

[16]

EBA

European Blood Alliance

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EBA

European Blood Alliance



An association of non-profit
Blood Establishments



Collecting about **17.000.000**
blood donations in Europe



Covering **470.000.000**
citizens

*In August 2016, EBA members joined the #missingtypes campaign: organisations, landmarks and celebrities were asked to drop the letters A, B and O from their names, to emphasise the need for all types of blood donors.



Picture Credit: Red Cross Flanders

INTRODUCTION

I'd like to take you back in time – to 1998, where nine executives of blood services officially met for the first time in a meeting in Helsinki on September 21st. These executives knew each other informally, but decided that the time was now ripe for establishing a formal association. The reason for this *Alliance*, as they called it, was that the European Commission planned to produce a common directive on blood components.

Back to the now: 2017 had just started when the official message from the European Commission came that the *EU Directives Concerning Blood and Tissues and Cells* would be evaluated, before possibly revising this. EBA had been preparing for this throughout 2016 with the establishment of an *EU Blood Directives Working Group*, who compiled four position papers on EBA's behalf. This evaluation offers EBA the opportunity to recall the reason for its original establishment.

Drawing on the combined resources of 26 countries, the EBA has the resources and knowledge of thousands of employees of our membership organisations. All those people are committed to providing safe blood components for the benefit of patients all over Europe. Through this close network, EBA is able to provide evidence and expertise to all European and national institutions.

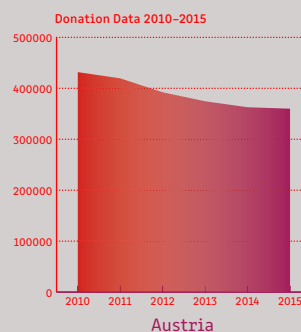
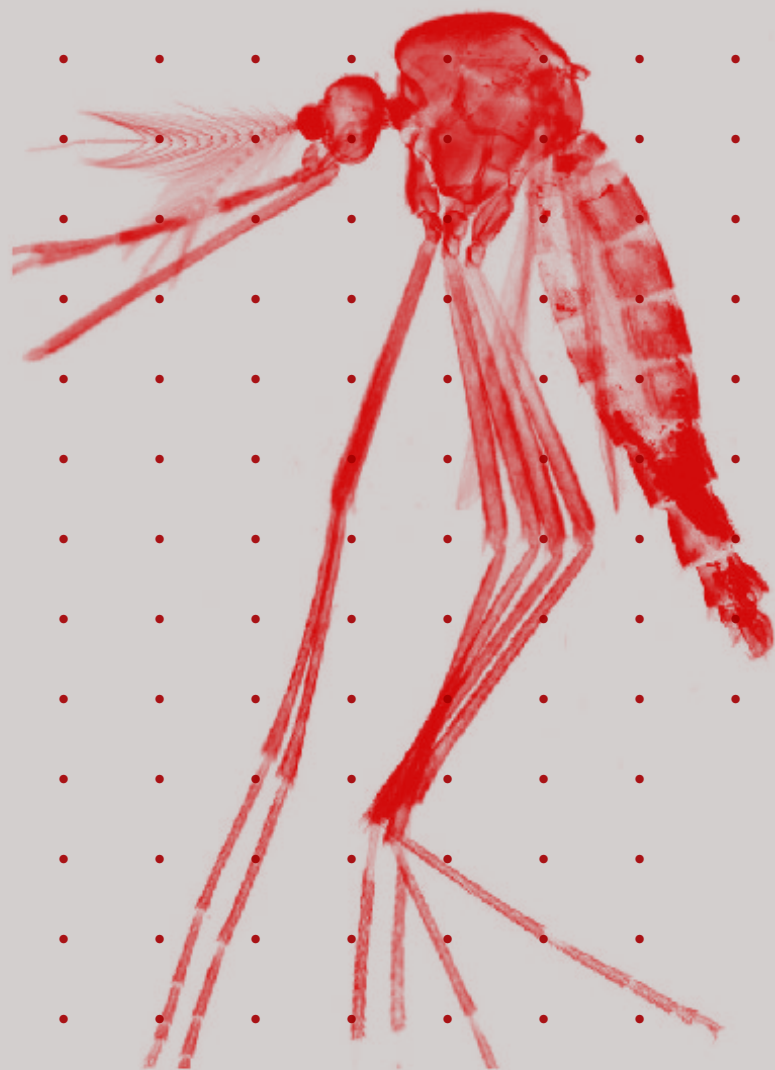
This *Annual Report* documents many of the great outcomes of the *EBA Working Groups*, projects and international collaborations. I thank all the people who helped achieve this and who are committed to achieving EBA outcomes!

Philippe Vandekerckhove

EBA President

ZIKA VIRUS

Since the end of 2015, the continuous ongoing new insights into the nature of and large epidemic in the Americas of Zika virus led to an increasing concern for blood safety in Europe. This large outbreak and consequences for safety of the European blood supply were closely monitored by blood establishments, competent authorities and government institutions. In 2016, EBA assisted EU institutions with Zika preparedness for Europe.



The rapid spread of the outbreak areas, the possibility of local outbreaks within Europe, and the severe neurological consequences for foetuses were the topics that raised most concern.

Virus and transmission

Zika virus is an emerging mosquito-borne flavivirus. The virus was first isolated from a rhesus monkey in Uganda in 1947 and caused sporadic human infections. The first outbreaks were described in 2007 and 2013-2014 on Yap island and French-Polynesia respectively.

In 2015, Zika virus emerged in South America, with a further spread across the Americas. The main transmission route of the virus is through a mosquito bite, from the vectors *aedes aegyptii* and less so, *aedes albopictus*. The risk for recipients of substances of human origin (SoHO) cannot be ignored, even though only a few probable transmissions through blood products were reported, and in the cases observed there did not seem to be any clinical consequences for the recipient of the blood product.

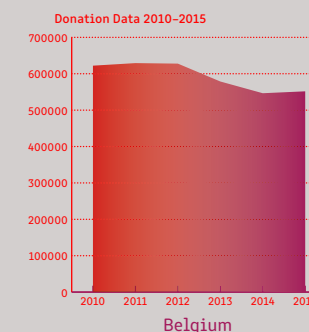
Up to 2016, although the competent vectors are present in Europe, no transmission of Zika virus through the vectors has been reported in Europe. However, some new insights have raised concern: the huge outbreak in the Southern part of the Americas; the fact that sexual contact is an alternative transmission route; the persistent viremia in semen and whole blood; and the devastating intra-uterine central nervous system malformations in foetuses.

EBA EID Monitor

Since 2009, a group of medical experts has formed the *EBA Emerging Infectious Disease Monitor*. This group not only comprises European experts, but also has members in Australia, Canada and in the US. In monthly teleconferences, they monitor emerging diseases and discuss measures that blood establishments could take against these threats. For each (potentially) blood transmittable pathogen, the group discusses the measures that are taken in different countries to secure the safe supply of blood components. Also, recent literature and the latest scientific developments are discussed. The group consists of 50 participants, of whom 25 in various configurations are actively participating in the monthly teleconferences. All its members along with EBA members are updated via the minutes of the calls.

EuFRAT

What chance does a travelling donor run of getting infected on a tropical vacation and introducing this pathogen into the blood supply? That is the question to which the EUFRAT tool can give an answer. EUFRAT is an online tool that can estimate this risk based on the input of a relatively limited number of variables. Last year, EBA collaborated with the European Centre for Disease Control (ECDC) on further developing this online tool which, along with manuals and examples supporting assessment, can be reached at ECDC website.



As far back as 2013-2014, Zika virus was already on the EID Monitor's radar. During the outbreak in French Polynesia, 3% of the donors were found to be Zika virus RNA positive. During that time, the main risk for European donors concerned only the travelling donors. In 2016, Zika virus was the main topic, with hepatitis E and West Nile virus being not far behind, in all the teleconferences, which discussed the continuous updates of new developments and publications.

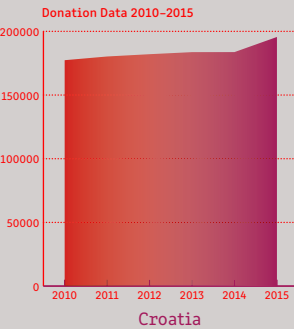
Collaboration with ECDC and EC

In February 2016, the European Centre for Disease Prevention Control (ECDC) contacted the EBA requesting assistance with drafting a guide for preparedness activities in Europe concerning the Zika virus in relation to the safety of substances of human origin. The draft of the document was sent to the EBA EID Monitor and several subsequent versions were sent and received. To further discuss the preparedness plan, EBA took part in two teleconferences in May 2016 together with ECDC, the National Competent Authorities and the European Commission. The first points discussed in these teleconferences were the activities and responsibilities of BEs, NCA and ECDC. The EBA stressed to the ECDC that it is important to be able to perform risk assessments and, if feasible, to conduct a cost-effectiveness study at national level before decision making. Tools like EUFRAT (see side bar for more info) could help to analyse the data.

The ECDC
The European Centre of Disease Prevention and Control (ECDC) was established in 2005. It is an EU agency with aim to strengthen Europe's defences against infectious diseases. ECDC's mission is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases. To achieve this mission, ECDC works in partnership with national health protection bodies across Europe to strengthen and develop continent-wide disease surveillance and early warning systems. By working with experts throughout Europe, ECDC pools Europe's health knowledge, to develop authoritative scientific opinions about the risks posed by current and emerging infectious diseases.

See more at: <http://ecdc.europa.eu/en/aboutus/Pages/aboutus.aspx#sthash.cR4WIbNE.dpuf>

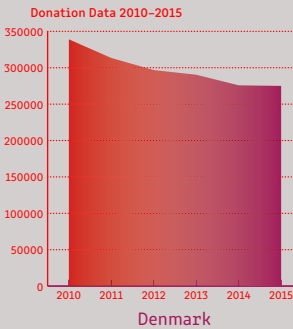
A total of **25** answers from **22** countries, including answers from the USA and Canada, were submitted.



Testing Capacity Survey

At the request of DG SANTE, EBA offered to monitor Zika virus screening capacity in the EU. The EBA survey on blood safety measures and testing capacities was launched in September. A total of 25 answers from 22 countries, including answers from the USA and Canada, were submitted. The main outcomes of the survey were as follows:

- A travel related donor deferral of 28 days for Zika virus risk has been applied in almost all countries:
 - Canada defers donors who have travelled outside of Canada, the continental U.S. and Europe for 21 days
 - Norway indicated that donors are deferred for 4 months
 - Belgium, Finland and the Netherlands apply the universal deferral for all donors for at least 28 days after travel outside Europe
 - Germany (Bavarian Red Cross) applies a universal deferral of 28 days after returning from areas between 30° of latitude North and South, with the exception of Australia, and returning from a travel to South America and Africa in general
- Regarding the sexual transmission risks, the deferral policies differed across the countries. Four countries had made risk assessments and, based on their findings, decided not to defer for transmission risks.
- France took measures for their Overseas Territories, the French Antilles: blood safety measures were taken such as implementing Zika NAT testing for all local blood donations, providing red blood cell concentrates from the mainland of France for pregnant women and distributing pathogen –reduced platelets when provided from local donors
- Within Europe, Zika virus nucleic-acid amplification testing (NAT) for donation screening was not implemented. Only EFS (France), NHSBT (England), German Red Cross Blood Services and Sanquin (Netherlands) had Zika virus donor NAT screening tests available and the overall testing capacity in Europe is limited. However, the blood services with appropriate testing facilities could be approached for support. Sanquin also developed an in-house test.
- Data on deferral due to Zika is often not available and is influenced by the overlap between existing geographic donor deferral for other mosquito-borne diseases (dengue, Chikungunya, WNV and malaria) and an unknown number of donors who self-defer.
- Some European countries estimated a donor loss of a few cases per country per day, while other countries estimated in percentages, but still below 1% per day.



