Hemovigilance is a "quality process" which aims to improve the quality and safety of blood transfusions by surveying all activities of the blood transfusion chain, from donors to recipients.

Hemovigilance programs have now been in existence for over 15 years, but many countries and centers are still at the development stage. This valuable resource brings together the main elements of such programs and shows the different types of models available. A general introduction includes chapters on hemovigilance as a quality tool for transfusion, as well as concepts of, and models for hemovigilance. The core of the book describes how hemovigilance systems have been set up and how they work in hospitals, blood establishments, and at a national level. These chapters are written according to a structured template: products and processes, documentation of jobs, monitoring and assessment, implementation and evaluation of measures, for improvement, and education and training. Chapters on hemovigilance at the international level, achievements and new developments complete the picture.

Hemovigilance: An Effective Tool for Improving Transfusion Safety is above all a practical guide to setting up and improving hemovigilance systems, while raising awareness for reporting adverse events and reactions. This is the first international book on hemovigilance, assembling all the vital issues in one definitive reference source – it is essential reading for all staff involved in the transfusion process.
Hemovigilance
Hemovigilance

An Effective Tool for Improving Transfusion Safety

EDITED BY

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Foreword

Hemovigilance is one of the most important activities for those of us who are active in the field of blood transfusion. Irrespective of your profession, whether blood banker, quality manager, donor physician, nurse, phlebotomist, laboratory technician, transfusing physician or hospital nurse, the safety of blood products from their “origin” in the blood donor until their use in the recipient is of utmost importance. The phrase “safety from vein to vein” was coined to illustrate the breadth of the field. Today, the field of hemovigilance is even more wide-ranging, covering blood components, tissues and cell preparations including donor vigilance, materiovigilance and safety of the patient.

While hemovigilance is well known to those who work in the field of transfusion medicine, there are important differences between countries when it comes to the implementation of national hemovigilance programs.

The International Hemovigilance Network (IHN) has done an excellent job in establishing common definitions and in bringing together the different national activities. Today in Europe, EU directives define our common standards in blood transfusion and similar approaches are taken in other regions of the world.

In June 2009, René de Vries, then President of the International Hemovigilance Network, was asked by Maria Khan, responsible for transfusion publications at Wiley-Blackwell, about the need for a handbook on hemovigilance that would outline and guide the reader on procedures of the transfusion chain. Maria asked René whether he believed such a book would be beneficial and, if so, who might make suitable editors and authors for the project.

The request from Wiley-Blackwell fell on fertile soil. After consultation with the IHN Board, René confirmed the need for such a book and moreover advised that the IHN Board had recently been discussing a similar idea. They were therefore willing to embark on the project. Finally, two IHN Board members agreed to take on the editorship of this book: René de Vries and Jean-Claude Faber.

Hemovigilance: An Effective Tool for Improving Transfusion Safety is the first book on this subject and its aim is to become the textbook on hemovigilance. This may well be the case since all the ingredients to achieve this aim are present: the editors developed a master plan and communicated this to all the authors, gathering the best experts from all over the world. Contributors demonstrated their commitment, writing their chapters according to the uniform instructions and definitions set out by the editors. The book is as comprehensive as is possible for such a big subject and many diverse examples from different settings are given.

It not only provides clear-cut answers to the ‘Whats?’ and ‘Whys?’, but also to the ‘How do Is?’ Examples of national and international hemovigilance systems and a summary of past achievements as well as new developments and future challenges will help readers to integrate their local or national experience into the global scheme.

We are very pleased with the new hemovigilance book and we hope that many readers from both within the field of transfusion medicine and from other fields such as quality and safety management, and regulatory affairs, will enjoy it. We are confident that Hemovigilance: An Effective Tool for Improving Transfusion Safety will contribute to the improvement of safety and quality of blood transfusion.

Erhard Seifried* and Markus M. Mueller
Frankfurt/Main, Germany
March 2012

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PART 1

General Introduction
CHAPTER 1
Introduction
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Why did we produce this book?
Hemovigilance deals with the safety of blood transfusion. Although such safety has been a major concern ever since blood transfusions started being given, both the concept and the name “hemovigilance” were born less than 20 years ago. Today hemovigilance is an established but also quickly developing field in transfusion medicine, for which a comprehensive text has thus far been lacking.

