

Opinion N°123

Ethical queries and observations concerning permanent deferral from blood donation for men disclosing sexual relations on one or more occasions with another man/other men

Introduction

The Minister for Social Affairs and Health referred to the National Consultative Ethics Committee (CCNE), requesting an “opinion on the pertinence, from an ethical viewpoint, of making changes to the policy of indefinite deferral from blood donation for men disclosing sexual relations with other men.”¹

The safety of blood transfusion and the protection of patients receiving a transfusion rests on a number of biological tests and a confidential interview with a doctor, with the purpose of evaluating the risk that the prospective donor is infected, with HIV in particular.

The mandatory biological screening tests currently applicable to blood donors detect HIV infection twelve days on average after contamination. This initial twelve-day average biologically silent period during which infection is not detectable is called the “window period” for HIV infection.²

The residual risk of HIV contamination through blood transfusion is therefore contingent on donations made during the “window period” preceding the appearance of the first detectable biological markers.

As a result, over and above biological test procedures, the safety of blood donation and the protection of recipients rests on:

- donor awareness and sense of responsibility,

¹ “Sir,

Currently, there are certain restrictions on blood donation. In particular, a man disclosing sexual relations with another man is barred indefinitely from being a blood donor.

This restriction is motivated by the high incidence in this population of contamination with certain agents, HIV in particular (the human immunodeficiency virus causing AIDS), with incidence rates as much as two hundred times greater than for heterosexual populations.

While several associations are asking for this prohibition to be rescinded because they consider it to be a form of discrimination based on sexual preferences, others are strongly opposed to any such action, arguing that this would be a potential risk for the safety of blood products. The subject of allowing men who have sexual relations with other men to be blood donors is being reconsidered in several European countries and is under review by the Council of Europe.

I would appreciate receiving an Opinion from your Committee on the pertinence, from an ethical viewpoint, of making changes to this policy, based on scientific data contributed by specialised agencies (Etablissement Français du Sang and Institut de Veille Sanitaire - French Blood Donation Agency and French Institute for Public Health Surveillance) and also on an assessment of the societal issues involved in a context where public health risks, personal and social responsibilities of donors and discriminatory practices are challenged.”

² With the ELISA serological tests detecting the presence of antibodies to HIV (these are the tests used generally for diagnosing HIV contamination, apart from their use in blood donation, but since August 1st 1985 they are mandatory for blood donors) the “window period” is on average 22 to 45 days. But since July 1st 2001, blood donors are required to be tested with ELISA plus another mandatory test, the viral genomic test which searches the blood for the presence of HIV genetic material (RNA). This RNA test can reduce the window period to an average of 12 days. So, on average 12 days following sexual intercourse causing contamination, the RNA test will be positive whereas the antibody screening test will not be positive until on average the 22nd to 45th day.

- a risk evaluation through an interview with the doctor in charge of donation safety,
- criteria for donor deferral if there is a risk,
- the degree to which donor statements can be trusted.

The only factors on which the risk of the donor being in the “window period” at the time of donation can be evaluated are:

- the quality of information provided to the public so that people engaging in risky behaviour do not volunteer as blood donors,
- a climate of trust between donors and the doctor in charge of transfusion safety,
- the quality of the questionnaire, but above all of the dialogue between doctors and donors on the subject of risk behaviour.

Currently, based on the information provided by people concerning risky sexual habits or behaviours, blood donor deferrals are:

- temporary for people stating that they have only ever had heterosexual relations but have recently had unprotected heterosexual relations with one occasional partner or several,
- permanent for men disclosing that they have had, in the course of their lives, at least one sexual relationship, protected or otherwise, with another man.

It is this difference in the duration of deferral from being a blood donor — considered by some as a precaution based on scientific and medical reasons and essential to the safety of blood transfusion, but considered by others as unjustified discrimination based on sexual orientation — which is the subject of the ethical questioning set out in this Opinion³.

³ The list of personalities heard by CCNE is in Annex 1.

I. The context

Blood transfusion safety⁴ is now considered to be excellent and there has been no case of HIV contamination by blood transfusion in France for the past thirteen years⁵.

Since the purpose of blood donation is to provide medical treatment and a significant quantity of blood must be sampled to achieve this, it is the object of a large number of biological tests and of strict contraindications.

Some of the contraindications to blood donation aim to safeguard the donor's health. Others are intended to safeguard the recipient's health.

Among the regulated contraindications to blood donation intended to protect the recipient's health are those related to the risk of transmission of infection with HIV.

A. Regulatory contraindications to blood donation in France, with the aim of protecting the recipients of blood transfusion from HIV infection, as yet undetectable by biological testing, transmitted by the donor

The preliminary questionnaire before blood can be donated and an interview with the doctor in charge of transfusion broach subjects such as recent⁶ sexual behaviour which may have exposed the person concerned to the risk of viral infection, HIV infection in particular, not as yet detectable by biological testing.

1. Temporary deferrals

For people who state that they have never, throughout their lives, had any other but heterosexual relations, blood donation is deferred temporarily in the following cases:

- the person has had sexual relations with more than one partner over the last four months (multiple partners);
- the person has had unprotected sexual relations with one or more occasional partners;
- the person has had unprotected sexual relations with a new regular partner since less than two months;

⁴ The question of blood transfusion safety is a particularly important, distressing and sensitive subject in this country as a consequence of the tainted blood disaster 30 years ago.

⁵ The last HIV contamination by blood transfusion was discovered in February 2002. The 2011 Hæmovigilance Activity Report. *Agence nationale de sécurité du médicament et des produits de santé - French Agency for the Safety of Health Products*. (No further cases of HIV contamination through transfusion have been reported since.

⁶ The term "recent risk-related sexual behaviour" in this context, means the existence of recent unprotected sexual relations at risk of being contaminated by a serious disease, transmissible not only through sexual channels but also by blood. This term does not designate any particular sexual orientation, but only recent risky sexual relations.

- the sexual partner of the person has had more than one sexual partner over the last four months;
- the sexual partner of the person has seropositive status for HIV or for other sexually transmitted or blood transmitted viruses or retroviruses⁷.

In all of the above cases, temporary deferral from blood donation is for four months after the latest risky sexual encounter or after the end of the multiple-partner situation of the person concerned or of his/her partner.⁸

2. Permanent deferrals

They concern:

- on the one hand, men disclosing sexual relations on one or more occasions with another man/other men in the course of their lives;
- and on the other, persons stating that they have taken drugs or other active substances parenterally⁹ (without any medical prescription).

In either case, the deferral is indefinite regardless of when the behaviour occurred or the frequency of its occurrence¹⁰.

B. Historical data

The HIV pandemic began to spread, undetected, in Africa in the 1930s, essentially via heterosexual relationships.

It was only in 1981 that the acquired immunodeficiency syndrome (AIDS) was identified in the United States, based on clinical and epidemiological data, in young men who had unprotected sexual relations with other men.

Very soon, it was suspected that those affected had been contaminated by blood and blood-derived products and this was confirmed by the identification of HIV as the causal agent of AIDS.

As soon as HIV was discovered and identified, in June 1983, before any serological tests were available to detect the infection, the *Direction Générale de la Santé* (French public health directorate) addressed an initial circular, based on the epidemiological data available at the time, to physicians working in blood transfusion facilities. Its purpose was to prevent the transmission of HIV by excluding people from blood donation if there was a risk they could transmit the virus.

⁷ HTLV-1, Hepatitis B virus, Hepatitis C virus.

⁸ Decree, January 12th 2009, setting out criteria for the selection of blood donors. Table of contraindications. (See Annex 2).

⁹ Meaning by injection, be it intravenous, intra-arterial, intradermal, subcutaneous, or intramuscular.

¹⁰ Decree, January 12th 2009, setting out criteria for the selection of blood donors. Table of contraindications. (See Annex 2).

The circular recommended that blood donors should be screened for the presence of suspect clinical signs evocative of the presence of disease and therefore making them unsuitable for donating blood and to “*identify persons belonging to at risk populations*”, in particular “*homosexuals or bisexuals with multiple sexual partners, users of intravenously injectable drugs, and the sexual partners (male or female) of people in these categories.*”¹¹

In 1989, the *Société nationale de transfusion sanguine* (National Society for Blood Transfusion) published a monograph recommending “*that people engaging in risk behaviour, i.e. men having or having had sexual relations, even occasionally, with one male partner or several, should abstain from donating blood.*”

In 1997, the persistence of a high proportion of donations with HIV positive markers led to strict and systematic implementation of indefinite deferral for men having had on one or more occasions sexual relations with another man/other men.

In 2003, the practice of giving prior information before donation on the subject of at-risk groups was discontinued and a nation wide questionnaire issued before donation was instituted, with confirmation of the indefinite deferral system.

In 2006, the questionnaire and its use were included by decree in the regulations of the Code of Public Health. The decree included a provision that persons wishing to be donors “*must state that all the information they have provided is, to the best of their knowledge, correct, as testified by their signature on the section of the questionnaire set aside for that purpose.*”¹²

In that same year, 2006, the French Blood Donation Agency (*Etablissement français du sang - EFS*), following a request from several associations, considered replacing the indefinite deferral by a temporary 5-year deferral after the last male-to-male sexual intercourse, with reference to a European Commission Directive dated March 22nd 2004¹³.

But, most ambiguously, the “*deferral criteria*” listed in this European Directive “*for donors of [whole] blood*” with respect to their “*sexual behaviour*”, are identical for temporary deferral and permanent deferral.

The Directive lists among the “*criteria for temporary deferral*”, persons “*whose sexual behaviour or activity places them at risk of acquiring severe infectious diseases that may be transmitted by blood.*”¹⁴

¹¹ Circular DGS/3B n° 569.

¹² Decree n° 2006-99 of February 1st 2006 modifying the Code of Public Health (regulations) referring to the French Blood Donation and Hæmovigilance Agency.

¹³ Directive 2004/33/CE European Commission, March 22nd 2004 for the implementation of the European Parliament and Council directive 2002/98/CE concerning certain technical requirements regarding blood and blood components.

¹⁴ “*Duration of deferral period: defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests*”
Annex III, 2.2.2 European Commission Directive 2004/33/CE.

And for “*criteria for permanent deferral*”, it uses almost identical wording: “*Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood.*”¹⁵

A 2013 resolution of Council of Ministers of the Council of Europe attempted to clarify this ambiguity. It quoted, in modified form, the deferral criteria of the European Commission, specifying that the criterion for decision on “*permanent donor deferral (a lifelong deferral from blood donation)*” or a “*temporary donor deferral*” is the gravity of the risk of transmission and the severity of the infectious diseases that could be transmitted by the transfusion.¹⁶

In September 2006 and again in December 2007, the French Government considered the possibility of changing the permanent blood donation deferral for men having had sexual relations with men into a temporary deferral. However, the permanent donor deferral remained in effect.

And the Decree dated January 12th 2009 confirmed “*the permanent blood donor deferral for men having had sexual relations with a man*”¹⁷.

C. Recent epidemiological data

Reliable data is now available in France, in particular since the entry into force in 2003 of mandatory anonymous reporting of positive HIV serological test results.

Models based on this data can predict:

- the *prevalence* of HIV infection in France, i.e. the number of persons infected by HIV,
- and the *incidence* of HIV infection, i.e. the number of persons infected each year (the number of cases annually).

¹⁵ Annexe III, 2.1 European Commission Directive 2004/33/CE.

¹⁶ “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”. (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

¹⁷Annex II-B Decree January 12th 2009 (See Annex 2).

1. The prevalence of HIV infection in France

Based on anonymised mandatory reports, the estimation is that 128,000 people have been diagnosed with HIV infection.

Studies based on models suggest that 30,000 more people are infected but are not aware of the fact as they have never been serologically tested for HIV¹⁸.

There would therefore be a total of 158,000 people infected with HIV in France, which would correspond to a prevalence of 0.24% of the population as a whole, i.e. on average 2-3 people in every 1,000.

Models were made to evaluate prevalence in various subgroups of people at different levels of risk for HIV infection, although at this stage of the modelling process these groups are still very heterogeneous.

The models involve the extensive use of approximation and extrapolation:

- an estimate of the number of anonymised mandatory reports that were not returned, and imputations for missing and incomplete data in partially filled anonymised mandatory reports;
- an estimate of infection prevalence in various at-risk groups — by relating the number of infected persons distributed in these various groups to the total number of people aged 18 to 69 belonging to various groups in France. The numbers are estimated on the basis of the national 2008 INSEE census and on a nation-wide enquiry in 2006 on sexual behaviour in France¹⁹;
- an extrapolation of infection prevalence in the various at-risk groups for the 30,000 persons who are thought to be infected with HIV but have not been serologically tested.

These models would lead to estimating that, on average, HIV infection prevalence is:

- 3% for men who had sexual relations with another man or other men in the last 12 months,
- 0.3% for women and men who have never experienced any but heterosexual intercourse throughout their lives and who come from countries where HIV infection prevalence is high (and where the predominant forms of transmitting the infection are via heterosexual intercourse);
- and 0.03% for women and men born in France and who have never experienced any but heterosexual intercourse throughout their lives²⁰.

