[20] EBA ANNUAL REPORT

EUROPEAN BLOOD ALLIANCE 2020

DEVELOPING AND MAINTAINING AN EFFICIENT AND STRONG COLLABORATION AMONGST EUROPEAN BLOOD, TISSUE AND CELLS SERVICES

CONTENTS

FOREWORD

I think it is fair to say that 2020 has been quite a challenging year for everyone. None of our colleagues and peers within blood establishments were spared the difficulties linked to the COVID19 pandemic, be they human or material. I would like to express the pride that both EBA Executive Director, Catherine Hartmann, and I feel that despite all this EBA members as usual managed to raise above it all and to put in place all necessary measures and to creatively find new solutions to deliver on their mission to supply blood and blood components to European patients, thank you!

Pierre Tiberghien
EBA President

For EBA it meant a shift of focus on our planned activities to provide more space for interactions, knowledge sharing and expert discussions among our blood establishment representatives.

They needed to hear from peers and to reflect together on decisions taken on donor deferrals, donor retention, personnel protection equipment, adaptation of donation centres and mobile collections, potential blood-based treatment (COVID-19 Convalescent Plasma) and contingency planning, to name just a few of the topics discussed during EBA facilitated meetings. SARS-CoV-2 meant there were new questions on transmissibility, epidemiology, donor health, immunology, and treatments – which all led to the mobilisation of EBA members to assess how they could take part in investing in potential treatments for people affected by COVID19. I am honoured to be leading, on behalf of EBA the Support-e EU project (see page 20), the outcome of this mobilisation process and a true reflection of the blood establishments' commitment to participate in attempting to find a cure to the disease. The pandemic demonstrated the ability of EBA and its members to rapidly interact with EU authorities, the European Commission, the ECDC and the EDQM to share guidance and actual information.

2020 also signalled the start of the anticipated revision of the EU Blood Directives, and the consequent launch of EBA's advocacy drive mainly through its EU Directives working group, which has already held a consultation round with the stakeholders, through an Inception Impact Assessment. In parallel, the Contingency Planning WG also reflected on how to secure a role for Blood Establishments in a potential new European agency addressing emergency planning, this, in addition to the regular work of the other EBA working groups. We are most grateful to all WG members for all their contributions which serve to significantly advance the science and expertise in blood banking and transfusion medicine.

Brexit and the potential continuation of our cooperation with ABO gave EBA the opportunity to reflect on its foundation, identity, values and mission: what is the association here for, for whom, and with whom? We were delighted to hold these discussions with all members and found a solution (early 2021) to continue our fruitful relationship with British colleagues and with ABO.

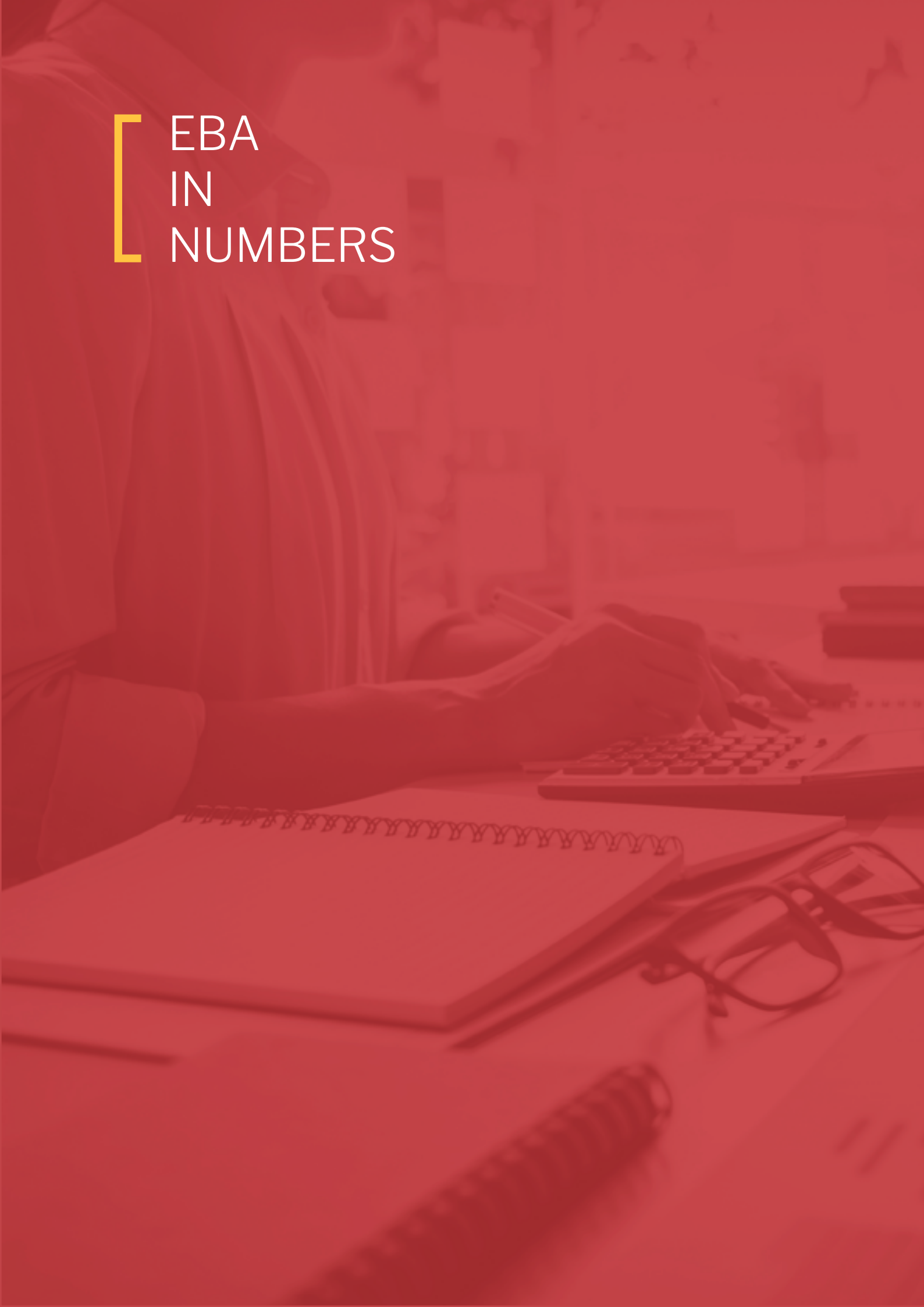
As I started my four-year mandate as the President of the EBA, I was happy to welcome three new members of the Executive: Veerle Compernolle, Stefan Laspina and Christof Jungbauer; we are delighted to have you on board with Daphne Thijssen, our Vice-President, and Polonca Mali, who was re-elected in June and hope to finally hold physical meetings with you soon.

Finally, we were sorry to say good-bye to our Medical Director, Peter van den Burg who went back to working full time with Sanquin but remains an active member of EBA. We were not successful in recruiting a permanent Medical Director to replace him but were grateful for the help of Cristina Caeiro who supported our work with the Secretariat until the end of the year. We welcomed a new staff member, Gaia Mori, who is project managing the Support-e project and whom we knew from the Transpose project.

As you will read in this report, 2020 was (again) quite a busy year and I wish to thank all EBA members, Executive, sister-organisations and staff who together made it possible to deliver so many achievements and to prove, once again, that EBA is THE unique place for European not-for-profit blood establishments to learn, share, build expertise and enhance the science and management in blood services.

The European Blood Alliance (EBA) is the only European association representing Blood Establishments, providing a public service through the supply of high-quality substances of human origin to European patients and ensuring a continuity of provision, and thanks to the generosity of donors, a key element of health systems.

EBA IN NUMBERS




11
EXECUTIVE MEETINGS
supported by 136 documents (drafted by EBA Secretariat)
8
Covid-19 calls in 2 months
222
meetings for EBA secretariat, all reported or minuted
awarded by the EC to an EBA led research project (Support-e), with 12 partners
4,4
MILLION EURO
meetings to prepare and launch Support-e
60
20+
projects and activities managed (or, co-managed) and coordinated
surveys / knowledge sharing
19
documents drafted: minutes, letters, reports, press releases, answers to consultations
160+

EBA IS GUIDED BY THREE PRINCIPLES:

1. Safeguarding donor health and wellbeing

2. Safeguarding and improving patient care

3. Safeguarding the blood supply and improving performance

Due to the COVID19 epidemic, some projects planned in EBA's 2020 work programme were not developed and implemented but others, unforeseen made it nevertheless a very busy year.

1. SAFEGUARDING DONOR HEALTH AND WELLBEING

1.1 IPFA/EBA workshop, 14 and 15 January

In January, the International Plasma and Fractionation Association (IPFA) and EBA co-organised a two-day plasma workshop with a core focus on:

- Blood establishments and public fractionators' contribution to strategic independence of plasma in the European Union (EU) and how to best respond to the increased need for Plasma Derived Medicinal Products (PDMPs)
- Donor recruitment and motivations to give blood and blood components
- Donor health and short to long term impact of plasma donations through plasmapheresis
- The Donation process and efficiency in collecting plasma, as well as
- Quality consideration and enhancing facilities and logistics

The workshop format was identical to the standard IPFA workshops, with a total of 9 sessions, including a "manufacturers" session and sponsors/exhibitors. Each session allowed some time for interaction with the audience at the end.

The full programme and presentations shared by speakers are available on the EBA website: www.europeanbloodalliance.eu/events

The EBA secretariat drafted a thorough report on this event which will be shared with EBA members, once entirely reviewed.

32 countries were represented at the workshop, including Nepal, Egypt and New-Zealand. In addition, presentations from Canada and Australia gave it a wider international aspect.

Concrete examples of actions undertaken to address the challenges of plasma collection and self-sufficiency were shared and are presented in the report EBA drafted. The EBA secretariat summarised the "take home messages" to present a list of recommendations drawn from the event, and to enable sharing of best practice.

The feedback provided by attendees and speakers was quite positive, both on the organisation and the content of the meeting. Quite a number of suggestions were made for future discussions and EBA Secretariat will analyse them for potential future work on the subject.

1.2 Impact of COVID19 on donor management and organisation

EBA members were all severely impacted by COVID19 and were left in the situation of having to make rapid and far-reaching decisions to protect both donor's and patient's health, as well as their personnel's. Much of this discussion occurred within the forum of EBA and many resulting measures were put in place across the EU by Blood Establishments to mitigate the risks while still ensuring a safe and continuous supply of blood and plasma.

In particular, the EBA Secretariat organised regular calls and surveys to facilitate exchange of ideas, experiences and measures.

EBA secretariat minuted all the meetings and shared the reports with all members, including those who could not attend the meetings.

Deferral of donors and donations was a key focus of discussion among EBA members, as rules were developed as the pandemic unfolded. These were based on the acquired knowledge of SARS-CoV-2 evolution, both at population level, and as an airborne virus. The measures in blood donation centres were adapted as expertise grew, and all this was shared among EBA members.

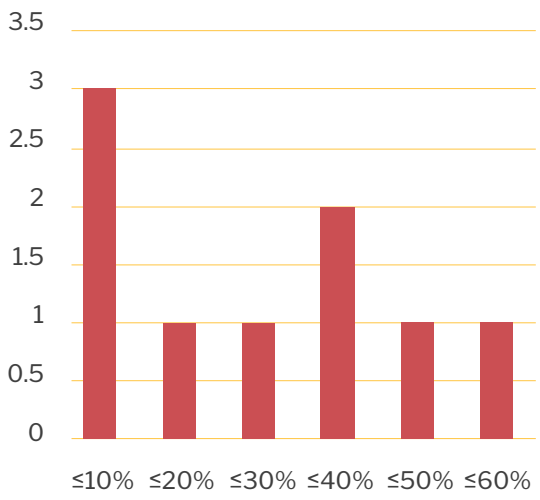
Most of the surveys on COVID-19 were run and reviewed either by the Emerging Infectious Disease Monitor (EID M) group with heavy participation from the group Chair, Wolfgang Mayr, from the Austrian Red Cross, and the group secretary Ryanne Lieshout-Krikke, from Sanquin, or by Andy Kelly, former CEO of the Irish Blood Transfusion Service and Chair of the EBA Contingency Planning group, together with Christof Jungbauer, Medical Director of the Austrian Red Cross.

