Hemovigilance: Definition and Overview of Current Hemovigilance Systems

Summary

Hemovigilance, as a safety concept, appeared in the beginning of the 1990s. Its primary aim is to assure the surveillance of blood transfusion, to collect data on (serious) sequelae of blood transfusions, to inform health policy, to improve transfusion standards, to assist in the formulation of guidelines in the field of transfusion and to increase the safety and quality of the entire transfusion process.

Two different “poles” of systems exist. In France, where hemovigilance was rendered mandatory by law in 1994, the system is centralized and nationwide, with a legal obligation to notify in written form each and every side effect related to blood transfusion. In the UK, hemovigilance is a national voluntary scheme between professionals (SHOT, Serious Hazards of Transfusion). Learning from the lessons generated by the British and French systems enables the introduction, in other countries, of models representing “hybrids” of the two systems.

Within the European Union, the recent European Blood Directive requires hemovigilance in each Member State; its provisions have to be transposed into national legislations within two years. In order to ally efforts at the Community level it would make sense to appeal to existing initiatives in this field that have proven that efficient cooperation is possible: the European Haemovigilance Network (EHN) has played a major role in bringing this important matter forward and in developing it into an efficient tool intended to increase safety and quality in European blood transfusion.
The primary aim of hemovigilance is to assure the surveillance of blood transfusion, to collect data on (serious) sequelae of blood transfusions, to inform health policy, to improve transfusion standards, to assist in the formulation of guidelines in the field of transfusion and to increase the safety and quality of the entire transfusion process.

Hemovigilance, as a safety concept, appeared in the beginning of the 1990s; the term was probably created in France and has Greek and Latin roots: haema, “blood,” and vigilans, “paying a particular attention to.”

Definitions

In France, hemovigilance was rendered mandatory by law on January 24, 1994; it was defined as “a set of procedures of surveillance organized from the collection of blood and its components up to the follow-up of its recipients with the purpose of collecting and evaluating information on the undesirable and unexpected effects resulting from the use of a blood product and of preventing their occurrence.”

There exist several other written definitions for hemovigilance; each one differs slightly in wording and meaning.1,2

In the European Blood Directive, “Directive of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC,”3 hemovigilance is defined as “a set of organized surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors.”

The Treaty of Amsterdam (1999) lays down in Article 152, 4(a) that “measures should be adopted setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives.” Mandated by this article, the European Commission submitted a proposal for a “European Blood Directive” which is now adopted.3

In the legal provisions there are two operating articles dealing with hemovigilance:

“Article 14: Traceability

1. Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa. To this end, Member States shall ensure that blood establishments implement a system for identification of each single blood donation and each single blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The system must unmistakably identify each unique donation and type of blood component. This system shall be established in accordance with requirements referred to in Article 29(a). With regard to blood and blood components imported from third countries, Member States shall ensure that the donor identification system to be implemented by blood establishments permits an equivalent level of traceability.

2. Member States shall take all necessary measures in order to ensure that the system used for the labelling of blood and blood components collected, tested, processed, stored, released and/or distributed on their territory complies with the identification system referred to in paragraph 1 and the labelling requirements listed in Annex III.

3. Data needed for full traceability in accordance with this Article shall be kept for at least thirty years.”

“Article 15: Notification of serious adverse events and reactions

1. Member States shall ensure that:
   - any serious adverse events (accidents and errors) related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious reactions observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components are notified to the competent authority
   - blood establishments have in place a procedure accurately, efficiently and verifiably to withdraw from distribution blood or blood components associated with the notification referred to above.

2. These serious adverse events and reactions shall be notified in accordance with the procedure and notification format referred to in Article 29(i).”

Although the definitions and the content of operating articles are clear and precise, the impact of these in “real life” is far less obvious, as Article 152(5) limits the field of application: “Community action in the field of public health shall respect the responsibilities of MS for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on donation or medical use of organs and blood.”

In other words, clinical activities depend upon the MS of the EU and the European Blood Directive lays down legally binding provisions only for the production element of the transfusion chain, excluding the clinical element: this also applies to the legal provisions relating to hemovigilance.

With the coming into force of this European Blood Directive3 (which is legally binding for the Member States of the EU) the provisions of this Directive have to be transposed into national legislations within 2 years. Furthermore, the European Commission (Health & Consumer Protection Directorate-General) has now taken up again hemovigilance and will bring it forward as required in the Directive.

