In this edition:

1. FDA Intends to Change MSM Deferral
2. Collaborative Procurement Blog
3. Small Changes, Big Impact!
4. Classifications of Donor Complications
5. Reporting on Serious Adverse Reactions and Events (SARE)
6. Blood Transfusion Institute of Serbia: new EBA observer
7. Executive Director handover
8. Ebola Protocol
9. ABC Annual Meeting
10. RBDM Communiqué
11. Job Opportunities
12. Agenda

1. FDA Intends to Change MSM Deferral

Draft decision announced
On December 23rd, the FDA’s decided to take steps to recommend a change in the blood donation deferral for men who have had sex with men (MSM) from a lifetime deferral to a one-year deferral. The actual implementation of this decision however will take time, according to Louis Katz, Medical Director of America’s Blood Centers: "At this point, I am awaiting the draft guidance from FDA [...], after which there will be months for comment and then months to a final guidance and more time for implementation".

ABC, ARC, AABB content
The FDA decision is consistent with the position of ABC, ARC and AABB, according to a statement they released the day after, where they state that the current lifetime deferral is unwarranted. It also stated that it supported the recommendations for sustainable monitoring of changes in blood safety following implementation of a new deferral policy. Louis Katz added that this decision has been also based on the data from BloodDrops, a federally funded study requested in 2010 by the Advisory Committee on Blood and Tissue Safety and Availability: this suggested
that the one year deferral will be viewed as more based in the appropriate science and epidemiology, and that MSM will be substantially more likely to adhere to the one year criterion than the current indefinite deferral. If that is correct, the result could actually be a decrease in the number of HIV infected donors presenting to donate”.

**MSM- HIV transmissions in Europe**

At the occasion of World Aids Day (December 1st), the ECDC published the HIV/AIDS Surveillance in Europe 2013 report. This publication documents vast differences in incidence of HIV in MSM throughout European countries, which is reflected in the different deferral policies. Data is showing that in the EU/EEA, sex between men is still the predominant mode of HIV transmission, which accounted for 42% of newly diagnosed HIV infections in 2013. Marc Sprenger, the ECDC Director, commented: “The number of HIV diagnoses among this group has increased by 33% compared to 2004 – and has been going up in all but four countries”. The full report can be read here.

2. The Collaborative Procurement Blog / by Joëlle Guerra

*Imagine it’s year 2020.*

The procurement function – as we know it – will no longer exist. In a similar way that nowadays people cannot easily remember they once did not have a mobile phone… we will hardly remember that once upon a time buyers were only in charge of issuing purchase orders…

So we are in 2020, and you, EBA Member representative and executive, now have within your blood establishment a team that is officially in charge of designing better value, by collaborating with internal and external experts, suppliers and other partners. On top of that your team is able to work, while being highly budget-minded and service-minded, with each and every of your blood establishment’s partner, that might include high level experts in molecular biology, marketing specialists, legal advisers and Japanese manufacturers.

Why did you have to set up this team?

Because you were urged by hospitals, by patients organizations, by national authorities, by public opinion and many other parties, to create more value for money. Because you truly believed that this team could highly contribute to save time and money that could be re invested into R&D and innovation activities.
Well, even though I’d love to keep writing about the future, I strongly keep in mind that the current questions are about today rather than tomorrow: “Well, what about today Joëlle? What are the quick wins for us?”

I believe stereotyped answers won’t help much. Instead we shall work together on tailor made and realistic answers. If not done yet, I will get in touch with you, EBA members, very quickly, to discuss about those answers and design the next steps of the European Blood Alliance Collaborative Procurement initiative.

Those first exchanges will also be in line with one clear major objective for EBA that is to bring Collaboration between EBA Members and partners, to a whole new level.

As big projects shall be associated with quick wins, please also note that the following quick term actions, approved by EBA Executives (full action plan, as approved by the Executive members can be found [here](#)), will be on going until April 2015:
3. **Small Changes, Big impact Webinar!**

Last Thursday, ABC hosted the Small changes, Big Impact webinar. EBA was well represented with presentations from Jørgen Georgsen and Steve Morgan, and a third talk being from the Mississippi Valley Regional Blood Center. The webinar was very well attended with nearly 100 participants joining in.

**Materials from the Webinar**
The entire webinar can be replayed on the protected [website](#) of ABC. Login details will be provided on request by the EBA Secretariat: w.kramer@europeanbloodalliance.eu. The presentations have been added to Basecamp. Willemijn Kramer can be contacted for login details. And the Donor End To End Time video can be watched [here](#).

4. **Classifications of Donor Complications**
Originating with the ISBT working party on hemovigilance - donor subgroup –, the International Haemovigilance Network and the AABB Hemovigilance working group, the combination of these groups wanted to come up with simple definitions for donor complications that are easy to apply in a standardized way and align with the AABB Donor Hemovigilance System definitions and IT system.

**Goals**
So, in 2013 a group was asked to review the 2008 definitions of donor complications and propose modifications. The goals of this revised classification system are:
1. Provide simple definitions that are easy to apply in a standardised way.
2. Provide minimal requirements for international comparison that meet the needs of a basic surveillance program.
3. Provide additional attributes that may be collected nationally if possible. This additional information may be important for process improvement by the blood centre, or lead to relevant
research in donor reactions. Comparisons may be made internationally by those blood centres that are able to collect this information.

