[17] EBA ANNUAL REPORT

European Blood Alliance

THE BLOOD REQUIRED FOR TODAY'S DISASTER WAS DONATED YESTERDAY*

eba
EUROPEAN BLOOD ALLIANCE

>4 million patients treated

EBA members provided high quality blood products for over 4 million patients in Europe and served over 6500 hospitals in Europe: there is a large variety in numbers: EBA member Malta serves 3 hospitals and France covers about 1500.

↓

>8 million active donors

Active donors are donors that have donated within the last 2 years: the EBA members have over 8 million active donors and all together, they donated about 17.5 million units of whole blood, platelets and plasma. Around 40.000 professionals with the support of countless volunteers ensure all the units donated are screened (with on average 8 screening tests) and processed into high quality blood products that reach the patients who need these.

↓

Since 1998

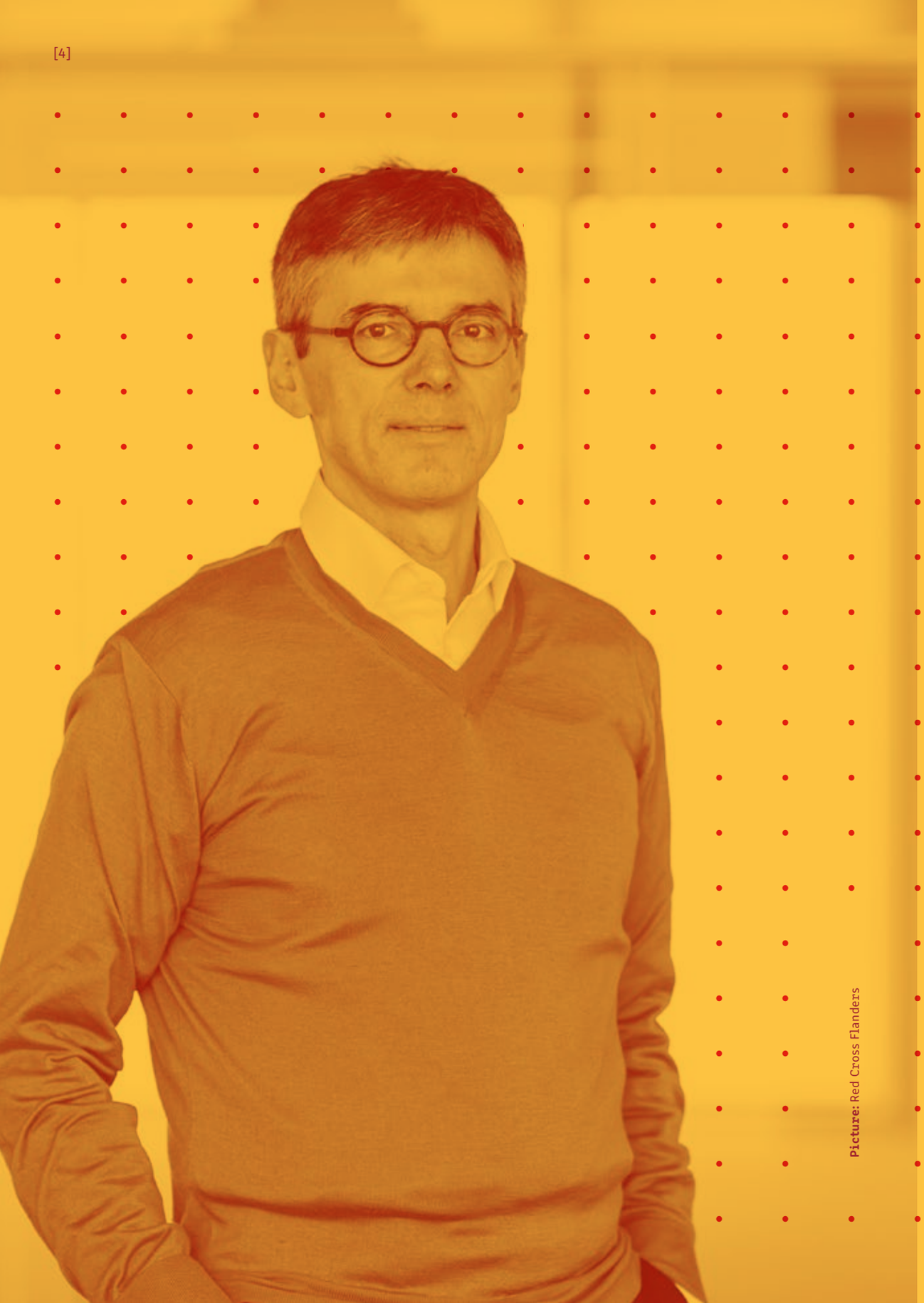
The EBA supports the membership since 1998. It has 26 members and 2 observers. The EBA Board meets 2 per year. From its membership, the Board has elected 6 voluntary Executives. The EBA Executive is supported it its duties by a small staff, located in Amsterdam. The yearly budget is about €500.000.

↓

10 working groups

EBA has currently 10 Working Groups: Benchmarking, EU Blood Directives Evaluation Group, Collaborative Quality Management, Collaborative Procurement Initiative, Contingency Planning, Education & Training, Emerging Infectious Disease Monitor, Tissues & Cells, Blood Donor Studies and Plasma Collection Working Group.

*This phrase was the conclusion of blood services having experienced disasters: there is no immediate need for blood donors during the crisis,, rather have regular donors come in often to keep the stocks robust!



Picture: Red Cross Flanders

FOREWORD

'DON'T WAIT UNTIL DISASTER STRIKES' WAS THE THEME OF THE 2017 WORLD BLOOD DONOR DAY ON 14 JUNE.

In recent years, Europe and other parts of the world have been badly shaken by grave political incidents that called even more upon the generosity of blood donors and stretched the capabilities of our blood establishments.

The general public perceive that terrorist attacks and other disasters require an immediate increase of donor blood. However, as more and more blood services have experienced crisis situations and have managed the blood supply under tough circumstances, it is now clear that the moment of crisis is not the moment to call upon increased blood donations.

Recent experiences in the USA, France, Germany and Belgium have taught us that donors are firmly committed to the needs of patients. Using social media, people called on each other to donate and there were queues for some blood donation centres both in the US and Europe.

However, during a crisis, when hospitals are flooded with emergency patients, many scheduled surgeries are delayed to free up resources and blood from the present stock is used for those who need it urgently. The Belgian Red Cross wrote an article on the use of blood during the Brussels bomb attacks and they observed that the level of blood needed during that event was not higher than usual on that week day. The conclusion was that "the blood required for today's disaster was donated yesterday", meaning that having donors come in regularly providing robust stocks at the blood bank is needed to ensure preparedness for all eventualities.

The fact that Blood Services report on their own experiences after such tragedies is a good illustration of the five important values that EBA consolidated in 2017: **Donor Care**, **Patient Safety**, **Information Sharing**, **Voluntary Non-Remunerated donations (VNRD)** and **Excellence through Evidence**. These core values are illustrated throughout this annual report highlighting how these values are incorporated in all EBA does.

Emergency response is at the epicentre of the values, acting positively towards donors and patients, with donations based on VNRD and informing each other on the effects of disasters on the blood supply in order that all services can take on their lessons learned.

The European Blood Alliance thanks all collaborators and especially donors who again made it possible for our members to supply the patients in Europe who need blood products, tissues or cells as effective therapies.

Philippe Vandekerckhove
EBA President

[01] SAFEGUARDING DONOR HEALTH AND WELLBEING

Ensuring the well-being of the donor in connection to the donation is a prime task for blood services.

EBA AGREED WITH FIODS ON VOLUNTARY NON-REMUNERATED BLOOD DONATIONS

In 2017, the EBA adopted the Voluntary non-Remunerated Blood Donations (VNRD) principle as a core value. To underline the importance of the issue, the EBA and the *International Federation of Blood Donor Organizations* (IFBDO/FIODS) have an aligned position on VNRD, which was agreed upon in December 2017.

"Voluntary non-Remunerated Blood Donations (VNRD) and sustainable supply of blood and blood products. VNRD have proven to secure a safe and sustainable blood supply in Europe. It is important to take measures to maintain and further develop this unique donation and volunteering culture. Accordingly, FIODS and EBA encourage all parties to take measures to maximise the contribution of VNRD as a source of blood and plasma in the high quality blood products for the benefit of patients."

Gian Franco Massaro, President of FIODS & Philippe Vandekerckhove, President of EBA

The agreement will be officially signed by the two organisations at EBA's 20th anniversary in Helsinki in 2018.

"The International Federation of Blood Donor Organizations is for the EBA an important partner on two of our values: **Donor Care** and **VNRD**! We are happy and proud to be able to have them on our side for these causes."

Philippe Vandekerckhove

ONLINE DONOR RECRUITMENT WORKSHOP

On October 19th and 20th, 2017, the *Austrian Red Cross* organised a workshop on "Content Marketing for donor recruiters." EBA blood services were invited to join us and discuss for two days how best to recruit, retain, and institute successful donor careers.

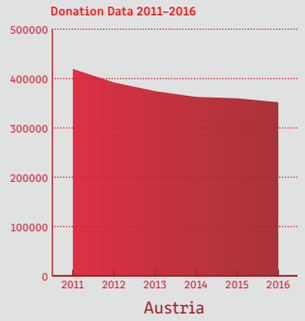
In depth on recruitment

The host, Lars Eberhart explained: "Since all blood services struggle with similar issues (demographics, digitalization, changes in lifestyle), we wanted to organise an event to address these challenges and also to enable donor recruiters and marketers to network". The idea was born in Cambridge during the last European Conference for Donor Health Management (ECDHM): "While such a conference provides vital information, the broad spectrum of topics addressed doesn't allow for depth. While discussing this, I volunteered to organise a workshop and narrow the agenda to look at donor recruitment from several perspectives".

Results

There were 18 attendees and three external speakers. According to Lars Eberhart: "the composition of the group was ideal; we had managers, researchers, and marketers". The feedback from the participants was very positive: they took home new ideas, compared their communication activities with other blood services, and learned about digital campaigning and social networks.

Seeing interventions working successfully in other countries made it easier for some of the participants to implement them in their regions. The lack of networks and collaboration on donor communication strategies and measures was pointed out, and participants agreed that further workshops should be organised, and that a communications/networking platform for donor recruiters at European level would be advantageous. The next steps will be to decide on a topic and location for the next workshop.



"Every blood centre yearly loses donors, either because donors reach the age limit or for other reasons. Recruiting new donors is costly; therefore, having efficient and effective means for recruitment saves money. This is connected to the values **excellence through evidence** and **information sharing**."

Polonca Mali

Picture: Lars Eberhart

DONOR HEALTH CARE

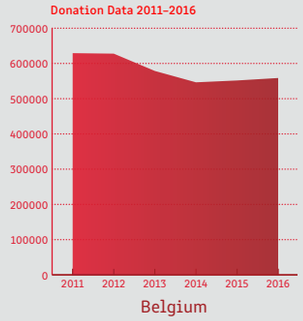
A core competence of Blood Establishments is dealing with donors and their health. To leverage on this, the Donor Health Care (DoHeCa) learning program started in 2013 from an Erasmus Lifelong Learning EU grant. The goal of the project was to develop a 100% distance learning program in Donor Health Care at Master's level, covering the whole donor spectrum. The project, in which 14 European partners participated, officially ended in 2017; however, the pilot of the last module will continue until March 2018.

Last consortium meeting

In February 2017, the final DoHeCa Consortium meeting was organised and took place in Amsterdam. Apart from Consortium members, teachers and developers, seven of the DoHeCa pilot students attended this meeting. They participated in the evaluations of the course and social programme, but were also offered a special session — an ethical debate — moderated by DoHeCa teachers. The debate was attended by a kidney donor, a nephrologist and a patient representative.

Closing the books

Dr. Anne-Marie van Walraven, DoHeCa Project leader spent many hours of work to gather the files that were sent to the *Education, Audiovisual and Culture Executive Agency* (EACEA) of the European Commission: "It was a lot of work compiling four years of work into one document! I collected 21 amendment and deviation documents, 72 product outcomes (including the 23 deliverables), four Consortium meeting reports and 200 meeting and conference call reports. Overall, this comprised more than 300 documents that we have often worked on together". She applauded the consortium: "what an impressive result!" After the summer, the final report was indeed approved by EACEA.



Continuing the work

Dr. Van Walraven is currently exploring the possibility of having DoHeCa developed by a University or College, as a post graduate or masters' programme "The advantage of a post graduate programme is that it is accessible and attractive for a much larger target group, including physicians and nurses" she explained.

"The Donor Health Care Project was a great initiative collecting a wide spectrum of knowledge on donor health into one learning program. The EBA was happy to contribute to and support this project, as we are very willing to share with all professionals working with donors all the knowledge we have gained on **donors' safety** and wellbeing."

Pierre Tiberghien

Picture: Anne-Marie van Walraven

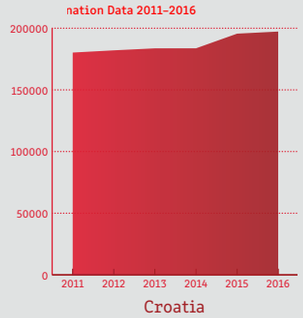
START OF TRANSPOSE – EU FUNDED PROJECT

A consortium, including EBA Blood Services, combined forces to quote in response to an EU request for proposals. Under the header of 'facilitating access to better and safer healthcare for Union citizens", they noted that the implementation of directives and Guides in Member States resulted in diverging donor selection and protection policies. A lack of quantitative risk-based selection and other criteria led to inflexibility and inconsistency. The grant was awarded to the consortium in 2017 and TRANSPOSE (**TRANS**fusion and transplantation: **PrO**tection and **SE**lection of donors) had its kick-off meeting in Amsterdam.

