The urgent need of mutually compatible criteria and behaviour for blood safety in Europe

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It has become increasingly clear, in the last years, that the series of measures concerning blood donation and transfusion, taken by several governments in Western European countries, have been largely dictated by **fear** of transfusion-transmissible diseases (TTD) in the **general public**: this fear, transfused to **politicians**, has generated an **even deeper fear**, of possibly being criticised -and politically blamed- for not having done enough to protect the population from TTD [57, 62]. Both fears have been favoured by **lack of proper information** in the schools and universities, by the prevailing episodic or "scandalistic" attitude of large part of the media: that **receiving a blood transfusion is today by far one of the safest medical procedures in Western Europe**, would sound new and be hardly believable for many a European Union citizen! [12, 110, 137] Transfusion has been more often looked upon as a negative procedure, against which to defend our life, rather than a positive act under well established criteria.

The **"principle of precaution"** [12, 39, 48, 110], implying that no already available scientific evidence of danger should be necessary to justify preventive measures (legitimated unless scientific evidence of lack of danger should be available), has gained wide popularity in the world of decision-makers.

Two equally dangerous risks are facing Europe since some time: the "**overdramatization**" [110, 111] (in "developed") and the "**underestimation**" [42, 43] of transfusion risks (in "developing" countries).

We see how easy it is to increase expenditures for blood safety, and we are approaching in Western Europe the point, where **homologous transfusion could become one of the most expensive medical procedures** [62, 137] and absorb an incredible part of our public health economies.

Besides the risk of **transfusion-induced bankrupt** of our public health systems, many more are the **risks originated by "overdramatization"** [110]: the risks of ignorance, of social anxiety, of commercial slavery, of decisional mimicry, of bureaucratic regulatory strabism, of increasing political discrepancies from country to country, of international disharmonies in transfusion treatment, of decreasing voluntary donors and social solidarity, of emotional refusal of transfusion therapy by critically ill patient, of disaffection and disappearance of Transfusion Medicine specialists, to be regarded by now like an endangered species.

Efforts should be made to understand the **real dimensions of transfusion risks, as compared with all other possible risks**: not only viral transfusion risk, but all other risks involved in our profession; and the risks of life and death, of peace and war, of health and diseases, of joy and sorrow; and the risk of not being aware of risks, and not being able to properly face them [12].

On the other side, in "developing" countries, the "underestimation" of transfusion risks (often bound to a fatalistic political attitude and to a helpless professional behaviour) is at the origin of an even larger diffusion of TTD, leading sometimes to a further, unforgivable, risk: that **expensive technological investments could absorb the available financial resources**, in a well meant effort to "keep up" with richer countries: honestly believing this is the best and quickest way to reach the target of a nation-wide safe blood; but also leaving no money for **essential investments** in **promotion of voluntary blood donation**, in **education of donors**, in **information of the**

public, in **training of Transfusion Medicine specialists**, in **rational and economic organization of Blood Transfusion Services**, which are **far more important basic requirements** for building up a safe Transfusion System [23, 55, 65, 116, 118, 131, 151].

Basic requirements for an acceptable safety of blood donation and Transfusion Medicine in Europe

It has been observed that legal and ethical issues, in our profession, are often perceived as **theoretical** and somehow **abstract** prescriptions, sometimes ignoring real problems and therefore difficult to be entirely observed, hardly answering to the needs of professional practice most of all in countries with limited resources.

Legal and ethical definitions are related to historical **periods** and to different **areas** of the world, and partly depend on **criteria** such as cultural background, traditional lifestyle, religious influences, political evolution.

To our aims, we need to specify their pertainance to an **historical** period (year 2000, beginning of the third millennium, 10 years after the fall of the Berlin wall) and to a **geographical** extension (our new broad Europe, as part of the world's global village).

Law and **ethics** may well be conceived as **complementary**, both aiming at regulating social and political life so as to ensure the respect of individual rights and the achievement of the highest social welfare [17, 120]. They exist in order to be applied, they must be applicable, and the measure of their value is also the degree of their **application**. They are at the origin of some cultural, social, political and professional criteria, leading to a series of **basic requirements**, all of them essential to build up an **acceptable safety of blood donation and Transfusion Medicine**, **today** and in the **future**, in all our **countries** and in the whole of **Europe** [120]:

1) A clear definition of what is meant by the medical **specialization in "Transfusion Medicine"** and the existence in the country of a sufficient number of dedicated **Transfusion Medicine specialists**.
2) The presence of a **minimum core of Transfusion Medicine competence** in the cultural background of general **doctors** and other specialists, of **nurses** and **technicians**.
3) A well functioning organization of **voluntary donation**, within the national system of public health and hospital assistance, with adequate consideration of **donors medical care**.
4) A general feeling of belonging to a **national**, but also to an **international (European) medical and transfusional community**.
5) A proper cultural approach to **blood safety** and **risk management**.
6) A widespread application of "**quality**" **principles**, in the frame of a quality management, to the national organisation (central and peripheral) of Transfusion Medicine.

I will try to analyse how these requirements have been fulfilled, so far, in Europe, thanks to the contributions of the **international** and **European Institutions** [17, 31, 32, 36, 47, 74, 150, 153, 154, 155, 157, 158], some **National Societies** [13, 88, 90, 113, 125, 127, 130, 141, 149], the **ISBT** (International Society of Blood Transfusion) [25, 53, 54, 126, 136, 149, 145] and the **ESTM** (European School of Transfusion Medicine) [95, 107, 114, 115, 122], firmly convinced that, for each of them, European harmonization is an absolute condition for an improvement of blood safety all over Europe.