4. Align definitions with those used in the AABB Donor Hemovigilance System, to permit comparisons and entry of data into an adapted version of the donorHART software.

Implementation
The EBA members were sent this document in the drafting phase and now subsequently, EBA has formally endorsed these definitions, so the logo of EBA has been added to the document. As the donor reactions are not addressed in the current EU legislation, there is no overlap with the EU Directives on this topic. On the other hand, EBA has advised the Council of Europe to adopt this new international classification in a future edition of the Guide to the preparation, use and quality assurance of blood components.

The full document “Standard for Surveillance of Complications Related to Blood Donation” can be read and downloaded from the EBA website

5. Reporting on Serious Adverse Reactions and Events (SARE)

Serious Adverse Reactions and Events have to be reported to the Competent Authorities. The EC Directorate-General for Health and Consumers now have published the Common Approach for definition of reportable Serious Adverse Reactions and Events as laid down in the EC Directive 2002/98/EC and Commission Directive 2005/61/EC (version 5, 2014).

The document states in its introduction that: "The common approach laid down here aims to facilitate comparisons between data sent to the Commission from Member States, and associated countries. The guidelines are meant to reduce the reporting burden on all parties concerned (reporting establishments, competent authorities, and the European Commission) by clarifying issues before data collection is undertaken each year",

further DG Santé* notes that: "[...] this document is a recommendation for the completion of the electronic reporting template for serious adverse reaction(s) and event(s) (PDF version 2.3), but is not legally binding for Member States."

No overlap with donor classifications doc
It is important to underline that this Common Approach brings definitions of reportable serious adverse reactions observed in recipients during or after transfusion which may be attributable to the quality and safety of blood and blood components. No classification is given for the serious adverse reactions observed in donors. So, there is no overlap with the ISBT classification of donor complications presented above.
6. Blood Transfusion Institute of Serbia: new EBA observer

At the occasion of a visit to Belgrade last November for a lecture on Patient Blood Management at the Transfusion Medicine Congress of Serbia, the EBA Executive Director met colleagues of the Blood Transfusion Institute of Serbia (BTIS) and visited this institute. The discussions led our Serbian colleagues to present a candidacy for an EBA observership. After careful scrutiny, the EBA Executive members have considered that this status would be compliant with the EBA Bylaws and agreed to grant it. The BTIS is the biggest blood establishment in Serbia, collecting annually 64,000 donations, all based on VNRD, and processing, screening and distributing the corresponding blood components to hospitals in Belgrade but also in all Serbia (particularly rare type RBCs). A number of other blood operators (44, not including the Serbian Army) are collecting another 168,000 donations and also processing, testing and distributing. The BTIS is actively involved in quality management and transfusion medicine programs. They consider EBA as a strong potential support to progress on the way of continuous improvement of BE activities, transfusion medicine, and harmonisation of BE activities in Serbia. The representative of BTIS at EBA Board meetings will be the CEO, Prof. Snežana Jovanović Szentić. We are happy to welcome her and her colleagues of BTIS at EBA with the status of observer.

7. Executive Director Handover

The induction period of Kari Aranko (right), as the successor of Gilles Folléa (left) in the position of EBA Executive Director, is actively ongoing. The plan of effective handover has been discussed at the Executive meeting on 11 December. Kari will officially take over as EBA Executive Director as of February 1st 2015. This will apply to all activities except the following ones: EID Monitor and relationships with ECDC, PaBloE project, Council of Europe...
Working Group on plasma supply management, and Creativ Ceutical report on blood landscape in Europe. For these activities, the handover will take place as of May 1st 2015. Up to the end of his contract with EBA, Gilles will continue to provide Kari with his best assistance to ensure a successful transfer of knowledge and experience.

We wish Kari all the best for taking over as Executive Director, and Gilles the same for his last months at EBA.

8. Ebola Protocol
As a follow up of the EBA information table launched last November, a new protocol for Coordination of European stock of Ebola convalescent plasma, developed and managed by our NHSBT colleagues (thanks to them) has been launched at the end of December. The attached table is now regularly updated and we wish that most if not all EBA members join this protocol. Recently, Lorna Williamson made available SOPs for blood transfusion tests and blood transfusion in High Security Infectious Disease Units and accepted to circulate these SOPs within the EBA Newsletter. Please find both SOPs on Basecamp.

Protocol for Blood Transfusion tests in High Security Infectious Disease Unit
(Link to Basecamp – General Notifications Site)
Blood Transfusion Procedure for HLIU

9. ABC Annual Meeting

America’s Blood Centers’ members, industry representatives, and healthcare professionals will convene in Washington at the Ritz-Carlton (Pentagon City) for ABC’s 53rd Annual Meeting from March 20 to March 24. From topics on global issues affecting blood centers to medical, operational, and leadership discussions, the educational sessions will give attendees from around the world the edge to thrive in today’s environment.