TRANSPOSE aims at a structured, alternative approach to construct risk-based guidelines for the selection and protection of donors. To this end, TRANSPOSE will involve a massive pool of experts and take stock of current practices and scientific insights. EBA will support TRANSPOSE with expertise, dissemination of information and, if necessary, with funding.

"The values **Donor Care** and **Patient Safety** are tied in here together, and should be in balance. As noted in EBA's position paper on Donor Selection, revised donor selection measures should have no negative impact on donor, recipient and blood products safety. With that in mind, we look forward to the results of this important project"

Pierre Tiberghien



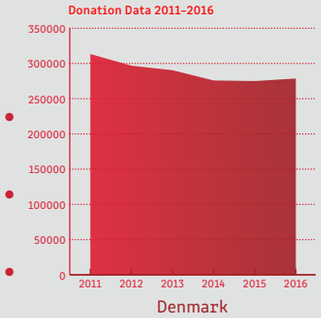
IRON DEPLETION IN DONORS

Recent studies have revealed that iron deficiency is frequent among blood donors. Detailed research on iron status indicates that blood donors may develop iron deficiency despite adequate haemoglobin levels at donations. The current regulatory requirement of minimum haemoglobin levels and donation intervals seems not to be sufficient to prevent iron depletion in frequent blood donors.

Predictors for iron depletion

Around the world, there is active research on iron depletion and the EBA Donor Studies Working Group is also addressing the phenomenon. The chair, Professor Christian Erikstrup, Denmark, explains that not all donors are affected by iron depletion: "the strongest predictors of iron depletion among blood donors are sex, age and donation frequency. However, we know that genetic constitution and environmental factors also affect the risk."

While research shows that premenopausal women are often iron depleted even when they do not donate at all, iron depletion is rare among post-menopausal women and men. However, men and post-menopausal women who donate frequently can develop iron depletion. Premenopausal women are at highest risk and it can affect up to 40% of frequent donors. Even though it only affects a part of the donor population, the effects can be serious, as iron depletion can lead to anaemia and fatigue and has also been associated with cognitive impairment, dysregulation of the immune system, and low birth weight of children born to iron deficient mothers. To study this issue in further detail, the Donor Studies Working Group is conducting ongoing research.



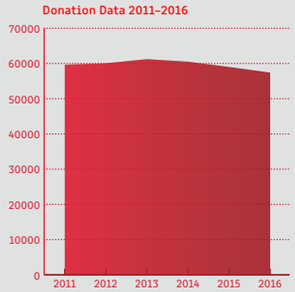
Countering the effects

"There is no consensus as how best to prevent blood donors from iron depletion" Christian Erikstrup says: "We cannot yet predict who will develop iron depletion and as haemoglobin alone is not a sufficient indicator, we need to measure iron stores, for instance by measuring serum ferritin." The main strategies used to prevent iron deficiency in blood donors are to have longer donation intervals based on ferritin measurements or to give iron supplements: "No large randomised trials have compared ferritin-guided iron supplementation regimens and thus we do not know how the side effects of iron supplementation among blood donors compares with the risk of iron depletion." Findings indicate that iron depletion can be mitigated by iron supplementation. Blood services are conducting studies to evaluate the effectiveness of various strategies to mitigate the risk for iron depletion and to share best practices.

What can donors do by themselves? Christian Erikstrup advises that: "For all blood donors it is important to keep good healthy diets and follow the instruction provided by the blood service". Blood services take seriously the responsibility to inform and take care of the donors so that the donors are as healthy when they leave the blood bank as when they arrive.

"Blood Services are responsible for the health of donors around their donation and the issue of donor depletion is high on the agendas of all blood services. **Donor safety** is one of our core values and we take that very seriously also as we are dependent on the donors' generous gifts!"

Polonca Mali



Estonia

"Donor safety is one of our core values and we take that very seriously also as we are dependent on the donors' generous gifts!"

[02] SAFEGUARDING AND IMPROVING PATIENT CARE

Safe blood products to all patients who need these as therapies is the core of the EBA's members business.

EMERGING INFECTIOUS DISEASE MONITOR

Through its monthly teleconference and regular information exchange, the Emerging Infectious Disease (EID) Monitor continued to watch emerging infectious diseases and exchange information about blood safety measures in the area of EBA and *Alliance of Blood Operators** (ABO) membership. On average, 19 EID Monitor members participated in each teleconference in the last twelve months. The rapid circulation of the telecons' minutes ensured a quick spread of information and recommendations to EBA and other ABO members. The following topics were particularly important this year.

West Nile Virus

The first confirmed human West Nile Virus (WNV) infections in the EU in 2017 were detected in southern Greece and reported by the ECDC on 21 July. Up to 23 November 2017, EU Member States (MS) reported 203 human WNV cases to the *European Centre for Disease Control* (ECDC): Romania (66 cases), Italy (57), Greece (48), Hungary (21), Croatia (5), Austria (4), France (1) and Bulgaria (1). Eighty-four human WNV cases were reported in neighbouring countries: Serbia (49), Turkey (7) and Israel (28).

There were no major changes in epidemiology compared with the previous years. The number of transmissions to humans was comparable to the number of human cases in previous seasons and large outbreaks in new areas did not occur. After an absence of reported human cases in Greece in 2015 and 2016, this year 48 West Nile fever cases were reported in southern Greece, including one (not confirmed) case in a newly affected area in Crete. In Italy, the newly affected areas were Livorno and Asti. Also, two cases were identified in a newly affected area in the Alpes-Maritimes in France.

The exact number of WNV infections remains unclear, due to the fact that there is cross reactivity with the Usutuvirus testing as observed in Austria (see section on Usutu virus).

Member States also reported WNV infections in horses (equidae), i.e. 100 cases in Italy, 13 in Greece, nine in Spain, three in Hungary, two in Austria, and one in Portugal.

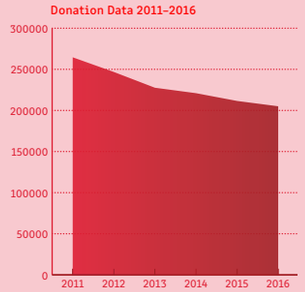
***ABO**
The *Alliance of Blood Operators* (ABO) is a network of not-for-profit blood operators with voluntary non-remunerated blood donor bases. Its members are America's Blood Centers, American Red Cross Australian Red Cross Blood Service, Blood Systems Inc., Canadian Blood Services, European Blood Alliance and NHS Blood and Transplant

The European Centre for Disease Control (ECDC), the *European Food Safety Authority* (EFSA) and the European Commission have been working together to identify avenues to further integrate animal and human data on West Nile fever collected at the European Union level. According to the Commission Directive 2014/110/EU, blood donors should be deferred for 28 days after leaving a risk area of locally acquired WNV unless an individual NAT is negative. Currently an area is considered affected by WNV following the occurrence of human cases (which is trigger for applying blood safety measures) and areas where equidae cases are detected are not considered to be affected, despite the evidence of WNV circulation in the area.

Surveillance of WNV in equidae confirms WNV circulation in an area, but the usefulness of equidae data as a trigger for blood establishments can be debated for the following reasons. Firstly, the provided data is selective and depends on the structure of surveillance, availability and quality of WNV testing and the reporting of the country. Secondly, the infected equidae confirms circulation of WNV in an area, but as far as we know there is no evidence of a direct correlation between confirmation of WNV infection in equidae and the risk of human WNV infections.

The EID monitor advised the ECDC to study the correlation between WNV infections in equidae and humans before furthering the plans. If there is evidence of a positive correlation, the cost-effectiveness of changing the trigger of blood safety measures should be studied as well. The EID monitor also advised that to support blood safety measures the map be organised in a multilayer way to allow extraction of relevant data for daily use, and separately, to allow analysis of more complex data for risk analysis and surveillance. The ECDC has planned an expert meeting for March 2018 in Vienna to evaluate the experiences in using of WNV maps, assess the need to integrate cases in horses into the maps, and involve other arthropod-borne viruses into the maps. The Experts from EID Monitor will attend this meeting.

Arbovirus
Prof. Wolfgang Mayr, chair of the EID Monitor explains: "An arthropod-borne virus, or Arbovirus for short, is any virus that is transmitted to humans (or other vertebrates) by certain species of blood-feeding arthropods, chiefly insects (flies and mosquitoes) and arachnids (ticks). There exist more than 250 arboviruses, e.g. WNV, Zika virus, dengue virus, Yellow Fever virus, TBE virus, or chikungunya virus."



Finland

WNV NAT Testing

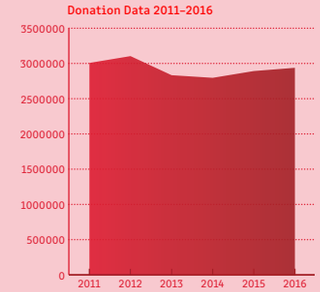
The EID monitor sent comments to the *Directorate General for food safety and health* (DG SANTE) concerning the Directive 2014/110/EU — the amendment of Directive 2004/33/EU — which replaces the previous donor selection criteria of temporary deferral and testing requirements for WNV by *"28 days after leaving a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative"*.

In response to those comments, in June of last year the EBA was invited to attend the *Competent Authorities on Substances of Human Origin Expert Group* (CASoHO) meeting to explain the concerns regarding individual WNV NAT testing in that amendment of the Directive 2014/110/EU. The Expert group agreed in that meeting on a working interpretation that grants discretion to the Member States to decide whether to use the deferral period or use NAT. Where NAT testing is permitted, Member States will have the discretion to decide which type of NAT testing is permitted and any conditions which should be placed on its use, i.e. whether a risk assessment is necessary to justify the use of a particular type of NAT or to set an acceptable sensitivity level. Also, based on comments by the EBA EID Monitor, the *European Commission* is currently preparing a working interpretation of the term *"risk area of locally acquired WNV"*.

Chikungunya in France

In August, a local transmission of chikungunya occurred in the South of France. In 2017 a total of 15 confirmed and two probable autochthonous cases of chikungunya were identified, clustered in two small areas in department Var. An index import case was not identified. All clinical cases appeared to be in the beginning of August up to 10 September. Anti-vectorial measures were taken in the affected area and these brought the situation under control. For blood safety, blood collection in the affected areas was temporarily halted and enhancement of post donation information was reinforced.

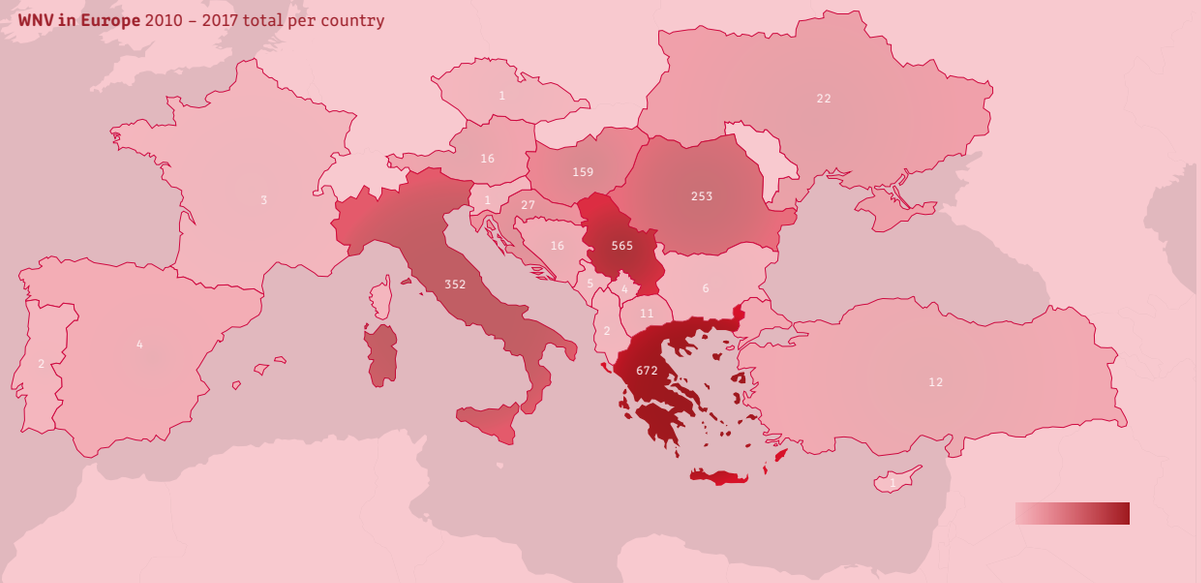
In the Southern part of Italy, a total of 197 confirmed and 201 probable cases of chikungunya infection were reported up to 12 December in the municipalities of Rome, Anzio and Latina (Lazio Region) and 62 confirmed and 37 probable cases in the municipality of Guardavalle Marina (Calabria Region). During the outbreak, the affected region was successfully supplied by the surrounding region's blood services.



