

# Strategies referring to the organization of the blood service in Portugal — a personal view

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## Abstract

*In Portugal there is a mixed system in matters concerning the national blood service. The reasons for such state of things are both historical and cultural nevertheless the system has been evolving since its early days from a fully-hospital-based form to the present mixed-system form. The increase in the number of blood collections/donations which has contributed to self-sufficiency in red cell and platelet components/products is the outcome of the strategies/policies described in this article. The activity of blood donor associations has been playing a crucial role in this process with its typical liaison to the community and citizens differentially motivated to donate blood as well as partnership with health structures involved in Blood Establishment (BE) activities.*

*Since 2012, the recently merged Portuguese Blood and Transplant Institute (by Decree No.39/2012 published in February) has launched some novel and more radical community communication strategies in order to recruit new donors mainly from the population of young people as well as donors who had already donated blood but only once. This change constitutes a modification in the communication with donors and with the prospective donors within the population.*

*The participation of Hospital Blood Establishments (BE)/Services in the national blood transfusion service is also undergoing important changes with emphasis being now put on blood collection “linked” to the 3 Blood and Transplant Centres of the Portuguese Blood and Transplant Institute (PBTI) where the screening, processing and distribution is performed allowing blood donors to continue their “donation story” within hospital premises.*

*Portugal has been evolving with good outcomes in what the national blood service is concerned and the current perspectives are to invest and continue in the pursuit of self sufficiency in blood, blood components and derivatives along with gains in efficiency within this direction at the country level.*

*J. Transf. Med. 2014; 7: 2–9*

## Introduction

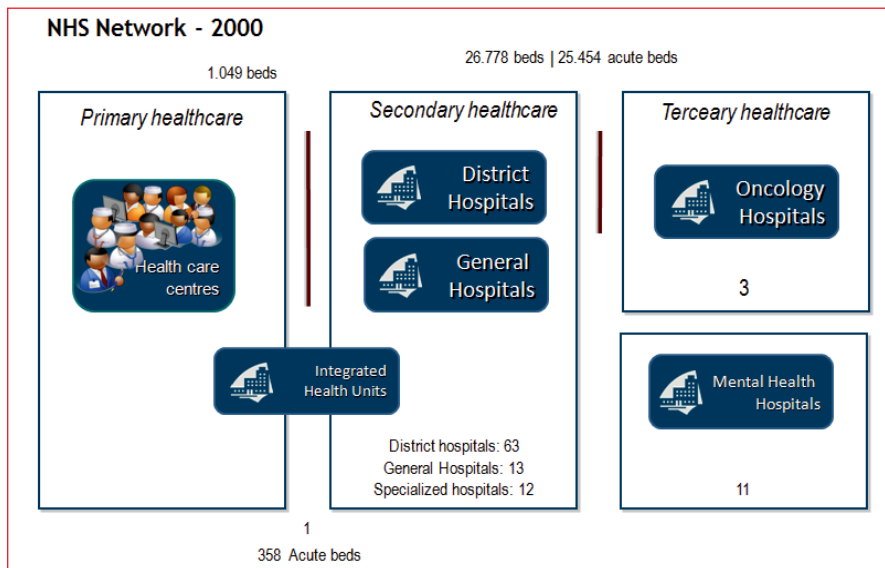
In terms of national policies regarding organization of what is usually referred to as “national blood service”, i.e. the organization of blood donation and transfusion services, there are many different approaches to be seen in European coun-

tries and the differences are observed even among European Union member states.

Since 2002 the European Commission/Parliament has issued several directives referring to the quality and safety of blood (2002/98/CE; 2004/33/CE; 2005/61/CE and 2005/62/CE). These directives covered the most relevant aspects related to

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**Figure 1.** National Health Service Network (ACSS/Central Administration of the Health System) in 2000

blood and blood components and the purpose was to establish a common framework and to facilitate free movement of people and goods within the boundaries of the EU.

Among the numerous definitions enclosed in the “mother directive” there is that of a ‘*blood establishment*’. Based on this definition a blood establishment (BE) is a structure or body responsible for the interaction with the community and prospective blood donors, organization of blood collection as well as processing, storage and distribution of blood components. Its counterpart is the hospital transfusion service which is closer to the patient (*de facto* the prospective recipient of blood components), and responsible for the subsequent elements of the blood transfusion chain until the moment of administration of the blood component to the recipient following compatibility testing along with hemovigilance procedures.