¹⁸ Cazein F. *et al.* Prevalence and characteristics of individuals with undiagnosed HIV infection in France. Evidence from a survey on hepatitis B and C seroprevalence. *J. Acquir. Immune Defic. Syndr.* 2012, 60: e 114

¹⁹ Bajos N, Bozon M, Beltzer N. *Enquête sur la sexualité en France: pratiques, genre et santé.* Paris, La Découverte, 2008.

²⁰ Information provided by D. Costagliola, heard by CCNE. The estimates for the number of people in each of the various groups, out of a population of nearly 41,000,000 people aged 18 to 69 in France in 2008, on which this incidence data is based, are respectively: 330,000 men having had sex with another man or men in the last 12 months; 81,000 users of injectable drugs; 3,500,000 women and men having had no other but heterosexual intercourse throughout their lives and coming from a country where HIV infection prevalence is high; and 37 million women and men born in France and having had throughout their lives none but heterosexual relations.

It should be noted that these estimates of the prevalence of infection with HIV does not concern the entire group of men stating that they have experienced in the course of their lives at least one sexual relation with another man. They are for a subgroup of men who had sexual intercourse with another man or other men over the past twelve months²¹.

Other studies were made of men reporting unprotected sexual relations with men, with a high risk of HIV infection, with multiple and often anonymous partners. Some of these enquiries²² estimated that such practices were associated with, in 2011, prevalence ranging from 13% to 17%, a figure 40 times higher than those for the same enquiries for the population as a whole (0.37%)²³

The 2013 resolution by the Committee of Ministers of the Council of Europe on sexual behaviours of blood donors that have an impact on transfusion safety states “*that persons engaging in male-to-male sexual acts and sex workers in many European countries are at the upper end of the risk scale for acquiring HIV*”²⁴.” But there is no data in France on the prevalence of infection in prostitutes and sex workers or persons having frequent unprotected heterosexual intercourse with multiple partners.

In total, evaluations of the prevalence of HIV infection vary widely depending on the stratification adopted by researchers for persons in the various at-risk subgroups, in particular as a result of the information collected on sexual behaviours or of the regions of origin of those concerned.

As regards the risk of transmitting HIV infection via blood donation, however, the essential item of data (which constitutes the direct cause of transfusion contamination risk, called the residual risk²⁵) is not the prevalence of HIV infection — that is the proportion of persons who are currently infected — but the incidence of HIV infection, that is the number of new cases of infection during the year, and therefore the probability that a person offering to donate blood has been contaminated very recently.

This is due to the fact that biological testing at the time when blood is donated cannot detect the existence of a very recent infection in the past two weeks on average

(Le Vu S. *et al.* Population-based HIV-1 incidence in France, 2003-08 : a modelling analysis. *The Lancet Infectious Diseases*, 2010, 10:682-7).

²¹ The number of men stating that they had sex at least once in the course of their lives with another man (and who were permanently deferred from giving blood) is estimated at 1,320,000. No models were made for this group estimating the prevalence of infection with HIV.

²² Communicated by J. Pillonel, heard by CCNE.

²³ The risk of HIV contamination also varies with the type of unprotected sexual relations: on average it is 10 to 20 times greater for unprotected genito-anal relations than for genito-oral or genito-vaginal relations. (P-M. Girard, C. Katlama, G. Pialoux. : *VIH, 1 vol.* Doin Éd. Paris 2003, 6ème édition, p. 46).

²⁴ Resolution CM / Res(2013)3 on sexual behaviours of blood donors that have an impact on transfusion safety (adopted by the Committee of Ministers of the Council of Europe on 27 March 2013).

²⁵ The residual risk is evaluated on the basis of two criteria: the duration of the biologically silent window (12 days on average for HIV) on the one hand, and incidence on the other hand.

preceding donation since this is the time corresponding to the “window period” of HIV infection.

2. Incidence of infection with HIV in France

Based on the mandatory anonymised notifiable disease reports of positive serology diagnoses (from which the date of infection cannot be calculated), models can be constructed after a certain time has elapsed to estimate the incidence of HIV infection.

Average incidence has been evaluated as 6,940 (between 6,200 and 7,690) persons infected in 2008, which would correspond to an incidence of 0.017% in the population as a whole.²⁶

There were also evaluations of the incidence in various subgroups with different risks of HIV infection.

Just like those concerning prevalence, the models involve the extensive use of approximation and extrapolation:

- an estimate of the number of anonymised mandatory reports that were not returned (approximately 30%) and imputations for missing and incomplete data in partially filled anonymised mandatory reports (approximately 30%);
- an estimate — based on an algorithm for the interpretation of the results of an enzyme immunoassay (EIA-RI) on a drop of serum sampled when diagnosing the infection — for recent HIV infection (occurring less than a year ago);
- an estimate of the incidence of infection in various groups of people (including the 30,000 persons that are thought to be HIV infected but who have not undergone any serological diagnostic testing) by relating the number of people infected over the year to the total number of people aged 18 to 69 belonging to these various groups in France, estimated using INSEE’s national census in 2008 on sexual behaviours in France²⁷. *“Calculation of the rate of incidence requires, as a denominator, a precise estimate of the size of the various at-risk subpopulations. Potential social stigmatisation of behaviours such as male-to-male sex or drug consumption may lead to under completion of enquiry questionnaires. As a consequence, the use of national behavioural data to extrapolate these behaviours to the total population could have led to*

²⁶ The models lead to estimating that global incidence has diminished between 2003 and 2005, ranging from 8,900 new cases of infection estimated in 2003, to 6,900 new cases estimated in the same way in 2008. Le Vu S. *et al.* Population-based HIV-1 incidence in France, 2003-08: a modelling analysis. *The Lancet Infectious Diseases*, 2010, 10:682-7. Le Vu S. *et al.* Incidence de l’infection par le VIH en France, 2003-2008. *BEH* 30 November 2010, 45-46: 473-6.

²⁷ Bajos N, Bozon M, Beltzer N. *Enquête sur la sexualité en France: pratiques, genre et santé.* (Inquiry on sexuality in France, practices, types and health). Paris, La Découverte, 2008.

underestimating the size of at-risk populations and therefore to an overestimation of the incidence rates."²⁸

Among the persons who may have been infected in France in 2008, it would appear that:

- 48% are men who had sex with other men in the past twelve months,
- 28% are women and men born in France who had no other but heterosexual relations,
- 23% are women and men who never had other than heterosexual relations and are from countries where HIV infection prevalence is significant (and where predominant transmission modes are heterosexual relations)²⁹,
- 1% are users of injectable drugs³⁰.

This work suggests evaluating the incidence of HIV infection in 2008, on average, as:

- 1% for men who have had sex with other men in the past twelve months,
- 0.08% for injectable drug users,
- 0.04% for women and men who have never had other than heterosexual relations and are from countries where HIV infection prevalence is significant,
- 0.005% for women and men born in France and who have never had other than heterosexual relations³¹.

These estimations (which should be taken as orders of magnitude and not as precise figures) therefore arrive at an incidence of HIV infection 200 times greater for men who had sexual relations with other men in the past twelve months than that of persons born in France who had exclusively heterosexual relations.

Moreover, these estimations suggest that the incidence of HIV infection has not diminished in the years 2003 to 2008 among the population of men who had sexual relations with other men over the past twelve months.

Incidence might well have even increased for young men, aged 18 to 25 — who had unprotected sexual relations with multiple other male partners, frequently anonymously — for whom the progression of HIV infection transmission is currently unchecked.

This is a clear failure of the prevention policy³² which led to considering antiretroviral treatment (using Truvada®) preventively (pre-exposure) for sexual behaviour with a significant risk of HIV infection³³.

²⁸ Le Vu S. *et al.* Incidence de l'infection par le VIH en France, 2003-2008. (Incidence of HIV infection in France, 2003-2008) *BEH* 30 November 2010, 45-46: 473-6.

²⁹ Two thirds of this population are from sub-Saharan African countries where the prevalence of HIV infection is very high.

³⁰ The major health problem for intravenous drug users is infection with the Hepatitis C virus.

³¹ S. Le Vu *et al.* Population-based HIV-1 incidence in France, 2003-08: a modelling analysis. *The Lancet Infectious Diseases*, 2010, 10:682-7. Le Vu S. *et al.* Incidence de l'infection par le VIH en France, 2003-2008. *BEH* 30 November 2010, 45-46: 473-6.

³² A. Giami. *La prévention bio-médicale est une prévention comportementale*, www.vih.org 13/10/2010. (Biomedical prevention is behavioural).

³³ This preventive treatment was approved in 2012 in the United States, by the Food and Drug Administration (FDA) and has recently been the subject in France and in the United Kingdom of the ANRS/Ipergay, NHS/Proud clinical trials, presented at the 22nd *Conference on Retroviruses and Opportunistic Infections (CROI)*, Seattle, USA, 23-26 February 2015.

It should be noted, however, that in this context, as in prevalence estimations, the estimated incidence does not concern all the men who declared that they had sexual relations with another man at least once over the course of their lives, but rather a subgroup — that of men who in the course of the past twelve months had sexual relations with other men.

3. Incidence of HIV infection in regular blood donors having declared that they had had no risky behaviour exposing them to HIV infection.

No case of HIV contamination by transfusion has been reported since February 2002³⁴.

As regard the prevalence of infection in new blood donors having declared no risky behaviour constituting a contraindication to blood donation, there were, for example, in 2010, out of the 368,000 new donors, 18 donors for whom biological tests revealed at the time of donation that they were in fact HIV positive, which corresponds to 0.005% of new donors³⁵.

This prevalence is 50 times less than prevalence in the population as a whole, which shows that the overwhelming majority of people who engage in risky behaviour decide not to volunteer for blood donation.

As regards the incidence of infection with HIV in regular blood donors³⁶, studies covering three periods of three years each (2006-2008³⁷, 2008-2010³⁸ and 2009-2011³⁹, with the latter two periods partially overlapping), show that — among regular blood donors up to then HIV negative for each of their donations, and declaring that they had not had risky behaviours constituting contraindication for donating blood — a very small number are contaminated with HIV every year, as evidenced by biological tests carried out at the time of their latest donation (which was therefore not used for transfusion).

In each of the three periods under study, the number of regular blood donors who had become infected with HIV (i.e. the so-called “incident cases”) was, on average, ten donors per year.

In the enquiries after donation, it was found that about half of these regular donors were men and women who had stated that they had never had any but heterosexual relations and had had no recent risky sexual encounters.

³⁴ <http://www.ansm.sante.fr/S-informer/Presse-Communiqués-Points-presse/Cas-de-contamination-post-transfusionnelle-par-le-VIH>

³⁵ See Annex 5.

³⁶ In this case, these are not models aiming to estimate incidence, but actual measures of incidence.

³⁷ Pillonel J. , Bousquet V, Pelletier B, Semaille C, Velter A, Saura C, Desenclos JC, Danic B. Deferral from donating blood of men who have sex with men: impact on the risk of HIV transmission by transfusion. *Abstract. XVIII International AIDS conference*, Vienna, July, 18-23, 2010.

³⁸ Pillonel J., V. Héraud-Bousquet, B. Pelletier, C. Semaille, A. Velter, C. Saura, J-C. Désenclos; B. Danic. Deferral from donating blood for men who have sex with men: impact on the risk of HIV transmission in France between 2008 and 2010. *Bull. Épidém. Hebd.* 2012, 23 October, n° 39-40

³⁹ Communicated by J. Pillonel, S. Le Vu et C. Saura at a hearing held by CCNE.

The other half of these regular donors were men stating initially that they had never had any other but heterosexual relations and had not engaged in any recent risky sexual behaviour, but who, when consulting a doctor after the tests revealed that they were HIV positive, stated that they had in fact had sexual relations with men⁴⁰.

It is worth noting that this data involves only a tiny proportion of regular blood donors. As it turns out, the incidence of HIV infection in regular blood donors is close to 0.0007%, i.e. some 24 times less than in the general population⁴¹.

However, the unease generated by these studies is not connected to the extremely low level of incidence but rather to the fact that they reveal that certain regular blood donors are making inaccurate statements concerning risky sexual behaviours which are currently contraindications for blood donation.

As it happens, in all of these cases, the HIV positive status of these regular blood donors was detected by biological tests at the time of their latest donation. But if one of these donors had come at a time when he or she had been newly infected in the last two weeks, and was in the “biologically silent window” of infection, these inaccurate statements would have given rise to an almost inescapable risk of contamination by the recipient of the blood transfusion.

This emphasises the importance of achieving an even greater degree of awareness in donors as regards the risk they may be representing for patients receiving transfusion.

D. Models aiming to evaluate the residual risk of transmission of HIV infection through blood transfusion

1. An estimation of the current residual risk

Some modelling work has been done based on the incidence for regular blood donors.

These studies attempt to estimate the probability that blood donors (who were not infected with HIV at the time of their latest donation) might volunteer for a new

⁴⁰ So that over the 2009 to 2011 period, 33 donors were involved, of which 27 men and 6 women, (the latter having been contaminated by heterosexual relations.) Among the 27 men, 14 stated that they had had sex with other men but only said so when consulting a doctor after biological tests had evidenced the infection; for the 10 remaining men, the mode of contamination was probably heterosexual and for 3 of them, it was unknown. After multiple imputation to account for missing data, the estimated number of men having had sex with other men and who did not say so before further donations was 16 (48%) and the number of people contaminated by heterosexual relations and who did not declare risky behaviour (or who did not know they were at risk) was 17 (11 men and 6 women). (Information given by Dr. C. Saura, Institut National de Veille Sanitaire). Over these three periods of time (2006-2008, 2008-2010 and 2009-2011) no instances were found of contamination through intravenous drug use.