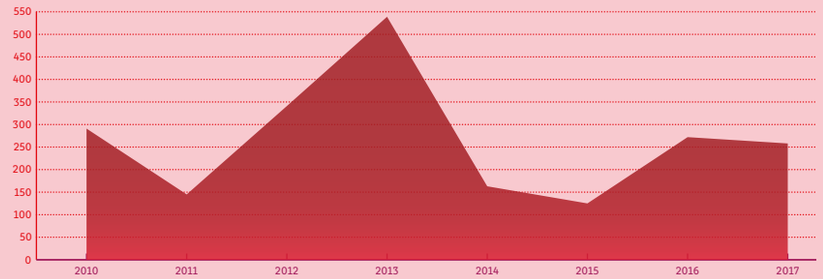
France

West Nile Virus (WNV)

WNV in Europe 2010 – 2017 total per country



WNV in Europe 2010 – 2017, total cases



WNV in Europe 2010 – 2017 per country per year
EID monitor data

Used symbols:
Non EU MS
***** Austria:
In 2015 seven verified human WNV-cases in (Eastern) Austria:
two infections in patients (1 WNV, 1 WNND) and five viremias in donors
In 2016 six verified human WNV-cases in (Eastern) Austria:
two infections in patients (1 WNV, 1 WNND) and four viremias in donors
In 2017 seven WNV positive donors; six were identified as Usutu virus infected, one donor was WNV infected; one clinical human WNV case (4 WNV cases reported by ECDC)
^ France:
In 2017 two cases reported by EID M in dep Alpes Maritimes (one case reported by ECDC)

	Albania #	Austria *	Bosnia #	Bulgaria	Croatia	Cyprus	Czech Rep	France ^	Greece	Hungary	Italy	Kosovo #	Macedonia #	Montenegro #	Portugal	Romania	Serbia #	Slovenia	Spain	Turkey #	Ukraine #
2010									262	15	3				1	9			1		
2011	2								100	3	14		4			11				3	8
2012				2	5				161	17	50	4	6	1		14	69				12
2013			3		16		1		86	31	69		1	4		24	302	1			1
2014		1	13						15	11	24					23	76				
2015		7		2				1		18	49				1	19	28				
2016		6		1	1	1				43	86					87	41		3	2	1
2017		2		1	5			2	48	21	57					66	49			7	

The latest date of the onset was November 5th, 2017 (Anzio, Lazio Region). Since this date, no additional cases have been reported in Italy. All additional preventive measures adopted for safety of blood components have been interrupted after absence of new cases.

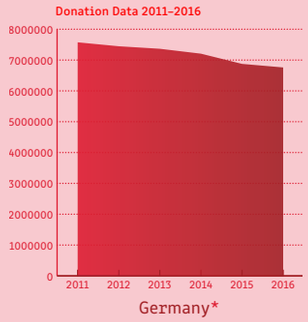
Transmission of chikungunya through blood products has never been reported in humans. If transmission through blood products is possible, as described for dengue virus or Zika virus, it is thought to be a very ineffective transmission route. For large outbreaks, as in Italy, members were more likely to implement blood safety measures by temporarily deferring donors who had travelled to the affected areas in comparison to sporadic transmissions.

Zika virus

In the Americas, although the Zika virus outbreak has declined since the end of 2016, transmission is still ongoing globally (in Caribbean, the Americas, Asia, the Pacific and Africa). In Europe, no autochthonous Zika cases related to vector-borne transmission occurred in 2017. In Brazil, after the four probable transmissions through blood products (of which three were published), no new transfusion transmitted cases were reported.

The EBA-EID monitor was involved in the updated version of the preparedness plan on Zika virus with the EC (DG SANTE) and ECDC in 2017. Before finalising the updated version, the EID Monitor was invited to an ECDC expert meeting, to discuss the recent changes in epidemics, classification of affected areas, assessment of sexual risk, evaluation of triggered activities, and share the experiences. Carrying out risk assessments and, if feasible, a cost-effectiveness study on national level before decision making must be continually emphasised. Tools like EUFRAT and the ABO RBDM could help in this analysis.

The possibility of an alternative transmission route through sexual contact, the persistent viremia, the intra-uterine effect on the foetus, neurologic diseases, the rapid spread of the outbreak areas and possibility of local outbreaks within Europe were topics continuously monitored.



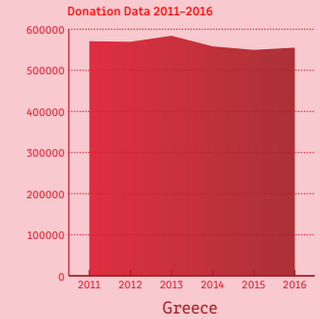
*Data for whole of Germany (source: PEI Institute)

It was found that Zika virus RNA persists longer in whole blood, due to the adherence of Zika virus RNA to red blood cells. Up to now there was no evidence that the persistence of RBC bound Zika virus RNA was clinically relevant. *The Food and Drug Authority* of the United States (FDA) guidance recommends that donors be deferred for 120 days after diagnosis or test reactivity. To prevent transfusion transmitted infection after clinical disease, the recently issued 19th edition of the EDQM Blood Guide, recommends a 120-day deferral after resolution of symptoms for WNV, chikungunya virus, dengue virus and Zika virus.

The recommendation in the ECDC preparedness plan is to defer the donor until 28 days after cessation of symptoms. As recommended in the Blood Guide and by the FDA, A 120-day deferral period could be considered as an alternative period after cessation of symptoms, but this would be based on precautionary principles. The EID monitor stresses that infectivity studies are needed to support an extension of the deferral period, not only for Zika virus but also for other vector-borne viral diseases. The EID monitor sent a letter to the European Committee on Blood Transfusion (Steering Committee) (CD-P-TS) of the Council of Europe asking for the rationale underlying their recommendation.

The European Medicines Agency published a report regarding viral safety of plasma-derived medicinal products (PDMP), in which they stated that the virus reduction capacity of the established steps for inactivation/removal of enveloped viruses is considered sufficient for the safety of PDMP with regard to Zika virus. Therefore, no additional safety measures such as deferral for plasma donors or NAT testing are needed.

The updated preparedness plan is published on the ECDC website and can be regarded as a valuable guide for blood establishments *(Zika virus and safety of substances of human origin — A guide for preparedness activities in Europe – First update. ECDC. August 2017)*.



Usutu virus

The ROCHE COBAS WNV assay which is used for screening Austrian blood donors is also reactive in viremias of the closely related Usutu virus (USUV). Of the seven donors who were initially reactive in the WNV NAT screening, six were confirmed to be infected with Usutu virus. Only one was a real WNV infection. As described recently in literature, cross reactivity is known to occur if testing is performed with this assay.

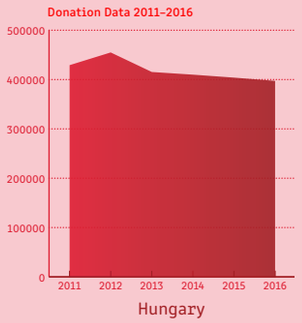
In Austria, donors positive for the Usutu virus RNA were all asymptomatic. Although Usutu virus is a deadly virus for birds, the clinical consequences for humans are, up to now, very limited. So far, transmission through blood transfusion has never been reported. The Usutu virus activity in animals is very high in Hungary and Eastern Austria. But the Usutu virus was also circulating in other European countries. The issue of cross-reactivity leaves us with several unanswered questions: Are more USUV cases detected because of cross-reactivity of Roche WNV NAT? Can we expect similar cross reactions on other WNV testing platforms? Are there more human Usutu virus cases? Is the virus evolving into a more pathogenic virus for humans?

Since it spreads through birds, Usutu virus spreads very quickly. It is important to be vigilant; to look for better evidence regarding prevalence, and to emphasise the importance of the density of birds. The outbreak seems not to be relevant for blood safety at the moment, but the increased awareness of this arbovirus and its cross-reactivity with WNV NAT screening should serve to keep us alert. The topic will be addressed in the ECDC expert meeting on WNV in March 2018.

Malaria

Multiple reports of locally-acquired malaria infections were reported in four countries:

1) **France:** Two vector-borne transmitted cases (plasmodium falciparum)
2) **Italy:** One possibly nosocomial (plasmodium falciparum) and four vector-borne cases (plasmodium falciparum)
3) **Greece:** Five vector-borne (plasmodium vivax) and one nosocomial (plasmodium falciparum) cases
4) **Cyprus**: Three vector-borne cases (plasmodium vivax)



Hungary

The risk of further spread of malaria in Europe associated with these events was considered to be very low. Therefore, most members did not implement additional blood safety measures, i.e. deferral for malaria risk of donor candidates who have travelled to these areas.

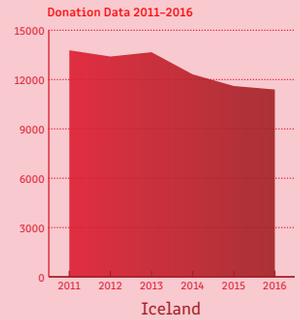
Hepatitis E virus

A number of blood establishments decided to start to screen on Hepatitis E virus (HEV) RNA. This is because of an increasing awareness about the incidence of HEV infections in the population and blood donors, together with the increasing reporting of transmissions through blood products 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 for patients in preventing disease is limited. Due to higher exposure of blood products the risk is higher in multi-transfused patients.

In 2016, the UK implemented selective donor screening on HEV NAT (mini pools of 24 donations) to supply safe blood components for patients with solid organ and stem cells transplant, but changed to universal screening in 2017. Ireland implemented universal screening on HEV RNA (individual donation testing) in 2016. The Netherlands implemented universal donor screening (tested in mini pools of 24 donations) in July 2017. Germany, France and Austria partially perform HEV RNA testing.

Blood safety implications of donors using HIV pre-exposure prophylaxis

A donor on pre-exposure prophylaxis (PrEP) could be infected, and due to suppression of viral load the virus can be missed in screening, even with individual donation NAT testing. As data is lacking, it is still a theoretical risk but it is an issue of which to be aware. Breakthrough infection under PrEP is very rare. Donor candidates may or may not tell if they use such prophylaxis, as they could perceive it as safe and feel that they are not at risk (so called 'risk compensation'). PrEP is not always provided by health services, but it can also be obtained through internet or other illegal routes, so use is not 100% monitored. Because PrEP is very effective in preventing HIV infection, a wider use of PrEP in the population should be considered and also the possibility that the development that PrEP becomes available for persons who could be exposed to other situations at risk (for instance health care workers or police).



Iceland

The greatest concern is the risk perception of the donors. Donors disclosing the use of PrEP should be deferred based on higher risk for acquiring HIV. Adding PrEP to the medication list used for prospective donors could be helpful.

Blood donation rules relaxed for MSM and sex workers in the UK

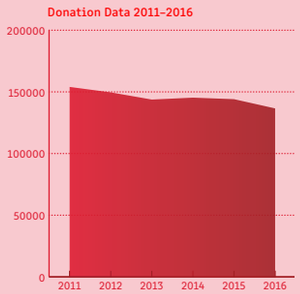
The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) committee has reviewed the donor selection criteria and donor motivation in their report based on UK data (SaBTO, *Donor Selection Criteria Report*, July 2017). The SaBTO committee recommended that the 12-month deferral for MSM be reduced to three months deferral from last sexual contact. But also other sexual risk behaviour, such as sexual contacts with sex workers is recommended to be reduced to from permanent deferral to three months. For the recommended changes of deferral rules for endoscopy, body piercing, tattooing, acupuncture or intravenous drug use, a legislative change is required.

Survey on detection limits for NAT screening

In Switzerland the shift of blood donation criteria for MSM, from permanent to temporary deferral, was adopted in July 2017. Before implementation, a survey was launched at the request of the Swiss National Competent Authority. The aim was to find which detection limits (if any) have been defined for the three screened viruses HIV, Hepatitis C and Hepatitis B in the EBA countries. Replies have been received from 14 countries. The sensitivity of tests is important to take into account in the review of the testing algorithm, regardless of the pool size. HIV is the main risk in MSM and the current HIV NAT screening is highly sensitive, an outcome that can also be achieved when testing in pools.

"This EID Monitor really captures what EBA is about: **sharing information in openness**, so all countries can take measures within their own blood service to ensure safe products. Because of the excellent preparation by the chairs and secretary, the efforts involved for the medical experts around the world in the calls are relatively low, as it is just an hour call per month. The outcome here really is more than just the sum of its parts!"

Polonca Mali



Ireland

PATIENT BLOOD MANAGEMENT IN EUROPE: PaBloE

The PaBloE group was set-up as a consortium to apply for an EU grant some years ago (which was not awarded). The group remained adamant, however, that it intended to further the Patient Blood Management (PBM) agenda and had a meeting in Amsterdam in May of 2017.

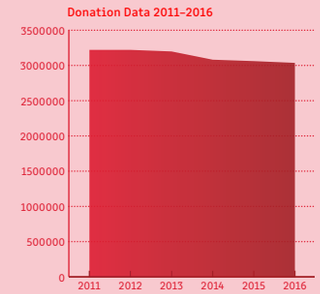
Comparing outcomes

The group compares with each other outcomes on patient blood management practices and assists each other with data for research. Earlier data resulted in the publication of "Patient Blood Management knowledge and practice among clinicians from seven European university hospitals: a multicentre survey" in *Vox Sanguinis* (Article DOI: 10.1111/vox.12599) in 2017.

They reviewed the results of a joint study on management of preoperative iron deficiency anaemia in eight European hospitals and the group accepted as the next step a follow-up study to first implement measures to improve management of iron deficiency anaemia, and then to re-audit the eight European hospitals to assess the effectiveness of the intervention. The results of this are expected in 2018.

"Patient Blood Management is a patient-focused, evidence-based approach to optimise patient management. It comprises the selection of appropriate high quality blood products and the careful assessment of when to transfuse or not. EBA supports PBM as a method of **improving patient care** which is EBA's first core value."