In some countries the organization of blood transfusion service follows centralised patterns and systems. An example of such system is found in the United Kingdom (UK) where the institutions in charge of what is now defined as BE, have been separate from hospitals responsible for administration of “blood” to patients since the middle of last century. In some other countries the system is entirely hospital-based-BE, in the same premises where the hospital transfusion service with the transfusion medicine responsibilities is located. In others (like in Portugal) the system evolved from this hospital-based-BE system to a mixed-organization form in which some hospitals perform only

services related to transfusion medicine practice, that take place in hospital transfusion services, others have both BE plus transfusion medicine practice responsibilities and there is also the Portuguese Blood and Transplant Institute (PBTI) with its BE responsibilities accounting for around 60% of the country blood collection.

PBTI assignments encompass not only “blood” responsibilities but also the field of cell, tissue and organ transplantation, as prescribed by the reorganization of the central structure of the State and Public Administration. The year 2011 witnessed the publication of the Reduction and Improvement Plan of the Central State Administration (PREMAC) to be implemented across the whole Public Administration. This document declares the intention to “eliminate overlapping structures in the state structure, reducing the number of agencies and entities, keeping quality in public service delivery”. This has proved quite effective particularly in the field of health organization as presented in Figure 1 (2000) and Figure 2 (2010) showing the schematic reorganization of Primary Healthcare structures, the nowadays Secondary Healthcare focus being in Hospital Centres resulting from the fusion of 2 or more hospitals and primary care structures instead of the former type of organization based on hospitals separated from each other and from the primary care structures.

The Portuguese Blood Institute (PBI) was created in 1989 with 3 regional Blood Centres (Porto, Coimbra and Lisbon) covering the continental country. The fusion of PBI with the previously

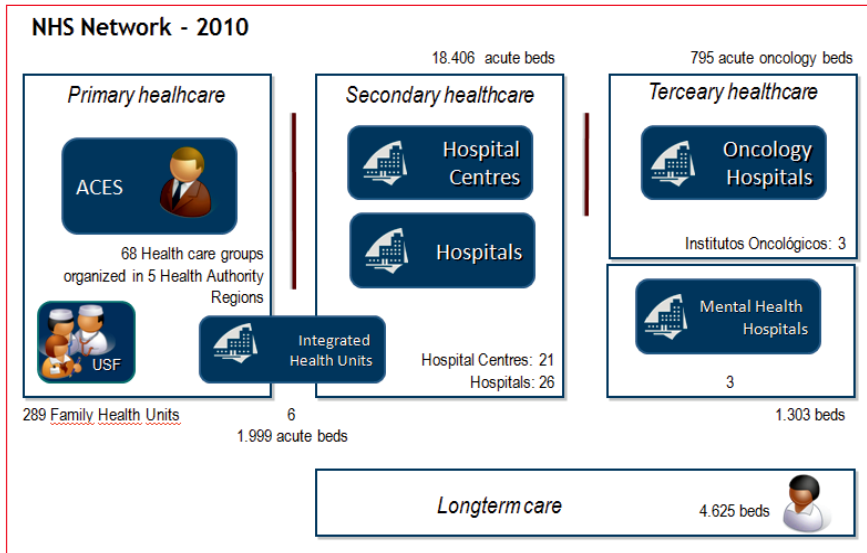


Figure 2. National Health Service Network (ACSS/Central Administration of the Health System) in 2010

