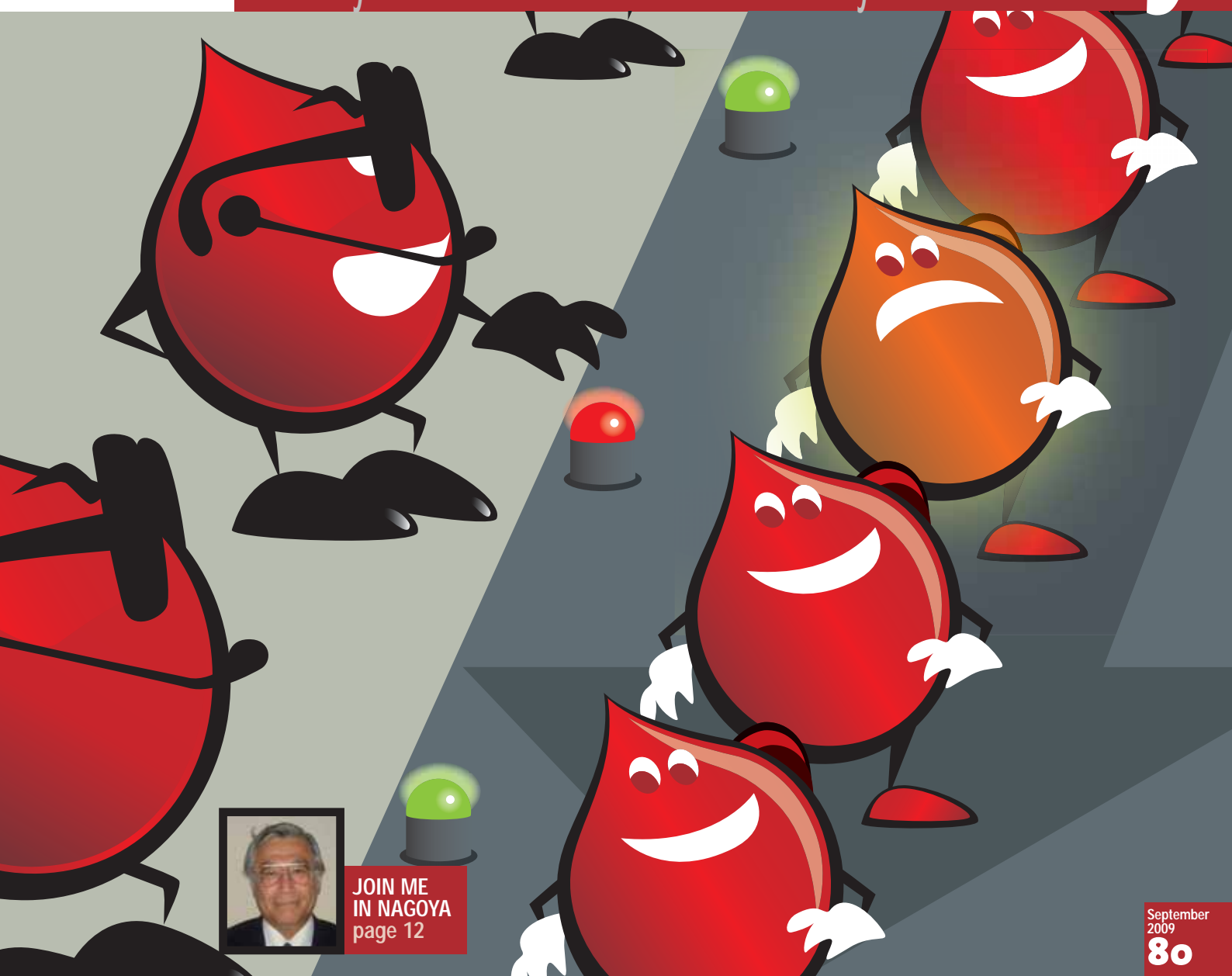




# TransfusionToday

Quarterly newsletter of the international society of blood transfusion



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IN NAGOYA  
page 12

September  
2009  
**80**

# VIGILANCES

BULLETIN TRIMESTRIEL D'INFORMATION  
DE LA SOCIÉTÉ INTERNATIONALE  
DE TRANSFUSION SANGUINE



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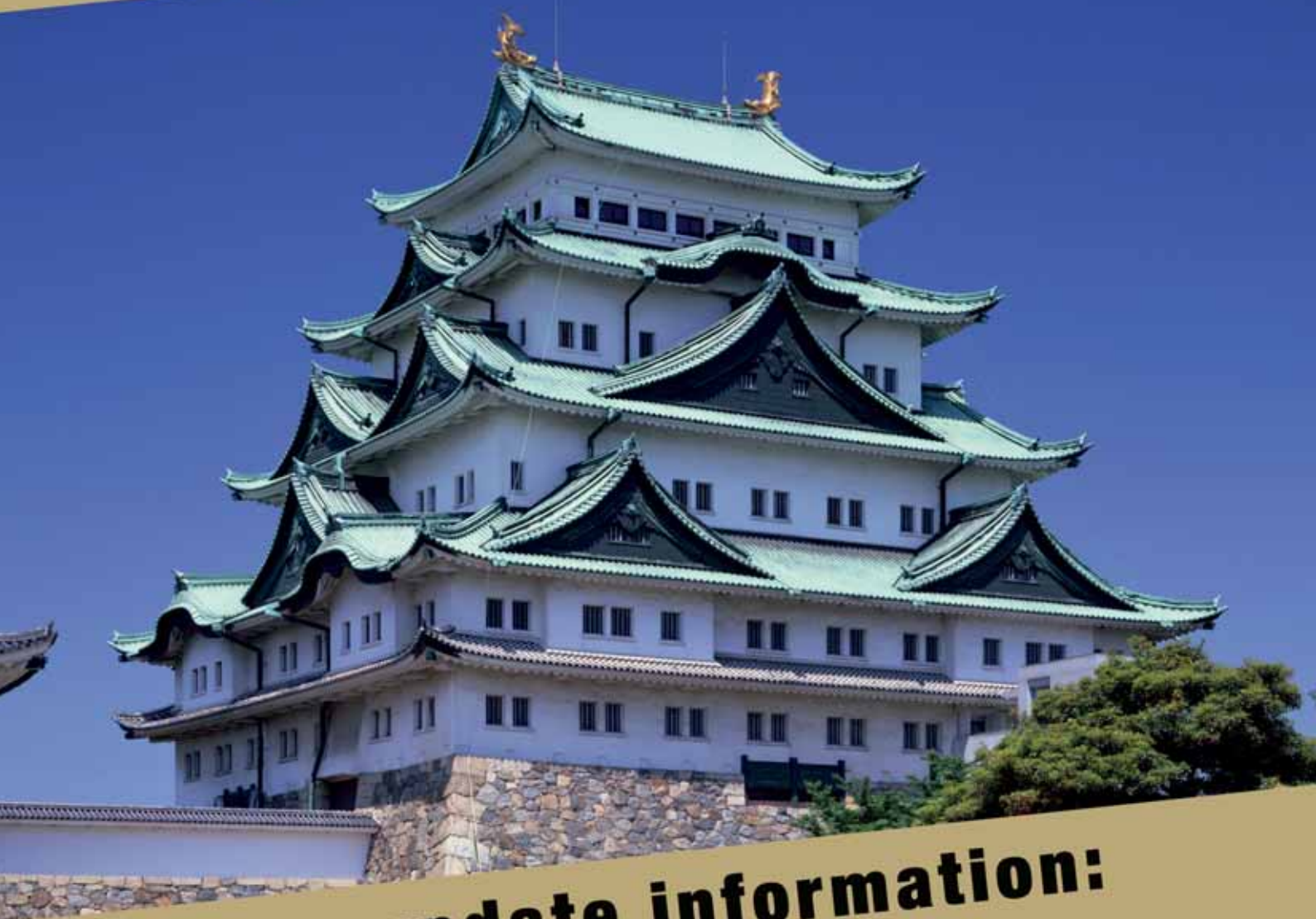


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# XX<sup>th</sup> REGIONAL CONGRESS, ASIA

INTERNATIONAL SOCIETY OF BLOOD TRANSFUSION



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**NOVEMBER 14 – 18, 2009**

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## Editorial

In the September 2006 issue of Transfusion Today haemovigilance was described in length and some of the work of the ISBT Working Party on Haemovigilance was presented. In this current issue the focus is on international perspectives in haemovigilance. On numerous occasions experts have emphasized the fact that international collaboration is crucial for haemovigilance in order to ensure that the data from various countries are comparable. Tremendous efforts have been made by multiple collaborators to strive towards this goal. The results are impressive as illustrated by the papers from our contributing authors. The work of the ISBT Working Party on Haemovigilance and of the International (formerly European) Haemovigilance Network (IHN) has been an extraordinary example of the international collaboration needed to develop standardised methodologies for surveillance of adverse blood donation and transfusion events. This fruitful collaboration has led to the development of international standard definitions for non infectious complications of transfusion, a multi-year process described in the paper by Jo Wiersum-Osselton from the Netherlands. The development of those definitions and their validation were made possible by the contribution of experts from numerous countries and were approved both by the ISBT and the IHN. The same collaboration between the two organizations has led to the development and validation of standard definitions for complications of blood donations. Jan Jorgensen from Denmark has been more than instrumental in the process that he and Jo Wiersum describe in an article of this issue of Transfusion Today. Donor vigilance is becoming an integral part of the quality process of blood donations.

P. Robillard - Invited editor ■

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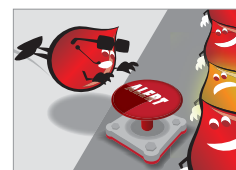
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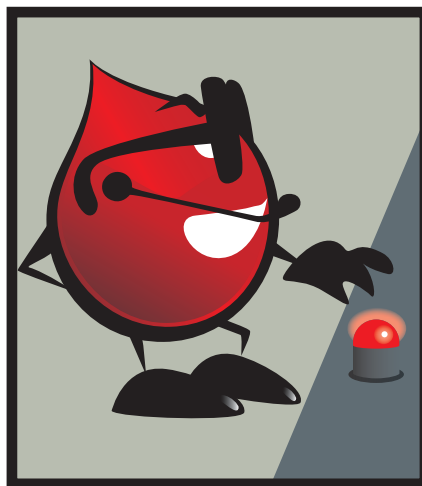
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## EDITORIAL (CONTINUE)

These standard definitions have already been adopted by many countries and organizations. They were also the basis for the construction of an international database on haemovigilance, a project sponsored by the International Haemovigilance Network with active participation from the ISBT Working Party on Haemovigilance. The surveillance of transfusion-associated adverse reactions and events (STARE) project, described by Constantina Politis from Greece, is an original initiative which objective is to compare haemovigilance results from multiple countries that use the same definitions for surveillance of adverse donations and transfusion events. Denominator data is also collected by the participating countries in order to provide meaningful rates for those adverse events. The results from the first year of the pilot project were promising and the project was renewed with a second year of data collection together with an improvement of the data collection tools.