⁴¹ To give an example, in 2011 there were 1,725,495 blood donors (of which 51% were women): 365,593 of them were new blood donors and 1,359,902 were regular donors (Etablissement Français du Sang. 2011 Activity Report). Extrapolating the data for the years 2006-2011 for the incidence of HIV infection in regular blood donors (i.e. an incidence of about ten new cases of infection per year for some 1,360,000 regular donors), the incidence of HIV infection in regular donors can be estimated as being 0.0007% in 2011.

donation at a time when they had been newly infected with HIV in the two weeks preceding donation (at a time when biological tests cannot yet reveal contamination)⁴².

In relation to the total number of donors⁴³, the risk of a contaminated donation, as evaluated for the period 2009 to 2011, was evaluated as one contaminated donation in two and a half million blood donations⁴⁴.

2. An estimation of the residual risk in the event of replacing permanent deferral with temporary deferral for risky sexual behaviour

The authors of these models tried to estimate the impact of changing the current permanent deferral from blood donation for men disclosing sexual relations with one man or several other men into a temporary deferral as long as existed recent risky sexual behaviour⁴⁵.

These models suggest that a modification in the current rule — it being replaced with a temporary deferral from blood donation applicable only to men disclosing they had had in the twelve months preceding donation, sexual relations with other men in a multiple partner situation — would give rise to a residual risk of HIV transmission through transfusion varying from no modification compared to the current situation

⁴² This cannot be estimated currently for new blood donors since the incidence of infection in new donors is not known. There are about 300,000 to 400,000 new donors per year compensating for a similar number of old donors dropping out (the total number of donors is fairly constant in recent years).

⁴³ In 2013, 3,204,883 labile blood products (LBPs) were used for transfusion. These LBPs were obtained from 2,854,874 donations sampled from 1,642,600 donors (on average, 1.7 donations per donor per year). These products were transfused to 538,159 patients in 2013. Each patient received an average of 6 LBPs. (Agence nationale de sécurité du médicament et des produits de santé (ANSM). *Rapport d'activité hémovigilance 2013*, September 2014). http://www.ansm.sante.fr/var/ansm_site/storage/original/application/8a2c3c478172fcfbc027742aed130adf.pdf

⁴⁴ Since there are between 1,650,000 and 1,750,000 donors every year and the risk of a contaminating donation was evaluated as one out of every 2,500,000 blood donations, the probability that a recipient receives a contaminated donation is currently about one case every two years, on average. The fact, therefore, that there has been no case of HIV contamination via transfusion in the last 13 years is rather more of a happy surprise than statistical data reflecting in the long term the degree of safety of blood donation. An alternative possibility is that the absence of any transmission of HIV infection from transfusion in the last twelve years reflects, statistically speaking, the current risk: in other words, that the estimation of the current risk of one contaminating donation out of 2,500,000 blood donations is overstated and that the risk is in fact less than one contaminating donation out of 20,000,000 blood donations.

⁴⁵ When considering only the male donors having disclosed sexual relations with another man or several men, the risk of a contaminating donation was estimated at between one donation out of every 42,000 and one out of every 115,000 depending on the chosen level of incidence. The models show that if all the men who have had any sexual relations with other men were to abstain from offering to donate blood, the risk of HIV transmission through transfusion would then be one contaminating donation out of every 4,600,000 blood donations collected. (Information provided by Dr. C. Saura, Institut National de Veille Sanitaire). But it should be noted that to achieve this same risk of one contaminating donation out of every 4,600,000 donations collected, it would be sufficient for men who have had recent unprotected sexual relations with one or several men to abstain from offering to donate blood.

(one contaminating donation out of every 2,500,000 blood donations), to multiplying the risk by 3.5 (one contaminating donation out of every 700,000 blood donations)⁴⁶.

These models should help to evaluate the impact of modifying the strategy for deferrals⁴⁷.

And yet, these models are difficult to interpret for at least two reasons:

- on the one hand, they are based on extrapolation from very small numbers which deprives them of statistical robustness and makes their results very unreliable;
- on the other, they only consider data on the incidence of infection in men who state that they had in the course of their lives, protected or unprotected sexual relations with one man or several other men. They therefore do not enter an essential factor, the accuracy or inaccuracy of statements by blood donors concerning their recent risky sexual behaviour.

⁴⁶ Information provided by Dr C. Saura, Institut national de veille sanitaire. This recent epidemiological work is presented in Annexes 3, 4, and 5 below.

⁴⁷ European Directorate for the Quality of Medicines & HealthCare. *European Committee on Blood Transfusion*. PA/PH/TS (11) 28R Strasbourg, December 2011, p18-31.

E. The debate in France: various positions adopted by associations, health care providers and society

The issue of retaining the permanent deferral from blood donation for all men who have stated that in the course of their lifetime they had sexual relations with another man or several other men, or of replacing this rule with a temporary deferral based on recent risky sexual behaviour, is the subject of debate between various associations, within the health caring community and in society.

For example, the Federation of LGBT associations (associations defending the rights of people who are lesbian, gay, bisexual and transgender) and certain associations concerned with fighting AIDS, Act Up among others, consider that the permanent deferral rule is a case of downright discrimination and claim the “*right to blood donation for everyone*”.

Other associations, AIDES among them, advocate caution when they say that “*blood donation should not be used to demonstrate equality of rights*”⁴⁸. These associations are worried about a possible aggravation of homophobic reactions in France if a case were to arise of patient contamination through transfusion using blood donated by a man who had disclosed sexual relations with other men.

The French Federation for voluntary blood donation⁴⁹ and the French Association of Haemophiliacs⁵⁰ consider that in view of the conclusions arrived at by national and international studies, permanent deferral should remain the rule for medical reasons.

As regards members of the medical professions, a survey in 2012 showed that two thirds of responders were in favour of keeping to permanent deferral from blood donation for men disclosing sexual relations with other men, while one third wanted the permanent deferral rule to be overturned⁵¹.

On the contrary, a general population opinion poll in 2009 showed that 75% of French people thought that permanent deferral was unjustified⁵².

Certain decision makers working in blood transfusion share this opinion and would not object to turning permanent deferral into temporary deferral. They argue that this permanent deferral rule has a negative impact on the way in which EFS (Etablissement français du sang) is regarded by some members of the public, younger people in particular who see it as homophobic.

⁴⁸ Contributed by Bruno Spire, President of the Aides Association.

⁴⁹ Contributed by Michel Monsellier, 1st Vice-president of the *Fédération française pour le don de sang bénévole* (French Federation for voluntary blood donation).

⁵⁰ Press release in September 2013 by the *Association française des hémophiles*:
<http://www.afh.asso.fr/Rapport-Veran-ou-comment-faire-fi>

⁵¹ Internet poll of 829 members of the medical professions between June 29 and July 10, 2012 (Site of *Journal of International Medicine (JIM)*, 11th July 2012).

⁵² BVA opinion poll on June 10, 2009.

The current situation seems to be uncomfortable for some of the doctors who interview candidates when blood donor campaigns are organised, since they have to exclude some of the volunteers even if they are men who state that their sexual relations with other men were very sporadic and took place a long time ago.

In 2013, a report by Olivier Véran, a member of the French parliament, titled *La Filière du sang en France* (Blood Donation in France) recommended that “*The safety of blood donation should be reinforced by focusing the questionnaire away from the donor’s sexual orientation and more in the direction of the donor’s individual risk level.*”⁵³

F. The situation in other countries

In Europe, 10 of the 28 member countries of the European Union — Sweden, the United Kingdom, Spain, Portugal, Italy, Finland, Poland, Hungary, the Czech Republic and Latvia — have adopted a temporary deferral rule for men disclosing sexual relations with other men, depending on how long ago the risky sexual behaviour happened. For the other countries in the European Union, deferral is permanent.

In Italy (since 2001)⁵⁴, in Spain (since the end of the 1990s) and in Poland, temporary deferral conditions are identical for risky behaviour in men disclosing sexual relations with one man or several men and for risky behaviour in both men and women stating that they had only heterosexual relations.

⁵³ “*The altruistic and disinterested nature of a donation does not guarantee that it is a safe donation, insofar as donors may be ignorant of their serological status. Certain populations do present a risk; it is a fact for example that HIV prevalence is higher in male homosexuals than in heterosexuals. But it is a mistake to focus entirely on sexuality since the risk could be due to risky sexual behaviour, regardless of sexual orientation. In the case of heterosexual donors, the questionnaire seeks to identify risky behaviours. For male homosexuals, the questionnaire comes to an immediate halt. A homosexual in a stable relationship, who has had no risky relations in a time frame when virological screening is effective, may perceive his exclusion as discriminatory.*

[...] *The mission is not required to adopt a position on a specific revision of all eviction criteria, but does call for an alternative to the status quo. Avoid confrontation or moral indignation. To neutralise all the moral tension and abuse, the questionnaire should be pared down to keep only health considerations which are not subject to interpretation. Now nearly thirty years after the contaminated blood crisis, people are ready to accept objective and strict criteria, in the knowledge that the sole objective must be the best possible safety for recipients without any risk to donors. The mission recommends that there should be no further delay in taking necessary decisions.*” Hence, ‘*Recommendation N° 5: ‘The safety of blood donation should be reinforced by focusing the questionnaire away from the donor’s sexual orientation and more in the direction of the donor’s individual risk level.’* Report by Olivier Véran, *La Filière du sang en France*, July 17, 2013, pp 35-36: http://www.sante.gouv.fr/IMG/pdf/Rapport_Veran_filiere-sang.pdf

⁵⁴ “...the change in legislation which occurred in the course of proceedings before the European Court of Human Rights also allowed the latter to avoid carrying out a review as to whether excluding homosexuals from giving blood is compatible with the ECHR: see *Eur. Court H.R., Tosto v Italy of 15 October 2002, Application No 49821/99*”. Conclusions of the Advocate General of the European Court of Justice delivered on 17 July 2014 in Case C-528/13, *Geoffrey Leger v Ministre des Affaires sociales et de la Santé and Etablissement français du sang*, note 59 : <http://curia.europa.eu/juris/document/document.jsf?text=&docid=155166&pageIndex=0&doclang=FR&mode=req&dir=&occ=first&part=1&cid=243422>).

In Italy, temporary deferral is ruled at four months after a change in partner or after cessation of multiple sexual partnerships. In Spain, temporary deferral is for six months after a change of partner and for one year after ending multiple partnerships when there has been more than one sexual partner over the last twelve months.

In the United Kingdom (since 2011), in Sweden (since 2012), in Finland, in Slovakia and in Hungary, temporary deferral is one year after the last male-to-male sexual relation, for men disclosing sexual relations with another man or several men⁵⁵.

In Latvia, the length of time applicable for deferral is not fixed *a priori*; it is set by the doctor when interviewing the donor based on a case by case appreciation of the risk of still undetectable HIV infection in the person concerned.

Outside the European Union, eight countries — Canada, Australia, New Zealand, Japan, Brazil, Argentina, Russia and South Africa — have adopted temporary deferral for men disclosing sexual relations with other men.

In Russia, temporary deferral is identical for risky behaviour in men who had sexual relations with one or several other men to what it is for risky behaviour in both men and women who have never had any but heterosexual relations.

In Australia (since 2000), in New Zealand (since 2014)⁵⁶, in Argentina, Brazil and Japan, temporary deferral for men who state they have had sexual relations with another man or other men is one year after the last sexual contact with a man.

In South Africa (since 2006), temporary deferral is for a period of six months after the last sexual encounter with another man.

In Canada (since 2013) temporary deferral time is five years after the last sexual contact with a man.

In some of these countries, recent studies were made of HIV contamination incidence in blood donations since the changeover from permanent deferral to temporary deferral⁵⁷.

⁵⁵ In the United Kingdom, temporary deferral of one year after the last sexual contact between one man and another was decided in November 2011 since an additional risk appeared to be very low compared to permanent deferral in residual risk models. *Advisory Committee on the Safety of Blood, Tissues and Organs*, April 2011:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216109/dh_129909.pdf.

⁵⁶ This modification was introduced in December 2014. Previously, since 2008, temporary deferral for men having sexual relations with another man or men was five years after the last sexual contact with a man.

⁵⁷ This was the case in Australia, where a one year temporary deferral was instituted in 2000 (Seed C, Kiely P, Law M and Keller A. No evidence of a significantly increased risk of transfusion-transmitted human immunodeficiency virus infection in Australia subsequent to implementing a 12-month deferral for men who had sex with men (CME). *Transfusion* 2010, 50:2722-30). In Italy, where the four-month temporary deferral was introduced in 2001 (Pupella S, Regine V, *et al.* Changing blood donor screening criteria from permanent deferral for men who have sex with men to individual sexual risk assessment: no evidence of a significant impact on the human immunodeficiency virus epidemic in Italy. *Blood Transfus.* 2013, 11:441-8), although the authors came to the conclusion that there was no significant impact, their study indicates that the risk that donors (new donors and regular donors) be discovered as being HIV positive at the time of donation was evaluated in 2010 compared to 1999, as multiplied by 1.5 for people reporting themselves as being exclusively heterosexual and by 2.9 for men

In other countries, in particular the United States, Spain and Denmark, there are ongoing debates and changes in the direction of moving away from the permanent deferral rule and replacing it with temporary deferral or a lengthening of the time of temporary deferral, or on the contrary to keeping the rule of permanent deferral⁵⁸.