Pierre Tiberghien



Italy

HEART VALVES QUALITY ROUND

In 2016, the EBA Tissues and Cells Working Group carried out a heart valve processing benchmarking exercise, as a collaboration between EBA and the Foundation of European Tissue Banks (FETB). This study identified numerous differences in how heart valves are processed by different Tissue Banks throughout the world and showed discard rates of heart valves between 19% and 65%. In view of the results of this study, the decision was taken to look in greater detail at the microbiology aspects of heart valve banking.

2017: quality round

As a follow-up to the results of the 2016 Benchmark, in 2017 a Quality Round was organised, again as a collaboration between EBA and FETB. The participating Tissue Banks were sent samples of heart valve tissue that had been purposefully contaminated with micro-organisms, and were asked to identify which micro-organisms (if any) were present on the heart valves. They were asked to then decontaminate these heart valves and repeat sterility testing in order to establish whether or not the heart valves had been successfully decontaminated. The Tissue Banks were asked to use their usual protocols for culturing and decontaminating the heart valves.

This initiative was met with enthusiasm by the Tissue Banks, with most indicating that they would wish to participate. In the end, 25 Tissue Banks confirmed their participation; 21 European Tissue Banks and four Tissue Banks from further afield, including Canada, South Africa, Iran and Argentina. The organisers of this initiative contributed their time and expertise on a voluntary basis.

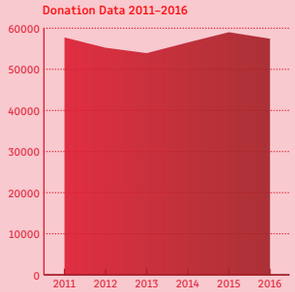
Heart valves (with the necessary consent and not suitable for clinical use) were supplied by the Oxford Heart Valve Bank and the European Homograft Bank in Brussels; the latter Tissue Bank also provided use of their premises, equipment and materials free of charge. Participating Tissue Banks were asked to pay a nominal fee to cover the cost of sending the heart valves. The heart valve samples were sent out by registered delivery in July 2017. Each Tissue Bank received three separate samples: two contaminated with micro-organisms, and one negative control.

Outcomes: identifying micro-organisms

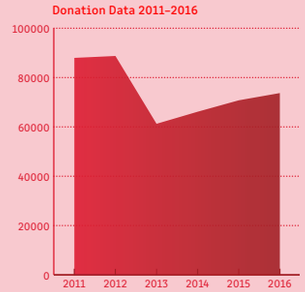
Twenty-two Tissue Banks successfully processed the samples and returned their results in a timely manner to allow the results to be analysed and then presented at the Annual Meeting of the European Association of Tissue Banks in Treviso in October 2017. It was retrospectively realised that the heart valves from the Oxford Heart Valve Bank contained antibiotics which interfered with the micro-organisms present in one of the samples (Sample A). This was taken into account when analysing the results. Results from the different Tissue Banks varied, with some Tissue Banks successfully identifying all the organisms present; some Tissue Banks failing to identify some or all of the micro-organisms, and some Tissue Banks appearing to contaminate the heart valves sent.

"This project touches on more than one of EBA values: **excellence through evidence**, **patient safety** and **information sharing**. External quality assessment schemes are important and known practice for laboratory services but so far there has not been specifically one for tissue processing. In a very practical way, this project enabled many tissue services to benchmark their procedures against others in the world. Many thanks are extended to the enthusiastic people involved."

Mary Morgan



Latvia



Lithuania

Table 1: Culture results for the three heart valve samples for the participating Tissue Banks

Tissue Bank Code	Sample A	Sample B	Sample C
A	No growth	No growth	Roseomonas
B	Bacillus spp	No growth	No growth
C	No growth	No growth	Roseomonas, B. pumilis
D	No growth	No growth	Staph. Hominis, Stenotrophomonas
E	No growth	No growth	Roseomonas, Staph. hominis
F	No growth	No growth	Roseomonas, Staph. hominis
G	No growth	No growth	Roseomonas, Staph. hominis
H	Non-fermentative Gram-negative rods	No growth	Roseomonas, Staph. hominis
I	No growth	No growth	Roseomonas, Staph. hominis
J	Staph. cohnii	P. acnes	Staph. schleiferi
K	No growth	Staph. hominis	No growth
L	No growth	No growth	Roseomonas
M	No growth	No growth	No growth
N	No growth	No growth	Roseomonas, Staph. hominis
O	No growth	No growth	Roseomonas
P	No growth	No growth	Roseomonas
Q	No growth	No growth	Roseomonas, Coagulase neg Staph.
R	No growth	No growth	No growth
S	No growth	No growth	Roseomonas, Staph. hominis
T	No growth	No growth	Roseomonas
U	No growth	No growth	Roseomonas
W	No growth	No growth	Roseomonas

Sample A: Sphingomonas paucimobilis – antibiotics were present in this sample so an acceptable result would be 1. Identification of the S. paucimobilis (Non-fermentative Gram-negative rods) or 2. No growth
Sample B: Negative control – acceptable result: no growth
Sample C: Roseomonas mucosae and Staphylococcus hominis – acceptable result: identification of both organisms.
Colour coding: in burgundy correct result, in red evidence of contamination, in blue partially correct result

Outcomes: decontaminating micro-organisms

The results following decontamination also varied. Some Tissue Banks managed to decontaminate the heart valves, while others failed to decontaminate the valves and one Tissue Bank appeared to have contaminated the heart valves.

Table 2: Decontamination results for the three heart valve samples for the participating Tissue Banks

Tissue Bank Code	Sample A Post-decontamination	Sample B Post-decontamination	Sample C Post-decontamination
A	No growth	No growth	Roseomonas
B	No growth	No growth	Staph. hominis
C	No growth	No growth	No growth
D	No growth	No growth	Not tested
E	No growth	No growth	No growth
F	No growth	No growth	Roseomonas
G	No growth	No growth	No growth
H	No growth	No growth	Roseomonas
I	No growth	No growth	No growth
J	No growth	No growth	No growth
K	No growth	No growth	Rodococcus, Staph. hominis
L	No growth	No growth	No growth
M	No growth	No growth	No growth
N	No growth	No growth	No growth
O	No growth	No growth	No growth
P	No growth	No growth	Roseomonas
Q	No growth	No growth	No growth
R	No growth	No growth	No growth
S	No growth	No growth	Roseomonas
T	No growth	No growth	No growth
U	No growth	No growth	Roseomonas
W	No growth	No growth	No growth

Acceptable result: No growth
Colour coding: in burgundy, correct result; in blue, failure to decontaminate; in red, evidence of new contamination

Next steps

The above results have all been fed back to the participating Tissue Banks. The organising group is now carrying out further analysis of the information, looking at the culture media and the decontamination protocols used by the different Tissue Banks with the aim of publishing the results in a peer-reviewed journal. The participating Tissue Banks have indicated the desire to have such an External Quality Scheme for Tissue banking on a regular basis. The organising group will be looking at the feasibility of setting this up on a regular basis, with the next Quality Round planned for Autumn 2018.

EBA CORE VALUES

1. Patient Care

- **Core value statement:** Through safe and sustainable supply of blood components, EBA members contribute to the patient's care.
- **Explanation:** Patient care is the ultimate goal of transfusion medicine: safe and adequate blood supply contributes to a well-functioning professional healthcare system. All actions that EBA members take, should therefore as a first priority aim to improve patient's care.

2. Donor Safety

- **Core value statement:** EBA members take good care of donors and actively take measures to avoid harm to them.
- **Explanation:** Donors represent a unique source and EBA members have to ensure the continuity of their gift. This can happen only if EBA members take good care of them through being aware of harm that may be caused in the context of donation, donation frequency and taking measures to avoid it. EBA and EBA members are open and transparent and take action to improve where possible donor safety. This could mean e.g. explaining deferral rules to donors and being open in the rationale behind any policy – evidence based.

3. Voluntary Non-Remunerated Donations

- **Core value statement:** EBA and EBA members are committed to voluntary non-remunerated donations (VNRD) for sustainable blood, tissues and cells supply for the benefit of donor and patient safety.
- **Explanation:** To protect donors' and patients' safety, transactions of human bodily materials should comply with the well acknowledged four principles of biomedical ethics: autonomy, non-maleficence, beneficence and justice. Protection of donor's dignity, involving the prohibition of making the human body and its parts as such a source of financial gain, has been strongly encouraged by the Council of Europe Oviedo Convention.

4. Helping each other for optimal use of health resources through openness in information sharing

- **Core value statement:** EBA shares information to support evidence based decision making and performance improvement of services in blood, tissues and cells.
- **Explanation:** EBA and EBA Members share information within the membership and when agreed, with regulators and other stakeholders with the goal of improving patient and donor care in Europe. Sharing information and collaborative activities leverage the economies of scale. The collateral benefits outweigh the time and manpower invested in joint activities. EBA respects the members' decision on the use of the disclosed information.

5. Excellence through Evidence

- **Core value statement:** EBA members are striving towards excellence by being innovative, adopting state-of-the-art processes and practices and implementing actions through evidence-based methods. Positions taken by EBA are based on evidence thereby avoiding bias in conclusions.
- **Explanation:** EBA Members constantly monitor whether the set targets for excellence are still relevant and update them from time to time. They implement actions to ensure that the set targets are reached and encourage continuous learning. Excellence in blood products supply chain cannot be characterised merely by high productivity and quality. It means right, evidence based, decisions to contribute to a well-functioning professional healthcare system. When EBA uses the term 'Evidence based', it is used in the strict sense of the Cochrane Collaboration.

[03] SAFEGUARDING THE BLOOD SUPPLY AND IMPROVING PERFORMANCE

EBA supports the operations of the Blood Establishments by identifying best practices. EBA members strive collectively to improve the supply of blood products and, where provided by members, other substances of human origin (SOHOs).

CONTINUITY OF SUPPLIES

In autumn 2017, some EBA members faced challenges with an sudden disruption in the supply of a donor blood screening test for Syphilis (Treponema pallidum). EBA raised the issue of continuity of supply in a broader context with the Directorate General for food safety and health (DG SANTE).

The issue of continuity of supplies and EBA's concerns were discussed in the ad hoc meeting of the Competent Authorities on Substances of Human Origin Expert Group (CASoHO) of 22-23 June 2017. The group acknowledged that *"the incident had caused difficulties for many blood establishments that used the particular test kit and did not have alternatives to ensure continued donor screening for syphilis"*.

The Competent Authorities agreed to set up a working group to take the topic of continuity of supply and contingency planning forward in collaboration with EBA and EDQM.

Picture: Sanquin Blood Supply

[1] Meeting of the Competent Authorities for Blood and Blood Components, 22-23 June 2017, Summary Minutes: https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/ev_20170622_sr_en.pdf

EMERGENCY RESPONSE

The Question as to how to prepare for possible disasters requiring blood products was not only the theme of the World Blood Donor Day 2017, but also the topic of an in depth session of the EBA Board Meeting. EBA invited the French, Belgian, German and US to speak on this topic, as each unfortunately had had experiences with disasters in the year(s) prior.

Four examples shared

EBA had asked the representative of America's Blood Centre to speak about the shooting in Orlando, Florida in June 2016; Établissement Français du Sang spoke about the terrorist attacks in Paris in November 2015 and in Nice in July 2016; the Belgian Red Cross Flanders Blood Service presented the actions after the terrorist attacks in Brussels in March 2016, and the Bavarian Red Cross presented the Bad Aibling train accident in February 2016.

Common themes

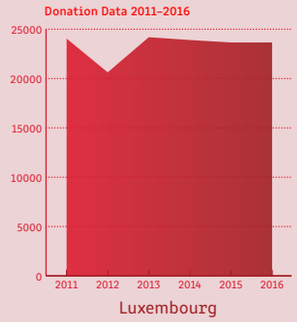
The four presenters all shared experiences with the disasters they had had in their countries and drew lessons from them for the other participants. It stood out that the general public wants to show care and aid by lining up to donate blood, but as was said by Professor Veerle Compernolle of Belgium Red Cross - Flanders Blood Service: "the blood required for today's disaster was donated yesterday". The key challenge is to convey the message to the public that there is enough blood in stock to last during the critical hours. In the aftermaths and the days after the disasters, donors are most welcome and needed to refill the stocks. It was also emphasised that in the light of this, having robust stocks is a prerequisite for being able to handle a crisis.

The second observation made was that the need of blood was generally not as high as publicly believed. France noted a 23% rise compared to an average weekend; the Red Cross Belgium Flanders Blood Service noted that the spike was not higher than on any other Tuesday.

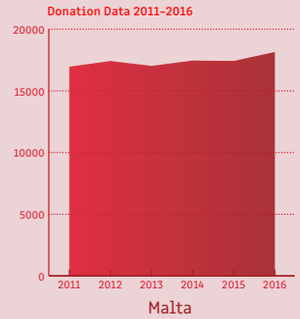
What was flagged up as an issue was that distribution of blood and personnel was hampered due to cordoned off areas: speakers noted that this has taught them to ensure better contact with the crisis team to ensure that blood service staff and products are allowed in the critical zones. The French representative worded it best in saying: hope for the best, prepare for the worst!

> "The gravity of the events captured us all in the meeting, but sharing this kind of information between each other strengthens the blood supply in Europe and gives us the chance to share valuable information on how to best prepare for urgent situations. The value of **information sharing** and **excellence through evidence** both are applicable."
>
> **Martti Syrjälä**

> "The blood required for today's disaster was donated yesterday"



Luxembourg



Malta

EBA DEVELOPMENT OF LEAN

The Benchmarking Working Group has been very busy with multiple activities in 2017, among them, the production of seven videos on *lean* manufacturing with the aim of providing all blood services the opportunity of understanding and implementing *lean* management in their facilities.