This book is the first book on hemovigilance. The only other book that comes somewhat near is Blood Safety and Surveillance, which mainly deals with product safety and has a quite different scope. Apart from that, there are only less detailed and less complete chapters on hemovigilance in books on transfusion medicine, such as in Rossi’s Principles of Transfusion Medicine and reviews in journals.

Our aim is that this book becomes the book on hemovigilance.

What can you expect to find in this book?
This book is an introduction to and a manual for the subject of hemovigilance.

You will find both “the how” examples of the actual information derived, and what is done with it. Of course, a book like this cannot be comprehensive with regard to all information, and so we include references to the most pertinent papers on the subject and links to websites with more details.

One thing we don’t include is detailed descriptions of different types of transfusion reactions in patients and how to deal with them. For this type of information, please consult general textbooks on transfusion medicine or, for example, the monograph on transfusion reactions written by Popovský. The same advice applies to information on complications in donors.

Part 1: General Introduction

How to use this book?

After reading the General Introduction (Part 1), you can go straight to one or more of the next parts depending on your area of interest. The content of each part is briefly summarized below:

• Part 1, a general introduction, contains (in addition to this introduction to the book), an introduction to hemovigilance (Chapter 2) and to its concepts and models (Chapter 3).

• Part 2, Surveillance of the Blood Transfusion Chain, is split into two sections. If you want to know how to establish a hemovigilance system in your hospital or blood establishment, go to Section 2.1 where the different parts of the transfusion chain are discussed: Setting up or consolidating a system (Chapter 4); preparation of blood components (Chapter 5); testing, issuing, and transport (Chapter 6); and clinical activities (Chapter 7). Section 2.2 (Chapters 8 to 11) describes how established hemovigilance systems work at the level of a blood establishment and a hospital.

• Part 3 deals with national and regional hemovigilance systems. The nine chapters provide examples of how different national hemovigilance systems function and what data they generate. The results of one of the best functioning hemovigilance systems (SHOT) are also presented and discussed in Part 5, Chapter 24.

• Part 4 covers hemovigilance at the international level. The European system is discussed as an example of international frameworks in Chapter 21. Chapter 22 deals with international collaboration, specifically the International Hemovigilance Network (IHN). Hemovigilance is still mainly confined to developed countries (as reflected by the membership of the IHN) and so the objectives and obstacles encountered in developing countries may be quite different. Therefore, we include a separate chapter on hemovigilance in developing countries (Chapter 23).

• Part 5 summarizes the most important achievements of more than 15 years of hemovigilance activities.

• Part 6 discusses three important new developments in hemovigilance: Vigilance of alternatives for blood components (Chapter 25); Surveillance of clinical effectiveness of transfusion (Chapter 26); and Biovigilance (Chapter 27).

• The three appendices include a Glossary with the main terms peculiar to the field of hemovigilance, and lists of definitions of adverse reactions in patients and donors.

For a more detailed guide to the book’s various parts and sections, please take a look at Chapter 2.

References


CHAPTER 2
Hemovigilance: A Quality Tool for the Blood Transfusion Chain

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This chapter is an introduction to hemovigilance, starting with a brief historical overview of the safety of blood transfusion as background.

History of blood transfusions

The first blood transfusions were attempts to transfuse humans with animal blood (lambs were the favorite creatures) to “treat” all kinds of illnesses in the 17th century. In the 18th century, however, the French king Louis XIV forbade the transfusion of animal blood to people by law because it was considered too dangerous.1 In the 19th century, Henri Leacock and James Blundell pioneered interhuman transfusion as a life-saving therapy for severe blood loss.2 Blundell warned others, however, to apply this therapy only as ultimum refugium because it was, again, considered dangerous.1 Particularly after the discovery of the ABO blood groups by Landsteiner,4 blood transfusion became less dangerous but certainly still not without risk.

There is only scattered documentation of the surveillance of the safety of blood transfusion and blood components in the literature (for example, see Reference 5) although this situation is improving.

Introducing hemovigilance

The word “hemovigilance” comes from the French hémovigilance and is derived from the Greek haema meaning “blood” and the Latin vigilans meaning “watchful.” It was coined in France in 1994 to function in the same way as the term “pharmacovigilance” does for drugs. Figure 2.1 shows a beautiful picture of a lion, already the symbol of vigilance in the 17th century.