Definition of Transfusion Medicine as an autonomous speciality

Already at the first International Blood Transfusion Congress, held in Rome in September **1935**, the Congress President Professor Leone Lattes expressed the need for *"... discussions among researchers of different and multifold experiences, in a field that in some big countries has become* **a veritable medical speciality** *..."* [60].

After the brutal interruption of the second world war, during an "extraordinary session" of the third International Blood Congress in **Turin** in **1948**, at which SIBT was reconstituted, the Congress listed, among its *"accepted wishes"*, that "**in all countries should the theoretical and practical teaching of blood transfusion and of related subjects be organized**".

In June **1963** the **Council of Europe (CE)** issued some "**Recommendation on instruction in blood transfusion**" [29], followed in March **1985** by a **Recommendation including a "model curriculum for the training of specialists in blood transfusion**" [32]. The CE's recommendation was rather poorly implemented by member countries [125]. Neither the Directives issued in June **1975** by the **European Community (EC)** [28], concerning the reciprocal recognition of diplomas and certificates of specialist doctors, nor its amendments and addenda issued in the following years, ever included blood transfusion as a speciality.

The subject of specialist training had received some attention at the 1st **ISBT** Regional European Congress in **Lugano**, in **May 1989** [25], during a session on "**Training and education**". Further progress was made at the 1st SIITS-AICT Symposium for European Cooperation in **Cernobbio** (attended by representatives of 21 European countries), in **October 1990** [125], on "**Teaching of Transfusion Medicine**", aiming *"to verify and discuss the teaching of immunohaematology and transfusion therapy in Europe, starting with the training programme proposed in the 1984-1985 document of the Council of Europe"*. Its validity was accepted but the need for some reshaping of its contents was recognised. The recent European socio-political developments, leading to a broader-based Europe, were also taken into account.

More **problems** had emerged recently and had to be faced in the world of blood transfusion: prevention of blood-transmittable viral diseases, autologous transfusion, cryopreservation, therapeutic haemapheresis, bone marrow donation and transplantation, tissue banking, forensic haemogenetics, massive transfusions, information technology and data processing, etc. [84]. "**Blood Transfusion**" or "**Transfusion Medicine**"?, first of all. Was this choice just a matter of semantic preference, or maybe a fashion, or did it imply a more meaningful **definition** of the contents of our discipline and of its boundaries with other neighbouring medical disciplines [84, 125]?

As a result of these endeavours, a "**Proposal of a recommended minimum European curriculum of post-graduate teaching of Transfusion Medicine based upon the 1984-1985's Council of Europe's document**" [85], aimed at *"the development of nationally recognised training programmes which may -subsequently- find international recognition of their degrees and diplomas in Europe"* [32], has been discussed, amended and defined, by the European transfusional community, during the main session on "**Teaching and education in Transfusion Medicine**" [126] at the 3rd **ISBT** Regional (2nd European) Congress in **Prague**, on **15th October 1991**, with the critical participation of representatives of the Council of Europe and of the European Community; has received the **scientific consensus of the 1991 ISBT European Congress**; has been **proposed by the ISBT to the Council of Europe**, and has been **positively evaluated by its Committee of Experts** in Blood Transfusion and Immunohaematology in **May 1992**.

The **proposal** has been later proposed **to the European Community (EC)**, as a term of reference for evaluation of any future national curriculum, and for official recognition of "**Transfusion Medicine" as a "new" speciality**, reciprocally recognizable between member States, according to the 1975 EC Directives [28, 126]. The implementation of a "**free circulation" of Transfusion Medicine specialists** within the European Union would imply several possibilities of stages and work in other countries, with a very meaningful result of mutual professional training and a progressive levelling of national differences.

A bilingual (English and French) **training course on Blood Transfusion** (coordinated by Prof. W.G. Van Aken and Prof. B. Genetet [150]), started in 1994/95, in form of an interactive distance-learning course, handled by the CNED (National Centre for Distance Education), with a final examination by the Strasbourg University and the issue of a **diploma validated by the Council of Europe**. The course has been unfortunately discontinued, but this initiative could well be conceived as a "core" of a future unified **European diploma of specialisation in Transfusion Medicine** [3, 112].

The Transfusion Medicine specialist

The core of the above proposal [84] lies in the following **definition of a Transfusion Medicine specialist**: *"the specialist in Transfusion Medicine is a medically qualified person, having a 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 to ensure a maximum of* **efficacy** *and* **safety** *-for the donor and for the recipient- for any procedure of blood transfusion, 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** *and who is able and willing to* **teach Transfusion Medicine further** *to doctors, medical students and any other collaborating professionals".*

In other words, the Transfusion Medicine specialist is the physician who provides the **bridge** linking the donor to the **patient** [126] and allowing the patient to be best helped by the donor.

Transfusion Medicine teaching to undergraduate medical students

The **1963** Council of Europe's "**Recommendation on instruction in blood transfusion**" [29], it was recommended *"that each Government should consider including* **courses of instruction for medical students**".

While it was quite obvious that "the **national framework for the professional training**" of medical students should have been represented in every member country by the University system, alone or in conjunction with the **Blood Transfusion Service** national organization, it became increasingly evident that little attention was paid to the teaching of **undergraduate** medical students, suffering from wide European variations [84].

Also the interest of the **WHO's** "Global blood safety initiative" **(GBSI)** on the training needs in Transfusion Medicine [157, 158] was not specifically directed to the problems of **undergraduate** teaching.