Council of Europe (CofE): Guide on the preparation, use and quality assurance of blood components; Recommendation No. R(95)15, Chapter 31 on Haemovigilance:4

“Haemovigilance consists of the detection, gathering and analysis of information regarding untoward and unexpected effects of blood
transfusion. It is expected that all the information provided by haemovigilance may contribute to improving the safety of blood transfusion by:

- providing the medical community with a reliable source of information about untoward effects of blood transfusion.
- indicating corrective measures required to prevent the recurrence of some accidents or dysfunctions in the transfusion process.
- warning hospitals and blood transfusion services about adverse events that could involve more individuals than a single recipient, including those related to the transmission of infectious diseases; those related to blood bags, solutions or blood processing.

Although most haemovigilance organizations have concentrated on observation of untoward effects in transfused patients, it should be realized that the scope of haemovigilance may cover the entire transfusion process, from donor selection to the transfused patients, as untoward effects may occur at any of these steps."

The following is the definition given by the European Blood Directive: Haemovigilance is a set of surveillance procedures covering the whole transfusion chain (from the donation of blood and its components to the follow-up of recipients of transfusions), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent the occurrence or recurrence of such incidents.

Other definitions are needed in the context of hemovigilance. Again, the European Blood Directive gives some definitions:

- **serious adverse event**: any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

- **serious adverse reaction**: an unintended response in donor or in patient associated with the collection or transfusion of blood and blood components that is fatal, life-threatening, disabling or incapacitating or which results in, or prolongs, hospitalization or morbidity.

For the following occurrences commonly agreed definitions in relation to hemovigilance are necessary, but still pending: events, incidents, effects, side effects - undesirable/unexpected, reactions, accidents, errors, near-misses, etc. Some of the definitions may be "borrowed" from other areas such as pharmacovigilance or industry (especially the airline industry).

The **types of blood components** used should be defined according to the Council of Europe: Guide on the preparation, use and quality assurance of blood components; Recommendation No. R(95)15, Part C: Blood components.4

The following aspects should be handled according to the European Haemovigilance Network (EHN: Internet site: www.ehn-org.net) and the Council of Europe: Guide on the preparation, use and quality assurance of blood components; Recommendation No. R(95)15, Chapter 31 on Haemovigilance:5

- grading for severity: 0 = no sign; 1 = immediate signs without vital risk and full resolution; 2 = immediate signs with vital risk; 3 = long term morbidity; 4 = death of the patient.
- grading for imputability: 0 = no relationship; 1 = possible; 2 = likely; 3 = sure.
- clinical and biological signs:
  - immediate reaction (hemolysis; non-hemolytic febrile transfusion reaction [NHFTR]; allergic reactions, like rash, erythema, urticaria, anaphylaxis; transfusion related acute lung injury [TRALI],…)
  - delayed reaction after transfusion (hemolysis; graft-versus-host disease [GvHD]; post-transfusion purpura [PTP],…)
  - microbiological / viral transmission
  - allo-immunization (against antigens of RBC, WBC, PLT,…)
  - incorrect blood component transfused (IBCT)
  - others

Data should be reported according to a common standardized validated matrix. The EHN Standardised Reporting Form has served in many countries in the past (see Table 1).

### The Blood Transfusion Chain

Hemovigilance, as a surveillance system based on ongoing and standardized collection and analysis of data, pursues several objectives:

- monitoring the prevalence and incidence of infectious markers in blood donors
- compiling adverse events / incidents that are suspected or have been confirmed to be associated with blood collection (relating to the donors) or transfusion of labile components (relating to the recipients), including transfusion errors and product-related side effects
- documenting confirmation of the transfusion of blood components to patients
- offering rapid alert / early warning procedures, thereby covering the entire blood transfusion chain and the respective activities.

### General Concept and the Components of the System

As can be concluded from the definitions and the list above, hemovigilance should cover the whole blood transfusion chain: conceptually it stretches over each step in the transfusion process, from the donor to the recipient ("from vein to vein").

Some important prerequisites for the success in establishing, running and maintaining a functional hemovigilance system may be summarized as follows:

- legal (or other mandatory) framework in place (matter of opinion, dependent on the country)
- common definitions agreed
- standardized reporting used
- continuous budgeting and financing guaranteed
- central evaluation site built up
- rapid alert/early warning organized
- culture of professionalism established
- Hospital Transfusion Committees working
mechanisms for corrective and preventive actions introduced
International / European cooperation anticipated.