Pharmacovigilance started in France in the 1970s in order to prevent a repeat of anything along the lines of the thalidomide/Softenon drama (also known as the Contergan scandal), in which more than 10,000 children were born with severe congenital deformities due to the use of thalidomide by their mothers during pregnancy. Similarly, as a reaction to the HIV/AIDS scandal in the 1980s and early 1990s, a complete surveillance system for blood transfusion was initiated in France in 1994, and was the start of hemovigilance.

Several definitions exist for hemovigilance and you will encounter several of them throughout this book. The International Hemovigilance Network (IHN) has formulated the following definition:

A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess
Plasma derivatives such as clotting factor concentrates, immunoglobulins, and albumin are called blood products. In Europe, these products are considered to be pharmaceuticals, and the manufacturers have to comply with regulations different to usual hemovigilance ones. The same applies to drugs that are used as alternatives for, or to minimize the use of, blood components, such as Erythropoietin, Tranexamic acid, and Clopidogrel.

**Quality system**

Hemovigilance is an important part of the quality system for blood transfusion (see Figure 2.2). Other methods for identifying errors, adverse events, and reactions include audits of practice and the investigation of complaints.

Like any discipline, hemovigilance involves the use of specific terms with precise meanings as follows:

- An **adverse event** is an undesirable and unintended occurrence in the blood transfusion chain (which consists of the collection, testing, preparation, storage, distribution, ordering, issuing, and administration of blood and blood components). It may or may not be the result of an error or an incident (see below) and it may or may not result in an adverse reaction in a donor or recipient.

- An **incident** is a case in which the patient is transfused with a blood component that did not meet all the requirements for a suitable transfusion for that patient, or that was intended for another patient. Incidents thus comprise transfusion errors and deviations from standard operating procedures (SOPs) or hospital policies that have lead to unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.

**Blood components**

There are three kinds of labile blood components: erythrocytes (red blood cells), platelets, and fresh-frozen plasma.

---

**Figure 2.1** This picture, from an edition printed in Brussels in 1649 and kept in the library of Leiden University, the Netherlands, is from Saavedra’s *Idea de un Príncipe Polítiu Cristiano* (Idea of a Political-Christian Prince) (http://www.emblematica.com/en/cd01-saavedra.htm). The lion was a symbol of vigilance because he needs little sleep. If he does sleep, it was believed that he was doing so with his eyes open because he knows that he is not safe in his majesty (non majestate securus). Reproduced from Bibliotheca Thysiana with permission from Leiden University Library.

Information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.

---

**Figure 2.2** Hemovigilance as part of a quality management system for healthcare.
Adverse reaction
Incident
Errors including deviations from SOPs
Near-miss

Figure 2.3 Adverse events: Relationship between adverse reactions, incidents, and near-misses (source: ISBT proposed standard definitions for surveillance of non-infectious adverse transfusion reactions, July 2011; developed by the ISBT working party on hemovigilance in collaboration with the International Hemovigilance Network; reproduced by permission www.isbtweb.org/working-parties/haemovigilance/definitions).

Another aspect in this regards is the imputability, which is the likelihood that an adverse reaction in a recipient can be attributed to the blood component transfused.

There are many different types of transfusion reactions (see Table 2.1 on page 9), which can be subdivided in several ways according to their pathogenesis. A common subdivision is into infectious and noninfectious transfusion or adverse reactions. We also use some internationally accepted definitions throughout this book (see Appendix B).7

Adverse reactions or complications in donors
Because the etiology of adverse reactions in a donor is quite different from those in a recipient, they are also known as complications. For several reasons, the severity of donor complications are graded according to a different scale to adverse reactions in recipients, although the two scales are similar. This donor scaling is also internationally accepted and evaluated (see Appendix C and/or www.isbt-web.org/members_only/files/society/StandardSurveillanceDOCO.pdf).

