BASIC CLINICAL AND ORGANISATIONAL REQUIREMENTS FOR AN EFFECTIVE HAEMOVIGILANCE

Umberto Rossi

Foreword

The title and contents of this lecture reflect and summarize the issues discussed during the recent (27/11-1/12/2002) ESTM residential course in Sofia (Bulgaria) [116].

This course was the second "Balkan-European" course, after the good success of the first course last year in Sarajevo [4] and of the subsequent work-meeting of June 2002 in Lecce [93]: representatives from South-Eastern European countries (such as Albania, Armenia, Bosnia-Herzegovina, Bulgaria, Croatia, Greece, Kosovo, Macedonia, Moldova, Montenegro, Romania, Serbia, Slovenia and Turkey) have convened, reported their national situation [1, 8, 9, 35, 43, 61, 62, 65, 67, 68, 109, 119] and discussed about basic problems of clinical transfusion practice in the view to reach a better blood safety [2, 17, 18, 19, 34, 47, 49, 56, 66, 91, 92, 110, 111, 115].

The issues that were dealt with during the course, as necessary prerequisites for an effective haemovigilance, did mainly concern the proper clinical use of blood and the hospital transfusion organisation, following the Directives and Recommendations of the WHO [124, 125, 126, 127, 128] and of the Council of Europe [11, 12, 23, 24, 25].

The course was organised in 6 consecutive sessions:

- Haemovigilance in Europe;
- Haemovigilance and the Blood Transfusion Service;
- Haemovigilance in the clinical administration of blood;
- Haemovigilance in the countries of South-Eastern Europe;
- "Preventive" haemovigilance: Good Clinical Transfusion Practice;
- Special problems of haemovigilance.

The course was coordinated by Paul Strengers, Elizabeth Love, Dina Politis and Toshko Lissitchkov.

The course Faculty included 17 teachers from 11 countries (6 Bulgarians, 2 British, 1 each from Croatia, Greece, Italy, Luxembourg, Macedonia, the Netherlands, Slovenia, Spain and Switzerland) and 13 national reporters: Tatjana Nurka for Albania, Hasija Hadžić for Bosnia-Herzegovina, Svetla Bakalova for Bulgaria, Damir Grgičević for Croatia, Anna Manitsa for Greece, Mazllum Belegu for Kosovo, Milenka Blagoevska for Macedonia, Victor Cojocaru for Moldova, Gordana Rašović for Montenegro, Ligia Burta (on behalf of Florentina Vladareanu) for Romania, Ninoslav Nedeljković for Serbia, Bojana Bizjak (on behalf of Marjeta Potočnik) for Slovenia, and Meral Sönmezoglu for Turkey.

Participants were 67, from 19 European countries: Bulgaria (34), Serbia (7), Macedonia (4), Croatia (3), Romania (3), Moldova (2), Portugal (2), Albania (1), Armenia (1), Bosnia-Herzegovina (1), Czechia (1), Greece (1), Italy (1), Kosovo (1), Latvia (1), Montenegro (1), Russia (1), Slovenia (1) and Turkey (1).

Introduction on clinical transfusion practice

Due to the increasingly frightening problems posed by the HIV/AIDS pandemics, clinical transfusion practice has been largely driven, in many areas of Europe, by feelings of extreme apprehension and fear, surprisingly coexisting with professional attitudes of easy and often unjustified prescription of whole blood and blood components, leading to an astonishing abuse of blood transfusion [5, 10, 42, 52, 53, 59, 102, 120].

The reason for this abuse can be easily found in a rather widespread **ignorance** of the basic principles of **clinical transfusion practice** [7, 79, 84, 121, 124].

The basic knowledge of Transfusion Medicine, unfortunately, still receives very little attention in the medical **undergraduate** curriculum of most European Universities [72, 78, 80, 107].

Some general agreement in the medical profession has been reached, however, on the paramount importance for a good practice of Transfusion Medicine of the four classical **"pillars" of blood safety** [107]: 1) promotion and maintenance of voluntary non-remunerated blood donation, 2) donor testing and prevention of blood-transmissible diseases, 3) rational clinical use of blood components, 4) general organisational measures (including a quality assurance system defined by official guidelines or regulations), concerning also the integration of Transfusion Medicine into the national policies of Public Health and clinical medicine [20, 126].

In many European countries, moreover, medical communities have become increasingly aware that, although basic financial resources are a pre-requisite for constructing any Transfusion Service, what makes blood transfusion **safe** and **effective** is certainly not wealth by itself, but rather political maturity, moral solidarity, cultural development and medical competency: all factors dependent much more on human dedication than on financial prosperity [28].

Responsible voluntary donors, essential blood testing, rational clinical use of blood components: these fundamental bases of blood safety can only be the result of a continuous "education to quality" of the public at large, of school children, University students, general practitioners, medical doctors, transfusion specialists, nurses and technicians, and public officers [37, 39, 54, 84, 99].

The need for education has been recognized by the **European Commission** since **1994**, in its *"**Communication on blood safety and self-sufficiency in the European Community**"*, stating that *"it is extremely important that the confidence of the citizens of the Community is re-established: this can be done by means of a number of measures including appropriate information and education campaigns"*.

The rational bases of transfusion therapy [87, 92, 95]

As any other kind of therapy, transfusion therapy needs to be **"rational"**: based on **scientific data**, fitting into **pathophysiological mechanisms**, and interfering with the "**natural history**" of the given disease to be treated; possibly with its aetiology, often with its pathogenesis, more generally with its symptoms (as a "replacement", or a supportive "therapy").

Further elaborated by **clinical reasonment**, transfusion therapy will finally have to be adjusted to the individual patient by a **clinical decision**, which implies a very well defined medical responsibility.

The spectacular progresses of today's transfusion therapy have been made possible by the use of selected blood components and specific plasma factors, aimed to meet selective recognised needs of individual patients and to avoid possible immunological disadvantages.

The collection and transplantation of stem cells (from bone marrow or from peripheral or cord blood), the administration of erythropoietin, thrombopoietin and artificial haemoglobin substitutes, the first therapeutic effects of immunomodulation: are but a few examples of fast developing fields of therapeutic activity.

As all good therapies, it should be ideally administered only **after** a diagnosis has been made, or at least a sound diagnostic orientation has been taken: the more complete the diagnosis has been established before treatment, the more effective the transfusion therapy will prove.

Transfusion also needs to be looked upon as only **one** of many therapeutic options, to be considered as either fundamental or complementary, in coexistence or in sequence with other forms of therapy (chemotherapy, immunotherapy, surgery, radiotherapy, etc.).

Beneficial effects of transfusion therapy

The **beneficial effects** of transfusion therapy must be envisaged without loosing consideration of some very important pathophysiological concepts [95]:

1) most of the blood cells and plasma constituents are present in more or less large **excess** with respect to the minimum (vital, or functional) requirements;
2) the **bone marrow** can **compensate** very quickly and very efficiently, in normal conditions, any peripheral loss of blood cells;
3) the same applies to the **liver**, concerning loss of plasma constituents;
4) any "passive" transfusion of cells implies a **decrease of "active" cellular production** and a **depression of endogenous synthesis**, which may sometimes not behave as "parallel", but "exceeding" the stimulus;
5) the above "**sparing**" **effects**, while usually to be considered critical (e.g. worsening of anaemia shortly after transfusion), can some times be beneficial (e.g. aminoacids for liver protein synthesis made available through erythroblastic depression of haemoglobin synthesis by transfusion of red cells).

Most of transfusion therapy is addressed to the treatment of haemorrhages, burns, surgery, anaemias (acquired, and hereditary haemolytic), leukaemias and disorders of haemostasis: each of the transfusion problems arising in these clinical situations requires a solution based on the evaluation of the quantitative deficit, of the time required for its appearance, of the intrinsic features of the disease ("quality" and function of the blood cells), and of the clinical status of the patient [95].

A clinical quality control?