It is important to point out that there are interfaces with other vigilance systems, e.g., pharmaco-, materio-, reacto-, and biovigilance.6 If, in theory, the limits of the different vigilance systems are defined, in practice it is far from so: there is considerable overlapping and interference.

In this context it may be useful to come up with an extended version of the classical blood chain (see Figure 1). According to this model there are different (potential) participants in the system: industry, blood centers, hospitals, the competent Authorities, etc. Key participants should be ready to collaborate in a constructive and coordinated way: in this way, hemovigilance can fulfill its overall aim, e.g., to increase safety and quality of the blood transfusion process in the best interest of those patients who are in need of labile blood components.

The Role of Industry

The manufacturers of materials, disposables, reagents, equipment, etc., are serving blood centers and hospitals. Regulatory requirements (Community, national) and the post-marketing procedures of companies have established a powerful tool for collecting and compiling data directly and indirectly related to blood transfusion: in the future the input of the industry into hemovigilance needs to increase and to accelerate.

The Role of Blood Organizations and Blood Centers

Blood centers/blood banks are the users of the materials, disposables, reagents, equipment, etc., manufactured by the industry. At the same time, they are also the producers of labile blood components of all types, as well as the providers of transfusion related services. In this way, they play a key role in hemovigilance, figuring on one hand as users and on the other hand as producers.

The Role of the Clinical Segment

If the focus of hemovigilance is mainly on the patient with a blood transfusion need, then the clinical side of the transfusion chain is of paramount importance with regards to surveillance. Being at the frontline, physicians and paramedics are at the primary site of blood transfusion: they are in a position to detect and report incidents, events, side effects, reactions, accidents, errors, near-misses, etc. Hospital Transfusion Committees play a crucial role in drafting guidelines, administering training, ensuring peer review, auditing, supervising reporting and initiating corrective/preventive actions.

The Role of the Authorities

The competent Authorities also have an important part in hemovigilance. In some countries the role of the competent National Authorities (cNA) may have to be developed further in the future: legislating, budgeting, inspecting, accrediting, and above all surveying (directly or by delegation). Each and every hemovigilance system (in whatever form it exists) needs the back-up of the cNA.
In some countries the cNA directly organizes and runs the system, in others, the cNA is provides a platform for operations, and in others its role is limited to “accompanying” an established hemovigilance system. In any case, the involvement of the cNA needs to become clearer and, in some cases, more efficient.

**Procedure**

Hemovigilance is a “quality process” that seeks to improve the quality and increase the safety of blood transfusion. At each and every step of the process it has both an “input” (= transfusion of a patient or intent to do so) and an “output” (= corrective and/or preventive actions and follow-up on them).

As is the case for the majority of processes, the hemovigilance process has different steps and interfaces as well as critical elements.

Taking into account that hemovigilance covers and surveys all parts of the blood transfusion chain (equally concerning those relating to both donors and recipients), the procedure is very similar for both branches and hereafter, the general process is described in relation to the recipient of labile blood components.

In practice and generally speaking, the different steps of this quality process are:
- recognition / assessment of an occurrence (deviating from the “norm”)
- reporting (according to established criteria and using a standard reporting form)
- collection of data (following written instructions)
- compilation (using a predefined matrix)
- evaluation (according to agreed techniques) conclusions (feedback to those concerned and published)
- actions (corrective and/or preventive) and follow-up on them.

In principle, the outline of this process is similar at each level where hemovigilance applies: wards, hospitals, blood centers, competent authorities, manufacturers, etc., and the main participants involved in this process are physicians, pharmacists, nurses, medical technicians, etc. It is paramount to ensure ascending and descending, predefined and established communication channels between the different levels.

In order to make this process work at each of the different levels, at different sites, and with many different people involved, it is essential that close and constructive cooperation is established between the different participants. For this reason it is important to settle the organizational aspects, to define the respective responsibilities and mandates, to increase sensitivity in a “no blame environment,” to have clear written procedures and to offer adequate and continuous training.

As a quality process, hemovigilance needs to be deeply and solidly embedded into the Quality Management Systems (QMS) of the different establishments: in the blood centers, in the manufacturing companies, and also in the hospitals.

In order to guarantee the final result (safe and efficient blood transfusion to the patient) there should be NO exception to this rule, at no stage and for none of the activities of the blood transfusion chain.