Legal framework
In the European Union (EU), certain aspects of hemovigilance (mainly product-related adverse events) are legal requirements that are governed by Directives. One important distinction made in the EU Directives concerning blood products is between Blood Establishments (BEs) and Hospital Blood Banks (hBBs):

- A Blood Establishment is any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hBBs.8
- A Hospital Blood Bank is a hospital unit that stores, distributes, and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital-based transfusion activities.8

Adverse reactions in recipients
An adverse reaction to the transfusion of a blood component is synonymous with a transfusion reaction. The severity of an adverse reaction in a recipient is graded according to an internationally accepted scale (see Appendix B).7
Summary
Hemovigilance is a system for
• observing, recording, reporting, and analyzing when something goes wrong in the blood transfusion chain (see the next section);
• using the lessons learned to take action to avoid that problem going wrong again.9
Hemovigilance systems exist at three levels:
• blood establishment and the hospital level (the blood transfusion chain);
• regional or national level;
• international level.

Hemovigilance in the blood establishment and the hospital:
The blood transfusion chain (Part 2)

Soon after the establishment of hemovigilance programs, it was recognized that blood products were actually extremely safe in the developed countries where these programs were functioning, but that transfusion safety consists of more than blood component safety. Notably the UK Serious Hazards of Transfusion (SHOT) scheme draws attention to the fact that transfusion errors are serious and unacceptably common (see Chapter 14). Later it also became clear that many adverse reactions are unavoidable and therefore they are a calculated risk of blood transfusion, as can be seen from Table 2.1.9

More recently the donor has received due attention in hemovigilance programs. Because the safety of the donor (rather than of the donated blood) is also the subject of vigilance, this part of hemovigilance is also called donor vigilance.

A donor can also be seen as the start of the blood transfusion chain (see Figure 2.4). We use this scheme of the blood transfusion chain throughout the book.

Establishing a hemovigilance system (Part 2, Section 2.1)

Hemovigilance systems exist at three levels: (i) the hospital and BE from which that hospital obtains the blood components for transfusion (the basic unit of hemovigilance); (ii) regional and national; and (iii) international.

The basic unit of hemovigilance is the blood transfusion chain shown in Figure 2.4. In order to establish a functioning hemovigilance system in this unit, one needs to follow general principles of a quality system and adapt these to the local situation. Section 2.1 provides a framework and guidance and gives practical tips and examples illustrating the do’s and don’ts.

Although there are certainly many similarities with hemovigilance in one transfusion chain, the establishment of a regional or national hemovigilance system faces some quite different challenges, such as confidentiality issues, governance, contact with media, and so on. These are discussed in Part 3. The establishment of an international hemovigilance system is discussed in Part 4.

Hemovigilance systems at three levels (Parts 3 and 4)

Regional and preferably national hemovigilance programs have added value compared to local systems as regards improving the safety of transfusion.

The first hemovigilance system was established in 1993 in Japan (see Chapter 13). As a reaction to the HIV scandal, the first national hemovigilance system in Europe was initiated in France in 1994. Soon after, other European countries followed this initiative, starting with the UK in 1996. Today almost all EU countries have established a hemovigilance system and the number of hemovigilance systems outside Europe is also steadily increasing.

The functioning of a European hemovigilance system meant to stimulate the development of a coordinated approach to the safety of blood and blood products is described in Chapter 21. In 1997, the initiative was taken to found the European Hemovigilance Network with the aim of increasing the safety of clinical blood transfusion medicine in Europe. Members of the network are (national) hemovigilance systems. The network started with five members and grew to over 25 members, including some from outside Europe. As a result of this growth, the scope and the name
## Table 2.1 Preventable and nonpreventable adverse events.\textsuperscript{9}