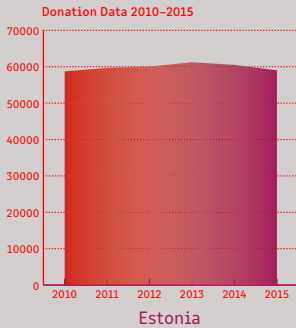
The US representative in the EID Monitor noted that, by December, US blood services had implemented NAT screening for all donations, as per FDA requirements.

As the temperatures dropped in Europe and in affected areas during the autumn, the risk of transmission resided, as the mosquito season came to an end. This EID Monitor network enabled the sharing of knowledge, not only between the blood services worldwide, but also between European Institutions, and ensured that, in 2016, measures were taken to guarantee safe supply of blood components. EBA remains in contact with these institutions in 2017 to provide knowledge and expertise for Zika and also for other emerging diseases.

Further considerations after 2016’s epidemic

After last year’s epidemic, some questions remain unanswered. The testing in the US now showed that applying individual donation NAT testing proved to be very specific and sensitive to detect Zika Virus. Conclusions on the cost-effectiveness of this intervention are still pending.

Secondly, although viral persistence in semen persists for up to six months, it remains uncertain whether it is infectious via sexual activity after this period, and whether this affects the safety of blood components as well. All of these uncertainties will have to be researched and a decision needs to be made as to how much safety should cost. The next mosquito season will surely answer some of these questions.



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[01]

**SAFE AND SECURE
SELF-SUFFICIENCY
FROM VOLUNTARY
NON-REMUNERATED
BLOOD DONATIONS**

The EBA argues in its position paper ‘EBA Fact Sheet on European self-sufficiency for blood components and plasma for fractionation’ for the importance of a broad donor base. To be able to match the trend toward more and more individualised therapeutic transfusions, the donor base should match the whole population in its diversity. A broad donor base will also help in being prepared for outbreaks of emerging infectious diseases, such as Zika Virus. The blood service will have to defer groups of donors who have travelled to some regions and will require compensating the supply by using other groups of donors. This matching of the donor to the right patient also is important when it comes to ethnicity which reflect the blood groups; more European countries are struggling to have the donor base mirror the ethnic composition of the entire population, but the NHSBT is already quite advanced in this area and has put a lot of effort in this.

MINORITY RECRUITMENT

For over a decade, the NHS Blood and Transplant in England (NHSBT) has had a small task force for the recruitment of blood donors of Black and Asian Minority Ethnicity (BAME). But increasingly, the NHSBT has noted the imbalance of donor and patient numbers and appointed a National BAME Marketing Manager to redress the balance.

The Sickle Cell Disease dilemma

Sickle cell disease mainly affects people of black heritage. The treatment can consist of regular blood transfusions, which – to most benefit the patient – needs to be well-matched to the patient’s blood group and specific type. There are approximately 15,000 patients within England suffering with sickle cell disease, with 250,000 people with sickle cell trait. The majority of sickle cell disease patients require Ro Red Blood Cells (RBC). Ro is a rare subtype of the Rh blood group system, which is mostly found within the black community (present in approximately 50% of black people, whilst present in only 2% of the Caucasian people).

However, there is currently unprecedented demand on Ro RBC and if NHSBT is unable to fulfil this demand, it means that other vulnerable stocks have to be substituted. This rise in the use of Ro RBC can be explained by the growth of the affected population, coupled with the fact that blood is now used more extensively with patients who are now also living longer than they used to. So more Ro RBC is needed, while only less than 1% of the donor population is of black or black mixed heritage. This clearly shows an imbalance.

As NHSBT needed to meet the demand for Ro blood, an Ro taskforce was launched in September 2014, with representation from all areas of NHSBT – from front line blood collection/marketing staff, to component manufacturing, testing, issuing and customer services/patient care. Central to the work of this task force was a far greater emphasis on black donor recruitment and retention.

Sickle-cells

Sickle cell disease (SCD) is a genetic haemoglobin disorder caused by a single amino acid substitution in the β -globin chain, producing the abnormal haemoglobin-S (HbS) in red blood cells (RBCs). SCD occurs when a person inherits two abnormal copies of the haemoglobin gene, one from each parent. This gene occurs in chromosome 11. SCD is characterized by chronic hemolytic anemia and recurrent vascular occlusion. During hypoxic conditions RBCs turn into a rigid, crescent or “sickled” shape RBC that obstructs blood flow in the microcirculation and destructs the RBCs. This sickling process is continual; however, episodic exacerbations occur resulting in severe pain (“sickle-cell crisis”) and secondary organ damage. Clinical manifestations usually appear after three months of age when the fetal hemoglobin decreases. The symptoms vary between mild/ almost asymptomatic till severe disease. Blood transfusion plays a prominent role in the management of patients with SCD.

'Represent' campaign

Last year saw a **48%** increase in the registrations of black blood donors, with nearly **6000** new recruits of black heritage.



Last year saw a 48% increase in the registrations of black blood donors, with nearly 6000 new recruits of black heritage. BAME Marketing Manager Theo Clarke explains: " NHSBT wants to be able to provide all people with the best suited products, and the issue of matching BAME patients with the best matched blood will not go away; it will only become more of an issue until the donor base reflects the diversity of the population and patients' ethnic heritage. This is not a quick process, as we endeavour to forge long lasting ties with the Black community in particular; but ultimately we are seeing progress being made and the communities themselves are playing a big part in that."

Recruitment efforts

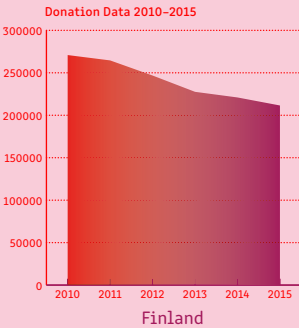
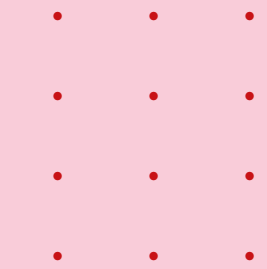
NHSBT uses specific communication channels to reach these potential donors, which might differ from recruiting donors in general: "we use the communication routes already well-established within these groups; talking to them as individual communities where possible, rather than as a homogenous group (i.e., calling everyone BAME). We use tried and trusted channels such as mosques, temples, schools or neighbourhood community hubs. We also worked together with the MOBOs (Music of Black Origin – music awards) to undertake an awareness campaign called 'Represent' amongst young black and Asian potential donors. Part of this campaign was a music video which provided an important message but within an authentic format, much more engaging to young people than standard communications" Theo Clarke continued.

The EBA has developed an action plan in 2012, called 'Missing Minorities' on the issue: "This is still a very useable manual for countries starting out with minority recruitment as it provides an excellent framework to work to and excellent foundations to build upon" Theo Clarke said. The manual can be downloaded from the [EBA website](#).



Ro Blood

Rh group is encoded by two genes: the better known RHD gene and the RHCE gene. If the RHD gene is present, the blood group is positive (+) and if the RHD gene is absent, it is negative (-). These are marked as D and d, respectively. Together with ABO blood groups these create the eight commonly known blood groups; A+, A-, B+, B-, AB+, AB-, O+ and O-. The RHCE gene is more complex, and can result in one of four variations of the C, c, E and e antigens: ce, Ce, cE, and CE. Ro blood type means Dce combination of these genes, which means that all persons with Ro type are Rh positive (+) with a specific Rh group subtype (ce).



FAINTING TUTORIAL

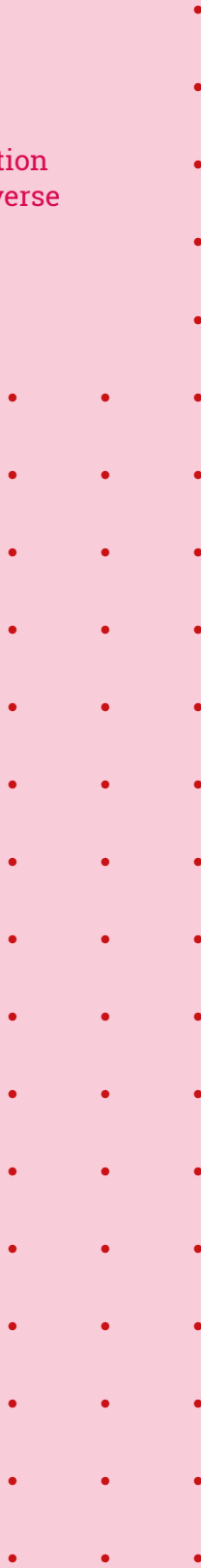
Fainting is one of the most common complications of blood donation and occurs in about 1 in 200 donations. This has, of course, an adverse effect on the donor in itself, but also on their subsequent attitude towards donation and might therefore also negatively impact the donor's return to the blood centre.

To ensure donor safety, transfusion professionals should do their very best to prevent and recognise the early signs of fainting. To raise the level of education, the EBA, the International Society of Blood Transfusion (ISBT) and Syncopedia set to work on an online course on fainting in donors.

The EBA Working Group on Education and Training partnered with these organisations and carefully wrote and recorded nine modules, with the assistance of the Academic Medical Centre of Amsterdam. These modules will provide insight and knowledge on the stages before fainting, during fainting and afterwards and, naturally, on how to prevent fainting, or vasovagal collapses, as they are called.

The modules are now freely available for all to watch and learn. The EBA and ISBT are continuing the work and developing test questions and a certificate for those successfully completing the test.

The modules can be watched [here](#).





MISSING TYPES

Following the huge success of the 2015 campaign by NHSBT, the Alliance of Blood Operators, EBA and the Asian Pacific Blood Network combined forces to create the world’s largest synchronised new donor recruitment campaign around the *Missing Types* theme. By masking the letters A, B and O, the need donors of all blood types was highlighted. Twenty-one countries, representing all of the continents, took part and International *Missing Types* was created:

- Canada
 - USA
 - Republic of Ireland
 - Northern Ireland
 - Scotland
- Wales
 - England
 - Nepal
 - Belgium
 - Netherlands
 - Switzerland
- Sweden
 - Lithuania
 - Japan
 - Brazil
 - South Africa
 - Hong Kong
- South Korea
 - Singapore
 - Australia
 - New Zealand

Each country agreed to do four things:

- Run a synchronised PR and Social media campaign to run from midnight local time on the 16th August
- Recruit well known organisations
- Recruit well known celebrities
- Get well known landmarks across the world

On August 16th, Australia launched their campaign and over the next 24 hours the Missing Type theme was unveiled across the world from East to West finishing on the West Coast of America. Throughout the world, letters disappeared from famous landmarks; well-known celebrities were tweeting their support, newspapers and TV stations joined in the fun and the main twitter handle **@missingtype** trended across the world.