The **marked differences in the organisation of medical teaching in member**

states, in fact, made it difficult to envisage a common frame in which the teaching of Transfusion Medicine to medical students could be given, at least before a certain European harmonisation of the post-graduate teaching for specialist formation could have been attained. The next logical step [81, 84, 135] did therefore appear to be the discussion of Transfusion Medicine teaching to undergraduate medical students [140], aiming at defining the desired level of necessary competence by medical doctors, during the 4th Regional European Congress of the ISBT in Barcelona, in 1993, leading to a "Proposal of a common minimum European curriculum for Transfusion Medicine teaching to undergraduate medical students" [135].

The training of nurses and technicians in Transfusion Medicine

In the 1963 Council of Europe's "Recommendation on instruction in blood transfusion" [29], it was considered *"that... nurses... have to carry* heavy responsibilities related to blood transfusion practice*"*, and it was recommended *"that each Government should consider including* courses of instruction *for... b) nurses and midwives; c) laboratory technicians;* ...within the national framework for the professional training *of these categories of staff..."*.

Moreover, in the Council of Europe's Agreement on the training of nurses [30], signed in Strasbourg on 25/10/1967, it was clearly indicated that the theoretical and technical teaching should include "theory of blood transfusion" and the clinical training should concern "all aspects... of treatment by blood transfusion", including organisation of services and laboratory practice.

After the very limited number of observations obtained at the European meetings of Lugano (1989) [25] and Cernobbio (1990) [125], efforts were made in the ISBT European Congress of Prague (1991) [84, 126] to receive information on the training of nurses and technicians working in Transfusion Medicine in Europe; a report from a representative of the ICN (International College of Nurses) originated discussions as to whether, and how, subjects and programmes could be defined and included in a common integrated European proposal of training for nurses [92, 126]. In the meantime, some National Transfusion Medicine Societies had started organising satellite courses for nurses and technicians during their scientific Congresses, in the firm belief that they are an essential part of the team work in Transfusion Medicine.

This preliminary work of analysis, in the years from 1989 to 1993, suggested a further study of the problem, during a session of the ISBT European Congress of Venezia in 1995, leading to a "proposal of a recommended minimum European curriculum of teaching Transfusion Medicine for nurses" [134], based on a proper basic teaching during the 3 nursing school years, and the organisation and recognition of a specific competence, through a well designed system of accreditation certificates, for nurses having acquired experience in Transfusion Medicine.

The situation of voluntary blood donation

Voluntary, non-remunerated blood donation is a precious heritage of pride for many European countries [82, 130]. The first Association (AVIS) was founded in Milan (Italy) in May 1927; the French Federation in 1949 (reorganized in 1972), several others followed. Independent blood donors Associations (or "Federations", or "Unions") exist nowadays in many European countries. In 1955 in Luxembourg the International Federation of Blood Donors Organizations (IFBDO-FIODS) was officially founded [130] by the Organisations of 7 European countries (Austria, Belgium, France, Great Britain, Italy, Luxembourg, Monaco); to date, the FIODS counts more than 80 members from the five continents.

All of us are aware of the importance of the **Federation of the Red Cross and Red Crescent Societies** (international), and of the national Red Cross Societies, in organising blood donors in **more than 10 European countries**. In some other European countries blood donors are not associated, or have been organised **around governmental institutions**.

And yet, in spite of all these organisational efforts, in some European countries blood donors are few and blood for transfusion and fractionation is insufficient [61, 82, 141].

At the Second SIITS-AICT Symposium for European Cooperation (**Cernobbio**, 6th October **1990**) on "**Voluntary blood donors Associations: present and future**" [125], attempts were made to compose a picture of European blood donation [82], and numbers of units of blood collected and of periodic (repeat) donors were estimated in 15 European countries.

Differences were observed [82] in the number of blood donors and in their motivations, in the ways of promotion of blood donation, in the organization of blood collection, in the public support to voluntary Associations, in the national legislations on the collection and distribution of blood, in the medical surveillance of blood donors, in the role of voluntary blood donors Associations in the prevention of diseases, in the relationship between donors and physicians; economic, social, political, ethnical, cultural, religious differences; differences between West and East, North and South. It became evident that a **European self-sufficiency in blood donation** could only be achieved as a result of **national and local self-sufficiencies** [82], and that many problems indeed are waiting for some solution by **political initiatives** of our National and European Authorities: intelligent legislation, even distribution of resources, international help, reciprocal integration, adequate blood collection, cost-effective plasma separation and fractionation. Proposals were also made of a European blood donors Association, of a European Community group of National Federations, and of a more active role and support to European developing countries by the Council of Europe and the European Community.

With the **fall of political walls** and the opening of borders between East and West, a new negative phenomenon has been registered in many Eastern countries: a worrying decrease in the number of voluntary blood donors and an obvious weakening of their motivations. As if the sudden lack of imposed discipline and material incentivations couldn't be substituted quickly enough by moral maturity and social solidarity. In a **survey of Blood Transfusion Services** of some **11 Central and Eastern European countries** (Estonia, Latvia, Lithuania, Poland, Czech and Slovak Republics, Hungary, Romania, Bulgaria, Albania and Slovenia), prepared by Prof. Heiniger [47] for the **Council of Europe** 1992-1993 co-ordinated research programme in blood transfusion, the **collection of whole blood donations** dropped in two years from 4.052.000 in 1989 to 3.426.000 in 1991, decreasing by 15,4%, in spite of a slight increase of 0,7% of the total population, resulting in a **decrease** of the number of donations/1.000 inhabitants of **16,0%**; decreases were as high as 17,6% in Poland, 23,0% in Romania and 36,6% in Bulgaria: giving evidence that **blood donation can't help being a reflection** of the political "health" of a country and of its national "cohesion".

