Innovation in Blood Establishment Processes, Strasbourg, 2025: a Conference Report

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This report highlights the main topics discussed during the international EDQM Blood Conference on Innovation in Blood Establishment Processes, hosted by the European Directorate for the Quality of Medicines & Healthcare (EDQM) of the Council of Europe in Strasbourg, France on 14-15 January 2025. The shift from the existing European Union (EU) directives to the new Substances of Human Origin (SoHO) Regulation (EU) 2024/1938 in 2027 will allow a more unified approach across the EU. It will establish measures to set high quality and safety standards for SoHO intended for human applications, thus ensuring high levels of health protection for donors and recipients while strengthening the continuity of the supply of critical SoHO. This conference was an opportunity for participants to share and discuss experiences and innovation in blood donation and blood components. It also raised awareness of the benefits and challenges in implementing the new SoHO Regulation in the blood transfusion field.

Keywords: *blood donation, blood components, best practices, donor protection, diffusion of innovation.*

INTRODUCTION

Providing safe and adequate supplies of blood and blood components, and their optimal use, is a challenge for most blood establishments (BEs) and hospital blood banks worldwide, especially as the demand for blood components is constantly increasing. In light of questions surrounding the sustainability of current blood supply levels, innovative strategies are needed to increase them, both by strengthening donor recruitment and retention and by improving blood components and extending their shelf-life.

The primary goal of the European Directorate for the Quality of Medicines & Healthcare (EDQM) of the Council of Europe is to protect public health by developing, promoting and supporting the implementation of quality standards for medicines and health products, including for blood and blood components, to ensure the safety of patients and donors. One of the main outcomes of these blood transfusion activities, overseen by the European Committee on Blood Transfusion (CD-P-TS), is the "Guide to the preparation, use and quality assurance of blood components", also called the "Blood Guide"[1], a compendium of widely accepted, harmonised standards to fulfil safety, efficacy, quality and ethical requirements for preparing and using blood components in Europe and beyond. This technical guide is one of the formal references within the new European Union (EU)

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Substances of Human Origin (SoHO) Regulation (EU) 2024/1938 that shall apply in 2027, replacing the Directives 2002/98/EC and 2004/23/EC relating to blood, tissues and cells, which were published more than 20 years ago and no longer reflect the latest advances and technical standards in the field[2,3].

To facilitate the sharing of current knowledge among transfusion medicine stakeholders and to help them prepare for the upcoming SoHO Regulation, the EDQM hosted the International Blood Conference on Innovation in Blood Establishment Processes in Strasbourg, France, on 14-15 January 2025 ("EDQM Blood Conference", **Figure 1**). This conference brought together almost 250 participants to discuss over 11 sessions (including 3 practical workshops) new developments in blood donation and blood component preparation and how these innovations could be implemented in practice in Europe and beyond. This report highlights the main topics discussed during the conference; the full programme, speaker list (with affiliations), abstract book and presentations are available on the EDQM website[4].

DONOR RECRUITMENT AND RETENTION

The conference opened with a presentation by Hans Vrielink, who highlighted the challenges related to blood supply faced by Europe due to diverse geographical, climatic, demographic and political situations, and national BE systems across the 51 countries of the European region, 27 of which are EU member states; tailored solutions for each country's unique circumstances were thus needed to better align resources and demand and anticipate potential crises. As Johanna Castrén highlighted, one of the key challenges is the proportion of blood donors in the population: according to the latest statistics from the EDQM's annual report (to be published in 2025), this proportion is generally lower than 5.5% but varies significantly between countries. The total blood donor numbers in Europe decreased by 17% between 2013 and 2023, with only five of 23 reporting countries observing an increase. Similarly, the median proportion of blood donors in the age-appropriate population decreased from 4 to 3.4% over the same period. Furthermore, the donor population is ageing, and recruiting younger donors will be crucial to ensuring the sustainability of the blood supply, as they are typically healthier and able to donate more frequently over the long-term.