It is customary to think of "**quality control**" [92] in terms of discovery and "treatment" of errors which may occur in a product, or in a productive process, leading -in the field of Transfusion Medicine- to a wrong **test result** or to a faulty or imperfect **blood component** [22, 25]. To apply the concept of "quality control" to the free and autonomous decision of the clinician when he sets the **clinical indication** for transfusion, as an end-product of his process of clinical reasonment, may engender surprise.

Similarly, thinking of "**quality assurance**" [21, 22] as the organisation of procedures to assure quality control, and of "**quality management**" [26, 88] as the critical re-assessment and re-organisation of all procedures in order to assure the "prevention" of errors, within the framework of a "quality system", would normally concern test results and blood components, but would be considered difficult (if not eccentric) to apply to clinical indications.

A clinical quality management?

Clinical activity, being personal and complex by its very nature, seems hard indeed to be considered a suitable object for quality control. Everyday's hospital experience, however, strongly suggests to explore this possibility.

How to achieve **a good "quality" of clinical indications** for transfusion therapy? Being conceptually difficult to effectively control the end result (i.e. any given clinical indication once it has already been set), the main focus should be **on the background medical culture** from which clinical indications originate [95, 98, 100]: more than a proper quality "control", therefore, a really preventive **"quality cultural management"** [77, 84, 88].

"Education to quality" of clinical indications

The **"quality" of clinical indications** to transfusion largely coincides with the **"quality" of the prescribing clinician**, which in turn depends on the **quality of his medical curriculum**.

It is essential that the **medical undergraduate curriculum** [53, 82, 94, 103, 105, 107] implies information and "education", for the doctor-to-be, concerning blood donation and blood transfusion, enabling him to become aware of clinical indications of transfusion in his medical practice.

Considering the roles and responsibilities of **nurses** in the medical team-work, a **European curriculum of teaching and training for nurses in Transfusion Medicine** [55, 81, 104] has also been proposed.

A European curriculum of postgraduate specialist teaching in Transfusion Medicine [69, 97, 103] has been proposed and is now available.

According to its definition, *"the specialist in Transfusion Medicine is a medically qualified person, having thorough knowledge and sound experience of **clinical medicine** and **laboratory medicine**, having achieved a specific training in **general haematology, immunology** and **blood transfusion practice**, who is capable of ensuring maximum **efficacy** and **safety** -for the donor and the recipient- for any blood transfusion procedure, who is **responsible** for the **planning** and **organisation** of the collection, preparation, storage, distribution and optimal use of blood and blood products under a controlled scheme of **quality assurance**, who can assist and advise on **any diagnostic and therapeutic problem** of patients requiring transfusion, who is actively participating in **research** and **development**, who is able and willing to **teach Transfusion Medicine further** to doctors, medical students and any other collaborating professionals".*

The **specialist in Transfusion Medicine**, in other words, provides the bridge linking the donor to the patients and allows the patient to receive the best care that the donor can help to give [69, 97].

A good "production" of "quality" transfusion specialists is essential for the adequate running of transfusion therapy, and their **specific competence** is the best guarantee against misuse of blood.

The contribution of the World Health Organization (WHO) to the education to the proper clinical use of blood

One can trace back to **1971** the first contribution of WHO to the organisation and management of Blood Transfusion Services. Since then, fundamental publications have often been produced.

Since 1993, first as Global Programme an AIDS and then as Blood Safety Unit, the WHO Headquarter in Geneva has published excellent educational material [128], caring about its worldwide diffusion and adoption: the ***Distance Learning Material on "Safe blood and blood products"*** ("The Red Book": 5 modules) [128], and ***"The clinical use of blood"*** (open learning module and Handbook) [125, 126, 127].

The European Region of WHO has organised **Workshops** in Annecy (France) on *"The rational, effective, clinical use of blood and blood products: adequate iron store and the "nil nocere" principle in Transfusion Medicine"* on 26-28 February 1998 [99], and on *"The use and abuse of blood and blood products in clinical settings"* on 28-30 January 1999 [79].

The WHO books on the clinical use of blood are the result of a competent expert team work and have been already translated in other languages.

However, as it has been observed and discussed last year during the ESTM course in Sarajevo [4], being **Governments** the obligatory partner Institutions of WHO, not in all countries the information concerning WHO's Transfusion Medicine activities is efficiently flowing. As a result, not in all countries the **outstanding didactic material prepared by WHO** [126, 127] is currently available in the user's hands.

A **side-channel of communication with WHO** could be implemented to this aim by **ISBT, National Societies** and the **ESTM**, to obviate these difficulties and to promote and obtain a full utilisation of WHO's didactic material [39].

Possible educational tools for improvement of good clinical transfusion practice

Little attention has so far been paid, however, to an adequate inclusion of Transfusion Medicine in the **curriculum of other postgraduate clinical specialisations** [70, 97, 108], which still lack a European proposal.

This makes even more important that **Hospital Transfusion Committees** should exist and function, to allow reciprocal "transfusion" -between clinicians and Transfusion Medicine specialists- of ideas, concepts, criteria and programmes.

The **involvement of anaesthesiologists** in the responsibility of surgical indications to transfusion, and their close collaboration in all transfusional problems, have always proved to be an essential requirement for a smooth running of hospital transfusion activities.

The distribution (as a gift by the Transfusion Committee) to clinicians of **books** and **guidelines** (more or less concise according to the estimate of their reading expectancy!) on clinical indications to selective transfusion therapy has also proved a useful tool.

Transfusional "audits", to examine and review **"non-conformities" of clinical indications**, may lead to their improvement.

The development of European haemovigilance [12, 31, 32, 46, 49, 58, 74, 118, 123, 129]

In **October 1995** the European Commission issued a tender for a feasibility study for the establishment of a **haemovigilance network** in the European Community [28].

Proposals (based on information collected until the end of 1996) within the European Union have been presented by the winning team (no formal implementation has taken place so far).

An application to the tender was also submitted by the ESTM [71], thanks to the collaboration of most European National Societies of Transfusion Medicine. Although the submission was not successful, the positive answers of 11 National Societies allowed some useful preliminary information to be collected on existing initiatives on haemovigilance.

Another appeal for further information has been sent on May 1997, originating reports from 14 European countries, most of which were presented at the ISBT European Congress in **Frankfurt** [75] in September **1997**.

After specific sessions during its European Congress of Venezia (1995) [106, 112] and Frankfurt (1997) [75], the ISBT is keeping a keen scientific interest in haemovigilance, that will be again debated at the next ***ISBT European Regional Congress*** in Turkey (Istanbul) in May 2003.

Originally hosted by France (Bordeaux, 1997; Lyon, 1998; Lille, 1999; Montpellier, 2000), the annual *European Haemovigilance Seminar* [29] has taken place in December 2001 [12, 14, 29, 33, 38, 41, 48, 63, 64, 113] in Greece (Athens), the next being scheduled in Amsterdam in February 2003.

In 1998, thanks to the initiative of 5 countries of the European Union (Belgium, France, Luxembourg, Portugal, The Netherlands), the *"European Haemovigilance Network" (EHN)* was born, having among its aims to allow rapid and efficient exchange of reliable information and experience (website: http://www.ehn-org.net) [32, 113].

A satisfactory development of haemovigilance certainly requires the previous fulfilment of a series of very simple requirements, concerning basic clinical care and hospital organisation [10, 13, 36, 83], which have already been recently debated.

The European Haemovigilance Network (EHN) is taking care of this programme, as also recently discussed in its last meeting (December 2001) in Athens [29, 113, 114, 116].

Basic professional and political requirements for an effective haemovigilance

I consider it essential that a **preliminary consensus** should be obtained from people working in the field, through scientific information, national and European consensus conferences, discussions in Congresses (as in Venezia [106, 112] in 1995 and in Frankfurt [75] in 1997) and other occasions (as in the recent ESTM course in Sofia [116], and in the present Slovenian/ESTM course in Portorož).

The **overall evidence** so far arising from the above documentation can be summarised as follows [75, 76, 89, 91]:

1) Many dispositions, initiatives and organizations **already** exist at national levels, born from very different legal or professional situations, that need to be very carefully known and analysed, to limit the tasks of the establishment of an **European haemovigilance network** to the intrinsic proper ones implied by the very word, connecting different settings by a really adaptable modular communication system, avoiding at any rate the risk of creating or imposing a different solution wherever it is already well functioning.

