



EBA fact sheet on Blood Donor Selection

Context

The ultimate goal of EU Blood Directives is the protection of the donors and the recipients of blood and blood components. The appropriate selection of blood donors plays an essential role in the safety of the blood products supply.

Donor selection is also a key element in the relationship between society (including prospective donors) and blood establishments, and donor selection measures can have a significant impact on the social acceptance and promotion of blood donation. Established blood donation culture is an important factor in securing safe and sustainable blood supply.

Directive 2004/33/EC established the first European-wide set of donor selection criteria. This Directive, which reflects the state of medical knowledge at the beginning of the 2000s, as well as public concerns regarding blood product safety that arose in the 1980s and 1990s, has been instrumental in improving the quality of donor selection by blood establishments throughout Europe.

However, ten years after the implementation of Directive 2004/33/EC, the experience and evidence gathered by the EBA members and the overall blood transfusion community in the EU has identified a need to revise the criteria for donor selection set out in European Union law.

Issues

Blood establishments and competent authorities have consistently reported issues in implementing Directive 2004/33/EC and national regulations on donor selection deriving from EU law^{1,2}. Those issues, which could be solved through revision of the Directives, can be summarized as follows:

- *Lack of risk based selection criteria.*

For many deferral criteria the evidence on efficacy and cost-effectiveness of selection criteria in reducing safety risks is lacking. For example:

- Efficacy: One of the key donor selection criteria, i.e. the criteria on acceptable haemoglobin levels, does not safeguard regular donors from developing iron deficiency;
- Cost-effectiveness: When expressed in costs per QALY gained³, the cost of several measures runs into the millions of euros, at the same time excluding huge numbers of candidate donors from donating.

¹ Competent Authorities on Substances of Human Origin Expert Group (CASoHO E01718) Meeting of the Competent Authorities on Blood and Blood Components 11-12 November 2015; [European Commission](#).

² Mapping of More Stringent Blood Donor Testing Requirements - Mapping Exercise 2015; Health and Food Safety (SANTE), [European Commission](#).

³ The cost per QALY (quality adjusted life year) gained is a standard health economics cost-effectiveness indicator measuring the cost incurred for one additional year of life in good health gained through a specific health policy measure. According to the WHO, health measures should be considered cost-effective when the cost-per-QALY gained is below 50 000 \$.



- *'One size doesn't fit all'.*
 - Minimum safety of blood and blood components should be set but the best means to achieve that might differ from country to country.
 - Geographical differences in epidemiology of infectious diseases are very significant⁴, while deferral criteria outlined in Directive 2004/33/EC do not vary accordingly.
 - Within supposedly homogeneous risk groups, the actual risk level varies widely, while the approach to managing these risks is the same.
 - Several improved techniques of processing of blood components (including pathogen inactivation), which significantly reduce the risk of transmission of pathogens by blood products, are not properly reflected in the risk assessment process.

- *Inflexibility.*

The Directive is rather inflexible regarding donor eligibility criteria. However, since its adoption, several risks of acquiring a transfusion-transmissible infection have evolved, either to a lower or higher level, for example:

- Endoscopy (lower risk), tattoo and body piercing (lower risk), major surgery (lower risk), travellers' borne infectious diseases (higher risk);

- *Inconsistency.*

In absolute measures comparable risks at times lead to highly variable deferral periods (see also Table 1 in Annex).

- For transfusion-transmittable infections, the length of the window period of donor screening tests should logically determine the deferral period, but in many situations this is not the case.
- Deferrals related to the use of medicinal products often lack the support of toxicological/pharmacological/pharmacokinetic reasoning;
- Risks related to both donor safety and possibly transmissible diseases, such as pre-malignancies or prion diseases show widely varying deferral periods.

Proposed solutions

The revision exercise should not only integrate medical and technical progress acquired in the last decade but go further, enabling the blood transfusion community to deal with future changes or emerging threats to blood safety without the need to revise European law.

- The acceptable risk to donors should be further defined and communicated to donors
- The acceptable risks to patients should be further defined and elaborated, eg by setting standards of acceptability [allowable/confidence range for predictive values] in identifying the true risk to an individual combined with morbidity or mortality

⁴ European Centre for Disease Prevention and Control. [Annual epidemiological report 2014 - sexually transmitted infections, including HIV and blood-borne viruses](#). Stockholm: ECDC; 2015.



- The framework Directive should refer to a dynamic and authoritative technical source allowing standards to evolve reflecting scientific advances and medical developments eg. the Guide on blood components put together by the Council of Europe;
- Further studies are needed to address both the optimal donor protection and donor selection criteria.

Principles for revision

- Revised donor selection measure should have no additional negative impact on donor, recipient and blood products safety.
- European legislation should ensure a uniform level of safety for blood donation and transfusion throughout the EU based on risk:
 - o This is different from a uniform set of rules for donor selection applied throughout the EU. Risk-based decision making should be encouraged to find the best blood safety measures, including donor selection, to reach the uniform high level of safety in each Member State or territory at a given time.
 - o EU legislation should enable to adapt the implementation of donor selection criteria to meet the changing needs and concerns over time, without lengthy revision process of EU legislation.