Global Blood Safety
With the growing interest in global blood safety initiatives among blood bankers in developed and Eastern European nations, the Annual Meeting’s International Blood Safety Forum on Friday, March 20 will allow attendees to engage in dialogue with leaders from around the world who are forging the next horizon of global blood safety. Co-hosted with Global Healing, the forum includes both the perspective of US blood bankers and of various international blood service representatives.

Economics of Plasma
On Saturday, March 21, ABC will host its first ever Business Forum on Saturday focusing on “The Economics of Plasma – Business Issues Impacting Blood Operators.” Attendees will learn about the current landscape of the plasma fractionation business and how to optimize their blood services’ plasma collections. In addition, experts and leading researchers will address hot topics
in blood banking and transfusion medicine that impact patient and donor care both in the US and Europe.

Cooperation and Competition
The Blood Center Leadership Forum on Monday, March 23 will discuss the legal and strategic aspects of cooperation and competition in blood banking, navigating and negotiating the hospital supply chain, and board engagement and leadership succession. Networking events will include “A Monumental Affair” on Sunday, March 23, which offers guests a unique Washington experience.

On Monday evening, attendees will enjoy the 18th Annual Awards of Excellence and Talent Show. The full agenda can be viewed online. Those interested in attending the meeting may register through the e-mail invitations sent by ABC. Contact Lori Beaston at lbeaston@americasblood.org if you did not receive an invitation.
Testing the Framework
Since the last communiqué, the Risk-Based Decision-Making (RBDM) Project Team conducted consultation events with a broad range of stakeholders interested in the risk-based decision-making framework. The feedback we received has been rich and valuable and we are now using it to improve the framework. Our second focus was a feasibility test to “stress” the framework. The objective of this stress test was to identify if there were gaps in the framework or sections that needed to be adjusted.

Using a fictional scenario that described a newly emerging pathogen with the potential to negatively affect the blood supply, specially assigned teams stepped through the RBDM process, identifying the issues related to the scenario, developing the problem statement, identifying the risk management options and then undertaking relevant risk assessments. In the case of this scenario, it was determined that the range of assessments would include blood safety, operational, health economics, social concern, legal, regulatory, and stakeholder engagement. A “decision makers” group acted as a mock management team and used the assessments to make their recommendations to address the emerging issue.

All participants agreed the framework helped them logically think through the problem facing them and to gather the relevant information to make a good decision. The exercise did highlight a few areas where the framework could benefit from various refinements, a more user-friendly approach, and some additional tools, and we are making the necessary revisions. The plan is to release the final version of the framework no later than March 31, 2015. It will be available on the Alliance of Blood Operators website at allianceofbloodoperators.org.

Sharing the Framework
Awareness building and targeted consultation is an ongoing activity. An event of note was a face-to-face consultation with a group of key regulators where we presented the framework and received positive and constructive feedback about use of such a tool. The framework was also a focal point at the AABB annual meeting in Philadelphia where we held an education session, explaining key components of the framework such as the risk management foundations and framework structure, the importance of stakeholder engagement, and how health economics is used in the decision-making process. The session was well attended and many of the attendees visited the RBDM exhibitors’ booth to obtain more information.

1 EBA members will receive this by email
Coming Up
Over the next two months our efforts will be devoted to finalizing the framework, incorporating the good ideas we received from the consultations and addressing the adjustments identified by the feasibility test. We also plan to have the framework peer reviewed by risk experts for a final level of assurance of its effectiveness before it is published.

The RBDM Project Team

11. Job Opportunities

- WMDA
Looking for a job where you can combine quality management, accreditation and stem cells? WMDA has a challenging job for someone who would like to bring the WMDA accreditation programme to a higher level. You can read here more details: https://www.wmda.info/images/pdf/20141209-Vacancy.pdf

- ARCBS
National Scientific and Technical Services roles in Australia. The Australian Red Cross Blood Service is currently seeking a National Scientific and Technical Services Manager and two National Scientific and Technical Services Senior Advisers. These roles, based in Australia, will contribute to the leadership and implementation of scientific and technical processes within the manufacturing division to ensure the reliable, efficient and effective supply of blood and blood products within Australia. The roles require a university degree in science in a biomedical discipline, experience in a senior scientific and technical management role preferably within a manufacturing environment, experience leading and implementing change according to a national agenda and strong analytical and communication skills, including stakeholder engagement experience.
Please contact the Australian Red Cross Blood Service before 30th January 2015 for further information international@redcrossblood.org.au.

12. EBA Agenda
The dates of the first Board meeting will be 9-10 April 2015 and it takes place in Brussels. The second meeting will be held in Berne, 24-25 September 2015. We hope to welcome you all there!
The agenda for EBA Staff and members for the coming period:

**2015**

**January**
12-13  Collaborative Procurement Manager at IBTS, Ireland
20-21  Collaborative Procurement Manager at German Red Cross Baden-Wurttemberg, Germany
28-29  Collaborative Procurement Manager at Red Cross Flanders

**March**
20-23  ABC March meeting, Washington DC

**April**
9-10   Board Meeting Brussels, hosted by Red Cross-French Speaking

**September**
24-25  Board Meeting Berne, Hosted by Swisstransfusion