All these results would not be possible without organisations that bring experts into networks of collaboration. Three major haemovigilance networks are described in this issue. The oldest, the European Haemovigilance Network (EHN) that has officially become the International Haemovigilance Network earlier this year has set the pace for collaboration in haemovigilance. The commitment of the participating countries is



impressive and allows the IHN to fund specific initiatives to improve haemovigilance systems worldwide. The ISBT Working Party on Haemovigilance, comprising experts and individuals involved in haemovigilance from all continents, has been closely working with IHN to standardise methods in haemovigilance. The latest networking initiative is from the World Health Organisation and is called the Global Steering Committee on Haemovigilance (GloSCH). Its main goal is to facilitate the development and implementation of haemovigilance in developing countries through collaboration with experts from IHN and ISBT.

Haemovigilance has reached beyond the developing stage and has matured to an impressive international collaborative effort both within and outside ISBT. Some results of these efforts are shown in this issue of Transfusion Today and more is to come in the future.

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## INTERNATIONAL HAEMOVIGILANCE NETWORKS

The overall goal of hemovigilance is to increase the safety and quality of blood transfusion. It is achieved by systematically collecting and assessing information on unexpected or undesirable effects resulting from the use of blood products. This data collection process needs to be standardised so that meaningful comparisons are made between countries that have different haemovigilance systems. Collaboration in haemovigilance has been achieved by networking systems and experts in new or existing organisations. Three such organisations are the International Haemovigilance Network (IHN), the ISBT Working Party on Haemovigilance and the Global Steering Committee on Haemovigilance (GloSCH).

### THE INTERNATIONAL HAEMOVIGILANCE NETWORK

Formerly established in the 1990s as the European Haemovigilance Network (EHN), the IHN now comprises 23 countries from four continents. Its objectives are to:

- Favour exchange of valid information between the members of the network;
- Increase rapid alert / early warning between the members of the network;
- Encourage joint activities between the members of the network;
- Undertake educational activities in relation to haemovigilance.

Each participating country has an official contact person (OCP) who is a member of the general assembly of IHN eligible to vote on all issues presented. The OCP is also responsible for posting alerts in the IHN rapid alert system, an online mechanism to inform member countries on possible threats to the blood safety. On an annual basis a seminar is organised by IHN to share methods and data and to promote haemovigilance. Eleven such seminars have attracted numerous people involved in haemovigilance either at the national, regional or local level. IHN member countries are contributing financially to an operational budget that allows for projects to be undertaken. One of the major undertakings of IHN is the development of an international haemovigilance database, the STARE project. Close collaborations have been established between IHN and the ISBT Working Party on Haemovigilance to develop standard definitions for adverse donation and transfusion events.

### ISBT WP ON HAEMOVIGILANCE

The ISBT Working Party on Haemovigilance was established in 2001 to develop the different elements to be included in haemovigilance, to help standardize data elements under surveillance, to exchange information on the operation of different types of haemovigilance systems, to exchange data on results of haemovigilance systems and to be a source of information and guidance for countries setting up new haemovigilance systems. It now comprises 52 individual members from 30 countries in five continents illustrated in the next figure:



Three task forces were struck to develop standard definitions, one on each of the following topics :

1. Complications of donations
2. Non infectious adverse transfusion reactions
3. Infectious adverse transfusion reactions.

The latter is a joint task force with the ISBT Working Party on Transfusion Transmitted Infectious Diseases. The work of this task force is still ongoing whereas for the first two ones, the standard definitions have been developed and validated and scientific publications are under preparation. For the future, other task forces will address:

1. International indicators for blood utilisation
2. Standard categorisations and definitions for errors and near-misses in transfusion
3. Traceability

The ISBT Working Party on Haemovigilance provides a unique international forum of expertise in haemovigilance that serves the transfusion community in order to improve transfusion safety.

## THE GLOBAL STEERING COMMITTEE ON HAEMOVIGILANCE

In December 2007, at the WHO Global Collaboration for Blood Safety (GCBS) meeting in Geneva, the importance of hemovigilance as a key element in the management of blood safety globally was emphasized and the members supported the need to establish a Global Hemovigilance Network. This network was to build on existing expertise and existing international haemovigilance organisations. At the initiative of WHO, the Global Steering Committee on Haemovigilance (GloSCH) was created with founding membership from WHO, the IHN, the ISBT, representatives of the Canadian government and the U.S. Department of

Health and Human Services. The main objectives of GloSCH are to :

- Provide an ongoing, international forum to develop and promote global hemovigilance
- Function as a forum for dialogue, advice and information gathering
- Promote standardized global hemovigilance reporting tools and determine whether these tools are useful and relevant
- Share information concerning hemovigilance data among member organizations.

The major project that GloSCH has undertaken is to support developing countries in building and implementing haemovigilance. To this end, a Haemovigilance Guidance Document will be developed that will identify:

- The needs and requirements for haemovigilance
- The various models for implementing haemovigilance
- The technical aspects of reporting, validating and analyzing haemovigilance data.

GloSCH, by providing such a tool, will contribute greatly to the safety of blood transfusion in developing countries.

International collaboration is well established in haemovigilance and the ISBT has been instrumental in developing standards of quality for haemovigilance. The need for collaboration will only grow in the future as more countries with varying degree of resources will collate haemovigilance data. Interpretation of these data and comparisons of data between numerous countries will be a challenge.

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# STARE\* - THE INTERNATIONAL HAEMOVIGILANCE NETWORK DATABASE: THE FIRST PILOT STUDY

\*The STARE Working Group consists of J.Jorgensen, C.Politis, C.Richardson, P.Robillard and J.Wiersum. Thanks are expressed to thirteen correspondents who provided comprehensive haemovigilance data for their countries and regions.

## BACKGROUND

One objective of the European Haemovigilance Network (EHN) is to exchange scientific information and provide technical advice to all those working for the development of a quality system focusing on the collection and analysis of data concerning adverse reactions and adverse events associated with the donation-to-transfusion chain (1-2). The ultimate goal is to contribute to international scientific efforts to prevent and correct errors, which cause a small but certainly not negligible risk in transfusion medicine, and thereby to promote the safety and effectiveness of the clinical use of blood and blood components and maximize the safety of donors and transfusion recipients.

The establishment of an international database for the surveillance of transfusion-associated adverse reactions and events (STARE) in donors and patients was decided upon in EHN's meeting in Frankfurt in February 2008. The ISBT WP on Haemovigilance subsequently decided to collaborate in the project, for the purpose of information sharing, surveillance and analyzing trends on adverse reactions and events. The aim is to construct an international tool (not restricted to the EU or Europe) for reporting and analyzing all adverse reactions and events that threaten the recipient's health status and quality of life, regardless of their level of severity or the extent of harm actually caused (if any). The donor's own health and well being is also of concern. STARE goes beyond EU requirements by including errors and mistakes in the clinical area, taking note of experience accumulated in those countries that apply haemovigilance measures more stringent than those imposed by the EU (3-5). Benchmarking, education and risk assessment are among the potential uses of the international database.

## METHODS

As a first step, the Working Group designed a pilot study to test the feasibility of data collection. A questionnaire consisting of a set of Excel

spreadsheets was prepared for distribution to haemovigilance experts who had volunteered to contribute their data anonymously. Data were sought for 2006 and 2007 separately.

Participating countries (or, in one case, a province) were requested to provide information on all adverse reactions and incidents (events) in each of the following categories:

- a) donor adverse events,
- b) errors-incorrect blood component transfused (IBCT),
- c) serious adverse events associated with transfusion,
- f) "near-miss" events,
- g) uneventful transfusion errors,
- h) adverse reactions associated with transfusion.

The definitions of serious adverse reactions and serious adverse events of EU Directives 2002/98/EC and 2005/61/EC (3-4) were used. ISBT/EHN standard definitions were used for donor and recipient complications and SHOT's definition of IBCT (6). Adverse transfusion reactions "possibly", "probably" or "definitely" associated with transfusion were reported, while cases "unlikely" to be associated, or whose imputability could not be assessed, were excluded. If a haemovigilance system did not record events by product subtype, the total for each main type of component was recorded.

Denominator data for donors and donations were requested in order to convert numbers of events and reactions into rates. Specific denominators for products, where available, were sought as well as general denominators for broader categories (e.g. total number of units issued and transfused, if available).

## RESULTS

For simplicity, only the results of 2007 are presented. Data were obtained for thirteen countries or regions (nine European, three Asian/Pacific and one North American). All but two had haemovigilance systems with complete or almost complete (> 99%) coverage; ten also have a system for reporting on transfusion medical devices and reagent problems; nine claimed com-

plete or almost complete traceability. Information was provided on 13,142 adverse reactions and 14,391,424 blood components issued.

Eleven participants (85%) were able to provide full information on donations, but only six (46%) also on donors. Twelve (92%) gave full information on blood components issued, but only three (23%) on blood components transfused.

Complete information on donor adverse events by type and severity was given by three (23%) participants. A further two (15%) provided these data with some deviation from the standard definitions. Four more (31%) lacked the breakdown by severity, while the remaining four could not provide this information from their resources.

Data on adverse reactions associated with blood transfusion in patients were intended to be broken down by type, blood component, severity and imputability. One participant could not provide these data. Twelve (92%) gave the breakdown by type and by component, eleven (85%) by imputability and ten (77%) by severity.

Results for all categories of information showed substantial differences between countries. In a fully functioning database, one purpose of the analysis would be to highlight these differences, leading to investigations at the national level of the causes behind them and, if necessary, improvements in processes. At this pilot stage, however, these large differences are to a large extent explained by the use of divergent definitions or interpretations and thus represent something to be resolved in the next step of the study.

Denominator data were used to calculate rates of events for individual countries and major geographical regions, as would be done in a fully operating international database. These results will be presented elsewhere.

## CONCLUSIONS

This pilot study has demonstrated the feasibility of setting up an international database for the surveillance of adverse reactions and events associated with

blood donation and transfusion. Although international definitions were used, compliance with them is not optimal. One outcome of STARE will be a contribution to improving that situation. In the light of the experience gained from this work, a second pilot study is now being implemented using a modified questionnaire which it is hoped will subsequently be employed in a permanent web-based data collection system enabling the collection and analysis of annual data from all the countries that are gathering detailed haemovigilance data.