2) For any project of European network to be "feasible", besides its cost and architecture, an essential pre-requisite is to be **acceptable** and easy to implement. For any **implementation**, most of all considering the wide variations in the development of blood transfusion systems existing in Europe, a **preliminary consensus** from the people working in the field (i.e. from the experience of most European National Societies) seems to be essential.

3) Considering the increasing political need of reassuring the public about "adverse events" of blood transfusion being under full control (and unfortunately the corresponding lack of attention on its beneficial effects!), one should absolutely avoid the **risk** that the incoming European legislation on haemovigilance be characterised by an excessive prevalence of "bureaucratic" and over-regulatory aspects, dictated by mostly legal precautions, rather than by a strict adherence to the **scientific** and **medical** contents of our profession.

What haemovigilance should, and should not, be

"**Haemovigilance**" is not yet a well accepted and perfectly understood word; it evokes doubts and uncertainties, its meaning is not perfectly clear to everybody, expectations mingle with fears:

- Is haemovigilance a **basic** need, or a **sophisticated** refinement of blood transfusion?
- Is it a **useful** tool to improve transfusion practice, or maybe a **disposable** luxury?
- Is it an **effective** way to increase transfusion safety, or rather a **cumbersome** obstacle?
- Is it a **straightforward** methodology, or a **complicated** system?
- Does it represent an **economic** measure, or possibly an **expensive** waste?
- Can it be considered a sign of responsible medical **culture**, or simply an expression of **ignorance**?
- Is haemovigilance an organisation of **medical** significance, or the result of a **political** imposition?
- Is it a **technical** improvement, or a **bureaucratic** involution of the Transfusion Service?

- A real **service** to citizens, or a response to **fear**?
- And then, and above all, is haemovigilance **already** present in our daily practice, or has it **still** to come? And from where? Is it for **us**, for our country, now, or mainly for **others**, whenever they like?

One can easily believe that haemovigilance **can be** a basic need, a useful tool, an effective way, a straightforward methodology, an economic measure, a sign of culture full of medical significance, a technical improvement, a real service to citizens, and that -after all- is often already present since a long time.

But one can as well observe that haemovigilance **can also be** a sophisticated refinement, a dispensable luxury, a cumbersome obstacle, a complicated system, an expensive waste, an expression of ignorance, a political imposition, a bureaucratic involution, a response to fear, and that may be better to consider it as still to come.

It **all depends** on whether it keeps strictly adherent to the scientific and medical contents of our profession, or is dictated by political needs of easy reassurance of a badly informed public opinion.

Or whether it is emerging "**from the bottom**", soundly grounded on the professional and ethical responsibility of transfusion specialists working in Blood Transfusion Services, or is imposed "from the top", elaborated by planning and communication experts with no experience in Transfusion Medicine and hospital life.

It also depends, on an European scale, on whether one considers local, regional and national existing realities, or one pretends to ignore the **wide variations** in the development of blood transfusion systems existing in Europe; or whether it is born within national scientific societies or organisations of Transfusion Medicine, or is falling from political authorities with no expert involvement [36, 75, 76, 89, 91].

Basic clinical and organisational requirements for an effective haemovigilance [13, 36, 83, 89, 91, 116]

Specific **tasks** necessary for the implementation of the surveillance of transfusion therapy in hospitals and clinical departments are:

- Definition of basic laboratory and clinical **indications** for the transfusion of blood products.
- System of **ordering** blood products and standardized forms for their request and forms that accompany them. This system must define labels, that have to be put on blood products that have been prepared for the transfusion of a defined patient, and labels that have to be put on withdrawn or recalled blood products.
- Unique **identification** system for the patient, blood product and laboratory results.
- **Collection** of patient blood **samples** and their labelling.
- **Transport** of requests and blood **samples** to the Blood Transfusion Centre.
- **Transport** of blood **products** from the Blood Transfusion Centre to the clinical departments.
- Temporary **storage** of blood products in the required conditions in the clinical departments until they are transfused, or if they are not used, until they are returned to the Transfusion Centre, and responsibility for them.
- **Identification** of the patient and blood product immediately before the transfusion, and comparison of the data obtained from the patient with the data on the blood product and with the results of laboratory testing that are written in the form accompanying the blood product.
- **Monitoring** the transfusion process. Although it is not realistic to expect it to be routinely done, the long-term monitoring of the transfused patient would give us much more information about the outcome of transfusion therapy.
- Documentation of transfusion and its outcome in the **patient medical file**.

- **Report** of the **outcome** of each transfused unit and of the monitoring of each transfusion event.
- The **alert system** involves recording the occurring of adverse events, measuring their prevalence and characteristics, notifying the Blood Transfusion Centre (and with their assistance withdrawal or recall of all blood products produced from the same donor), and notifying other institutions that are mandatory or necessary for prevention of adverse reactions in other patients.
- Return of every **empty blood product bag** after the completion of every transfusion or of every **non-transfused blood product** to the Blood Transfusion Centre.
- Monitoring documentation of **patients state** before and after the end of transfusion, or regularly at defined times during transfusion therapy (general state, blood pressure, frequency of heart beat).
- Documentation of the **blood product**.
- Documentation of the **medical person**, who performed the procedure and was responsible for it, in the patient's file.
- Documentation of each **adverse event** that occurred during or after the transfusion therapy in the patient's file.
- Collection of data on adverse reactions, and analysis, by hospital **Transfusion Committee**.

A "quality-based" haemovigilance?

Although haemovigilance can be properly conceived as a precious tool for improvement of the transfusion system, it is in the interest of the community that the system to be "vigilated" should be **already** originally based on criteria based on **quality management** [21, 26, 73, 91].

Basic concepts inspiring quality management

The **basic concepts inspiring quality management** [73, 91], that are usually understood, possessed and practised by anyone making part of any quality system, can be described as follows:

- general feeling that the results of the system (products, service, etc.) depend on **all** members of the system;
- distribution of jobs and tasks according to the individual role and abilities of **each** member of the system;
- clear **definition of roles** among persons and groups within the system, integrated in a **general frame**;
- awareness of a **personal responsibility** by any member of the system, not conflicting with the acceptance of a variety of different levels of responsibility, and of a higher responsibility for its **coordination**;
- **common desire of improvement** of the efficiency, efficacy and public image of the system;
- understanding of the advantages of **written documentation** of all steps of the personal and common work;
- feeling of initial adequacy, but of the need of personal **continuous improvement** as well, by **every** member of the system;
- awareness of the need of a programmed specific training to **increase personal abilities**, to the general benefit of the system;
- involvement of **all** members of the system to look for and find out "**non-conformities**", to report them, to correct and prevent them;
- increase of **mutual knowledge** between members of the system, improvement of personal relationships, easier acceptance of a **shared discipline**;

- improvement of the **relationships with "customers"** (donors, patients, colleagues) and of their appreciation and respect towards the system;
- gratification from being recognised -whatever the level of competence and responsibility- as "**essential**" to the system;
- feeling of personal satisfaction, and of humble pride, to **belong** to a "quality" system.

How do these basic "quality management "concepts, although unfortunately still not very popular in the clinical environment, coincide with the **concepts presently applied to everyday's work in Blood Transfusion Services** all over Europe [26, 73, 83, 89, 91], and to its wide variety of models of organization and performance?

An analysis of similarities between "quality concepts" and existing "working concepts" may turn out to be quite reassuring and help to conceive haemovigilance more rooted in everyday's work.

Are quality concepts already included in transfusion working concepts?

Most of the "quality concepts" are **already** present, felt and practised in the organisation of Blood Transfusion Services [37, 39, 73, 83, 91].