As Prof. L. Hirszfeld already expressed in **1935** [50], in his opening address at the First International Congress of Blood Transfusion in **Rome**, "our science does not only express the intellectual progress, but also the **moral values of a nation**".

At the Fourth SIITS-AICT Symposium for European Cooperation (**Roma**, 6th June **1992**) on "**Mass-media and blood donation**" [127], the relevance of an intelligent and technically effective occupation of mass-media for the promotion of blood donation was adequately stressed. It was concluded that the **attention devoted by mass-media** to the necessity of increasing the number of voluntary non-remunerated blood donors is presently -all over Europe- still fairly low, and that a "**chronic**" **strategy**

of attention by mass-media -ensuring a stable and high level of promotional activity- is certainly far more productive and avoids any need for **expensive** "**acute**" **campaigns**, which seldom bring any positive results, but more often disconcert and disillusion [86].

In the two ESTM residential courses on "**Promotion and maintenance of voluntary, non-remunerated blood donation**" (in June **1996** [143] in **Santiago**, Spain, and in September **1999** [139, 142] in **Bucharest**, Romania), more than 100 participants from 14 European countries could exchange their experiences. Another ESTM course on the same subject is planned for 2002 in Lithuania.

A "**European Youth Forum**" on blood donation [116] has recently (September **2000**) taken place in **Italy**, organized by the **IFBDO/FIODS** and by the Italian **AVIS**, allowing more than 250 participants, from 13 European countries, to compare their different national situations, leading to a project of further cooperation to establish a network for the progress and harmonisation of voluntary blood donation in Europe.

"Quality" donors

There is a general agreement that donors should be "**voluntary**" and "**non-remunerated**", always excluding "financial profit", according to the ISBT "**Code of ethics for blood donation and transfusion** [41, 53, 54]. The concession of free working time or of a "food coupon", for example, or of any other kind of material incentivation, is **not** compatible with the "**non-remuneration**" of the voluntary blood donation. A voluntary blood donor is somebody who has made a **free decision** out of a **personal conviction**, not resulting from any pressure of emotions or necessity, but originating from the **moral awareness** of the donation being a **social duty** from the healthy to the sick [80, 146].

A strong motivation is represented by the **feeling of social pride** given by the certainty of belonging to an undoubtely self-selected group of citizen. The **moral gratification** connected with this feeling is possibly the highest spiritual expression among the many motivations to blood donation, and is certainly the source of the active involvement of many donors themselves in the promotion of blood donation and in the active participation in campaigns of prevention against blood-transmissible diseases [21, 93, 116, 118]. Blood donors are therefore citizen endowed with particular feelings of **personal, social and moral responsibility**, giving their blood **voluntarily**, **freely**, **anonymously and periodically**: this is what we mean by "**quality**" **donor** [42, 131, 133].

The "critical" (if not sometimes dramatic) situation of **real** voluntary blood donation in many European countries is justifying to give a strong priority to its establishment, or reconstruction, as an absolute pre-requirement to any possible development of Transfusion Medicine [93, 99, 116, 118].

To this aim a powerful help is represented by a well organized **donors medical care** [116, 118, 130].

Medical care of voluntary blood donors

Donor selection and care strictly implies an **organised medical control**.

If there is no doubt that a **strict medical control is necessary** (and will furthermore represent a powerful motivation for recruitment and retention of donors), a warning should also be given **against the** "**overmedicalization**" of blood donors medical control beyond the borders of its real necessity: **excessive proliferation** of laboratory tests may negatively impress the feeling of safety of donors, scare new prospective

donors, and reduce the number of active donors; **useless repetition** of physical examinations, radiographs and instrumental investigations, without adequate consideration of previously performed similar procedures (family physicians, work-place medical check-ups), may induce an unjustified increase of social costs of blood transfusion; **prevailing of more bureaucratic and legalistic worries** over sound medical acquisitions may lead to a scientific dequalification of Transfusion Medicine [49, 94, 101, 116].

The **highest degree of safety** will be given by **blood donors being fully aware** of their duties and made responsible for their decisions concerning blood donation [42, 80, 82, 118, 119, 133, 142, 143, 146].

A side problem in many European countries, where thalassaemia is widespread and blood donors are relatively few, is **the exclusion or the acceptance as blood donors of thalassaemia trait carriers**.

Although very few physiopathological and clinical data are available on the effect of blood donation in thalassaemia trait, **healthy thalassaemia trait carriers**, regularly enrolled as periodic donors, only very seldom show any sign of anaemia and should therefore in principle **not be excluded from blood donation**.

Vaccination of voluntary periodic blood donors against hepatitis B virus has been proposed in 1984 [124] as an **effective** and **economic** measure to drastically reduce the prevalence of post-transfusional B hepatitis, due to the decreased risk of donors being unnoticeably infectious at the time of blood donation. The availability of cheaper recombinant vaccines has made the proposal even more suggestive and practicable. The financial burden of the donors vaccination should not be considered an obstacle to its generalized extension: besides any medical or moral considerations, the cost of reagents for repeated markers investigations, which could obviously be spared, accounts for much more than the actual cost of vaccination [40, 83, 97, 104, 105, 121].
The **promotional impact on donors recruitment**, arising from the appreciation of a concrete benefit being offered to voluntary donors, is an other important side-effect of the vaccination campaign [116, 124, 138].