The Alliance of Blood Operators
The Alliance of Blood Operators was established in 2002 and is a worldwide network of blood services, comprising Australian Red Cross Blood Service, American Red Cross, America’s Blood Centers, Blood Systems Inc., Canadian Blood Services, NHS Blood and Transplant and the European Blood Alliance. Its mission is defined as seeking to be a high performing inter-national collaboration of blood operators who drive member performance improvement, knowledge exchange, and resolution of strategic issues for the benefit of patients and the health systems they serve.



Some highlights of the campaign were as follows:

- In the UK, over 200 million letters were franked with the *Missing Type* logo-stamp
- In America, the New York Stock market bell, indicating the opening of the stock exchange, was run by a heart transplant and blood recipient
- All 21 countries took part in a video highlighting the need for new donors and this was run across many platforms
- In Australia, the largest online catalogue company ran their edition for that week with the letters missing
- Famous landmarks removed their letters: Sydney Opera house; BAFTA building; Tokyo Tower; Giants Causeway in Ireland; longest railway station in Wales; various organisations in New York Times Square
- Famous brands around the world joined in such as Samsung, Microsoft, Aston Martin, Lloyds Bank etc.
- Celebrities such as the Neighbours cast, along with Olivia Newton John, Jamie Lee Curtis and many more, sent in pictures with the letters removed
- Newspapers in the Netherlands, Australia, and Ireland dropped letters from their mastheads

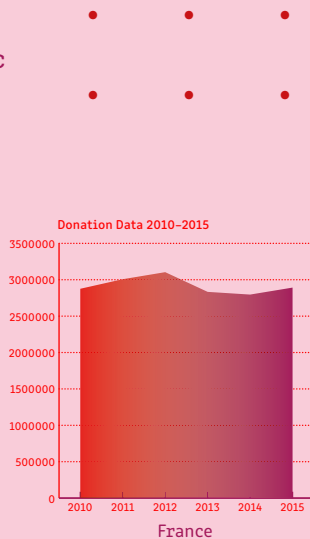
Did it work?

For most countries the answer was a categorical yes. Over 50,000 tweets were sent on the #missingtype-hashtag with countries across the world trending at number one during the first 24 hours of the campaign. At one stage, the campaign trended at number one across the world. Most countries saw substantial uplifts in the traffic going to their websites, along with a rise in the number of registered donors.

The ultimate goal, recruiting more donors, was also met. While some countries only saw a small increase in their new donor registrations, others saw rises of up to 340% extra registrations compared with average.

Missing Type

In June 2015, NHSBT launched the so-called “Missing Type” programme across England and Wales as part of its National Blood Week: Letters associated with the four main blood groups (A, B and O) were taken away from organisational brands to create awareness for the need for new donors. This campaign was, by far, NHSBT’s most successful new blood donor recruitment campaign ever with 32,000 potential new donors signed up over a ten-day period. During the campaign, over 1000 organisations – including many of countries biggest names: Google, Cadburys, and Sony etc. –dropped these blood related letters away from their mastheads. In 2016, this programme was taken on globally.





'Missing Type' campaign
Over 50,000 tweets were sent on the #missingtype-hashtag with countries across the world trending at number one during the first 24 hours of the campaign.



DOHECA – EDUCATION IN DONOR HEALTH CARE: FROM SCRATCH TO PILOT

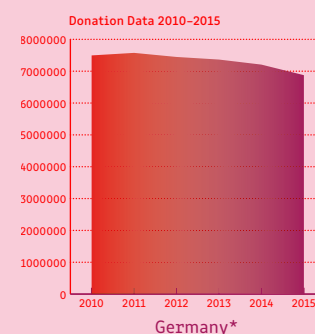
Education in donor health care, covering the whole donor spectrum (alive, deceased, anonymous, related, adult, paediatric, blood – tissues – cells - organs) in particular on an academic level, was to date not available, although there were many similarities between the different fields.

Over the past three years, an international Consortium led by Sanquin, the Dutch Blood Bank, has been working on a curriculum in donor health care in a project that is co-funded by the European Union Erasmus Life Long Learning Programme. This sounds much easier than it is in practice, since DoHeCa is 100% distance, or e-learning. Students from countries all over the globe should be able to go online and follow the lectures, interact with their international peers, and submit their assignments. For the further success, development and expansion of the programme, we have sought cooperation from the Academic Medical Centre / University of Amsterdam.

The programme comprises five modules, covering the topics of each stage of the donation process:

1. Basic Principles in Donor Health Care
2. Donor Suitability
3. Donation and Complications
4. Specification and Applications of Substances of Human Origin
5. Quality management in Donor Health Care.

A module in Personal Development (to help develop Leadership skills, Critical Appraisal of Literature, Communication Skills, and Reflective practice) is running parallel during the 15 months of the programme.



*Data for whole of Germany (source: PEI Institute)

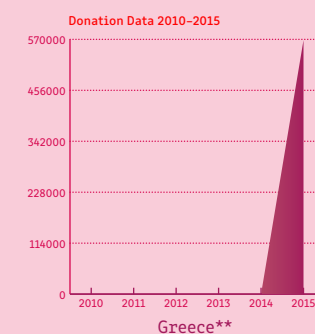
A call for pilot students resulted in over **60** persons showing interest, of whom **34** submitted an application.

Pilot started

On September 5th the pilot programme started, with 12 international students. A call for pilot students, earlier in 2016, resulted in over 60 persons showing interest, of whom 34 submitted an application. Twenty-three applicants met the inclusion criteria (former level of education at least at EQF6, i.e. at a bachelor level, working in the field of donor care management, sufficient knowledge of the English language). The selected pilot group of twelve is a truly mixed company: different levels of education (physicians, nurse specialists, technicians); different countries (Australia, Denmark, Estonia, India, Lithuania, Spain, United Kingdom); and working with different types of donors: blood, tissues & cells, organ.

The first weeks were tough for the students. Although they were informed on the expected study load (20 hours per week), they still were unpleasantly surprised on the amount of work. On the other hand, they were very positive about the content of the programme, about the way the course material was offered (in lectures, online fora, presentations), and there was a lot of interaction between students on the discussion boards.

In 2017, having completed the pilot and submitting a final report to the EACEA (Education, Audiovisual and Culture Executive Agency) the formal programme will be finished. Also, endeavours are ongoing to try to obtain a Master's accreditation for the course. (<http://www.donorhealthcare.org>)

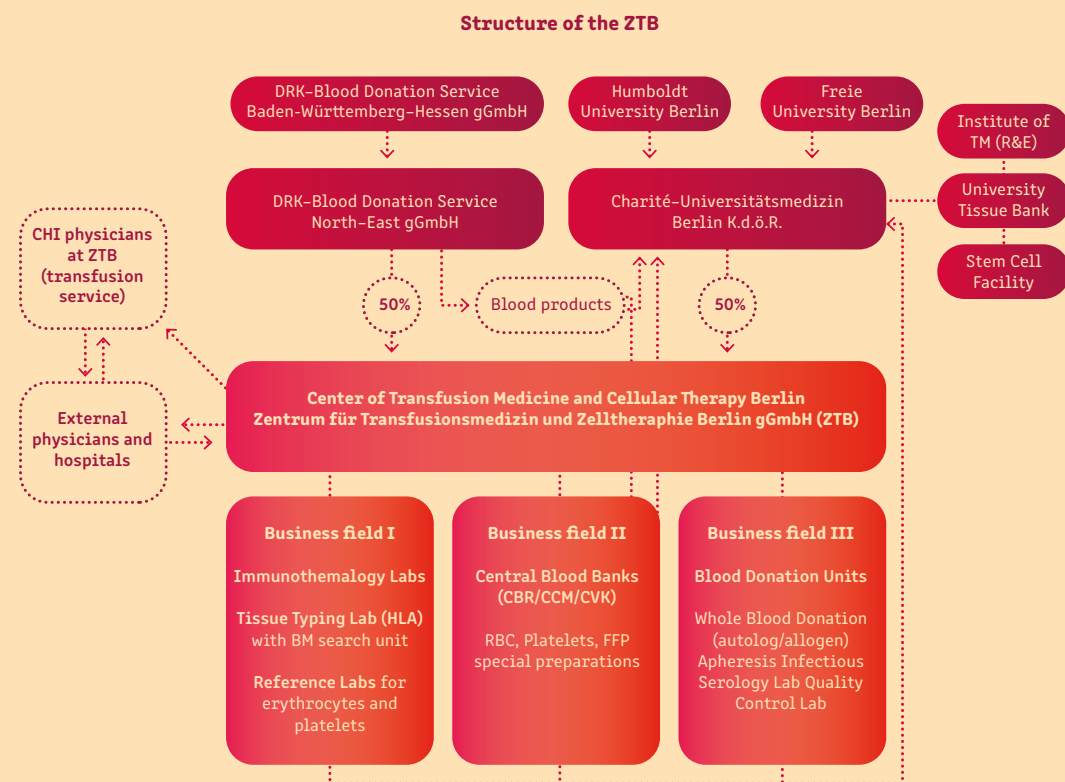


**No data on earlier years available



[02] PERFORMANCE IMPROVEMENT THROUGH COLLABORATION

This strategic objective can take quite different forms: from sharing Best Practices on improving discard rates for heart valves to discussing ways to enhance business models. Each of the initiatives on the next pages could improve the performance of EBA members. The ultimate goal is to benefit patients by encouraging joint activities and projects between members to enhance the capability of the members.

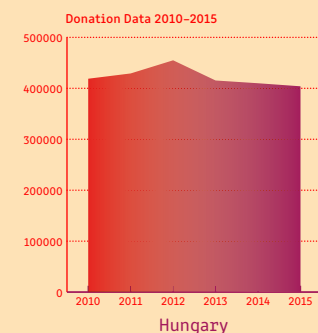


INTEGRATED TRANSFUSION SERVICES (ITS) WORKSHOP

In February 2016, the German Red Cross hosted an EBA Benchmarking Workshop on Integrated Transfusion Services (ITS) at Charité Hospital in Berlin. It was a very successful event, attended by 28 participants from 12 different EBA and ABO member blood services.

The subject provided blood operators with an opportunity to view a variety of different business models of supply chain integration across Europe. The workshop discussed in detail the benefits and challenges of joining the supply chain from blood donor to patient recipient and delivered presentations demonstrating good practices.