<table>
<thead>
<tr>
<th>Type of adverse reaction</th>
<th>Related to the quality of blood component?</th>
<th>Related to failure in clinical transfusion process?</th>
<th>Preventable by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion-transmitted bacterial infection</td>
<td>Yes</td>
<td>Possibly due to failure to inspect component before transfusion</td>
<td>Donor skin cleansing, Diversion pouch on donation line, Pathogen reduction, Correct storage conditions</td>
</tr>
<tr>
<td>Transfusion-transmitted viral infection (HBV, HCV, HIV-1/2, other)</td>
<td>Yes</td>
<td>No</td>
<td>Donor selection, Donation testing, Pathogen reduction</td>
</tr>
<tr>
<td>Transfusion-transmitted parasitic infection (malaria, other)</td>
<td>Yes</td>
<td>No</td>
<td>Donor selection, Donation testing, Pathogen reduction</td>
</tr>
<tr>
<td>Hemolysis due to incorrect storage</td>
<td>No</td>
<td>Yes</td>
<td>Quality assured clinical transfusion process</td>
</tr>
<tr>
<td>Immunological hemolysis due to ABO incompatibility</td>
<td>No</td>
<td>Yes</td>
<td>–</td>
</tr>
<tr>
<td>Immunological hemolysis due to other alloantibody</td>
<td>No</td>
<td>Yes</td>
<td>–</td>
</tr>
<tr>
<td>Anaphylaxis or hypersensitivity</td>
<td>No</td>
<td>No</td>
<td>Unpredictable and unavoidable</td>
</tr>
<tr>
<td>Post-transfusion purpura</td>
<td>No</td>
<td>No</td>
<td>Unpredictable and unavoidable</td>
</tr>
<tr>
<td>Transfusion Related Acute Lung Injury (TRALI)</td>
<td>Yes</td>
<td>No</td>
<td>TRALI risk may be reduced with Fresh Frozen Plasma (FFP) from male donors</td>
</tr>
<tr>
<td>Graft-Versus-Host Disease</td>
<td>Yes</td>
<td>Yes, due to failure to select component or failure to recognize patient at risk</td>
<td>Use of irradiated components for at-risk patients; use of amotosalen treated platelets</td>
</tr>
<tr>
<td>Transfusion Associated Circulatory Overload (TACO)</td>
<td>No</td>
<td>Yes, due to failure to recognize patient at risk</td>
<td>Avoid over-infusion</td>
</tr>
<tr>
<td>Febrile non-hemolytic TR</td>
<td>Yes</td>
<td>No</td>
<td>Incidence may be reduced by leucodepletion</td>
</tr>
</tbody>
</table>

**Figure 2.4** The blood transfusion chain.
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was changed to the International Hemovigilance Network (IHN). See Chapter 3 for more on the IHN.

Results and achievements (Part 5)

Probably the most important result of hemovigilance has been that it has shown that since the mid-1990s, blood transfusion in Europe is quite safe and notably that blood products are extremely safe compared with other activities and products in healthcare.

The majority of the serious adverse reactions and events that nevertheless do occur happen in the hospital part of the blood transfusion chain. Particularly, the data from the UK hemovigilance system Serious Hazards of Transfusion (SHOT, see Chapter 14) have drawn attention to the fact that about 50% of these are due to administrative errors. The measures installed subsequently resulted in a further increase of the safety of clinical blood transfusion in the hospital.

Well-functioning hemovigilance systems, such as AFSSAPS in France (Chapter 12), Serious Hazards of Transfusion (SHOT) in the UK (Chapter 14), and TRIP in the Netherlands (Chapter 15), have documented the success of various measures to even further improve the safety of blood products. Two examples—(i) the deviation pouch applied during blood drawing from a blood donor in order to minimize the risk on contaminating skin bacteria and (ii) the decision to use only plasma from male donors—have been demonstrated to result in significant decreases of serious adverse reactions due, respectively, to bacterial contamination of blood products (particularly platelets) and TRALI reactions.

The results of many activities of the EHN/IHN, such as the contribution to the high quality of hemovigilance in Europe through digital information exchange, meetings, and seminars, are difficult to measure but are certainly important. Concrete results include: (i) the standardization of definitions and reporting of serious adverse events and reactions in collaboration with the International Society of Blood Transfusion (ISBT) Working Party for Hemovigilance (see Appendix C); (ii) the stimulation and structuring of donor vigilance also in collaboration with the Working Party for Hemovigilance (see Appendix C).

These definitions (see www.isbt-web.org/documentation and www.ihn-org.com) are being used by the European Commission for the reporting according to the EU Directives requirements.

After completing the standardization of the definitions, IHN decided to embark on an ambitious project to establish an international hemovigilance database. The compliance with the international definitions was not yet optimal and the database project will contribute to improving that situation. With these results, it will be possible to make comparisons between data generated by different systems.

