Disponible en ligne sur ScienceDirect www.sciencedirect.com

Elsevier Masson France EM|consulte www.em-consulte.com

TRANSFUSION CLINIQUE ET BIOLOGIQUE

Transfusion Clinique et Biologique 22 (2015) 141–147

State of the art

The revision of the European blood directives: A major challenge for transfusion medicine☆

La révision des directives européennes : un enjeu majeur pour la médecine transfusionnelle

G. Folléa*, K. Aranko , on behalf of the European Blood Alliance

European Blood Alliance, Plesmanlaan 125, 1066 CX Amsterdam, The Netherlands

Available online 6 June 2015

Abstract

Aim. – Using both patient-focused and donor-focused perspectives, to review the current EU blood directives, in order to derive proposals, in principle, for what should evolve during the revision process of these directives.
Methods. – Review of the EU blood directives in the light of scientific literature, related reports from the Directorate General Health and Consumers (DG SANTÉ), and from the Council of Europe (CoE).
Results. – The analyses led us to present the main following proposals: developing voluntary unpaid donations: the directives should consider taking into consideration ethically acceptable forms of compensation consistent with altruistic donation (including plasma donations for fractionation); current expertise: more extensive utilization of the expertise of blood establishments and their consultants should be considered; donor selection: an evidence-based approach for basing donor deferral criteria on sound scientific evidence should be promoted; donor reactions: measures to prevent donor reactions and to make donations safer for the donors should also be included; quality control: The quality control requirements should relate to the Council of Europe Blood Guide specifications: these should become minimum standards (as is the case with monographs of the European Pharmacopeia), facilitating regular update of blood component lists and related specifications and compliance with the specifications; haemovigilance: because of reporting difficulties (e.g. lack of number of blood products transfused), the effectiveness of haemovigilance has so far been limited. This should lead appropriate bodies to investigate alternative or complementary ways to help improve patient safety, taking into consideration, in principle, patient blood management and the appropriate use of blood products. Furthermore, donor vigilance, which is still absent from the current directive should be included in a revised directive.
Conclusions. – These proposals for revising the current EU blood directives (if taken into account and given appropriate regulatory formulation) should help to optimize patient safety and donor care, progress the compliance with the ethical principles for donors and improve the efficiency of the healthcare systems dedicated to transfusion medicine.

Keywords: Blood; Blood components; Blood transfusion; Blood products; EU blood directives; Public healthcare; Transfusion medicine

Résumé

But. – Dans la perspective de leur révision probable, revue des directives sang UE actuelles avec des approches centrées à la fois sur le patient et le donneur, pour dégager des propositions d'évolutions.
Méthodes. – Revue des directives sang UE à la lumière de la littérature scientifique et des rapports de la Commission européenne (DG SANTÉ), et du Conseil de l'Europe (CoE).
Résultats. – Le développement du don bénévole, intégrant des formes de compensation éthiquement acceptables, y compris pour le plasma pour fractionnement, et une meilleure utilisation de l'expertise des établissements de transfusion sanguine devraient être considérés. Une approche basée sur l'évidence pour déterminer les critères de sélection des donneurs devrait être défendue, et des mesures pour prévenir les réactions

☆ This communication was made during the 27th Congress of the "Société française de transfusion sanguine" (SFTS), which took place in Montpellier, 15th–17th September 2015.

* Corresponding author. Current address (as of May 1st, 2015): Blood Consult, 1, allée des Fougères, 35760 Montgermont, France.
E-mail addresses: gilles.follea@efs.sante.fr (G. Folléa), k.aranko@europeanbloodalliance.eu (K. Aranko).

http://dx.doi.org/10.1016/j.tracli.2015.05.003
1246-7820/

indésirables chez les donneurs et rendre leurs dons plus sûrs devraient être intégrées. Les exigences du contrôle de qualité des produits sanguins labiles (PSL) devraient se référer aux spécifications du Guide du CoE, mises à jour régulièrement, qui devraient devenir des standards minimums (comme les monographies de la Pharmacopée européenne), ce qui favoriserait l'adhésion à ces règles. L'efficacité de l'hémovigilance a été limitée jusqu'ici, principalement en raison du manque de transmission de certaines données (dénominateurs). Ceci devrait conduire à envisager des voies complémentaires ou alternatives pour améliorer la sécurité des patients. De plus, la vigilance des donneurs, absentes des directives actuelles, devrait être incluse.

Conclusions. – La prise en compte de nos propositions pour une révision des directives sang, avec une formulation appropriée, devrait aider à optimiser la sécurité des patients et la santé des donneurs, à faire progresser le respect des principes éthiques du don et à améliorer l'efficience des systèmes de santé dédiés à la médecine transfusionnelle.

Mots clés : Sang ; Produits sanguins ; Produits sanguins labiles ; Transfusion sanguine ; Directives européennes du sang ; Santé publique ; Médecine transfusionnelle

1. Introduction, aim of the review

The European Union (EU) countries have transposed the four EU directives regulating blood and blood components, enforced between 2003 and 2005 [1–4]. The Directive 2002/98/EC sets standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. The Directive 2004/33/EC provides requirements on information and eligibility of donors, as well as storage, transport distribution and quality control for blood and blood components. The Directive 2005/61/CE provides requirements for traceability and notification of serious adverse reactions and events. The Directive 2005/62/CE provides requirements for community standards and specifications relating to a quality system for blood establishments. A recent transposition check performed by the European Commission (EC) has shown that the EU blood directives have been properly transposed by all the member states (MS), apart from one ongoing infringement still proceeding [5].

In relation to the EU Constitution, stating that "The responsibilities of the Member States shall include the management of health services" [6], the current EU blood directives are mainly product centered and probably not sufficiently patient centred or donor centred.

However, since the publication of these directives, a major evolution in the field has been the development of patient blood management (PBM), a patient centred, multidisciplinary approach, aiming to optimize the use of blood products [7,8], based on the re-emergence of well-known basic transfusion medicine principles. In the meantime, scientific knowledge of donor reactions and measures to improve donor safety has increased.

Ten years, after initial publication, is an appropriate and usual time to expect the revision of EU directives. In this context and perspective, the aim of this article is to review the current EU blood directives with both a greater patient and donor centred focus, in order to derive proposals, at the level of principles, for what should evolve and what should remain unchanged, in the case of such a revision.

2. Methods

The review used available data in the field from current sources: reports in scientific literature; related reports and documents from the Directorate General Health and Consumers (DG SANTÉ); related reports and documents from the Council of Europe (CoE); and current guidelines (e.g. AABB, NHSBT guidelines). The review investigated whether the requirements of the EU blood directives now accords with current knowledge and the state of the art as proposed in these reports and guidelines.

The proposed ways to improve or leave (partially) unchanged the current EU blood directives came from two European Blood Alliance (EBA) working groups (WG): the WG on voluntary non-remunerated donors (VNRD); the WG on donor selection; as well as from presentations and discussions at EBA Board meetings.

3. Results

The analyses conducted at these working groups and other meetings motivated us to present the case for the evolution of the EU blood directives since their publication, to present points of concern and proposals about the blood Directive 2002/98/EC, donor selection, vigilance requirements, quality control, quality system and to argue for joint action in relation to blood and tissues and cells.

3.1. Evolution of the EU blood directives since 2005

The legislative process for revising the current directives is usually lengthy, often requiring several years. However, an examination of the evolution of the EU blood directives reveals that in very specific circumstances, where limited revision is required, this process could be much shorter (as illustrated in both examples below).