The ITS model exemplified by the German Red Cross and das Charité Hospital group was especially interesting: Essentially, an entirely new company had been established to manage the blood supply chain from collection to transfusion, and a number of people from both the Red Cross blood service and from the hospital group had been employed. The governance arrangements were clearly set out, ensuring that accountability for performance, and any income and expenditure surpluses were shared equally. The objectives of the partnership were also clear – to provide excellent patient outcomes in a cost-effective manner, by reducing supply chain wastage, by ensuring effective use of joint resources, and by sharing data and information in a timely manner in support of good patient blood management practice.



MEDICAL LEADERSHIP SCHEME

Two years ago, the Alliance of Blood Operators conducted a research initiative which outlined the competencies and skills required by a successful Chief Medical Officer of a Blood Establishment. As a result of this, the Medical Leadership Scheme was developed, in which delegates can enhance their leadership skills to become potential successors for the Chief Medical Officer Role in their respective organisations.

This nine-month scheme will focus on three areas for development:

- Managing Self
- Leading Others
- Leading Strategically

In Orlando (October 2016), the group had its initial module as a face-to-face meeting during the AABB meeting. A delegate from Finland noted it was a good start: "From the very beginning we were 'put to work', all together, in small groups and by ourselves; we were not just listening in a passive way." EBA sent four delegates from three countries to the training. The group has now completed three of the 14 planned (web)modules and plans to complete the course in 2017.



Picture Credit: Jouni Lauronen

COLLABORATIVE PROCUREMENT

The progress of the collaborative procurement projects was ambivalent. Even though a lot of work was done, in relation to one of the projects, EBA experienced severe delay.

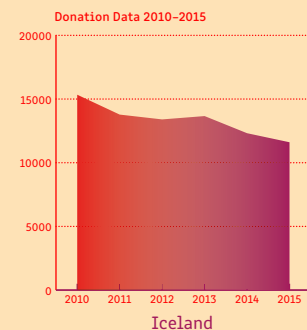
Eurobloodpack II

The Whole Blood Collection Systems and Ancillary Processing Systems ("Eurobloodpack II") collaborative procurement project with NHSBT as host has made good progress in 2016. Currently two EBA Members, consisting of five blood services and two non EBA Members who were already involved in Eurobloodpack I, confirmed their interest in joining the Eurobloodpack II (EBP II) project. Additionally, three new EBA Members (five Blood services) confirmed their interest in joining EBP II.

This project has provided a fantastic opportunity to work collaboratively in multiple stages of the project. The EBA technical committee contributed and agreed to the final version of the specification. At audit stage, the EBA audit committee has led the way in ensuring that all suppliers meet the required standards. The invitation to tender was sent out and is now in the final evaluation phase. The target date for award of the framework agreement is June 2017.

Tubes

This year, a lot of work went into preparing the necessary documents for the start of the tendering for blood sample collection systems ("Tubes"). Since September, the tender and all the necessary background project papers and requirements have been ready for launch. The project member composition, however, was not coherent enough to start the tender. The EBA is repositioning the project and assessing the options for re-engaging this in 2017.

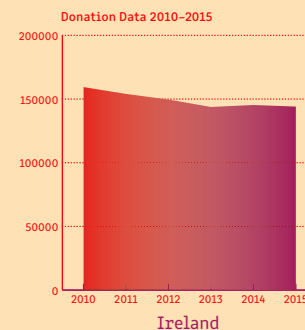


HEART VALVE BENCHMARKING WORKSHOP AT THE 25TH EATB ANNUAL MEETING, HANOVER

The annual European Blood Alliance (EBA) Tissue and Cells Benchmarking exercise identified that in 2014 the heart valve discard rate in EBA tissue banks ranged from 19% to 65%. Given this significant discard rate of such a precious, potentially life-saving resource, at a time when most tissue banks are struggling to meet clinical demand, a decision was taken to carry out a worldwide benchmarking exercise with the aim of establishing what process pertains in the different tissue banks.

In collaboration with the Foundation of European Tissue Banks (FETB) a questionnaire detailing the heart valve process was developed and sent out to tissue banks in Europe and beyond. Nineteen completed questionnaires were received from fifteen European tissue banks and four non-European tissue banks.

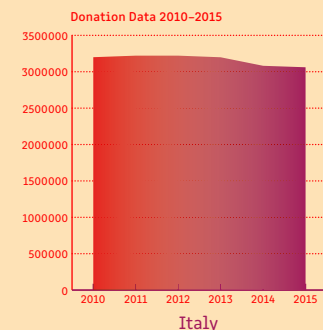
The data provided confirmed that there is a significant discard rate of heart valves with 0-92% (median 43% from tissue-only donors; 50% from multi-organ donors) of aortic valves and 0-65% (median 32% from tissue-only donors; 20% from multi-organ donors) of pulmonary valves being discarded. The causes of discard varied in the different tissue banks, but microbiology contamination and anatomical reasons were the main reasons leading to heart valve discard. The results of the questionnaire highlighted that there are significant variations in practice in the different tissue banks in relation to the following: how donor suitability is assessed; critical timings for heart retrieval and processing; heart rinsing; how heart valves are decontaminated; and methods of microbiological testing.



In November 2016, the results were presented at a heart valve workshop organised by EBA and FETB in the European Association of Tissue Banks (EATB) meeting in Hanover. Fifty-two participants from at least twenty different countries attended the workshop, which was very well received: numerous questions were asked and a great willingness was shown by all present to continue taking the work forward. The results of the questionnaire highlighted that there are several aspects of heart valve banking that should be properly validated and standardised, including heart valve retrieval and processing timings; method of decontamination and microbiological/environmental monitoring.

Following the workshop at EATB, the planned next step is to organise further meetings with interested tissue banks to carry out more in-depth analyses of the data. The aim will be, wherever there is scientific evidence to do so, standardising the methodology of various aspects of heart valve banking.

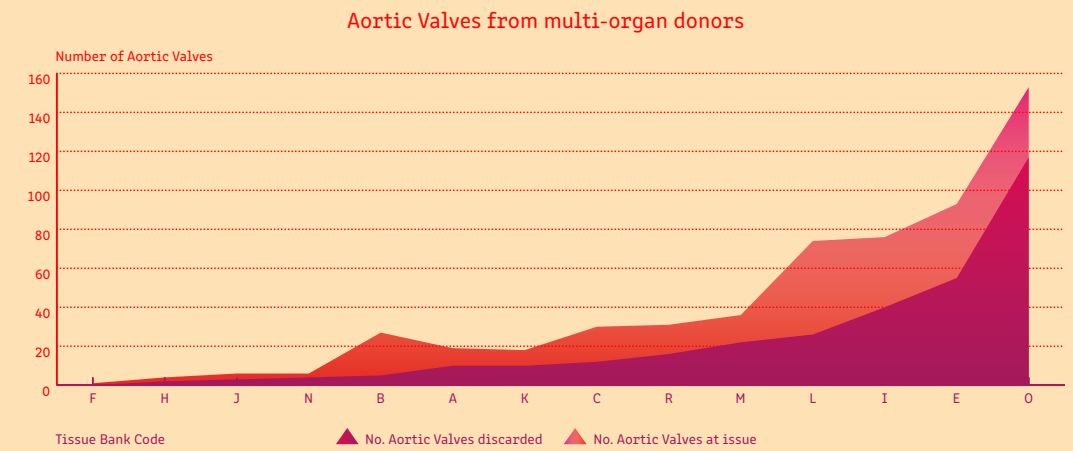
In 2014 the heart valve discard rate in EBA tissue banks ranged from **19%** to **65%**.





Heart valve banking process

At the time of tissue donation the heart is retrieved from the donor. It is then sent to the tissue bank where the aortic valve and the pulmonary valve are dissected out. The heart valves are then put into antibiotics for decontamination, after which the heart valves are rinsed and cryopreserved. They can be stored for up to 10 years. Multiple cultures are taken throughout the whole process to establish whether the heart was contaminated or not and to ensure that the heart valves have been successfully decontaminated.



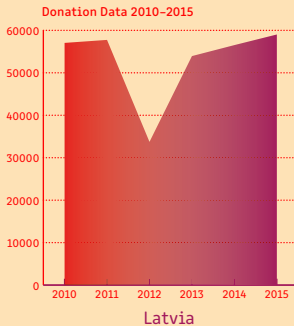
REPORT WORKING GROUPS

A lot of the work of the EBA is done in working groups. Those groups gather experts from the field from all over Europe for networking and also for creating added value for all EBA members. Also, they serve as experts whenever EU institutions query the EBA on certain matters.

Currently, EBA has eight working groups:

- Benchmarking
- Collaborative Procurement Initiative
- Collaborative Quality Management
- Contingency Planning
- Donor Studies Special Interest Group
- Education and Training
- Emerging Infectious Disease Monitor
- Tissue and Cells

Key activities of some working groups are summarised below, while some are featured in specific articles throughout this annual report.



REPORT COLLABORATIVE QUALITY MANAGEMENT

In 2016, both the audit and validation subgroups of the EBA Working Group on Collaborative Quality Management (WgcQM) were involved in the Eurobloodpack II procurement:

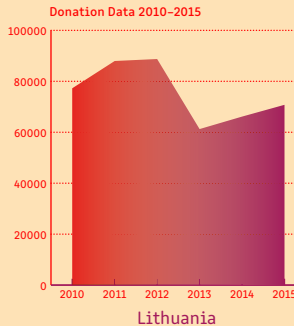
- An EBA pre-audit questionnaire was used to collect information prior to the audit of suppliers at their manufacturing bases
- Validation protocols were developed in conjunction with NHSBT

In parallel:

- An online EBAs database was created to share validation and audit information between the EBA members. Based on this database, individual BE's can cooperate in order to reduce validation and audit cost.
- A new EBAs discussion forum was created, acting as an information platform regarding QA issues (e.g. eQMS, inspection guidelines, etc.).

The group is looking forward to 2017, where a benchmark on quality systems will be set up in synergy with the EBA Benchmarking Working Group, focusing on quality departments, quality management and related IT systems (eQMS).

The objective of the Collaborative Quality Management Working Group is to actively involve more EBA members with: Aligning with the EBA Procurement projects Use of the EBA members' site for the Working Group in order to increase efficiency by working together on audits and validations



Through its monthly teleconference and regular information exchange, EID Monitor continued to watch emerging infectious diseases and blood safety measures in the area of EBA and ABO membership (Europe + Australia, Canada, USA). The timely circulation of the teleconference' minutes ensured a quick spread of information and recommendations to all EBA and ABO members. The following topics were particularly important this year.

West Nile Virus (WNV)

See article on WNV and the amendment on EU Directive 2004/33 (page 53).

Chikungunya- and dengue virus

In 2016 no local transmission of Chikungunya- or denguevirus has occurred in Europe. The Chikungunya outbreak in the Caribbean and South- and Mid-America is still ongoing.

Zika virus

See article on Zika virus (page 6).

Hepatitis E virus (HEV)

The following factors enhanced the discussion on HEV-safe blood components: more awareness about the increasing incidence of HEV infections in the population and blood donors; the reported transmissions through blood components; and knowledge of the risk for certain patients (prolonged viremia in immunosuppressed patients). Since diet is the main transmission route of HEV, the benefit of HEV-safe blood is argued.