It is important to emphasize that STARE's holistic approach to haemovigilance avoids restricting the observations to just the "tip of the iceberg" represented by the most severe events. It thus differs from European Union and Council of Europe

data collection systems in aiming at the surveillance of all adverse reactions and events, not just the serious ones. Amongst other things, this will permit better assessment of trends.

C. Politis, Greece ■

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## THE DONATION PART OF THE BLOOD TRANSFUSION CHAIN

### FROM SURVEILLANCE OF DONOR COMPLICATIONS TO VIGILANCE OF BLOOD DONATION

#### COMPLICATIONS RELATED TO BLOOD DONATION

Most important in donation vigilance is monitoring and minimising the risk of complications related to blood donation. Therefore, this has also until now been the main topic of the work on haemovigilance of the donation part of the transfusion "chain". In 2004, some ten years after introduction of haemovigilance related to receiving a blood transfusion, a common *International Society of Blood Transfusion* (ISBT) and *International Haemovigilance Network* (IHN) (then the *European Haemovigilance Network*, EHN) working group was established with the task of describing the kinds and occurrence of these complications. At that time, little work had been published on this subject and there was no publicly available set of definitions.

Draft versions of definitions for donor complications and a questionnaire for data collection were presented, discussed and progressively improved during successive years. In June 2006 the draft document was used for an initial data collection exercise. A total of ca. 100,000 complications related to 10 million bleedings from 15 countries worldwide for the year 2005 were presented at the 9th European Haemovigilance Seminar (Dublin 2007).

In Europe, the definition of "serious adverse reaction" in the European Directive (2002/98/EC) triggered debates concerning descriptors for serious level of severe donor complications. It was recognised that the objectives for international data collection are different from those of institution-level or national recording and evaluation. Thus a vasovagal reaction in a donor with brief loss of consciousness is important and should be professionally treated. Internationally however it would not be classed as "serious" under existent international definitions, which use criteria

such as (prolongation of) hospital admission or long-term morbidity.

In 2007-8 a validation exercise was performed using hand-drafted scenarios of donor complications were prepared. Twenty two volunteer international experts, members of the EHN board and IHN working group, classified the scenarios according to the definition set. The findings were presented and discussed at the Frankfurt EHN meeting, which led to some adjustments to the list.

Notably, "serious" was defined in a generic way (the same for all donation complications, and also the same as for transfusion reactions). It was decided that imputability levels should be assessed, particularly for late events, which may follow blood donation but not have been caused by it.

The important category of nerve injury could not be reliably distinguished from other causes of painful arm following donation. Experts felt that a separate category should be kept in the list in order to focus attention on the problem; nevertheless cases which are not clear-cut can be reported as "painful arm" of unspecified cause. Finally, complications of apheresis procedures should be included in the list.

Thus after successive presentations and debates at the EHN and ISBT meetings, a *Standard for Surveillance of Complications Related to Blood Donation* was finally approved by EHN and ISBT in 2008. The working group hopes that countries will map their own definitions to this set, and share their results in the interests of improving donor care. The standard is available at the public part of the web sites of ISBT ([www.ISBT-web.org](http://www.ISBT-web.org)) and of IHN ([www.EHN-org.net](http://www.EHN-org.net)).

Future improvements of the standard may be necessary, but these should be infrequent.

### FROM DONOR COMPLICATIONS TO DONATION VIGILANCE

To make it easy to be updated with the newest findings within the field, the group should promote the development of guidance documents, recommendations and standards, which after approval of the mother organizations (ISBT and IHN) could be published on their web sites.

Vigilance is the intensive surveillance of an area for unexpected events which could involve a risk. The surveillance gives accurate information about the kinds of risk and the rate of occurrence. This information provides the background for changes of procedures in order to avoid or reduce the occurrence of specific risks or increase safety through general measures.

Donation Vigilance is the surveillance of the first part of the blood transfusion "chain" from donor to recipient (the donation part) and deals with handling of the donor and the delivered raw material. Vigilance in this part of the line is very important as it - the only part of the line to do so deals with safety and risk for both donor and recipient.

### DONOR CARE

Donors voluntarily give their blood to help another human being and may expect for ethical reasons that the bloodletting facility handle this situation professionally. If not, the donors will be justified in not feeling appreciated and will hesitate to return as a repeat donor.

The state of the art for donor care is:

- Donation process shall be safe and efficient;
- Procedures which keep the risk of complications as low as possible should be preferred;
- Complications should be treated in such a way that the best possible outcome is ensured;
- Donor Insurance should be established to cover expenditures related to complications;
- The technology used for the donation process should ensure an optimal possibility for the best use of the raw material in treating patients;

- Donors shall receive accurate information about all details of the process especially acceptance criteria for blood donors, risk related to donation and use of the donated blood.

This state of the art for donor care should be used for all donors worldwide, whether they are altruistic volunteers (voluntary and non-remunerated which internationally is the golden standard), have received some form of compensation, or have responded to need when a family member requires transfusion.

### THE DONATION VIGILANCE GROUP

Like the broadening charge of the International Haemovigilance Network, IHN, now more international and dealing with haemovigilance in a broader sense, the brief of the donor working group has widened to include all aspects of vigilance related to the blood donation. In 2009 in Rome, a tentative plan with examples of issues which could be included in the future work was presented and accepted at the IHN board meeting.

Activity should now focus on those projects where national data and international collaboration can lead to exchange of expertise and to concrete projects in order to improve awareness of donor safety and best practice in donor care.

The name of the existing working group "Working Group on Complications Related to Blood Donation" should be changed to indicate the new scope, and the group will be opened for more members in order to have a more international representation. The renewed group hopes to present a strategic plan for its future work at the next IHN board meeting in Croatia in 2010.

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## HAEMOVIGILANCE IN RECIPIENTS: DEFINITIONS FOR INTERNATIONAL SURVEILLANCE

### INTRODUCTION

Regional and national hemovigilance data are increasingly being gathered, often on a mandatory basis. For comparison and surveillance purposes uniform definitions are needed, not only for the types of event but also for sub-classifications such as severity grades and imputability levels. Another relevant area is that of the denominators. This work was taken up by the European Hemovigilance Network in 2004 and became a joint project with the hemovigilance WP of the International Society for Blood Transfusion in 2006. Until the present time the working party has addressed only definitions of non-infectious transfusion hazards

because the infectious complications of blood transfusion are the domain of the ISBT WP on Transfusion-Transmitted Infections.

### DEVELOPMENT OF THE DRAFT DEFINITIONS

The list of draft definitions, initially prepared by J. Bux and presented at the European Haemovigilance Seminar in 2004 (Zürich), was repeatedly presented and improved on the basis of comments by EHN participants and later by ISBT working party members. A number of guiding principles emerged.

1. For surveillance purposes the focus should be on clear-cut adverse reactions which are defined with high

specificity. For instance, febrile non-hemolytic transfusion reactions (FNHTR) for comparison purposes will be those of  $\geq 2^\circ\text{C}$  accompanied by rigors. It is recognised that not all FNHTR will be captured in this definition, but there will be less likelihood of comparing "apples with pears".

2. Countries are not obliged to use the definitions within their own systems but it is hoped that they will "map" their definitions to the international list for comparison purposes.
3. Once adopted the list should not be subject to frequent revisions.

### VALIDATION

It was decided to "validate" the draft



definitions. If professionals in the field of haemovigilance are asked to assign a category to case scenarios using the definitions, do they arrive at the same answers? We therefore compiled a set of 35 case scenarios from a larger number submitted by volunteers. The scenarios, covering all the main non-infectious types of transfusion reaction, were actual reports received by haemovigilance registries in two countries. Nine volunteer members of the haemovigilance working group (eight countries) were sent the scenarios in 2008 and codified them according to the draft definitions: type of reaction, severity and imputability. Following an initial evaluation and discussion of the results at the ISBT Macao meeting, several further members volunteered to do the exercise (the same version of the definitions was used for this).

### RESULTS

In all, 12 responses were obtained (eleven countries). Volunteers commented that the exercise had taken them several hours to complete. Agreement on the category varied from 25 to 100% but was 66% or higher for 72% of the scenarios coded. The categories which gave the lowest agreement were FNHTR and non-specific respiratory complications.

Slight modification of the "transfusion-associated dyspnoea" had already been agreed on in Macao; there was also

some confusion concerning delayed serologic transfusion reactions. Agreement on severity varied from 33% to 100%, being 66% or higher for 22/35 scenarios. That on imputability was poorer, ranging from 33% to 89% and with only 16/35 scenarios coded the same by 66% of the volunteers.

### DISCUSSION

The results were presented in the meetings of the WP in 2008 (Macao) and 2009 (Cairo). Some minor adjustments to the category definitions were decided upon. The lower agreement in assessment of severity and especially imputability was commented upon. It was felt to be inappropriate to modify those definitions because they are already widely used worldwide. It would appear better to group cases assessed as having a possible, probable or definite imputability (relationship) to transfusion for the purpose of international comparisons.

Disappointingly, not all who volunteered to take part in the second round actually returned the assessment form. This is partially offset by the fact that in one country at least a panel of experts rather than an individual performed the assessment. As a possible way to increase the input from professionals, the working party discussed whether an online module might be developed in which clear cut cases are

presented for practice in assessing reports and less obvious cases are included for testing the definitions and factors influencing the diagnosis decision.

To professionals working in haemovigilance, the level of debate between experts will come as no surprise. Transfusion reactions arise in patients who often have multiple pathologies and medications. There may be clinical findings which do not fit in with the "best fit" diagnosis or classical features may be masked. The margin for debate may surprise those who do not regularly assess haemovigilance reports, including regulators. While on occasions this could mean the definition needs fine-tuning, the main problem is the variability of clinical presentation.

### CONCLUSIONS

The validation of the draft definitions for non-infectious transfusion reactions showed generally acceptable levels of agreement between experts. However the response level was lower than hoped for. Some minor adjustments were shown to be necessary and will be made prior to definitive adoption of the definitions.