Quality control in laboratory work and in preparation of blood components, double-check controls in procedures of acceptance of requests and release of results or units, need and acceptance of written documentation in all fundamental steps of blood from the donor to the patient, validation of test results and of units delivery, clear perception of transfusion activities as a team work, frequent consultations of co-workers in common meetings, deep acceptance of the need of continuous education for all the personnel, acquaintance with written rules and service orders for the most delicate sectors of our work: all these are but a few most essential aspects of our already existing behavioural predisposition to be permeated by "quality concepts".

Accordingly, also the **main forms of teaching, learning and training** practised in Transfusion Medicine seem to adequately correspond to the learning requirements imposed by quality systems [73, 83].

Although widely different in their external organizational shape, all Blood Transfusion Services already largely practise -in order to keep and improve their present standards of competences and performances- the following "didactic" behaviours: continuous and self-perpetuating teaching "in the field"; learning to teach by teaching; desire to learn requiring a basic belief (that we don't know enough) and a moral decision (that we want to know more); learning by reading and studying; learning by hearing and by talking and discussing; learning by writing (synthetising, schematising, reporting); learning by working, meaning both by watching and by doing; learning by watching other people doing the things one wants to learn; learning by doing things, being watched by other people.

Most of the **motivations** implied for a **good learning** of quality criteria are already present in most of the personnel of our Services, and are well expressed by the very meaning of the word "watching": which is beyond seeing, looking, noticing; it implies an intellectual trend to perfection, a social desire of interaction, a moral urge to share, a personal feeling of interest and solidarity [73, 83, 89, 94].

Quality **before** haemovigilance?

Can one hope to base on these **already existing basic "quality" behaviours** the future progress of European haemovigilance?

Can one, in other words, succeed to reduce the actual need of haemovigilance as a corrective tool for system improvement by **previously** implementing a **quality-based** transfusion management system?

I firmly believe that this is not only possible, but necessary.

One should not expect from haemovigilance suggestions to correct what can be **already** avoided by quality management of the whole transfusion chain, including - and above all- clinical transfusion practice.

In other words, haemovigilance should be optimally conceived as a **further** tool, for **further** progress, and **not** as an **initial** tool, to discover what should already be known and avoided by quality management: haemovigilance **based** on quality, and **not preceding** -or vicariating- quality!

If this maybe has not always been the story of European haemovigilance in the past, it may well be conceived as a common challenge for scientific and professional engagement of the transfusion community in the **future**.

Proposals for an effective implementation of haemovigilance in Europe, and in South-Eastern European countries

Along these lines, which proposals can be made in order to achieve as early as possible a satisfactory degree of **implementation** of organized and interconnected systems of haemovigilance in all European countries? Which are the pre-requisites for the concrete development of a well functioning haemovigilance **regional** network in the countries of South-Eastern Europe [36, 39, 93, 116]? Which could be the most rewarding lines of action that should be undertaken by transfusion specialists, communities and institutions, by scientific societies, by public health and hospital rulers, by medical directors, by governmental authorities to establish a sound and receptive ground for considering haemovigilance as a valuable tool for medical progress?

The following **proposals** [36, 39, 91] are by no means exhaustive, but could greatly contribute (with much less financial investment than political intelligence and dedication being involved) to implement an effective haemovigilance:

1) Diffusing **Transfusion Medicine basic culture at all medical levels**: undergraduate students, medical and surgical specialists, medical and scientific societies [39].
2) Educating a **sufficient number of Transfusion Specialists** to allow the presence of at least one of them in every hospital [39].
3) Caring that each hospital should have a **functioning Transfusion Committee** [36].
4) Reducing the reasons for the haemovigilance by **good clinical practice**, so introducing a sort of "**preventive" haemovigilance** [10, 93].
5) Establishing a well defined **set of obligatory minimal rules** (request forms, establishment of criteria for the indications of transfusion therapy, definition of parameters that have to be followed up, the assessment of the effect of transfusion therapy, return of empty bags, return of non-used blood products, written report of the outcome of each transfusion event and for each transfused blood bag, etc.) to be observed in every hospital between Transfusion Service and clinical ward [36, 83].
6) Establishing an **adequate information system** in Blood Transfusion Services in every European country, allowing a regional exchange of data and their regional elaboration and diffusion [6, 50, 122].
7) Fostering the participation of Transfusion Medicine and Public Health specialists to **educational courses** on haemovigilance and to the meetings of the **European Haemovigilance Network** [36, 39].
8) In particular, supporting the continuation of the series of the **ESTM "Balkan-European" courses** (the third one foreseen in Belgrade in Autumn 2003, on the contribution of clinical medicine to blood safety), in order to reach as soon as possible the necessary **integration** of Transfusion Medicine in South-Eastern Europe [4, 60, 93, 101, 116].

Conclusions

It has become more and more evident that the «clinical» side of Transfusion Medicine represents nowadays the «pillar» of blood safety which urgently requires the highest degree of professional attention and educational care [3, 10, 15, 16, 44, 45, 51, 60, 93, 117, 121].

Clinical indications to transfusion can be of good quality, both in "high-income" and "low-income" European countries, thanks to some of the above discussed measures, requiring far more medical intelligence and **political responsibility** that financial investments [7, 30, 39, 51, 85, 86, 90, 93]: distribution of guidelines on clinical use of blood to all practitioners and hospital doctors, and adequate performance of Hospital Transfusion Committees.

Any psychological resistance to accept the workload of introducing new "quality" initiatives (as Hospital Transfusion Committees, and at least some forms of basic haemovigilance) in our medical establishment could be easily overcome by considering the very high financial **costs**, moral **unsatisfaction**, and professional **risks** of the "**non-quality**" of clinical transfusion practice, and of their possible disastrous disadvantages [39, 57, 73].

On either side (clinicians and specialists), transfusion therapy must be practised by professionals with **open mind** and **critical attitude**, fully aware of their medical and moral **responsibility**, willing and able to **adjust transfusion therapy to medical progress**, and to adequately profit of the increasing ease of scientific communications and interchange of medical expertise that characterise the world of today.