EBA is most grateful for their support and help which undoubtedly increased EBA's members knowledge on COVID-19 and Blood management.

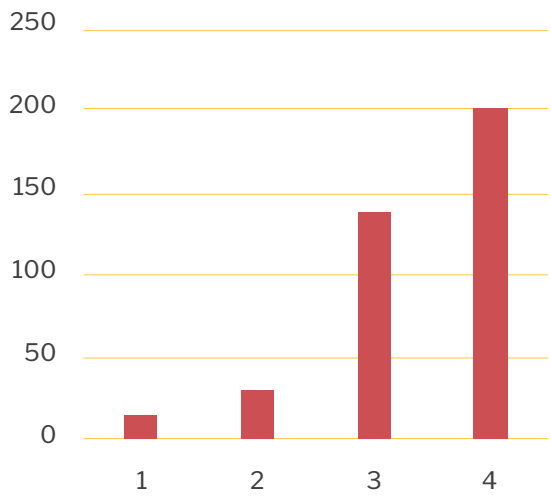
The EBA Secretariat shared the surveys among EBA members and beyond (some were also shared with experts who were not members of EBA depending on the topic), collected all answers, and when possible analysed and derived conclusions from the answers.

Number of staff working from home 2nd survey

Percentage / WFH



Actual numbers



1.3 "Prediction and impact of personalised donation intervals" project (research grant)

EBA funded a piece of research through its annual research grant on "Prediction and impact of personalised donation intervals". The research project led by the Finnish Red Cross in 2019 was completed in 2020 and findings shared with EBA and its members.

The aim of this project was to evaluate how state of the art computational prediction tools would facilitate nationwide personalised donation intervals.

The results show that although linear predictors developed with available data predict haemoglobin relatively well, they fail to predict haemoglobin on the deferral limit. Hence, they are in a practical sense useless. Instead, the researchers found that a non-linear predictor might perform well enough to bring savings. They concluded that deployment of a predictor of deferral, for example inside a personal mobile applet for blood donors, could bring significant benefits for blood donors and blood establishments alike.

1.4 Research grant: Ferritin measurement IN Donors – donor Population LongitUdinal

Study: FIND +

This piece of research was run by Sanquin Research, Department of Donor Medicine Research in 2020 and 2021 with the objective to investigate ferritin trajectories in new whole blood donors from stored samples to help tailor deferral strategies. The project was financially supported by EBA through a €48.850 grant.

The researchers were: Sara Moazzen, PhD, Post-doctoral researcher on Donor Health, Sanquin Research, Dept of Donor Medicine Research; Maike Sweegers, PhD, Post-doctoral researcher on Donor Health, Sanquin Research, Dept of Donor Medicine Research; Mart Janssen, PhD, Head and Principal Investigator of Transfusion Technology Assessment, Sanquin Research, Dept Donor Medicine Research and Katja van den Hurk, PhD, Head of Donor Studies, Principal Investigator for the Donor Health research line, Sanquin Research, Dept of Donor Medicine Research

Preliminary findings from spaghetti plots showed rather linear reductions in ferritin levels among 85.4% of male donors and 90.3% of female donors (Figure 1A & Figure 1B). Baseline characteristics of the donors are presented in Table 1 below. For the remaining group of donors, steeper declines in ferritin levels were observed. Ferritin levels at screening and inter-donation intervals varied greatly between groups. Figures 2A & 2B demonstrate group-based trajectories for male and female donors, respectively. Based on the Bayesian Information Criterion, two classes are detected for both genders. Among female donors, models with four and three classes showed slightly improved BIC values, however, the additional classes were discarded because of the small size (<1%). Therefore, the researchers selected a model with two classes for female donors. Using ferritin levels measured at 10 donations for male donors and 6 donations for female donors, it can be concluded that a male donor has a probability of 85.1% to belong to Class 1 (the class with rather linear reduction in ferritin levels) in 10 donations and a female donor has the chance of 90.1 to belong to Class 1 after 6 donations.

Further discussion is needed since haemoglobin levels do not reflect iron stores of donors, information regarding ferritin trajectories may provide superior information on donors more and less prone to the development of iron deficiency and becoming at risk for low Hb deferrals. The latter in turn could lead to tailored donation intervals and to prevent iron deficiency and donor deferrals.

In spite of some delays due to the COVID-19 pandemic, the measurements were finalizsd in December 2020, data analysis was finalised in March 2021, the final results will be ready for publication by second quarter of 2021.

Table 1. Descriptive statistics of the donors in the FIND+ dataset with more than two blood donations in study period; September 2017_September 2019.

VARIABLES	MALE DONORS (N=101)	FEMALE DONORS (N=199)
Age (years)	29.96 (25.08-38.12)	24.62 (22.58-29.60)
BMI (kg/m ^{2})	24.22 (22.48-26.10)	23.14 (21.55-26.44)
Number of donations	4 (2-6)	3 (2-4)
Hb at screening visit (ng/ml)	9.30 (8.90-9.60)	8.30 (8.00-8.70)
Ferritin at screening visit (ng/ml)	103.35 (56.77-137.76)	36.66 (23.21-56.59)
Ferritin at last donation [2] (ng/ml)	28.13 (17.80-43.24)	13.04 (10.63-29.30)
Inter-donation interval (weeks)	10.00 (9.00-17.00)	20.00 (17.00-26.00)
Donation in cold seasons (%)	47.1	48.2

[1]The variables are presented as median and interquartile range or as stated otherwise.
[2]Ferritin levels at 6th donation in men and 4th donation in women during study period (September 2017-September 2019).

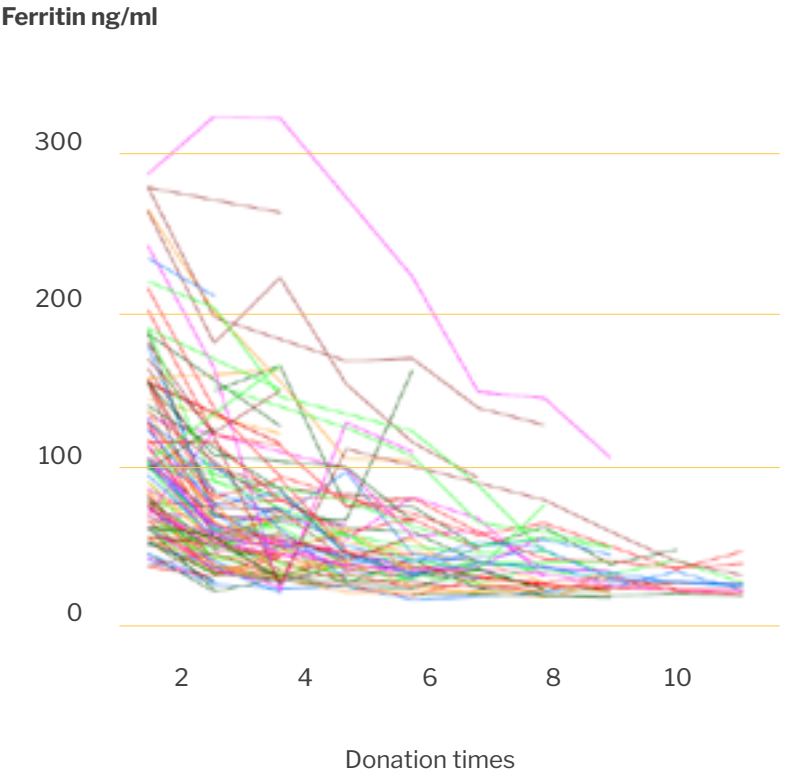


Figure 1A.

Spaghetti plots demonstrating changes in ferritin levels by number of donations among male donors in the FIND+ dataset with more than two blood donations in study period; September 2017_ September 2019.

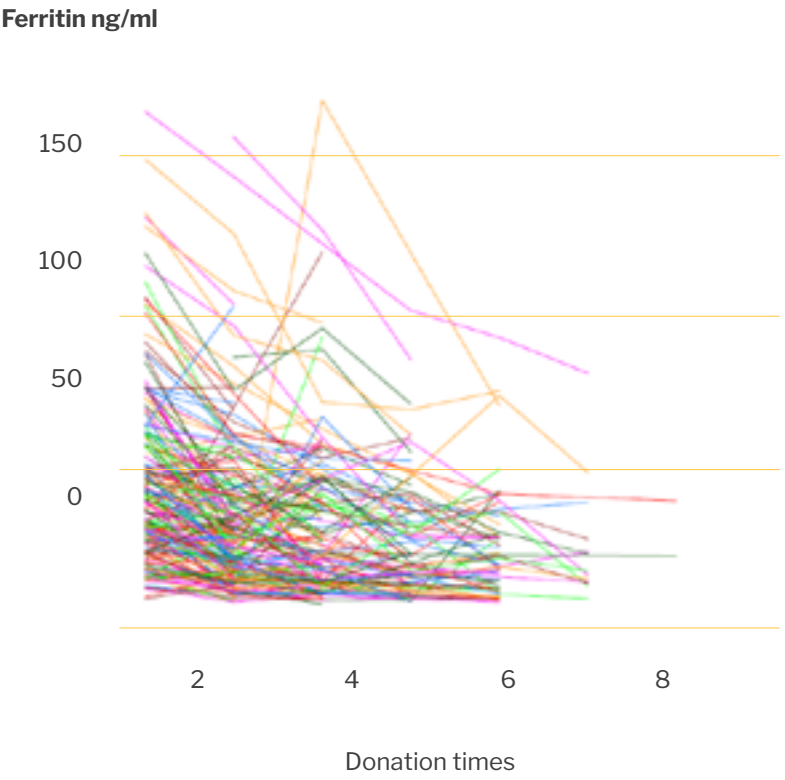


Figure 1B.

Spaghetti plots demonstrating changes in ferritin levels by number of donations among female donors in the FIND+ dataset with more than two blood donations in study period; September 2017_ September 2019.

1.5 Collaboration with the ECDC

All throughout the COVID-19 pandemic, EBA has maintained regular exchange of information with the European Centre for Disease prevention and Control (ECDC) who was publishing regular information about COVID-19/SARS-CoV-2 and SoHO.

In particular, EBA:

- Provided data and assessment for the ECDC "COVID-19 and supply of substances of human origin in the EU/EEA - second update", published on 10 December 2020
- Provided data and assessment for the ECDC "COVID-19 and supply of substances of human origin in EU/EEA - first update, published in April 2020. EBA shared ECDC's questionnaire on blood supply during the pandemic with its members
- Reviewed the ECDC "COVID-19 and supply of substances of human origin in EU/EEA", published in March 2020
- Facilitated discussion between the Chairs of EIM with ECDC Principal Expert Blood, Tissues and Cells of Human Origin, Dragoslav Domanovic (former member of EBA from Slovenia).

The EBA Secretariat handled extensive discussions and exchanges of emails on a potential project to be funded by ECDC on available SARS-CoV-2 seroprevalence studies performed in blood donors in different Blood Establishments (and members of EBA) throughout Europe. The primary objective of the study was to determine the proportion of seropositive donors in the blood donor population of EU/EEA Member States. The secondary objectives include the determination of the titer of neutralizing antibodies in seropositive donors and the distribution of seropositive donors by age, gender and AB0 blood group.