**Overview of Currently Existing Hemovigilance Systems**

Basically the existing systems can be classified according to:
1. their legal status: mandatory vs. voluntary
2. their field of application: all events vs. very serious reactions in the patient
3. their organization: strictly centralized vs. more or less decentralized
4. their financing: costly vs. cost-efficient.

In combining the characteristics from each category, different possible schemes result, some of them are in place or being created in different countries around the world.

Classically two different “poles” of systems are cited: the British and the French. In the UK, the scheme is centralized at a national level in the SHOT Office, notification of side effects is on a voluntary basis, covers only serious reactions (of grades 2-4), includes events even in the absence of clinical signs (IBCT), as well as near-misses, and is run by the professionals in the field, probably at an acceptable cost (although there are no detailed cost-effectiveness analyses available). On the other hand, France has a national system, showing two separate parallel institutional avenues (of the competent national authority, AFSSAPS, “Agence Française de Sécurité Sanitaire des Produits de Santé,” and of the operator, EFS, “Établissement Français du Sang”, centralized at head offices, both with an intercalated regional level, notification of side effects is on a mandatory basis, covers all events (of grades 1-4), does not include events in the absence of clinical signs (for example IBCT) or near-misses (at least not in 2001, the reference year of this article; this changed in 2002). As the French model is of complex structure and nature, and involves many different players (around 2,000 “correspondents” in hospitals with transfusion activities, hundreds of them being dedicated full-time to this task, and 150 “correspondents” in blood establishments, 26 regional officers, now extended to 28, and the staff in the HQs) it is probably cost prohibitive (although there are no detailed cost-effectiveness analyses available for the moment, however AFSSAPS has announced to undertake such cost studies).

The difference between these two systems is also shown in the overall incidence rates: 8.5 notifications per 100,000 blood components distributed in the UK versus 325.2 reports per 100,000 blood components distributed in France.

These two programs represent two different directions in both thinking and acting; meanwhile, learning from the lessons generated by the British and French systems, enables the introduction, in other countries, of models representing “hybrids” of the two afore mentioned systems.

Table 2 gives an overview of the situation in the Member States of the European Union (as of December 31, 2001, updated from Ref. 8).
Particularities

It should be noted that in Germany (as well as in Austria) there exists a particular situation in relation to the administration of blood products: in Germany, labile blood components are considered as medicinal products and are therefore covered by the German Drug Law. According to the national legal provisions covering medicines, side effects have to be reported in accordance with the rules of pharmacovigilance. Nevertheless, it should be mentioned that the recent German Transfusion Law also established hemovigilance as a separate entity. There are some significant differences with other systems; for example, the severity grading is just opposite to what the other countries use.

In 2004, there will be 10 new Member States in the EU, the “accession countries” being: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia. Little is known about their hemovigilance: such systems are either non-existent for the moment or being planned/constructed.

Some Overall Results From Existing Surveillance Systems

The following figures illustrate, once more, the diversity and difference that exists throughout the European Union.

In France, where the hemovigilance system is centralized and nationwide, with a legal obligation to notify in written form each and every side effect related to blood transfusion (grades 0 to 4), the number of notifications is significant. In 1997 there were 7,604 reports, in 1998 7,725 reports, in 1999 7,089 reports, in 2000 approximately the same number as in 1999, and in 2001 7,452 reports, with some 2.5-2.8 million blood components transfused every year.9,10,11,12,13,14

In the UK, where hemovigilance is a national voluntary scheme between professionals (SHOT, Serious Hazards of Transfusion), covering transfusion reactions of grades 2 to 4, the number of notifications is much lower than in France. In 1996/97 there were 169 reports, in 1997/98 197 reports, in 1998/99 252 reports, in 1999/2000 291 reports, and in 2000/2001 283 reports, with some 3.0-3.5 million blood components transfused every year.15,16,17,18,19,20 More than 55% of the reports fell into the category “wrong blood to wrong patient” or IBCT (independently of the presence or absence of clinical signs).

Changes in the Near Future (2003 and Later)

In several countries (e.g., Italy, Spain and Sweden) where hemovigilance is not in place as a national program, the respective Scientific Societies of Transfusion Medicine have taken the initiative and have set up a plan for establishing national hemovigilance in one form or another.