Different strategies were launched in 2016 in Europe. The UK implemented selective donor screening to supply safe blood components for patients with solid organ and stem cells transplan Ireland implemented universal screening on HEV RNA.

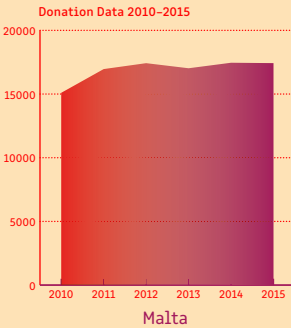
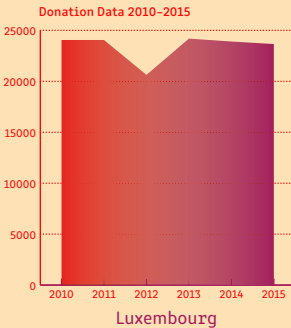
The EBA-EID Monitor collaborated in the ECDC expert meeting in order to develop an ECDC position statement/ expert opinion on the interventions necessary to prevent transmissions of HEV through donated blood and blood components.

Predonation screening (PDS)

The international study reviewing the current selection strategies of newly registered donors (NRDs) in EU/EEA member states and evaluating the value of PDS in the quality and safety of donated blood was published in *Blood Transfusion*. The limited data available, especially regarding recent infection among newly registered donors and first-time donors, complicated the study. Further research and more data are needed to assess the potential capacity of PDS to reduce the residual risk in first-time donations.

Donor epidemiological data which substances of human origin (SoHO) establishments collect and report show a broad variability. For this reason, in order to maintain an equivalent level of quality and safety of SoHO in the EU, a new project under the aegis of the ECDC was launched in September 2016 to discuss the current situation in the epidemiological data collection and analysis, and to evaluate the need for enhanced epidemiological data collection. The next steps will include organising a meeting in 2017 in order to work further on developing a guide for enhanced epidemiological data collection and analysis by establishments for SoHO.

- The objectives of the EID monitor are:
- To organise appropriate information exchange between the EID Monitor members on the emerging infectious agents and diseases.
 - To discuss, elaborate and disseminate to members recommendations on blood safety measures to cope with the risks of EIDs.
 - To discuss, elaborate and promote at European institutions level (eg ECDC, EC, EMA, CD-P-TS/ EDQM) the adoption of recommendations / guidance / legislation on blood safety measures to cope with the risks of EIDs.

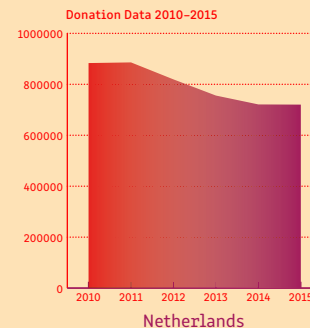


EU BLOOD DIRECTIVES WORKING GROUP

In 2016, the EU Directives Working Group held two plenary teleconference meetings, as well as many subgroup meetings and exchanges of email. Based on the input gathered at the Board meeting in Berne (September 2015) and a subsequent survey, and in the context of a future revision of the EU Directives on blood products, the working group focused on producing advocacy position papers on four priorities identified as key for EBA: VNRD, self-sufficiency, establishing a relationship between the Council of Europe Guide and future EU Directives, and donor selection.

Each advocacy position paper explains the context and progress achieved so far, the problems or shortcomings identified, and EBA proposals to the EU institutions to address these problems and ensure future safer and better transfusion systems. These proposals have been endorsed by the Board in October 2016, and were used in the preparation of the PLUS Consensus Conference and the International Plasma Protein Congress. The papers will be re-evaluated to serve as a basis for the EBA response to the public consultation on the evaluation of EU Blood Directives, which is expected to be launched by the European Commission in the first half of 2017.

The Objective of the European Blood Alliance EU Blood Directives Working Group is to prepare EBA positions on the upcoming EU Blood Directive revision and help to convey those to EU Institutes. Key objective for the WG is to develop and propose Executives and Board recommendations for an EBA position regarding revisions of the related Directives.



CONTINGENCY PLANNING WORKING GROUP

A member consultation in 2015 demonstrated interest amongst member countries in the re-establishment of a Working Group on Contingency Planning. Some years ago, EBA had a WG on this subject, which delivered the EBA Document on Pandemic influenza in May 2009.

The EBA Board nominated Andy Kelly (ISBT) to chair this Working Group. Representatives from blood services in 12 countries joined the group. First the Working Group concentrated on the following:

- (1) Sharing lessons learned during past contingencies
- (2) Exchanging contingency plans
- (3) Test run contingency plans

Members discussed the following: the lessons learned from the flooding of the main manufacturing site of NHSBT in Filton, England; a report on a desktop exercise to test contingency plans of the Irish Blood and Transplantation Service. These discussions generated a list of practical tips. Sharing contingency plans and training material in the EBA Members site EBAse further supported the members to move towards best practice.

One of the agreed objectives is to identify opportunities for mutual aid in business continuity and emergency planning of processes, consumables and the provision of services and product. To facilitate collaboration, the Working Group shared a template of heads of agreement for aid arrangements in bilateral or multilateral mutual use. Based on the findings in the collaborative procurement initiative, the work of identifying critical consumables, equipment and the provision of services is ongoing.

The agreed objectives of the Contingency Planning Working Group are as follows:

- 1) To share and leverage the knowledge of EBA members so all can move toward best practice (e.g. ISO 22301)
- 2) To share experience, documentation, risk and other relevant materials and identify common training needs and opportunities.
- 3) To identify opportunities for mutual aid in business continuity and emergency planning processes, consumables, and in the provision of services and product, and to develop these into heads of agreement in bilateral or multilateral mutual aid arrangements.
- 4) To create routes and mechanisms of communication on business continuity and emergency planning issues between EBA members, and to maintain a forum for discussion on these matters (e.g. EBA newsletter, EBAsE).
- 5) To engage in and lead the conversation on business continuity and emergency planning with commission and competent authorities to ensure a workable and consistent approach across EBA member states.

[03] SUPPORT TO NATIONAL AND EUROPEAN AUTHORITIES TO PROMOTE BEST PRACTICES

The EBA will provide technical and professional support to national and European authorities, particularly those involved in preparation / revision of regulations, standards, recommendations, guidelines. In the past year, the Zika epidemic has shown that both the EU institutions appreciate evidence based input from the field and that EBA can source this through its extensive network of experts.

Picture Credit: European Commission



MEETING WITH DIRECTORATE GENERAL SANTE

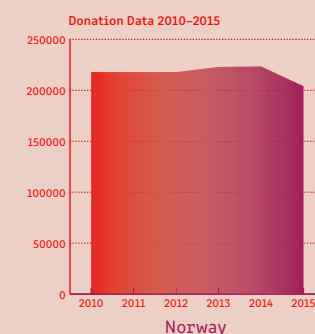
On 11 January, the EBA met with representatives of the European Commission, Directorate General for health and food safety (DG SANTE). On the agenda of the meeting were, among other things, the Patient Blood Management implementation guide and the EBA proposal to revise the so called West Nile Virus Directive (2014/110/EU).

To increase transparency, the Commission noted on their side the implementation of a new policy: all meeting reports between DG SANTE and stakeholders would become public. The meeting report between EBA and DG SANTE was the first of its kind to be made publicly available.

Meeting EU Health Commissioner Dr. Vytenis Andriukaitis

On May 2nd the European Commissioner for Health and Food Safety, Dr. Vytenis Andriukaitis, received a delegation from the EBA in Brussels. Together they discussed the questions of voluntary and unpaid donations, and EU legislation on blood.

The Commissioner showed a lot of interest in blood donation: he himself had been a donor in his home country, Lithuania, until age limits prevented him, and as a medical doctor, he had good knowledge of blood products. He supported the voluntary and unpaid nature of blood donations and advised the EBA to discuss this matter also with the European Parliament and Permanent Representation of the EU Countries in Brussels



COMMON REPRESENTATION OF SOHO'S ASSOCIATIONS WITHIN OFFICIAL INSTITUTIONS OF EUROPEAN UNION

The need for representation of stakeholders before European Union bodies was identified by four European associations:

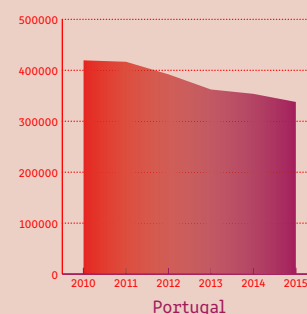
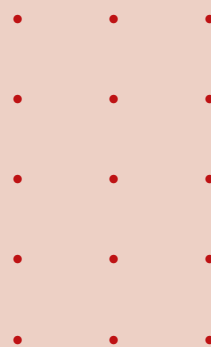
- European Association of Tissue Banks (EATB)
- European Society for Blood and Marrow Transplantation (EBMT)
- European Eye Bank Association (EEBA)
- European Blood Alliance (EBA)

All four associations are committed to ensuring that substances of human origin (SoHO) activities in EU member states are governed by the same principles:

- Not-for-profit/non-financial gain
- Voluntary and altruistic donation
- Sufficiency
- Sustainable pricing facilitating patient access to current and future therapies

The main goal of this consortium is to provide expert opinion and supporting data to European Union decision-makers and their respective organisations in the field of SoHO. The majority of its members are working in tissue establishments, academic GMP-facilities and in some cases, collaborating with industrial partners in developing and delivering innovative new therapies. Therefore, as technical experts working in the field with direct access to the experience and opinions of the members, the associations wish to actively contribute to all legal and regulatory discussions affecting the SoHO field.

The EBA Board agreed in spring 2016 to join this Common representation of SoHO's Associations as it was a good fit with EBA's mission and goals.



EUBIS MEETING

From Good Practice (GP) to Good manufacturing Practice (GMP) – blood components and medicinal products

The successful EU Funded project EuBIS had its 8th meeting from the 5th to the 7th of October, 2016 in Rome. The seminar built on previous EuBIS courses whose aim was that of training to implement the new regulation of Good Practice Guidelines for blood and blood components in the European Union (Commission Directive (EU) 2016/1214).

As with earlier meetings, this one was well attended by thirty participants, with twenty-five coming from Italy; three from Spain, and two from Brazil. The seminar comprised lectures and group work in a face-to-face fashion based on cases covering several aspects of GP and GMP such as the following:

- GP guidelines
- Inspection/audit
- Validation
- Change control
- Corrective actions
- Risk assessment

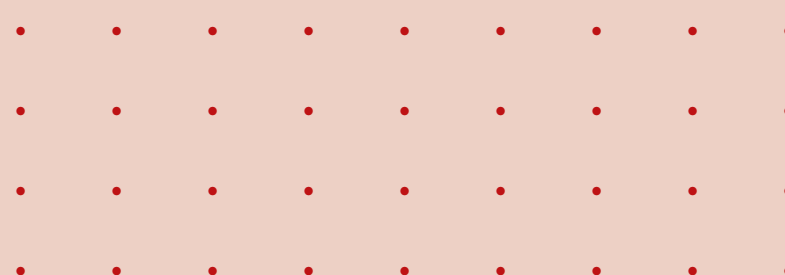
The Italian Competent Authority Centro Nazionale Sangue (CNS) offered several exercises guided and monitored by the facilitators, which allowed an evaluation of the participants' acquisition of the skills. For the Italian participants, the EUBIS course was another training opportunity in addition to the national training programme for the inspectors' maintenance of the competences offered by CNS. For CNS, a collaboration is planned for future courses between CNS and the German Red Cross.