This project would have had the strong support of the Danish blood establishments who are collecting SARS-CoV-2 seroprevalence data at national level. However, different elements, including legal ones and others related to human resources, did not make it possible to complete an application for an ECDC grant.

1.6 Completion of Transpose project

TRANSPOSE - TRANSfusion and transplantation: PrOtection and SElection of donors is a European Commission co-funded project, which adds to harmonising European donor selection and protection policies related to SoHO (Substances of Human Origin) donations whilst keeping adequate health & safety protection of patients.

EBA was a Collaborating partner in this project which ended in spring 2020, with a final project meeting in Rome on the 24th and 25th of February, showcasing interactive sessions with educational lectures, quizzes, the launch of the webinars and a panel discussion with experts in the field. The training programme for healthcare professionals on the use of donor selection criteria & the Donor Health Questionnaire, based on the WP5 and WP6 output, , included webinars and a questionnaire for training purposes. In the webinars, specific donor selection issues were illustrated.

The outcome of the Transpose project was presented during the meeting of the National Competent Authorities in Brussels (February) and included the main deliverables: the creation of both the Donor Selection & Protection Guidelines and the Donor Health Questionnaire The two deliverables will be useful and strategic tools to pursue the harmonisation of donor selection and protection policies in Europe and to contribute to the revising process of the current EU Directives.

Training materials are available here:

https://www.transposeproject.eu/transpose-webinar/

More information:

www.transposeproject.eu

2. SAFEGUARDING AND IMPROVING PATIENT CARE

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, therefore have, as a first priority, the aim to improve patient care.

EBA supports its members and the development of science and innovation towards improving patient care, through a number of projects, activities and working groups:

2.1 COVID-19

COVID-19 kept the EBA secretariat busy for the largest part of 2020, with the production of presentations, the collection and sharing of articles related to on-going research or positions, the analyses of surveys, the discussions with other health NGOs dealing with the same matters, and the forwarding of information from the European Commission (on the Emergency Support Instrument, for the purchase of apheresis machines, for instance) and other EU bodies to EBA members.

EBA held 10 COVID-19 meetings throughout 2020, with a high participation of members and non-members.

2.2 SUPPORT-E

'SUPPORTing high quality evaluation of COVID-19 convalescent plasma throughout Europe' (SUPPORT-E) is a project led by EBA and fully funded by the European Commission, through its Horizon 2020 programme. Its origins are a request by EBA to the European Commission to support a piece of research EBA had in mind on whether COVID-19 Convalescent Plasma (CCP) could be a potential therapy for actual patients with COVID-19.

Support-e
SUPPORTing high quality evaluation of covid-19 convalescent plasma throughout EUROPE

From April to June, EBA held a record number of 33 meetings to discuss, draft, and finalise the project. The project started in July 2020 and will last until the 30th of June 2022 (two years). Gaia Mori is the EBA project manager. EBA was helped by the consultancy company MINT to draft the application.

Seven work packages (WP) cover the development, implementation and sharing of the project and its findings, with EBA being the coordinator.

The main goal of the project is to help EU countries in both assessing the efficacy of a potential new therapeutic solution to deal with the current Coronavirus crisis and developing new strategies to face potential future pandemics.

A budget of over 4 million euros has been allocated to this project and is shared between 12 partners (EBA members).

Funds go towards:

1. Assessing CCP, conducting clinical evaluation and defining best practices (WP1)

2. Supporting high quality clinical evaluation (funding clinical trials and monitored access programmes) and producing data-sets for inclusion in the database (WP2)

3. Collecting, monitoring and analysing EU-CCP Database data (WP3): a database created and maintained by the European Commission with data provided by Blood Establishments and clinicians on the collection, distribution and use of CCP

4. Improving plasma potency assessment: partners from WP4 facilitate anti-SARS-CoV-2 antibody testing, facilitate access and cross-border standardization of the Plaque Reduction Neutralisation Test (PRNT), compare commercially available PRNT and/or Microneutralisation (MN) assays and work on characterising antibody content (WP4)

5. Developing recommendations and preparing for the future mainly through WP5 which specifically integrates all project-generated information, conducts cost benefit analysis, performs a SWOT assessment to support future SoHO development, develops recommendations for CCP collection, for CCP use to treat COVID-19 and for future outbreaks of SARS-CoV-2 or other novel pathogens

6. Dissemination, exploitation and communication, the role of WP6, and

7. Overall coordination and management of the project, performed by WP7

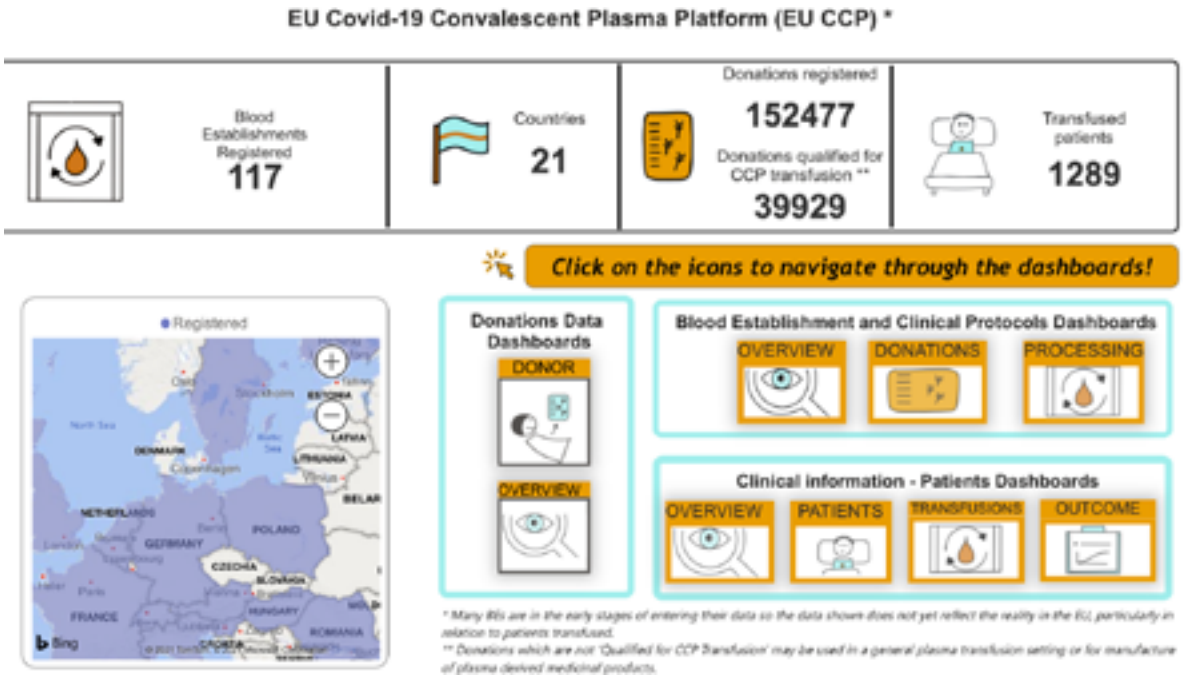
This is the first ever project fully funded by the European Commission EBA is in charge of, and despite the difficulties linked to the size of its Secretariat for such a big project and the absence of a Medical Director (a huge thank you to EBA President, Pierre Tiberghien, for stepping in), EBA is proud that it can contribute to the research on therapeutics means to treat COVID-19, hence demonstrating its commitment to finding therapeutic solutions for patients.

EU CCP Database - COVID-19 convalescent plasma collection and transfusion in the EU

The EU CCP database[1] was developed by the European Commission (DG SANTE, DG DIGIT, and DG CNECT) in collaboration with EBA and is managed jointly by EBA and the European Commission.

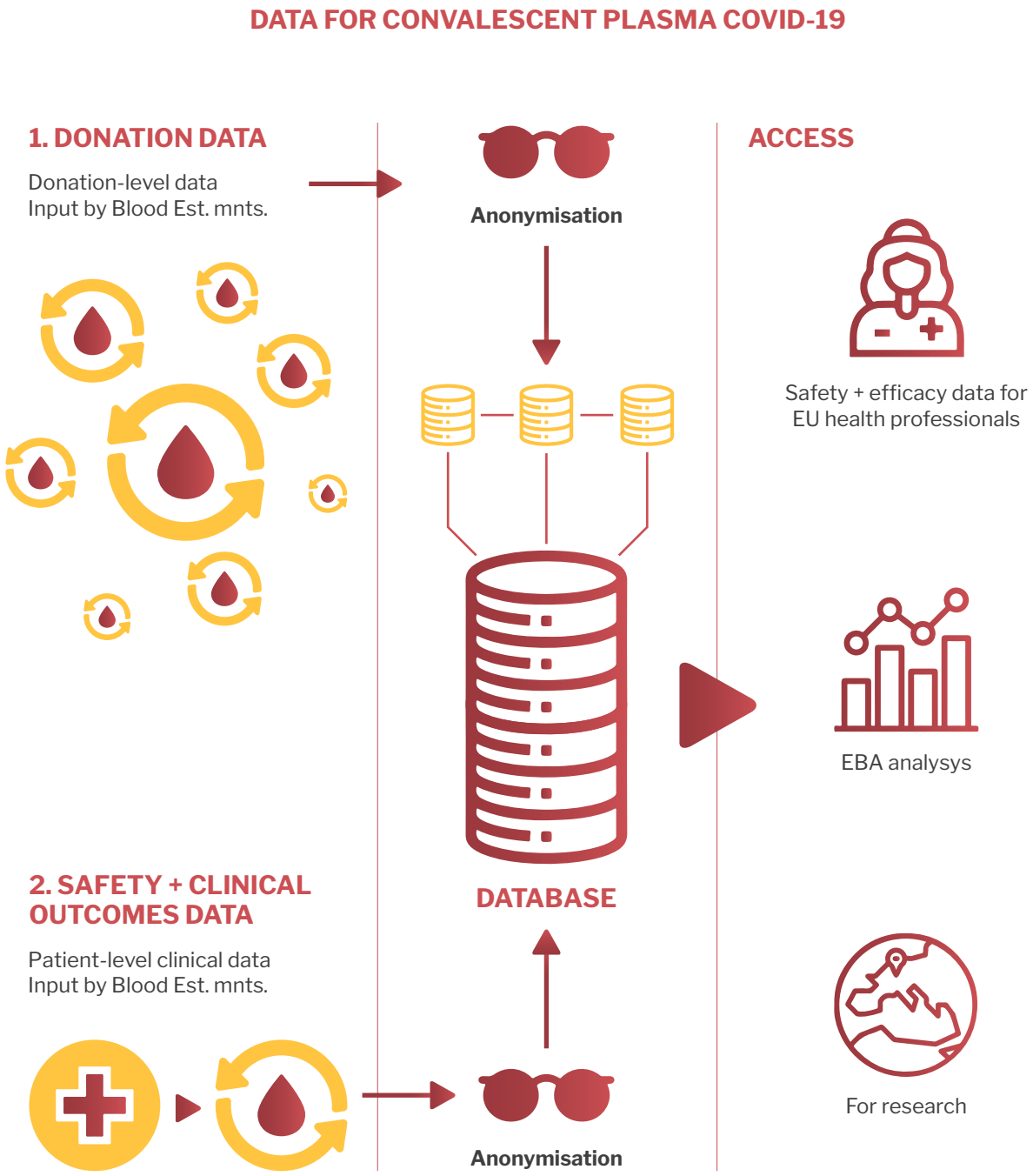
The open-access database gathers and makes available data on convalescent plasma donations and patient outcomes following transfusions. It includes data from blood establishments regarding convalescent donors, plasma collection, and plasma components, as well as from clinical trials and from wider monitored use and will consolidate EU evidence on the safety and effectiveness of this therapy.