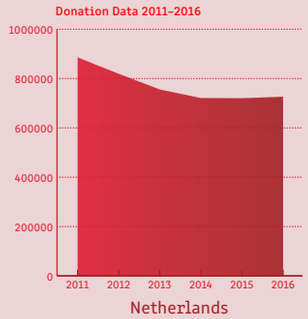
Background

At the Board meeting in Berne in September 2015, following the submission of an outline paper by the EBA Benchmarking Group, the EBA Board agreed to provide financial support for the development of *lean* expertise within EBA Member blood services. It was decided to develop good practice case studies using supporting video presentation, assisted by professional input, demonstrating good *lean* practices with a specific focus on manufacturing within the blood operator environment. Intended for use by existing specialists, new specialist employees, and other non-specialist staff, the output needed to be simple to understand. The scope was two-fold: "awareness training", and "how to implement".

Lean cells
A *lean* cell is a subdivision of the department, where a part of the work is done on a few square meters by staff members who can follow up each other's work without interruption, and where the equipment needed to finish the stage is all within reach. This enables an efficient production process.

The project

The core project team was made up of NHSBT Training & Development, who were in the lead; Prof. Nick Rich, Professor of Operations Management at Swansea University, and the Director of the video production team. The team decided on a modular approach, focusing on the basic elements of a *lean* cell, which would enable learners to use each module independently to make incremental, practical improvements or as a complete set where appropriate.



The videos

The project team identified three sections to address:

1. **Introduction to *Lean***
   This section explains the history of lean and introduces the five main principles of lean. This section consists of one module.
2. ***Lean* Cell**
   This section is a suite of five modules: Pull, Flow, 6s, Standard Work and Visual Management are the subjects of the modules.
3. **Problem Solving**
   This explains the basics of problem solving methodology and how to use the tools to support daily improvement and consists of one module.

Lean management
Lean management is a method stemming from the car manufacturer Toyota and strives for creating maximal output with maximum efficiency, by eliminating all sorts of waste: in efforts, materials and work unevenness.

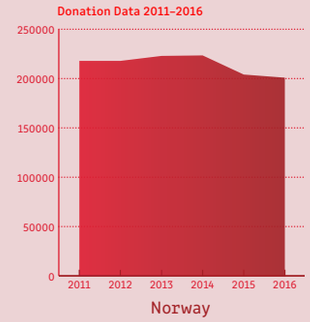
Each module consists of three core sections: An introduction and explanation of the academic concept or tool, examples and footage of how they have been applied in NHSBT, and finally interviews with operators within NHSBT sharing their experience.

Finished product

The project is now in its final stages with all seven modules at the point of final edit and an online learning platform being built from which learners can access the videos, manuals and other materials.

The online platform will provide the opportunity for learners to complete a test and receive a certificate following their learning and an area for facilitators with workbooks to support them when leading a team through implementation of any elements covered in the modules.

EBA members will be able to use the modules either as independent learning, or as part of a facilitated group activity. Each module provides enough information for teams to begin making small incremental improvements within their workplace, as well as enabling wider consideration as to how well we flow blood through our existing systems and deliver to hospitals.



"Improving efficiency and cutting out waste is clearly a good example of the EBA Value **Excellence through Evidence**: EBA members will continuously strive to improve. Having a member-service willing to open up its facility to share their experience with lean and show best practices is exactly what the value **Openness through information sharing** is about: not re-inventing the wheel, but sharing in order that scarce health care resources can be used wisely and economically!"

Philippe Vandekerckhove

Picture from recording © NHSBT

BLOOD DIRECTIVES EVALUATION

As was announced in 2016 already by the European Commission, the Directorate General for Health and Food Safety (DG SANTE) this spring the evaluation of the EU Blood Directives and the EU Tissue and Cells Directives started. Both have been created in the early '00 and in light of all technological advances the question as to whether or not it needs to be revised needs to be assessed.

The evaluation period, scheduled from early 2017 to the end of 2018 will encompass stakeholder consultations and stakeholder meetings after which a report will be drafted with a recommendation with regard to revision, if deemed necessary.

After consulting with the EBA Board in the April Board Meeting, the EBA submitted comments to the stakeholder consultation.

The EBA was assisted by its working group on the EU Directives, delegated by the EBA Board. EBA also attended the stakeholder event organised by DG SANTE that was held in September. EBA President Philippe Vandekerckhove presented the section: "A changing world – Technological, societal, epidemiological and international developments."

"EBA will offer expertise to the EU institutions, where available based on scientific evidence and where lacking with expert views. This is based on our value **Excellence through Evidence**"

Philippe Vandekerckhove

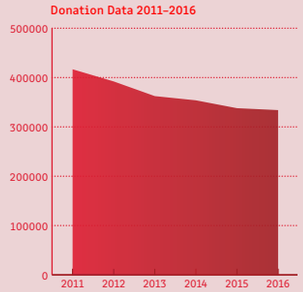
He made the following arguments:

1. There often is quite spectacular press coverage of different types of synthetic blood, but they will remain expensive niche products in the foreseeable future. Blood products remain unique and needed; therefore, equal access to this limited strategic resource should be secured

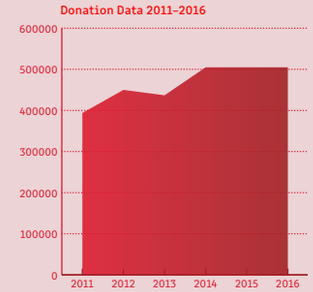
2. Aging & Migration – this could be cause for new requirements for donor base and for patients in future
   - New and re-emerging EIDs will continue to appear: new legislation should follow a precautionary approach in terms of future infections, and be based on the best scientific evidence
3. Another change concerns the regulatory framework: the European Court Justice case law has been driving blood regulation more towards a **consumer market regulations**
   - whereas the legal base of the blood directive is art 168 of the EU treaty, the **public health article**
   - Blood, also labile blood products, are now increasingly treated as goods rather than as medical services
   - so case law has had unintended consequences that were never explicitly discussed at the EU level, in contrast to, for instance, the discussion about the freedom of movement of health care services, where the EU Parliament intensively discussed the impact on the national healthcare systems
   - EBA believes such far-reaching changes should be decided explicitly not implicitly through case law
     - EBA suggests that the EU directive should be more precise and explicit on this in the future

EU should further choose direction on the following issues:

- Donor safety as of paramount importance to the sustainable supply of blood products
- And on VNRD as a cornerstone for this, as VNRD is important for patient safety
- Harmonising inspections by different national Competent Authorities should be a priority
  - EU has done a great job on standardizing requirements throughout the EU, which has lifted quality
  - Not an equally good job on standardizing inspections
    - Which may affect the **quality** of the products between countries
    - Which also affects the discussion about **paid vs unpaid:** what is labelled compensation in one country, would be called payment and, therefore, forbidden in another country
  - EBA calls for better and more precise standardisation of inspections



Portugal



**No new data received

Romania**

EBA President Philippe Vandekerckhove

EBA President Philippe Vandekerckhove, EBA Executive Director Kari Aranko

ECDC senior expert for cells and tissues Dragoslav Domanovic

EU Stakeholder meeting

Pictures: DG SANTE

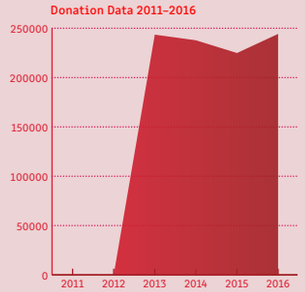
THE START OF THE PLASMA COLLECTION WORKING GROUP

As said in the EBA fact sheet on European self-sufficiency for blood components and plasma for fractionation, achieving an agreed level of European self-sufficiency in plasma for fractionation is a key factor in ensuring the long-term supply of plasma-derived medicines (PDMPs) needed by patients in the EU. An active role for EBA Members is, therefore, warranted.

Current status

Currently, about 70% of plasma for fractionation worldwide is collected in the USA. Furthermore, it is estimated that the current demand for plasma-derived medicinal products increases by 7% per year. These figures emphasise the need for the development of sustainable programmes for plasma collection by apheresis within the EU. Furthermore, there is a need to reduce wastage of recovered plasma.

A number of European Blood establishments have already developed plasmapheresis collection programmes, based on voluntary non-remunerate donors; i.e. Denmark, Belgium, Italy, France, Germany and the Netherlands. Although the amount of plasma collected has gradually increased over the past few years, there are still important issues regarding plasma collection that need to be considered. A workshop was organised on 7 February 2017 by the Benchmark Working Group to discuss best practices and concerns with regard to the efficient collection of plasma. A follow-up meeting took place in Copenhagen at the ISBT conference in June to draft the set-up for a Plasma Collection Working Group.



Serbia***

***Data on earlier years not available

Issues identified

During the meetings, the following topics were highlighted as important for further discussion and research:

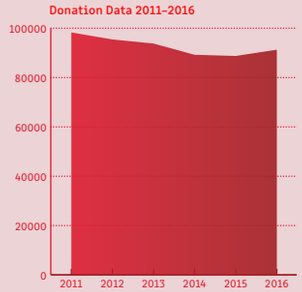
1. **Plasma donor recruitment and retention**
   Blood services have to develop new strategies for introducing plasmapheresis to the public and recruiting plasma donors, while at the same time to be aware that this may be in competition with whole blood donor recruitment. Loyal plasma donors would form the basis for a sustainable and cost-effective supply of plasma for fractionation, but to be able to do this efficiently, blood services should better understand the expectations and needs of the plasma donors.

2. **Define appropriate selection criteria and donation patterns for plasmapheresis donors and contribute outcomes to EDQM Guide**
   Selection criteria for plasma donors can differ from whole blood donors, but should minimally be in accordance with current directives and guidelines[1]. More research is needed to develop evidence and risk-based selection criteria and to test algorithms. The donation pattern of plasma donors may vary depending on individual amounts of plasma protein and specifically immunoglobins; currently this is not the case and more insight is needed.

3. **Collection centre logistics**
   Plasmapheresis is costly in the current settings. Collection centre logistics, apart from Good Manufacturing Practice conditions, should also be based on cost-effectiveness: i.e. scale of the collection centre, number of staff, ICT solutions etc.

4. **Technical aspects of collection processing and freezing plasma for fractionation**
   There are several methods of collecting plasma by apheresis, depending on apheresis machine, collection bags/ bottles, collection speed, collected volume, etc. Apart from the question as to how and what amount to collect, the safety for plasma donors is of paramount importance. Shared knowledge and evidence-based research may lead to optimisation of plasma collection. This also goes for methods and degree of freezing plasma for fractionation.

[1] Commission Directives 2004/33/EC, 2002/98/EC, 2005/61/EC and EMA/CHMP/BWP/706271/2010 Guideline on plasma-derived medicinal products, EMEA/CHMP/BWP/3794/03 Rev 1 Guideline on the scientific requirements for a PMF



Slovenia

5. Reduction of wastage of recovered plasma
Within Europe, shared adaptation of quality measures to ensure the utility of recovered plasma may increase the amount of plasma suitable for plasma for fractionation. Implementation of Good Practice Guidelines of the EU Commission by the deadline in February 2018 will support this goal.

These plans were endorsed by the EBA Board in September 2017: the Working Group will work on these themes and report back to the Board on their findings in 2018.

"To ensure an increase in the collection of high standard plasma for fractionation from voluntary non-remunerated plasma donors within Europe, collaboration among European Blood establishments is crucial and fits well with EBA's values in **Donor safety**, **Patient care** and **Openness through information sharing**. Countries like Italy are showing that it is possible to achieve a higher number of apheresis collections with VNRD donors."
Rudolf Schwabe

Picture: European Blood Alliance

EBA FLYING SQUAD

In November, the EBA Flying Squad, consisting of a team of experts in blood supply, conducted a visit to the Swiss Red Cross Blood Bank in Bern. The team was asked to evaluate the performance of the collection, processing and distribution departments of the Bern organization; to look for areas for improvement, and identify potential cost saving opportunities.

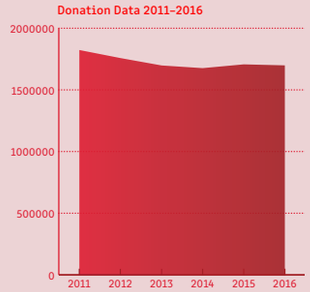
Method of the Flying Squad

Any EBA member can request a Flying Squad visit. The Flying Squad's purpose is to look for ways to improve the organization through the use of lean principles and to focus on identifying waste in the organisation. The team look for waste in the following categories: Transport, Inventory, Motion, Waiting time, Overproduction, Over-processing, Defects and Skills unused.

As the team are multi-national and experts in a wide variety of blood supply aspects, they are able to bring this to bear in ways which can really add value to the host. Using this wide experience and recognising that there are unique characteristics to any blood service, the team are able to adapt solutions to fit local circumstances. This in-depth experience enables the Flying Squad to quickly address opportunities in a way that a non-specialist external consultant would be unable to do. In short, they know what works and what does not! If there is time, the Flying Squad are also able to conduct some initial lean training for host employees. To date, the EBA benchmarking group has organised over 10 Flying Squad visits, all of which have been regarded as a success by the hosts.

The visit

A Flying Squad visit is conducted over four to five days and is generally structured as follows:
Preparation phase: before the visit starts the team will ask the organization to send key figures (KPIs) to enable an initial desktop comparison to be made with other EBA members. From this first analysis it is possible to identify areas that offer the biggest potential for improvement.