The European Blood Inspection Project was an EU funded project that officially ran from 2007 to 2010 and had as its overall objective developing and implementing commonly accepted criteria and standards to ensure equivalent recognition of inspection of blood establishments among Member States.

It delivered this through developing a manual outlining the following:

- Common inspection criteria and standards for the inspection of blood establishments
- Requirements for the implementation or expansion of quality management systems to be inspected
- Development of inspection checklists which closely follow Directive 2002/98/EC and its technical annexes
- Evaluation criteria for inspections and a benchmark system for deviations and improvements

The manual could be used as a basis of a training programme for the inspectors of blood establishments and can be downloaded from the EuBIS website.





EuBIS meeting

Director **Dr. Giancarlo Maria Liumbruno** noted after the meeting that “The initiative definitely gives a significant added value to the inspectors’ qualification in the light of benchmarking and mutual recognition of the training paths between different countries.” The meeting also contributed to the original goal of the EuBIS project: developing Pan-European standards and criteria for the inspection of blood establishments. According to Liumbruno: “the meeting set the basis for a common culture of the blood establishments inspectors”.



RISK-BASED DECISION-MAKING

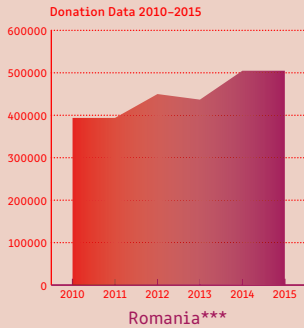
Within the Alliance of Blood Operators, a framework has been developed to help Blood Establishments take decisions in the context of emerging risks. This framework can be adapted according to the local needs and takes into account the different stakeholders that a blood establishment needs to consider.

The framework's objectives are as follows:

- Optimise the safety of the blood supply while recognizing that elimination of all risk is not possible
- Allocate resources in proportion to the magnitude and seriousness of the risk and the effectiveness of the interventions to reduce risk
- Assess and incorporate the social, economic, and ethical factors that may affect decisions about risk

The framework online tool and can be accessed through the [Alliance of Blood Operator's website](#). In 2016, an infographic and video-scribe have been developed to advertise education sessions around the tool. Also, a number of case studies have now been completed using the framework including the following:

- Canadian Blood Services: Babesia risk in Canada, Canadian security of supply of Immunoglobulin (Ig)
- AABB: Babesia risk in United States
- Australian Red Cross Blood Service: HTLV testing
- Irish Blood Transfusion Service: HTLV testing (see next page)



***No new data received

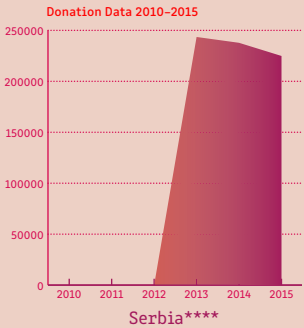
Picture credit: IBTS



The RBDM framework at use in the Irish Blood Transfusion Service (IBTS) to review the current HTLV testing strategy

"The IBTS decided to test the RBDM framework on a specific activity and as part of a development programme for one of our scientific staff", according to IBTS CEO, Andy Kelly: "This gave IBTS the opportunity to use the Framework in a learning environment". His conclusion after finishing was that "the experience was very positive; the web based RBDM portal is easy to navigate and the guidance documentation and workbooks were very helpful. The next step will be for the IBTS to embed the RBDM Framework into its risk management process".

Reviewing the current HTLV (Human T-lymphotropic Virus) testing strategy, it was determined that the prevalence of HTLV in Irish Blood donors is very low, (<0.0002%) and that the greatest risk is from first time tested donors (1.95 per 100,000 first time donors). There are potential cost savings if selective HTLV testing is introduced, but there are logistical difficulties associated with this such as the potential to introduce possible process errors, increased manual selection, and a delay in release of results.



****Data on earlier years not available

- Three risk mitigation options were presented:
- Continue with the Status Quo: Universal HTLV testing mandatory for all blood donors
 - Withdrawal of all HTLV testing for all blood donors
 - HTLV testing of 1st time donors only and donors not previously tested for HTLV (i.e. donated prior to 1997) and a rare requirement in the IBTS for products that are not leucodepleted e.g. granulocytes

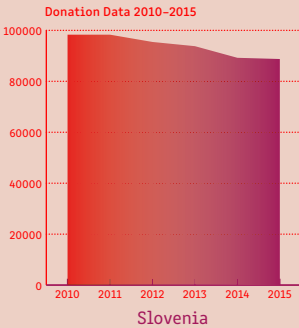
After reviewing all risks using the framework, it was decided that it would be feasible to change from universal HTLV screening of all donations to HTLV screening of new donors only, but this would require continued surveillance on HTLV prevalence in new donors and continued surveillance on leucodepletion failure rates.

The recommendation from the framework was that in order to make the change to first time donors only and to benefit from the cost savings, an IT solution should be sought whereby it is possible to have a bidirectional link from the IBTS Laboratory Information Management System (LIMS) to the Virology testing platform allowing automatic testing of first time donors for HTLV. “Without this, Andy Kelly said, “there would be too many manual interventions and we would not be maximising the test kit usage”.

He further explained: “The value of the framework is that all aspects of a decision are pulled together in one place including operational capability; there is one formal process and the output is a decision document that can be referenced by all stakeholders both now and in the future”.

Unlike previous frameworks in use, risk communication and stakeholder participation is an integral part of framework. Social, economic, and ethical factors specific to each country can be incorporated into the decision making process.

Since the IBTS used the Framework, substantial work has been done in streamlining aspects of the Framework to make it more user friendly.



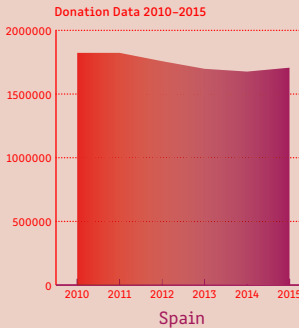
CASOHO MEETING ON WEST NILE VIRUS

In December an EBA-delegation was invited to a meeting with the Competent Authorities on Substances of Human Origin Expert Group in Brussels to elaborate on EBA’s letter written on the issues of the EU Directive 2014/110/EC on West Nile Virus.

CASoHO meetings
EBA could attend this meeting because in 2016 the European Commission invited organisations to enlist as stakeholders to take part when appropriate in ‘ad hoc meetings between Stakeholders and representatives of members of Competent Authorities on Substances of Human Origin Expert Group’, also known as CASoHO meetings. The first of these ad hoc meetings was held on the 2nd of December.

West Nile Virus Amendment
One of the two topics on the CASoHO agenda was the 2014/110/EC Directive concerning the West Nile Virus amendment. EBA sent a letter to the Commission in April 2016, outlining concerns with this recently adopted amendment. EBA was invited to present the evidence in the CASoHO meeting. The concerns were twofold: Definition of Risk area and NAT testing: individual or minipools?

Definition of Risk area
The term “a risk area of locally acquired West Nile Virus transmission” was not a known definition. The introduction of this new term in parallel with well-established and acknowledged terms for risk areas could lead to confusion and different interpretations across Europe. In the letter, EBA suggested the use of the European Centre for Disease Prevention and Control (ECDC) definitions: *an affected area is a risk area with ongoing transmission of an arthropod-borne disease to humans*. This means that at least one case of transmission of autochthonous arthropod-borne disease to a human has been confirmed in the area according to the agreed, standardised and disease-specific case definition.



NAT testing: individual or minipools?

EBA values the rationale of Directive 2014/110/EU to secure the blood supply and allow use of Nucleic Acid Tests (NAT) as an alternative to donor deferral with the aim of reducing the risk of transmission of West Vile Virus from donors to patients. However, the amendment requires that all donations be tested individually, instead of in minipools, without taking into account the sensitivity of tests. The limited benefit of individual donation testing was illustrated with a research example and showed that individual donation (ID) NAT testing could only shorten the diagnostic window period by 0.7 or 0.8 days, compared to minipool (MP) testing. Using the EUFRAT tool, EBA has calculated the differences between NAT individual and NAT minipool testing (see infographic/table) for all areas that are not endemic in itself. This means that in an area where WNV is prevalent, the estimated risk is higher and, therefore, measures should be more stringent than in areas which only concern donors who travelled to a risk area.

EBA recommended that the EC should accept the use of minipool NAT testing of WNV when justified by a risk assessment for travellers. The available data indicated only a small difference between the minipool and individual donation testing in the window period and both reduce the risk of WNV infected products to a level which is comparable to, or less than, that of other tested transfusion transmissible viruses.

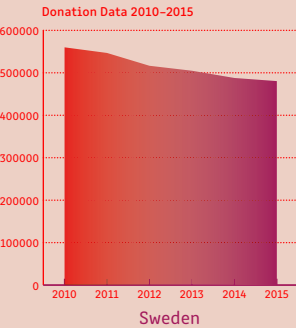
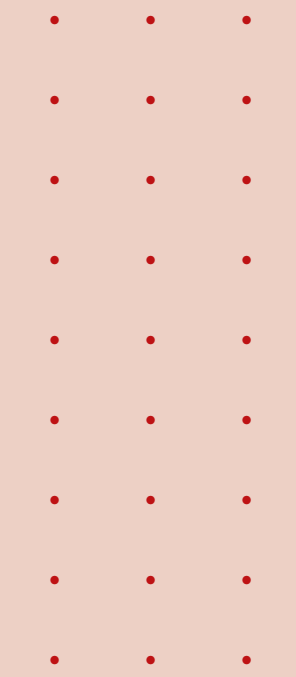
Economic considerations

Individual-Donation-NAT is more expensive than minipool-NAT testing. National Health Service Blood and Transplant (NHSBT) has calculated that IDT-NAT testing of 40,000 donors who have visited WNV risk areas would cost 220,000 GBP (ca 280,000€) more than the current MP-NAT testing (MP of 6). Assuming the same proportion of tested donors in other EU countries, population based extrapolation would lead to about two million euros extra testing costs in EU per year if 'Individual-Donation-Testing' is required for WNV.

Next steps

The feedback from the CASoHO members at the meeting was good and the evidence presented was well received. However, the outcome of the CASoHO meeting is still awaited, and the amendment on WNV might take some time to be adjusted and approved. This will most likely not happen before the upcoming seasonal rise of WNV.

West Nile Virus in 2016
Since the start of WNV season in 2016 a total of 259 WNV cases were reported on the European continent (European Centre for Disease Control (ECDC) update 15 December 2016). Newly affected areas with human transmissions this year appeared in Spain (Seville) and several regions in Romania.