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12<sup>th</sup> International Haemovigilance Seminar - 17-19 February 2010; Dubrovnik, Croatia  
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## FROM THE PRESIDENT



**W**orld Blood Donor Day (WBDD) is celebrated on June 14<sup>th</sup> World Wide. ISBT together with the World Health Organization, the Red Cross and Red Crescent Society and the International Federation of Donor Organizations are the core agencies for this important day. The regional supplement accompanying Transfusion Today has a feast of pictures and reports on this important day, which is celebrated worldwide. The theme this year was 100% voluntary non-remunerated blood donation and the WHO held a global consultation on this issue in Melbourne just prior to the WBDD global launch. ISBT participated in the consultation and in the global launch event. The WBDD core agencies are working hard on ways to promote and grow the activities of June 14<sup>th</sup> in future years. ISBT was also pleased to be present at the Africa Blood Transfusion Society meeting in Nairobi in June. Thanks to the generosity of a number of organisations, ISBT is able to offer exempt membership to people under 40, who are working in blood transfusion in UN low and medium development index countries. We recruited several new exempt members at the ISBT stand in Nairobi.

The focus section in this issue of Transfusion Today is on haemovigilance. The ISBT Working Party on Haemovigilance is very active with different task forces working on various aspects of haemovigilance. They are also working closely with the International Haemovigilance Network (IHN) and are collaborating with IHN in the development of an international database on haemovigilance. Congresses are a core activity of the ISBT. I particularly hope that, if you are a member in the Asia/Western Pacific region, you are planning to participate in the XX<sup>th</sup> Regional Congress in Nagoya Japan in November. Professor Takamoto the Congress President has written a special invitation to all ISBT members, which can be found in this edition of Transfusion Today. The Scientific programme is complete now that the abstracts have been reviewed and oral and poster presentations have been selected. Further information is available on the ISBT website. In Germany, preparations are well under way for hosting the XXXI<sup>st</sup> International Congress in our capital Berlin in June 2010. Please come and join this important international congress, which will present exciting new insights in all aspects of transfusion medicine and cellular therapies from all over the world. With your participation at ISBT congresses, you not only receive important new information first hand, but also add to the weight and importance of transfusion medicine in the scientific world. In addition, Berlin offers a great place for meeting with your old friends and getting into contact with new ones! ISBT has recently announced that the 2012 congress will take place in Mexico City. This is an exciting development, since it is 20 years ago that ISBT held an international congress in South America.

Looking forward to seeing most of you soon!

**Your president**  
Erhard Seifried, Germany ■

## FROM THE SECRETARY-GENERAL



**T**hat blood transfusion is life-saving is a well known fact. For the health care of many patients, a transfusion of blood has made a difference between day and night. In order to have sufficient high quality blood products, all blood establishments in the world try to organise themselves as best they can. A safe blood supply relies on selected and qualified donors, GMP (-like) blood component production, quality assurance, and optimal blood transfusion therapy. A difficult but rewarding task. Sometimes however a blood bank may face circumstances where all these activities are overwhelmed by a situation which is unimaginable and has not been anticipated. The demand for blood is not based on the individual patient but on many requests for blood at the same time. It is caused not by a disease, syndrome or trauma of the individual but by a serious disaster in which many people are involved.

Recently in New York, the World Disaster Report 2009 was published by the International Red Cross and Red Crescent Societies (IRCS). The information in the report was shocking. In 2008, more than 213 million people suffered from 326 natural disasters. In that year, the number of disasters was smaller than in previous years but the intensity was bigger and resulted in more casualties. Worldwide, natural disasters were the cause of 235,000 victims. The cyclone Nargis which struck the coasts of Myanmar was the worst. It caused 138,366 deaths. The earthquake in Sichuan in China resulted in 87,476 deaths. These two disasters were the cause of 93% of the total number of deaths and this figure is therefore the second highest of this decade. The year 2008 accounted for 326 nature disasters of which 296 were weather related. There were 158 floods, 99 hurricanes, and 21 earthquakes. Asia was the continent that was hit the most followed by America and Africa. The financial damage as a consequence of these disasters was 181 billion dollars. Although the number of disasters has decreased, statistics show that the number of weather related disasters in the last decade has increased dramatically. This increase is caused partly by climate change leading to more floods, long lasting draughts, violent hurricanes, heat waves and further spread of diseases such as malaria. These high numbers reflect enormous suffering and pain, while in this report the number of wounded people is not even taken into account. If these events continue to occur, it is expected that health care specialists including those working in blood banks will have to organise themselves in order to be prepared for the unthinkable.

In case of a new virus like the Mexican flu or a potential increase of the spread of malaria, dengue, SARS or Chagas disease, systems are in place and task forces are prepared. The occurrence of infections is a familiar subject to blood transfusion specialists and they are used to working with these because blood borne infections and transmission of infections is part of our field. The increase in disasters however is new, frightening and unexpected. I think that regarding disasters we should help each other within ISBT in the same way as we help each other with all other problems our profession is encountering. We help each other in order to increase the number of blood donors, to improve the quality of the products, tracing systems and the optimal usage of blood. At ISBT Congresses, invited speakers have occasionally addressed massive transfusion, the organisation of the supply of blood in case of disaster and disaster blood management. However I think this is not enough. In 2003 at the time of the Tsunami in Thailand there was not enough Rh(D) negative blood available for the affected tourists due to the difference between the incidence of Rh(D) in the Asian and western populations and the Thai Red Cross had to organise special blood drives in the capital using western donors. On September 11, 2001 the contribution of blood donors to the blood supply in New York was so much more than the actual demand that it created problems with the blood system.

Working in blood transfusion medicine is challenging because the problems are always different and changing. We have to be creative but we need to be prepared if possible. With the warnings in the IRCS 2009 report, I think that within the ISBT community we should prepare ourselves and think on how we can help each other in case of a disaster in a region where other ISBT members are active. In the global ISBT community, we should think beyond borders.

**Paul Strengers, NL** ■

## FROM THE HISTORIAN

# TRANSFUSION BEFORE THE FIRST INTERNATIONAL CONGRESS, 1935

Transfusion was very different before 1935 when the first international meeting was held in Rome. That meeting led directly to the founding of our International Society of Blood Transfusion.

**N**ext year, in 2010, we will celebrate 75 years of international cooperation and exchange of ideas. The Proceedings of the First International Congress of Blood Transfusion set the stage for what has happened since then.

## IN THE BEGINNING: THE SURGEONS AND THE SEROLOGISTS

In 1935, it was 140 years since human blood was first transfused as a therapy for blood loss and 35 years since Landsteiner described the ABO blood groups. Those who came to the meeting represented two separate specialties, those who did the transfusions and those who studied other applications of serology. Neither group of workers was much interested in what the other was doing.

The first specialty of surgeons and obstetricians took care of patients and received the most acclaim and recompense for their work. They controlled the whole process, from the recruitment of donors to the performance of direct transfusion from artery to vein. In the legal parlance of the day the surgeon was 'captain of the ship'. If the ship sank they were generally not found responsible because they were usually transfusing patients who were already moribund. The donors were often reluctant participants and there was no time to do laboratory tests, especially in the patient's home by gaslight.

The other specialists worked in the newer science of immunology, later to be graced with the grander name of immunohematology. They had delivered the facts on the ABO blood groups to the surgeons years earlier and worked on little of clinical care importance since then. The only other known blood group was MN.

## SURGICAL TRANSFUSION 1935

Landsteiner reported that in 1929, ten thousand transfusions had been done in the New York area alone. Surgeons who did the transfusions often had designed and publicized their own apparatus for

transferring blood directly from the donor to the patient.

In 1930, the Scannell syringe pump came with everything necessary to do "accurate matching" with the blood of five donors and a manual, *BLOOD TRANSFUSION SIMPLIFIED* for use by a "doctor engaged in General Practice". There was a microscope, hand centrifuge, racks and tubes and solutions and pipettes, all to be used in 28 described steps before thirty-minute incubation at room temperature. The actual pump had the advantage of built-in handles that gave the operator an apparatus that could be "used without any assistance, especially if the transfusion must be done in the patient's home." Pity the general practitioner who arrived at the patient's home with his portable laboratory ready to perform the 28 steps necessary to make his choice from among five waiting donors for a dying patient.

## SEROLOGY, 1935

The status of serology had been presented by Italian, Leone Lattes, who was the President of the 1935 Congress, in his monograph *INDIVIDUALITY OF THE BLOOD*; the English translation of the third French edition of 1929 had been revised and updated by the author in 1932 to include 91 pages of references (more than 2,000). He does devote 14 of his total 405 pages to ABO and transfusion, but his interest was in heredity, anthropology and forensics. Agglutination tests were as described by Landsteiner and standardized reagents were unavailable. There were no tests for incomplete antibodies.

## THE MIDDLE GROUND

The Russians were the first to organize research and applications of transfusion. The Bogdanov Institute in Moscow had opened in 1926 and more had followed in major cities of the USSR.

British Surgeon Victor Riddell attended the 1935 Transfusion Congress on a traveling fellowship that brought him to

most European countries and the large cities of Canada and the United States. His book *BLOOD TRANSFUSION* gives useful comparative information about the transfusion world of the time.

American Alexander Wiener's monograph *BLOOD GROUPS AND BLOOD TRANSFUSION* first appeared in 1935, of course predating his fixation on Rh. Wiener was then a believer in the biological test for compatibility of Oehlecker in Germany that he described as the slow injection of 20 cc of donor blood followed by observation of the patient for two minutes. (Another biological test, used by Arnault Tzanck in France, involved injecting blood from both donor and recipient into the heart of a guinea pig. If the animal did not go into shock, the donor blood was considered compatible for the patient).

Errors committed by the immunohematologists went down the sink whereas those committed by the surgeons were more likely to be discovered. The major fault was not theirs; it was the existence of the competing ABO nomenclatures of Moss and Jansky. One urologist reported on the kidney failure he saw in patients who had received AB blood identified as "universal donor" as a result of that serological mix-up. (Even as late as 1944 an American Professor of Surgery wrote that "type AB may be used as donor for all other groups" and "Type O patients are universal recipients".)

When those interested in blood transfusion were invited to Rome in 1935 there were as yet no donor programs that would put blood on the hospital shelf in advance of need. The citrate anticoagulant had been available for twenty years but the surgeons used it only to facilitate direct donor-to-patient direct transfers. Yet, there was a remarkable amount of information exchanged at that first meeting.

**Paul J Schmidt, USA ■**  
ISBT Historian  
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## XXth REGIONAL CONGRESS, ASIA

NAGOYA CONGRESS CENTER, NAGOYA, JAPAN NOVEMBER 14 – 18, 2009



Dear Readers,



I am looking forward to welcoming many ISBT members and non-members to the ISBT XX<sup>th</sup> Regional congress in Nagoya which is now only a few weeks away.