New developments: Vigilance of alternatives for and appropriateness of transfusion and tissue-/bio-vigilance (see Part 6)

Data from an anesthesiology survey in France indicated that many more perioperative deaths are due to under-transfusion or delayed transfusion than to adverse reactions of transfusions given in time.10 Also the safety of measures that are often proposed to stimulate blood saving strategies (e.g., cell savers) and medicinal products (e.g., anti-fibrinolytics) have to be taken into account. Presently, not enough is known about the safety of these alternatives to be sure whether they can be recommended.

Another issue is optimal blood usage. The awareness that apart from vital indications the efficacy of blood transfusions is often unknown, not established, or even negative has resulted in a significant reduction of the use of blood products as documented by many hemovigilance systems. One step further would be the surveillance of appropriate or optimal blood use in a more detailed way, for example, through the collection of a set of indicators, which may be provided easily by most hospital information systems. In a still broader framework, there is also a need for data on the benefit of transfusion of a blood component in different clinical
Chapter 2: Hemovigilance: A Quality Tool for the Blood Transfusion Chain

Audit methods may sometimes be more appropriate to measure and analyze critical parameters for optimal blood use, such as compliance with guidelines (see www.optimalblooduse.eu). Nevertheless, it is expected that existing hemovigilance systems, including the hemovigilance officials in hospitals, may in the near future also contribute to the surveillance of optimal blood use.12

Hemovigilance systems will also be exposed to the vigilance and surveillance of other human products that are transplanted: first, cells and tissues, and at a later stage, organs for transplantation. In the USA, the word “biovigilance” has already been coined for this combined activity (www.aabb.org/programs/biovigilance). The European Commission has combined these activities in one directorate. It is clear that there are many similarities with hemovigilance and this will present opportunities for other activities to be shared and based on the expertise obtained in hemovigilance.

Appendices

The appendices of this book contain a Glossary with the main terms peculiar to the field of hemovigilance (Appendix A), definitions for the surveillance of noninfectious adverse transfusion reactions (Appendix B), and complications related to blood donation (Appendix C).

References


CHAPTER 3

Concepts and Models

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This chapter introduces you to the concepts and models of hemovigilance.

Introduction

Current hemovigilance systems contain significant conceptual and organizational differences, related to scope and structure. In effect, many roads lead to Rome, and irrespective of the structure of the system hemovigilance can provide valuable data for priority settings and evaluation of corrective strategies.

These system differences, however, may have important implications for the interpretation and comparison of the data from different systems. On the one hand, as shown in Table 3.1, there are more reports per 1000 units in systems where all reactions are reported compared to those where only serious reactions need to be reported. On the other hand, whether the reporting is mandatory (as in France) or voluntary (as in the Netherlands) does not have to affect the reporting rate and differences in reporting rate may be observed in systems using the same concepts and models.

Some systems and methods are more efficient and/or cheaper than others. Certainly, there has been a learning process during the establishment of hemovigilance systems. For instance, lessons were learned from both the early French and UK systems,1,2 despite them being quite different, and later systems have been developed according to hybrid and novel models.

It is still too early to draw conclusions regarding cost-effectiveness of the different concepts and models.

Scope

Products and processes

The discipline of hemovigilance was triggered by the fact that blood components were unsafe. Therefore, in the beginning activities were mainly focused on product safety, the products in this case being blood components. Soon, however, it became clear that hemovigilance should not be confined only to product safety, because some processes in the blood transfusion chain appeared to be weaker links than the blood components themselves.3

In Europe, an international scheme has been operating since 2008, in which each EU member state has to provide the European Commission (EC) annually with blood component-related incidents.4–8 (See also Chapter 21 on page 244–247.)

Recipients and donors

At first, hemovigilance focused exclusively on the safety of the recipient of a blood component. But as the concept of the blood transfusion chain extended “from vein (of the donor) to vein (of the recipient)”,3 donor safety also became a subject for hemovigilance. Since 2006, an increasing number of systems have also started to collect data of donor complications data.9
Table 3.1 Reporting in different hemovigilance systems.

<table>
<thead>
<tr>
<th>Country/region</th>
<th>*Reports/1000 units</th>
<th>What is reportable</th>
<th>Type of system (at creation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>0.20</td>
<td>Serious reactions + IBCT</td>
<td>Voluntary</td>
</tr>
<tr>
<td>Ireland</td>
<td>1.22</td>
<td>Serious reactions + IBCT</td>
<td>Voluntary</td>
</tr>
<tr>
<td>France</td>
<td>2.83</td>
<td>All reactions</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Netherlands</td>
<td>2.90</td>
<td>All reactions</td>
<td>Voluntary</td>
</tr>
<tr>
<td>Québec</td>
<td>7.07</td>
<td>All reactions</td>
<td>Voluntary</td>
</tr>
</tbody>
</table>

*P. Robillard, personal communication; data are from 2006.