REFERENCES

1) Bakalova S.: Report on clinical transfusion practice and haemovigilance in Bulgaria. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 141-146. ESTM, Milano, 2002.
2) Bakalova S.: Rationalising the requests of homologous blood to be transfused. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 207-214. ESTM, Milano, 2002.
3) Balint B.: The "quality" (and quality control) of clinical indications to transfusion: an essential key to blood safety. In: Barbara J.A.J., Blagoevska M., Haračić M., Rossi U. (editors): The future of blood safety, a challenge for the whole Europe: how can international regulations be implemented all over. Proceedings of the ESTM course, Sarajevo, Bosnia-Herzegovina, 25-28/10/2001: pp. 117-124. ESTM, Milano, 2001.
4) Barbara J.A.J, Blagoevska M., Haračić M., Rossi U. (editors): The future of blood safety, a challenge for the whole Europe. How can international regulations be implemented all over. Proceedings ESTM residential course, Sarajevo (Bosnia-Herzegovina), 25-28/10/2001. ESTM, Milano, 2001.
5) Barbara J.A.J., Leikola J., Rossi U. (editors): Risk perception and risk assessment in Transfusion Medicine: how to achieve a sound transfusion practice based on scientific truth. Proceedings ESTM residential course, Brussels (Belgium), 26-29/2/2000. ESTM, Milano, 2000.
6) Bayik M., Haračić M., Peres E., Gessoni G., Lai M.: Ideas and proposals for the harmonisation of exchanges of blood components, in normal and emergency situations, in South-Eastern Europe. In: Rossi U., Aprili G. (editors): Present and future problems of Transfusion Medicine in South-Eastern Europe. Proceedings of the SIMTI-ESTM Meeting, Lecce (Italy), 5-6/6/2002: pp. 239-247. Edizioni SIMTI, Milano, 2002.
7) Begović M.: Organisational aspects and clinical indications of transfusion in emergency situations. In: Barbara J.A.J., Blagoevska M., Haračić M., Rossi U. (editors): The future of blood safety, a challenge for the whole Europe: how can international regulations be implemented all over. Proceedings of the ESTM course, Sarajevo, Bosnia-Herzegovina, 25-28/10/2001: pp. 107-115. ESTM, Milano, 2001.
8) Belegu M.: Report on clinical transfusion practice and haemovigilance in Kosovo. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 157-158. ESTM, Milano, 2002.
9) Blagoevska M.: Report on clinical transfusion practice and haemovigilance in Macedonia. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 159-160. ESTM, Milano, 2002.
10) Bogdanović G., Kretschmer V., Walterová L.: Reality and prospects for the rational clinical use of blood in South-Eastern Europe. In: Rossi U., Aprili G. (editors): Present and future problems of Transfusion Medicine in South-Eastern Europe. Proceedings of the SIMTI-ESTM Meeting, Lecce (Italy), 5-6/6/2002: pp. 147-163. Edizioni SIMTI, Milano, 2002.
11) Bopp K.-F.: Analysis and report of Council of Europe's regulations on Transfusion Medicine. In: Barbara J.A.J., Blagoevska M., Haračić M., Rossi U. (editors): The future of blood safety, a challenge for the whole Europe: how can international regulations be implemented all over. Proceedings of the ESTM course, Sarajevo, Bosnia-Herzegovina, 25-28/10/2001: pp. 189-190. ESTM, Milano, 2001.
12) Bopp K.-F.: Council of Europe: Recommendations on Quality Assurance and Haemovigilance. In: Abstracts 4th European Haemovigilance Seminar, Athens, Greece, 12-13/12/2001; pp. 11-14.
13) Brand B.C.: Local, regional and national requirements for an effective haemovigilance organization in Europe. In: Luzzatto L., Brand A., Rossi U. (editors): Laboratory Haematology and Transfusion Medicine in the year 2000: reality and prospects; pp. 383-390. Proceedings ESTM residential course, Castellanza (Italy), 22-25/6/2000. ESTM, Milano, 2000.
14) Brand B.: A comprehensive Haemovigilance system in Switzerland. In: Abstracts 4th European Haemovigilance Seminar, Athens, Greece, 12-13/12/2001; pp. 53-55.
15) Brubnjak-Jevtič V., Rossi U. (editors): "Blood therapy in surgery. Autotransfusion". Proceedings ESTM residential course (2nd postgraduate course on "Blood safety in surgery"), Portorož (Slovenia), 9-11/12/1999. ESTM, Ljubljana, 1999.
16) Brubnjak-Jevtić V., Rossi U. (editors): Safety assurance in blood therapy. Proceedings ESTM residential course (3rd Postgraduate course on "Blood safety and surgery"), Portorož (Slovenia), 14-16/12/2000. Blood Transfusion Centre of Slovenia, Ljubljana, 2000.
17) Cárdenas J.M., Martín-Vega C.: Reaching from the bottom a national haemovigilance network: the Spanish experience. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 197-198. ESTM, Milano, 2002.
18) Castelli D.: The need for proper documentation on the destination and use of blood components. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 115-119. ESTM, Milano, 2002.

19) Castelli D.: History and experience of the haemovigilance in Switzerland. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 193-195. ESTM, Milano, 2002.

20) Castelli D., Genetet B., Habibi B., Nydegger U. (editors): Transfusion in Europe. Proceedings of the First ISBT Regional Congress European Region, Lugano, 7-10/5/1989. ISBT - Arnette, Paris, 1990.

21) Chapman J., Grgièeviæ D. (editors): Quality assurance in Transfusion Medicine. Proceedings ESTM residential course, Dubrovnik (Croatia), 23-26/4/1998. ESTM, Milano, 1998.

22) Council of Europe: Guide to the preparation, use and quality assurance of blood components. Appendix to Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components. ISBN 92-871-2687-9. Council of Europe, 1995.

23) Council of Europe: Recommendation No R(95) 14 on the protection of the health of donors and recipients in the area of blood transfusion, adopted by Committee of Minister on 12 October 1995. Council of Europe, Strasburg, 1995.

24) Council of Europe: Recommendation No R (96) 11 on documentation and record-keeping to guarantee the traceability of blood and blood products especially in hospital. Available from: *Http://www.coe.int/T/E/Social_Cohesion/Health/Recommendations/Rec(1996)11.asp*

25) Council of Europe: Guide to the preparation, use and quality assurance of blood components; 8th edition. Chapter 31: Haemovigilance, pp. 229-234. ISBN 92-871-4770-1. Council of Europe Publishing, Strasbourg, 2002.

26) Emmanuel J.C., Massaro A.L., Vesga M.A., Padilla A.: Organisation and quality management of Blood Transfusion Services. Proceedings ESTM residential course, Sevilla (Spain), 1-3/6/1997. ESTM, Milano, 1997.

27) Engelfriet C.P., Reesink H.W.: Haemovigilance Systems International Forum. Vox Sang, 77, 110-120, 1999.

28) European Commission: The establishment of a haemovigilance network in the European Community: a feasibility project carried out by HAEMAN Consortium. December 1998.

29) 4th European Haemovigilance Seminar, Athens, Greece, 12-13/12/2001. Abstracts.

30) Everaus H.: Clinical importance of blood safety. In: Barbara J.A.J., Sultsmann M.-K., Rossi U. (editors): Detection and prevention of transfusion-transmitted infections. Proceedings ESTM residential course, Pärnu (Estonia), 12-15/9/1998; pp. 117-124. ESTM, Milano, 1998.

31) Faber J.C.: L'hémovigilance en Europe. Transfus Clin Biol, 7, 5-8, 2000.

32) Faber J.C.: Haemovigilance in Europe: the European haemovigilance network. Transfus Clin Biol, 8, 285-290, 2001.

33) Faber J.-C.: Alert systems in haemovigilance and reactovigilance. In: Abstracts 4th European Haemovigilance Seminar, Athens, Greece, 12-13/12/2001; pp. 42-45.

34) Grgičević D.: The role of informatisation in favouring the documentation of the outcome of all delivered units. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 129-131. ESTM, Milano, 2002.

35) Grgičević D.: Report on clinical transfusion practice and haemovigilance in Croatia. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 147-149. ESTM, Milano, 2002.

36) Grgičević D., Rašović G., Brubnjak V., Begović M., Rossi U.: Ideas and proposals to meet basic clinical and organisational requirements for implementing an effective haemovigilance in South-Eastern Europe. In: Rossi U., Aprili G. (editors): Present and future problems of Transfusion Medicine in South-Eastern Europe. Proceedings of the SIMTI-ESTM Meeting, Lecce (Italy), 5-6/6/2002: pp. 249-263. Edizioni SIMTI, Milano, 2002.

37) Hafner V.: Education to quality as an essential prerequisite for the safe practice of Transfusion Medicine. In: Luzzatto L., Brand A., Rossi U. (editors): Laboratory Haematology and Transfusion Medicine in the year 2000: reality and prospects. Proceedings ESTM residential course, Castellanza (Italy), 22-25/6/2000; pp. 407-412. ESTM, Milano, 2000.

38) Hafner V.: Haemovigilance and limited resources: a continuous challenge. In: Abstracts 4th European Haemovigilance Seminar, Athens, Greece, 12-13/12/2001; pp. 49-50.

39) Hafner V., Rossi U.: Ideas and proposals for the improvement of cultural interchanges and European education in Transfusion Medicine in South-Eastern Europe. In: Rossi U., Aprili G. (editors): Present and future problems of Transfusion Medicine in South-Eastern Europe. Proceedings of the SIMTI-ESTM Meeting, Lecce (Italy), 5-6/6/2002: pp. 287-328. Edizioni SIMTI, Milano, 2002.

40) Hafner V., Turek P., Walterová L.: BTS in Central and Eastern Europe in the 90-ties. Lecture at the Symposium "Quality management - European aspects" (11/7/2000), Joint ISBT/DGTI/ÖGBT Congress, Vienna, 9-14/7/2000.

41) Hellenic Coordinating Haemovigilance Centre (SKAE): Epidemiological data on infections in blood donors (1998/1999), serious adverse events associated with blood transfusion (1997-2000). Hellenic Centre for Infectious Diseases Control (KEEL) Publishing, Athens, 2000.

