

# The Portuguese Haemovigilance web site

Jorge Condeço

Portuguese Blood and Transplantation Institute/Porto Blood and Transplantation Centre  
North Regional Coordinator of the Portuguese Haemovigilance System  
Administrator of the Portuguese haemovigilance web site

## Abstract

*Management of Portuguese Haemovigilance System (PHS) lies within the scope of responsibilities of the steering committee of the Portuguese Blood and Transplantation Institute (PBTI). All the notifications related to haemovigilance and the accountability of the activity of blood establishments and blood services are done through a website.*

*In the process of development of the notification structure and of the web interface, a User Requirements Specification methodology was applied. Requirements and recommendations of Portuguese and European laws, as well as guidelines and definitions of relevant scientific societies and organizations were also taken into consideration.*

*It took two years to complete the process of implementation of the reporting structure. During this time the system was under continuous development following the evolution of the concepts and definitions in haemovigilance as well as of the mainstream tools and tendencies in programming. At this point it can be said that the Portuguese Haemovigilance System is a fully implemented structure that is being constantly elaborated. The online notification process is a fundamental tool for the assessment of transfusion risk.*

**Key words:** informatics, blood safety, information storage and retrieval, health information systems, safety management, risk management

*J. Transf. Med. 2014; 7: 33–36*

Management of Portuguese Haemovigilance System (PHS) is currently within the scope of responsibility of the steering committee of the Portuguese Blood and Transplantation Institute (PBTI). In 2008, the Portuguese Haemovigilance System was implemented by the Portuguese Blood Institute (PBI) following entry into force of the accordant European Directives. This system resulted from the collaboration between PBI and the competent authority for the Blood Transfusion Services and Transplantation.

In 2012 there occurred major changes in the organization of many Portuguese governmental structures. This was the case with PBI that became the Portuguese Blood and Transplantation Institute (PBTI) where activities related to blood transfusion medicine merged with the areas of transplantation,

cells and tissues, making it one of the largest Portuguese institutes. The role of competent authority was also modified in this process. The PBTI is now the competent authority for the area of transfusion and transplantation medicine, and the Directorate General of Health (a department of the Ministry of Health) is the competent authority for blood establishments. PBTI is therefore responsible for Haemovigilance and Biovigilance in Portugal.

Within the Portuguese haemovigilance system all notifications related to adverse reactions in donors and recipients of blood components as well as errors and near miss events observed at any stage of the transfusion chain are reported through a website ([www.hemovigilancia.net](http://www.hemovigilancia.net)). Apart from simply establishing a basis for registration of various events related to haemovigilance, the web

site also supports the entire notification process by providing an appropriate interface to all users. It is therefore an important way of communication between different participants.

The beginnings of the notification structure and the web interface date back to the year 2006 when the User Requirements Specification (URS) methodology was developed based on the Portuguese and European laws and guidelines as well as definitions provided by relevant scientific societies and organizations (among others the International Society of Blood Transfusion; International Haemovigilance Network). National laws on privacy and data protection were also taken into consideration.

The following additional requirements for the website were defined by the PBTI steering committee:

1. Notification-extension must be minimal but sufficient to characterize each event.
2. Precise/compact data recording.
3. Availability of automatic alert and warning.
4. Data reporting adjusted to provide information/statistics at both the local and national level.

According to this URS the Entity Relationship Diagrams (ERD) were elaborated and the web site was developed. An ERD illustrates the logical structure of databases and is a graphical representation of entities and their relationships to each other. It is typically used in computing in regard to the organization of data within databases or information systems. In a database model an entity is defined as any object or concept that you wish to track. A relationship is about how the data is shared between entities. This is useful for demonstrating the development and monitoring of the project and to determine the impact of the introduced changes.

The chosen strategy for the development of the web site was to use mainstream open-source tools for database structuring and programming (MySQL and PHP). This choice was dictated by the intention to anticipate developments and updating of the tools used as well as to secure a broader base of developers ready to cope with new challenges. It also served to maintain adequate control of expenditures/cost.

The web site has a public area for general access and a private one for notification, consultations and private communication. The access is differentiated into local and national levels. Each local notifier can only view data on their own institution.

It took two years to implement the reporting structure. In early 2008 we released the notification

of adverse reactions in blood component recipients. In the first two months we proceeded with the registration and training of notifiers and we collected data from the year 2007, which served as basis for training and testing of the system. In 2009 the complete set of notifications was released (errors and near-miss events in blood banks were only available in late 2009). We quickly concluded that notifications of exclusion were necessary (when there are no events to report) and such notification was implemented.

