

Resolution CM/Res(2013)3 on sexual behaviours of blood donors that have an impact on transfusion safety

(Adopted by the Committee of Ministers on 27 March 2013
 at the 1166th meeting of the Ministers' Deputies)

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50),¹

- Considering that the aim of the Council of Europe is to achieve greater unity between its member States and this aim may be pursued, *inter alia*, by the adoption of common regulations in the health field;
- Considering the essential place for blood components and blood-derived therapeutic products in the health sector;
- Considering the inherent risks of human blood and therapeutic substances of human origin;
- Being mindful of the societal debates and legal cases in relation to blood donor deferral criteria and particularly those deferrals related to sexual behaviour;
- Expressing appreciation to donors and potential donors of blood and blood components for their altruistic efforts and for their sense of responsibility, whether they choose to donate or to appropriately abstain;
- Recalling Recommendation Rec(88)4 on the responsibilities of health authorities in the field of blood transfusion;
- Recalling Recommendation Rec(95)14 on the protection of health of donors and recipients in the area of blood transfusion;
- Having regard to the requirements set out in Recommendation Rec(95)15 on the preparation, use and quality assurance of blood components;
- Having regard to Resolution CM/Res(2008)5 of the Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia, on donor responsibility and on limitation to donation of blood and blood components, and in particular its points 3.3, 3.4, 3.7 and 4.1;
- Having regard to Directive 2004/33/EC of the European Commission, Annex III, point 2.1, that sets out permanent deferral from allogeneic blood donation for “persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood”;
- Taking into account that according to Directive 2004/33/EC, Annex III, points 2.1 and 2.2.2, a decision on permanent or temporary donor deferral depends on the distinction between “high risk of acquiring severe infectious diseases that can be transmitted by blood” and “risk of acquiring infectious diseases that may be transmitted by blood”;
- Recalling Recommendation CM/Rec(2010)5 on measures to combat discrimination on grounds of sexual orientation or gender identity;
 Recalling the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS n° 108);
- Considering that donor selection aims at preventing the transmission of infections to patients, and that decisions for donor selection should be proportionate to risk and based on epidemiological data in order to ensure sustained safety of the blood supply;
- Considering that the available epidemiological data and modelling studies,² most of which focus on human immunodeficiency virus (HIV) as it is the most studied infection in relation to transfusion risk, indicate that there is a varying risk of acquiring a transfusion-relevant infection³ and that, for some serious infections such as HIV and hepatitis B virus (HBV), this risk considerably depends on the sexual behaviour of the donor;
- Considering the forms of sexual behaviour, referred to herein as “risky sexual behaviour”,² and the persons concerned by such behaviour, and observing that, according to the epidemiological data available on the prevalence and incidence of sexually transmitted infections, persons engaging in male-to-male sexual acts and sex workers³ in many European countries are at the upper end of the risk scale for acquiring HIV and other sexually transmitted transfusion-relevant infections, with this risk classification being totally independent of sexual orientation per se;

¹ States concerned: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, “the former Yugoslav Republic of Macedonia”, Turkey and United Kingdom.

² See Appendix, point 2.

³ See definition in Appendix.

- Considering that currently available epidemiological data do not make it possible to define the precise risk of acquiring a transfusion-relevant infection with respect to donors' individual risky sexual behaviour and that there appears to be a high risk of acquiring severe transfusion-relevant infections for persons engaging in male-to-male sexual acts and sex workers;
- Considering that the impact of donations from persons engaging in male-to-male sexual acts on transfusion safety has been assessed by modelling studies, which conclude that the HIV transmission risk is expected to increase if these persons were allowed to donate and that a rapid spread of new and emerging sexually transmitted infections may be promoted by certain aspects of this particular risky sexual behaviour;
- Noting that donor deferral policies should be strictly adhered to for the collection of blood and blood components;
- Noting that despite the testing of blood donations with highly sensitive test systems, there remains a residual risk of transfusion-transmitted infection due to donations given in the period when infection is not yet detectable ("window period") or due to test failures and that this residual risk is significantly reduced by donor adherence to/compliance with deferral criteria;
- Noting, however, that adherence/compliance is not complete, as indicated by studies and by the reporting of risky sexual behaviour in post-donation interviews,