It is mandatory that donors with markers of blood-transmissible viral infections, or other abnormal laboratory or clinical findings, should be **notified** of their situation by the Blood Transfusion Centre physicians under the strictest medical **confidentiality**, and enrolled in a **regular follow-up in donor care clinics**, either by the Transfusion Centre itself, or in close collaboration with other specialist out-patient Departments [16, 116, 118, 119]. Medical care of blood donors is a price that the community has to pay, being justified not only by **ethical considerations**, but by its **positive effects** on blood donors recruitment and retention as well.

If all procedures relating to motivations, promotion, recruitment, retention, organization and medical care of donors are properly conceived and performed, many blood donors indeed will become **highly committed partners of the Blood Transfusion Service** [82, 93, 106, 130].

Education to voluntary blood donation during military service

The **number of voluntary blood donors** in Europe is subject to **wide variations** [82, 93, 119] in different countries (irrespective of their affiliation to European Union, or Council of Europe, or "geographical" Europe), and is often **inadequate** to the growth and selective needs of modern medicine, mostly in Southern European countries.

Compulsory military service (CMS) is still present in many European countries (mainly South-European), conceived as a civic duty, involving a considerable part of the male population [89, 104, 105]. **Alternative civilian service (ACS)** is offered in some countries

to individuals unwilling to engage in CMS. The peculiar features (both technological and characterial) of modern war have made military Defense a specialised job and led many countries to build up an army mainly -or only- based on **professional military service (PMS)**. While on one side CMS has become **obsolete** from a **military** point of view, on the other side -being mostly conceived as purely military- CMS is also **failing** to make the best use of its precious opportunities for **civilian** education and training to professional abilities, civic behaviour and community feelings: not to speak of ACS, often reduced to useless and bureaucratic clerical tasks.

It may then be high time for a collective European meditation on the convenience of **abolishing CMS and ACS** and **reinforcing PMS**, whilst instituting for **all** citizen, in **all** countries, a really **compulsory military-civilian service (CMCS)** (under a combined responsibility of the Ministry of Defence, Education and others), whose main aims should be [104, 105]:

1) **Integration and back-up of professional Army** in war and catastrophes.
2) **Education of character** to social solidarity, ethnical tolerance, sexual responsi bility, civic behaviour, community feelings.
3) **Professional and technical training**, complementing previous scholastic teaching
4) Employment in **initiatives of social utility** (public works, agriculture, forests, environment, medical and psychological assistance, etc.).
5) **Education to medical responsibility, blood donation and Transfusion Medicine**.

This last goal is **already receiving attention in some countries, during CMS**, at present time. CMS is indeed long enough to allow an effective deep **education to blood donation**, through lectures by Transfusion Medicine specialists, group visits to civilian Blood Transfusion Centres, joint activities with groups of periodic voluntary blood donors, thus acquiring knowledge of the nature of blood and blood products, and being initiated to **proper blood donation** [104]. Through repetition of blood donation, the attitude to periodical blood donation can be consolidated during the whole period of CMS (or future CMCS).

"**Military-initiated**" **donors** would be likely to remain periodic blood donors in later civilian life, so greatly contributing to reinforce feelings of appreciation of the CMS (or future CMCS) by the general public.

Vaccination against HBV would greatly increase the quality and safety of blood donated by military (or future military-civilian) donors. Increased awareness can be reached of many problems concerning blood **safety** (prevention of hepatitis and AIDS, sexual education) and medical **aptitude** to blood donation (genetic counselling for red cell hereditary traits as thalassaemia, Hbs and G6PD), so exerting a further positive side-effect on public health.

Positive **experiences** on the above issues have so far been accomplished in Italy, Portugal and Spain [138], and in other European countries. Noteworthy the experience of Croatia, where blood donation was necessarily intensified during the war period, resulting also subsequently (in peace time) in a higher percentage of blood donors in the general population [104, 105].

The present **consistency of military blood donations** in Europe, however, although not negligible, is far from being optimal. The presence sometimes of some relevant fringe-benefits (licence, days-off, food supplement, etc), moreover, casts some shadows on its really "voluntary" nature. **Blood donation by military citizen** should be made as similar as possible to the one by civilians: same Centre, same procedures, same times, same organization, so that by itself could allow reciprocal acquaintance and would become an important element of integration. Ultimately, every military setting (barrack, headquarters, school, centre, etc) should be "**twinned**" with a

particular Blood Transfusion Centre, and a **common** annual programme of activity should be laid down and accomplished.

In the past 6 years, increasing interest for the promotion of voluntary blood donation has been shown during the last 3 **NATO Blood Conferences** (Istanbul, **1994** [89], The Hague, **1996** [138], Lisbon, **1998** [104, 128, 129]).

Inquiries on the **involvement of military service in the promotion of voluntary blood donation**, and on the **planning of military-civilian co-operation in emergency Transfusion Medicine**, have been proposed at the last 5th NATO Blood Conference in **Lisboa** in **1998** [104], and a preliminary report has been given at the last Conference in **Washington**, in November **2000**.

Belonging to a European blood donation and Transfusion Medicine community

The initiatives taken in the **last ten years**, in the whole of **Europe**, by the ISBT, by some National Scientific Societies and by the ESTM have considerably helped to clarify the theory and practice of Transfusion Medicine in most European countries and to establish some **network** of scientific and professional communication, to the benefit also of countries of other continents (Africa and Asia) bordering the Mediterranean Sea.