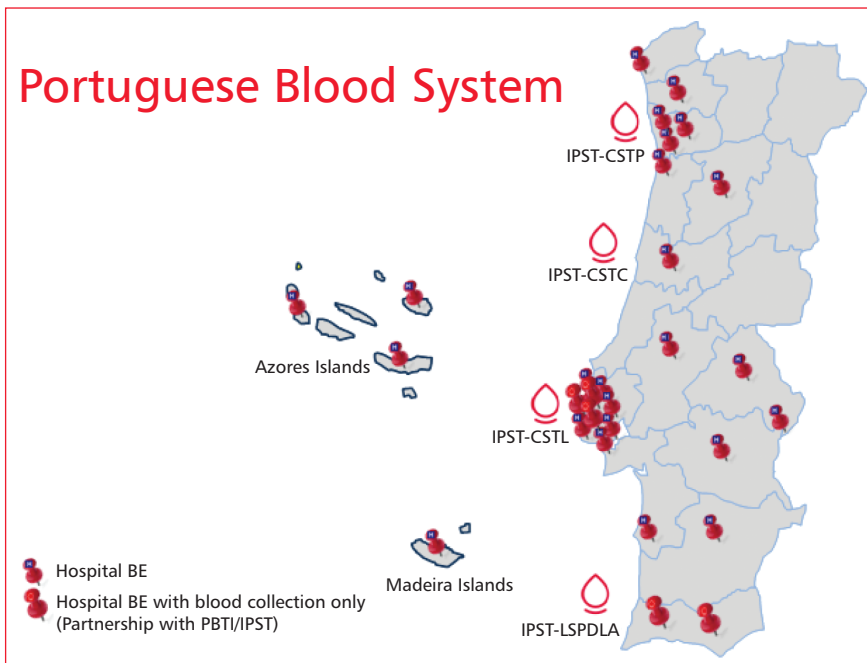
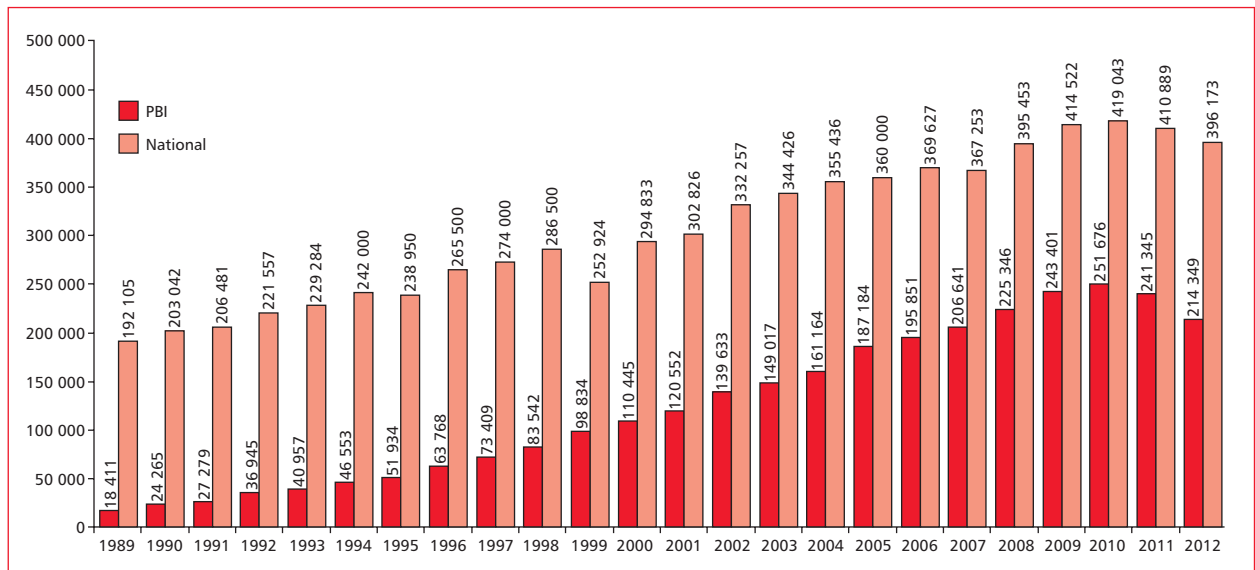


Figure 3. Distribution of blood establishments in Portugal (the mainland and the islands)

existing and fully independent from each other 3 Histocompatibility Centres located in the same cities as the Blood Centres and dedicated to the laboratory support to organ, cells and tissue transplantation including the takeover of some functions of the Authority for Blood and Transplantation Services was therefore made by order of superior authority. This merger which was published in 2012 to become effective in August 2012, was made of-

ficial in January 2013. The many processes entailed will most predictably take 2 to 3 years to become stabilised. This merger also means that the PBTI takes over the responsibilities of the Portuguese Bone Marrow Donors Registry (CEDACE), the Multiorgan Tissue Bank, the Public Cord Blood Bank and histocompatibility testing to support cell, tissue and solid organ transplantation as well as regulatory responsibilities in blood and transplantation areas.