In other countries, the existing systems have been completely switched: in Austria, where the side effects of blood components had to be notified through pharmacovigilance, a major change occurred on January 1, 2003, when national hemovigilance was officially launched by the Ministry of Health. In Belgium, the approach of local reporting on a voluntary basis has been turned into a system with national coverage on a mandatory basis. In the United Kingdom, the SHOT scheme (Serious Hazards of Transfusion) is still on a voluntary
basis for professionals in the field. Nevertheless, the NHS (National Health Service) has made it clear that hospitals have to contribute information when transfusion reactions occur. In this way, the British surveillance will move a little closer to the French system, although significant differences continue to exist between the two systems.

In France, the principles underlying hemovigilance remain unchanged: national and mandatory. Meanwhile the French system has learnt from the experience of the British system with IBCT (Incorrect Blood Component Transfused): Grade 0 has now been introduced in France and serves to record events such as near-misses or IBCT without clinical signs. In this sense, the French system is beginning to close the gap that exists between the two systems.

In the new MS (“accession countries”) of the EU, little is known about hemovigilance, such systems are either non-existent or are currently being planned. There will be rapid and important progress in this field in the near future, perhaps not in all of the candidate countries, but at least in some.

Table 3 gives an overview of the situation in other parts of the world, outside the EU (as of December 31, 2001, updated from Ref. 8).

### European Haemovigilance Network (EHN)

Aware of these differences and difficulties, five countries took the initiative in 1998 to work together in the field of hemovigilance: Belgium, France, Luxembourg, Portugal and The Netherlands. The 1st meeting was organized in Paris on February 10, 1998: the European Haemovigilance Network (EHN) was born. Soon after, Denmark, Greece, Ireland, Finland and the United Kingdom joined the EHN and Switzerland, Norway and Canada were adopted as associate members. Several other countries (inside and outside the EU) have shown their interest in cooperating with this Network. The objectives of the EHN are as follows:

- facilitating close contacts in the field of hemovigilance between countries in Europe
- enabling rapid and efficient exchange of reliable information and of experience
- maintaining a rapid alert system
- developing joint activities (like organizing European Seminars on Haemovigilance).

### European Haemovigilance Seminars

The 1st European Seminar on Haemovigilance was organized by France and took place in Bordeaux (November 1997), followed by Seminars in Lyon (November 1998), in Montpellier (September 2000), in Athens (December 2001) and in Amsterdam (February 2003).

### Internet Site of EHN: www.ehn-org.net

At the same time an Internet site was developed and put in place: the website contains a rapid alert module. It allows efficient and quick exchanges of information on different matters concerning hemovigilance. The website is divided into a public domain and a protected (private) domain, the latter housing the rapid alert: this section can only be accessed by authorized persons, using a password.

### Table 3

<table>
<thead>
<tr>
<th>Country</th>
<th>National HQ</th>
<th>Status</th>
<th>Responsible/Charge</th>
</tr>
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<tbody>
<tr>
<td>Canada</td>
<td>Established/Functioning</td>
<td>M: fatalities to HC; V: side effects</td>
<td>CBS/HQ + MoH</td>
</tr>
<tr>
<td>USA</td>
<td>No; ARC: unified system (50% of tx)</td>
<td>M: fatalities to FDA; V: side effects to ARC ? ABC</td>
<td>FDA</td>
</tr>
<tr>
<td>Brazil</td>
<td>Building up</td>
<td>V</td>
<td>Local Hospitals + NHP</td>
</tr>
<tr>
<td>RSA</td>
<td>Established/Functioning</td>
<td>V</td>
<td>NHP + MoH</td>
</tr>
<tr>
<td>China</td>
<td>No</td>
<td>?</td>
<td>Local Hospitals, no central structure yet</td>
</tr>
<tr>
<td>India</td>
<td>No</td>
<td>M: TAA - accidents</td>
<td>Drug Control Office</td>
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<tr>
<td>Japan</td>
<td>Established/Functioning</td>
<td>V</td>
<td>Red Cross + MHLW</td>
</tr>
<tr>
<td>Thailand</td>
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<td>Australia</td>
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</tr>
<tr>
<td>New Zealand</td>
<td>No</td>
<td>Planned</td>
<td>?</td>
</tr>
<tr>
<td>Russian Federation</td>
<td>No</td>
<td>M: severe and fatal transfusion reactions</td>
<td>MoH</td>
</tr>
</tbody>
</table>

**Abbreviations:** V = voluntary notification; M = mandatory by law; HC = Health Canada; CBS = Canadian Blood Services; HQ=Héma-Québec; MoH = Ministry of Health; ARC = American Red Cross; FDA = Food and Drug Administration; ABC = America’s Blood Centers; NHP = National Hemovigilance Program; DCO = Drug Control Office; MHLW = Ministry of Health and Welfare, Japan; SCNBC Thai Red Cross = Scientific Committee of the National Blood Center
The address of the site is: www.ehn-org.net, it is protected by a certificate system.