New initiatives are thus needed to support donor recruitment efforts in Europe, especially when it comes to attracting younger donors, and novel communication strategies and artificial intelligence (AI) technologies may provide innovative solutions to these challenges. An example of a successful intervention came from Türkiye (Nigar Ertuğrul Örüç), which adopted a programme called "Target 25" to mobilise young people up to 25 years of age and recruit regular donors through diverse recruitment campaigns in universities, training activities for potential future blood donors in primary and secondary schools and annual ceremonies to honour regular donors. In parallel, materials were

Figure 1 - The speakers, moderators, workshop hosts and organisers of the EDQM Blood Conference

developed and training sessions and campaigns were organised in pilot schools to increase awareness of the importance of blood donation among children and, by extension, their families. A mobile application was also developed to facilitate donations. Altogether, these interventions contributed to a rapid and gradual increase in voluntary non-remunerated blood donation from 9.2 to 31 per 1,000 population between 2008 and 2023.

In Austria, a blood-donation incentive strategy was implemented to improve donor retention. An application was developed to introduce a "gamification" concept consisting of virtual badges awarded for various donation-related activities, in addition to the more classical digital donor questionnaire and access to personal laboratory results (Norbert Niklas)[5]. The benefits of this application were streamlined processes, decreased on-site deferral rates and improved donor retention among more engaged users.

Switzerland had developed another useful digital application to help assess travel-related donor eligibility and apply deferral periods as needed, based on international monitoring of transfusion-transmitted diseases (Sandra Kurth). This tool, called "Travel-Check", could be used by both BE staff and donors and has led to simpler, more accurate and harmonised travel-related deferrals over the last five years[6].

Given the healthcare sector's increasing interest in AI, the European Blood Alliance (EBA) mapped AI initiatives in Europe among 28 European BEs from 24 countries (75% response rate) in 2024. Rodica Popa stated that only 5% of respondents were already in the planning stage for implementing AI initiatives, whereas 52% were considering AI initiatives and 24% were not considering any. This survey showed that people believed AI could be used to enhance operational efficiency, improve diagnostic accuracy, optimise resource management and reduce costs. However, its use is currently limited by challenges such as a shortage of in-house expertise, regulatory issues, poor data quality, lack of sufficient resources and decision-making barriers. Therefore, these results suggest that BEs and regulatory authorities still need to build up expertise in AI.

DONOR AND RECIPIENT PROTECTION

A robust pool of regular donors is key to maintaining an adequate and safe blood supply. However, factors such as temporary deferrals and adverse reactions influence donor retention. Betina Samuelsen Sørensen highlighted the importance of donor vigilance as part of haemovigilance; monitoring blood donation-related adverse reactions through standardised data collection across countries could improve donor availability and retention.

One of the most frequent reasons for donor deferral is haemoglobin (Hb) or ferritin blood levels. Global data suggest that frequent blood donations may reduce Hb and ferritin blood levels over time[7]. It is therefore recommended that BEs put in place measures to minimise iron depletion in frequent donors[1]. Such measures may include extending donation intervals, testing iron status or iron supplementation. Personalised approaches may be needed rather than a one-size-fits-all policy across Europe, considering the resources available to BEs and the specific characteristics of each donor population.

Katja van den Hurk addressed iron deficiency among whole blood donors by comparing different donor management strategies, such as iron supplementation or ferritin-guided donation intervals, across four European countries (England, Denmark, Finland and the Netherlands)[8]. Despite significant diversity in donor iron-management strategies, Hb blood levels were similar across the four countries and Hb-related deferral rates were low, except in England where Hb blood levels were checked but not routinely measured and supplements were not provided. This confirmed that effective iron-management strategies were essential for maintaining adequate iron and Hb blood levels in whole blood donors.

Recent research has suggested that single deferral thresholds are insufficient in preventing cumulative iron loss in donors. The impact on donation varies significantly between donors depending on genetic factors, gender, lifestyle and previous Hb and ferritin blood levels. Using data from multiple countries, Amber Meulenbeld identified different functional iron deficiency cut-offs for ferritin based on Hb changes that could be used to modify donor management strategies, thereby reducing deferral rates and increasing the donor pool. The interactive practical workshop on this topic highlighted the need for individual donor deferral thresholds and personalised

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iron-management strategies because single thresholds would not protect donors against cumulative iron loss. These strategies should be simple, cheap and safe for donors. According to the participants in the workshop, menstrual blood loss and diet were the most important elements to consider. They also highlighted the need to update the Blood Guide accordingly.

