



RISK BEHAVIOURS HAVING AN IMPACT ON BLOOD DONOR MANAGEMENT

BACKGROUND

During the November 2009 meeting of the Transfusion Committee (CD-P-TS) of the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe (CoE), the difference of opinion between the two Swedish Competent Authorities for Blood Establishments was presented concerning article 2.1, Appendix III of the Commission Directive 2004/33/EU. This difference could have consequences for the evaluation of the Plasma Master File (PMF). The European Medicines Agency (EMA) advised they would consult the CD-P-TS. An ad-hoc working group (TS057) was appointed to address the issue.

Extract from Commission Directive 2004/33/EU

2.1. Permanent deferral criteria for donors of allogeneic donations

Sexual behaviour	Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood
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2.2. Temporary deferral criteria for donors of allogeneic donations

Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood	Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests
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OBJECTIVES

The goal of the TS057 working group is to provide information and to propose a definition for an appropriate deferral period and specifications for sexual behaviour that puts persons at a high risk of acquiring severe infectious diseases that can be transmitted by blood. The proposal is intended both for the Directive 2004/33/EU (appendix III, article 2.1) and the CoE Guide to the Preparation, Use and Quality Assurance of Blood Components.

METHODS

Experts from member states (MS) and representatives from observers such as the European Commission (EC), the European Medicines Agency (EMA), the European Centre for Disease Control (ECDC), the European Blood Alliance (EBA), the US Food and Drug Administration (FDA), American Red Cross (ARC), Health Canada and the Australian Therapeutic Goods Administration (TGA) have participated in TS057 meetings. Ten (10) MS volunteered to collect national data on possible differences between regulations of blood components intended for transfusion and regulations of plasma for medicinal products and epidemiological data on the prevalence and incidence of HIV, HBV and HCV in the general population, risk groups and blood donor populations. The focus being on HIV as the most documented infection. Any published or unpublished studies on modelling, compliance and probable causes for infection were sought. Donor deferral criteria and questionnaires were collected focusing on the identification of risk behaviour.

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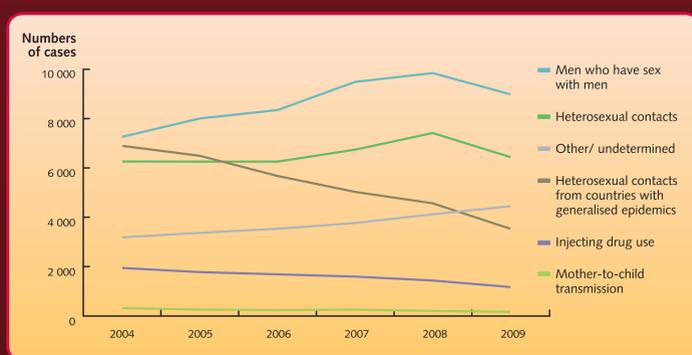
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RESULTS

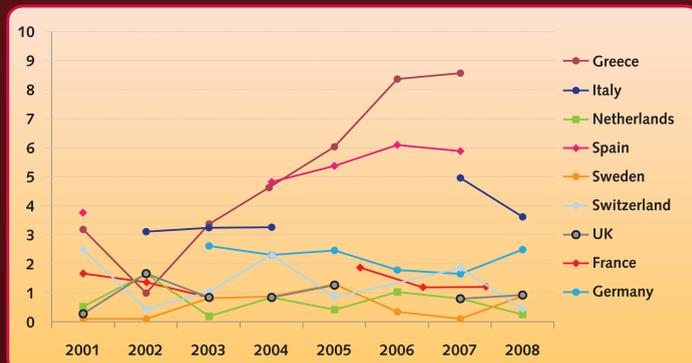
No single European body collects all the epidemiological data we requested. Eight (8) MS provided national data. Additional data from the 8 MS and 2 other MS was extracted from CoE Questionnaires and ECDC surveillance reports. Studies of modelling, compliance and reviews of donor deferral were also analysed, ie all data available up to 24 February 2011. The HIV incidence in several EU/EEA MS has increased in the general population as well as amongst donor populations. There are differences in the epidemiological situation. There are also differences in the availability of epidemiological data deemed necessary for the evaluation of donor deferral criteria. The aspect of donor compliance to the assessment procedure before blood donation was discussed and found crucial. It is not possible to make a distinction between risk and high-risk of acquiring relevant infections on an individual basis, even if Men having Sex with Men (MSM) has a higher HIV-prevalence and incidence compared to the general heterosexual population in most European countries.

HIV INFECTION BY TRANSMISSION GROUP AND ORIGIN IN EU/EEA COUNTRIES 2004 ▶ 2009



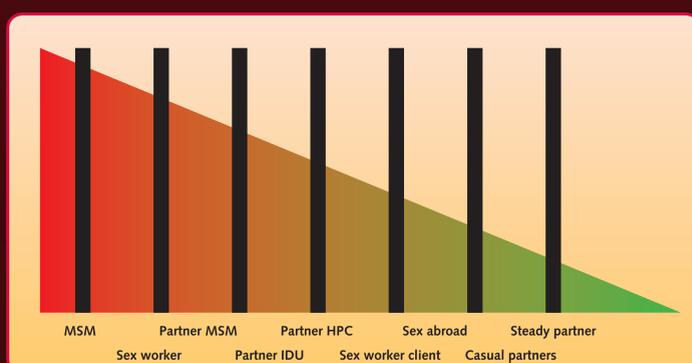
Source: ECDC/WHO. HIV/AIDS Surveillance in Europe, 2009

INCIDENCE HIV REPEAT DONOR (RD) (x 100.000)



Source: Jansen & Oyonarte, February 2011

DEFINITION, RANKING AND DEFERRAL FOR SEXUAL "HIGH RISK" BEHAVIOUR ARBITRARY IN AN INTERNATIONAL PERSPECTIVE



Source: Offergeld, February 2011

Conclusions

Evidence-based deferral time and specifications for risk behaviours as a basis for minimal requirements must be evaluated over time, as stated in the CoE Resolution CM/Res(2008)5 on donor responsibility and on limitation to donation of blood and blood components. A number of necessary measures were identified that will be formulated in the forthcoming Resolution with the background document to be presented to the stakeholders during autumn 2011.