In the eighteen countries who have ruled on a temporary deferral period from blood donation in the case of men disclosing sexual relations with a man or several men, the length of time for this temporary deferral as well as the nature of the sexual relations to which the deferral applies, vary considerably from one country to the other⁵⁹.

Indeed, based on the same risk of HIV transmission by blood transfusion — linked to the biologically silent window period of twelve days on average, during which tests to reveal the donor's infection are of no avail — the various countries around the world

reporting sexual relations with other men. In the United Kingdom, where temporary deferral was introduced in 2011, results are not yet properly evaluated because the data is too recent. However a report produced by the United Kingdom shows that in 2012, neither prevalence nor incidence were modified in blood donors. Among the 16 donors found to be HIV positive in 2012, 12 disclosed that they had been contaminated heterosexually and 4 were men having relations with other men, 3 of them with another man in the last 12 months. (Safe supplies : Completing the picture. *Annual review from the NHS Blood and Transplant/PHE Epidemiology Epidemiology Unit*, 2012. Public Health England, see:

http://webarchive.nationalarchives.gov.uk/20140714084352/http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317139826539).

⁵⁸ For example, in the United States, the Food and Drug Administration (FDA) has recently declared, on December 23rd 2014, that they are going to recommend changing indefinite deferral for men disclosing sexual relations with other men into a temporary deferral of one year after the last sexual contact with another man:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427843.htm>

In Denmark, on the contrary, while a discussion was on-going on reversing the indefinite deferral policy, the case of a child infected by HIV after receiving blood from a regular donor, bisexual, who had not disclosed his bisexuality, put an end to the discussion. (*Journal du Sida*, 2011, n° 221, octobre-novembre-décembre, pp. 44-46). (It is worth noting, however, that in this case the problem was not related to the length of time for temporary deferral, but to the non disclosure by the donor of a deferral applying to him and which, at the time, was indefinite). (*Journal du Sida*, 2011, n° 221, octobre-novembre-décembre, pp. 44-46).

In Spain, the Viral Genomic Test (VGT) which is mandatory in France since 2001 and is a method to test for the presence of HIV genetic material (RNA) in the blood, thus reducing the window period to 12 days on average, has only recently been included in the biological testing array for blood donors. It was then found that there was an increase in the number of HIV positive donations as detected by the VGT (at a time when HIV serology is still negative), in very recently infected donors (in the 12 to 45 days preceding donation). Most of these were regular male donors, of which a large number revealed in the interview after contamination was discovered, that they had had sex with other men. This data would suggest that some of these donors had volunteered because of the introduction of VGT and for selfish, not altruistic, reasons, with the object of getting a test result as quickly as possible to dispel doubts regarding possible contamination after risky sexual practices. The authorities have considered extending the period for temporary deferral from six months to twelve after ceasing risky behaviour for men who have sex with other men. (Benjamin RJ et al. Deferral of males who had sex with other males. *Vox Sang*. 2011, 101 (4) : 339-67, and reported by Dr J. Pillonel). (It is, however, worth noting that the problem in this case was not connected to the duration of the temporary deferral period (six months) but due to the non disclosure by donors of risky behaviour, in at most the previous month and a half).

⁵⁹ Wilson K, Atkinson K, Keelan J. Three decades of MSM donor deferral policies. What have we learned? *International Journal of Infectious Diseases*. 2014, 18:1-3.

[http://www.ijidonline.com/article/S1201-9712\(13\)00308-1/pdf](http://www.ijidonline.com/article/S1201-9712(13)00308-1/pdf). Donor Selection Criteria Review. *Advisory Committee on the Safety of Blood, Tissues and Organs*, April 2011.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216109/dh_129909.pdf

have responded very differently as regards men disclosing sexual relations with another man or men.

More generally, it is worth noting that the differences between countries do not just bear on the permanent or temporary nature of the deferral policy for men who have engaged in male-to-male sexual relations. They also refer to the permanent or temporary character of deferral from blood donation for injectable drug users.

As an example, donor deferral in the event of injectable drug use is temporary in the United States, Italy and Spain but indefinite in France.

These different deferral policies from one country to another are therefore not solely based on scientific and medical reasons; they are also influenced by the recognition of the complex outcome of social and cultural dimensions.

G. A court decision under advisement by the Court of Justice of the European Union

The case bears on the permanent exclusion in France from blood donation for men disclosing that they had had at some point in their life sexual relations with another man or other men.⁶⁰

The Advocate General of the European Court of Justice delivered his opinion on this case on July 17th, 2014:

“The Court has repeatedly held that ‘the health and life of humans rank foremost among the assets and interests protected by the EC Treaty’.

[...]Although the legislation at issue in the main proceedings does pursue a legitimate objective, it remains to be ascertained whether it also observes the principle of proportionality, that is to say whether it is appropriate and necessary in order to attain the objective pursued, which means that when there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.

[...] Further, there is some doubt as to whether permanent deferral is consistent⁶¹.

⁶⁰ This is Case C-528/13 Geoffrey Léger v Ministre des Affaires sociales et de la Santé and Etablissement français du sang.

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=155166&pageIndex=0&doclang=FR&mode=req&dir=&occ=first&part=1&cid=243422>).

⁶¹ “Accordingly, a question arises: does the permanent deferral of men who have sex with men seek to affect a particular sexual orientation or rather a true behaviour strictly speaking?

Indeed, the criterion for deferral used by the ministerial decree is the fact that a man has had or has sexual activity comprising sexual relations with another man and the conditions of those relations, their frequency and the practices involved are of little importance. Of course, the criterion is not explicitly and directly expressed on the basis of sexual orientation, since the MSM category is not officially defined according to sexual orientation. It nevertheless raises a kind of irrebuttable presumption that an MSM relationship necessarily and systematically puts a person at high risk of contamination. Moreover, in practice, it is essentially, if not exclusively, the entire male homosexual and bisexual population which is, in fact, forever excluded from donation for the sole reason that those

[...]the fact that a man has had, at least once in his life — albeit ten years ago —, sexual relations with another man leads to his permanent deferral from giving blood. It must be inferred from this that the ongoing nature of the risk behaviour is irrelevant, whereas, since all blood donations are tested for HIV, it is, in fact, the window period which is the most critical period and which places recipients at the highest risk. However, once again, if the primary motivation is that of the window period, it may be considered that a temporary deferral, determined according to the date of the last sexual relations, is more appropriate.

[...]It is also necessary to consider the case of a man who has had, once in his life or occasionally, protected homosexual relations (who is permanently excluded) in the light of that of a heterosexual person who regularly has unprotected sexual relations, but who will nevertheless be subject only to a temporary contraindication. Is the mere fact of that an individual belongs to the MSM population capable of justifying, in such a case, a permanent deferral?

[...] Finally, and perhaps above all, the questionnaire could be revised so that it can be used to identify risk behaviours in the MSM population, as it does, in a seemingly satisfactorily manner, for the rest of the donor population. More targeted questions — concerning the period since the last sexual relations, the number of partners, the nature of the sexual relations, whether the sexual relations were protected, attendance at certain nightspots — would make it possible not to identify sexual orientation, but instead to assess the level of risk that each donor individually presents on account of his own sexual behaviour.”⁶²

The Advocate General’s Opinion is not binding on the Court of Justice of the European Union.⁶³

men have had, or currently have, sexual relations with another man. In my view, the national criterion adopted is formulated in a way which is both too broad and too general, while the concept of ‘sexual behaviour’ used by the EU legislature requires a specific behaviour or attitude which places the prospective donor at a high risk of contamination to be identified. Moreover, the Commission has already highlighted the fact that the ‘sexual behaviour’ referred to in Directive 2004/33 should not be understood as synonymous with ‘sexual orientation’.”

⁶² Opinion of the Advocate General of the European Court of Justice delivered on July 17th 2014 on Case C- 528/13:

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=155166&pageIndex=0&doclang=FR&mode=req&dir=&occ=first&part=1&cid=243422>

⁶³ “It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.” (Press release No 111/14, Court of Justice of the European Union, 17 July 2014).

II. Ethical queries

A. The safety of blood transfusion and the protection of transfused patients: an essential ethical issue

Recipients of blood transfusions are patients suffering from serious diseases or who have endured grievous accidents and their condition is frequently life threatening.

The dual objective of the blood donation system is therefore to collect blood products in sufficient quantity to help recipients while also reducing to the maximum extent any risk of contaminating recipients, i.e. by guaranteeing as much as possible the quality and the safety of these products.

It is for this reason that biological tests are systematically applied to donor blood and that donation is preceded by a questionnaire to be completed and an interview with the doctor in charge of transfusion so as to seek out any contraindication to donation and, in particular, evaluate the risk of recent donor infection that biological tests cannot yet detect at the time of donation.

Donating blood is a generous and altruistic action accomplished in a spirit of solidarity. It is also voluntary, benevolent, anonymous and unpaid. It is an essential act for the protection of public health, on the condition that it be made in the service of improving the health of patients in need of blood transfusion and in no way represent an avoidable risk, notably the risk of transmitting a serious infection.

This was expressed in a 2008 Resolution of the Council of Ministers of the Council of Europe when they insisted on “*donor responsibility*” and referring to the “*the right of blood recipients to the protection of their health [...] and asserted that “These rights and obligations override any other considerations, including individuals’ willingness to donate blood”*”⁶⁴.

On this subject, it is a matter of concern to find that a proportion, albeit extremely small, of people volunteering to donate their blood do not seem to understand — or care — that their recent risky behaviour is a contraindication to the donation.

For this reason information to donors about impediments to blood donation should not be restricted to the short while before giving blood when they are interviewed by the health care professionals tasked with collecting the samples. Clear information to the public is essential on current contraindications to donation and current limitations of the biological tests performed at the time of donation so as to implement a policy of getting all those committing themselves to the generous project of donating their blood, to do so in full acceptance of the need to protect the health of transfused patients and of their responsibility in achieving this. “*Benevolence and solidarity can*

⁶⁴ *Resolution CM/Res(2008)5 on donor responsibility and on limitation to donation of blood and blood components* (Adopted by the Committee of Ministers on 12 March 2008 at the 1021st meeting of the Ministers’ Deputies). See Annex 6).

be expressed as forcefully in donating blood as in excluding oneself from doing so."⁶⁵

B. First query: is permanent deferral from blood donation for men disclosing sexual relations with another man/other men an essential and proportionate measure for the protection of public health?

The French Code of Public Health rules that "*no one can be excluded from donating blood for reasons unrelated to medical contraindication.*"⁶⁶

Currently applicable contraindications to blood donation are medical and their only aim is to ensure the safety of blood transfusion and the protection of the life and health of transfusion patients. This is the reason why some people are of the opinion that this is purely a public health problem, based on epidemiological data, which should not therefore be raising any ethical issues.

But contraindications must not be excessive in their relation to the public health objectives they seek to ensure. A 2013 resolution by the Committee of Ministers of the Council of Europe states "*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*"⁶⁷.

As a result, in recent years some queries have surfaced in the name of an ethical principle of pertinence, on the validity, medically speaking, of the permanent character of deferral from blood donation — lifelong exclusion from donation — for men disclosing sexual relations on one or more occasions with another man/other men, however long past, however frequent, and regardless of whether these sexual relations were protected or unprotected.

Recent epidemiological data (see above) clearly reveals that if they are considered as a group, men disclosing sexual relations with other men are characterised by a greatly higher rate of prevalence and incidence of HIV infection than is the case for the population as a whole.

But this group, like any other group, is made up by including only one characteristic of the people forming the group; it is therefore, by its very construction, extremely heterogeneous. In particular, as regards the risk of being infected only in the last two or three weeks — i.e. being within the "window period" of infection undetectable by biological tests — heterogeneity is obvious.

As an example, a man who has had recent unprotected sexual relations with several other men in a multi-partnership setting, all the more so if anonymous, is running a significant risk of being in the "window period" for HIV infection, whereas a man

⁶⁵ Reply from the President of CCNE and the President of the Technical Section of CCNE to the President of the *Etablissement français du sang*, on January 24th 2002. *Cahiers du CCNE N° 31, 2002.* (Annex 7).

⁶⁶ Article L1211-6-1 of the *Code de la santé publique*.

⁶⁷ Resolution CM/Res(2013)3 on sexual behaviours of blood donors that have an impact on transfusion safety (adopted by the Committee of Ministers of the Council of Europe on 27 March 2013).

who had protected sex with another man ten years ago is in no risk whatsoever of being in the “window period”.

At this point, CCNE would like to reiterate its response in 2002 to a referral from the *Etablissement français du sang (EFS)*. The referral was specifically related to issues arising from the permanent exclusion of homosexuals from blood donation for health safety reasons:

“All the questionnaires state from the outset that being homosexual, that having had homosexual relations, is cause for definitive exclusion from blood donation. This is expressed in different forms, sometimes bracketing together prostitution and homosexuality. This disqualification in connection with homosexuality is irrevocable while other clearly risky behaviours only lead to temporary exclusion.