**Figure 4.** Blood collection in Portugal

Portugal is a European country situated on the south western tip of the Iberian Peninsula (Figure 3) with a total area of 92 090 km<sup>2</sup>. It comprises the mainland and two autonomous regions constituted by the Azores and Madeira archipelagos in the Atlantic Ocean. According to the last 2011 census the population of Portugal was 10 561 614 and has remained fairly stable over the years. The persistently low birth rates in the last 2 decades however provide imbalance between the older and the younger population and signal difficulties in maintaining donor population (typically below 65 years of age) in the near future. It is therefore predictable that there will be consequences for blood collection and blood supply as it is well recognised that the demands in transfusion support increase in the elder population.

## History

The beginnings of blood banks or blood transfusion services in Portugal date back to early 1920s. They were first organized in the main hospitals of the 2 major cities (Lisbon and Porto) and in the following decades in almost each and every existing hospital because of the donor-recipient proximity and in most cases as family or replacement donation. About 30 years later, in 1958, the National Blood Institute (NBI) was established by the Decree Law 41495 of 2 January 1958 published in the Portuguese Official Journal with the aim to: “Coordinate, guide and supervise [...] activities related to collection, preparation and delivery of

blood as a therapeutic agent [...], blood collection, preparation, storage and distribution”, “promotion of voluntary blood donation”, “staff training”.

The established goals were not fully accomplished particularly as regards blood collection. These blood service activities were performed in most hospitals in Portugal. Instead the NBI main focus was on educational and laboratory development fulfilling an important part of the needs in this field.

In the meantime, very important developments were going on in education. In 1981 transfusion medicine was recognized and introduced as a specialty (*Imunohemoterapia*) for medical doctors and a year later it was applied in practice. The 60-month curriculum followed the “model curriculum for the training of specialists in blood transfusion”, Recommendation R (85)5 of the Council of Europe. Those were the years which brought about a new threat to blood safety due to the newly identified HTLV-III (HIV-1), the diagnosed cases of transmission through blood and the AIDS epidemic. The challenge to all “blood systems” and health professionals in this field was serious as no blood tests were then available and blood safety relied upon strict donor information, implementation of risky-behavior-questionnaire and straightforwardness of donors who supplied the data on their risky behavior. The same applied to HIV-2 (1986) and HCV (1989) although in the case of these two viruses the pharmaceutical industry reacted more promptly by bringing approved tests on the market.

Implementation of a blood policy more appropriate for the country’s needs, requires a vision and

political decision which have to be based on correct diagnosis. In Portugal such diagnosis was made in the late 1980s and covered several issues i.e. the number of blood services, blood collection, screening tests applied and the type of blood components among other information.

Following this diagnosis, the Portuguese Blood Institute (PBI) (Law 25/1989; Decree Law 294/1990) was established with 3 Regional Blood Centres. The purpose was to “plan, coordinate, direct, supervise at the national level [...] activities [...] to promote blood donation, procurement, preparation, quality control, storage, distribution and administration of blood”. In other words, the aim of the PBI was to implement a blood service at a national level and to work towards self sufficiency in blood components as well as to comply with the needs to inform the population about everyday demand for blood, to promote blood donation, to organize (at a national level) the activities of collection and processing of blood to be distributed to hospitals. In the legal document it was clearly stated that “collected blood is a gift to the community [...] not susceptible of compensation”, emphasizing the voluntary non remunerated blood donation and including the issue of penalties in cases of non compliance. In those days blood collection at the national level was far below the standard of blood self-sufficiency (Figure 4). Luckily, specialists in transfusion medicine were already working in all the hospital clinical fields, namely in consultancy activities towards the other medical specialty areas, facilitating the supply of blood components to patients in need.

### **The years 1990 and 2000**

Through the WHO Resolution WHA28.72 adopted in 1975, the world assembly encouraged the General Director to assist member states in the organization of national blood transfusion services, because “it is necessary to have blood components produced in services solidly implanted and with high technicality” in order to respond to transfusion needs (*Gestion des Services de Transfusion Sanguine*, OMS, Geneve).