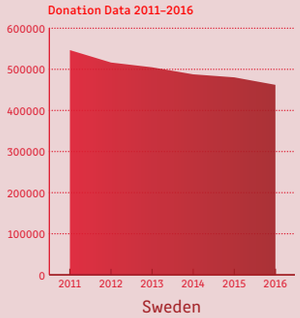


Day 1: presentation of the initial results and observations from the desktop analysis to the management team. Senior leaders must be present.
Day 1-3: visit the departments of interest. Witness the complete end to end process, measurements, interviews with staff (especially people on the shop floor and department managers). Understanding the organization
Day 3: evaluate results and prepare draft observations and analyses
Day 4: report observations to senior management and, if needed, correct conclusions and observations. Where necessary, the team will return to shop floor for additional information. Prepare final report with observations and recommendations
Day 5: Report to management team and senior management. Make arrangements for follow up contact.

The detailed outcomes of the Flying Squad's visit remain confidential and are not shared more widely unless the host agrees to do so. The costs of the visit are limited to the reimbursement of the team's travel and living expenses and, where required, the costs of using an external resource if not currently employed by an EBA member. The costs of the visit (generally €5,000 - €10,000) have always been outweighed many times over by the value of the improvements identified.

In general terms, the Flying Squad were able to advise the Bern organization on how the collection organization could move from a push to a pull model of supply. Amongst a series of recommendations, they were also able to suggest ways to reorganise the processing operation so as to create more flow in the overall process, reduce waiting times and allow earlier release of pathogen inactivated platelets.

"The Flying Squad is a very good tool, based on the value Helping each other for optimal use of health resources through **openness in information sharing**. We trust that the visit of the Flying Squad to one of our regional blood transfusion services will surely lead to savings there."
Rudolf Schwabe



BENCHMARKING OF QUALITY DEPARTMENTS

Over the summer of 2017, the EBA Working Group on Collaborative Quality Management did a benchmarking exercise of the Quality Departments of the member blood services, including Australia and Canada. The participation was high, and the outcomes showed that there were quite some differences between the services, that also related to efficiency.

Process

The group had made a survey on quite a large number of items which was sent to the entire membership. The return exceeded expectations: 22 blood establishments from 15 countries (including two non-European) responded. The questionnaire was divided into two parts: one for the blood establishment director, and one for the quality manager. EBA received answers from 18 directors and 20 quality managers.

Main outcomes

The outcomes of this benchmark were discussed with the EBA Board members during an in-depth session at the Board Meeting in September. The results showed that there are still quite some differences in efficiency relating to quality departments between EBA Members. Also, the survey identified areas of harmonisation and standardisation. Some member services have a risk-based approach to quality, which showed to reduce costs and efforts needed for compliance. Lastly, there were differences in the interpretation of guidelines and legislation. The differences in interpretation could cause in certain services 'over-quality', and even 'pseudo quality': the department has imposed too stringent measures compared what is asked by guidelines and legislation, causing over-effort and over-spending, or, in case of 'pseudo-quality', a misguided focus of the quality departments on non-efficient and non-adding value measures. These last points will be taken up by the EBA in 2018.

Improvements to make

This is the first time the EBA has undertaken such a benchmarking and the knowledge gained on the state of all the quality departments could already prove to be worthwhile. The EBA Board and the Collaborative Quality Management Working Group have agreed to actively investigate, promote and support the following topics:

- Evidence-based and lean quality systems, and through that create an added value
- Common interpretation of the guidelines and legislation
- EBA guidance on specific topics (eg. risk-based approach)
- Common external audits (eg. supplier audits)
- Common validation

The chair of the Working Group, Jan Ceulemans, was surprised with the variations in interpretations of the Good Practice Guidelines: “Although most of the EBA members are regulated by the same EU regulation, there remain differences in the national interpretation of the legislation and the practical implementation in the quality systems." Based on the outcomes, the group will now focus on harmonising the interpretations.

“Providing the highest quality blood products to patients is at the heart of EBA members’ goals. However, we do have to be realistic and take into account the costs involved. Adding more layers of safety does not necessarily mean better products. For me, weighing those two is part of the value **Excellence through evidence**: to establish through evidence how to get the best quality blood products, without burdening society for unnecessary costs.”

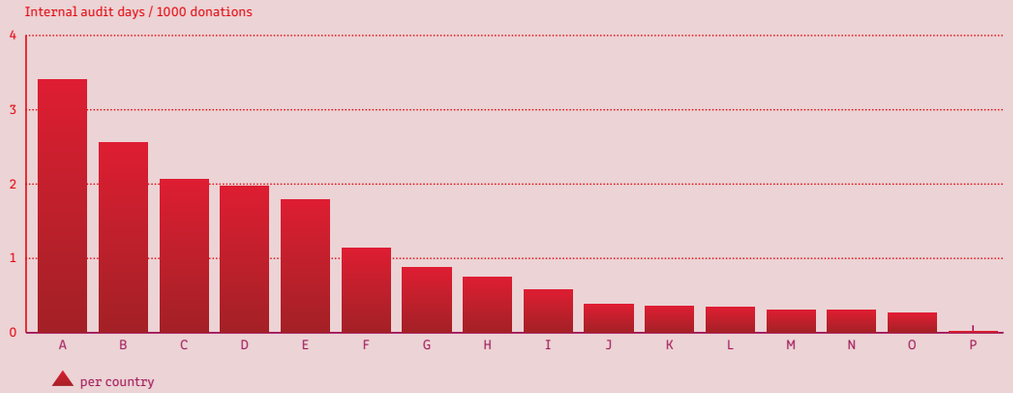
Martti Syrjälä

Q-benchmarking multiple outcomes

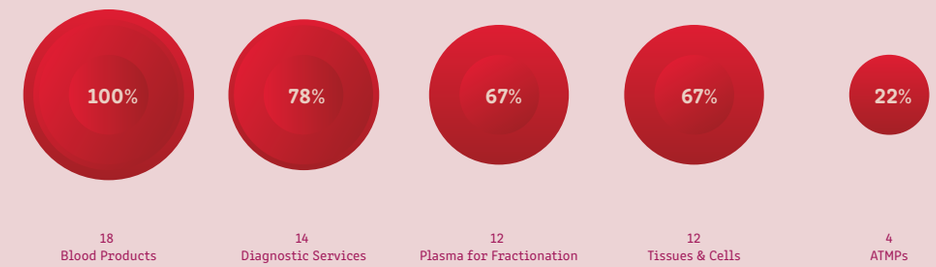
Some outcomes note: country letters were randomly assigned per question.

The total number of days of internal auditing in 2016

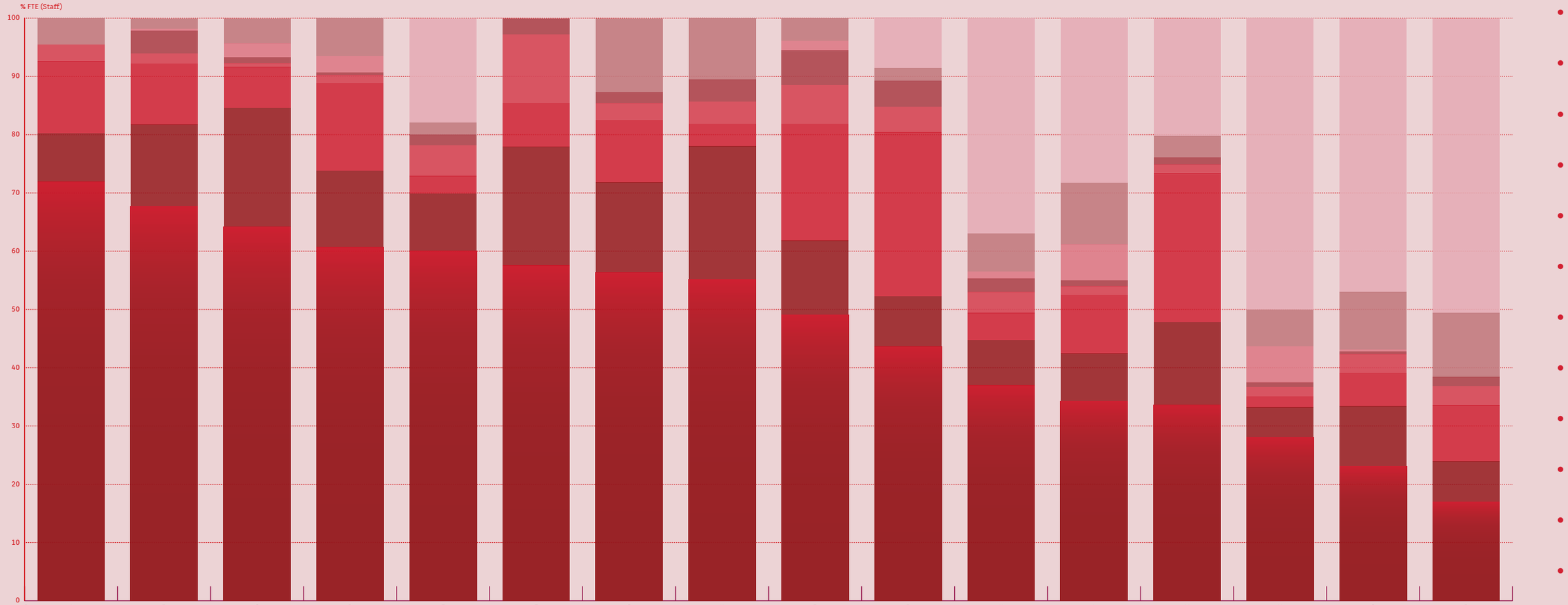
Including an estimation of report and follow-up days for both auditors and auditees



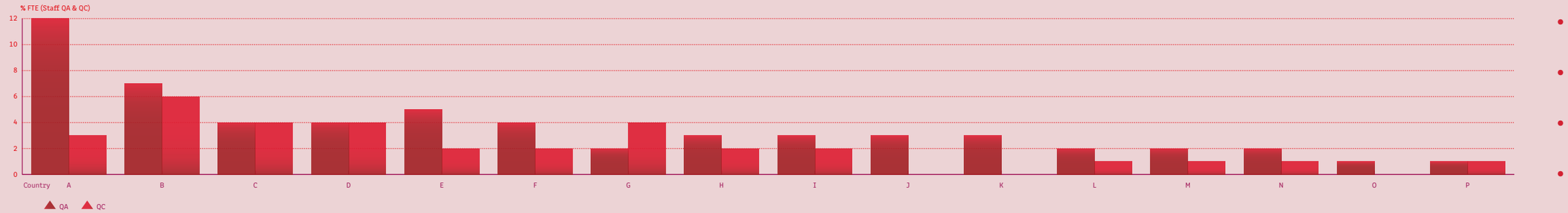
Operations covered by the surveyed blood establishments



Percentage of staff per organisation/deptartment



Country	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
Collection	71,9	67,7	64,2	60,7	60,1	57,5	56,3	55,2	49,1	43,6	37	34,3	33,6	28,1	23,1	17
Production	8,3	14	20,4	13,1	9,8	20,4	15,5	22,8	12,7	8,7	7,8	8,1	14,2	5,1	10,3	6,9
Testing	12,4	10,5	7	15	3	7,6	10,7	3,9	20,1	28,1	4,6	10,1	25,5	1,9	5,7	9,6
QA	2,9	1,7	0,7	1,4	5,3	11,7	2,9	3,8	6,6	4,4	3,6	1,5	1,6	1,6	3,2	3,3
QC	0	3,9	1	0,5	1,8	2,7	1,9	3,8	5,9	4,4	2,3	1	1,2	0,7	0,5	1,6
Validation	0	0,4	2,3	2,8	0	0	0	0	1,7	0	1,2	6,1	0	6,3	0,3	0
Distribution	4,5	1,7	4,3	6,5	2,1	0	12,6	10,5	3,9	2,2	6,5	10,6	3,6	6,3	9,9	11
Other	0	0	0	0	17,8	0	0	0	0	8,7	37	28,3	20,2	50	46,9	50,5



COLLABORATIVE PROCUREMENT INITIATIVE

After the EBA had halted some of the Collaborative Procurement projects early in 2017, the Board decided a different approach would be initiated, as the principle of Collaborative Procurement was deemed as worthwhile and the projects Eurobloodpack I (EBPI) and Eurobloodpack II (EBPII) have proved to be very successful.

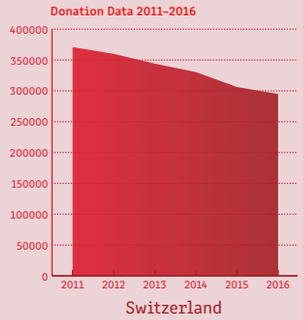
A task force consisting of high-level procurement experts from within the membership advised the Board and from that discussion, a new group was set up: the Collaborative Procurement Initiative (CPI).

Advice from experts

The previous projects had been led by the EBA office and were, unfortunately, not successful in achieving the goals. To establish a new way forward, an expert task force advised the EBA Board. They reviewed the past projects, surveyed the willingness of EBA members and, in the end, advised starting anew by building a group of interested countries, beginning with sharing information and best practices.

Procurement Seminar

In November, the new group came together for a Procurement seminar. The Task Force members had committed themselves to presenting their items of interest to the new group. This way, the group would gain knowledge and the first steps towards building trust would be taken. During the meeting, Paul Behan, Procurement & Supplier Relationship Manager of the Irish Blood Transfusion Service (IBTS), agreed to chair the CPI. "As a small blood service, IBTS sees enormous potential in collaborative procurement. The Eurobloodpack tendering has shown us the benefits: not only did we make material savings, but also we shared quality data with colleagues in England, Scotland Northern Ireland and Wales, strengthening our collective position with the suppliers. The IBTS has also seen the real benefits of sharing market information and quality data between Blood Services" he argued.



