



Blood Donor selection - Summary

Context

The ultimate goal of EU Blood Directives is the protection of the donors and recipients of blood and blood components. The appropriate selection of blood donors plays an essential role herein. However, Directive 2004/33/EC on donor selection criteria reflects the state of medical knowledge at the beginning of the 2000s. Now, ten years after the implementation, a need to revise the criteria for donor selection set out in European Union law is identified.

Issues

- *Lack of risk based criteria:* evidence on efficacy and cost-effectiveness of selection criteria in reducing safety risks is lacking.
- *Lack of local selection criteria:* countries might differ in epidemiology, demographics and technological capacities.
- *Inflexibility:* due to its nature, the Directive is rather inflexible, while several risks in e.g. transfusion-transmissible infection have evolved.
- *Inconsistency:* comparable risks at times lead to highly variable deferral policies

EBA recommendations on blood donor selection in future European Directives

It is to be noted that revised donor selection measures should have no additional negative impact on donor, recipient and blood products safety. However, the acceptable risk to donors and patients should be further defined, elaborated and communicated and further studies should to address both the optimal donor protection and donor selection criteria.

1. Define general donor selection guiding principles and default criteria in the Blood Directive

General principles could guide Member States in assessing selection criteria best fit for themselves and default criteria would be used in case available data is insufficient to assess local/regional/national 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.

Selection criteria and methods should be validated by blood establishments and the competent authorities, leading to risk-based methods. This would empower the blood establishments to carry out risk assessments to validate the best blood safety measures for their own local situation.

2. Reference to Council of Europe Guide for detailed deferral criteria and methods for risk assessment

Flexibility should be ensured by referring to the Council of Europe's 'the Guide' regarding specific deferral criteria and methods of risk assessment. See also EBA Fact Sheet "Establishing a formal relationship between the European Directives on blood products and the Council of Europe Guide".