The disadvantages of small blood services have been identified and include among others high blood component losses due to expiry, misuse of economic resources and dispersion of skilled human resources. The need for a national blood program was therefore recognized in order to implement and supervise the organization and the legal regulations related to this area of activity if blood sufficiency was to be achieved and high standards

of quality and management of financial resources were to be assured.

Self-sufficiency in blood and blood components has two main branches: one is at the collection side in interaction with the community where the PBI BE attributions and actions fit best; the other is at the hospital side in close contact with the patient, prospective transfusion-recipient where the major goal is optimization of blood use and transfusion safety. This is the field of action for the hospital transfusion service. The role of transfusion medicine (TM) specialist is crucial in both these cases. Fortunately in the 1990s we already had country coverage by TM specialists that were being trained since 1982.

These two branches need to be brought together through a relationship between blood centers and hospital transfusion services. Such network has to be built to secure the best possible outcome within the national blood transfusion network which will further facilitate optimal management of blood components within the country along with reducing the losses due to expiry.

### **Collection, processing and testing**

In 1990 the statistics for blood collection were as follows: 203 042 units of blood: 24 265 (12%) collected by the PBI (2 Regional Blood Centres) and 178 777 (88%) collected by the 92 Hospital Blood Services) [Ministry of Health data]. One of the crucial aspects of blood policy defined at the time was to discontinue collection, processing and analytical screening of blood donated in hospital blood services of reduced capacity. Those functions were transferred to the PBI Regional Blood Centers.

The goal was not easy to accomplish. From the hospital perspective there was the expected resistance towards change as well as the fear of losing blood donors and becoming dependent on PBI for blood components. There was also the anxiety that the supply of blood components may be insufficient. The process of evolution in blood collection demonstrates the progress in reaching blood sufficiency and shows how difficult it was to build. At the same time residual blood collection by private entities was gradually eliminated (Figure 4).

We may judge by the increasing volume of collected blood that there was large donation capacity in the community and citizens could donate blood through the PBI blood mobiles that covered almost the whole territory of our country. Although the

number of hospitals with blood service/BE was decreasing, their overall blood collection capacity was maintained due to the proximity link between blood donors and hospitals.

In the meantime, haemovigilance programs were being implemented and blood component bacterial contamination was gaining importance at an international level. In 1997 screening of platelet concentrates for bacterial contamination was first implemented in the PBI as an important measure for blood and blood component safety.

The eruption of Bovine Serum Encephalopathy (BSE) and the anxiety that the abnormal prion could be transmitted through blood gave rise to a series of decisions, namely the implementation in 1998 of universal prestorage leukodepletion of blood components.

Buffy coat derived platelets processing was subject to optimization in the early 2000 which led the way for the validation of the first pathogen reduction technology (Intercept Platelet) in 2004. This technology was first used in Lisbon Regional Blood Centre, and started being distributed to hospitals some time later (in 2010).

Another important issue was the encouragement to hospital BE/Blood Services not to go forward in performing Nucleic Acid Testing (NAT) screening of blood units collected. That function would be assumed by the PBI, either along with transmissible agents serology or not. Systematic NAT screening started in January 2003 in one of the Regional Blood Centers and the growing concerns related to efficiency lead to an increasing number of blood services to send their samples to PBI for screening. In 2006 an automated NAT testing covering the 3 Viruses (HIV, HCV and HBV) was implemented.

### **Hemovigilance**

The beginnings of Portuguese Hemovigilance System date back to 1997 and were introduced by the PBI; the decision to assign professionals to the coordination and work on the dedicated software was made in 1998. The model was defined in cooperation with physicians/TM specialists and other health professionals from the PBI and hospital blood services throughout the country.