The **birth (in April 1992)** and the rapid **growth** of the **European School of Transfusion Medicine (ESTM)** are a clear witness of the profound need for increasing harmonisation of the teaching of Transfusion Medicine **within a geographical Europe wider than the "political" definitions**, given by the European Union and the Council of Europe.

The **ESTM** is a non-profit Association under the Italian law, managed by a Council of Administration and an Executive Committee, and guided by European Scientific and Advisory Committees.

The **aims** of the ESTM were defined as to provide a specialist teaching of Transfusion Medicine, of an international and European character, for specialist doctors already established from a scientific and professional standpoint, physicians, other graduates and para-medical personnel under specialist training [95, 99, 107].

The establishment of the ESTM has been the result of a series of study documents and discussions on the teaching of Transfusion Medicine, originated by the **Council of Europe** (in 1963 and 1985) [29, 32] and developed by the **ISBT** [25, 126, 134, 136, 140] within its European Regional Congresses and by the Italian Society of Transfusion Medicine **(SIMTI)** [90, 125, 127, 130, 141] through its "Symposia for European Cooperation" (from 1990 to 1994), following the recommendation issued, in 1989, at the end of the ISBT 1st European Regional Congress in Lugano [25].

- **Teaching of Transfusion Medicine** *(U. Rossi, J.D. Cash: editors [125])*

  Proceedings of the First SIITS-AICT Symposium for European Cooperation - Cernobbio (Italy), 1st October 1990

- **Voluntary blood donors Associations: present and future** *(U. Rossi, V. Fresia, B. Genetet: editors [130])*

  Proceedings of the Second SIITS-AICT Symposium for European Cooperation - Cernobbio (Italy), 6th October 1990

- **Teaching and education in Transfusion Medicine** *(U. Rossi, J.D. Cash: editors [126])*

  Proceedings of the main session of the 3rd ISBT Regional (2nd European) Congress - Prague (Czechia), 15th October 1991

- **Therapy with plasma and albumin: production and clinical use** *(U. Rossi, W.G. Van Aken, M. Orlando: editors [141])*

Proceedings of the Third SIITS-AICT Symposium for European Cooperation - Rome (Italy), 6th June 1992

- **Mass media and blood donation** *(U. Rossi, I. Cipriani, V. Fresia: editors [127])*.
  Proceedings of the Fourth SIITS-AICT Symposium for European Cooperation - Rome (Italy), 6th June 1992
- **Teaching of Transfusion Medicine to undergraduate medical students** *(U. Rossi, H. Seyfried: editors [140])*
  Proceedings of the Symposium of the 4th ISBT Regional (3rd European) Congress - Barcelona (Spain), 15th June 1993
- **Therapeutic haemapheresis** *(U. Rossi, A. Bussel, M. Valbonesi: editors [90])*
  Proceedings of the Satellite Symposium for European Cooperation - Genova (Italy), 9th June 1995

Common features of these **European Symposia** have been the **recognition** of the present situation possibly in all countries of the new "broader" Europe, the **trial of "transfusing"** all the scientific data and documentation work gathered by the Council of Europe and by National Societies into the European Community, and the elaboration of some concrete **proposals** and **guidelines** for further harmonisation within Europe.

51 courses have so far been organised in **21 European countries** (Russia, Spain, Italy, Greece, Switzerland, Norway, France, Belgium, Czechia, The Netherlands, Portugal, Great Britain, Slovenia, Germany, Austria, Croatia, Estonia, Poland, Israel, Romania and Slovakia). More than **80 coordinators** and more than **380 teachers** have been involved, from **23 European countries** (and some from Australia, Brazil and USA). **Participants** have been so far **more than 2.000**, from **35 European countries** (and some from Canada, Argentina, Cuba, Brazil, Hong-Kong, Egypt and Gambia). A course, in January 1999, has been co-organized in Senegal [95, 99, 107, 115].

In the last ten years, opportunities have been given by some National Societies (Czechia, Germany, Israel, Italy, Portugal, Switzerland, Turkey) during their Congresses to discuss **European issues** concerning education in Transfusion Medicine. Many National Societies, or equivalent Institutions (Croatia, Czechia, Estonia, France, Germany, Greece, Israel, Italy, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Switzerland), have been actively collaborating in the **preparation of ESTM residential courses** [95, 115, 119], some of them more than once (Czechia, Greece, Italy, Slovenia, Spain). A concrete financial **support**, through the sponsorization of participants's fees, has been given to the ESTM residential courses occasionally by the British, German and Polish Societies, and periodically by the Italian Society. ESTM courses have been increasingly taking place in **Eastern European countries**, touching so far Russia, Estonia [14], Poland, Czechia, Slovenia [20], Croatia [27], Romania [139, 142], and Slovakia [59].

The Royal College of Pathologists (London), in 1995, has recognised ESTM courses as being appropriate for **Continuing Medical Education (CME)** purposes, enabling course attendants to receive CME credits at the rate of one credit per hour [107, 109, 119]. The recognition has been awarded again in 2000. An "**ESTM Fellowship Programme**" has been established, to collect funds in order to enable Eastern European Colleagues to participate in ESTM courses. A **study group** on the teaching of Transfusion Medicine to undergraduate medical students has been constituted after the ISBT European Congress of Barcelona in 1993. Prospects and achievements of **Transfusion Medicine teaching** have been discussed in scientific Congresses of **National Societies** in Czechia (1993, 1994 and 1998), Israel [122] (1993), Germany [88] (1993), Turkey [117] (1993 and 2000), Spain (1994), Portugal (1994), Italy (1996), Slovakia [59] (1997), Macedonia [118] (2000), Ukraine [120] (2000) and of the **ISBT** (Taipei [107], 1999; Vienna [115], 2000).