Following the creation of the EU CCP Database, the database-related-work commenced with SUPPORT-E members liaising with the Blood Establishments (BEs) who had registered to the EU CCP Database, to receive feedback on how to optimise the registration process and submission of data. In 2020, WP3 (WP leading the Database) focused on carrying out a basic analysis of the data received on donations, recipients, and plasma. Additionally, the WP3 team updated the Data Management Plan for the project as well as a report on the current functionalities of the database dashboard. WP leaders additionally added functionalities through the use of the Kibana tool, a user interface that allows visualisation of data. EBA plays a key role in the EU CCP database as it is leading the registration process for BEs as well as clinical trial groups, in addition to being the main point of contact for all questions regarding the database.



[1] https://www.euccp.dataplatform.tech.ec.europa.eu/

EU CCP Database



Powered by: EU servey, BOTI, EBA, DG SANTE, DG DIGIT

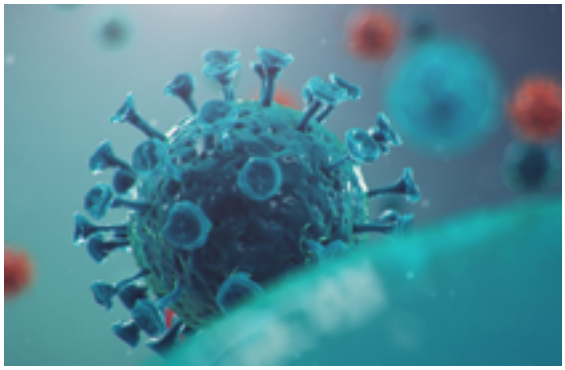
2.3 EID Monitor group report

Summary report provided by the EID Monitor group:

Through its monthly teleconference and regular information exchange, the Emerging Infectious Disease Monitor (EID M) continued to observe emerging infectious diseases and to exchange information about blood safety measures in the areas pertaining to the work of EBA and of the Alliance of Blood Operators[2] membership. On average 22 EID M members were participating in each teleconference in 2020. Compared to previous years (19 in 2019 and 17 in 2018) more members attended the monthly meetings this year, very likely attributable to the COVID-19 pandemic. The prompt circulation of the teleconference minutes ensured a rapid dissemination of information and recommendations to EBA and ABO members. The following topics were particularly important this year:

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

Since the first reported cases in Wuhan, China, in December 2019 and subsequent rapid spread of SARS-CoV-2 worldwide, the EID Monitor remained vigilant concerning blood safety throughout the year. Especially at the beginning of the coronavirus disease 2019 (COVID-19) pandemic the number of meetings was increased, collaboration was sought with the contingency planning working group and with the EBA office for situation updates (see above). Through surveys, members were regularly updated concerning donor eligibility, blood safety measures and other mitigation measures to maintain the blood supply.



In general, the central question for the EID Monitor is the risk for blood safety: can the virus be transmitted via blood and cause disease in the recipient? From a technical and virological point, as other respiratory viruses, the transmission via blood is not very likely, but a precautionary approach, however, seemed to be necessary because it concerns a new virus and virological characteristics may differ. The duration of viable virus is relatively short-lived. SARS-CoV-2 viral load in the upper respiratory tract appeared to peak in the first week of illness, with shedding of the virus and thus likely infectivity up to 3 days before symptom onset. No study detected replicative virus beyond day 9 of illness, despite persistently high viral (RNA) loads in the upper respiratory tract. Detection of SARS-CoV-2 RNA is rare in blood and if found, appears to have a low viral load and involves mostly very ill patients. More than 80 million COVID-19 cases were reported worldwide at the end of December 2020, and so far, reports on transmission through blood transfusion remain absent. Even the active surveillance through lookback studies triggered by post donation information from donors who developed COVID-19 shortly after donation or the SARS-CoV-2 RNA donation screening did not reveal any transfusion transmission. The donor selection procedure, by excluding donors with active COVID-19, donors symptomatic for infection and donors who are exposed and advised for quarantine, is sufficient in reducing this theoretical risk for blood safety. The biggest challenge for blood services in the COVID-19 pandemic is to maintain the sufficiency of the blood supply and limit transmission to staff and donors within donor and processing centres.

[2] 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 the American Red Cross, Australian Red Cross Lifeblood, Canadian Blood Services, NHS Blood and Transplant, Sanquin Blood Supply Foundation and Vitalant. A Memorandum of Understanding support information exchange between ABO members and members of the European Blood Alliance and the Asia Pacific Blood Network.

West Nile virus

The seasonal West Nile virus (WNV) transmission of 2020 was relatively mild in the known affected areas compared to previous years. For 2020, 316 human cases were reported on the European continent (2015: 125; 2016: 272; 2017: 258; 2018: 1.955; 2019: 453). Noteworthy are the large outbreak in Spain, the increasing number of human cases in Eastern Germany and the first occurrence of WNV circulation in the Netherlands.

The last ECDC update was published in week 48. By 26 November 2020, 8 EU countries reported through The European Surveillance System (TESSy): Greece (143 cases), Spain (77), Italy (66), Germany (13), the Netherlands (7), Romania (6), Hungary (3) and Bulgaria (1). It is to be noted that a lower number of observed cases and diagnoses could be attributed to COVID-19. On the other hand, seasonal variation of WNV may explain the reduced circulation; WNV RNA donation screening in Austria did not find a single WNV RNA infected donor this year (only one confirmed Usutu virus (USUV) case).

The trigger for applying blood safety measures for WNV (WNV NAT or donor deferral), based on confirmed human WNV infections, remained unchanged. It is known that WNV NAT may be reactive with other arboviruses, such as USUV. In 2020 the circulation of USUV in Europe appeared to be very low.

Other vector-borne viruses:

Zika virus

Transmission of Zika virus declined worldwide to low levels. For Europe no autochthonous cases have been reported in 2020.

Chikungunya virus

The virus is largely spreading in the Americas, especially in Brazil. No autochthonous cases have been reported in Europe in 2020.

Dengue virus

Outside Europe outbreaks during the year occurred in some French overseas territories (the French Antilles, la Réunion and Mayotte).

Within Europe there were several local clusters of autochthonous transmission in France and Italy, with no more than 5 human cases per cluster. In France clusters were situated in Cessenon-sur-Orb (Department Hérault), Nice and Juan-les-Pins (Department Alpes Maritimes), La Croix-Valmer (Department Var) and Saint-Jean-de-Valériscle (Department Gard). In Italy transmission occurred within one family. The index case was a family member who returned from a denque endemic country. Due to the presence of competent vectors (Aedes albopictus) during the mosquito season, clusters can be seen every year in these Southern European regions. As long as clusters are controlled, the risk for blood safety in Europe is very low and additional blood safety measures are not indicated.

Crimean-Congo haemorrhagic fever virus

A few Crimean-Congo haemorrhagic fever virus (CCHFV) cases were reported in Bulgaria and Spain. The virus is transmitted to humans through infected tick bites (Hyalomma marginatum) or direct contact with infected animals or blood. For humans, the virus causes a severe disease with haemorrhagic fever. The disease is more prevalent in the Middle East, Russia and in some regions of Turkey. In Europe the virus is endemic in the Balkan region and South of Spain, with very sporadic transmission to humans. So far, in Europe an outbreak did not occur. It is important to follow further developments and the spread in Europe carefully.

Anaplasmosis

Although the disease is not apparent in Europe, it is very common in the US where this tick-borne bacterial infection comes second after Lyme disease. Anaplasma phagocytophilum is transmitted to humans by the bite of an infected tick and is endemic in states where the tick vectors (Ixodes spp) are found. There is growing evidence of emergence occurring in Canada. Climate and environmental changes contribute to the expansion of ticks in North America. Transfusion transmission is rarely described. In the literature, there are 12 transfusion transmitted cases reported in the US. Asymptomatic and pre-symptomatic anaplasma infection is possible, just like with babesia. If the bacterial concentration in blood is low, leukoreduction appears to be effective in reducing infectivity. However, transfusion transmission has been observed with leukodepleted blood products, assumed due to higher bacterial loads. For Europe it is important to follow the local situation. The current European situation is unclear, with questions such as the real increase and spread of ticks on the continent. Undiagnosed cases in Europe cannot be excluded. An increase of anaplasma may be one resulting from climate change with rising temperatures, similar to mosquito-borne (tropical) infections.

Malaria

A local Plasmodium vivax case in a non-touristic area of Evros in Greece was reported. The case was found in a rural area where migrants from malaria risk areas are living and vectors are present. Sporadic events of local malaria transmission are known in Europe and a few local cases occur yearly. Due to very limited clusters of malaria transmission, the risk for blood safety can be regarded as very low. Due to decreased travel in the era of COVID-19, risk is likely further reduced.

HIV Pre-exposure prophylaxis (PrEP)

The EID M continued to monitor the developments of PrEP. HIV infection in donors using PrEP, post-exposure prophylaxis (PEP) or on antiretroviral treatment to control a current HIV infection and not disclosing the usage of such, can potentially be undetected in HIV donation testing. Blood products derived from donors on this medication may still be infectious and they should therefore be (temporarily if undergoing a preventive treatment) deferred. The current PrEP medications on the market are mainly daily oral medications with a short half-life. Trials of long-acting injectable drugs, such as cabotegravir are ongoing and it seems to be highly effective in preventing HIV acquisition. The new (injectable) drugs seem to be more effective, and the trend could be that it is preferred versus daily oral medication in specific risk groups. Long-acting PrEP has a very long half-life and the drug can be detectable for more than a year. It may have a longer suppressive effect on the viral load and on the detection of HIV in donation screening. What and how long the effect is on the HIV assays is currently unknown. This should be taken into account for the acceptance of blood donors.

2.4 Plasma collection self-sufficiency

The Plasma Working Group resumed its work in October 2020 with the new chair, Markus Jarnig, (Austrian Red Cross) as the lead. The Chair collaborated with the Benchmarking WG Chair to work on KPIs on plasma to be introduced in the 2021 benchmarking exercise. Working method and timings were agreed. The WG would focus on:

1. Calculation Model & Financial Aspects

a. Goal: Build up a basic calculation model for defined volume of plasma to be collected

2. Demand & Supply

a. Goal: Initiate a survey on the demand of plasma-derived products

b. Define demand per member country in volume measurements which will establish the level of self-sufficiency per member country.

c. Gather the data from EBA plasma Collection survey and from the year 2019

3. Best Practices in Plasma Collection

a. Goal: Promoting the efficiency of plasma collection, success stories and assessing and selecting measures recommended at EBA/IPFA workshop

b. Set up a document/reader with success stories of best practices

c. Establish what is successful in recruitment campaigns

d. Establish what is successful in donor retention activities

Reflect on the legislative framework in EU

Another subgroup of the Plasma WG, worked on the concept of Services of General Economic Interest (SGEI) and had discussed the concept, its interpretation and how it could help for plasma collection by not-for-profit BE. The sub-group drafted a brief that would be the basis of the roundtable planned with the EBA Board and Prof. Tamara Harvey.

2.5 Research grant: Towards evidence-based Patient Blood Management: systematic reviews to scientifically underpin the appropriate use of red cells

This research project was run by the Centre for Evidence-Based Practice (CEBaP), associated with EBA member Flanders Red Cross. The project was financially supported by EBA through a €40.000 grant.
Period of implementation: 01.01.2019-31.01.2021 This research project was run by the Centre for Evidence-Based Practice (CEBaP), associated with EBA member Flanders Red Cross. The project was financially supported by EBA through a €40.000 grant and ran between the beginining of 2019 and the end of 2020.

The general aim of this project is to evaluate and publish the best available scientific evidence by conducting systematic reviews regarding the effectiveness (PICO 1), safety (PICO 2) and cost-effectiveness (PICO 3) of using Erythro-Stimulating Agents (ESAs) and/or iron therapy in patients with preoperative anaemia undergoing an elective surgery.