In 2007 two important legal documents were published in the Portuguese Official Journal. One was the Decree Law 267/2007 that transposed the European Union directives on quality and safety of blood (2002/98/CE; 2004/33/CE; 2005/61/CE; 2005/62/CE) into the Portuguese legal order and

the other Decree 67/2007 established the competent authority for Blood and Transplantation Services as required by EU directives. The Portuguese Hemovigilance System, created by the PBI in the late 1990s was immediately prepared to fulfill the requirements of Directive 2005/61/CE and Decree Law 267/2007. In 2008 the notifications from 2007 and 2008 could already be reported to the EU. On the other hand, Quality Management Systems were already implemented and duly certified in PBI and most Hospital Blood Services. Establishment of the Competent Authority contributed to marked advancement in the organization of the blood system in Portugal.

There are several tools and actions recommended at the international level for more effective management of blood components, particularly related to reduction of losses due to expiry, in close relationship with the transfusion medicine specialists and their clinical advisory roles within the hospitals. These tools include such moves as organization of hospital transfusion committees, teams of health professionals, i.e. doctors of different medical specialties working together in order to define guidelines and implement the best practice. In 1999 certain proactive measures were taken at the main regional health administration level (on which hospitals are dependent) which encouraged hospital administrations to organize and maintain hospital transfusion committees for optimal use of blood and blood components. The results were promising.

### **Plasma**

Once the blood policy was defined and oriented towards blood self sufficiency and development of a more effective blood collection system and better correlation of related fields of activity, more attention could now be paid to self-sufficiency in “plasma” matters.

The first objective was to secure supplies of fresh frozen plasma (FFP) inactivated with the only method known at that time, namely the Octapharma solvent detergent (SD) technique. Unfortunately, the eruption of bovine serum encephalopathy (BSE) and the suspicion that the abnormal prion could be transmitted through blood gave rise to a series of decisions namely the implementation of universal prestorage leukodepletion of blood components. In 1998 Portugal was one of the first countries to implement such measures. The context of BSE control led to the ban of Portuguese beef on the international market.

This fact as well as the dramatic UK situation with human variant Creutzfeldt Jacob disease (nvCJD) cases, diagnosed one after another followed by the decision not to use their own FFP had immediate impact on the sequence of events in Portugal; the “plasma” program was stopped and postponed until epidemiological evidence and control of eventual nvCJD cases proved it safe enough to be continued. In the meantime, other approaches to pathogen reduction and inactivation were being developed and the scope of action covered also other pathogens besides those targeted by the SD method.

Quarantine FFP (QFFP) was then implemented enabling its clinical use for transfusion along with SD Plasma supplied by Octapharma (7635 QFFP units and 50958 SD Plasma units respectively — 2012 national data).

### After 2010

Before March 2011, each of the 3 PBI Regional Blood Centers fitted in the definition of Blood Establishments according to the EU Directives. They comprised all activities from collection, screening, processing to distribution. The year 2011 witnessed the implementation of measures introduced to concentrate sites which perform analytical screening of donations (from 3 to 2 locations); quality control of production (from 3 to 1) and processing (from 3 to 2). Furthermore, standardization of medical devices for blood collection began and brought about positive results at the level of purchase with scale effects because of the overall cost reductions.

Of great organizational impact were the changes in both theoretical and practical training, as well as evaluation and qualification of health professionals for clinical screening of donors and blood collection. The changes which had such significant impact on the institution consisted in the inclusion also of nurses in clinical screening of donors. The model in place until then was based on doctors only. The change became stabilized in the course of 2012 and blood collection sessions always include 1 doctor. Laboratory technicians started being trained to collect blood units that were previously only collected by nurses. Blood collection sessions always include nurses.

Some decisions regarding blood screening were also made. ALT testing was discontinued. The HTLV-I/II tests previously performed for each and every donation started to be performed in the first donation as well as in special situations. In reference to malaria, the tests for donor candi-

dates were introduced in 2012 as replacement for quarantine. This allowed PBTI to recover some donor candidates.

As stated above platelet concentrates subjected to pathogen inactivation (pathogen reduction technology with Intercept Platelet) started being distributed to hospitals at the end of 2010 although not for the whole platelet production.

The tendency towards concentration of BE processes in the PBTI leaves place to former hospital BEs to maintain the function of blood collection in proximity with donors. Thus it was decided that some hospitals could maintain blood collection with a new approach. Medical devices for blood collection are distributed by the PBTI and there are two possible options: one is that PBTI health professionals are given access to hospital premises, the other that blood collection is performed by their own trained hospital health professionals. In the latter case hospitals are reimbursed per blood unit collected at a price published in the Official Journal. In both situations whole blood units are sent to the PBTI for analytical screening and processing.