"Hot and cold" hemovigilance

"Hot" hemovigilance means the immediate reporting of an incident. This allows immediate corrective measures to be taken, which is very important for product-related incidents and hemovigilance at the level of the hospital or the blood establishment. (See also the Rapid Alert System discussed on page 15.)

Regional, national, and international hemovigilance systems and activities mainly deal with "cold" hemovigilance, for instance the analysis of data and trends on an annual basis and the follow-up of corrective measures proposed on the basis of these data and/or trends.

Report all adverse events/reactions or only the serious ones?

The reporting of all adverse events is better for vigilance purposes and for creating awareness, because serious adverse events are rare. It does, of course, require more resources, however.

In most hemovigilance systems, all adverse events (AE) are reported, and in most countries only the reporting of serious adverse reactions (AR) is compulsory. The advantage of also reporting incidents and near-misses, is that these reports offer more and "relatively cheap" (namely, no harm is done) learning opportunities.

Data on more than just blood components?

Safety data of measures that proposed to stimulate blood-saving strategies (e.g., cell savers) and the use of medicinal products (e.g., anti-fibrinolytics or erythrocyte stimulating agents) as compared with blood components are lacking. Some hemovigilance systems (e.g., the Dutch system TRIP) are considering broadening their scope in order to help with providing the data on which an advice on the treatment with blood components or blood alternatives should be based.10

Structure

Integration in quality systems

Hemovigilance should be part of a quality system for the blood transfusion chain. In several systems this is indeed the case and some are able to close the Deming quality circle of plan, do, check, act for their system. However, other systems do not go much beyond the reporting of transfusion reactions.

Errors and adverse events occur in many aspects of the process of healthcare. For most patients and clinicians, blood transfusion is only one element of the whole process of clinical care and transfusion risks are a small proportion of the risks to which patients are exposed. Moreover, compared to medicinal drugs, blood components are very safe.11,12 For these reasons a quality management system for blood transfusion should be part of a hospital’s wider quality system in general and an integrated part of the quality system of the patient’s safety activities in particular.

Integration in other patient safety activities

Blood safety activity globally is not well integrated into other aspects of patient safety, which are very
active in many countries. Efforts need to be made to improve this situation. For instance, in Italy there are plans to integrate the hemovigilance program with the program for clinical risk management for other patient safety movements.

International collaboration
We will briefly introduce here two activities on the field of international collaboration. The first is the International Hemovigilance Network (IHN), which has operated successfully for more than 10 years and grew from the European Hemovigilance Network (EHN).13,14 The second is the Global Steering Committee on Hemovigilance (GloSCH), a recent initiative with the aim of stimulating hemovigilance particularly in developing countries.

The aim of the IHN is to develop and maintain a worldwide common structure with regards to the safety of blood/blood products and hemovigilance of blood transfusion. The objectives are exchange of valid information between the members of the Network, rapid alert/early warning between the members, joint activities between the members, and educational activities in relation to hemovigilance.

The main activities of the IHN are: a website (www.ihn-org.com) with an open part and a closed part only for official contact persons (OCPs) and participants; an annual general meeting where the Board informs the members of their activities in the past year and important decisions are taken; the organization of an annual Seminar (IHS), which is a scientific two-day meeting; working parties to harmonize definitions and make comparisons on quality indicators, both for safety and appropriate use; and finally the running of an international database on hemovigilance.

In 2008, the World Health Organization, the Government of Canada, the ISBT, and the IHN took the initiative for a Global Steering Committee for Hemovigilance (GloSCH). The goal of this initiative is to promote hemovigilance specifically in developing countries. One of the objectives is the production of a guidance document providing Recommendations for Establishing a National Hemovigilance System.

Reporting structure
Safe incident reporting must be blame-free.15 By creating a failures management culture where physicians and nurses are not afraid of reporting incidents and where reporting is not anonymous but done in an atmosphere of confidence, transfusion practice is improved. In the complex system of healthcare, attention to the safety for the patient therefore also implies attention to the safe functioning of the employer and of the healthcare process.

