

TERMS OF REFERENCE

OF THE SUBORDINATE AD-HOC WORKING GROUP OF THE CD-P-TS ON
RISK BEHAVIOURS HAVING AN IMPACT ON BLOOD DONOR MANAGEMENT
(TS057)

I. Background information

In many countries the exclusion criteria for blood donors especially with regard to sexual risk behaviours are being debated.

The present situation with a precautionary categorical permanent exclusion of individuals, whose behaviour places them in an epidemiological "group with higher risks of acquiring infectious diseases that are transmissible by blood", is questioned: is this kind of donor deferral rightful, appropriate, efficient and required?

Selection criteria for blood donors as laid down by national competent authorities can be based on estimates or modelling of risk for transfusion-transmitted infections (TTI) (HBV, HCV, and HIV) in the specific national epidemiological situation. Information on donation patterns and on the mode of acquisition of confirmed HBC, HCV and HIV infections in regular and applicant donors is important in such modelling.

For example, in Sweden, the National Board of Health and Welfare (NBHW) has prepared for revision of the donor selection criteria as laid down in its Codes of Statutes by modelling of risk for TTI (HBV, HCV, HIV) in the specific Swedish epidemiological situation. Information on donation patterns was obtained from the Scandinavian Donor and Transfusion Database (SCANDAT) and information on the mode of acquisition of confirmed HBC, HCV and HIV infections in regular and applicant donors was obtained by personal information from the Swedish Institute of Infectious Disease Control.

An inquiry among "Men Having Sex with Men" (MSM) distributed through local societies of the Swedish Federation of Lesbian, Gay, Bisexual and Transgender Rights (RFSL) was conducted by NBHW and the Department of Sociology at Stockholm University in 2007 and the report was considered in the context of the modelling study.

The conclusions by the NBHW on the results was that the modelling study supported a change from permanent to temporary deferral (6 months) of all individuals with "sexual risk behaviour", including MSM, given a $\geq 99\%$ acceptance of compliance with the selection criteria by all donors/by these donors at risk. The modelling showed that there is a relatively high sensitivity to acceptance levels, and in most variations, the risks were lower with a 6 months deferral period and 99% acceptance than with a lifetime deferral and 95% acceptance. The results of the inquiry among MSM led to expectations of an improved acceptance. However, even without any improved acceptance the modelling showed that the risk for TTI was very small and it was not possible to establish any clear differences between lifetime deferral and a 6 months deferral. However, there was concern whether the expected improved safety by increased acceptance and compliance will be realised.

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2 Other critical questions arose, in case Sweden would change the permanent deferral of all
3 individuals with “sexual risk behaviour”, including MSM, to a temporary one:
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- 5 a. Is this change in compliance with the Commission Directive 2004/33/EC, Annex III,
6 2.1, to 2.2.2 which requires a permanent deferral for persons with sexual risk
7 behaviour but allows a re-entry after cessation of the risk behaviour?
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9 b. Will medicinal products, produced from recovered or apherisis plasma from Sweden,
10 be accepted in other member states of the European Community if the selection
11 criteria are changed in the described manner?
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13 Beside these considerations it is commonly recognised that despite of testing of blood
14 donations with highly sensitive test systems there remains a residual risk of TTI due to
15 donations given in the window period. This residual risk can only be further minimized by
16 provision of information and educational material to prospective donors on risk behaviour that
17 might put blood recipients at risk and a careful and efficient donor selection based on a
18 validated donor questionnaire and guided by the national epidemiological situation.
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20 In the light of the information detailed above, the European Committee on Blood Transfusion
21 of the Council of Europe (CD-P-TS) decided at its last steering Committee to create a
22 subordinate ad hoc group aimed at monitoring current practices and defining a harmonised
23 approach to establishing rules for donor deferral linked to risks attributable to sexual
24 behaviour. In order to maximise the expertise of the group and to give the group a global
25 impact it was decided to involve the other regulatory bodies and scientific agencies and
26 interested parties involved in the field in Europe.
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28 Dr. Rut Norda (Dept of Clinical Immunology and Transfusion Medicine, Uppsala University
29 Hospital, Sweden), is the project leader of the ad hoc experts group on “Risk behaviours
30 having an impact on blood donor management”.
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33 ***II. Objectives and tasks of the subordinate ad-hoc working group Risk behaviours***
34 ***having an impact on blood donor management”.***
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36 The tasks of the subordinate Working Group (WG) will be:
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- 38 a) To make an inventory of existing experiences (Sweden, UK, NL, Spain, Italy,
39 Switzerland, Germany, Greece and others);
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41 b) To define the needs in terms of extra data: e.g. epidemiological data, assessment of
42 compliance to donor questionnaire, data on social and psychological factors related to risk
43 behaviour particularly among regular donors;
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45 c) To consider the impact of changes in donor’s selection criteria on the transfused patient;
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47 d) To define risk behaviour with regard to blood donation at European levels and in countries
48 with comparative circumstances in a global perspective;
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- 1 e) To formulate a text on this issue for the donor questionnaire that can be used as a uniform
2 text, to describe the interpretation in great detail of this text, including the criteria for
3 deferral and deferral time;
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- 5 f) To harmonise practices for the management of blood donor with risk-behavior
6 management;
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- 8 g) To present the material in a written form with a proposal for a harmonised approach for
9 deferral rules. It is the ambition that the text is appropriate for EDQM and the EU
10 Commission.
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12 The final outcome should be a resolution of the Council of Europe with the goal to harmonise
13 the practises with regard to blood and components for transfusion and for fractionation.
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16 ***III. Working Methods***

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18 The working group will make use of regular meetings but also e-mail communication and
19 teleconferences whenever needed.
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22 ***IV. Composition of the Working Group***

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24 In addition to European experts nominated by the European Committee on Blood Transfusion
25 of the Council of Europe (CD-P-TS), European Commission (EC), European Medicines
26 Agency (EMA), European Centre for Disease Control (ECDC), Unites States Food and Drug
27 Administration (US-FDA), World Health Organization (WHO) Blood Regulators Network,
28 and European Blood Alliance (EBA) are involved.
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31 ***V. Time frame***

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33 The working group is appointed for 2010-2011.
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35 The primary task is to submit proceedings from the group to the CD-P-TS-meeting in
36 November 2010. The proceedings will be submitted to authorities, professional bodies and
37 stakeholder organisations during 2011.
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39 The drafting of a Resolution will be started in November 2010 and submission to the
40 Committee of Ministers should take place in 2011.
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