CEBaP completed the systematic reviews and presented and discussed the detailed systematic review reports with an external expert panel (4 subject matter experts and 2 methodologists) and formulated conclusions accordingly. Subsequently, CEBaP prepared 3 manuscripts for publications in a peer-reviewed journal.

The expert panel was composed of:

Name	Role	Affiliation(s)
Jørgen Georgsen	Subject matter expert	South Danish Transfusion Service, Odense University Hospital, Odense C, Denmark
Paola Maria Manzini	Subject matter expert	SC Banca del Sangue Servizio di Immunoematologia, University Hospital Città della Salute e della Scienza di Torino, Torino, Italy
Patrick Meybohm	Subject matter expert	Department of Anesthesiology Intensive Care, Emergency and Pain Medicine, University Hospital Wuerzburg, Wuerzburg, Germany
Yves Ozier	Subject matter expert	University Hospital of Brest, Brest, France
Geertruida Bekkering	Methodologist	Center for Evidence-Based Medicine, Leuven, Belgium; Cochrane Belgium, Leuven, Belgium; Department of Public Health and Primary Care, Faculty of Medicine, KU Leuven, Leuven, Belgium
Mattias Neyt	Methodologist	Belgian Health Care Knowledge Centre (KCE), Brussels, Belgium

The results and conclusions of the three systematic reviews are presented below.

Effectiveness iron supplementation with or without ESA therapy (systematic review 1)
CEBaP identified 29 randomized controlled trials (RCTs) and 2 non-RCTs comparing the effectiveness of preoperative iron monotherapy, or iron + ESAs, to control (no treatment, usual care, placebo).

They found that:

1. IV and/or oral iron monotherapy may not result in a reduced number of units transfused and IV iron may not reduce the number of patients trans- fused (low-certainty evidence)

2. Uncertainty exists whether the administration route of iron therapy (IV vs oral) differentially affects RBC utilization (very low-certainty evidence)

3. IV ferric carboxymaltose monotherapy may not result in a different number of patients transfused compared to IV iron sucrose monotherapy (low-certainty evidence)

4. Oral iron + ESAs probably results in a reduced number of patients transfused and number of units transfused (moderate-certainty evidence)

2.6 Preparation work on rare blood groups

EBA was planning to organise a two-day workshop on Rare Blood Provision in November 2020, in Filton, UK which was to be hosted by the NHS Blood and Transplant. Due to the pandemic the physical workshop was cancelled, and it was agreed to organise it as a virtual event at the beginning of 2021. The EBA Secretariat organised a programme committee that met regularly throughout autumn/winter 2020 to build the programme and identify speakers for the virtual workshop. The programme committee drafted a survey on rare blood provision that was distributed by EBA to all EBA members as well as to the ISBT working party on rare donors (44 countries in total). This survey was aimed at making an inventory of current practices related to the provision of rare blood groups and to give insights into relevant subjects for the workshop.

2.7 Work of the DPO WG

One of the core requirements of the General Data Protection Regulation (GDPR) is that Data Controllers must put in place appropriate Data Processing Agreements (DPA's) with any third parties who are acting as Data Processors and processing personal data on their behalf. Processing personal data can take many different forms including storing, maintaining, or accessing personal data in the provision of the agreed service. These DPA's outline the Controller and Processor responsibilities with regard to the personal data and how it must be securely managed. In late 2019 a subgroup of the DPO/Privacy working group with 6 EU Blood Establishments was formed in order to address the requirement for a DPA with a large, shared supplier who was processing data on behalf of their organisations. Having secured the willingness of the supplier to collaborate in this collective manner the subgroup then spent a number of months into 2020 working first together to agree an acceptable common baseline which would meet their own Blood Establishment requirements and then collaborating with the supplier/Data Processor to agree a final acceptable DPA template which would meet all parties' requirements. This piece of work was concluded successfully in May 2020 with an agreed template which was then available for all members to use as required.


00095444203
450 ml

3. SAFEGUARDING THE BLOOD SUPPLY AND IMPROVING PERFORMANCE

One of the core values of EBA is helping each other for optimal use of health resources through openness in information sharing.

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. During 2020, a great focus was placed on facilitating the exchange of information between EBA members, with the European Commission, the ECDC (see above) and the EDQM, in the context of a pandemic, which secured a fluid communication flow which allowed for knowledge acquisition and shared guidance.

3.1 EBA Consultations 2020

EBA encourages and facilitates collaboration within Europe and supports Blood Establishment members who want to circulate a survey within the EBA network. The surveys and their answers allow EBA members to benchmark their services or activities with others, to collect information on processes and technology, to share experience and best practice. The EBA secretariat centralises the answers, and collates them in a report. Respondents are asked for consent to share the information. If this is forthcoming, the report is circulated to all members, including those who did not provide any answers. The final report is for internal use only, not to be distributed outside of EBA. There were 28 such surveys in 2020.

On October 27, 2020, the Croatian Institute of Transfusion Medicine initiated a consultation on the selection of optimal Red Blood Cell (RBC) components for "top-up" and large-volume transfusions (except for exchange transfusions) in neonates. Leukoreduced CPDA-1 red cell concentrates have traditionally been used in the management of these patients at the Croatian institute. Along with the issue of planning the collection and preparation of such a small number of units, the question arose on the necessity of using this type of red cell concentrate instead of red cells in additive solution (or its modification). Looking for alternative solutions, they decided to investigate the practice of other EBA members in selection of RBC components for neonatal transfusions. 11 responses were received from EBA members. The analysis of the data confirmed their position on the need to change the current practice, and to terminate the production of CPDA-1 red cell concentrates. The change control procedure was initiated and as of January 1, 2021, CPDA-1 red cell concentrates would no longer be produced. In rare situations, when additive solution is considered contraindicated by the treating physician, removal of additive solution with the addition of saline or compatible plasma is offered as an alternative blood component.

3.2 Interaction with technical and political pan-European institutions

European Commission

The EBA secretariat and President maintained very regular relations with DG SANTE, after EBA sent a letter to DG SANTE's Directors to highlight the importance of EU collaboration during this COVID-19 pandemic and suggested opening a specific call for research on convalescent plasma. The research project was set up and awarded through DG RTD (research and development- see above, section on Support-E). The EBA office held more than 30 official meetings with DG SANTE, mainly in relation to Support-E and the CCP database, but also to discuss guidance documents on COVID-19 and donor protection and deferral. EBA also helped collecting important data (in addition to what they could collect through the Competent Authorities) for the European Commission and ECDC to guide their assessments and positions.

EBA also exchanged information with EC services dealing with Medical Devices and In Vitro Diagnostics (see more in section 3.3 of this report) in particular on the qualifications of software used in laboratories and on the future removal of DEHP from blood bags. Although EBA is not registered as an official stakeholder within the EC expert groups in charge of reviewing guidance documents in these two fields, the EBA Secretariat did its utmost, through other health organisations and regular follow-up with the EC, to ensure that the final guidance and decisions from the EC match the needs of EBA members. This work is on-going in 2021.

In view of the upcoming revision of the EU Blood Directive, the EBA reinstated its EU Directives Working Group whose first task was to answer to the Inception Impact Assessment on the said Revision, laying out its key priorities for the next EU BTC legislation, and indicating its preferred policy option from the four presented by the EC.

EDQM- European Directorate for the Quality of Medicines & Healthcare (Council of Europe)

At the beginning of the year, the EBA Secretariat worked with its members to contribute to the review of the EDQM Blood Guide, and to ensure that the maximum number of plasma donations per donor and per year, as set, would remain unchanged, contrary to the request made by the plasma pharmaceutical companies: the EBA sent official letters and emails to EDQM, after it had made its comments in the draft text of the new edition of the Blood Guide.

Guy Rautmann, then Secretary to the European Committee on Blood Transfusion (CD-P-TS) of the EDQM, was invited to speak at the IPFA/EBA workshop in Amsterdam in January 2020. It gave IPFA and EBA (and some of its members who were present) the opportunity to question him about the plan to hold another meeting of the CD-P-TS to discuss maximum plasma donations per year/per donor. This direct interaction has contributed to not holding a CD-P-TS extraordinary meeting meant to open up discussions on increasing the number of plasma donations per donor to 60/year in the Blood Guide, contrary to what the CD-P-TS had already agreed.

EBA was also invited to speak at EDQM's October meeting celebrating the 10th anniversary of collaboration with the EU: "Keeping up with Reality and Quality: A Challenge for European Blood Establishments". Under the heading: "the COVID-19 pandemic, impact of the continuity of blood supply and lessons learnt", Paul McKinney, from the Irish Blood Transfusion Service (IBTS), Ireland, Chair of EBA's Contingency Planning working group presented "The importance of ensuring business continuity for BEs". Stéphane Bégué, from the Etablissement Français du Sang (EFS), France presented the "Challenges in auditing suppliers, BE perspective" under the section of "Globalisation of the supplier marketplace – state of play, opportunities and issues in the blood sector", as the co-chair of EBA's Innovation and New Products Working Group. Finally, Dirk de Korte, from Sanquin in the Netherlands shared his knowledge and opinion under the programme section: "New regulatory environment for medical devices: state of play, opportunities and issues the blood sector" on Reclassification of DEHP: Impact on Blood Establishments.

EBA liaised with EDQM on issues pertaining to GDPR, in preparation for an EDQM event on the subject matter, to be held in 2021.

World Health Organisation

EBA also sent comments to WHO's "Maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease (COVID-19)" guidance at the end of February, which was published on the 25th of March.

Through all these interactions and opportunities to share knowledge and expertise, the EBA significantly increased its visibility with EU decision makers and reasserted its position as the leading partner for pan-European organisations in the field

3.3 Ensuring safety and availability of Medical Devices

Innovation and new products working group and sub-groups: DEHP

Throughout the year the Innovation Working Group, with the coordination of the EBA secretariat, continued exchanging views and arguments, in particular with representatives of Blood Bag producers within the BTA (Blood Transfusion Association) to assess options for removal of DEHP from blood bags and its replacement with new components/plasticizers to provide patients and donors with safe blood bags. The group worked specifically on:

1. Supporting BTA's initiatives whilst gently nudging the group to put all efforts into finding other plasticizers and confirming that finding an alternative to DEHP remains EBA's priority; the group is aware that several companies are conducting trials on new devices

2. Meeting with the DG SANTE unit in charge of Medical Devices

3. Drafting and sharing a FAQ on DEHP

4.Compiling an overview of national requirements for authorisation

This reflection also included work on the REACH regulation.

Communicating on the risks of up-classification of blood bags

The EBA secretariat, based on information shared by the Innovation Working Group, initiated advocacy work in April towards the European Commission and EBA members to raise concerns about the risk of up-classification of blood bags from Class IIb to Class III, with the new Medical Device Regulation and its accompanying Guidance document drafted by the Borderline and Classification Expert Group. EBA sent its arguments against this up-classification and comments on the draft guidance document to DG SANTE and asked its members to also contact their respective Competent Authority, who are part of the expert group, so that they could represent their views in the final draft of the guidance document related to blood bags.

EBA's positions and comments were shared among the Expert group and work on the matter continued in 2021.

3.4 Performance improvement: Inter-laboratory proficiency assessment of QC analytical processes across European jurisdictions

The EBA Working Group on Quality Control Proficiency Testing Survey (QCPTS-WG) was created in June 2019 to promote a European-wide proficiency testing survey scheme on quality control analysis for labile blood products. An inter-laboratory proficiency assessment of QC analytical processes across European jurisdictions would allow for a comparative assessment of blood products QC Europe-wide. By achieving such a goal, a European QC PTS could contribute to the quality of blood products produced in Europe while limiting costs through pooling of resources. In 2020, the working group on QC-PTS proceeded with a Pilot Phase, based on for 4 cycles for RBCs and 2 cycles for PCs, to assess the feasibility on technical, practical sides and to initiate a financial analysis of the programme.