There are many different reporting structures depending on local situations, legal frameworks, and so on.16,17 Examples may be found in Chapters 4–21.

Governance
Goverance of a hemovigilance system can be organized by a competent authority, a manufacturer, professional organizations, or a Public Health Organization. Combinations are also possible. Examples will be further discussed in Chapters 4–21. Here we briefly summarize the main advantages and disadvantages of each type of governance, by using a particular system as an example:

- Competent Authority (France: afssaps): A competent authority (CA) is any person or organization that has the legally delegated or invested authority, capacity, or power to perform a designated function. Advantages are the creation of a centralized system, with sufficient resources and personnel, and that the hemovigilance system is embedded in a multidisciplinary organization including pharmaco- and materio-vigilance. Disadvantages are a top-heavy system, influenced by politics and public opinion, and that reporting to the competent authority may result in under-reporting of errors.
• **Manufacturer (Singapore):** Advantages are the availability of better qualified people, more impetus for change, and less fear for error reporting. The main disadvantage is that the manufacturer may have a conflict of interest.

• **Professional organizations (the Netherlands, TRIP):** Advantages are high qualities of the reports because they are checked by an expert committee, and the whole transfusion chain is covered. Disadvantages are that reporting is on a voluntary basis and therefore is dependent on the willingness of the professionals to report. Also central steering is lacking.

• **Public Health Authority (Canada):** Advantages are the expertise in surveillance methodology and that the handling and analysis of databases can easily be implemented. Disadvantages are no prior knowledge of blood transfusion and therefore confidence of the blood transfusion community was lacking.

### Centralized or not

Hemovigilance systems may be organized in a strictly centralized way or be more or less decentralized.

The classical example of a centralized system is the French system (see Chapter 12). Advantages of such a system are that it may guarantee uniformity of data and thus comparability. Disadvantages may be that it is more expensive and that healthcare professionals may be less motivated to report.

An example of a more decentralized system is the UK system SHOT (see Chapter 14), which has certainly provided valuable data and advices (see Chapters 14 and 24) and at much lower costs.

### Legal status

Reporting may be on a voluntary or a mandatory basis, and each arrangement has its advantages and disadvantages.

Within the EU, all legal provisions in the Blood Directives have to be transposed into national law by Member States. This has been achieved by most of the Member States within two years time. Member States are free to go beyond what the Directives require: in the context of hemovigilance and traceability several Member States have done so, for example by requiring mandatory notification of all reactions/events to the Competent Authority or by requiring systematic documented feedback of the transfusion of a blood component in a hospital (user) to the blood establishment (producer). This leads to an extensive corps of data available, but whether such extended national requirements in the context of hemovigilance increase safety for the patient and induce change in transfusion practice is not really known. At least it has the potential of raising penalties when cases of infringements to the laws are encountered.

### Passive or active

In general, hemovigilance systems deal with passive hemovigilance. Examples of active hemovigilance would be specific transfusion safety research projects and post-marketing surveillance of new components by manufacturers.

### Rapid alert system

The rapid alert system (RAS) is an information channel for very quick diffusion of important information in relation to emerging threats, of whatever kind. It allows for quick and safe transmission of precise, correct, and reliable data to competent contact persons in a system. They may decide on possible action in order to maintain or increase safety (through corrective or preventive action) in the case of a proven problem or defect, a potential problem or risk, or even a justified doubt.

In the case of the IHN, the RAS works via fax, e-mail, and website (protected domain). The OCP in one member country of the IHN is informed that a problem has emerged in his or her country, for example through the national hemovigilance system or by other means. This key person analyses the information and decides whether this information should be diffused to the contact persons in the other country members of the IHN. It is the responsibility of the respective contact persons in the other countries to take up the information, evaluate it, and decide upon the actions in their country. In the past, the RAS has been used on different occasions, including the following:

• appearance of clusters of clinical signs after transfusion;
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- hidden or apparent defects of disposable material used in transfusion (such as leakages of filter housings, holes in collection bags, defects in apheresis material);
- difficulties with reagents (lack of performance in terms of sensitivity or specificity);
- problems with equipment.

References