Calculation of the transmission risks using the EUFRAT tool Description	France (Gard)	Italy (Northern)	Austria (Vienna)
Number of cases	1	49	1 Neuro-invasive case
Population	740,660	9,231,108	1,741,000
Donors	17,776*	221,547*	34,764
Correction for undetected cases	80%		0%
Duration of infectivity		6 days	
Duration of latent period of acute infection		1.5 days	
Donation testing		86%	
- Sensitivity MP-16 NAT testing		96%	
- Sensitivity ID NAT testing			
RISKS FOR THE LOCAL POPULATION			
Risk of transmissions per year without testing (years between events)	0.0040 (249)	0.20 (5.1)	0.21 (4.9)
Risk of transmissions per year with MP testing (years between events)	5.6 x10-4 (1,777)	0.028 (36)	0.029 (35)
Risk of transmissions per year with ID NAT testing (years between events)	1.6 x10-4 (6,220)	0.0079 (127)	0.0082 (121)
Estimated number of infected products per year without WNV testing	1.1 x10-7 (=1 infection every 9,011,363 products)	4.4 x10-7 (=1 infection every 2,292,078 products)	2.4 x10-6 (=1 infection every 413,714 products)
RISKS FOR DUTCH TRAVELLERS			
Visitors per year (8% of total population)	60,076	748,745	141,214
Donors per 1000 inhabitants*	24	24	24
Blood products per 1000 inhabitants*	49	49	49
Visiting donors per day*	4.0	49.2	9.3
Visiting donors per day (based on travel statistics for the country/region considered)	7.8	47.9	12.6
Visiting donor home population size (Netherlands)	17,000,000	17,000,000	17,000,000
Risk of infected products per year without testing (years between events)*	4.0x10-6 (248,807)	2.0x10-4 (5,078)	2.1x10-4 (4,860)
Risk of infected products per year (no test), corrected for visiting donors per day	7.9x10-6 (126,526)	1.9x10-4 (5,220)	2.8x10-4 (3,594)
Risk of infection per product without testing* (billion products between infection)	4.8x10-12 (207)	2.4x10-10 (4.2)	2.5x10-10 (4.1)
Risk of infection per product with MP-NAT testing* (billion products between infection)	6.8x10-13 (1,447)	3.3x10-11 (30)	3.5x10-11 (29)
Risk of infection per product with ID-NAT testing* (billion products between infection)	1.9x10-13 (5,171)	9.5x10-12 (106)	9.9x10-12 (101)

* Using European median value

[04]

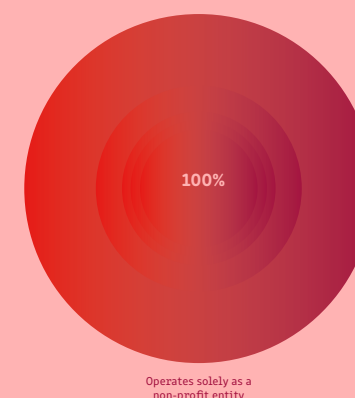
INFORMATION EXCHANGE AND DISSEMINATION

As an association, information exchange is prime. The EBA office will forward news and noteworthy information to the membership and the EBA members inform each other. through informal networking during EBA Board and working group meetings. The EBA Office also serves as a hub to exchange information easily between the membership and other organisations in the field.

VALUES, ISSUES AND POLICIES SURVEY

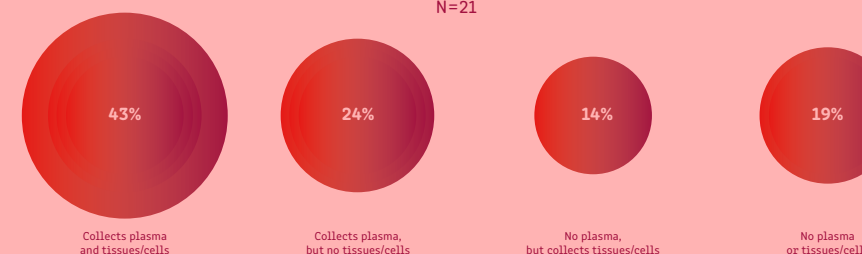
To consolidate EBA's core values, EBA surveyed in May 2016 its members. The outcomes of the survey and the longlist of possible values were presented to the Board in the Autumn 2016 Board Meeting. The final version of the document was approved in spring 2017.

Establishment's non-profit status
(as reported by EBA voting representatives)
N=21



The voting representatives reported that their establishments were operating **exclusively** as not-for-profit entities.

Scope of establishment's responsibilities
(as reported by EBA voting representatives)
N=21



Beyond collecting blood
Two-thirds (67%) of the establishments represented in the study were responsible for collecting plasma. A somewhat smaller share (57%) had responsibilities for collecting tissues and/or cells.

LIST OF CONSULTATIONS

Survey Number	Survey Requested By	Survey Title	Members surveyed	# of EBA responses
1	EBA	Contingency Planning: The ability of the Blood Services to supply in different scenarios	EBA Members	11
2	EFS/Sanquin	Donor deferral NSAIDS/medical devices utilizing materials of animal origin	EBA/ABO Members	15
3	EBA	ISBT128_standards for comments	EBA Members	3
4	NHSBT/ABO	HLA matched platelets selection and supply	ABO/EBA Members	16
5	EBA	EBA Benchmarking Scorecard questionnaire	EBA Members	19
6	EBA/NHSBT	HEV screening	EBA EID-Monitor members	13
7	EBA EID-Monitor	WNV testing: Individual Donation or mini pool	EBA EID-Monitor members	14
8	EBA	Regenerative Medicine	Tissues and Cells WG members	4
9	EBA	Problems processing certain types blood bags on universal cannula breaker of MPS	EBA Members and Collaborative Quality Management WG members	1
10	ABO	Horizon Scanning for emerging themes	EBA/ABO members	20
11	ABO	Preparation of washed red cells, platelets and serum eye drops	Certain specific EBA members	1
12	EBA	EBA Values, Issues and Policies	All EBA members separately (not per country)	43 of 55 Board members
13	Swedish Blood Alliance	Granulocyte donations/transfusions	EBA/ABO Members	16
14	T&C WG	Tissues and Cells Scorecard Questionnaire 2015	EBA Board Members/Tissues and Cells WG members	19
15	ARCBS	Needle dislodgements	ABO/EBA Members	18
16	EFS	CJD history in donor's family and aseptic procedure survey	EBA/ABO Members	19
17	ABO	Business development	Certain specific EBA members	4

Survey Number	Survey Requested By	Survey Title	Members surveyed	# of EBA responses
18	ICCBBA	ISBT128 data structures validation	EBA Members	2
19	ABO	Cybersecurity	ABO/EBA Members	8
20	EFS	The acceptance to donation of donors with disabilities to understand the Donor Health Questionnaire (hearing impaired, illiterate, other language)	EBA/ABO Members	15
21	EBA	Guideline on GMPs for AMTPs	EBA Members	7
22	EBA	WHO: guidance Essential Medicines List	EBA Members	10
23	EBA	Member consultation on Eurobloodpack II	EBA Members	8
24	EID-Monitor	Zika virus Questionnaire	EBA/ABO members/3 non-members	26
25	T&C WG	Heart valves benchmarking	Heart valve processing organisations worldwide	20
26	EBA	Consultation draft WHO guidelines on estimation of residual risk of HIV, HBV and HCV infections	EBA members	3
27	NHSBT	HLA-platelets	EBA/ABO Members	10
28	WHO	WHO - Medicinal Products of Human Origin	EBA members	3
29	EFS	Field Safety Notice Syphilis test	EBA members	18
30	ABO	Transgender donor acceptance/deferral	EBA/ABO Members	21
31	ARCBS/ABO	Confirmatory Malaria Testing and Quality Assurance Programmes (QAP)	Certain specific EBA members	7

List of abbreviations used:

ABO:	Alliance of Blood Operators	HBV:	Hepatitis B Virus
AMTP:	advanced therapy medicinal product	HCV:	Hepatitis C Virus
CJD:	Creutzfeld-Jacob Disease	HEV:	Hepatitis E Virus
GMP:	Good Manufacturing Guidelines	NSAIDs:	Non-steroidal anti-inflammatory drugs
		WHO:	World Health Organisation



EBA EXECUTIVE BOARD

In 2016, there was no change in the membership of the EBA Executive Board. The team consisted of the following members:



Philippe Vandekerckhove – President Red Cross Flanders Blood Service



Erhard Seifried – Vice-President German Red Cross Baden Wurttemberg – Hessen



Rudolf Schwabe – Treasurer Swisstransfusion SRC



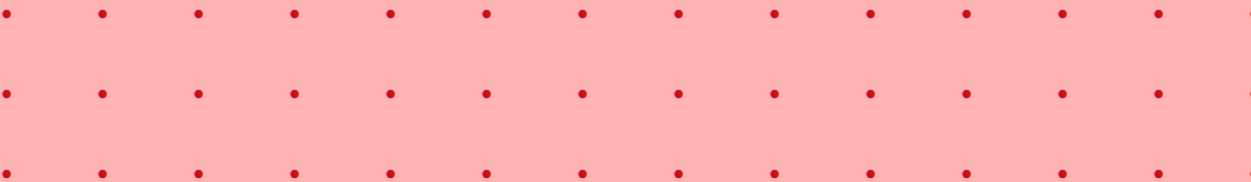
Mary Morgan – General Secretary Scottish National Blood Transfusion Service



Jørgen Georgsen Organisation of Transfusion Centres Denmark



Pierre Tiberghien Établissement Français du Sang



BOARD MEETINGS

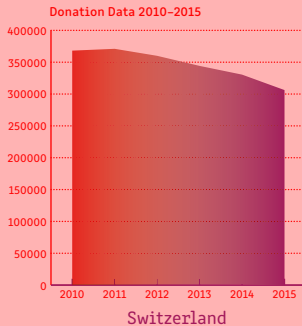
As in previous years, EBA had two Board Meetings; one in Zagreb, Croatia, hosted by the Croatian Institute of Transfusion Medicine; one in Frankfurt, hosted by German Red Cross Baden Wurttemberg – Hessen.

Zagreb

The meeting in Zagreb was held on the 6th and 7th of April 2016. In this meeting, EBA changed its statutes, which had been in place since 2009. In the interest of the current affairs of the EBA, the EBA Office asked the Notary to review the Statutes and suggest updates where needed to reflect current practice. These proposed changes encompass not only the articles on the Term of Office of Executives, but also some other minor changes, since upon re-reading the statutes, some additional articles benefitted from amendment. EBA's current statutes can be read on the [EBA website](#).

Frankfurt

On the 6th and 7th of October, the Autumn Board meeting was held in Frankfurt, hosted by German Red Cross –Baden Württemberg Hessen. In this meeting, the current EBA President Philippe Vandekerckhove was re-elected by the Board for a term of office up to 31st of December 2019.