We have put together a scientific programme that covers a wide range of topics in transfusion medicine. There are symposia on aspects related to donors, transfusion transmitted infection, red cell and platelet immunology, cost effectiveness, clinical aspects of blood transfusion and cellular therapies. New symposia on massive haemorrhage and transfusion, TRALI, HEV and red cell and platelet immunobiology have been added.

There will be three plenary sessions. The first is on Cellular Therapies, with one presentation examining state of the art and the future of cellular therapies and the other heterogeneity and hierarchy with the haematopoietic stem cells. The second plenary on Transfusion Transmitted Infection will have a presentation on Occult Hepatitis B infection and the epidemiology, clinical features and prevention of HTLV-1 infection. The third plenary on Clinical Transfusion examines patient blood management and translational research.

There will be an opportunity to “meet the expert” at a breakfast session with Paul Holland, USA. He will lead a discussion and answer questions on Transfusion Associated Graft versus Host Disease and TRALI.

We have attracted speakers from inside Japan as well as the wider Western Pacific Region and the USA and Europe.

As well as the scientific programme delegates can visit a large industry exhibition where a wide range of companies will be exhibiting their products. Refreshment breaks and lunch will be taken in the industry exhibition area.

There will be an attractive social programme with welcome and closing parties.

Please note that the next registration deadline is October 16<sup>th</sup>. The registration fee will rise by another €50 for each category after this date.

Visit [www.isbt-web.org/nagoya](http://www.isbt-web.org/nagoya) for details on registration and hotel accommodation.

I do hope that you will join me and many other delegates from around the region in Nagoya. Attending the congress presents good opportunities to learn more about topics in our field and to network with colleagues and learn more about what is happening in the individual countries in the Region.

I look forward to welcoming you in Nagoya.

Shigeru Takamoto ■  
Congress president

# WELCOME TO OUR NEW MEMBERS

- Amr Ahmed - SUDAN
- Alani Sulaimon Akanmu - NIGERIA
- Temilola Alayande - NIGERIA
- Senet Awocker Ibrahim - ERITREA
- Morris Ayikanying - UGANDA
- Munkhgerel Baatar - MONGOLIA
- Sumit Bagaria - INDIA
- Erik Beckers - NETHERLANDS
- Nidhi Bhatnagar - INDIA
- Erwin Cabana - UNITED STATES OF AMERICA
- Jose Castell Martinez - MEXICO
- Mobojali Dada - NIGERIA
- Robert Deitenbeck - GERMANY
- Maxime Kouao Diane - COTE D'IVOIRE
- Ukwubile Celestine Ejeh - NIGERIA
- Sylvia Froelicher - SOUTH AFRICA
- Eric Israel Gutierrez Juarez - MEXICO
- Abdelaziz Hamad - SUDAN
- Kirsten Henneberg-Quester - GERMANY
- Emad Jawabreh - JORDAN
- F. Judiartini - INDONESIA
- Philip Kibor - KENYA
- David Kimani - KENYA
- Scolastica Kimani - KENYA
- Sirichularit Kittivorakit - THAILAND
- Sixten Körper - GERMANY
- Patcharakorn Kramkratok - THAILAND
- Boronty Kroyune-Byabazarre - UGANDA
- Edwin Kubo - UNITED STATES OF AMERICA
- Despoina Kvriakou-Kourelis - GREECE
- Scott Macpherson - UNITED STATES OF AMERICA
- Muhammad Mahbub-Ul-Alam - BANGLADESH
- Muddassir Mahmood - UNITED ARAB EMIRATES
- Lucy Mary Marowa - ZIMBABWE
- Emmanuel Masvikieni - ZIMBABWE
- Ngali Mbuuko - KENYA
- Ahmed Hassan Mohamed - SUDAN
- Abeer Mohammed - UNITED ARAB EMIRATES
- Irene Muramba - KENYA
- Dixon Mchana Mvvaludindi - KENYA
- Bernard Natukunda - UGANDA
- Richard Njoroge - KENYA
- Andy Numby Ngoy Congo - THE DEMOCRATIC REPUBLIC OF THE RITESH PAMNANI KENYA
- Pieter Potstra - NETHERLANDS
- Gilbert Rumanywdha Sunday - UGANDA
- Meriam Safi El Jil - UNITED ARAB EMIRATES
- Janet Sampson - UNITED KINGDOM
- Mahamoudou Sanou - BURKINA FASO
- Peter Schubert - CANADA
- Ibrahim Sheik-Yousouf - MAURITIUS
- Harprit Singh - INDIA
- Younis Skaik - ISRAEL
- Betina Sorensen - DENMARK
- Yaovaluk Vipsoongnern - THAILAND
- Bramwel Wafula Baraza - KENYA
- Tamunomieibi Thompson Wakama - NIGERIA
- Edwin Walong - KENYA
- Hans Zaaijer - NETHERLANDS

## ISBT AWARDS 2010

### ISBT PRESIDENTIAL AWARD

#### ISBT members are invited to propose candidates for the ISBT Presidential Award

The Foundation Transfusion Medicine grants this Award to a senior person who has made eminent contributions to transfusion medicine or a related field through original basic or applied research, the practice of transfusion therapy or through significant educational and/or service contribution to the field. A short curriculum vitae of the proposed candidate and a description of his/her contribution to transfusion medicine, accompanied by three signatures of ISBT members, who support the nomination, should be sent to Dr Henk Reesink, the Secretary- General of the Foundation - Email : [internationalforum@kpnplanet.nl](mailto:internationalforum@kpnplanet.nl)

The closing date for nominations is **October 1<sup>st</sup>, 2009**.

### JEAN JULLIARD AWARD

#### Applications are invited from scientists under 40 years of age

The prize is reserved for scientists who are under 40 years of age at the time of submission of their manuscripts. It is given in recognition of recently completed scientific work

on blood transfusion and related subjects. In general, the prize will be awarded to one individual however in special cases the Prize may be shared by more than one individual.

Further details can be found on :

[www.isbt-web.org/awards/jeanjulliardprize.asp](http://www.isbt-web.org/awards/jeanjulliardprize.asp)

The closing date for submission of applications is **November 30<sup>th</sup>, 2009**.

### INTERNATIONAL WOMAN IN TRANSFUSION AWARD

#### Nominations are invited for the International Woman in Transfusion Award

The award is given to a woman professional whose cumulative record - in research, innovative educational methods or outstanding clinical practice - demonstrates important and significant contributions to the body of medical and/or scientific knowledge or to the understanding and practice of transfusion medicine.

Further details can be found on :

[www.isbt-web.org/awards/womenintransfusion.asp](http://www.isbt-web.org/awards/womenintransfusion.asp)

The closing date for submission of applications is **November 29<sup>th</sup>, 2009**.

# WHAT ABOUT INFORMATION TECHNOLOGY MANAGEMENT IN TRANSFUSION MEDICINE\* (II)

The use of information technology (IT) in transfusion medicine aims primarily to assure donors selection and safety, quality of blood components as well as patient safety. It is also used for assuring the viability of the business which is the foundation for reaching goals just like for any kind of organization.



**T**raceability is another important topic which is still under progress as long as the required information is not yet clearly defined. Nevertheless, under the umbrella of Haemovigilance, a big effort has been made to establish a classification of adverse incidents related to the use of blood components. The future would be to merge all vigilance systems (e.g. Pharmacovigilance, Materiovigilance, Biovigilance, Haemovigilance) aiming at providing healthcare with a common patient vigilance knowledge base.

Therefore, from the technology perspective, this would results in technical requirements with the aim of providing the practitioner with adequate mechanisms for managing vigilance efficiently globally within healthcare systems.

In order to face such challenges, many aspects of IT management need to be considered such as: requirement definitions, system selection, development, implementation and maintenance, resources and competencies, information organization and its role in the organization.

Information technology has to be seen in an interoperability environment, which means "the ability of two or more systems or components to exchange information and to use the information that has been exchanged" [1]. IT is no longer considered as a stand-alone system but is rather integrated within a network that aims to share adequate information for the decision-maker.

## MANAGEMENT REQUIREMENTS AS MEANS OF COMMUNICATION BETWEEN STAKEHOLDERS

Managing requirements is becoming a big issue. One of the aims of requirement specifications is the ability to communicate between stakeholders.

Requirements related to IT may come from as many sources as we have stakeholder groups [2]. From the client perspective, the concerned stakeholders include - but are not limited to -: product manager (supplier) application specialist (supplier and client), service engineer (supplier and client), systems architecture and software engineers (supplier), quality management (supplier, client and regulator). Requirements can be improved through: user evaluations, enhancement requests from users on existing systems, standards and regulations, and clinical literature.

Requirements are not limited only to the concerned process. It may need to be extended to other business processes where the required system has an indirect impact, which may have influences on the whole business organization such as: availability of human resources, competency improvements, business budget recalculations and infrastructure planning.

Therefore, it is important to keep requirements up to date as much as possible in order to assure that all stakeholders understand the needs of any system and their implications in the organization as well as within the interoperability environment.

## LET'S NOT FORGET THE PROJECT HAS TO BE SUCCESSFUL!

As shown by Lou Ansaldi from ITSC (Information Technology Support Center) in a 2008 presentation, according to The Standish Group surveys conducted each year from 1994 to 2004, the average of successful projects is 27% (meaning delivered on time, within budget, with required features and functions), canceled projects 26% and the rest, 47%, are for challenged projects (late, over budget, and/or less than the required features and functions).

How could this happen? We thought that we are well organized, well motivated. But still such a constellation occurs.

Most organizations follow best practices of project management as well as quality assurance. However, the suitability of such practices defines the level of success of a project.

Why are best practices suitable to project management and quality assurance? There are two main reasons: first, interoperability environment is of growing in importance, meaning that more than one organization may be involved. Secondly, the expectations of IT projects are higher today in term of size, speed at which it has to be deployed, and complexity.

What exactly makes a project successful? In their study, The Standish Group has established 10 heuristic criteria to be considered when starting any complex IT project.

1. User involvement
2. Executive management support
3. Clear statement of requirements
4. Proper planning
5. Realistic expectations
6. Smaller project milestones
7. Competent staff
8. Ownership
9. Clear vision & objectives
10. Hard-working, focussed staff

**Table 1:** Criteria for a successful project

Considering these criteria should help stakeholders to understand the aims, the importance and the impact of any complex

*\* See also (I) in Transfusion Today June 2009)*



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project within the organization and the related business processes, especially when different organizations are involved.

Difficulties encountered in managing IT projects may occur in any type of organization. Recipes alone don't work. However, recipes with adequate and motivated stakeholders give a good chance of success.

