
<td>42.86</td>
<td>1º</td>
</tr>
<tr>
<td>GALICIA</td>
<td>114.126</td>
<td>111.355</td>
<td>-2.52</td>
<td>2.748.695</td>
<td>40.48</td>
<td>4º</td>
</tr>
<tr>
<td>LA RIOJA</td>
<td>11.291</td>
<td>10.556</td>
<td>-0.61</td>
<td>319.002</td>
<td>33.09</td>
<td>14º</td>
</tr>
<tr>
<td>MADRID</td>
<td>241.002</td>
<td>250.932</td>
<td>4.12</td>
<td>6.454.449</td>
<td>38.88</td>
<td>8º</td>
</tr>
<tr>
<td>MELILLA</td>
<td>1.790</td>
<td>1.459</td>
<td>-18.55</td>
<td>94.509</td>
<td>17.25</td>
<td>17º</td>
</tr>
<tr>
<td>MURCIA</td>
<td>51.764</td>
<td>51.345</td>
<td>-0.74</td>
<td>1.456.818</td>
<td>34.94</td>
<td>11º</td>
</tr>
<tr>
<td>NAVARRA</td>
<td>25.876</td>
<td>24.118</td>
<td>-6.79</td>
<td>640.790</td>
<td>37.64</td>
<td>8º</td>
</tr>
<tr>
<td>PAIS VASCO</td>
<td>95.465</td>
<td>91.301</td>
<td>-4.36</td>
<td>2.188.985</td>
<td>41.71</td>
<td>3º</td>
</tr>
<tr>
<td>VALENCIA</td>
<td>176.346</td>
<td>175.783</td>
<td>-0.32</td>
<td>5.004.844</td>
<td>35.12</td>
<td>10º</td>
</tr>
<tr>
<td>FUERZAS ARMADAS</td>
<td>9.364</td>
<td>9.273</td>
<td>0.00</td>
<td>46.771.341</td>
<td>36.18</td>
<td></td>
</tr>
<tr>
<td>TOTALES</td>
<td>1.707.114</td>
<td>1.692.072</td>
<td>-0.88</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 11. Summary of blood donations in autonomous communities for the years 2013 and 2014 (Antolin Denizot 2015)

In 2014, 1,692,072 donations were carried out, as seen in figure 11 above (ibid 2015).

What publications are suitable for communication about this project?

SETS – https://www.sets.es

Comments

Hard to gather contact information via phone due to language difficulties.
References


3.9 Germany

How are blood transfusion operations organized?

The German structure of the blood donation system has three pillars: 1. the Blood Transfusion Services of the Red Cross (Deutsches Rotes Kreuz – DRK; Bayerisches Rotes Kreuz – BRK), 2. university medical hospitals/schools and community hospitals organized as the German Association of Blood Transfusion Centres (Arbeitsgemeinschaft der Ärzte staatlicher und kommunaler Bluttransfusionsdienste - StKB) as well as 3. privately owned ones, organized as an association of independent blood donation services (Verband Unabhängiger Blutspendedienste - VUBD) (Zeiler 2015).

In Germany, blood services are provided by four types of organizations: German Red Cross Blood Transfusion Services, state and communal blood transfusion services, commercial blood centres and plasmapheresis centres of the plasma fractionation industry. Of these, the German Red Cross Blood Transfusion Services and the German Society for Transfusion Medicine and Immunohematology (DGTI) are European Blood Alliance members. German Red Cross has seven blood transfusion services including 36 donation centres and institutes. Of these 26 offer also an opportunity for plasmapheresis. The German Red Cross Blood Transfusion Services is a not-for-profit organization. They do not receive any funds from the state or the Red Cross (European Blood Alliance nd).

The German Red Cross Blood Transfusion Service Baden-Württemberg- Hessia and its affiliates, the German Red Cross Transfusion Service East, the German Red Cross Blood Transfusion Service North, the Centre for Clinical Transfusion Medicine at the University of Tübingen, and the Institute for Clinical Transfusion Medicine and Cellular Therapy at the University of Heidelberg, fulfil important functions in the provision of blood components and research in the field of transfusion medicine (ISBT 2010).

Who collects the blood, stores, handles, distributes and transports it between regions?