Samples were prepared and shipped by the French Blood Services (Etablissement Français du Sang -EFS) Sites to 11 BEs around Europe. The pilot phase highlighted minor issues pertaining express shipment of blood samples, temperature control up to destination and use of the procedure. Results show a satisfactory level of standardisation of contributing BEs to provide quality control results on regulatory quality attributes of RBC and Platelet concentrates.

The success of the pilot study encourages the WG to proceed towards the next step of implementation of this programme on a regular basis, with the help of additional BE (Belgium and Luxemburg with EFS) as organising sites. A plan has been established for 2021 and 2022 with a widening of quality attributes (haemolysis on RBC and residual leucocytes on RBC and PC).

3.5 Benchmarking Working Group

Due to the pandemic, there were no workshops organised by the WG in 2020. However, the groups continued to meet and in June 2020 held a special meeting on benchmarking the COVID-19 actions.

Benchmarking exercise

Yearly, the EBA Benchmarking working group circulates a scorecard for EBA Members to complete. Some notable outcomes of 2020 survey were as follows:

- **19 countries** (vs 18 last year)
- Survey respondents serve a population of **c349 million** (c70% of total EU)
- **9.0 million** red cell issues = -1.1% reduction. Previous year was -2.6%
- **1.64 million** platelet issues = +0.3% increase. Previous year was +0.3%

3.6 Participating to the GAPP Joint Action: Facilitating the Authorisation of Preparation Process for blood, tissues and cells

The EU Joint Action (JA) aims at facilitating the development of a common and optimal approach to assess and authorise preparation processes in blood and tissues establishments. EBA is an associated partner (not a beneficiary of funds) and attended two of the JA's meetings. The EBA's contribution included the provision of feedback, and comments on definitions of new risk assessment methodologies and tools applicable to the blood sector. The EBA Secretariat also commented on the Project deliverable guidance for Member States' Competent Authorities on how to assess clinical data when authorising novel BTC products or changes in their preparation processes.

3.7 Advocacy and intelligence gathering

Throughout the year, the EBA secretariat monitored the positions expressed by other key health stakeholders in the field of Blood and Plasma, especially as the subject of potential shortages due to COVID-19 started to be raised, by fractionators and the European Commission and patient groups. EBA secretariat followed news in the press, publications by other Blood and Blood component related groups, public meetings, and conferences.

3.8 International collaboration: Relations with ABO

During the year, the EBA secretariat liaised with the ABO secretariat to discuss a continuation of collaboration, after ABO had decided that it would only have individual members, eliminating the possibility of association membership. This meant that EBA and ABC could no longer be full members of ABO. The two secretariats agreed on a partnership in which the two parties would be equal and would share information. This was formalised through a Memorandum of Understanding and an EBA/ABO confidentiality agreement, in addition to a confidentiality agreement with each individual EBA member. The subject matter triggered some discussion among EBA members which continued in 2021.

4. EBA FUNCTIONING

4.1 Communication

Due to the volume of work dedicated to COVID-19, the EBA secretariat was not in a position to publish more than 2 newsletters in 2020.

However, regular communication was maintained with members through emails and meetings, which were far more numerous this year than in 2019.

The EBA website was reviewed making it more user friendly.

EBA published two press releases, one on the potential benefits of CCP and another one on the commitment from not-for-profit Blood Establishments to increase plasma collection. Both were picked up by the EU specialised press and like-minded health associations.

EBA also took care of developing and launching the European Conference on Donor Health and Management (ECDHM) website and initial communication.

4.2 Governance

Due to the extraordinary circumstances created by COVID-19 and Brexit and its impact on EBA membership, the Executive Board met 11 times in 2020 (instead of the standard 6 times). The Executive did not have the possibility to meet physically due to COVID-19. Likewise, the Board was consulted by email more often than usual and bilateral conversations on internal matters were held to ensure the EBA secretariat was adequately representing the views of its members.

The EBA Executive welcomed three new members: Veerle Compernolle, from the Belgian Red Cross – Flanders, who took the role of Treasurer, Stefan Laspina, from Malta National Transfusion Services, Secretary, and Christof Jungbauer, from the Austria Red Cross. Polonca Mali was re-elected an Executive member in June. EBA said good-bye to Rudolf (Rudi) Schwabe, long-time member of EBA and former Treasurer in the Executive, who retired from the Swiss Red Cross.

Pierre Tiberghien started a four-year term as EBA President in January 2020. At the same time, Daphne Thijssen-Timmer started a four-year term as EBA Vice-President.

The EBA Executive Board consists of the following members:

Pierre Tiberghien, France – President

Daphne Thijssen-Timmer, The Netherlands – Vice President

Veerle Compernolle, Belgium, Flanders – Treasurer

Stefan Laspina, Malta – Secretary

Polonca Mali, Slovenia

Christof Jungbauer, Austria

In March, Peter van den Burg left his Medical Director position in EBA to return full time with Sanquin and it proved difficult for EBA to recruit a new Medical Director. The EBA benefited from the help of Cristina Caeiro (Portuguese Blood Transfusion Institute) and Pierre Tiberghien, EBA President, stepped in to support the EBA Secretariat for medical/scientific matters.

The EBA staff is composed of the following:

- **Catherine Hartmann, Executive Director**
- **Rodica Popa, Administration and Project officer**
- **Peter van den Burg, Medical Director – until March**
- **Gaia Mori, Project Manager Support-e (3 days/week), from July**

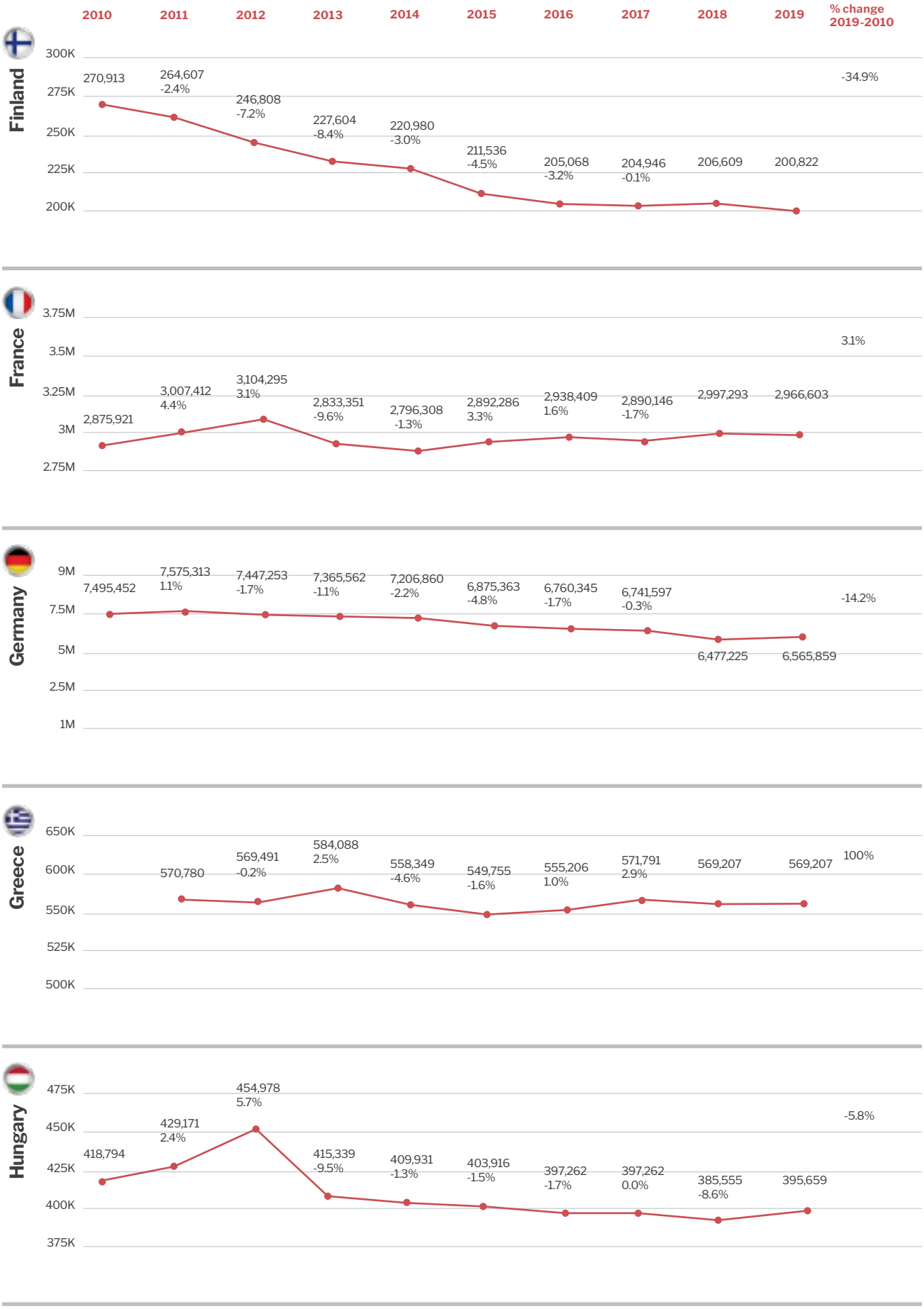
With the final exit date of 31st of December 2020 for the UK to leave the European Union, the EBA Secretariat and Executive spent some time discussing internally, and with members, the impact Brexit would have on the UK's EBA membership. Different options were assessed and submitted to the Executive and Board and a solution found within the EBA statutes.