Less well recognised than with regular whole blood donation, regular plateletpheresis donation may also cause iron deficiency. Data from Australia revealed that 37% of platelet donors were iron-deficient, reaching 75% in those with 20 or more plateletpheresis collections in the previous 12 months (Joanne Pink). A plasma "rinseback" step at the end of the collection[9] was used to mitigate red-cell and lymphocyte loss during plateletpheresis. This procedure was well tolerated by donors and only added 2-3 minutes to the collection time.

Although travel-related deferrals and routine testing reduce the risk of transfusion-transmitted diseases, they may still occur, especially in the case of emerging pathogens that may not be systematically tested for. Johannes Blümel presented a surveillance system for novel viruses based on next-generation sequencing techniques and AI. After comparing the sensitivity of non-targeted metagenomics and targeted virus enrichment using the World Health Organization reference virus panel, this approach was able to efficiently identify various viruses in blood samples from Mexico. Pathogen-reduction technologies are also increasingly used for blood components, such as amotosalen and UV-A for fresh frozen plasma and platelet concentrates in France (Xavier Delabranche)[10,11]. Another example is treatment with amustaline and glutathione that is intended to replace irradiation for red blood cells (Richard Benjamin)[12]. It should be noted, however, that the high cost of these technologies, despite their importance for improving blood safety, may still limit their use.

BLOOD COMPONENTS

Technologies used to process whole blood and blood components are being continuously adapted to improve process efficiency and optimise the use of the existing blood supply while ensuring the safety of donors and recipients. Conflicts and emergencies are key drivers for developing new components or production methods and bringing old components back to the fore.

Although blood components, such as red blood cells, platelets and plasma, are generally used in standard hospital settings, logistical constraints may limit storage and access during crises or in remote settings. Accordingly, the new SoHO Regulation requires the implementation of systems ensuring blood preparedness for all types of patients in situations or areas where banked blood is unavailable or insufficient. Among the preparedness strategies explored, fresh whole blood could represent a logistically feasible alternative to blood components for trauma patients with life-threatening bleeding when traditional blood banks are unavailable (Torunn Oveland Apelseth). Walking blood banks offer an interesting alternative in both military and civilian settings. These structured systems rely on the emergency collection of whole blood from a preselected pool of available "on call" donors to treat patients with life-threatening bleeding. The feasibility of this emergency collection system was confirmed in small rural communities and local hospitals in northern Norway[13].

In addition to whole blood donations, apheresis is essential for blood transfusion therapies and manufacturing plasma-derived medicinal products. European countries rely largely on plasma imported mainly from the United States to cover immunoglobulin needs in particular[14]. It is necessary to enhance European self-sufficiency in plasma collection to reduce its dependence on external resources. One of the discussion points is the frequency of allowed donations for regular donors: the maximum permitted plasma-donation frequency per donor varies from country to country and is lower in Europe than in the United States (24-60 *vs* 104 times per year). Hans Van Remoortel presented a systematic review that assessed the impact of plasmapheresis frequency on donor safety or health, as part of the SUPPLY project[15]. The results suggested that the immunoglobulin G levels decreased in frequent donors, but the quality of existing evidence is low. The proposed outcome of this review was thus to maintain the current recommendations of a maximum of two plasma donations per month[1], pending sufficient evidence from prospective studies to confirm the safety of more frequent donations.

Another proposed potential solution for improving European self-sufficiency in plasma is to increase the volume of plasma collected per donation. Jan Hartmann

presented a nomogram personalised to a donor's total plasma volume calculated using height, weight and haematocrit level. This tool, cleared by the United States Food and Drug Administration for use in plasma collection centres, was modelled to the German donor population and donation schedule. The results suggested that this personalised nomogram could increase the total volume of plasma collected per donation by 10% without impairing donor safety, compared to the current simplified weight-based nomogram.

As frozen plasma for transfusion is often logistically impractical in certain situations (e.g., for the treatment of major haemorrhage in the pre-hospital setting), national and international plasma strategies should include civilian and military stakeholders and consider all current and anticipated plasma requirements, potentially including dried plasma stockpiles. Clear technical guidelines for producing dried plasma and their regulatory classification as a blood component rather than as a medicinal product would be helpful. Peter O'Leary presented a survey from the EBA showing that 53% of responding countries use dried plasma in various settings, including military and emergency services. Of this subset of respondents, all of them used commercially available products and 73% either did not produce or did not consider producing dried plasma in their BEs. Mike Wiltshire and Stephen Vardy showed preliminary data from a United Kingdom BE suggesting that it was possible to produce a spray-dried plasma of acceptable quality with a shelf-life greater than 12 months at 4°C.