Moving forward

Mr. Behan also does understand the hesitancy within continental Europe to embark in collaborative purchasing: "Blood services seem to be very willing, but act with caution, unsure of the resources and the legal implications. We are, as a group, now willing to take it step by step to take all along the route and establish first the trust and share some simple metrics and when that's established, possibly move forward." The role of the NHSBT in collaborative procurement cannot be understated either: "they have really shown that it is possible and worthwhile, and also the mainland Europe is seeing the benefits!"

The group now consists of 27 members from eleven countries and is having regular teleconferences.

> “As a small blood service, IBTS sees enormous potential in collaborative procurement”

EUROBLOODPACK II

After the successful project Eurobloodpack I, where multiple EBA Members jointly procured blood bags against a common specification, the Eurobloodpack II ran in 2017, with updated specifications.

Pre-market engagement study
In the summer of 2017, the tender process was completed according to EU public procurement regulations. As part of the pre-market engagement, the initiator NHS Blood and Transplant worked with an Asian Sourcing company to identify potential new suppliers. They identified 142 companies. However, this number reduced to six after thorough screening (four in China and two in India). These six companies were an addition to four known market leaders in producing blood bags.

Awarding of the tender
The tender for the Framework Agreement was awarded on 20 June having agreed the following:

- Overarching terms and conditions
- Terms and conditions for the mini competition (the second phase of the tender)
- Specifications
- EBA members are responsible for running their own mini competition: upon completion, purchase orders can be raised. EBA members may receive blood packs under this agreement until 28 February 2022
- Fixed prices for the blood packs have been secured and remain in place for the duration of the agreement (all in GBP, EUR, AUS$ NZ$) each country will obtain their own service price (including delivery, reporting, contingency stock) via the mini competition process.

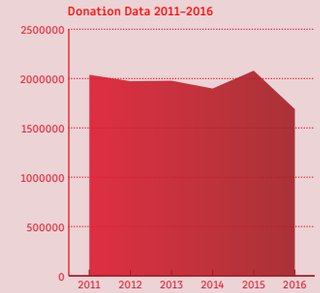
The following suppliers qualified:

- Lot 1 – Wholeblood collection Systems: Fresenius and Macopharma
- Lot 2 – Ancillary processing packs: Fresenius, Haemonetics and Macopharma

Mini competition
The system of mini-competitions ensures that countries can choose their own supplier, within the OJEU (Open Journal of the European Union) process, so there is no need to run this again. Beneficiaries can place their own emphases in their mini-tender so to make the offer well-adjusted to local needs.

Over the last winter months, the UK Blood Services, Irish Blood Transfusion Service, Australian Red Cross Blood Service and New Zealand Blood Service jointly ran a mini-competition. The final award is due to be made in late February 2018. The contract remains available for other beneficiaries: members could run a mini-competition by themselves or along with other organisations.

"We as Executive see real benefits of collaboration between blood services in several fields and through that help each other. The Collaborative Procurement initiative is a really good match to the EBA Values as it is all about **saving health care resources by sharing information** and joint action. The new set-up of the group has huge potential because it is driven by the members. Also, we are very happy that NHSBT is leading the way and showing that collaborative projects lead to synergies and savings."
Rudy Schwabe



United Kingdom

CONSULTATIONS

Survey Requested By	Survey Title	responses
ARCBS	consultation on label adhesives	11 EBA Members
ARCBS	Consultation on organisational charts, functional activities and team structures	Specific (4) EBA Members
ISBT Working Party	Standard interface for instrument to system communications by the ISBT Working Party	7 EBA members
EBA	Interest in Donor Studies Interest Group (SIG)	5 EBA members
WG Benchmarking	Plasmapheresis collection Survey	WG Benchmarking
NHSBT	Centrifuge supply and maintenance	12 EBA members
EBA	Roadmap to the Evaluation of the EU Directives	12 EBA members
EBA	Member consultation on Collaborative Procurement	18 responses
Swisstransfusion	Survey on detection limits for NAT screening	EID-Monitor members
EBA	Board Meeting evaluation	24 EBA members
Canadian Blood Services	Recruiting diverse ethnicities	4 EBA members
Donor Studies Working Group	Blood volume of Donors	Donor Studies Working Group
Donor Studies Working Group	Research including blood donors	Donor Studies Working Group
Red Cross Flanders	Donor Selection & Physical assessment	18 responses
EBA	QMS Benchmarking/Directors questionnaire	22 responses
Alliance of Blood Operators	Donor Iron Management	24 responses
Australian Red Cross Blood Service	Workplace health and safety metric info	3 specific EBA Members
MoH Netherlands	Organisation and regulation of European blood services	22 responses
NHSBT	Donor arm disinfection	Specific (2) EBA Members
Alliance of Blood Operators	Testing strategy	9 responses
Alliance of Blood Operators	Donations and Donor Adverse Events by donor age	Specific (1) EBA Member
Alliance of Blood Operators	Knowledge Exchange on labels	8 responses
EFS/ABO/EBA	Risk of single supplier	9 responses
National Blood Centre Italy	Survey on blood component transport	10 responses
International Haemovigilance Network	TACO consensus roadmap and the TACO Issues Questionnaire	EBA Executive Board
Alliance of Blood Operators	Donor consent and contact	Donor Studies Working Group 5 replies
Canadian Blood Services	**Children in Blood Donation Centres**	**33 (worldwide)**
Australian Red Cross Blood Service	Monitoring donors post donation	20 (worldwide)
EBA/WG Tissues & Cells	Annual questionnaire on T&C	14 responses
Alliance of Blood Operators	NHSBT Questionnaire on volunteers in collection	10 responses
Council of Europe / EDQM	Safe and sustainable plasmapheresis survey of current practice	Sent out at request of Council of Europe/EDQM
Canadian Blood Services	Auditing and Training	WG Collaborative Quality Management
Alliance of Blood Operators	Protocols for stability testing/studies of manufactured blood components	Specific (2) EBA Members

EBA CONSULTATIONS: CHILDREN IN DONATION CENTRES

One of the strong points of the European Blood Alliance for members is the possibility of asking advice from other blood services on topical items. The network even stretches beyond the boundaries of Europe, and includes US and Canada and Australia. One of the items requested in 2017 was the acceptance of children in donor centres.

Results

All 33 blood establishments that responded to the survey allow children in their blood centre. However, not all children are allowed to stay with the donating adult during the entire donation session. For privacy reasons, some countries will not allow older children to be present at the donor interview and some will not allow children to be present in the clinical donation area, but there are also some who will even encourage kids to attend. Denmark writes: “All children are welcomed. We see them as potential donors for the future. They will get a soft drink, chips and chocolate. To attend a donor session is thus a very positive experience” and NHS Blood and Transplant secures a seat next to the parent in the donation area: “We provide colouring books and refreshments to help entertain them. This is not included in any formal training, it is just good customer care”.

More centres take a practical approach: kids can stay in the donor café/canteen but need to be supervised by a relative or they need to be old enough to stay there alone. In Luxembourg, the volunteers usually are willing to babysit: “The supervision can be made by the volunteers, they are happy to take care of the children during the blood donation in the room next to the donation room”. Blood establishments do provide toys in some of the centres, as North-Estonia: “We have a little corner for children with toys, pencils and paper where they can stay.”

All in all, on the one hand, all services want to be welcoming to donors and their relatives, but on the other hand, as the SOP of the Welsh Blood Service states: “no part of a blood collection venue should be considered as free from risk to children”, so vigilance is in order for the services. All results were collated by Canadian Blood Services, who requested the survey.

> “Member consultations are a very simple but effective tool to assess how other blood services deal with a certain issue. Within a short timeframe the country requesting information will have information from colleagues across Europe and beyond. This is a good example of **helping each other for optimal use of health resources through openness in information sharing**!”
>
> **Mary Morgan**

Picture: Sanquin Blood Supply

EBA BOARD MEETINGS

Spring meeting

On 6 and 7 April 2017, the EBA board had been invited by the *Welsh Blood Service* to meet in Cardiff. Approved in that meeting was a new position on MSM deferrals, now following the Resolution CM/Res(2013)3 on sexual behaviours of blood donors and the scientific basis for that[2]. The Position can be read on the EBA website. EBA will continue to keep the situation in Europe and around the globe under constant review.

Also in that meeting, the Board was presented with information on the increase of plasma collections by Italy and Belgium both showing how to practically upscale plasma collections from voluntary unpaid donors. Italy had set itself four goals, including measures for promoting the appropriate use of PDMPs, and the improvement of the efficiency of plasma collection, with particular regard to apheresis plasma procedures.

As the *European Commission* had announced that it would start the evaluation of the EU directives on Blood, Tissues and cells, the EBA Board took time to discuss positions and comments to the current directives. It delegated a Working Group to condense all the information collected and to submit those to the consultation.

The Board had in depth sessions on Emergency response, on which more can be read elsewhere in the Annual Report. It also discussed preparedness for the General Data Privacy Regulation and the implications on blood Services

Autumn meeting

On 28 and 29 September, EBA met in Florence upon invitation of the *Centro Nazionale Sangue* of Italy. The meeting had two in depth sessions, one on testing IT recovery plans and one on the Benchmark of quality departments, on which more details can be read elsewhere in this report. The Board also took the time to discuss the presentation of Prof. Erikstrup on Donor Iron Management and the English INTERVAL study, and how Blood Services could ensure the safety of blood donors.

[2] Offergeld R et al. Vox Sang 2014, 107: 420–7

EXECUTIVE BOARD

The EBA Executive Board consisted in 2017 of the following:

Philippe Vandekerckhove
- President
(Red Cross Belgium Flanders Blood Service)

Erhard Seifried
- Vice President up to 30/6
(German Red Cross Blood Donor Service)

Pierre Tiberghien
- Vice President from 1/7 onwards
(Établissement Français du Sang)

Rudolf Schwabe
- Treasurer, re-elected for a second term starting 1/10
(SwissTransfusion SRC)

Mary Morgan
- Secretary
(Scottish National Blood Transfusion Service)

Martti Syrjälä
- Executive member
(Finnish Red Cross Blood Service)

Polonca Mali
- Executive Member from 1/7 onwards
(Blood Transfusion Centre of Slovenia)

The EBA Executive Board is assisted by a staff in Amsterdam, consisting of the following:

Kari Aranko • Executive Director
Joëlle Guerra • Collaborative Procurement Manager (up to 30/4)
Willemijn Kramer • Communications and Administrations Officer
Karin Liefting-Sikkens • Management Assistant

"There have been two changes in the Executive in the last year; Erhard Seifried's second term on the EBA Executive ended on 30 June and he was not eligible for another term according to the statutes. Pierre Tiberghien was elected as his successor in the position of Vice-President and Polonca Mali was elected as Executive Member."

Philippe Vandekerckhove

FINANCIAL DATA

Balance sheet

ASSETS – 31 DECEMBER 2017	2017	2016
Tangible Fixed Assets		
Equipment	7.368	7.842
	7.368	**7.842**
Current Assets		
Amounts to be received	1.977	4.323
Prepaid costs	3.935	681
Accounts receivable	43.855	6.800
VAT 2016	-	1.068
VAT 2017	1.113	-
	50.880	**12.872**
Liquidities		
Rabobank	35.866	5.361
Rabobank	275.000	360.000
Rabobank	405.074	401.976
	715.940	767.337
Total	**774.188**	**788.051**

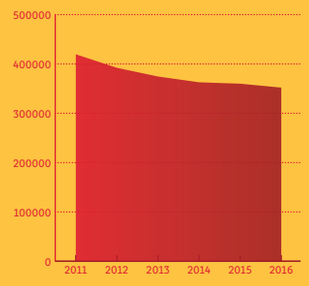
LIABILITIES		
Accumulated result	676.201	618.134
	676.201	618.134
Current liabilities		
Accounts payable	97.987	169.917
	97.987	169.917
Total	**774.188**	**788.051**

State of income & expenses

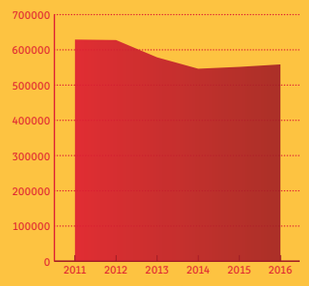
INCOME	2017	2016
Membership fees	385.000	371.500
Interest Bank account	1.977	4.324
EU Grant		
Revenue Collaborative Procurement	88.629	100.501
Other income	16.785	
	492.391	**476.325**
EXPENSES		
Personnel costs	268.475	317.491
Depreciation	2.696	2.781
Meetings/Workshops etc	27.493	3.022
Travelling etc	19.680	22.658
Office costs fixed	12.157	16.690
Office costs variable	34.913	25.181
Other costs	68.910	58.359
	434.324	**446.182**
Collaborative Procurement		
Revenue	88.629	100.501
Expenses	–73.401	–111.701
Result CPI	15.228	–11.200
Result CPI	15.228	–11.200
Result Association	42.839	41.343
Balance	**58.067**	**30.143**

About the EBA

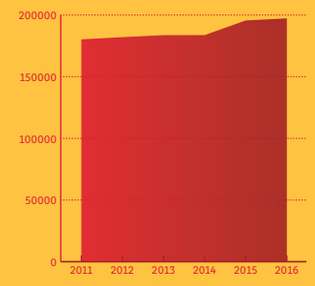
Yearly, EBA collects donation data from its members. The current trend of declining use of red cells can be observed for many countries and for EBA on the whole.