The referral notes that “this unqualified exclusion of an entire group, by essence heterogeneous, is denounced as discriminatory by homosexual associations claiming access to blood donation as a fundamental and inalienable right.”

To our thinking, the gift of blood, in its context made up of generosity, solidarity and awareness of others, is a duty of help and assistance rather than a fundamental and inalienable right. This duty of assistance implies respect for essential safety requirements.

It is nevertheless fitting that this legitimate principle of safety is not transformed into stigmatisation or measures that can be seen as discriminatory, such as may appear to be the case in documents handed to future donors (and frequently displayed at blood establishment reception desks).

The EFS’ future questionnaire should make it possible to evaluate the risk attached to an individual, taking into consideration his/her behaviour rather than related to risky groups.

[...]It is not the prerogative of any particular group to claim blood donation as a right, but nor is a transfusion establishment entitled to entertain an a priori judgment which may be considered stigmatising.”⁶⁸

In 2006, the Haute autorité de lutte contre les discriminations et pour l’égalité (Halde) (French Equal Opportunities and Anti-Discrimination Commission) remarked: “It would appear, however, that EFS did not take into consideration the opinion on this point they had asked the French National Consultative Ethics Committee (CCNE) to provide in 2002”⁶⁹.

⁶⁸ Reply from the President of CCNE and the President of CCNE’s technical section to the President of the *Etablissement français du sang*, on January 24th, 2002. *Cahiers du CCNE N° 31, 2002*. (Annex 7).

⁶⁹ La Halde, *Délibération n° 2006-17 February 6th 2006 (Case n° 31)* : <http://www.halde.fr/IMG/alexandrie/1530.PDF>

At the end of 2011, speaking on the occasion of World AIDS Day, in a forum on the subject of *homosexuals also being able to donate their blood* published in *Libération*⁷⁰, (posted on line of the *Défenseur des droits* website⁷¹ with the heading *Pour la levée de l'interdiction des hommes homosexuels à pouvoir donner leur sang : Respect de la personne humaine, la solidarité et l'égalité de tous*) (In favour of reversing the prohibition for homosexual men from donating their blood: Respect for human beings, solidarity and equal dignity for all), Dominique Baudis (Defender of Rights) wrote:

“[...] Finally, I find that in France itself, blood donation is still not allowed for male homosexuals solely because of their sexual orientation, regardless of what might be their sexual behaviour.

And yet, the European Commission, recalling that Article 21 of the European Charter of Fundamental Rights prohibits any discrimination based on sexual orientation, emphasised that while Union law justifies exclusions from donating blood of persons representing a high risk of transmitting serious infectious diseases, this was by reason of the sexual behaviour of such persons and not related to their sexual orientation.

Thus, as was recommended by HALDE in a decision made in February 2006 and as is already the case in Italy, Spain and Portugal and, more recently in the United Kingdom, France should also limit restrictions to giving blood to only those, men or women, who represent an increased risk exclusively because of their risky sexual behaviour.

A priority for health and social reasons, the fight against HIV is a test of our democratic societies' attachment to their ideals: amongst which respect for human beings, solidarity and equal dignity for everyone. Our own values impose on us democratic demands. To fail in this would be evidence of culpable dereliction of our democratic ideals. On all these matters, action is urgent.”⁷²

C. Second query: the credibility of statements by men disclosing sexual relations with another man/other men

When people declare that they have never in their life had any other but heterosexual relations, deferral — always temporary — applies only to recent risky sexual behaviour, that is the real, measurable risk of sexual behaviour as opposed to the nature of sexual practices, including high risk sexual behaviours that people may have engaged in at some point in their lives.

⁷⁰ http://www.liberation.fr/societe/2011/11/30/pour-que-les-homosexuels-puissent-eux-aussi-donner-leur-sang_778532

⁷¹ <http://www.defenseurdesdroits.fr/sinformer-sur-le-defenseur-des-droits/linstitution/editorial/pour-la-levée-de-linterdiction-des>

⁷² In its December 8th 2011 issue, the *Quotidien du médecin* reported that: “Today, as clearly stated by Dominique Baudis, this exclusion is discriminatory. Why”, he asks, “should a homosexual taking all necessary precautions, in a stable relationship or even sexually inactive, be excluded from giving blood?”.

Unprotected penetrative anal sex represents a much higher risk of infection, by HIV in particular, than is the case for vaginal or oral sex. This much higher risk is similar for men and women⁷³. And yet, when this practice involves a woman — in heterosexual intercourse which may include multiple partners, in some case anonymously — it is not considered to be a risk requiring permanent deferral from blood donation⁷⁴.

At this point must be raised the issue of whether donor statements can be trusted.

Indeed, if we consider *a priori* that those stating that they have never had any but heterosexual relations will be truthful about their recent risky sexual behaviour, then what are the arguments in favour of considering *a priori* that a man who had sexual relations with another man or with other men — which he has disclosed in the questionnaire to be completed before donating blood or in the medical interview — will not be truthful regarding possible risky and recent sexual behaviour⁷⁵?

There is a paradox raising an ethical issue in considering that when a man discloses sexual relations with another man or other men, in order to ensure the best possible safety in blood donation:

- it is essential to trust him to be truthful about whether he had in the course of his life, sexual relations with another man or other men,
- but that it is also essential, at the same time, not to trust him at all regarding possible disclosure of whether his risky sexual behaviour was recent or not and, for this reason, to exclude him permanently from blood donation without even questioning him on the subject.

Finally, not considering the person individually, but only as a member of a group into which he has been put, makes it all the more difficult to appeal to the sense of responsibility of these donors and is also detrimental to the creation of a truly trustful relationship between donors, recipients and doctors handling blood transfusion.

D. Third query: the specific issue of the risk of transmitting an infectious agent, as yet unidentified or unidentifiable by current biological tests

This issue is very different from the one addressed above.

⁷³ On average, the risk is much higher in male-to-male relations than in heterosexual relations, taking into account a much greater prevalence of HIV infection in men having had unprotected sexual multiple-partner relations with other men. But the difference dwindles if the woman's partner is a man who has unprotected bisexual relations with multiple partners.

⁷⁴ This leads back to the question of the proportionate or disproportionate nature of the permanent deferral rule based on sexual practices (homosexual or bisexual) that men may have had in the course of their lives, but not based on the degree of risk arising out of their recent sexual behaviour.

⁷⁵ This difference in the degree of trust in the truthfulness of people depending on their sexual orientation is difficult to understand and accept, all the more so in view of recent legal provisions (including the May 17th 2013 law allowing same-sex marriage) urging that people should not be treated differently because of sexual orientation.

We are not here addressing the problem of deciding permanent deferral because of the risk of transmitting an infectious agent, such as HIV, which can be the subject of biological tests, epidemiological studies or evaluations using models.

The problem is, in the name of caution, to decide on permanent deferral because of:

- either a risk of transmitting a known infectious agent which cannot as yet be identified by current biological tests;
- or an undefinable risk of transmitting an as yet unidentified infectious agent, which raises complex scientific, medical and ethical issues⁷⁶.

1. One example of permanent deferral from blood donation: people who were themselves transfusion recipients

Events taking place in a distant past in people's lives may expose them to risks which, for medical reasons, constitute a permanent contraindication to donating blood.

In this case, the risk being addressed is not that donors may be in the silent "window period" of HIV infection which follows shortly after contamination, but rather the risk that a donor may be infected by an as yet unidentified infectious agent, or infected by an agent as yet unidentifiable by current biological tests.

Precisely in order to avoid this very specific kind of risk, a permanent deferral for blood donation is the rule in France for anyone who has ever been the recipient of blood transfusion.

Permanent deferral in this instance became regulatory in France in 1996, the year when cases of human contamination were confirmed in the United Kingdom by a very special infectious agent — the prion — which was then the cause of a lethal epidemic in cattle, bovine spongiform encephalopathy (BSE), also known as "mad cow disease"⁷⁷.

⁷⁶ CCNE notes that current research on blood substitutes could at some future time preclude the use of blood donations.

⁷⁷ It was in 1986 in the United Kingdom, that an epidemic of bovine spongiform encephalopathy (BSE) broke out in cattle fed on meat and bone meal. The cause was a variant of a particular kind of protein called a prion.

The variants of protein prions, or pathogenic protein prions, are the cause of diseases such as bovine spongiform encephalopathy, scrapie in sheep and Creutzfeldt-Jakob disease (CJD) in humans. Prions are misfolded proteins with two specific characteristics: the form is extremely stable and the pathogenic protein prions force refolding of normal protein prions into the diseased form when they are in contact. This is how the pathogenic prions propagate, not by increasing in number but by converting the body's normal proteins into the pathogenic form.

On March 20th 1966, the UK Government announced officially the existence of highly probable transmission of the fatal disease to people who had consumed beef.

Contamination was later confirmed by the identification in people ill with CJD of the variant form of the prion causing bovine spongiform encephalopathy.

That same year, results of animal experimentation demonstrated that the prion which mainly targets the nervous system, the brain in particular, could also spread to the lymphatic system, be present in the blood stream and be transmitted experimentally through blood.

In 2004 in the United Kingdom two cases were reported of probable transmission of this variant pathogenic prion, through transfusion of blood donated by someone who was contaminated⁷⁸. A retrospective analysis by the *Institut de veille sanitaire* (French Institute for Public Health Surveillance) in June 2013 reports four cases of transmission via blood transfusion in the United Kingdom (no cases were detected in France)⁷⁹.

Prion diseases can be preceded — before any clinical signs are visible and before any of the currently available biological tests can detect them — by a long period of clinically silent incubation.

The probability of anyone in France being currently a carrier of the prion, and therefore liable to transmit it by blood transfusion, is estimated to be very low, or even nil. But the permanent deferral from blood donation of anyone who has ever received a transfusion was decided as a precaution against an infinitely small, but not precisely quantifiable, risk.

This lifelong deferral is the subject of some debate⁸⁰.

It is often difficult to understand and accept by recipients of blood transfusion and may lead them to become anxious about their own state of health.

On the one hand, these people wish to show their gratitude for the altruistic act which saved their lives or helped them recover from a serious medical condition by performing the same altruistic action for other people and they find it difficult to understand why they are forbidden to do so.

On the other hand, being told that they may possibly be at risk of developing a disease which for the time being is clinically silent and undetectable by existing biological tests, may be very worrying in some cases.

⁷⁸ Martin M, Trouvin JH. Risk of transmission of Creutzfeldt-Jakob disease via blood and blood products. The French risk analysis over the last 15 years. *Transfus Clin Biol.* 2013, 20,398-404. Brandel JP, Peckeu L, Haik S. The French surveillance network of Creutzfeldt-Jakob disease. Epidemiological data in France and worldwide. *Transfus Clin Biol.* 2013, 20 :395-7.

⁷⁹ Blood donors. *Institut de veille sanitaire*. Update on June 14th 2013: www.invs.fr

⁸⁰ “Another problem is the systematic lifelong eviction of recipients of blood transfusion, [...] and many other criteria, originating a large number of queries widely put forward by many of those concerned with blood donation, both donors and health carers. Consulted on these eviction criteria, recipient associations were of different opinions, although the majority were inclined to let the scientific community, considered to be worthy of trust, take the necessary decisions.” Hence “*Recommendation n° 4: Refer the issue of lifelong eviction for recipients of transfusion to the Haut Conseil de la Filière du Sang.*” Olivier Véran Report, *La Filière du sang en France, July 17th 2013*, pp 35-36: http://www.sante.gouv.fr/IMG/pdf/Rapport_Veran_filiere-sang.pdf

Finally the insistence on the safety of blood and blood products used for transfusion may appear to contradict the fact of considering that transfusion recipients could transmit an infection simply because they had themselves received a transfusion.

This apparent contradiction, if it cannot be dispelled, could at least be clearly explained in blood donation information campaigns. While emphasising that any medical procedure can present a risk, however small (as is the case for the risk of transmission of a pathogenic variant of a prion), it could be explained to transfusion recipients that, in order to protect them and for the previously stated reasons, the blood they received was not a donation from a donor who had previously received a transfusion.

It is also important to make it perfectly clear that while transmission of a variant pathogenic prion may in extremely rare cases be caused by blood transfusion, no item of data — including data derived from animal experimentation — has ever suggested the possibility that variant pathogenic prions could be sexually transmitted.

So that this motive for permanent deferral for medical reasons — even in connection with the trauma induced in France by the contaminated blood tragedy — does not in any way apply to the issue of the length of deferral time for men disclosing sexual relations with another man/other men.

2. Historical data on the identification of viral and retroviral infections transmissible both by sexual relations and blood transfusion

In the past fifty or so years, several viruses and retroviruses infecting human beings and whose existence was hitherto unknown have at last been identified.

With extremely variable frequency, they cause serious diseases and can be transmitted both through sexual intercourse and the blood.

This is the case in particular of infection by the Hepatitis B virus (identified in 1966), the HTLV-1 retrovirus (identified in 1980), retroviruses HIV-1 (identified in 1983) and HIV-2 (identified in 1985) and the Hepatitis C virus (identified in 1989).

For each of these, a certain amount of time, sometimes quite a long time, elapsed between identification of the disease and identifying the infectious agent involved or developing a reliable biological diagnosis test.