42) Höcker P., Walterová L. (editors): Therapeutic haemapheresis - Diagnosis and treatment of emergencies in haemostatic disorders. Proceedings ESTM residential course, Prague (Czechia), 12-15/11/1998. ESTM, Milano, 1998.

43) Kirova M.: "Transversal" analysis of the basic organisational and clinical regulations for haemovigilance in South-Eastern Europe. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 181-190. ESTM, Milano, 2002.

44) Kretschmer V., Fehérvízyová E., Walterová L. (editors): Use and abuse of blood and blood products. Proceedings ESTM residential course, Bratislava (Slovakia), 6-9/7/2000. ESTM, Milano, 2000.

45) Kretschmer V., Walterová L., Novak V. L., Rossi U. (editors): Blood-sparing medicine and surgery: the absolute need of safe autologous and homologous blood donation. Proceedings ESTM residential course, Lviv (Ukraine), 19-21/9/2002. ESTM, Milano, 2002.

46) Leikola J.: Recent developments in the European Union legislation concerning blood transfusion. In: Barbara J.A.J., Blagoevska M., Haracic M., Rossi U. (editors): The future of blood safety, a challenge for the whole Europe: how can international regulations be implemented all over. Proceedings of the ESTM course, Sarajevo, Bosnia-Herzegovina, 25-28/10/2001: pp. 191-194. ESTM, Milano, 2001.

47) Love E.M.: Hospital Transfusion Committees and their engagement in haemovigilance. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 133-135. ESTM, Milano, 2002.

48) Love E. M., Jones H., Williamson L. M., Cohen H., Todd A., Soldan K., Revill J., Norfolk D. R., Barbara J., Atterbury C.L.J., Asher D. on behalf of the SHOT Steering Group: Haemovigilance and experience of the Serious Hazards of Transfusion (SHOT) Scheme in the United Kingdom (UK). In: Abstracts 4th European Haemovigilance Seminar, Athens, Greece, 12-13/12/2001; pp. 20-29.

49) Love E.M., Jones H., Williamson L.M., Cohen H., Todd A., Soldan K., Revill J., Norfolk D.R., Barbara J., Atterbury C.L.J., Asher D., Chapman C., on behalf of the SHOT Steering Group: Lessons learnt from 5 years of implementation of national haemovigilance systems in Europe. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 17-33. ESTM, Milano, 2002.

50) Lukić L.: The role of informatisation in favouring the feedback from clinical ward to Blood Transfusion Centre. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 127-128. ESTM, Milano, 2002.

51) Lukić L., Brubnjak-Jevtić V., Kremžar B., Rossi U.: Transfusion Medicine and intensive care in surgery. Proceedings ESTM residential course (4th Postgraduate course on "Blood safety and surgery"), Portorož (Slovenia), 13-15/12/2001. Blood Transfusion Centre of Slovenia, Ljubljana, 2001.

52) Mandalaki T., Renieri N., Rossi U. (editors): Optimal use of blood and blood components - Immunohaematology in Transfusion Medicine. Proceedings of the ESTM course, Athens (Greece), 25-26/2/1994. ESTM, Milano, 1994.

53) Martín-Vega C.: Planning of further achievements in the harmonization of Transfusion Medicine teaching in Europe. In: Rossi U., Bar-Shany S.: How to learn Transfusion Medicine. Proceedings of the session jointly organised by the European School of Transfusion Medicine (ESTM), the Israel Society of Haematology and Blood Transfusion and the Mediterranean Blood Club - Jerusalem, 13th May 1993; pp. 51-58. ESTM, Milano, 1995.

54) Martín-Vega C., De Sousa G. (editors): Inmunohematologia/immunohematología de eritrocitos, leucocitos y/e plaquetas. Proceedings 2nd ESTM "Iberic" residential course, Barcelona (Spain), 27-29/11/1998. ESTM, Milano, 1998.

55) Martín-Vega C., Rossi U. (editors): Teaching Transfusion Medicine to nurses. In: Rossi U., Massaro A.L., Sciorelli G. (editors): Proceedings of the ISBT 5th Regional (4th European) Congress (Venezia, 2nd-5th July 1995); parallel session; pp. 1093-1116. European Transfusion Medicine, 1. Edizioni SIMTI, Milano, 1997.

56) Masharova N.: Haemovigilance in emergency transfusion. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 245-249. ESTM, Milano, 2002.

57) Massaro A.L., Rossi U. (editors): Autosufficienza del sangue e dei suoi prodotti: promozione della donazione volontaria; gestione di qualità dei Servizi Trasfusionali. Atti del corso residenziale ESTM - Roma, 17-20 aprile 1997. ESTM, Milano, 1997.

58) McClelland B.: Haemovigilance: concept, Europe and UK initiatives. In: Love E., Scott S., Williamson L.M. (editors). Vox Sang, 74, (suppl. 2), 431-439, 1998.

59) Mempel W., Mercuriali F. (editors): Problems of autologous blood donation and transfusion. Proceedings ESTM residential course, Bled (Slovenia), 8-11/5/1997. ESTM, Milano, 1997.

60) Nakaš B., Skodlar J., Antoncecchi S., Bresolin G., Zucchelli P.: Ideas and proposals concerning the support of governmental and political Institutions to the progress of transfusion organisation in South-Eastern Europe. In: Rossi U., Aprili G. (editors): Present and future problems of Transfusion Medicine in South-Eastern Europe. Proceedings of the SIMTI-ESTM Meeting, Lecce (Italy), 5-6/6/2002: pp. 265-286. Edizioni SIMTI, Milano, 2002.

61) Nedeljković N.: Report on clinical transfusion practice and haemovigilance in Serbia. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 171-174. ESTM, Milano, 2002.

62) Nurka T.: Report on clinical transfusion practice and haemovigilance in Albania. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 139-140. ESTM, Milano, 2002.

63) Politis C. (editor): Epidemiological data on infections in blood donors (1998-1999). Serious adverse events associated with blood transfusion (1997-2000). Hellenic Centre for Infectious Diseases Control (KEEL) - The Hellenic Co-ordinating Haemovigilance Centre (SKAE). Athens, October 2001.

64) Politis C.: Hellas: developing a National Network for Haemovigilance. In: Abstracts 4th European Haemovigilance Seminar, Athens, Greece, 12-13/12/2001; pp. 30-36.

65) Politis C.: Report on clinical transfusion practice and haemovigilance in Greece. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 151-156. ESTM, Milano, 2002.

66) Politis C.: Haemovigilance in the transfusion follow-up of thalassaemia patients. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 271-278. ESTM, Milano, 2002.

67) Potočnik M.: Report on clinical transfusion practice and haemovigilance in Slovenia. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 175-176. ESTM, Milano, 2002.

68) Rasović G.: Report on clinical transfusion practice and haemovigilance in Montenegro. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 161-164. ESTM, Milano, 2002.

69) Rossi U.: Proposal of a recommended minimum European curriculum of post-graduate teaching of Transfusion Medicine based upon the 1984-1985 Council of Europe's document. In: Rossi U., Cash J.D. (editors): Teaching and education in Transfusion Medicine. Proceedings of the main Session on 15th October 1991 at the ISBT 3rd Regional (2nd European) Congress in Prague; pp. 19-33. ISBT-SIITS-AICT, Milano, 1992.

70) Rossi U.: Introduction about the ESTM: why and what for? In: Van Aken W.G., Burnouf T.: Production and clinical use of plasma fractions. Proceedings of the ESTM residential course - Tours, 15th-18th November 1995: pp. 1-3. ESTM, Milano, 1995.

71) Rossi U.: Application to the European Commission for a feasibility project for the establishment of a haemovigilance network in the European Community (95/S 194-69094/EN) presented on behalf of the ESTM (European School of Transfusion Medicine). Milano, 1995.

72) Rossi U.: Introduction on the ESTM: a quality School for a quality Transfusion Medicine? In: Emmanuel J.C., Massaro A.L., Vesga M.A., Padilla A. (editors): Organisation and quality management of Blood Transfusion Services. Proceedings ESTM residential course organized with the assistance of the WHO Blood Safety Unit and Biological Unit and in collaboration with Sociedad Española de Transfusión Sanguínea (SETS), Sevilla (Spain), 1-3/6/1997; pp. 1-15. ESTM, Milano, 1997.