Recommends that the governments of States Parties to the Convention on the Elaboration of a European Pharmacopoeia take the following measures, having due regard to their national laws, regulations and administrative provisions and considering Directive 2004/33/EC, Annex III, points 2.1 and 2.2.2:

- 1. Adopt the following interpretations** for "permanent deferral" and "temporary deferral":
 - 1.1. Permanent deferral: Donors cannot be re-admitted for donation within the regulations in force and, thus, will be subject to lifelong deferral from blood donation.
 - 1.2. Temporary deferral: Donors can be re-admitted for donation within the regulations in force provided that the conditions defined by the donor-selection rules in force are met;
- 2. Collect, evaluate and publish epidemiological data**, as this is of utmost importance to facilitating risk analysis and making a quantitative distinction between "risk" and "high risk" and, ultimately, to guaranteeing the safety of transfusion recipients;
- 3. Decide on a temporary deferral policy for a given risky sexual behaviour only when having demonstrated that this sexual behaviour does not put the donors at high risk of acquiring severe infectious diseases that can be transmitted by blood;**
- 4. Launch and support initiatives to decrease the risk of transmission of infections to recipients of blood components by improving donor adherence to all donor-selection criteria in force by the following means:**
 - 4.1. providing appropriate educational material for use in donor recruitment, for pre-donation information (including the availability of HIV testing at sites separate from the blood establishments) and informed consent or self-deferral of donors and by presenting them with state-of-the-art media techniques;
 - 4.2. promoting the use of an optimised and standardised pre-donation donor-health questionnaire as proposed in the "Guide to the preparation, use and quality assurance of blood components" (appendix to Recommendation Rec(95)15);
 - 4.3. ensuring confidentiality during the donor-assessment procedure;
- 5. Promote standardised collection of data on risky sexual behaviour having an impact on blood donor management and transfusion safety for an internationally harmonised interpretation of related deferral criteria:**
 - 5.1. collect epidemiological data on the incidence and prevalence of sexually transmitted infections in the general population, in blood donors and among individuals with risky sexual behaviour, for use as a basis for decision making in donor-selection policy;
 - 5.2. collect data on risky sexual behaviour through standardised post-donation interviews with donors with confirmed positive screening tests for HIV, HBV, hepatitis C virus (HCV) and syphilis;
- 6. Encourage health authorities to:**
 - 6.1. support blood establishments by publically communicating the relationship between available data on the safety of the blood supply and subsequent decisions on donor-selection criteria;
 - 6.2. promote co-ordinated European discussions with interested parties and, in particular, with respect to paragraph 3.3 of Resolution CM/Res(2008)5: "guarantee that blood establishments provide prospective donors with clear and appropriate information, including ... possible risks for the recipient of blood or blood components of a given donor";
 - 6.3. envisage the establishment of quantitative assessments of risky sexual behaviour and the setting of acceptable levels of risk;
- 7. Propose to the Committee of Ministers to review this resolution**, notably in light of the experience acquired in the implementation of its recommendations, not more than five years after its adoption or sooner when given cause to by new developments, insights or data.

Appendix to Resolution CM/Res(2012)3

1. Definitions

For the purpose of this resolution, the following definitions were used:

- “transfusion-relevant infection”: an infection that can be transmitted by blood transfusion;
- “sex worker”: a person who receives money or equivalent goods/services (in particular, injectable drugs) in exchange for sexual services and, especially, penetrating sex; this is also termed “commercial sex worker” in some States;
- “risky sexual behaviour”: a sexual behaviour which puts persons at risk or at high risk of acquiring severe infectious diseases that can be transmitted by blood.

2. Technical Memorandum

This resolution is supplemented by a Technical Memorandum that summarises available data provided to and assessed by the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS).



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BILINGUE

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EUROPEAN COMMITTEE (PARTIAL AGREEMENT) ON BLOOD TRANSFUSION (CD-P-TS)

Technical Memorandum

Memorandum Technique

TS057 Risk behaviours having an impact on blood donor management
Final version
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TS057 Comportements à risque ayant un impact
sur la gestion des donneurs de sang
Version finale
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