These infections, which today can be detected biologically, pass through an undetectable clinically silent latency period which can be as long as several weeks for viruses or several years for retroviruses, or even several decades (for the HTLV-1 retrovirus).

Based on this historical data, it may well be that in future, risky sexual behaviour could contribute to the propagation of pathogenic infections, transmissible both sexually and by blood, and that these infections would not be identified or identifiable with existing biological tests and that they could be transmitted by blood donated for transfusion.

This was expressed in 2013 by a resolution of the Committee of Ministers of the Council of Europe when they wrote that “*a rapid spread of new and emerging sexually transmitted infections may be promoted by certain aspects of this particular risky sexual behaviour.*”⁸¹

Permanent deferral could therefore be justified, from a purely medical point of view, in the event of risky sexual behaviours, even long past, as a precaution against a risk of infection as yet unknown and therefore neither assessable nor measurable.

But for the past 25 years and more, no unknown infectious agent, transmissible sexually or through the blood, with protracted clinical latency and causing serious diseases, has been identified.

This is probably due to the fact that infectious agents transmissible sexually or by the blood causing serious diseases, hitherto unknown (HIV-1, HIV-2, HTLV-1, Hepatitis C) were identified in the 1980s when extremely sensitive methods of biological analysis were developed, in particular methods of genetic analysis.

Since that time, there has been a considerable acceleration in the development of these methods of analysis (allowing for extremely fast and extensive analysis using very small samples of genetic material⁸²) and there has also been a considerable global intensification of epidemiological surveillance over emerging infectious diseases.

In the circumstances it seems difficult to lay down rules of permanent deferral based solely on precautions against unknown risks, not one example of which was evidenced in over twenty-five years.

But in this case also, it is the nature, the importance and the frequency of a person’s risky sexual behaviour that would essentially need to be considered, whether or not these risk factors are or are not connected to heterosexual relations. And the simple fact of placing people in a heterogeneous group defined solely by whether they have disclosed at least one male-to-male sexual relation (however long in the past this or these relations took place, regardless of their nature and frequency, whether they were protected or unprotected, involved one other man or several men, involved a single partner or multiple anonymous partners) does not suffice to determine if the person

⁸¹ Resolution CM / Res (2013)3 on sexual behaviours of blood donors that have an impact on transfusion safety (adopted by the Committee of Ministers of the Council of Europe on 27 March 2013).

⁸² To quote some examples of this ever greater acceleration over the past 30 years, the Polymerase Chain Reaction (PCR) used to considerably amplify DNA or RNA samples and therefore do a genetic analysis based on minute quantities of genetic material, was discovered in 1983; the first whole human genome sequencing was completed in 2001 (it took 13 years and cost some 13 billion dollars; today a whole human genome sequence can be done in 2 hours for under 1,000 euros); whole foetal genome sequencing, based on the analysis of small quantities of free-floating foetal DNA in a drop of the mother’s blood as early as the 10th week of gestation, was developed in 2012; etc. (For an idea of the speed of progress in this field of research, see CCNE’s Opinion n° 120, *Ethical Issues in Connection with the Development of Foetal Genetic Testing on Maternal Blood*, published on 25th April, 2013.

concerned is at any significant risk of being contaminated by some as yet unidentified infectious agent⁸³.

⁸³ The 18 countries replacing permanent deferral from blood donation for men disclosing sexual relations with another man/other men by a temporary deferral, decided not to take into account the risk of transmitting an as yet unknown infectious agent.

III. CCNE observations arising out of these ethical queries

A. First observation: improving methods of informing donors and heightening their sense of responsibility, improving the questionnaire and the dialogue with a doctor on the subject of risky behaviour and the importance of deferrals

As a general rule, the safety of blood donation and the protection of the life and health of patients receiving transfusion depend first and foremost on clear information and a responsible attitude on the part of potential donors, on the reliability of their replies to the questionnaire and the quality of their dialogue with the doctor in charge of transfusion, so that a donor's risky behaviour and misgivings regarding any such risky behaviour can best be evaluated.

CCNE considers that, more than the questionnaire, the quality of dialogue with the health care professional is best suited to help potential donors understand the importance of their statements and ease the way for more communicative discussions of risky sexual behaviour.

In particular, it must be said once again, although CCNE has stressed the point on many occasions on other subjects, how much the quality of any medical act depends on the amount of time that doctors and other health care providers can devote to people approaching them. This is bound up with subjects such as a training for doctors and other health care professionals, rules for their remuneration and the pricing of health caring activities and more generally to the organisation of the health care system.

Independently of any decisions that may be made in the future on contraindications to blood donation (see below), making potential donors aware of their responsibilities and of their consequences, i.e. the reliability of spoken and written statements in the interview before donation, presupposes:

- beforehand, the distribution and appropriation of quality information on risky behaviour and the importance of ensuring that patients receiving transfusions are adequately protected;
- and, when people come to give their blood, a well-drafted questionnaire and, even more important, enough time to dialogue and create a climate of mutual trust. However, the constraints prevailing in blood donation campaigns more often than not preclude devoting sufficient time to would-be donors.

CCNE therefore recommends:

- necessary changes to be made to information campaigns so as to improve everyone's understanding of how important it is to observe the contraindications to blood donation in order to protect the health of transfusion recipients. The effectiveness of such campaigns would be measured by the voluntary abstention of people whose risky behaviour is a contraindication to blood donation;
- essential rewriting of the questionnaires so that they explain clearly and respectfully all the public health issues involved and the medical justification for all deferrals;
- necessarily devoting enough time for a meaningful dialogue between doctor and donor so that this exchange can bring about a better grasp of the real consequences of risky behaviour and also help people to speak out on the subject of their risky behaviour and on any doubts they may entertain regarding such behaviour.
- necessarily providing an exacting training course for doctors and other health care providers to help them with managing a sometimes difficult exchange since it touches upon intimate matters and may be viewed as stigmatising.

B. Second observation: engage in extensive reflection and scientific research to reassess the appropriateness of the rule for permanent deferral from blood donation for men disclosing sexual relations with another man/other men

Regarding the risk of very recent infection with HIV, dating back to less than two or three weeks and as yet undetectable by biological tests, clear information, a detailed questionnaire and an in-depth dialogue with the doctor in charge of blood donation should aim to arrive at an evaluation of the existence or otherwise of recent risky sexual behaviour on the part of the prospective donor, be it somebody disclosing no other but heterosexual encounters or a man disclosing sexual relations with another man or other men.

It is in fact in both of these circumstances, the existence of recent risky sexual relations with one or several new partners (or uncertainty regarding the recent risky behaviour of a sexual partner of either gender with whom the prospective donor has unprotected sexual relations) which constitutes a real risk of having been recently infected with HIV, regardless of the particular at-risk group in which the donor may be classified.

High-risk sexual relations may include — for either men or women — unprotected sexual relations with multiple partners, the anonymity of these partners, remunerated activity as a prostitute or professional sex worker, and unprotected sexual activity involving anal sex.

CCNE recommends thought be given and research engaged, particularly in the human and social sciences, for the purpose *inter alia*:

- of trying to understand the reasons motivating a certain number of regular donors each year to abstain from mentioning their recent risky sexual behaviour; of evaluating the forms of information and dialogue that would be best suited to solve this problem;
- of trying to evaluate the reliability of statements about their recent risky sexual behaviour made by people engaging in such behaviour;
- of refining transfusion risk models taking into account the data on the reliability of statements on recent risky sexual behaviour; including in the estimation of the risk linked to blood donation not only data on infection incidence but also infection incidence connected to recent risky behaviour;
- of making modelling studies of transfusion risk taking into consideration, as regards men disclosing sexual relations with other men, temporary deferral rules existing in other countries, such as the United Kingdom, Sweden or Australia, i.e. a period of complete abstinence from sexual relations with another man⁸⁴.
- of arriving at a precise assessment of blood transfusion safety, of the methods for informing members of the public and for conducting interviews between donors and doctors in countries which have replaced lifelong deferral by temporary deferral for men disclosing sexual relations with other men.

C. Third observation: if doubt persists, consider the possibility of asking the donor to come back after having donated blood for a second biological test.

In circumstances where the doctor or the person concerned is in doubt regarding the existence of recent risky sexual behaviour (be that a person stating that he or she has never engaged in any but heterosexual relations or a man disclosing sexual relations with another man/other men, there is a way of checking that the person wishing to donate blood is not in the “window period” after recent HIV infection: ask him or her to take a further biological test after donating blood.

Since the period of time that donated blood can be stored is as long as four weeks, and, more to the point, that the shelf life of plasma and of certain blood-based products is much more extensive⁸⁵, a second biological test once the “window period” is considered to be terminated, would be compatible with therapeutic uses of the donated blood.

⁸⁴ Modelling studies of transfusion risk in France to date only take into consideration a period before donation without multiple partners, not excluding the possibility, as in Italy, Spain or Poland, of relations with a single stable partner.

⁸⁵ In 2013, 3,204,883 labile blood products (LBPs) were used for transfusion, of which 78% were red blood cell concentrates; 12% therapeutic plasma; and 10% platelet concentrates. (Agence nationale de sécurité du médicament et des produits de santé (ANSM). *Rapport d'activité hémovigilance 2013*, September 2014).

http://www.ansm.sante.fr/var/ansm_site/storage/original/application/8a2c3c478172fcfbe027742aed130adf.pdf

However, at least two problems would arise as a result of this procedure:

- firstly, an increase in the overall expense of transfusion due to the cost of a second biological test;
- and secondly, inconvenience for the person concerned due to the need to come back at a later date for this second test.

CCNE recommends further thought and research, in human and social sciences *inter alia*, to evaluate the feasibility and acceptability of this approach.

D. Fourth observation: develop scientific research and specific strategies for providing information, for screening and for prevention against HIV infection in an effort to reduce the incidence of infection in people engaging in high-risk sexual activities.

Such research and strategies focusing on information and prevention could consider as a priority men who have unprotected sexual relations with other men, in multiple sexual partnerships, often anonymously, for whom the incidence of infection is particularly high.

In conclusion, CCNE underlines that issues concerning deferrals from donating blood imply two ethical obligations:

- on the one hand, the ethical obligation to protect the life and health of the recipients of transfusions for whom the blood is donated, which requires that deferrals from donating must aim to ensure the highest degree of protection for recipients;
- and on the other, the ethical obligation to ensure that policies for deferral from blood donation are proportionate to the essential needs of public health and based on scientific and medical principles so as not to transform the “*legitimate obligation of blood donation safety into stigmatisation or into a measure that may be seen as discriminatory*”⁸⁶.

CCNE considers that ethical queries regarding permanent deferral from blood donation for men disclosing sexual relations with another man/other men at some time in their lives, fully deserve in-depth reflection and research to make certain that this permanent exclusion from donation is sound in scientific and medical terms.

The authorities and society as a whole, as well as those managing blood transfusion, public health officials and blood donors should be given sufficient time to reconsider the whole issue of deferrals, to gauge the complexity of decisions governing an

⁸⁶ Letter from the President of CCNE and the President of the Technical Section of CCNE to the President of the *Etablissement français du sang*, on January 24th 2002. *Cahiers du CCNE N° 31, 2002*. (Annex 7).

essential facet of public health and have available the scientific data they need to underpin their decisions.

At this point of our understanding of the problem and as long as the reflection, developments and research that have been requested have not produced results, any modification to the rules of deferral would open the way to medical risks which must be considered with due respect for ethical considerations.

These risks would seem to be related not only to prevailing scientific uncertainties but also to an absence of the kind of improvement in information campaigns that could bring about a real sense of responsibility in people whose recent behaviour has put them at risk; furthermore not enough time is allowed for the interviews between donors and health care professionals managing donation safety.

As was already noted in CCNE's letter replying to the *Etablissement français du sang* in 2002, the Committee underlines that deferrals from blood donation in connection with risky sexual behaviours should be based on an evaluation of "*the risk for an individual, taking into account his or her behaviour, rather than of groups of people at risk.*"⁸⁷

But it will only be if sufficient time is set aside for the donor's interview with the doctor responsible for the safety of blood donation that it will be possible to move away from the statistical view of an at-risk group, to establish meaningful interchange with donors and, during the interview, to gain a better understanding of donors' risky behaviour including any uncertainties they themselves may entertain about that behaviour.

These thoughts and recommendations were agreed almost unanimously by member of CCNE.⁸⁸

There was, however, a difference of view on whether it was — or was not — necessary to consider at this point the possibility of reversing the permanent nature of deferral from blood donation for men disclosing sexual relations with other men.

Some members of the Committee, while recognising that considering today's available scientific data on the one hand, and the flaws in the system for donor declarations on the other hand, may be reason for maintaining for the time being the deferral for men disclosing sexual relations with another man or other men, but are of the opinion that this deferral should not be thought of as definitive nor as the sole possibility of avoiding risks. They therefore request that the research and changes recommended above, with the aim of adjusting deferral policies so that they are more fit for purpose, should be set in motion at the earliest opportunity.

⁸⁷ Letter from the President of CCNE and the President of the Technical Section of CCNE to the President of the *Etablissement français du sang*, on January 24th 2002. *Cahiers du CCNE N° 31, 2002.* (Annex 7).