Blood transfusion is done by physicians in hospitals or medical practice. Blood components prepared from these donation services are sold and delivered to the hospital blood depots and laboratories all over Germany for further use and transfusion. Storage, distribution and transport is organized mostly by the Blood Transfusion Service (Zeiler 2015).

Mobile Blood Collection: With 1.3 million whole blood donations and 300,000 other types of donations such as plasma and platelet apheresis, the service generates the major supply of blood components for clinics and hospitals in the federal states of Baden-Württemberg,
Hessia, Saxonia, Schleswig-Holstein, Hamburg, Berlin and Brandenburg. The major share of blood donations is collected through mobile donation campaigns. More than 85 mobile collection teams organize about 14,000 donor drives per annum that generate about 93% of the entire volume. The fraction of first-time donors is approximately 7%, and the donor deferral rate is approximately 8%. The mobile collection teams are associated with individual institutes and collect blood donations within their region (ISBT 2010).

Fixed-site blood collections: the German Red Cross Blood Transfusion Service Baden-Württemberg institutes maintain blood donation/clinical transfusion medicine facilities. These supply the following medical interventions:

- Whole blood donations, including antilogous blood donations
- Platelet apheresis, plasmapheresis, and erythrocyte apheresis
- Therapeutic apheresis and outpatient transfusions
- Granulocyte and lymphocyte apheresis
- Stem cell apheresis
- Cellular therapeutics and good manufacture practice (GMP) facilities

These blood donor facilities complement the spectrum, providing all-inclusive blood product supplies and transfusion medicine services in all regions served by the blood service institutions (ibid 2010).

**Who is in charge of purchasing/procurement of blood bags?**

The Blood Transfusion Service is responsible for the purchasing of blood bags (Zeiler 2015).

**Who sets environmental requirements for blood bags?**

Blood bags are CE certified and must be registered by the Paul-Ehrlich-Institute (federal authority) (Zeiler 2015).

**Deciding what type/model of blood bags – do people who work with the bags have any say?**
How many blood transfusions are done per year?

In 2014:

- RBC (red blood cells) = 3,812,693
- PLT (trombocytes) = 492,985
- PLS (plasma) = 830,803 (data from Paul-Ehrlich-Institute) (Zeiler 2015)

![Blood components produced in 2008 and 2009](image)

**Figure 12.** Blood component production numbers from ISBT (ISBT 2010).

How many blood bags are purchased/procured per year?

What publications are suitable for communication about this project?

The scientific journal “Transfusion Medicine and Hemotherapy”

References


Zeiler, PD Dr. Thomas (2015) Medical CEO DRK Blood Donation Service West gGmbH Medical Director Centre for Transfusion Medicine Ratingen-Breitscheid Tel. 02102 189-178 Fax 02102 189-107 https://www.blutspendedienst-west.de, Questionnaire on blood transfusion, (t.zeiler@bsdwest.de), 30 July 2015 [17 September 2015]
3.10 International publications

- Transfusion (the official journal of the AABB)  
  http://www.aabb.org/programs/publications/Pages/transfusion.aspx

- Vox Sanguinis (the official journal of the International Society of Blood Transfusion)

4 Conclusion

The blood transfusion operations are organized either on a national level or in a more decentralized fashion, with regional blood centres and organizations. Procurement follows these operational structures; on a regional level, hospitals themselves can be in charge and, in contrast, a national tender sets the procurement standards nationwide. Regarding environmental requirements, not much can be said, as little is known by the participants in this study. At most, they refer to EU legislation or what seems to be fairly general national legislation. Employees who work hands-on with blood bags appear to have the opportunity to give feedback to the procurement process, although this doesn’t seem to be emphasized. The statistics gathered in this study more or less follow the population size of each country, with the most densely populated countries having the most significant transfusion numbers for transfusions carried out annually and blood bags procured annually.
<table>
<thead>
<tr>
<th>1. How are blood transfusion operations organized?</th>
<th>Norway</th>
<th>Denmark</th>
<th>France</th>
<th>England</th>
<th>Finland</th>
</tr>
</thead>
<tbody>
<tr>
<td>The transfusion service is a part of the specialized health care, owned by the regional health authorities and administered by each &quot;health company&quot;. Every health region organizes production for its own use. All blood banks are integrated to hospitals and are owned by regional health trusts.</td>
<td>Each region has its own blood bank organization responsible for the complete blood chain in that region. By law only publicly owned hospitals are allowed to collect blood.</td>
<td>EFS is the only transfusion operator in France and is in charge of the whole transfusion chain. It is placed under the authority of the Ministry of Health and is present throughout the country.</td>
<td>The UK blood services collect, test, manufacture and distribute blood components collected as whole blood or by aphaeresis.</td>
<td>The Finnish Blood Service is the nationwide blood service operator in Finland and is a financially and operationally independent organization within the Finnish Red Cross. It provides Finnish hospitals with all the blood products they need.</td>
<td></td>
</tr>
</tbody>
</table>