### INFORMATION REQUIREMENTS

Questions are : why do we need information ? In other words, for which purpose is it necessary ? What kind of information do we need ? When is information needed ?

It is true that information is essential for establishing organization strategy and accomplishing business objectives. Nevertheless, nowadays the amount of information to be managed and its complexity are big challenges for assuring consistency and integrity.

Looking at the definition of data, information and knowledge (see table 2), data will never change, and their meaning may change in time (information) as well as its impact on our judgment (knowledge). Therefore, information may have different interpretations depending on whom it is intended for and which purpose it is bound to.

**Data:** Information in raw or unorganized form (such as alphabets, numbers, or symbols) that refer to, or represent, conditions, ideas, or objects.

**Information:** Raw data that has been verified to be accurate and timely, is specific and organized for a purpose, is presented within a context that gives it meaning and relevance, and which leads to increase in understanding and decrease in uncertainty.

**Knowledge:** Human faculty resulting from interpreted information; understanding that germinates from combination of data, information, experience, and individual interpretation.

[www.businessdictionary.com](http://www.businessdictionary.com)

**Table 2:** Definitions

The understanding of these definitions helps to focus on the essential information needed in the organization and to organize it appropriately in order not to misinterpret it after many years. This is essential, especially for information that needs to be tracked for a long time (e.g. in transfusion medicine, in regards to the EU directives, the information related to donor-products-patient has to be tracked for 30 years). The meaning of the information today may not necessarily be the same in 30 years. There are so many factors that could alter the signification such as: social behavior evolution, political and regulation evolution, business process evolution, knowledge acquisition.

### INFRASTRUCTURE REQUIREMENTS

From the technological perspective, we have to be sure that the adequate technology is available for managing the information not only today but also in the short-, mid- and long-terms.

Infrastructure is necessary for keeping the information under control and for accessing it adequately by the concerned stakeholders at appropriated times and locations. It is the main information safeguard other than human factor.

The means of infrastructure are diverse. The investment in an infrastructure depends on different parameters related to the size and the configuration of the organization, the importance of the information throughout the business processes and undoubtedly to the business strategy.

Table 3 presents some examples of criteria to be considered in establishing infrastructure requirements.

- Information requirements
- The amount of information to be managed in an adequate period of time
- Speed at which the information should be available
- Business continuity policy
- Functions related to information processing in order to select/develop adequate applications
- Simultaneous interfaces with other systems such as automated systems, business management systems (e.g. accounting and billing systems), data warehouses, ERP systems, hospital base and other organization IT systems
- Network configurations
- Workplace configurations
- Data management systems (e.g. backup, archiving)

**Table 3:** Criteria for implementing adequate infrastructure

Due to the development of internet and the ever increasing needs of exchanging information between locations within the organization and/or through different organizations, more sophisticated network components and functionalities are required. Such growing complexity may have an impact on competency requirements as well as infrastructure management.

In this situation, outsourcing the infrastructure management either in whole or in part may be a solution. This approach imposes to define the requirements precisely in terms of infrastructure expectation such as its architecture, configuration, availability (e.g. downtime, uptime, respond time at any request), accessibility, speed and security.

### SECURITY REQUIREMENTS

The growing information complexity and the amount to be managed as well as the availability of the information to be given to external organizations require from the information owner to have an information security policy.

The policy should be established considering enforceable regulations as well as vulnerabilities related to such as : IT network configurations, application architectures, concerned stakeholders, changes made to the infrastructure.

From 2003, the ISBT Working Party on Information Technology has been aware of the necessity of providing guidance on information security. In 2006 the first version of **Guidelines on information security in transfusion medicine** was published [3] - available on [www.isbt-web.org](http://www.isbt-web.org) under the documentation section. These guidelines were established to help transfusion medicine organizations in assuring the information confidentiality, availability and integrity (see table 4 for definitions) in regards to their national regulations as well as their internal information and infrastructure requirements.

- Confidentiality: "Ensuring that information is accessible only to those authorized to have access"
- Integrity: "Safeguarding the accuracy and completeness of information and processing methods"
- Availability: "Ensuring that authorized users have access to information and associated assets when required".

**Table 4:** Basic ISO definitions for information security

These guidelines are established referring to the ISO 17799 (which is today replaced by ISO 27002) and the Health Insurance Portability and Accountability Act (HIPAA) in force in the United States.

### INFORMATION TECHNOLOGY MANAGEMENT

As seen above, requirements for information, infrastructure and information security are the most important elements to establish in any organization that wants to use information in an appropriate way.

IT infrastructure should consider interoperability of systems as well as information portability between the business processes. In transfusion medicine, it concerns collection facilities, processing facilities, diagnostic laboratories, blood banking, transfusion medicine laboratories and hospitals as well as industries such as fractionating industries.

The IT management should not only be involved at the operational but also at the strategic level. Nowadays, IT is much closer to the business process and therefore, IT strategy has to be aligned with the business strategy.

Furthermore, we can assume that the cost of IT is less today when compared to the past. We get more today than what

we got for the same price, for instance, 10 years ago. However, the value of information is higher since it has a higher impact on the business.

Besides ISO 9001 : 2000, ITIL (recognized by the ISO organization through the ISO 20000 standard) provides a management model leading IT management to a service level. The aim is to make IT services part of the business success. As an example, IT should be more involved with business and customer in the requirements definition process where IT is needed. It allows to anticipate any change as well as any disruption in the infrastructure.

In today's transfusion medicine, information technology plays an important role, and the importance will continue to grow. Considering the potential of nanotechnology, the need of automating processes, the need of better business control and the role of the information in providing adequate products and services, IT infrastructure management will gain in importance and, if not yet, will have to be integrated into the business strategy of the organization.

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## ICCBBA, PRESENTED INAUGURAL "ONE WORLD AWARD" TO DR. CHARLES MUNK

**J**une 9, 2009, REDLANDS, CA and NICE, FRANCE - Honoring original research and innovative technical development for the advancement of global information standards in transfusion and transplantation medicine, ICCBBA has presented Dr. Charles Munk with its inaugural One World Award.



## ORGANISATIONAL, TECHNICAL AND CLINICAL ASPECTS OF CORD BLOOD BANKING

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11-15 NOVEMBER 2009**

### Some topics and sessions

Current results and future of cord blood transplant  
Public cord blood banks worldwide and Netcord organisation  
Autologous versus allogenic cord blood banking programmes  
Sibling cord blood banking  
International regulations  
Cord blood banking: organisation and standards  
Cord blood banking: quality, equipment and personnel  
Cord blood donation  
Cord blood processing and storage  
Cord blood selection and clinical outcome

### INFORMATION AND DETAILS AT

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Tel.: +39/02/58.31.65.15 - Fax: +39/02/58.30.81.11  
E-mail: [estm.secretariat@estm.info](mailto:estm.secretariat@estm.info)

**Course venue:** Meeting room of the Sea Lion Hotel, where participants will be hosted  
Tel.: + 39 085 4492736, Fax: + 39 085 4492738;  
email: [commerciale@sealionhotel.com](mailto:commerciale@sealionhotel.com);  
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# THE ROLE OF EDUCATION AND RESEARCH IN TRANSFUSION MEDICINE IMPROVEMENT

The most important goals that Iranian Blood Transfusion Organization-Research Center (IBTO) pursues through its research and education activities are to make all the staff involved in technical affairs in all blood centers across the country informed on the most recent specialized scientific developments in the fields of transfusion medicine and transfusion sciences as well as to raise the knowledge of specialists, physicians, and paramedics about these sciences.

## Measures taken by IBTO Research Education Research Center

- Establishment of "High Institute for Education and Research in Transfusion Medicine" in 2008,
- Establishment of the discipline of lab hematology and blood banking at MS level for the first time across Ministry of Health (with annual recruitment of 7 students),
- Establishment of the discipline of lab hematology and blood banking at PhD level jointly with Iran University of Medical Sciences in 2005 and then independently by High Institute for Education and Research in Transfusion Medicine in 2008,
- The 1<sup>st</sup> International Congress on Transfusion Medicine held in partnership with ESTM, IPFA, ISBT, WHO-GCBS and with the presence of more than 1500 participants, 14 foreign and 26 Iranian speakers,
- The 1<sup>st</sup> and 2<sup>nd</sup> scientific seminars held with joint cooperation of IBTO Research Center and France Blood Transfusion Organization (EFS) in 2007 and 2008,
- The 1<sup>st</sup> and 2<sup>nd</sup> scientific seminars held with joint cooperation of IBTO Research Center and Bordeaux University 2 in 2006 and 2008,
- Proposal submitted to ISBT for hosting ISBT Regional Congress in 2013,
- GMP workshop held by WHO and hosted by IBTO with the participation of EMRO member states in 2008,
- Establishment of IBTO Research Center in 2003 in order to expand and employ the knowledge of transfusion medicine, make all research and production activities in the field of preparation of safe blood and blood components organized and orientated; the center was selected as the superior research center of Iran during the last three years,
- Contribution of 34 faculty members ,
- Approval and implementation of 260 research projects during the last 10 years,

- Publication of 28 books,
- Publication of more than 120 articles,
- Active participation in ISBT congresses with many abstract submissions,
- Publication of IBTO Research Center Quarterly "Scientific Journal of Iranian Blood Transfusion Organization Research Center".

## Education Department

- Establishment of training courses including educational target-oriented programs, workshops, and scientific-specialized seminars,
- Preparation of scientific-specialized handouts, brochures and pamphlets,
- Involvement in the educational programs of medical and paramedical students including residents and fellows of universities of medical sciences in the fields of transfusion sciences,
- Initiative to hold MPH course within the domain of transfusion medicine.

## Research Department

- Orientation of research projects,
- Assessment and follow up of research projects,
- Plans to make regular visits to blood centers across the country to exert control and surveillance,
- Arrangement of research workshops,
- Research prioritization,
- Plans to make research findings practical for the purpose of innovation and accomplishment in the domain of transfusion medicine,
- Authorship, compilation, and translation of specialty books,
- Preparation and incorporation of the most up-to-date scientific books and resources in IBTO central library with access to electronic books and journals.

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# ON JOB TRAINING PROGRAMS ACROSS THE EGYPTIAN GOVERNORATES

## A milestone for achieving uniformity of NBTS in Egypt

In 1997, the project for restructuring the NBTS was initiated in Egypt aiming to establish customized, modern blood transfusion services that covers the whole country. The Egyptian National Blood Transfusion Services (ENBTS) is a network consisting of the National Blood Transfusion Center (NBTC) (the headquarters), 17 large and small Regional Blood Transfusion Center (RBTC) and 6 district (DBBS) present in mostly all the Egyptian governorates. According to the national policy, uniformity of this network was an important prerequisite and required challenging the obstacles of distance limitations and extension of the 27 Egyptian governorates all over Egypt.