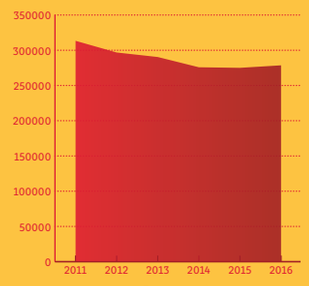
Austria



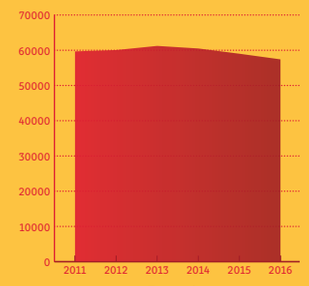
Belgium



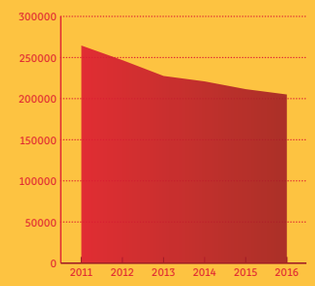
Croatia



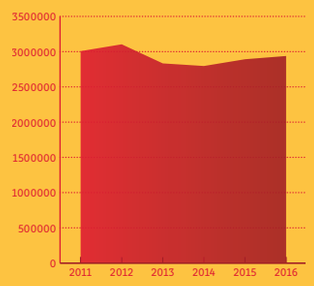
Denmark



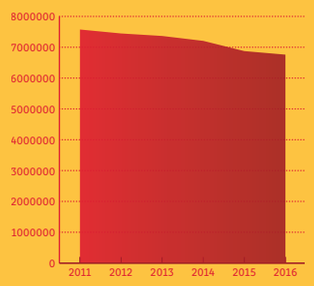
Estonia



Finland

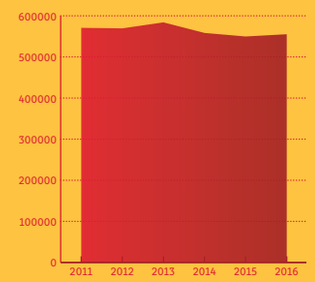


France

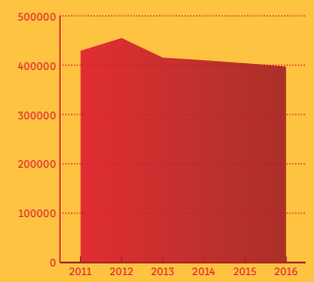


Germany*

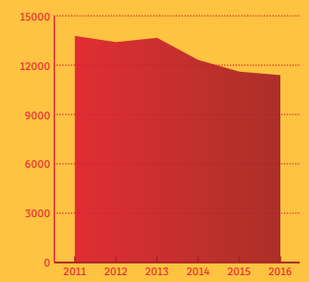
*Data for whole of Germany (source: PEI Institute)



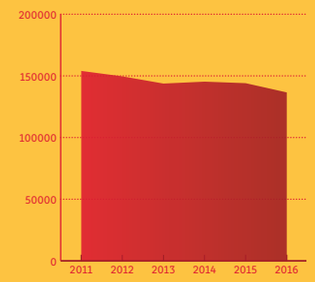
Greece



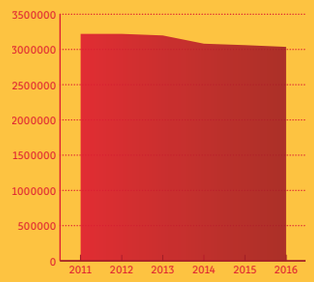
Hungary



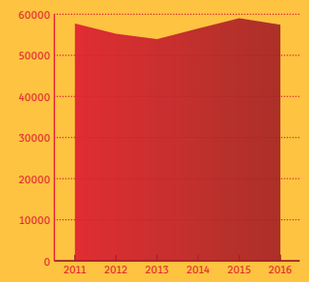
Iceland



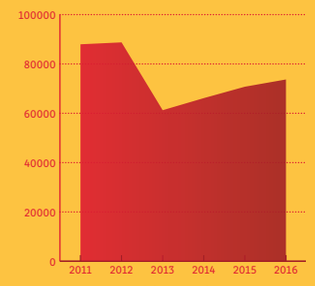
Ireland



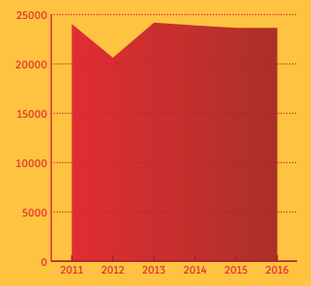
Italy



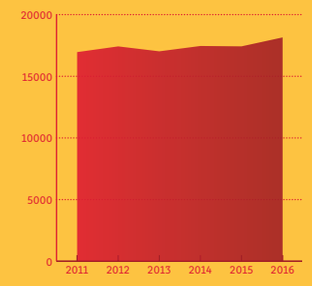
Latvia



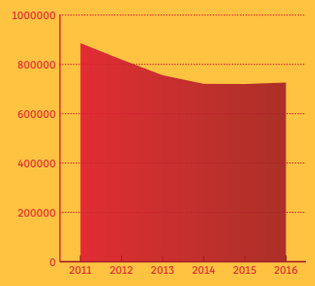
Lithuania



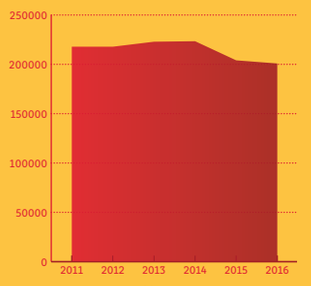
Luxembourg



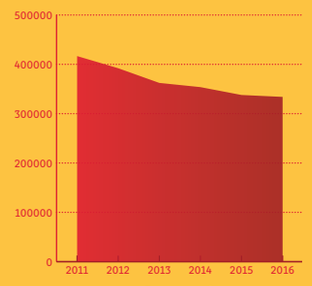
Malta



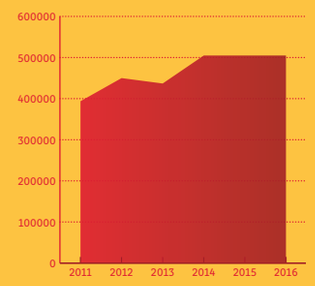
Netherlands



Norway

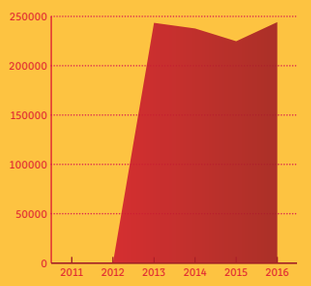


Portugal



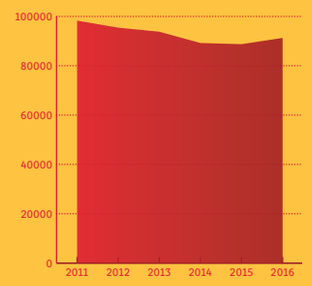
Romania**

**No new data received

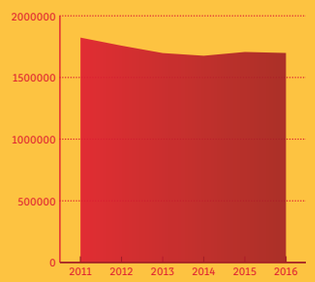


Serbia***

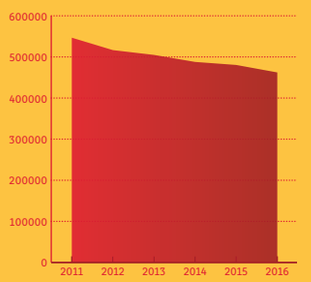
***Data on earlier years not available



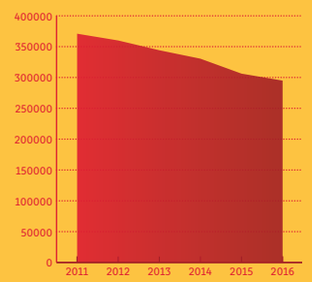
Slovenia



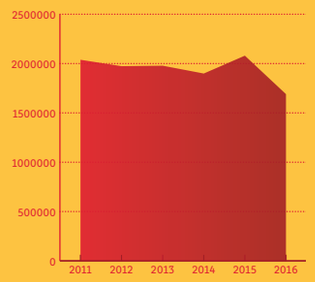
Spain



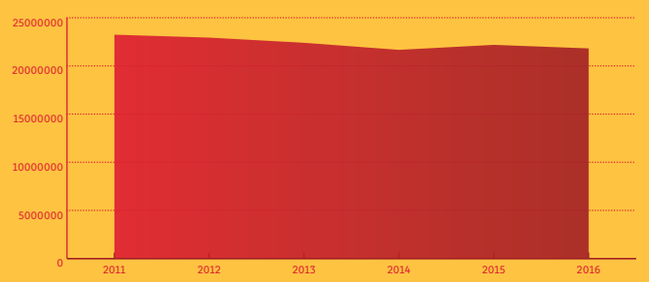
Sweden



Switzerland



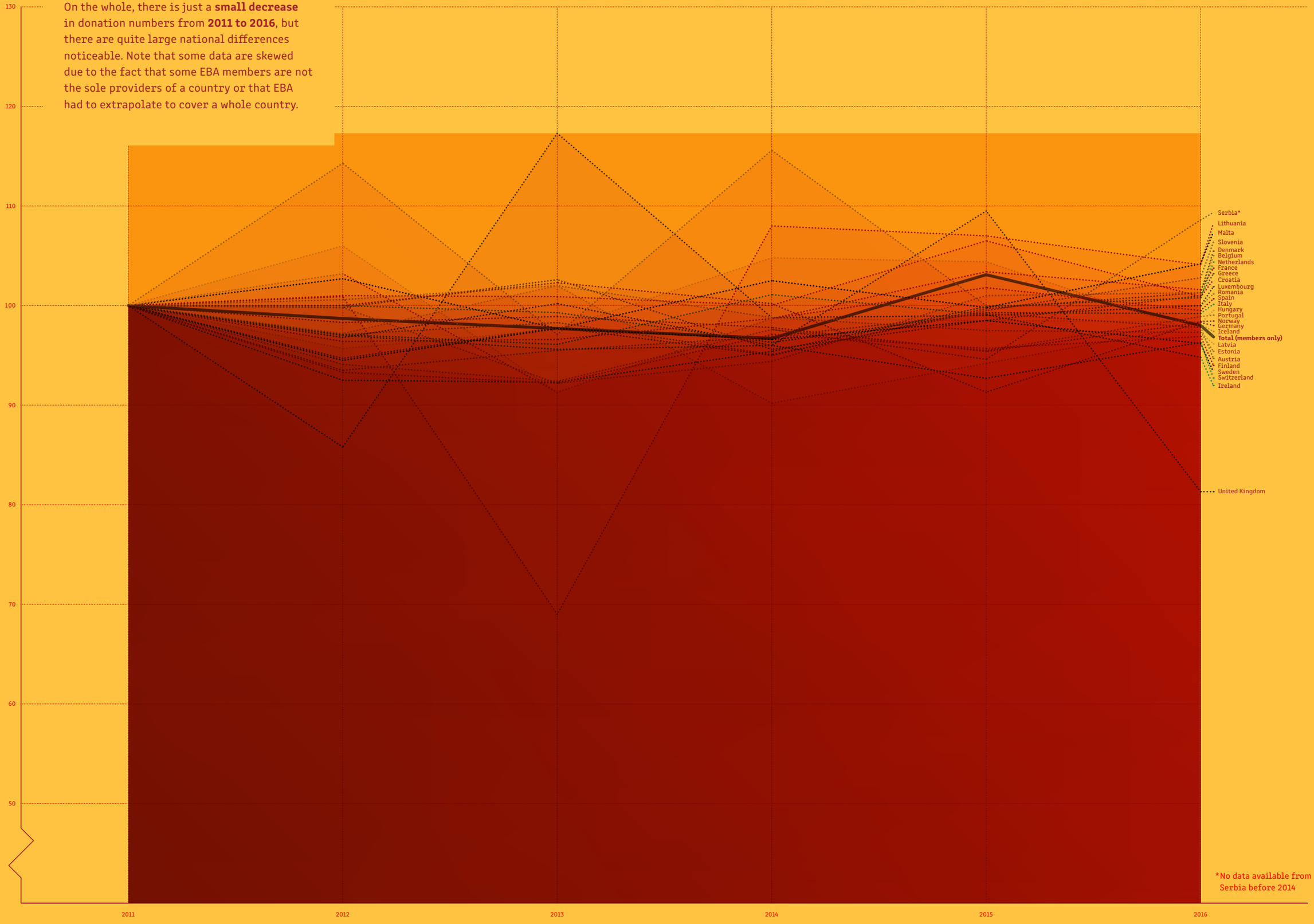
United Kingdom



Total (members only)

About this graph

On the whole, there is just a **small decrease** in donation numbers from **2011 to 2016**, but there are quite large national differences noticeable. Note that some data are skewed due to the fact that some EBA members are not the sole providers of a country or that EBA had to extrapolate to cover a whole country.



*No data available from Serbia before 2014

Hyperlinks
All hyperlinks in this document can be accessed through the digital version of the Annual Report: europeanbloodalliance.eu/downloads/eba-annual-reports

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

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