In remote locations or cases of supply chain failure, cryopreserved and cold-stored platelets may represent interesting alternatives to fresh platelets. Thibaut Bocquet described a new simple and quick thawing method for cryopreserved platelets. Beatrice Hechler showed that cold-stored platelets, obtained from pathogen-reduced buffy coat platelet concentrates, had an activated profile and presented procoagulant activity during storage, resulting in greater haemostatic efficacy compared to platelets stored at room temperature. Cold-stored platelets could therefore have clinical and operational benefits, especially in acute bleeding patients, despite lower recovery yields that may make them unsuitable for prophylactic use. Marco Amato presented another innovative strategy for enhancing pooled platelet production: by optimising the pooling protocol of buffy coats and maximising yield and efficiency through double-dose units, platelet unit production could be increased by more than 45%, accompanied by a reduction in costs and workload. Furthermore, a novel approach using a haematology analyser equipped with the so-called "blood-bank" mode to measure residual cells in blood components was presented by Anita Siller, and its accuracy and performance was compared to conventional flow cytometry. This approach was suitable for measuring residual cell in red blood cell concentrates and plasma, but some limitations were observed when measuring residual cells in platelet concentrates[16].

THE ROLE OF THE EDQM

Early patient access to a novel SoHO that addresses unmet clinical needs or provides potentially improved safety and efficacy requires specific regulatory tools and concepts using risk-based approaches. The new SoHO Regulation aims to facilitate the authorisation of such new components. The EDQM, as a recognised expert body in the regulation, plays a central role in supporting BEs by providing technical guidelines and co-ordinating the innovations under the framework of its activities.

The Blood Guide's technical guidelines are developed based on scientific knowledge and the evaluation of the latest available scientific evidence. They also address quality and safety at all stages of the blood supply chain from collection to issuing, including testing, processing, storage and distribution. These guidelines are thus key to implementing the standards for novel components, as per the new regulation.

To train EU member states in the preparation of SoHO authorisation dossiers before the new regulation becomes effective, a "piloting GAPP model approach for assessing and authorising novel SoHO processes" (GAPP-PRO) joint action was launched to help both professionals and competent authorities (Simonetta Pupella). This approach emphasises the importance of systematic risk-benefit assessments to ensure the safety, quality and effectiveness of blood components and the submission of a clinical outcome monitoring plan that is proportionate to the risk and novelty. Such assessments should cover the entire process from donor selection

to distribution. To help BEs and healthcare professionals assess novel blood component preparations more easily, the EDQM will build upon the framework developed for tissues and cells –the EuroGTP II guide and the associated online interactive risk assessment tool[17]– to promote standard approach principles and provide support tools for stakeholders to evaluate associated risks and to determine the need for and extent of adequate clinical studies.

Because blood transfusion medicine is constantly progressing, the Blood Guide requires ongoing review and revision to remain up to date. The forthcoming 22nd edition, due to be published in spring 2025, includes a comprehensive review of all chapters, with a renewed focus on donor selection criteria, a complete revision of the chapter on haemovigilance and two new chapters on blood components for topical use or injection and blood supply emergency and contingency planning. A dedicated EDQM session provided stakeholders present at the conference with the opportunity to provide feedback on emerging trends and priorities for future editions of the Blood Guide through a live polling system. The innovations most frequently cited by participants were dried plasma, cold-stored platelets and the integration of AI (**Figures 2** and **3**). Some participants suggested including blood components with provisional agreement or components in clinical development, which may be considered for future editions.

On the other hand, it is important to recognise that some monographs will become outdated due to evolving clinical practices. For instance, non-leukodepleted red blood cells and platelets have been largely replaced by leukodepleted components as the standard of care across Europe. Approximately half of the attendees said that they would prefer these outdated monographs to remain accessible in the form of an archive (e.g., on the Blood Guide webpage), rather than having them removed completely.