73) Rossi U.: Basic aspects of the training of the personnel in the frame of the general quality systems of BTS. In: Emmanuel J.C., Massaro A.L., Vesga M.A., Padilla A.: Organisation and quality management of Blood Transfusion Services. Proceedings ESTM residential course, Sevilla (Spain), 1-3/6/1997; pp. 171-174. ESTM, Milano, 1997.

74) Rossi U.: Problemi e prospettive dell'organizzazione di un sistema di "emovigilanza" in Europa e in Italia. In: De Stasio G., Rossi U. (editors): Sicurezza del sangue e dei suoi prodotti; emovigilanza: indicazioni cliniche alla trasfusione. Atti del Corso residenziale ESTM - Roma, 26-29 giugno 1997; pp. 89-92. ESTM, Milano, 1997.

75) Rossi U.: Problems and perspectives of haemovigilance in Europe. ISBT 5th European Regional Congress, Frankfurt, 1-4/10/1997. Book of Abstracts.

76) Rossi U.: Europe and haemovigilance. Opening lecture at the National Meeting on Haemovigilance, organized by the Coordinating Haemovigilance Centre of the 3rd Regional Blood Transfusion Centre, Athens (Greece), 12/12/1997.

77) Rossi U.: The quality control of clinical indications for transfusion therapy. In: Chapman J., Grgičević D. (editors): Quality assurance in Transfusion Medicine. Proceedings ESTM residential course, Dubrovnik (Croatia), 23-26/4/1998; pp. 287-295. ESTM, Milano, 1998.

78) Rossi U.: The European School of Transfusion Medicine (ESTM): a report on seven years' experience (1992-1999). Special plenary lecture (12 November 1999) at the ISBT 10th Regional Congress, Western Pacific Region, Taipei (Taiwan), 11-14/11/1999. Abstract Book, SL, pp. 47-50.

79) Rossi U.: The contribution of the ESTM to the rational, effective use of blood and blood products and to the "quality" of clinical indications for transfusion therapy. Lecture at the WHO/EURO "Third Workshop on the use and abuse of blood and products in clinical settings" (Annecy, France, 28-30/1/1999). Report on a WHO Workshop; p. 12. European Health 21, Target 16. WHO, Copenhagen, 2000.

80) Rossi U.: ESTM and Transfusion Medicine teaching in Europe. Lecture at the Symposium "Quality management - European aspects" (11/7/2000), Joint ISBT/DGTI/ÖGBT Congress, Vienna, 9-14/7/2000.

81) Rossi U.: Basic requirements for an effective education of nurses and technicians in Transfusion Medicine. Opening lecture, First National Congress of the Blood Banks and Transfusion Society of Turkey, Ürgüp (Turkey), 24-29/9/2000.

82) Rossi U.: Blood safety: The impact of the medical care of blood donors and of the quality of clinical indications. Lecture, 1st Congress of Macedonian Society of Transfusion Medicine, Ohrid (Macedonia), 10-13/10/2000. In: Book of Abstracts, ISSN 0025-1097, pp. 8-12. Mak. Med. Pregled., 54, (suppl. 46), 2000.

83) Rossi U.: Basic requirements for an effective haemovigilance. Salzburg Cornell Blood Banking Seminar, American-Austrian Foundation, Salzburg, 25/11-1/12/2001.

84) Rossi U.: Improving the clinical nature of Transfusion Medicine: the quality control of clinical indications to transfusion. Salzburg Cornell Blood Banking Seminar, American-Austrian Foundation, Salzburg, 25/11-1/12/2001.

85) Rossi U.: Lessons learnt from an ESTM residential course on "The future of blood safety, a challenge for the whole Europe" (Sarajevo, Bosnia-Herzegovina, 25-28 October 2001). In: Martini M. (editor): HIV/AIDS. Prevention and care among mobile groups in the Balkans. Part I, January 2002; pp. 155-162. ISBN-92-9068-120-9. IOM, Rome, 2002.

86) Rossi U.: The European dimension of Transfusion Medicine: present and future in South-Eastern Europe. Lecture, 2nd International Thalassemia Summerschool, Kyrenia/North Cyprus, 1-5 April 2002. Proceedings; pp. 153-174.

87) Rossi U.: Rational bases of transfusion therapy. Lecture at the 3rd Summer School on Intensive Care Medicine, Brijuni (Croatia), 20-24/6/2002.

88) Rossi U.: Quality control of clinical indications for transfusion. Lecture at the 9th Symposium on Intensive Care Medicine, Brijuni (Croatia), 24-27/6/2002. Neurol. Croat., 51, (Suppl. 3), 61-71, 2002.

89) Rossi U.: Haemovigilance as a tool for progress in Transfusion Medicine. In: Kretschmer V., Walterová L., Novak V.L., Rossi U. (editors): Blood-sparing medicine and surgery: the absolute need of safe autologous and homologous blood donation. Proceedings ESTM residential course, Lviv (Ukraine), 19-21/9/2002; pp. 281-287. ESTM, Milano, 2002.

90) Rossi U.: Safe blood: an absolute or relative duty? Plenary lecture, 2nd Yugoslav Congress of Transfusion Medicine (Beograd, 30/10-1-11/2002). Bilt. Transf., 48, (1-2), 26-46, 2002.

91) Rossi U.: Haemovigilance based on quality: a challenge for scientific and professional engagement. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 35-44. ESTM, Milano, 2002.

92) Rossi U.: The quality control of clinical indications to transfusion. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 227-237. ESTM, Milano, 2002.

93) Rossi U., Aprili G. (editors): Present and future problems of Transfusion Medicine in South-Eastern Europe. Proceedings of the SIMTI-ESTM Meeting, Lecce (Italy), 5-6/6/2002: pp. 329-334. Edizioni SIMTI, Milano, 2002.

94) Rossi U., Bar-Shany S. (editors): How to learn Transfusion Medicine. Proceedings of the session jointly organised by the European School of Transfusion Medicine (ESTM), the Israel Society of Haematology and Blood Transfusion and the Mediterranean Blood Club - Jerusalem, 13th May 1993. ESTM, Milano, 1995.

95) Rossi U., Biagiotti S., Chianese R.: Rational basis of transfusion therapy. In: Duguid J.K.M., Stathopoulou R., Mandalaki T.: Paediatric Transfusion. Proceedings of the ESTM residential course - Athens, 28th February - 1st March 1997; pp. 119-132. ESTM. Milano, 1997.

96) Rossi U., Cash J.D. (editors): Teaching of Transfusion Medicine. Proceedings of the First SIITS-AICT Symposium for European Cooperation - Cernobbio, 1st October 1990. SIITS-AICT, Milano, 1991.

97) Rossi U., Cash J.D. (editors): Teaching and education in Transfusion Medicine. Proceedings of the main session of the 3rd ISBT Regional (2nd European) Congress - Prague, 15th October 1991. SIITS-AICT, Milano, 1992.

98) Rossi U., Hafner V.: Increasing transfusion safety through education to quality and adequate blood testing. Lecture at the 4th OCD Romanian meeting (Sinaia, 11-13/12/1997). Journal of Fundeni Hospital, under publication .

99) Rossi U., Hafner V.: Adequate use of blood and blood products. Lecture of the WHO/EURO "Workshop on the rational, effective, clinical use of blood and blood products: adequate iron stores and the "nil nocere" principle in Transfusion Medicine" (Annecy, France, 26-28/2/1998). Trasf. Sangue, 43, (6), 323-336, 1998.

100) Rossi U., Hafner V.: Increasing blood safety through education to quality. In: J.A.J. Barbara, M.-K. Sultsmann, U. Rossi (editors): Detection and prevention of transfusion-transmitted infections. Proceedings ESTM residential course, Pärnu (Estonia), 12-15/9/1998; pp. 243-256. ESTM, Milano, 1998.