A **translation of the AABB Technical Manual into Russian** will soon be ready, to be sponsored by Institutions and Firms and distributed free to doctors and technicians

working in blood transfusion in Russian-speaking countries. A **"twinning programme" between Romanian and Italian Blood Transfusion Centres** has started in 1998, in agreement with the WHO and the Romanian Government, and is currently developing thanks to the help of many Italian Colleagues. The participation to some ESTM courses of a few Colleagues from South America has brought the idea that an educational initiative similar to the ESTM could be incubated, and proposed, in **Latin America**. This possibility has been discussed during the **ESTM "Iberic" courses** (in Spanish and Portuguese), successfully performed in 1996 and 1998, and will be further discussed in the next "Iberic" course in 2001.

To ensure a wider diffusion of their contents, it has been decided that ESTM course Proceedings will be published -in updated editions- as **books**, on sale at a cost price, and shall be soon available at an **Internet** site. The proposal of a distance-learning pluriennal specialization course, leading to a **European specialist diploma of Transfusion Medicine**, has been discussed and approved by the ESTM Scientific Committee, and is waiting to find the way to overcome the many obstacles to its implementation.

The ESTM courses have been performed, at varying degrees of complexity, dealing with **many aspects of** Transfusion Medicine, including promotion of voluntary blood donation [139, 142, 143], detection and prevention of transfusion-transmissible infections [10, 14], blood safety and transfusion risks [12], emergency Transfusion Medicine, autotransfusion [20, 108], haemapheresis, quality assurance and quality management [27, 35], immunohaematology, clinical use of blood [109], prospects of Transfusion Medicine [63].

Some **relevant national differences** still exist in different countries or areas of Europe, waiting for proper recognitions, studies and solutions.

Issues and problems such as the organization of real voluntary non-remunerated blood donation, the consistence of periodic donor population, the optimal index of donation, the contribution of autotransfusion, the development of bloodless surgery, the organization and responsibility of Blood Transfusion Services and plasma fractionation plants, the economic conditions of the supply of plasma related to the need of plasma fractions, the definition of the real clinical need of albumin, the extent of genome testing, the implementation of leucodepletion, are all of paramount importance for the future of Transfusion Medicine in Europe.

Blood safety

"Safety" has a probabilistic nature. We can **"increase" safety** by understanding, counteracting and **"reducing" risks**. **Absolute blood safety**, and "zero-risk", do not exist [1, 10, 12, 57, 99, 110]. But **"maximum" blood safety** could be reached. How? Not with blood testing **alone**. Blood safety is a multifactorial human achievement and can only be **built** gradually, by steps, of which blood testing is of course an extremely important, but not the only one [33, 37, 96, 131, 133]. **Blood testing** must always "come **with**" a series of measures and behaviours aiming at transfusion safety [12, 36, 49, 94].

What should, then, "come **first**"? Our answer is: **"education of people to quality"** [44, 101, 116, 118, 131, 133]. Donors, medical doctors, transfusion specialists, health professionals, hospital administrators, public health officers, politicians, journalists, teachers, priests of good quality: **all** of them are really necessary to build up blood safety [101 116, 118]. Blood safety, however, is mostly the result of good blood donors and physicians: responsible blood donors, and knowledgeable physicians, caring about a good quality of clinical indications [101, 103, 109, 118].

Quality of medical doctors and of clinical indications

General practitioners, hospital doctors, Transfusion Medicine specialists: **all** are important for an acceptable blood safety and for a good quality of clinical indications. The "**quality**" **of clinical indications** to transfusion [34, 101, 103, 118], however, mainly 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** [118, 135] implies information and "education" concerning blood donation and blood transfusion, enabling him to become aware of clinical indications of transfusion in his medical practice.

The "**quality**" **of clinical indications** is obviously the result of them having been weighed against all possible **side-effects**, or real **contra-indications** (as, for example, circulatory overload in patients with congestive heart disease), and of the **intrinsic risks of transfusion** having been adequately considered [132].

Silly sentences such as *"the best transfusion is the one never given"*, on the other side, may run the risk to become dangerously popular, as a reaction to an indiscriminate and unnecessary use of transfusion. *The* **best transfusion** *is the one given when it is really* **necessary**, *on proper clinical* **indications**, *being conscious and after careful evaluation of its* **side-effects**, *performed with a selected blood* **component**, *and adequately expecting and evaluating its* **beneficial effects** [123, 132].

A definite progress in blood safety, and in the quality of clinical indications, is to be expected by the implementation of Hospital Transfusion Committees [65] and of local, regional and national schemes of haemovigilance [19, 73, 91, 98, 100, 102].

Increasing blood safety by education and quality management

The **basic concepts inspiring quality management** [15, 35, 117], 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 "**essentia**l" to the system;
- feeling of personal satisfaction, and of humble pride, to **belong** to a "quality" system.

How do these basic "quality management" concepts coincide with the **concepts presently applied to everyday's work in Blood Transfusion Services** all over Europe, and to its wide variety of models of organization and performance? Can **education to "quality management"**, being fairly independent from financial resources and rather addressed to human behaviour, be considered an **adequate common tool to progress towards decreasing national differences concerning blood safety?**

It may be useful, and encouraging, to analyse the **similarities** between **"quality concepts"** and **existing "working concepts"**:

A) **Most of the "quality concepts" are already present**, felt and practised in the organisation of Blood Transfusion Services.

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".

B) 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.

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 (synthetizing, 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.

C) **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.