Finally, to support European BEs in their day-to-day work and improve their capacity, the EDQM co-ordinates two programmes that are available free of charge to all Council of Europe member states: the Blood Proficiency Testing Scheme (B-PTS) and the Blood Quality Management (B-QM) Programmes. The B-PTS was created in 2010 and provides external quality assessment schemes to blood testing laboratories to improve the safety of blood components, plasma-derived medicinal products, organs, tissues and cells. The B-QM Programme was created in 2012 and provides on-site or virtual training and assessment schemes to help BEs and hospital blood banks

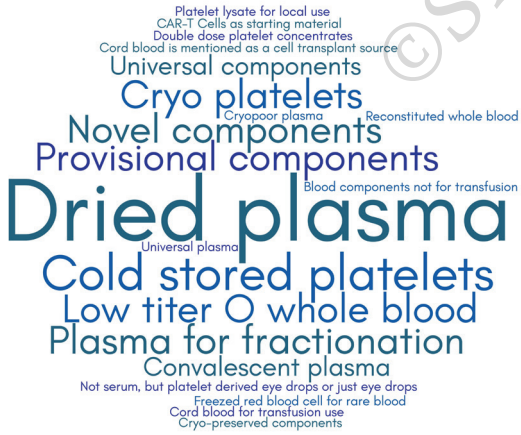

Figure 2 - Are there any monographs, currently not covered in the Blood Guide, which you would like to be included in future editions?
Responses from the attendees of the EDQM interactive workshop of the conference (No.=62) were obtained with the Slido online live polling platform and expressed as a word cloud. The size of a word/group of words represents its popularity among the responses.

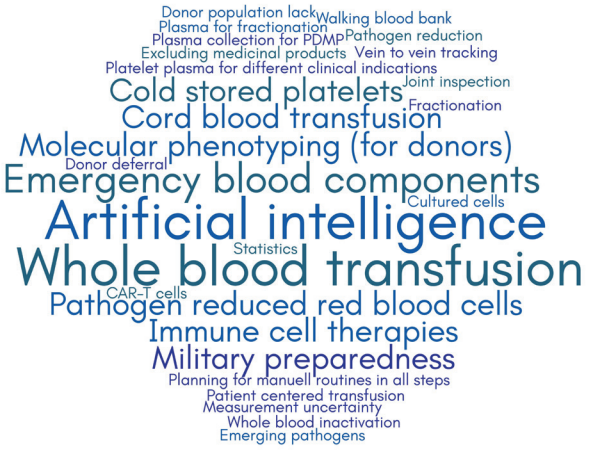

Figure 3 - Which emerging trends and innovations should be considered for the future editions of the Blood Guide?
Responses from the attendees of the EDQM interactive workshop of the conference (No.=56) were obtained with the Slido online live polling platform and expressed as a word cloud. The size of a word/group of words represents its popularity among the responses.

establish and develop a comprehensive and integrated quality management system and improve their existing systems.

CONCLUSIONS

The EDQM has a long history of providing robust, high-quality standards in the blood transfusion field and co-ordinating operational activities to support the implementation of these standards in Europe and beyond. Overseen by the CD-P-TS, its Blood Guide, which has long been recognised as a technical benchmark for EU member states, is now referenced in the new SoHO Regulation under the new "expert body" role for the EDQM. This formal reference, supported by implementation tools such as guidance, assessments and training, provides a more dynamic framework for applying technical guidelines based on up-to-date scientific evidence to foster innovations in blood donation and blood component preparation. To help BEs, professionals and competent authorities, shared EU procedures (GAPP-PRO and the EuroGTP II guide) are being implemented to assess and authorise novel SoHO products and production methods such as freeze-drying and cold storage. In this context, the EDQM Blood Conference provided a forum for participants to exchange experiences and gain new knowledge. It also raised awareness of the benefits and challenges of implementing the new SoHO Regulation, to ensure a more unified approach across the EU and beyond.

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AUTHORS' CONTRIBUTIONS

MP, AS, JH, and RF contributed to the design and content of the manuscript. JH wrote the first draft of the manuscript. All Authors made critical revisions to the manuscript and approved the final version.

CONFLICT OF INTEREST DISCLOSURES

LM is Deputy Editor of Blood Transfusion but had no role in the peer-review process or editorial decision. The other Authors declare no conflicts of interest.

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