As stated above, the Decree 39/2012 published in 2012 established the Portuguese Blood and Transplant Institute IP with 3 Blood and Transplant Centres (in Lisbon, Coimbra and Porto). The areas of blood (former PBI with Regional Blood Centres) and transplantation (former independent 3 Histocompatibility Centres) were thus combined. In relation to blood collection capacity, PBTI performs about 60% of the country blood collection and covers all geographical regions in the continental part of Portugal.

Last year the PBTI Executive Board went forward with some immediate, totally new and more radical strategies of communicating with the community for new donor recruitment mainly from the young population as well as for recruitment of donors who had donated blood only once. A call/contact center was established and is being expanded in order to stay in touch with donors from our files. This innovation brought about an important change in the methods of communication and promotion of blood donation and the results are truly promising. In 2013 a mobile phone application for bidirectional performance management (Android, iOS, FB, web “www.dador.pt”) was developed to impact mainly in the younger population with information on the needs for blood components and places where blood sessions are taking place. Other strategies include a thorough dissemination of daily blood donation needs (Hospitals, Health Centres, etc.) parallel to

the advertising annual donation campaign with high impact on the population between 18 and 35 years (stress on membership and loyalty).

In what the Portuguese plasma program is concerned, with the stabilization of the blood collection and the national situation of vCJD cumulative cases that are in line with a great majority of European Countries, measures are under development with the goal of providing hospitals, in the shortest possible time with FFP inactivated by two different methodologies; one is amotosalen treated plasma produced by the same blood centre that performs the procedure with platelets and the other is SD Plasma subject to treatment by the manufacturer — Octapharma). The surplus of FFP is intended as raw material for the manufacture of plasma derived medicinal products subject to open competition outside the PBTI IP.

## Conclusions

The major impact of the blood policies implemented before 1989/1990 was brought about by the decision to create a new medical specialty in transfusion medicine (*Imunohemoterapia*) with emphasis on the prolongation of training time and scope. Specialists in transfusion medicine were employed in blood centres and in hospital blood services and/or transfusion medicine services since 1987.

From 1989/1990 onwards, the focus was on implementation of specific measures for establishing and organization of an effective “National” Blood Service, directed at self sufficiency in blood and blood components which would adhere to the state of the art regarding technologic and scientific areas and organizational trends.

Since 2012 we have been facing a new challenge brought about by the initiative for reorganization of the Portuguese Public Administration sector namely by the Ministry of Health New Organic Law which was applied to the whole health structure and redefined it. Opportunity was created for a vast and deep change in the structure of the health care system (Hospitals and Primary Health Care) that is being currently rebuilt with the reorganization of Primary Healthcare structures, the nowadays Secondary Healthcare focus being in Hospital Centres resulting from the fusion of 2 or more hospitals and primary care structures instead of the former type of organization based in hospitals separated from each other and from the primary care structures. The same applies to the PBTI and has great impact on it.

As regards the policy for concentration of blood collection sites we may say that although not yet fully implemented it is approaching its goal and the current situation is almost in reverse to that which existed twenty years back (88% of blood was collected in 92 hospital blood bank services, 12% was collected by PBI while in 2012, 40% of blood is collected by 30 hospital BE and 60% by PBTI).

As regards to sufficiency in blood and blood components, the effects of the 20 year effort are as follows: from less than 20 blood units per 1000 inhabitants collected in 1990 we reached the level of 39 units per 1000 inhabitants in 2011 and 38 units per 1000 inhabitants in 2012.

As presented above, the internal restructuring of the system of blood collection, processing and analytical screening, along with the consolidation of the many previously existing quality management systems into one quality management system applied to the PBTI as a whole as well as standardization of procedures and devices will result in cost savings that can be expected to increase in the process of further restructuring along with the processes associated with the transplantation functions and responsibilities.

Regardless of the type of organization or the direction in which this field of medicine evolves, we must keep in mind the issue of the major importance, which is the safety and care of blood donors and blood component recipients. In this respect cooperation and effective communication has an important role to play and should bring together all professionals involved.

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