Furthermore revised donor selection criteria should improve the blood supply, through:

- o The reduction of the number of “undue” deferral (without a proven benefit for the safety of blood products or the safety for the donor), therefore increasing the number of potential blood donors in the general population.
- o Adaptation of donor selection rules to local context and risk assessment

EBA recommendations on blood donor selection in future European Directives:

- 1. Define general donor selection principles and default criteria in the Blood Directive:**
 - a. General principles would guide the Member States in assessing the selection criteria best fit for the Member State and default criteria would be used in case available data is insufficient to assess local/regional/national risks.
 - b. Default criteria should reflect minimal standards in preventing both donor and recipient risks. Methods for data collection in the default setting should include:
 - i. A standard health questionnaire for the default baseline criteria.
 - ii. Minimal requirements regarding physical condition and biometrics.
 - iii. Minimal requirements for laboratory testing to safeguard donor and recipient.
- 2. Validated eligibility criteria based on risk assessment**
 - a. Proposed selection criteria and methods should be validated by the blood establishments and approved by the competent authorities, leading to risk-based methods. Member States together with the blood establishments should be empowered and encouraged to carry out risk assessments to validate the best blood safety measures for the local/regional/national situation.
- 3. Reference to Council of Europe Guide for detailed deferral criteria and methods for risk assessment**



- a. The Council of Europe Guide should be referred to regarding specific deferral criteria and methods of risk assessment, thus allowing adjustments to reflect the advances of medicine and science based on the timely revisions of the Guide. This reference document could include example donor health questions and questionnaires, suggestions on laboratory tests, and scientific background information.
- b. See also EBA Fact Sheet “Establishing a formal relationship between the European Directives on blood products and the Council of Europe (COE) Guide”.

Proposed content of the general and default criteria

Only risk based criteria should be included, and should be based on the following questions:

- a. What is the safety risk for donors donating whole blood or blood components?
- b. What is the hazard of a certain transfusion transmitted infections (TTI), in terms of morbidity or mortality?
- c. What is the risk level, i.e. incidence and prevalence of transmissible infections?
- d. Is the risk concentrated in certain, identifiable groups or subgroups?
 - What are the available tools to identify risk (sub) groups, in terms of laboratory tests, questionnaires, and history taking?
- e. Is it possible to set standards of acceptability [allowable/confidence range for predictive values] in identifying the true risk in an individual and is it possible to distinguish high-risk individual behaviour from low-risk individual behaviour?
 - The risk of emerging, yet unknown TTIs can be a reason for preventive measures, such as deferral of certain groups for a certain period of time [precautionary principle].
 - The possibility of taking alternative measures to reduce risks, such as vaccines or extra product processing steps, must be taken into account.



Annex

Table 1. Comparing the risk appraisal between travellers and sexual behaviour of candidate-donors.

Issue	Travellers to or former residents from countries with prevalent TTIs	Sexual behaviour in subpopulations with risk of TTIs, such as MSM and transgenders
TTIs, known to exist for more than two decades.	Malaria Leishmaniasis Chagas' Disease AIDS (HIV)	AIDS Hepatitis B Hepatitis C Syphilis
Emerging TTIs, with a highly increased incidence and prevalence	Dengue West Nile Virus Chikungunya SARS Hanta virus Usutu virus Ebola (Q-fever) Babesia ZIKV	Over the past two decades, no new TTIs have emerged in this group. However, known TTIs remain prevalent and occasionally new epidemics show up (ZIKV is currently under debate, but appears not to be limited to this group)
Relative Risk	Depending on infectiousness and route of infection: low to high	Generally high, depending on local/regional/national incidence and prevalence
Circumstances with enhancing or mediating effects on the level of risk	<ul style="list-style-type: none"> • Travel movements and duration • Number of locations visited • Local activities (exposure) • Use of prophylactics/protection • Endemic prevalence/incidence of infectious vector 	<ul style="list-style-type: none"> • Frequency of sexual intercourses • Number of partners • Type of sexual activity • Use of prophylactics/protection • Prevalence/incidence in subpopulations
Compliance to Donor Health Questionnaire (false-negatives)	Unknown, but certainly lower than 100%	97-99% ^{5,6,7,8}
Risk of discriminating candidate-donors	Travellers: low Former residents: low to medium	Paid sex (drugs or money): low MSM/Transgenders: high

⁵ Custer B, Sheon N, Siedle-Khan B, et al. Blood donor deferral for men who have sex with men: the Blood Donation Rules Opinion Study (Blood DROPS). *Transfusion* 2015;55:2826-34.

⁶ Seed CR, Lucky TT, Waller D, Wand H, Lee JF, Wroth S, McDonald A, Pink J, Wilson DP, Keller AJ. Compliance with the current 12-month deferral for male-to-male sex in Australia. *Vox Sang.* 2014 Jan;106(1):14-22.

⁷ Goldman M, Yi QL, Ye X, Tessier L, O'Brien SF. Donor understanding and attitudes about current and potential deferral criteria for high-risk sexual behavior. *Transfusion* 2011 Aug;51(8):1829-34.

⁸ Romeijn B, van Dongen A and Kok G. Reasons for noncompliance in donor risk reporting regarding male-to-male sex. *Transfusion* 2016 July; 56(7): 1899–1906.