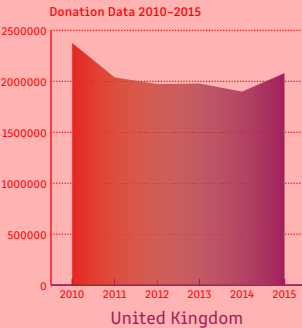
FINANCIAL DATA

Balance sheet

Assets – 31 December 2016	2016	2015
TANGIBLE FIXED ASSETS		
Equipment	7.842	4.877
	7.842	4.877
CURRENT ASSETS		
Amounts to be received	4323	6152
Prepaid costs	681	6166
Accounts receivable	6800	
VAT 2015		3815
VAT 2016	1068	
	12.872	16.133
LIQUIDITIES		
Rabobank	5.361	2.492
Rabobank	360.000	375.000
Rabobank	401.976	400.000
	767.337	777.492
Total		
	788.051	798.502
LIABILITIES		
Accumulated result	618.134	587.991
	618.134	587.991
CURRENT LIABILITIES		
Accounts payable	169.917	210.511
	169.917	210.511

State of Income & Expenses

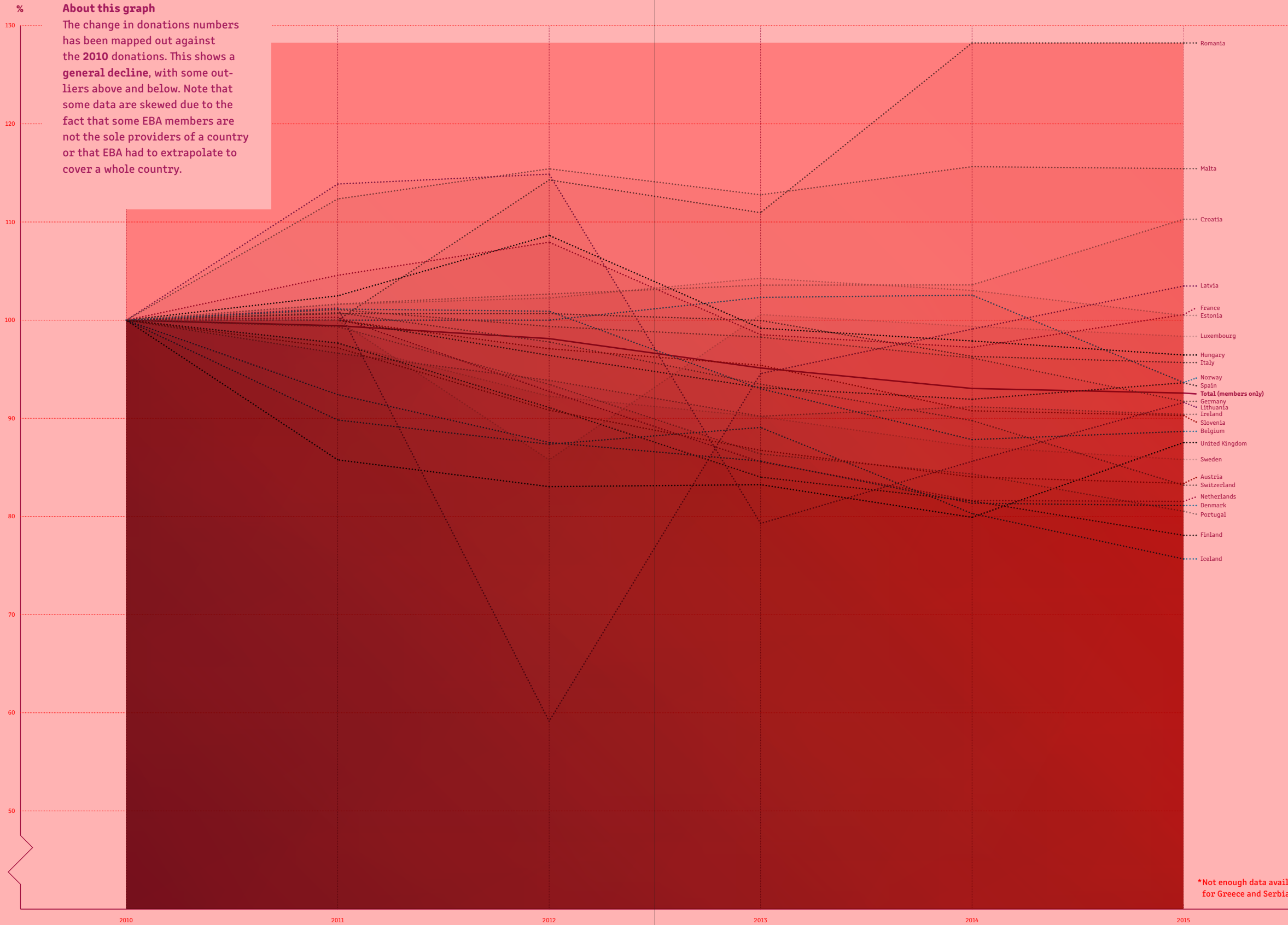
Income	2016	2015
Membership fees	371.500	381.200
Interest Bank account	4.324	6.152
EU Grant		9471
Revenue Collaborative Procurement	100.501	61.473
	476.325	458.296
EXPENSES		
Personnel costs	317.491	351.000
Depreciation	2.781	37.209
Meetings/Workshops etc	3.022	8.410
Travelling etc	22.658	47.380
Office costs fixed	16.690	11.614
Office costs variable	25.181	47.155
Other costs	58.359	75.293
	446.182	578.061
COLLABORATIVE PROCUREMENT		
Revenue	100.501	61.473
Expenses	111.701-	135.217-
Result CPI	11.200-	73.744-
Result CPI		
	11.200-	73.744-
Result Association	41.343	46.021-
Balance	30.143	119.765-



About the EBA

Yearly, EBA collects donation data from its members. The current trend of declining use of red cells can be observed for many countries and for EBA on the whole.





*Not enough data available for Greece and Serbia

EBA MEETINGS & CONFERENCES

11 January – Brussels Meeting DG Sante
Topics for discussion included **Patient Blood Management**, reorganisa-tion of DG SANTE and plan for stakeholder meeting, West Nile virus Directive 2014/110/EU and Medical Device/In vitro Diagnostic legislation

14/15 January – Estoril PLUS stakeholders
Consensus meeting Platform of Plasma Protein Users (PLUS): Blood and Plasma Regulations- Towards a **revision of the EU Blood Directive**: What is needed in a new Directive / Should Plasma be included in the Blood

14/15 January (WK) – Berlin Donor Health Care (DoHeCa) project meeting
DoHeCa partners meeting to finalise the **training program on donor management**

08 February – Strasbourg Tissues and Cells Non-Profit Consortium meeting
1st meeting: **Common representation of SoHo's Associations** within Official Institutions of European Union at EDQM

09/10 February – Berlin Integrated Transfusion Service Models Workshop
EBA BMG workshop organised by team Morgan, Rüstig, Aranko

19 February – Brussels Meetings with DG Sante, DG Research and EU Parliament
NHS European Office has organized meetings with key officers in Brussels to discuss **research funding in EU, final wordings of Medical Device and IVD Directives recast, and update on regulations regarding Blood Directives**

18 March – Naples 5th International Congress by AVIS (Italian Blood Donor Association)
Projects and research for everybody, beyond donors and donation Moderator and **invited talk**: "Current activities in the blood transfusion field"

22/23 March – Barcelona International Plasma Protein Congress by PPTA
Round Table discussion "Blood and Plasma: visions for a sustainable system"

30 March – EFS Paris T&C benchmarking meeting
Finalizing the **EBA Tissues and Cells benchmarking questionnaire**

03/05 April – Zagreb ABO Chief Executives and Point Contact meeting
Jointly with the President Represented EBA

06/07 April – Zagreb EBA Executive and Board meeting

02 May – Brussels Meeting with EU Health and Food Commissioner
EBA President and ED **discussed with Vytenis Andriukaitis, Health and Food Commissioner**, Paula Duarte Gaspar, Cabinet of Commissioner and DG SANTE officers self-sufficiency, VRND, The Transatlantic Trade and Investment Partnership and EU Blood legislation.

12/13 May – Berlin EBA Tissues and Cells Working Group meeting

23/25 May – Estoril PLUS stakeholder's Consensus Conference on blood directives
Platform of Plasma Protein Users (PLUS): Towards a **common position statement on the review of the Blood Directive** - what are the keypoints that could be agreed on and included?

14 June – Brussels Seminar at EU Parliament to support World Blood Donor Day
Invited talk "Transfusion Policies and Strategy across EU" at "Voluntary Blood Donation and Transfusion Policies In Europe"

27/28 June – Mechelen Executive meeting

29 June – Brussels European Health Parliament meeting
Networking with the Stakeholders

13/15 July – Cambridge 2nd European Conference on Donor Health & Management
Member of the Scientific Advisory Committee supporting

22 August
Exec telecon

26 August – Amsterdam Contingency Planning WG Meeting
Business contingency and emergency planning with EBA

9 September – Edinburgh EBA Cellular Therapies Meeting
Teleconference to discuss the ATMP manufacturing network of EBA

20 September – Strasbourg TS093 Extended Plasma Supply Management group (CoE)
Discussion with stakeholders on the **European self-sufficiency** and addressing knowledge gaps and limitations regarding plasmapheresis

24 September – Rome FIODS Seminar on self-sufficiency on plasma
International Federation of Blood Donor Organizations (FIODS/IFBDO) Plasma-derived products and self-sufficiency programmes which are the perspectives in Europe? Invited talk: The EBA view on plasma in EU, increased supply by VNRBD?

05/07 October – Frankfurt EBA Exec & Board meeting

13 October – Amsterdam Meeting with ISBT
Discussion on collabo-ration on Transfusion Medicine Training, Fainting tutorials and beyond

14 October – Helsinki National Expert Group meeting on Blood Safety
Invited talk: EBA and update on Zika virus and MSM in blood safety

21/25 October – Orlando AABB Annual Meeting
Meeting with the AABB Executives to discuss co-sponsoring Patient Blood Management Con-sensus Conference

06 November – Sydney Meeting with the ABO Secretariat
Discussion on EBA's contribution to ABO and Efficient ways to share the ABO deliverables within EBA membership

07/9 November – Sydney ABO Chief Executive and Point of Contact meeting

10 November – Sydney Meeting with the National Blood Authority of Australia
Jointly with ABO Chief Executives discuss the challenges of blood supply and safety in Australia

23 November – Hannover EBA Tissues and Cells WG meeting

23 November – Hannover Round table discussion at EATB Congress
EU-Regulation, Ethics and Oeconomics in coopera-tion with EBA and EATB

24 November – Hannover Joint EBA-SEGB workshop on heart valves
Open workshop to improve the efficiency of procurement of heart valves

30 November – Amsterdam Meeting with European Hematology Association
Discussion on collabo-ration on adverse event reporting and patient blood management

2 December – Brussels Ad hoc stakeholder meeting with NCA and DG SANTE
Invited talk to present EBA's proposal to change West Nile virus Directive 2014/110/EU regarding donor eligibility

5/6 December – Geneva EBA Executive Meeting



Thank you
A big thank you to all EBA members who helped compile this Annual Report.

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Design & layout: Studio Duel, The Hague

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