On risk appraisal of behaviour

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The brief report by Dr den Exter discusses the ruling of the European Court of Justice (CoJ), regarding the referral of the French "Court's case on banning homosexuals permanently from donating blood"[1]. It is a good case to present, because it may help thinking on the acceptability of eligibility criteria for blood donation. The ruling is, first of all, a discourse on whether banning men having had sex with other men (MSM) from donatind blood is an act of discrimination. Essentially, the CoJ's ruling concludes that lifelong banning of MSM is indeed an act of discrimination[2].

The author appropriately states that there is no "right to donate". One could argue that there could be a "right to offer your services, for example, to offer your blood to treat patients in need". The patient on the other hand, may decline any treatment, and consequently does have the right to refuse such an offer. Subsequently, the reverse "right to refuse a donation" seems ethically justified. Blood banks, on their part, consider it to be their task to safeguard patients who receive blood products, and nobody, including the author himself, disputes the objective of the Directives to rule out risks for recipients[3,4].

Now, should blood banks be indeed labelled "evil" institutions that discriminate without thinking? Of course not. To understand how their behaviour, judged discriminatory, may have developed gradually and inadvertently, some thoughts should be given to the construction of blood banks' risk avoidance procedures.

These starts with the blood banks' concern on how to prevent cases of transfusion-transmissible infections (TTI) from coming true, given the precautionary principle[5]. The tools for preventing TTI, which blood banks have at their disposal, are laboratory tests that identify the agents themselves directly or indirectly, and questionnaires that identify groups of candidate donors who may carry these agents in case laboratory tests are absent or insufficient[7].

As a rule, laboratory tests are very accurate, their sensitivity and specificity being very high. But they are not 100% sensitive, especially in the early stages of infections, in the so-called window period[6].

The only means of preventing window period donations is to try to identify people who have a relatively high likelihood of being in such a window period. Risk appraisal takes place on a group level, meaning that blood bank staff aim at assessing whether a candidate donor is a member of a group known to carry a relatively high risk.

Examples of groups with a relatively high possibility of having a window period TTI include:

- travellers to countries or regions where certain TTI are prevalent;
- previous residents and their family from countries or regions where certain TTI are prevalent;
- people who may have had contact with blood or with blood-contaminated sharp objects, such as needles;
- people with recent sexual behaviour with a relatively high likelihood of acquiring a TTI, such as paid sex or sex for illicit drugs;
- people with sexual behaviour known or assumed to be at a relatively high risk.

  NB: an important distinction must be made between sexual behaviour, such as MSM, and sexual orientation (homosexuality, bisexuality, complicated by sexual activities of transgenders). Groups with a certain sexual orientation show a strong overlap with groups displaying corresponding sexual behaviour, but are not identical: e.g. MSM may or may not be homosexuals and vice versa.

The "gold standard questionnaire" identifying with certainty all individuals carrying a TTI, not yet detectable through laboratory testing, does not exist. Only "circumstantial evidence" is made available, creating the obligation to defer many candidate donors who do not, in fact, carry the TTI. If it is deemed reasonably certain that the candidate donor belongs to a high-risk group, the risk level of this individual is assumed to be equal to the risk level of the group. To illustrate this course of events, while comparing the group of travellers to the groups of persons having high-risk sexual behaviour, thoughts and considerations on the risk level include the following (see also Table I).

a) What is the risk level - i.e. incidence and prevalence of transmissible infections - in the group of concern? These are often countable facts that may vary on where people live, circles they move in, or locations they have travelled to. For example, the risk profile of MSM in the United Kingdom differs from that in the Netherlands, or Spain. Correspondingly, the risk for

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Table I - Comparing risk appraisal of candidate donors between travellers and those with at-risk sexual behaviour.

Issue	Travellers to or former residents of countries with a high prevalence of TTI	Sexual behaviour in subpopulations at risk of TTI, such as MSM and transgenders
TTI, known to exist for more than two decades	Malaria Leishmaniosis Chagas' disease AIDS (HIV)	AIDS (HIV) Hepatitis B Hepatitis C Syphilis
Emerging TTI, with a highly increased incidence and prevalence	Dengue West Nile virus Chikungunya SARS Hanta virus Usutu virus Ebola (Q-fever)	Over the past two decades, no new TTI have emerged in this group. However, known TTI remain prevalent and at times new epidemics occur.
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	Travel movements and duration Number of locations visited Local activities Use of condoms Endemic prevalence/incidence of infectious vector	Frequency of sexual intercourse Number of partners Sexual technique Use of condoms Prevalence/incidence in subpopulations
Compliance to Donor History Questionnaire (true positives)	Unknown, but certainly lower than 100%	98-99%
Risk of discriminating candidate donors	Travellers: low Former residents: low to medium	Paid sex (drugs or money): low MSM/transgenders: high.

TTI: transfusion-transmitted infections; MSM: men-having-had-sex-with-other-men; AIDS: acquired immuno deficiency syndrome; HIV: human immunodeficiency virus.

travellers to Country A differs from travellers to Country B[8]. In assessing the risk level, the hazard of a certain TTI, in terms of (curable) morbidity or mortality, seems less influential than the risk of acquiring a TTI, no matter which hazard they include.

b) Is the risk level (with regards to transmit infections) of a certain sexual behaviour higher than of other forms of sexual behaviour? Yes, generally speaking male-male sexual behaviour is more risky than male-female sexual behaviour, which in turn is more risky than female-female sexual behaviour. Likewise, hiking through rural areas poses a higher risk than city trips, or an uninterrupted travel through specific regions[9].

c) Is the risk equal for all MSM behaviours or all travel behaviours? No, this is not the case: it varies according to, among others, frequency, variation in contacts, technique, and protective measures. Effectiveness of protective measures has been shown to be limited or even poor. This holds for both sexual behaviour and travelling[9-10].

d) Is it possible to identify the true risk in an individual and is it possible to distinguish high-risk individual behaviour from low-risk individual behaviour? In practice, this is very difficult, since unambiguous questions are hard, if not impossible to formulate with sufficient accuracy[11-13]. Regarding sexual behaviour, to get the full picture of the risk, blood bank staff should also try to assess the (sexual) risk of a donor's (new) partner: a problematic task.

e) The risk of emerging, yet unknown, TTI has been a reason for preventive deferral for a longer period of time. It is worth noting that emerging TTI are much more prevalent in travellers than in groups with a certain sexual behaviour[14].

Risk-appraisal and subsequent measures should be transparent, consistent, and objective. Comparing risk-appraisal in travellers with that in groups with a common sexual behaviour illustrates that conclusions on eligibility and - notably - on the length of deferral periods are, at times, not consistent, while assumptions on unidentified risks divert between these two groups[15]. Objective risk assessment could avoid questionably justified distinctions, which subjective norms (including partly the precautionary principle) may unintentionally bring about[16]. On the other hand, since it is impossible to assess the true individual risk status, it is inevitable that numerous preventive, albeit false-positive, deferrals are made. The CoJ's ruling rightly points out that donors, and even more so candidate donors, deserve a fair treatment, explainable with facts, data and logic.

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