More specifically, when for the purpose of scientific evaluation, people are included in at-risk groups, these groups should not be defined on the basis of sexual orientation or of past sexual practices, but rather on recent individual sexual behaviour presenting a risk of HIV infection and therefore of transmission to transfusion recipients of infection during the period when it is not yet detectable by the biological tests made when taking samples for blood transfusion.

⁸⁸ With the exception of a minority opinion which is the subject of the contribution below (page 38).

While sharing the opinion that early implementation is to be desired, a majority of the members of the Committee consider that it is not within CCNE's purview to decide in advance on what should be done, thus prejudging the results of scientific and medical research and of the changes that would be proposed.

For these reasons, the majority CCNE view is that — while awaiting the results of requested research and changes — current deferral policies should remain as they are.

March 28th 2015

Minority Position
Marie-Angèle Hermitte

I. How should the question be put?

A certain number of groups are excluded from donating blood, among which, men having had sexual relations with another man. Many voices are heard denouncing this discrimination against homosexual men. Just as many voices are heard to the contrary, including within certain associations defending homosexual interests.

The *Minister for Health's* question to CCNE on the “on the pertinence, from an ethical viewpoint, of making changes” to the policy, would mean replacing a contraindication based on the collective risk of a group defined by sexual practices with a contraindication based on the individual risk of each member of the group. This question was reformulated by the *majority opinion* in the form of various “ethical queries” with which I agree.

And yet, no one has thrown any light on what seems to me to be an “*ethical dilemma*”: to avoid what is seen by some as discrimination, should society accept even one single supplementary contamination, however exceptional? *This blunt formulation of the question appears to me to be part of the ethical approach*, since these are the terms in which it will be submitted to decision makers and interested parties when society will be confronted with the first case of contamination following a donation by a homosexual man, to the accompaniment of the risk of a surge in homophobic attitudes that it will lead to.

To the question put in those terms, my reply is therefore in the negative.

II. Argumentation

A. The question of discrimination

Donating blood is neither a right as demonstrated by a multiplicity of contraindications, *nor an obligation*; it is a manner of expressing solidarity. As such, it is difficult to see how there could be discrimination which presupposes a right. Even leaving aside this exclusively legal approach, for there to be discrimination there would need to be proof that changing the rule does not introduce any extra risk.

However, the existing rule does have one negative consequence which is to *designate* publicly an *epidemiological fact* particular to a group which does not necessarily correspond to the state of health of individuals belonging to that collective group. It will therefore be necessary to reflect on how to attenuate or sidestep the consequences of that designation.

As regards the idea of discrimination, it is worth noting that exclusion is justified by sexual *practices*, not sexual *orientation*; obviously the exclusion does not involve homosexual women. On the opposite side, other categories are the object of permanent deferral (such as people who have had cancer, or who are allergic, or who have spent some time in the United Kingdom or have a family member affected by

Creutzfeldt-Jacob disease). Such contraindications are unrelated to equality of rights, as emphasised by AIDES: “*donating blood should not be used to demonstrate equality of rights*”.

B. The two pillars of transfusion safety

- ❖ *I agree with the majority opinion on two findings.*
- The first line of defence for transfusion safety is the reliability of biological tests — this is the first safety net. The limits of biological tests as regards HIV are a seroconversion window of twelve days during which the donor’s contamination cannot be detected by the tests.
- The second line of defence of transfusion safety are the answers given during an interview so that a questionnaire containing some questions addressing sexual behaviour can be completed. Among other objectives, the questionnaire is designed to preclude contaminated donors from donation in the window period when tests are ineffective. The limits of the interview are due to the fact, rare but not unheard of, that the donor may fail to mention the risk incurred.
- ❖ *However, the matter needs taking a step further with an analysis of the causes of inexact replies which can be classified into four different categories.* The donor may not know (for example of a spouse’s adultery), or be consciously lying, or blacking out a risk incurred but “forgotten”, or the result of the donor’s personal analysis of the risk, considering that the risk described by the questionnaire does not apply (not mentioning partner-swapping because it takes place between regular partners who see themselves as mutually “trustworthy”). Improvement to information campaigns could possibly reduce the number of such occurrences but could not eradicate them.

Real transfusional risk can be defined as the crossover point between these two limits: donation made during the window period based on an unreliable questionnaire — unreliable for whatever reason — leading in certain rare cases to a contaminated donation, be it from heterosexuals or homosexuals.

C. Is there a specific characteristic of homosexual men as regards transfusional risk? Is a collective instead of an individual approach justified?

- ❖ The Opinion clearly establishes a certain number of facts:
 - **Prevalence** of contamination in homosexual men is not pertinent in terms of transfusional risk,
 - **Incidence** of contamination is pertinent, in both homosexual and heterosexual men, since it is from new cases that donations are made during the window period when detection by tests is not possible.

- But there is a considerably increased **incidence** for homosexual men compared to the population as a whole⁸⁹. Feedback from transfusion centres reveals that the incidence of new contaminations affects on average 10 regular donors per year: half of whom are heterosexual men and women who state that they did not engage in any risky behaviour (who are therefore ignoring the risk, or lying, suppressing or reinterpreting the risk) and the other half are men who concealed during the interview that they had had sexual relations with other men and only revealing this fact once their contamination was discussed retrospectively.
- ❖ The Opinion does not put enough emphasis on a certain number of points which I believe to be important:
 - The cases studied within the hæmovigilance framework illustrate the defective reliability of replies to the questionnaire, **these defects being found in equal proportions in heterosexuals and homosexuals**. However, the consequences of this lack of reliability in the replies to the questionnaire are quantitatively different in the two groups. The incidence of HIV contamination is significantly higher in homosexual men and since the lack of reliability is identical, **the risk of a contaminating donation during the window period is higher. It is this lack of reliability of replies which prohibits considering that replacing an approach by category with an individual approach would be justified⁹⁰. If the permanent deferral rule were to be overturned, this would mean that there would be cases, certainly very rare cases, of a donation during the window period to be contaminating.**

The ethical dilemma⁹¹ consisting in setting the satisfaction of a claim for equality for some against the risk of contracting a particularly serious disease for others calls for a negative reply because although there are inevitable risks and benefits to be derived from any form of treatment for the person receiving it, in this case, the recipient would be bearing the burden of the entire supplementary risk in exchange for a moral but questionable moral advantage for the donor.

- The first ethical requirement would be to strive for reducing the incidence of contamination of homosexual men, particular in the 18 - 25 year age group.
- Among CCNE's recommendations is giving more time for the interview with a doctor, in an economic juncture when blood transfusion is operating within the general budgetary constraints weighing on the health care system as a whole, aggravated by growing competition with the private sector which is not subject to the same restrictions. Recommending a solution knowing that it is rather unrealistic strikes me as being unethical.

⁸⁹ 48% of new cases concern men who had sexual relations with other men, the category most involved being men between 18 and 25 years old; 28% concern women and men born in France who have only had heterosexual relations; 23% concern women and men from other geographic areas who have only had heterosexual relations.

⁹⁰ It is doubtful that the statistical robustness of the models can be improved in view of the small number of cases.

⁹¹ When the United Kingdom did away with permanent deferral, it was based on the assumption that the "additional risk was extremely low".

- In order to attenuate the impact of designating a group, all interested parties should consider how to demonstrate solidarity:
 - The Opinion has already proposed that a second test should be made once the window period has expired on the condition that any extra cost should be borne by the donor;
 - The possibility might be entertained of using the donation for non therapeutic purposes (research for example) or in industrial processes known for certain to inactivate viruses;
 - There could also be a consideration of the possibility for volunteer homosexual men to participate in blood donation campaigns with the aim of raising awareness of the various risks of contamination. They could also be associated with blood sampling services for the same purposes.

- Finally, I am not in possession of sufficient data on the dangers of donations from prostitutes and heterosexuals (male or female) in frequent multiple unprotected sexual partnerships, nor on the serological status of heterosexuals engaging in anal penetration in which case the risks are ten or twenty times greater than with genito-oral or genito-vaginal intercourse. It would seem legitimate to consider the possibility of extending permanent deferral to such situations.

Annex 1

Members of the Working Group:

Claire Legras, Claude Matuchansky, Didier Truchet, Jean-Louis Vildé (rapporteur) and Bertrand Weil. Re-read by Jean Claude Ameisen, Alain Cordier and Patrick Gaudray.

Personalities heard by CCNE:

Dominique Costagliola, Director of the *Institut Pierre Louis d'Epidémiologie et de Santé Publique, Inserm, Université Pierre et Marie Curie.*

Dr Bruno Danic, *Établissement français du sang.*

Véronique Doré, *Agence nationale de recherche sur le sida et les hépatites virales.*

Tim Greacen, *Établissement public de santé Maison Blanche, Paris.*

Georges Kutukdjian, *Commission nationale consultative des droits de l'homme.*

Prof. Jean-Jacques Lefrère, Director General, *Institut national de la transfusion sanguine.*

Jean-Marie Legall, Director of Aides association.

Dr. Stéphane Le Vu, Department of Infectious Diseases, *Institut de veille sanitaire, Saint-Maurice.*

Michel Monsellier, First Vice-President of the *Fédération française pour le don de sang bénévole.* President of the *Union nationale des associations de donneurs de sang bénévoles de la Poste et de France télécom.*

Jean-Marc Ouazan, *Établissement français du sang.*

Dr. Josiane Pillonel, Department of Infectious Diseases, *Institut de veille sanitaire, Saint-Maurice.*

Dr. Christine Saura, Department of Infectious Diseases, *Institut de veille sanitaire, Saint-Maurice.*

Bruno Spire, President of Aides association.

Samuel Valcke, *Établissement français du sang*.

Annex 2

Decree, January 12th 2009 setting out criteria for the selection of blood donors.

Annex II - Contraindication Tables.

B- Risks for recipients (Extracts)

- **Transmission of viral infection; risk for a prospective donor of exposure to a sexually transmissible infectious agent:**
 - Unprotected sexual relation(s) with an occasional partner: four months deferral after latest unprotected sexual relation.
 - Multiple sexual partnerships: more than one partner in the last four months: four months deferral after end of multiple partnership.
 - Male-to-male sexual relations: permanent deferral.
 - Unprotected sexual relations with a new partner since less than two months: four months deferral after the latest unprotected sexual relation.
 - Parenteral use of drugs or doping substances without a medical prescription: permanent deferral
-

Annex 3

Men having sexual relations with other men and blood donation. HIV Infection: Prevalence – Incidence. Sexual behaviour⁹²

1-Prevalence of HIV infection (2011) :

General population aged 18 to 69: 0.37%

Men disclosing unprotected sexual relations with other men, with multiple partnerships, frequently anonymous: 13 to 17.7%

Persons stating that they had none other but heterosexual relations (18-69 years): 0.2%

2- Incidence of HIV infection in 2008: per 100,000 person-years:

male homosexuals: 1006

intravenous drug users: 91

foreign heterosexuals: 44

French heterosexuals: 5

3- Sexual behaviour. Men having sexual relations with men and multiple sexual partnerships.

- At least two partners in the last 12 months:

73% (EPG* 2011); 42% (CSF** 2006)

(Heterosexuals: men 12%; women 7% - CSF** 2006)

- Declaring stable relationship: 61% (EPG* 2011), which included:
occasional partners in the last 12 months: 68%; ignorant of partner's HIV status: 17%; ignorant whether stable partner has other partners: 22%

- Sexual practices (last 12 months): *** Out of 10,500 men having sexual relations with other men:

--Median number of partners: 5

--Unprotected anal penetration with occasional partner whose status is HIV serodiscordant or unknown: 38%.

* Enquête Presse Gays 2011; hearing InVS January 2013

** *Comportements Sexuels en France*. 2006.

*** Presentation 25th Nov. 2013: A. Velter *et al.*. *Enquête Presse gays et lesbiennes 2011*. Preventive sexual strategies of men having sexual relations with other men during latest sexual relation with a male partner. Web page: www.invs.sante.fr

⁹² J. Pillonel . Contribution to CCNE.

Annex 4

Residual risk of HIV transmission after modifying blood donation strategy for men who have sex with men⁹³.

- Residual risk of transfusional HIV transmission from 2006 to 2008, i.e. in 3 years: 31 seroconversions of regular donors (incident cases), i.e. an incidence of 1.3/100,000 year-donors; residual HIV risk estimated at 1/2,444,000 donations.
- Fraction of residual risk attributed to men having sex with other men. Out of the 31 incident cases: 15 (48%) are men having sexual relations with men. The residual risk would be reduced to 1/4,700,000 donations, i.e. by a factor of 2, if all men having had sexual relations with other men were to abstain from blood donation.

Impact of a new strategy if contraindication for men having sexual relations with men concerned those who had more than one sexual partner in the last 12 months.

Scenarios	: Best case	Worst case
HIV Incidence in men having sexual relations with men:	blood donors 0,08%	in general 1%
Number of newly infected men likely to donate blood (over 3 years):	9	96
Residual risk	1/3,000,000 donations	1/670,000 donations

With the best case scenario, the situation is identical to what it is currently. In the worst case scenario, the risk is multiplied by 3.6 compared to the situation today. Therefore, modifying the permanent deferral strategy can increase the risk.

“However, some men who had sex with other men, considering that their indefinite exclusion from blood donation is discriminatory, give blood without disclosing these relations. A less strict strategy could be perceived as more equitable and could increase their sense of responsibility regarding blood donation. With this in mind, a later qualitative evaluation would be needed to complement our quantitative analyses.