D) The present explosion of "quality" criteria, meetings, rules, proposals, regula-tions, initiatives, courses, fashions, impositions, interests, temptations may be con-fusing for most of us, and maybe wrongly lead us to the dreadful conclusion that "quality",

for us, could only start "**after**": *after* money has been poured in, *after* automatic equipment has become available, etc. But if we are "watching" these phenomena carefully, with the same degree of attention and involvement we are used to, we may easily learn that **we only need to "increase" quality**, analysing identities and "non-conformities" with all what we presently do, and to quickly adjust our organisation to the standard requirements of a quality system.

E) The **rules of "quality"**, apparently so invariable and standardised, remind me of the psychological difficulties most of us experienced when computers stepped in our organisation: they looked to some of us as limiting our freedom and exacting our brain to adjust to their schemes, but we quickly learned to discover how intelligent we were in accepting them.

F) I feel that any psychological resistance to accept the **heavy workload of introducing a quality system** in our long-established work organisation could be easily overcome by considering the very high financial costs, moral unsatisfaction, and professional risks of **"non-quality"**.

G) **Learning to teach "non-quality", and teaching to analyse and avoid its (so far little recognised) disastrous disadvantages**, may well turn out to be the most important didactic task for all of us in the next future.

"Quality as a way of life", once generally accepted and practiced, can greatly contribute to quickly reduce throughout Europe the existing huge differences in Transfusion Medicine performance and in blood safety.

A proper cultural approach to transfusion risk management

A recent ESTM course (Bruxelles, 26-29 February 2000), on **"Risk perception and risk assessment in transfusion practice: how to achieve a sound transfusion practice based on scientific truth"** [12], has initiated a wider discussion on the current criteria of scientific, professional and political behaviour concerning the **residual** transfusion risk in Europe [11, 57, 58, 144, 148].

The aim of the course was to give the participants a sound knowledge on the probabilistic nature of risk and of the **real dimensions** of risks in today's life [75, 76, 147, 152], from the existential, natural, environmental, behavioural, economical risks to the biological and medical risks in general [2, 18, 69, 77], more specifically focusing on the risks (not only viral!) of transfusion practice [4, 5, 7, 38, 70, 159, 160]. To obtain that knowledge of its medical advantages and clinical indications could be weighed against its risks, **scientifically** and **comparatively evaluated** [75, 76, 77]. The ultimate aims was to make European transfusion specialists more aware of their responsibilities in exerting a positive influence on mass media, on public opinion, on administrators and on politicians in order to make a **correct use of public resources**, based upon **scientific evidence** of the usefulness of their allocation and upon a **critical analysis** of cost/benefit ratios, influenced not by fear but by reason [1, 71, 148].

Haemovigilance surveys, in "developed" countries, have shown how important by now, as compared with viral risk, have become some **other** transfusion risks, like bacterial contamination [6, 9, 72, 159], wrong identification [66, 67, 68, 137], and improper clinical indications [5, 103].

Public opinion should be encouraged to a **better perception** of the real dimension of life risks in general, and of medical risks in particular [45, 52, 58, 64, 78, 79, 147], so that **decision on possible further reductions of transfusion viral risk** could be correctly understood, evaluated and discussed by all citizens, and maybe submitted (in some cases) to their own decision.

This **critical re-evaluation of the existing measures on blood safety** (further developed in the recent ISBT Congress in Vienna) should not loose awareness of the **widely different situations existing in today's Europe**, where a generalized blood safety hasn't yet been reached [111, 118, 120, 156].

The future of blood safety, a challenge for the whole Europe

The time has come for a **more responsible collective meditation** on the present strategies of prevention of the relevant transfusion risks [3, 8, 22, 24], and on the **drafting of national and European regulations concerning blood safety**.

We are, indeed, facing the **risk that an uncontrolled progress in the practice of Transfusion Medicine could lead us to a situation**, where **differences in the quality of transfusion treatment between European regions and nations** could increase, rather than diminish, due to a different pace, and most of all to a different concept, of progress [74, 110, 111, 116, 118]. Measures should then be taken (at a political, scientific and professional level) to ensure that "developing" countries could **develop faster** [111, 116, 119], to reduce the quality gap as soon as possible.

The "door" of blood safety should first be fully open, all over Europe [43, 44, 131, 133], at the lowest possible financial cost, counting mostly on the **education of people** (at all possible levels) and on the generalized application of **simple screening procedures**: the **basis** (and quickly!) **before the top** of the pyramid!

More sophisticated (and expensive) technologies can **only** have a significance if they are implemented **to integrate and perfection already existing means**, never to substitute and bypass them.

To this aim, to counteract the **risk of an increasingly diverging quality** of Transfusion Medicine in Europe, money is far less important than **education** and **political awareness** [46, 51, 110, 111, 116, 118]: no decision on blood safety in the West should any more be taken without a clear insight into its reflexes on the blood safety of the whole of Europe, that must become a priority interest for all European Nations.

Prof. Cazal's introduction [26] to a Council of Europe's document [31], in 1983: *"to create a "Red Europe" ... and to assure "***Homo Europaeus***" of the same security as regards transfusion -the same transfusion rights and duties- wherever he lived and travelled")* can be appropriately quoted as an obvious motivation for the **harmonisation of blood transfusion practice**: that should be a matter of common and equal concern, in all European countries, for the Ministries of Health, Education and Defence, which should be jointly responsible of a governmental, internationally linked, **programme of blood donation and Transfusion Medicine** [104, 119, 120].

Let us consider this as one of our challenges for the third millennium of our history.

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