| 3. Who is in charge of procurement? | Norway has a national tender, the same type/model of blood bags are used nationwide. | Each of the five regional authorities in Denmark has a central “procurement department”. | The blood bags used by NHS are procured through the Eurobloodpack initiative under the aegis of the EBA. | The Finnish Red Cross Blood Service. |

| 4. Who sets environmental requirements? | The provider meets requirements regarding health, safety and environment standards in business. Apart from that, there have been no environmental requirements for blood bags. | Denmark, as a member of the EU, has to comply with EU legislation. Three Danish regulations are referred to in the results. | Guidelines for materials for therapeutic and diagnostic use are defined in The ‘Red’ Book'. The NHS follows EU guidance on environmental requirements | The Red Cross refers the EU regulation. |

| 5. People working with blood bags do they have any say in the procurement process? | In a national tender, the degree of freedom will be less, as all participating blood banks will have to loyally follow the decision made. | They may have the opportunity to come up with their opinion during testing/evaluation and to participate in user groups. | Maybe they can give feedback from the user-point of view. The Blood Service defines the specifications. |

| 6. Number of transfusions | 2013: 208,383 | 2014: 330,000 (Red blood cell units 246,000, plasma units 52,000, platelet-pools (each consisting of 4 platelet units) | About 2.5 million blood transfusions per year. | 2013/2014: England issued: 1,691,868 red blood cells and 268,344 platelets. | The number of whole blood donations was about 216,000, in addition to over 4,000 plasma and platelet donations. |
7. Number of blood bags procured

| In Oslo: Slightly below 35,000 (estimation) | Number of “blood bag systems” (each consisting of more than one bag) should be around the same as the total number of collections. | Looking at the transfusions numbers, one can say they need at least 220,000 blood bags per year. |

8. Publications

<table>
<thead>
<tr>
<th>Publications</th>
<th>British Journal of Haematology, Transfusion Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="https://www.bioingenioren.no">https://www.bioingenioren.no</a>, <a href="http://tidsskriftet.no">http://tidsskriftet.no</a></td>
<td></td>
</tr>
<tr>
<td><a href="http://www.dbio.dk/Sider/forside.aspx">http://www.dbio.dk/Sider/forside.aspx</a></td>
<td></td>
</tr>
<tr>
<td>1. How are blood transfusion operations organized?</td>
<td>CNS is the national coordinating organization in the country. It is one of the national technical centres of the Ministry of Health and it operates at the National Institute of Health in autonomous position.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>2. Who works hands-on with the blood bags?</td>
<td>Public hospital-based blood establishments and blood collection units managed by the Associations of blood donors.</td>
</tr>
<tr>
<td>3. Who is in charge of procurement?</td>
<td>Administrative regional bodies or BEs. On a more local level: By the hospitals themselves, regional PP agency, or national PP agency. Things can be quite different in other regions i.e. most of the hospitals may be private, so they buy by themselves.</td>
</tr>
<tr>
<td>4. Who sets environmental requirements?</td>
<td>According to national law all disposables used by BEs and collecting units must be CE marked.</td>
</tr>
<tr>
<td>5. People working with blood bags do they have any say in the procurement process?</td>
<td></td>
</tr>
<tr>
<td>6. Number of transfusions</td>
<td>2013: 3,195,077 and 2014: 3,131,416 units of blood components. According to a 2011 study: 2,470,000 whole blood units annually.</td>
</tr>
<tr>
<td>7. Number of blood bags procured</td>
<td>2013: 3,144,724 collection procedures were carried out while in 2014 the figure was 3,083,694.</td>
</tr>
</tbody>
</table>

Table 5.2. Brief summary of the answers to the questionnaire.