An institutional mail was available, allowing assistance and the exchange of information between all participants (the notifiers, webmaster and the general public).

In the meantime, due to:

- the web site rapid growth (both in size and complexity),
- the increasing number of internal and external requests,
- the ongoing developments in the field of haemovigilance,
- the technical developments in programming and hardware,

it became necessary to use a project management application for recording and tracking all changes at the web site, improving control of requests, solution design, modifications and new implementations.

In 2012 the PHS collected information on the activity of blood transfusion services for the year 2011 and thus supplemented the data collected by the Portuguese Competent Authority for Blood Services and Transplantation. The beginning of 2013 witnessed the development and implementation of an interface for collection of activity-data from blood establishments and blood transfusion service. This data is used as denominator for the evaluation of transfusion risk in Portugal.

In the period 2008–2012 there was a consistent increase in the number of institutions and notifiers registered in the system. This increase became more pronounced in 2009 with the growing number of registered small private institutions, which — though characterized by less intensive transfusional activity — had a marked consumption of blood components.

The increase in the number of all types of notifications demonstrates a better geographic coverage of the registered institutions within the haemovigilance system but also an improved understanding of the system and its effectivity. It might also imply that the notifiers have greater trust in PHS in terms of confidentiality. In

**Table 1.** Numbers of registered institutions and notifiers in the period 2007–2012

	2007	2008	2009	2010	2011	2012
Institutions	78	82	84	160	163	188
Public	70	74	76	89	89	108
Private	8	8	8	71	74	80
Notifiers	128	129	163	254	258	294
Local	121	124	153	243	247	284
National	7	5	10	11	11	10

**Table 2.** Notification types per year

		Exclusion	BTS			BE		
			ARP	NM	E	ARD	NM	E
2012	Number of institutions that reported	64	61	18	16	27	6	4
	Notifications		549	166	28	1455	15	8
2011	Number of institutions that reported	45	52	18	24	27	4	2
	Notifications		515	127	41	1297	8	6
2010	Number of institutions that reported	45	53	19	22	24	4	6
	Notifications		494	84	32	731	7	6
2009	Number of institutions that reported	10	44	2	2	14	2	0
	Notifications		322	6	2	160	7	0
2008	Number of institutions that reported	NA	38	NA	NA	NA	NA	NA
	Notifications		277	NA	NA	NA	NA	NA
2007	Number of institutions that reported	NA	17	NA	NA	NA	NA	NA
	Notifications		137	NA	NA	NA	NA	NA

BTS — blood transfusion services; BE — blood establishments; ARR — adverse reaction in patients; ARD — adverse reaction in donors; NM — near miss; E — error

Tables 1 and 2 we present selected data referring to involvement of the PHS activity.

A series of important improvements is being currently prepared to be implemented in the year 2014. They can be summarized as follows:

- implementation of a module for collection of information on the donors’ epidemiological profile; the module will be a supplement to the already available indicators of transfusion risk;
- improvement in notification of exclusion with the aim of simplifying it for local users and making it more understandable for national users;
- development of forms specific to particular events;
- change of the website graphical layout.

The mainstream tools and tendencies in programming are evolving in the “back-office”; we are performing a consolidation of data structures and their relations with the decrease in the numbers of tables and construction of meta-data

tables. In the “front-office” there is an ongoing study on methods of facilitating registration. The best choice seems to be the use of Ajax (an acronym for Asynchronous JavaScript and XML) a set of interrelated web development techniques used on the client-side to create asynchronous web applications. With Ajax, web applications can send data to, and retrieve data from the server asynchronously (in the background) without interfering with the display and behavior of the existing page. Data can be retrieved using the XMLHttpRequest object (for exchanging data asynchronously between browser and server to avoid full page reloads). By dividing the computational resources between the server and clients (notifiers computers) it is possible to have a better performance of the application. Also the shift to a Model View Controller (MVC) paradigm will facilitate the implementation of new web content in the long term.

Although the implementation of a haemovigilance system is a legal requirement, it is currently understood as a means of information transfer and a valuable tool in the management of transfusion risk both at national and international organization levels.

Despite certain drawbacks such as under reporting the Portuguese haemovigilance network continues the efforts to improve blood safety according to international recommendations for

quality assurance and safety of blood and blood components. Risk management ultimately guides the responses of individuals and society to risk issues, and transfusion risk is no exception.

About the Portuguese haemovigilance system it may be said that it is fully implemented but is subject to continuous modification and development. The online notification process facilitates all the related tasks.