101) Rossi U., Haračić M., Blagoevska M., Barbara J.A.J.: Transfusion Medicine in the Balkans: an essential part of European Transfusion Medicine. In: Barbara J.A.J., Blagoevska M., Haračić M., Rossi U. (editors): The future of blood safety, a challenge for the whole Europe: how can international regulations be implemented all over. Proceedings of the ESTM course, Sarajevo, Bosnia-Herzegovina, 25-28/10/2001: pp. 1-13. ESTM, Milano, 2001.

102) Rossi U., Kretschmer V., Walterová L., Novak V.L.: Transfusion Medicine: from abuse and fear to quality and safety *(how to transfuse as little, as safe and as useful as possible)*. In: Kretschmer V., Walterová L., Novak V.L., Rossi U. (editors): Blood-sparing medicine and surgery: the absolute need of safe autologous and homologous blood donation. Proceedings ESTM residential course, Lviv (Ukraine), 19-21/9/2002; pp. 3-5. ESTM, Milano, 2002.

103) Rossi U., Marcu I., Martín-Vega C.: Bilancio delle attività della Regione Europea della ISBT (International Society of Blood Transfusion) per il raggiungimento di un curriculum europeo di specializzazione e di insegnamento in Medicina Trasfusionale. Abstact, 32° Convegno Nazionale SIMTI (Taormina, 25-29/5/1996).

104) Rossi U., Martín-Vega C.: Proposal of a recommended minimum European curriculum of teaching Transfusion Medicine for nurses. In: Rossi U., Massaro A.L., Sciorelli G. (editors): Proceedings of the ISBT 5th Regional (4th European) Congress (Venezia, 2nd-5th July 1995); pp. 1106-1116. European Transfusion Medicine, 1. Edizioni SIMTI, Milano, 1997.

105) Rossi U., Martín-Vega C., Seyfried H.: Proposal of a common minimum European curriculum for Transfusion Medicine teaching to undergraduate medical students. In. Rossi U., Seyfried H. (editors): Teaching of Transfusion Medicine to undergraduate medical students. Proceedings of the symposium of the 4th ISBT Regional (3rd European) Congress - Barcelona, 15th June 1993; pp. 47-63. ISBT-SETS-SIMTI, Milano, 1995.

106) Rossi U., Massaro A.L., Sciorelli G. (editors): Proceedings of the ISBT 5th Regional (4th European) Congress Venezia, 2-5/7/1995. European Transfusion Medicine, 1. Edizioni SIMTI, Milano, 1997.

107) Rossi U., Seyfried H. (editors): Teaching of Transfusion Medicine to undergraduate medical students. Proceedings of the symposium of the 4th ISBT Regional (3rd European) Congress - Barcelona, 15th June 1993. ISBT-SETS-SIMTI, Milano, 1995.

108) Rossi U., Walterová L. (editors): Transfusion Medicine, Haematology and Clinical Pathology. Proceedings of the ESTM residential course. Prague, 25th-28th April 1996. ESTM, Milano, 1996.

109) Sönmezoglu M.: Report on clinical transfusion practice and haemovigilance in Turkey. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 177-180. ESTM, Milano, 2002.

110) Starbova M.: Haemovigilance in autologous blood donation and transfusion. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 263-269. ESTM, Milano, 2002.

111) Strengers P.F.W.: The need for rational clinical indications to transfusion in clinical care. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 203-205. ESTM, Milano, 2002.

112) Strengers P.F.W.: Haemovigilance, an important method to improve Transfusion Medicine. In: Rossi U., Massaro A.L., Sciorelli G.: Proceedings of the ISBT 5th Regional (4th European) Congress, Venezia (Italy), 2-5/7/1995; pp. 954-959. Edizioni SIMTI, Milano, 1997.

113) Strengers P.F.W.: The website of EHN: two zones on information and a window of messages. In: Abstracts 4th European Haemovigilance Seminar, Athens, Greece, 12-13/12/2001; pp. 46-48.

114) Strengers P.F.W.: What is haemovigilance? The European Haemovigilance Network (EHN). In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 3-6. ESTM, Milano, 2002.

115) Strengers P.F.W., Faber J.-C., Salpeteur Ch.: Haemovigilance in clinical care: uniform reporting form for serious adverse events. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 109-113. ESTM, Milano, 2002.

116) Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002. ESTM, Milano, 2002.

117) Todd A.A.M., Rossi U. (editors): Current problems of Transfusion Medicine in clinical practice. Proceedings ESTM residential course jointly organized with the Ministry of Health of Russian Federation and the Research Institute of Paediatric Haematology of Moscow, St. Petersburg (Russia), 6-8/9/1993. ESTM, Milano, 1993.

118) Van Aken W.G.: Safety monitoring and epidemiological surveillance of blood transfusion in Europe. Trans Clin Biol, 1, 13-15, 1995.

119) Vladareanu F., Dobrota A.M.: Report on clinical transfusion practice and haemovigilance in Romania. In: Strengers P.F.W., Love E.M., Politis C., Lissitchkov T. (editors): Basic clinical and organisational requirements for an effective haemovigilance. Proceedings ESTM residential course, Sofia (Bulgaria), 28-30/11/2002; pp. 165-169. ESTM, Milano, 2002.

120) Voljć B., Rossi U.: Reality and prospects for the general organisation of Transfusion Medicine Services in South-Eastern Europe. In: Rossi U., Aprili G. (editors): Present and future problems of Transfusion Medicine in South-Eastern Europe. Proceedings of the SIMTI-ESTM Meeting, Lecce (Italy), 5-6/6/2002: pp. 95-116. Edizioni SIMTI, Milano, 2002.

121) Walterová L.: Overview of clinical indications and optimal use of blood components: the role of Hospital Transfusion Specialist and Transfusion Committee. In: Barbara J.A.J., Blagoevska M., Haračić M., Rossi U. (editors): The future of blood safety, a challenge for the whole Europe: how can international regulations be implemented all over. Proceedings of the ESTM course, Sarajevo, Bosnia-Herzegovina, 25-28/10/2001: pp. 99-105. ESTM, Milano, 2001.

122) Walterová L., Lukiæ L., Prinoth O., Rossi D.: Ideas and proposals for the informatisation of Blood Transfusion Services, and for the implementation of ISBT 128 for labeling blood components, in South-Eastern Europe. In: Rossi U., Aprili G. (editors): Present and future problems of Transfusion Medicine in South-Eastern Europe. Proceedings of the SIMTI-ESTM Meeting, Lecce (Italy), 5-6/6/2002: pp. 221-238. Edizioni SIMTI, Milano, 2002.

123) Williamson L., Cohen H., Love E. et al.: The serious hazards of transfusion (SHOT) initiative: The UK approach to Haemovigilance. Vox Sang, 78, 291-295, 2000.

124) World Health Organization (Global Programme on AIDS), League of Red Cross and Red Crescent Societies: Guidelines for the appropriate use of blood. Geneva, 2-5 May 1989. Global Blood Safety Initiative, WHO/GPA/INF/89.18. WHO/LAB/89.10.

125) World Health Organization, Blood Safety Unit: Developing a National Policy and Guidelines on the Clinical Use of Blood. Recommendations. WHO/BLS/98.2. WHO, Geneva, 1998.

126) World Health Organization: The Clinical Use of Blood in Medicine, Obstetrics, Paediatrics, Surgery and Anaesthesia, Trauma and Burns. WHO/BTS/99.2. WHO, Geneva, 2001.

127) World Health Organization, Blood Transfusion Safety: The Clinical Use of Blood: Handbook. WHO/BTS/99.3. ISBN 92-4-154538-0. WHO, Geneva, 2001.

128) World Health Organization, Blood Safety and Clinical Technology: Strategy 2000-2003. WHO, Geneva, 2001.

129) Zamora de Pedro C., Ibarra A., Blanco Peris C., Jurado L., Aramburu E.: El camino hacia la instauracion de un sistema de Hemovigilancia en Espana. Boletin SETS, 4, (42), 15-17, 2001.