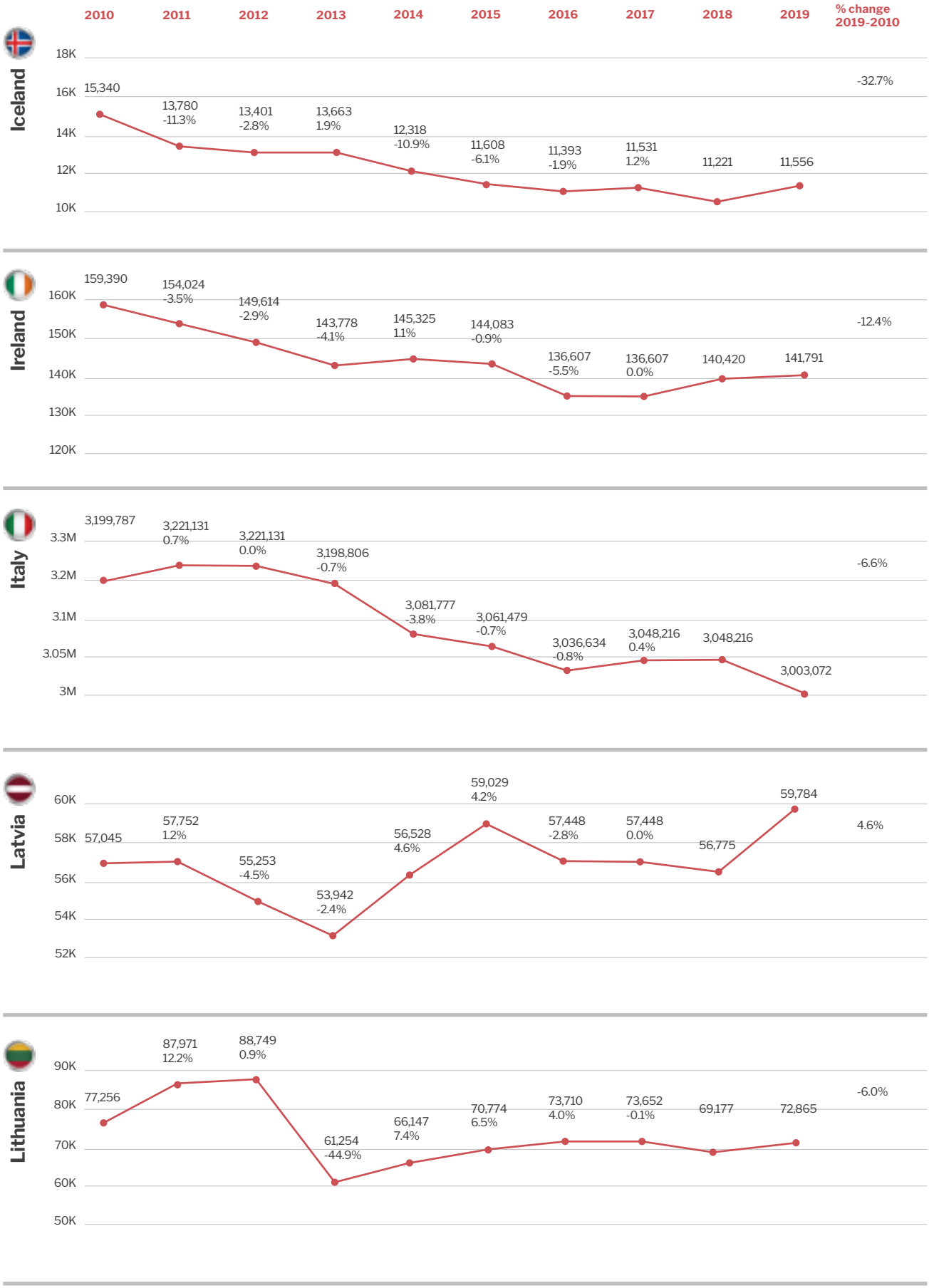
Two virtual Board meetings were organised, but their respective agenda shortened compared to previous years, to take into account that on-line long meetings are not the favourite means of communication of EBA members. In April, Christof Jungbauer presented an in-depth session on "The challenges of the implementation of the MD and IVD regulations".

5. DONATION DATA OF EBA MEMBERS

Yearly, EBA collects donation data (whole blood and apheresis collections) from its members. The current trend of declining use of red cells can be observed for many countries and for EBA as a whole

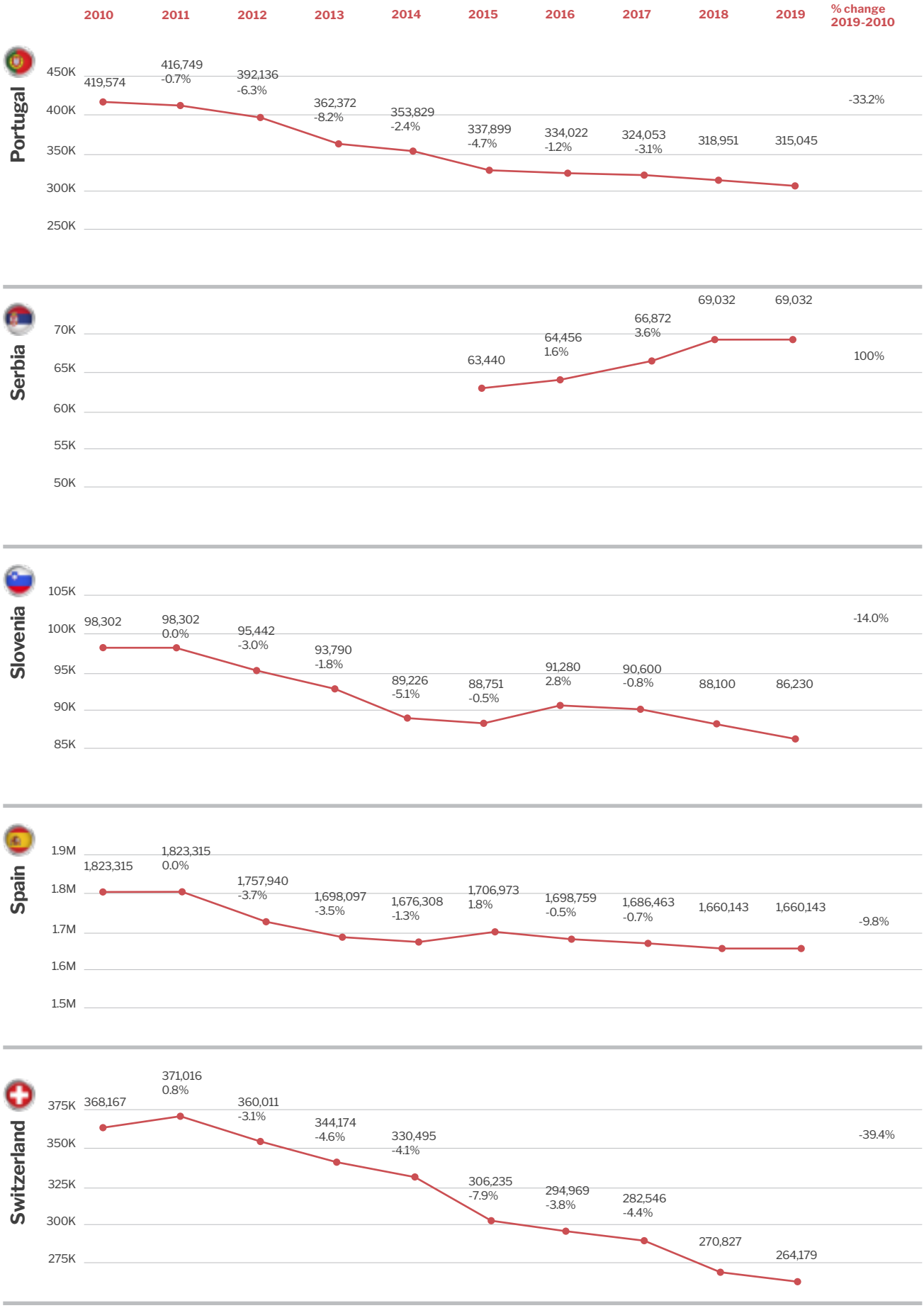

2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
% change 2019-2010
Austria
500K
450K
400K
350K
300K
431,770
419,575 -2.9%
392,195 -7.0%
374,526 -4.7%
362,809 -3.2%
359,954 -0.8%
352,024 -2.3%
359,055 2.0%
356,871
350,397
-23.2%
Belgium
700K
650K
600K
550K
500K
622,197
629,238 1.1%
627,830 -0.2%
578,701 -8.5%
546,478 -5.9%
551,710 0.9%
558,698 1.3%
551,058 -1.4%
563,336
593,316
-4.9%
Croatia
200K
175K
150K
125K
100K
177,355
180,266 1.6%
182,068 1.0%
183,688 0.9%
183,716 0.0%
195,599 6.1%
197,294 0.9%
197,876 0.3%
193,829
193,650
8.4%
Denmark
350K
325K
300K
275K
250K
339,094
313,401 -8.2%
296,833 -5.6%
290,400 -2.2%
275,864 -5.3%
275,051 -0.3%
278,614 1.3%
278,639 0.0%
278,776
281,500
-20.5%
Estonia
70K
65K
60K
55K
50K
58,729
59,676 1.6%
60,057 0.6%
61,234 1.9%
60,506 -1.2%
59,013 -2.5%
57,417 -2.8%
55,057 -4.3%
53,486
56,787
-3.4%


2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
% change 2019-2010
Finland
300K
275K
250K
225K
200K
270,913
264,607 -2.4%
246,808 -7.2%
227,604 -8.4%
220,980 -3.0%
211,536 -4.5%
205,068 -3.2%
204,946 -0.1%
206,609
200,822
-34.9%
France
3.75M
3.5M
3.25M
3M
2.75M
2,875,921
3,007,412 4.4%
3,104,295 3.1%
2,833,351 -9.6%
2,796,308 -1.3%
2,892,286 3.3%
2,938,409 1.6%
2,890,146 -1.7%
2,997,293
2,966,603
3.1%
Germany
9M
7.5M
5M
2.5M
1M
7,495,452
7,575,313 1.1%
7,447,253 -1.7%
7,365,562 -1.1%
7,206,860 -2.2%
6,875,363 -4.8%
6,760,345 -1.7%
6,741,597 -0.3%
6,477,225
6,565,859
-14.2%
Greece
650K
600K
550K
525K
500K
570,780
569,491 -0.2%
584,088 2.5%
558,349 -4.6%
549,755 -1.6%
555,206 1.0%
571,791 2.9%
569,207
569,207
100%
Hungary
475K
450K
425K
400K
375K
418,794
429,171 2.4%
454,978 5.7%
415,339 -9.5%
409,931 -1.3%
403,916 -1.5%
397,262 -1.7%
397,262 0.0%
385,555 -8.6%
395,659
-5.8%