The Home Page of the website (Figure 2) gives access to information on the EHN, contact addresses, the National Menus of the participating countries and the Rapid Alert (protected by password). The general section of each National Menu contains information on the organization of the blood transfusion system as well as detailed data on donors, donations, blood components, etc. The section on hemovigilance contains specific information and data relating to the surveillance system in the selected country. The last section of the National Menu presents news, developments and possible problems in the field of blood transfusion.

**Rapid Alert System (RAS)**

This is an information channel enabling rapid diffusion of important information concerning emerging threats, of whatever kind they may be. It works via fax, e-mail and website (protected domain). The contact person in one member country of the EHN is informed that in his country a problem has emerged, for example through the national hemovigilance system or by other means. This key person analyses the information and decides whether this information should be transmitted to the contact persons in the other countries, members of EHN. 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 to be taken in their country. In the past the RAS has been used on several occasions:

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

**Exchange of Information**

Another objective of the EHN is to favor the sharing of data between member countries concerning the:

- organization of the blood transfusion system with emphasis on hemovigilance
- collection, preparation, usage of blood products
- epidemiology of donors and recipients
- incidents in the context of transfusion.

In order to exchange information and to compare results (for example in relation to hemovigilance), standardization is important. Therefore, it was crucial to find consensus definitions for some of the key parameters.

**The Problems and the Difficulties**

Numerous problems exist concerning hemovigilance at different levels: institutional, regional, national, European/International. None of these problems could not be overcome. In general, there is still a deficit in relation to hemovigilance when it comes to common definitions, terminology, standardized reporting, uniform matrix. With a few exceptions, in Europe there are still organizational problems, funding shortages, unclear mandates, undefined responsibilities, low sensitivity, insufficient training, hesitation to move forward by implementing strong actions.

In several countries across Europe hemovigilance is really established and working. But a national hemovigilance system is not in place in every European country: in some countries it is required by law, officially established but not functioning; in others it is not mandatory by law, yet is nevertheless established, but generating poor results (underreporting).

At the Community level the intention to rely on existing national hemovigilance systems and to coordinate these activities for Community purposes was expressed; up until now no official hierarchic structure in has been in place, and the longer this situation exists the greater the risk that the difference between national systems will widen, making it increasingly difficult to harmonize them.

**Solutions and the Future**

With the European Blood Directive, hemovigilance has become mandatory and therefore an obligatory element of blood safety and quality. The trend is towards comprehensive national systems, designed in order to favor international cooperation and the exchange of information. A strong network in European hemovigilance will be vital. Common definitions, standards, forms, exchangeability of information, rapid alerts and early warnings, etc., will require a strong effort to make them suitable for Community purposes. Mechanisms of corrective and preventive actions at Community level will need to be developed. It would also make good sense to rely on existing European initiatives that have proven to be functional and have generated results, not least because they are working “bottom-up.”
and therefore have valuable input from experts in the field. The players in the blood transfusion chain will see their respective roles valued and their input into the system will quickly grow in importance. The problem of current vigilance systems interfering with blood transfusion needs to be resolved: spinning off or bridging and bundling will be crucial issues when it comes to modern, advanced hemovigilance, especially at the Community level.

Conclusions

Hemovigilance is indispensable when it comes to safety and quality of blood transfusions. In relation to hemovigilance systems, significant differences currently exist worldwide moment in the countries around the world, in terms of definition, organizational schemes, state of development, impact and efficiency, cooperation, etc. Each country should have an established system with national coverage.

Within the EU, the European Blood Directive requires hemovigilance in each Member State: the intention has been shown to rely on existing/building up national systems. In order to ally efforts at the Community level it would make sense to appeal to existing initiatives in this field that have proven that efficient cooperation is possible: the European Haemovigilance Network (EHN) has played a major role in bringing this important matter forward and in developing it into an efficient tool intended to increase safety and quality in European blood transfusion.

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