A crucial step towards achieving this uniformity was the continuous training programs serving the entire NBTS network, therefore; well planned and organized training programs & workshops are continuously held in the NBTC considering both the NBTC staff as well as the RBTC & DBB staff.

Holding on job training programs in other governorates required a group of highly qualified trainers mostly from the NBTC, each representing his/her field; also transportation & accommodation of the trainers for 3 to 5 days on the area where the training was to be held as well as availability of learning facilities at these remote areas, finances, transportation of materials or samples, etc ...



*On job training course: The picture shows the general manager of the ENBTS with a group of cascade trainers, & a group of DBB trainees at el AREESH city, the capital of north Sinai governorate)-Egypt.*

Throughout the on job training programs the trainers did their utmost efforts to raise the performance level of the trainee, to develop their knowledge and to give them long lasting learning effects.

These programs, under the umbrella of total quality management system, have an extremely great impact in standardizing policies & procedures and in improving clinical practice; this in turns results in improved patient outcomes & better use of scarce resources.

Hand by hand we are continuing proceeding for more & more on job training programs across the whole country until the goal is reached.

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# VENEZUELAN ASSOCIATION OF SICKLE CELL DISEASE AND THALASSEMIAS: A LIGHT AT THE END OF THE TUNNEL

Though Sickle Cell Disease is the most frequent genetic disease in the world and has major morbidity, after almost a hundred years from its discovery, it continues being a disease little understood by health professionals and little supported by the diverse governmental agencies of the whole world.

Venezuela does not escape this reality. In 2005, Dr Olimpia Pérez-Báñez, one of the most prestigious and dedicated Venezuelan hematologists in this topic, being worried and motivated by this situation, stimulated a group of patients and their relatives in creating the Venezuelan Association of Sickle Cell Disease and Thalassemias (AVDT). This Association has as its mission, getting and fomenting the integral attention of patients with such pathologies and improving the management of the disease inside the familial bosom.

As patients and their relatives, physicians, nurses, educators, employers, etc, increase knowledge of the disease, a suitable management of the same will be achieved. This will affect directly and favorably the education, job assistance, morbidity, mortality and quality of life of these patients. Therefore, one of the principal tools used in this association is education at different levels.

Since 2005 the AVDT has dictated courses directed to patients and their relatives in Caracas and the principal cities within the country. In addition, it has designed a workshop to train nurses who handle patients with Sickle Cell Disease and Thalassemias.



*Group of sickle cell disease patients. At the center, Dr Olimpia Perez Bandez, promoter of the Association*

In 2009, the AVDT organised courses directed to patients and their relatives and at the same time is giving special education to medical personnel. So it has programmed three symposiums: Sickle Cell Disease; Treatment of the acute pain Sickle Cell Disease; Diagnosis and treatment of the diverse emergencies in Sickle Cell Disease. This year AVDT will publish a manual of norms and procedures elaborated by the hematologists constituting the Medical Commission of the AVDT.

In relation to the governmental actions, the AVDT has achieved that the Venezuelan Institute of the Social Security acquired an oral iron chelator which from the year 2007 is available free for all Venezuelan patients with secondary overload of iron through transfusions.

The AVDT has taken a national position. At present, it relies on three chapters: The Central chapter that includes the Metropolitan District and the central states of the country; Western-center chapter shaped by the states of this region and the Zulia state chapter. This year the South Eastern chapter will be installed.

This year, on June 19<sup>th</sup>, like many worldwide associations, the AVDT celebrated for the first time the "World Sickle Cell Disease and Thalassemia Day". This Day was decreed by the UN in March 2009, after the UNESCO, in 2005, made a statement concerning same at the request of the Organizations of the Congo Republic and Senegal and the International Association of Sickle Cell Disease. This resulted that in 2006 the WHO decreed that Sickle Cells Disease is a problem of public health and urged state members to create special programs for patients affected by this disease.

The AVDT plan of actions for the next few years will be directed to involve pertinent governmental entities, to create health programs that allow for the realization of early diagnosis and the suitable treatment of the disease and its complications, in order to diminish morbidity, number of hospitalization days, work and school absenteeism, mortality and to improve the expectancy and quality of life of the affected patients.

**Graciela León de González** ■  
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*Local group playing typical Venezuelan music during the celebration*



## CHAGAS DISEASE : A HISTORICAL REVIEW, AND CURRENT PERSPECTIVES

*From the discovery of the causative agent and its life cycle to the demonstration of its transmissibility by transfusion*  
*Jean-François Leblanc, Gilles Delage, Héma-Quebec, Canada, and Silvano Wendel, ISBT President-Elect, Brazil*

Carlos Justiniano Ribeiro Chagas was born on July 9<sup>th</sup>, 1879 in a coffee farm in the state of Minas Gerais (Brazil). In 1900, he dedicated his initial efforts to the control of malaria, where in 1908 he was commissioned by the Brazilian Government to control malarial attacks amongst workers on a very important railroad under construction. A headquarters was settled in a railroad car (which served as consultation room, laboratory and sleeping quarters) in the small town of Lassance (Minas Gerais). After one year of exhausting work, Carlos Chagas was advised by a railroad engineer about the existence of a hematophagous bug that was typically biting humans on the face while they were asleep. As Chagas himself described: "We spent more than one year in that area, without having any notice about the existence of a hematophagous insect in the huts, currently known as *barbeiro*, *chupão* or *chupança*" (1).

Chagas became interested about the possibility that this bug could transmit any kind of parasite to humans or other vertebrates. Soon thereafter, he detected flagellates in the hindgut of this insect. Intrigued by the possibility that this parasite could represent an intermediate stage of *Trypanosoma minasense*, previously described in 1908 in marmosets, he sent some bugs to Manguinhos Institute (Rio de Janeiro) to be fed on infection-free primates. Few weeks later, the same flagellates were recovered in the bloodstream of these animals, prompting him to recognize a new species, distinct from *T. minasense* or "any other species of the same genus". First named *Schyzotrypanum cruzi*, in honour of Oswaldo Cruz, his former mentor, the parasite was subsequently renamed *Trypanosoma cruzi*.

Carlos Chagas returned to Lassance, looking for the presence of vertebrate hosts for this newly discovered parasite. After several tests in human beings and animals, he found a cat with parasites in the bloodstream. Two or three weeks later (April 14<sup>th</sup>, 1909), he was asked to investigate the possibility of an acute malarial episode in a 2-year old girl (Berenice) living in the same house where this feline was found. Berenice had showed no parasites during a previous examination. However, several parasites were detected this time. Thus, Chagas suggested the possibility of an acute phase of a disease yet to be described. Serial blood tests showed the disappearance of flagellates in the bloodstream as the symptoms vanished, raising the possibility of a chronic phase of a new disease. On April 23<sup>rd</sup>, Oswaldo Cruz announced Carlos Chagas' discovery at a session of the Brazilian National Academy of Medicine and subsequently in the medical literature (2,3,4,5). Carlos Chagas described patterns of human infection, the parasite's morphology in the bloodstream, its life cycle in the invertebrate vector's digestive tract, its cultivation in agar-blood and the transmission to vertebrates of flagellates from infected triatomines. Although some slight errors were committed in relation to the parasite's life cycle, the great contribution of his work clearly surpassed the minor mistakes.

After these initial observations, Chagas returned to endemic zones to study the clinical stages of this disease. He described the effects on heart and gastrointestinal systems, and also neurological manifestations from a lethal meningoencephalitis case. Furthermore, the main cardiac disturbances such as those related to the degeneration of the Hiss bundle, premature beats, atrio-ventricular blockade, Stoke-Adams syndrome, bradycardia and congestive heart failure, were also reported by Chagas. In 1911, he presented at the National Academy of Medicine (Rio de Janeiro) the first con-

genital case (6), and in 1912, he suggested the possibility of a sylvatic cycle in armadillos. In 1916, he was the first to suggest that the digestive system could also be a site of pathologic manifestation (7), especially those aspects related to megaesophagus and dysphagia, which had been regionally known for over a hundred years. After the death of Oswaldo Cruz in 1917, he replaced him as director of the Manguinhos Institute, a position held until his death on November 8<sup>th</sup>, 1934, at the age of 55.

The possibility of transfusion-transmitted Chagas disease (TxCD) was first raised by Mazza in 1936 (8), followed by Dias in Brazil (1945) (9), Bacigalupo in Argentina (1945) (10), and Talice in Uruguay (1947) (11). Blood donors found to be reactive by complement fixation tests were first described in 1949 in Belo Horizonte (Brazil) (12), followed by São Paulo in 1951 (13).

The first reported cases of TxCD were published in São Paulo in 1952 by Pedreira de Freitas (14). At the same time, development of whole-blood chemoprophylaxis was proposed, which led to the description of gentian violet (crystal violet) as a useful agent by Nussenzweig in 1953 (15,16). Further cases of TxCD were described in Brazil, Argentina (17), Venezuela (18), Chile (19), Bolivia (20) and eventually in all Latin American countries. More recently, cases have been reported in North America (21,22,23,24,25,26,27) and in Europe, particularly in Spain (28,29,30,31).

#### Transfusion-Transmitted Chagas Disease : The South and Central American Perspective

Given that vectorial transmission of Chagas disease occurs in nearly all South and Central American countries, the Southern Cone (32,33) and the Andean (34) Countries Initiatives were developed with the goal of eliminating domiciliary infestation by *Triatoma infestans* and complete control over transfusional transmission as a result of strong governmental commitments (35) and mandatory serological screening (36,37). These actions were enhanced by the 51<sup>st</sup> World Health Assembly, which declared Chagas disease control as one of its main priorities (38).

*T. cruzi* infection remains highly prevalent among blood donors from selected areas of South and Central America (39,40,41). Nevertheless, in the past 20 years, a progressive and still ongoing decrease in the prevalence of *T. cruzi* among blood donors from Latin American countries has been observed (42).

Universal screening has dramatically reduced the transfusional risks of Chagas disease transmission in the past two decades in Latin America, to the extent that in those regions where this strategy has been fully implemented, the residual risk of infection is estimated to be around 1 : 200,000 (40, 43).