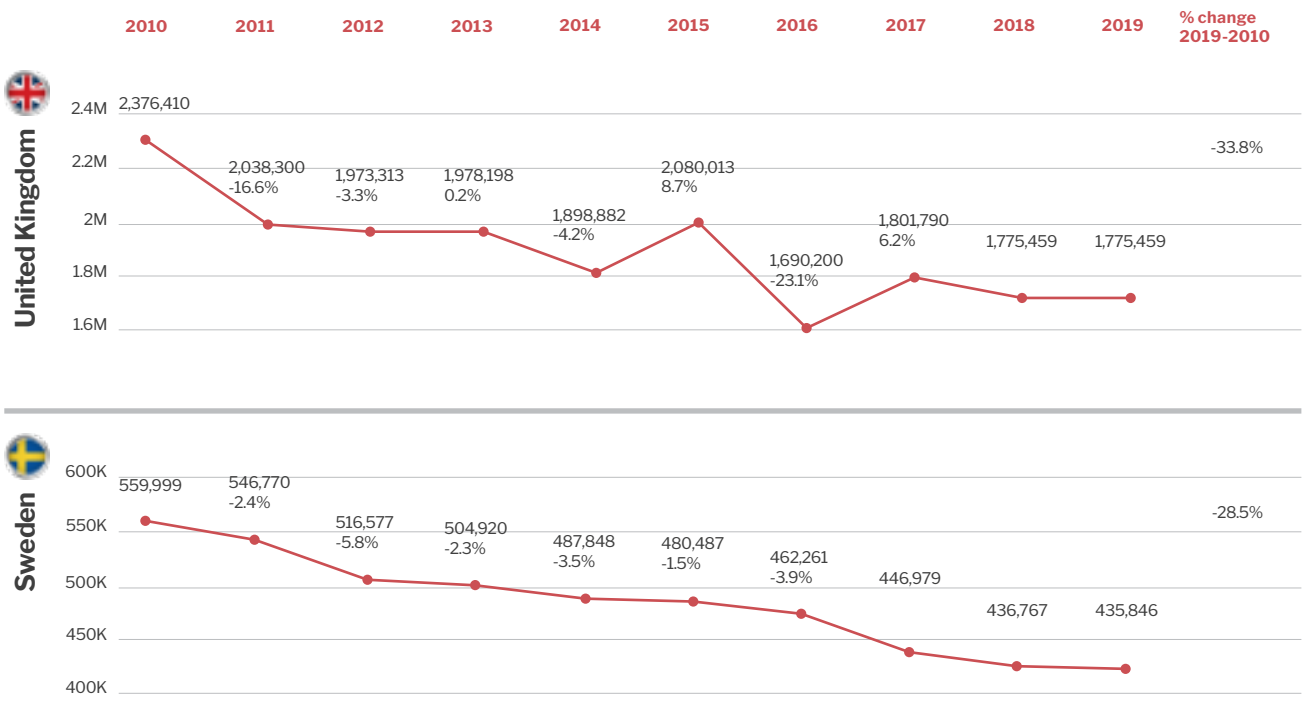


[1] Latvia - no data for 2017 received

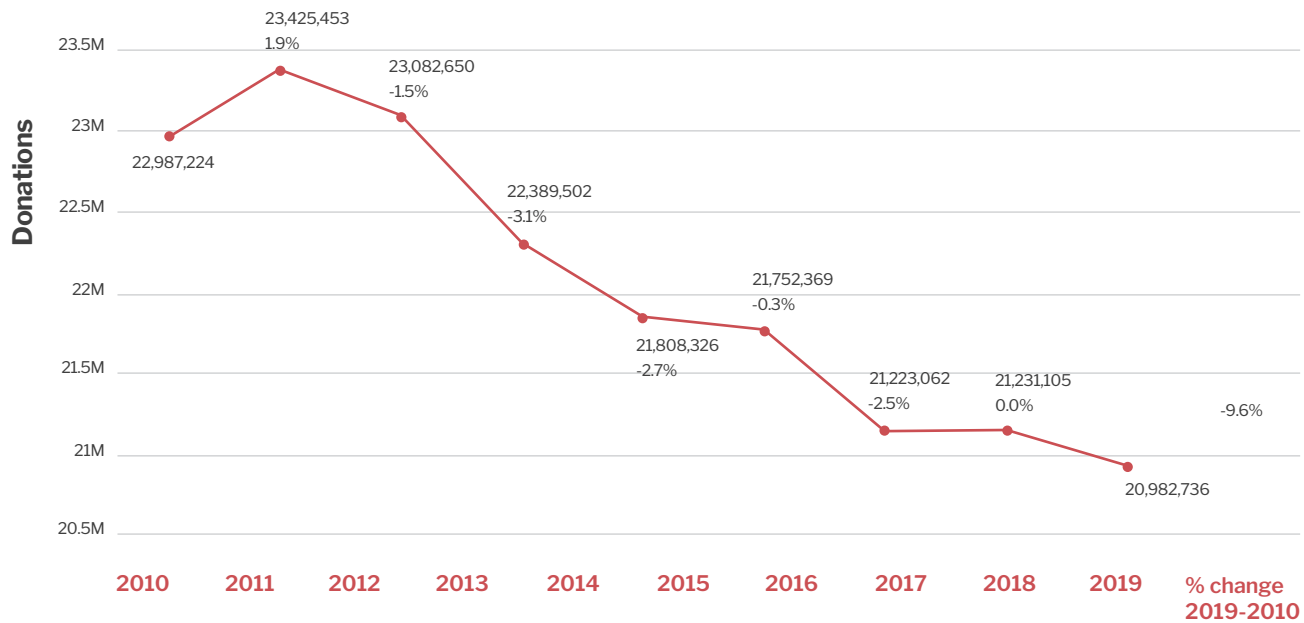

2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
% change 2019-2010
Lithuania
90K
80K
70K
60K
50K
77,256
87,971 12.2%
88,749 0.9%
61,254 -44.9%
66,147 7.4%
70,774 6.5%
73,710 4.0%
73,652 -0.1%
69,177
72,865
-6.0%
Luxembourg
26K
24K
22K
20K
24,055
24,055 0.0%
20,631 -16.6%
24,191 14.7%
23,904 -1.2%
23,657 -1.0%
23,657 0.0%
24,172 2.1%
22,486
21,555
-11.6%
Malta
19K
18K
17K
16K
15K
15,096
16,960 11.0%
17,424 2.7%
17,024 -2.3%
17,457 2.5%
17,427 -0.2%
18,152 4.0%
16,363 -10.9%
16,547
17,528
13.9%
Netherlands
900K
850K
800K
750K
700K
883,346
885,971 0.3%
819,301 -8.1%
755,833 -8.4%
721,012 -4.8%
720,251 -0.1%
726,273 0.8%
720,646 -0.8%
724,002
727,462
-21.4%
Norway
250K
225K
200K
175K
150K
217,907
217,907 0.0%
217,907 0.0%
222,954 2.3%
223,455 0.2%
204,065 -9.5%
200,888 -1.6%
193,723 -3.7%
190,408
188,814
-15.4%



[2] Serbia - %change 2015-2018



Total donation data EBA members 2010-2019



6. ABOUT EBA

The European Blood Alliance (EBA) is an association of not-for-profit Blood Establishments, with 25 members (including observers) throughout the European Union and EFTA States. The official seat and office of the Alliance is Amsterdam, the Netherlands. Its mission is threefold:

1. To contribute to the availability, quality, safety and cost-effectiveness of the blood and tissue supply for the citizens of Europe by developing and maintaining an efficient and strong collaboration amongst European blood and tissue services.

2. To increase public and professional awareness of voluntary and non-remunerated donation (VNRD) of blood and blood components, and of preparation of blood components as an indispensable therapeutic means to help patients.

3. To assist European blood establishments to continuously improve their performance, based on scientific and ethical principles for the benefit of patients.

EBA strives towards this mission by assisting our members to improve performance through collaboration, to engage in regulatory affairs to promote best practice and to facilitate information collection and knowledge exchange.

EBA event in the European Parliament, January 2019

6.1 Vison, mission, core values

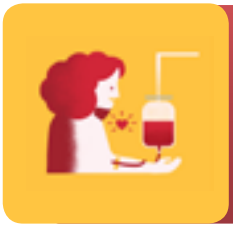
EBA is operating with the following core values:

Patient Care

Donor safety

Voluntary non-remunerated donations

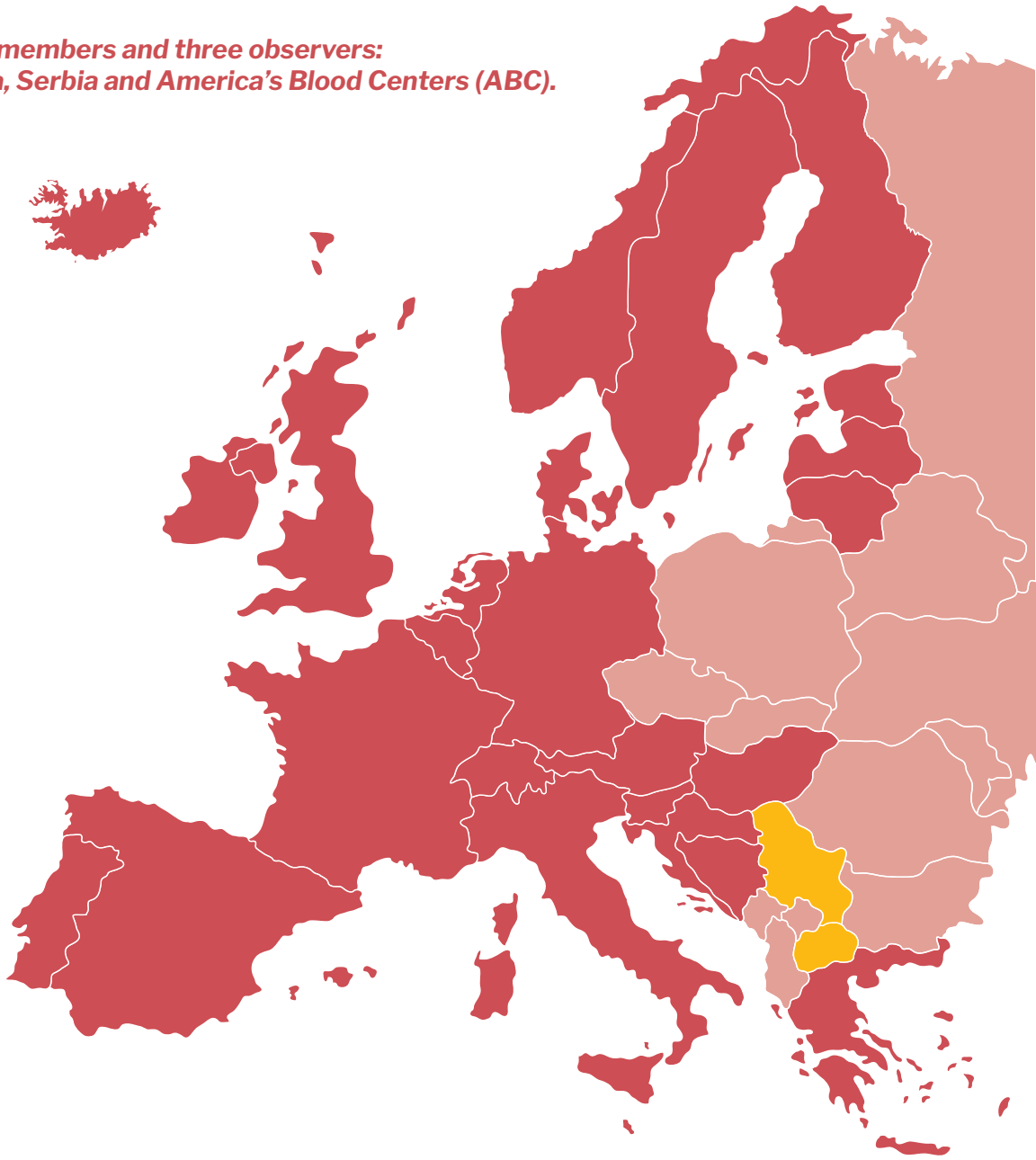
Helping each other for optimal use of health resources through openness in information sharing



Excellence through Evidence

CURRENT MEMBERSHIP

EBA now has 25 members and three observers:
North Macedonia, Serbia and America's Blood Centers (ABC).



Members :

- Austria
- Belgium
- Croatia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Norway
- Portugal
- Slovenia
- Spain
- Sweden
- Switzerland
- United Kingdom

Observers :

- Serbia
- North Macedonia
- America's Blood Centers

Balance sheet

Assets

Tangible fixed assets	31 December 2020	31 December 2019
Inventory	€4.874	€6.937
	€4.874	€6.937
Current assets		
Amount to be received	€878	€944
Warrant fee	€1.960	€1.960
Prepaid costs	€3.370	€3.095
Accounts receivable	€900	€-
	€7.108	€5.999
Liquidities		
Rabobank .542	€192.720	€102.986
Rabobank .620	€180.040	€180.022
Rabobank .338	€408.637	€407.711
Rabobank .341	€186.254	€-
	€967.651	€690.719
Total	**€979.633**	**€703.655**

Balance sheet

Liabilities

Capital	**31 December 2020**	**31 December 2019**
Accumulated result	€767.390	€682.440
	€767.390	€682.440
Current liabilities		
Accounts payable	€9.639	€21.215
Horizon 2020 Project/Support-E	€180.815	€-
Wage tax to be paid	€1.506	€-
VAT 2020	€20.283	€-
	€212.243	€21.215
Total	**€979.633**	**€703.655**

State of income and expenses

Income	2020	2019
Membership fees	€396.100	€357.300
Interest bank account	€290	€944
CPI income	€-	€13.748
EBA/EPFA Intern. Blood and Plasma	€13.053	€-
	€409.443	€371.992
Expenses		
Personnel costs	€172.948	€210.013
Depreciation	€2.063	€5.242
Meetings and workshops etc.	€602	€6.747
Travelling etc.	€3.425	€20.862
Office costs fixed	€13.746	€15.813
Office costs variable	€22.285	€21.183
Other costs	€109.424	€101.955
	€324.493	€381.815
Total result	**€84.950**	**€9.823**

CPI income	€-	€13.748
CPI expenses	€-	€35.028
Result CPI	€-	€21.280
Result Association activities	€84.950	€42.271
Balance	**€84.950**	**€63.551**

EUROPEAN BLOOD ALLIANCE

ANNUAL REPORT

2020

Thank you

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

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eba

Safe blood for Europe