⁹⁴

⁹³ Pillonel J, Bousquet V, Pelletier B, Semaille C, Velter A, Saura C, Desenclos JC, Danic B. Deferral from donating blood of men who have sex with men: impact on the risk of HIV transmission by transfusion. *Abstract, XVIII International AIDS Conference, Vienna, July 18-23 2010.*

⁹⁴ Pillonel J, Bousquet V, Pelletier B, Semaille C, Velter A, Saura C, Desenclos JC, Danic B. Deferral from donating blood of men who have sex with men: impact on the risk of HIV transmission by transfusion. *Abstract, XVIII International AIDS Conference, Vienna, July 18-23 2010.*

Annex 5

HIV prevalence and incidence in blood donors compared to the general population.

According to information provided by the *Fédération nationale pour le don de sang bénévole* (National Federation for Volunteer Blood Donation).

Sources: InVS, EFS, INTS, CTSA

- **HIV incidence** in donors 2008-2010 (for 10⁵ persons- years)

Donors		General population (18-69 years)	Ratio
Number	Rate for 10 ⁵ P-Y	Rate for 10 ⁵ P-Y	Gen. Pop. /Donors
28	1.05	17*	16

*Le Vu *et al*, Lancet Infect. Dis. 2010 Oct;10(10):682-7

- **HIV prevalence** in new donors 2010 (n= 368,000)

New donors		General Population (18-69 years)	
Number	Rate for 10 ⁴	Rate for 10 ⁴	Gen. Pop./Donors
18	0.49	35**	70

** InVS data

Conclusion: HIV incidence and prevalence low in donors compared to general population.

Annex 6

Resolution CM/Res(2008)5 on donor responsibility and on limitation to donation of blood and blood components

(extracts)

*(Adopted by the Committee of Ministers on 12 March 2008
at the 1021st meeting of the Ministers' Deputies) Council of Europe*

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia⁹⁵,
Considering that the aim of the Council of Europe is to achieve greater unity between its members and this aim may be pursued, *inter alia*, by the adoption of common regulations in the health field;

Taking account of the ethical principles set out in the Committee of Ministers' Recommendation No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion, and in particular Article 1 on voluntary non-remunerated blood donation;

Taking into account the requirements set out in Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components;

Considering the inherent risks of human blood and therapeutic substances of human origin,

Recommends that the governments of States Parties to the Convention:

3. guarantee that blood establishments provide prospective donors with clear and appropriate information, including at least the following:
 - 3.1. the essential nature of blood, blood donation procedure, testing of collected blood, components derived from collected blood;
 - 3.2. possible risks to the health of the donor associated with blood donation;
 - 3.3. possible risks for the recipient of blood or blood components of a given donor;

⁹⁵ 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.

- 3.4. the donor's duty to provide the blood establishment with all relevant information to the best of his/her knowledge, in particular on factors and activities which may increase risks for the recipient;
 - 3.6. the importance for the donor to give the blood establishment post-donation information if the donor has doubts about his/her suitability or in the event of change in health status after donation;
 - 3.7. the consequences of failure to provide the information as specified above during the donor assessment procedure;
 - 3.8. the confidentiality of all personal information given by donors to the blood establishment, notably those related to health and behaviour;
4. ensure that blood establishments are ultimately responsible for the quality and safety of the blood and blood components collected; in particular, blood establishments should:
 - 4.1. be responsible for the final acceptance or deferral of donors on the grounds of a risk assessment based on regularly updated epidemiological data, and bearing in mind the right of blood recipients to the protection of their health, and the resulting obligation to minimise the risk of transmission of infectious diseases. These rights and obligations override any other considerations, including individuals' willingness to donate blood;
 - 4.2. set up arrangements for fair compensation providing for cases where harm is caused to the recipient and/or the donor of blood and blood components.

Annex 7

Letter from the President of the National Consultative Ethics Committee for Health and Life Sciences,
71, rue Saint-Dominique
75007 PARIS
January 24th 2002,
ref. JAL/DS/AM/02.03

addressed to:

Monsieur Christian CHARPY
President of the Etablissement Français du Sang
100, avenue de Suffren
BP 552
75725 PARIS CEDEX 15

Dear Sir,

In your letter of September 25th 2001, you referred to the National Consultative Ethics Committee on issues related to the exclusion of homosexuals from blood donation as a strategy for taking health and safety precautions.

As you stated, new cases of HIV infection through sexual relations are currently more frequent in France in heterosexuals than in male homosexuals. However, if the numbers in each of the groups concerned, geographical origins and gender are entered into consideration, prevalence of infection is still much higher in the male homosexual group (which is not the case for HCV infection). It also seems to be recognised that “sexual promiscuity” in stable partnerships is more frequent for homosexuals than it is for heterosexuals.

Despite the recent introduction of sophisticated and costly biological tests (PCR), a residual viral risk — even if it has become minimal — persists for newly infected people during the short lapse of time preceding the appearance of viral markers. For HIV, this risk is in the order of 1 per 3 million donations. This “biological” safety which increasingly tends to exclude people from given geographical areas (because of the prion risk), must not lead to attaching less importance to donor selection which is still an essential parameter of transfusional safety.

At this time in France, donor selection is based on a two-step procedure: a questionnaire handed to each person wishing to donate blood, followed by an interview with a physician.

The questionnaire aims to incite potential donors to consider their state of health, their past history, their lifestyle, their environment and to encourage possible self-exclusion. At this point, in France, questionnaires vary from one region in the country to another, and the *Etablissement Français du Sang (EFS)* (French Blood Donation Agency) wishes to harmonise it country-wide. All the existing questionnaires state from the outset that the fact of being homosexual, of having or having had homosexual relations, is cause for permanent exclusion

from blood donation. This is expressed in different forms sometimes bracketting together prostitution and homosexuality. This disqualification connected to male homosexuality is irrevocable while other clearly risky behaviours only qualify for temporary exclusion.

Your referral states that "this unqualified exclusion of an entire group, by essence heterogeneous, is judged to be discriminatory by homosexual associations claiming access to blood donation as a fundamental and inalienable right."

To our thinking, the gift of blood, in its context made up of generosity, solidarity, awareness of others, is a duty of help and assistance rather than a "fundamental and inalienable right". This duty of assistance necessarily implies respect for essential safety requirements. Benevolence and solidarity cannot, in any circumstances, lead to neglecting the principles of responsible action and protection owed to others. It is nevertheless fitting that this legitimate principle of safety is not transformed into stigmatisation or measures that can be seen as discriminatory, such as may appear to be the case in documents handed to future donors (and frequently displayed at reception desks).

The EFS' future questionnaire should make it possible to evaluate the risk attached to an individual, taking into consideration his/her behaviour rather than related to risky groups. The questionnaire should not fail to mention any question serving to further improve the transfusion safety that is of enduring concern, while respecting the dignity of potential donors. It should emphasize that benevolence and solidarity can be expressed as forcefully in donating blood as in excluding oneself from doing so. The questionnaire should appeal to each person's sense of responsibility and encourage everyone to speak of his or her doubts to the doctor, even when no recognised risky behaviour is involved.

The questionnaire, which combines questions and information, aims to sensitize potential donors to the contents of the medical interview which can only be effective if the physician has enough time to give it full justice and a climate of trust can be created (as indicated in a note sent by the EFS). It is within the context of this dialogue between the physician and the future donor that case by case decisions must be taken regarding eviction from blood donation, considering male homosexuality as one particular case among others. Selection of donors should be a purely medical decision with no involvement of any public and definitive stance.

It is not the prerogative of any particular group to claim blood donation as a right, but nor is a transfusion establishment entitled to entertain an a priori judgment which may be considered stigmatising.

Yours sincerely,

Signed:

Didier SICARD, President of the National Consultative Ethics Committee
Jean-Antoine LEPESANT, President of the CCNE Technical Section



COMITÉ CONSULTATIF
NATIONAL D'ÉTHIQUE
POUR LES SCIENCES DE LA VIE ET DE LA SANTÉ

Paris, le 24 JAN. 2002

N/Réf. : JAL/DS/AM/02.03

Le Président

Monsieur Christian CHARPY
Président de
L'Etablissement Français du Sang
100, avenue de Suffren
BP 552
75725 PARIS CEDEX 15

Monsieur le Président,

Vous aviez bien voulu saisir le Comité consultatif national d'éthique par lettre en date du 25 septembre 2001, sur les questions posées par l'exclusion du don de sang des homosexuels comme mesure de sécurité sanitaire.

Comme vous le rappelez, les nouvelles infections VIH par voie sexuelle sont actuellement en France plus fréquentes chez les hétérosexuels que chez les homosexuels masculins. Toutefois, si l'on tient compte de la taille de chacun des deux groupes concernés, de l'origine géographique et du sexe des personnes, la prévalence de l'infection reste très supérieure dans le groupe des homosexuels masculins (ce qui n'est pas le cas pour les infections par le VHC). Il semble avéré par ailleurs, que le « vagabondage sexuel » dans les couples stables soit plus fréquent chez les homosexuels que chez les hétérosexuels.

Malgré l'introduction d'examen biologiques sophistiqués et coûteux récents (PCR), un risque viral résiduel, même s'il est devenu minime, subsiste chez les personnes nouvellement infectées pendant le court délai qui précède l'apparition des marqueurs viraux. Ce risque est de l'ordre de 1 pour 3 millions de dons pour le VIH. Cette sécurité "biologique" qui tend à exclure de plus en plus des sujets provenant de telle ou telle zone géographique (en raison du risque prionique), ne doit pas faire relâcher l'importance donnée à la sélection des donneurs, qui reste un paramètre essentiel de la sécurité transfusionnelle.

.../...



Actuellement en France, cette sélection des donneurs est réalisée en deux temps : un questionnaire remis à chaque personne désireuse de donner son sang, puis un entretien médical.

Le questionnaire a pour but de provoquer la réflexion de chaque donneur potentiel sur son état de santé, son histoire, son mode de vie, son environnement et de susciter une éventuelle auto-exclusion. Actuellement, en France, les questionnaires diffèrent selon les régions et l'Etablissement français du sang souhaite procéder à une harmonisation. Tous les questionnaires actuels indiquent d'emblée que le fait d'être homosexuel, d'avoir ou d'avoir eu des relations homosexuelles, représente une cause d'exclusion définitive du don du sang, ceci sous des formes variées en mettant parfois sur le même plan prostitution et homosexualité. Cette éviction liée à l'homosexualité masculine est définitive alors que d'autres conduites à risque notoire n'entraînent qu'une exclusion temporaire.

La saisine indique que « cette exclusion sans nuance d'un groupe par essence hétérogène est taxée de mesure discriminatoire de la part des associations d'homosexuels qui revendiquent en outre cet accès au don du sang comme un droit fondamental et inaliénable ».

Il nous semble que le don du sang, à travers les concepts qui lui sont liés de générosité, de solidarité et de conscience de l'altérité est un devoir d'aide et d'assistance plutôt qu'un droit, qui serait "fondamental et inaliénable". Ce devoir d'assistance implique nécessairement le respect des impératifs de sécurité. La bienfaisance et la solidarité ne doivent en aucun cas faire négliger les principes de la responsabilité pour autrui et de la protection de l'autre. Cependant, il convient de ne pas transformer ce principe légitime de sécurité en stigmatisation ou en mesure qui peut être considérée comme discriminatoire, tel que cela peut apparaître sur les textes remis aux futurs donneurs (et souvent affichés sur les stands d'accueil).

Le futur questionnaire proposé par l'EFS devrait permettre d'évaluer un risque pour un individu en prenant en compte ses conduites plutôt que de porter sur les groupes à risques. Ce questionnaire ne devrait éluder aucune question susceptible de favoriser la quête permanente d'une sécurité transfusionnelle maximale, tout en respectant la dignité du donneur potentiel. Il devrait souligner le fait que la bienfaisance et la solidarité peuvent s'exprimer, avec autant de force, dans le fait de donner son sang que dans celui de s'en exclure. Le questionnaire doit faire appel à la prise de responsabilité en incitant chaque personne, même en l'absence de conduite à risque reconnue, à parler de ses incertitudes avec le médecin.

.../...



Le questionnaire, qui conjugue interrogations et informations, à pour but de sensibiliser le donneur potentiel au contenu de l'entretien médical qui, pour être efficace, suppose que le médecin dispose d'un temps suffisant et que s'établisse une relation de confiance (comme l'indique une note transmise par l'EFS). C'est en effet dans le cadre du colloque singulier entre le médecin et le futur donneur que doit être prise, au cas par cas, la décision d'éviction du don du sang, en considérant que l'homosexualité masculine n'est qu'un cas particulier parmi d'autres. La sélection des donneurs ne doit être que de la seule responsabilité médicale, n'entraînant aucune prise de position publique et définitive. S'il n'appartient pas plus à un groupe qu'à un autre de revendiquer le don du sang comme un droit, il n'appartient pas non plus à un établissement de transfusion de porter a priori un jugement qui peut être considéré comme stigmatisant.

Nous vous prions de croire, Monsieur le Président, à l'assurance de nos sentiments les meilleurs.

Didier SICARD
Président du Comité Consultatif
National d'Ethique

Jean-Antoine LEPESANT
Président de la
Section Technique du CCNE

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