#### Transfusion-Transmitted Chagas Disease : The North American Perspective

Despite the presence of insect vectors carrying *T. cruzi* in the southernmost parts of the United States, very few indigenous cases of Chagas disease have been documented from these areas. This low prevalence, which is in marked contrast with the situation in South America, is likely a consequence of housing facilities that are unfavourable to insect vector proliferation and sustenance in the US.

Seven cases of transfusion-transmitted Chagas disease have been documented in North America since 1987, five in the United States, two in Canada (21,22,23,24,25,26,27). Given the recent upward shift in travel and immigration from Latin America,

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particularly to the United States (44), it has been hypothesized that these seven cases could be an underestimation, and that more cases of transmission by blood transfusion have gone unnoticed in the past two decades. These trends point to *T. cruzi* as an emerging threat to transfusion safety in North America.

In the face of this safety issue, U.S. and Canadian health authorities have asked blood agencies to address this risk. In January 2007, the Food and Drug Administration (FDA), the U.S. health authority, has licensed a test aimed at screening blood donations for the presence of antibodies to *T. cruzi*, thereby setting the stage for the implementation of a more extensive blood donor screening. As of July 2009, more than 65% of U.S. blood donations were being screened with this test. From inception in January 2007 up to July 2009, more than 20 million blood donations have been screened with this test. A total of 3,664 repeat reactive donations have been intercepted, of which 938 were confirmed by a more specific test (45). These results indicate that although the seroprevalence of *T. cruzi* among US blood donors is relatively low, one cannot exclude the possibility that donor screening has prevented a few cases of Chagas disease transmission by transfusion.

Canada also has an increasing blood donor pool from Latin America (44), as well as donors who may at times travel to rural areas of South America where Chagas disease remains endemic. Given this emerging risk to transfusion safety, the two Canadian blood collection agencies have recently introduced additional questions in the donor history questionnaire. Donors are being asked questions related to their country of origin, the country of origin of their mother and grandmother, and whether they have recently travelled or lived for a while in Latin America. Based on their answers to these questions, donors who are considered "at-risk" for Chagas disease are either selectively tested, and/or blood components most likely to be infectious, i.e., platelet concentrates and transfusable plasma, are not produced (plasma is sent for fractionation). This moderate approach to risk mitigation was justified by the extremely low prevalence of Chagas disease in Canada. Europe is also concerned by the recent emergence of Chagas disease resulting from increased immigration and travel to South America. Accordingly, some European countries have undertaken selective testing of at-risk blood donors, and succeeded in intercepting a few donors seropositive for *T. cruzi* (46).

## Conclusion

This year marks the 100<sup>th</sup> anniversary of the discovery of Chagas disease. For almost eighty years, this infectious disease has remained an almost exclusively Latin American medical issue. The recognition that the causative agent could be transmitted by blood transfusion, and the increased concerns regarding transfusion safety in the past 10-20 years, were powerful driving forces for health authorities throughout Latin America to implement several measures aimed at reducing this transfusion risk. These efforts were very successful, to the extent that nowadays insect vectors remain the dominant mode of transmission of *T. cruzi*, while scattered foci of high endemicity are localized to specific regions of South and Central America. Global changes in immigration and travel patterns over the past twenty years have contributed to the emergence of Chagas disease in North America and Europe. There, health authorities and blood agencies have recently addressed the issue, and will certainly continue to monitor the emergence of *T. cruzi* in the Northern Hemisphere.

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# Upcoming events

## 2009

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KARACHI, SINDH, PAKISTAN

Recruitment and Retention of Voluntary Non remunerated Blood Donation & use of Safe Blood

[asadjafferiy2k@yahoo.com](mailto:asadjafferiy2k@yahoo.com)

## 2010

■ January 23 - 25

CALCUTTA (KOLKATA), WEST BENGAL, INDIA

National Conference and Workshop on Strategies for Blood Donor Recruitment and Total Voluntary Blood Programme.

[avbdwb@gmail.com](mailto:avbdwb@gmail.com)

■ October 21-24

BEAUNE, FRANCE

XI European Symposium on Platelet and Granulocyte ImmunoBiology

<http://sfts.asso.fr/sympo-platelet>

## 2011

### ISBT CONGRESS

■ June 18-23

LISBON, PORTUGAL

XXI Regional Congress of the ISBT, Europe

[isbt.lisbon@eurocongress.com](mailto:isbt.lisbon@eurocongress.com)

[www.isbt-web.org](http://www.isbt-web.org)

### ISBT CONGRESS

■ November 25-29

TAIPEI, TAIWAN

XXII Regional Congress of the ISBT, Asia

[isbt.taipei@eurocongress.com](mailto:isbt.taipei@eurocongress.com)

[www.isbt-web.org](http://www.isbt-web.org)

### ISBT CONGRESS

■ June 26- July 1

BERLIN, GERMANY

XXXI<sup>st</sup> International Congress of the ISBT

[isbt.berlin@eurocongress.com](mailto:isbt.berlin@eurocongress.com)

[www.isbt-web.org](http://www.isbt-web.org)





## Individual Membership Form 2009

To be sent to: **ISBT Central Office** c/o Jan van Goyenkade 11, NL-1075 HP Amsterdam, The Netherlands

Tel: +31 (0)20 679 34 11, Fax: +31 (0)20 673 73 06, E-mail: [membership@isbt-web.org](mailto:membership@isbt-web.org)

### PERSONAL DATA: \*

Family name \_\_\_\_\_ Initials \_\_\_\_\_ Mr. / Ms. / Mrs.

First name \_\_\_\_\_ Title(s) \_\_\_\_\_ M / F

Year of Birth  (only for those who apply for the 65 years of age fee)

Organisation \_\_\_\_\_

Address \_\_\_\_\_

Postal code and City \_\_\_\_\_ Country \_\_\_\_\_

Telephone \_\_\_\_\_ Telefax \_\_\_\_\_

E-mail \_\_\_\_\_

### INSTITUTION

Code: \_\_\_\_\_ Other: \_\_\_\_\_

(please refer to appendix I)

(if your position is not mentioned in appendix I)

### SPECIALITY

Code: \_\_\_\_\_ Other: \_\_\_\_\_

(please refer to appendix II)

(if your speciality is not mentioned in appendix II)

### POSITION

Code: \_\_\_\_\_ Other: \_\_\_\_\_

(please refer to appendix III)

(if your speciality is not mentioned in appendix III)

#### APPENDIX I

Institution
Blood Bank / Blood Establishment
Blood Group Reference Laboratory
Blood Transfusion Service
Faculty of Medicine
General Hospital
Hemophilia Centre
Institute of Health - Ministry Of Health
National Blood Center
National Blood Transfusion Laboratory
Nursing
Plasma Fractionation
Private Firm
Research Center
Red Cross / Red Crescent
School of Medicine of Technology
University Hospital

#### Code

Speciality
54 Anaesthesia/reanimation
60 Anthropology
55 Apheresis
63 Blood Transfusion
50 Chemistry-biochemistry
59 Clinical Transfusion
51 Continuing Education
56 Donor Organization
57 Forensic Medicine
78 Haemophilia-coagulation
58 Hemotherapy
65 Histocompatibility
52 Immunogenetics
53 Immunohematology
64 Immunology
62 (Internal) Medicine
Management/administration
Med.lab.sciences/pathology
Microbiology
Oncology
Pediatrics
Pharmacology
Quality Control
Serology
Surgery

#### APPENDIX II

#### Code

Position
10 Assistant Director
11 Blood Bank Director
37 Chief Executive Officer
14 (Chief) Laboratory-assistant
15 Commercial/Consultant
16 Director
17 Graduate Student
18 Hospital Scientist
27 Internist
19 Managing Director
21 Medical Director
22 Nurse
25 Physician
24 Production Manager
23 Professor
26 Research Fellow
28 Scientific Director
29 Technical Director, Technician, Analyst
30
31
32
36
35
33
34

#### APPENDIX III

#### Code

Position
99
80
101
84
10
79
95
89
86
83
81
91
90
96
92
88
82
87



Family name \_\_\_\_\_

## WORK EXPERIENCE

Duration of active work in the field of blood transfusion/transfusion medicine: \_\_\_\_\_ years

Academic / scientific / other qualifications: \_\_\_\_\_

**INDIVIDUAL MEMBERSHIP FEE 2009\*** (including Vox Sanguinis, Transfusion Today, reduced fee for congresses, access to the ISBT membership website, access to the ISBT working parties and standing committees documentation, ISBT academy etc...)

☐ Under 65 years: € 98,-

☐ Over 65 years: € 87,-

\* Please tick the appropriate box

## PAYMENT

Undersigned declares to pay the total amount due in Euro's with the following means of payment:

☐ **Bank transfer:**

Please transfer payment to ABN AMRO, 57.48.05.842, to ISBT Central Office Amsterdam, The Netherlands.

The BIC code of the bank is ABNA NL 2A. The IBAN Code is NL45ABNA0574805842. **Clearly state your name.**

☐ **Credit card:**

☐ Euro/Master/Access card

☐ American Express

☐ Visa

Charge my card nr:

CVC number:

(the last 3 or 4 digits of the number printed on the back of the card)

Expiration date:

 / 

Signature: \_\_\_\_\_

Date: \_\_\_\_\_  
day month year

Please note:

1. Only the forms of payment listed above are acceptable.
2. When your name is NOT clearly stated on the bank transfer, your payment cannot be linked.  
Consequently, your payment will be unknown to the ISBT Central Office.

**PLEASE DO NOT FORGET TO COMPLETE BOTH SIDES OF THE REGISTRATION FORM!**



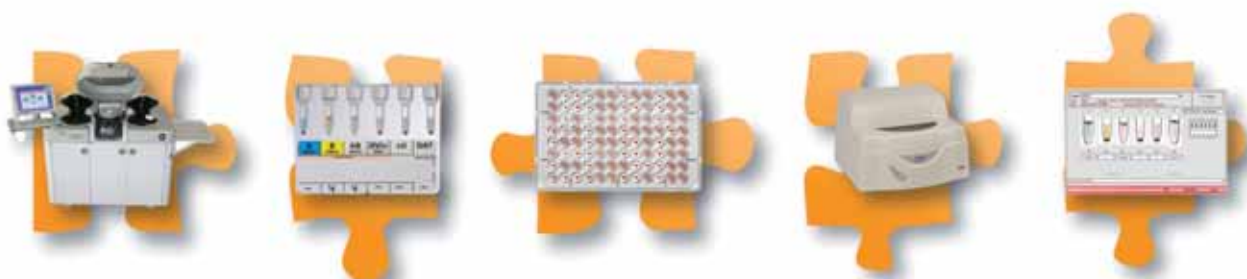


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