THE BLOOD SAFETY LEAFLET

BACKGROUND INFORMATION FOR TRANSFUSION SERVICE STAFF

Prepared by Dr Peter Flanagan
On behalf of the SAC on Donors
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1. Introduction

The maintenance of a safe blood supply is a primary objective of Blood Transfusion Services. A number of mechanisms are employed to aid achievement of this objective . Screening for virological markers is a key element of such programmes. Improvements in assay design have increased the effectiveness of screening programmes due to improvements in sensitivity especially during the early phase of infection. However assays may fail to identify a proportion of infected individuals. This is particularly the case in the early stages of infection before the development of positive markers, the so called 'window period'.

The careful application of appropriate donor exclusion criteria can add to the benefit of screening assays by identifying prospective donors whose behaviour puts them at risk of acquiring transfusion transmissible infections and thereby reducing the likelihood of infectious seronegative donations entering the blood supply.

The new Blood Safety Leaflet is designed to outline the key donor exclusions which are currently regarded as important in maintaining a safe blood supply. This will replace the current AIDS Leaflet which has been in use over the last few years. The revision should serve two key purposes. Firstly it provides an opportunity to review existing donor exclusion criteria and ensure that they remain appropriate given current knowledge on the epidemiology of HIV infection. Secondly it is recognised that the impact and effectiveness of written information, such as that presented in the leaflet, declines with familiarity. A new form of presentation will increase the likelihood of donors reading and taking note of the contents of the leaflet, thereby becoming more likely to be effective.

A number of changes have been introduced with this revision and the purpose of this document is to provide Transfusion Centre staff with the reasoning behind the new exclusions in the belief that this will help them in ensuring the consistent application of the new criteria.

The introduction of HCV antibody screening in 1991 showed that a significant number of donors found to be infected with this virus should have been excluded on the basis of the current AIDS leaflet. It was agreed to extend the scope of the new leaflet to include Hepatitis B virus (HBV) and Hepatitis C virus (HCV) in the belief that this may increase the effectiveness of the leaflet .

It will be necessary to develop training programmes for staff who will be directly involved in the implementation of the new leaflet. It is particularly important that blood collection team staff are given instruction in the new exclusions and that staff receive training in handling the sensitivities raised. Explanatory information will be made available for donors if required.

The leaflet will be used by all Transfusion centres within the United Kingdom and its introduction will be co-ordinated to ensure that a consistent approach to change is made.

A number of people have contributed to the final version of the leaflet. The main contributors are listed in appendix 2 of this document.

2. The Revision Process

The new leaflet has been prepared by the Standing Advisory Group on Donor Selection, one of the 'Red Book' committees. The process of preparing the new leaflet can be divided into three distinct stages.

(1) An analysis of currently available information on the epidemiology of HIV and other blood borne infections . Advice was sought from experts outside of the Services and in addition the views of the Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) was sought. This process resulted in the development of a number of exclusion categories.

(2) The next stage was to draft a new leaflet. The Department of Health commissioned professional leaflet designers who have experience of working in the health care setting. There was discussion with a number of interested groups, including the Commission for Racial Equality (CRE) and other groups working in the HIV field. Comments that had been received from Transfusion centres were also considered. A number of draft versions of the new leaflet were prepared taking into account feedback on the current leaflet and the need to make the leaflet appear different to ensure that it would attract the attention of donors. Three suggested designs were then thoroughly researched by a professional research company. This involved discussions with donors and with potential donors who might be considered to be "at risk" .

(3) The proposals were then considered by two expert groups from within the Department of Health. These were the Expert Advisory Group on AIDS (EAGA) and the Committee for the Microbiological Safety of Blood and Transplants (MSBT).

At the end of this process which has taken over a year the presentation and content of the new leaflet was finalised and it is now ready for introduction within the service.

3. Summary of Recommendations

The move towards more confidential assessment of donor eligibility has increased the opportunities to obtain information from donors in relation to risk activities. However it remains important to offer prospective donors sufficient information to permit them to self-exclude. Hence a leaflet will continue to be the main mechanism whereby information is made available to donors.

The final recommendations of the group which have been incorporated into the leaflet are as follows:

(1) Risk activities that should result in exclusion from donation

(a) Permanent Exclusion

You should NEVER give blood if:

(i) You, or your partner, are HIV positive
(ii) You carry the hepatitis B or C virus
(iii) You are a man who has had sex with another man, even 'safe sex' using a condom
(iv) You have ever injected yourself with drugs, even once
(v) You have ever worked as a prostitute

(b) Temporary Exclusion (1 year period recommended in line with international practice)

You should ~~never~~ not give blood FOR A YEAR after sex with:

(i) a man who has sex with another man (and you are female)
(ii) a prostitute
(iii) anyone who has injected themselves with drugs
(iv) anyone with haemophilia or a related blood clotting disorder who has received clotting factor concentrates
(v) anyone, of any race, who has been sexually active in Africa* in the past year. This is because the main route of HIV infection there is ~~now~~ heterosexual sex. (*other than Morocco, Algeria, Tunisia, Libya or Egypt).

(c) Trigger clause - Please do not give blood if you think that you need a test for HIV or hepatitis or if you have had sex in the past year with someone you think may be HIV positive or hepatitis positive. **If you have any doubts or questions, talk to the nurse or doctor.**

4. Outline of the main changes

The new leaflet incorporates a number of changes from the currently used AIDS leaflet. The main changes are:

4.1 Extension of the exclusion criteria to include hepatitis B and C in addition to HIV.

This should bring a number of benefits. Firstly it will ensure that donors are made aware of wider issues in relation to the safety of the blood supply, and it should also help defuse many of the issues that have been raised by the CRE and other groups.

4.2 An increase in the number of risk behaviours that result in temporary exclusion.

The introduction of a temporary exclusion for heterosexual sex in Africa or with a prostitute in the current AIDS leaflet has worked effectively and not resulted in a reduction in the safety level of blood for transfusion. It was therefore agreed that all risks which related to heterosexual exposure, except for individuals who have undertaken sex for reward, should be considered as temporary exclusions. The importance of keeping the exclusion categories as simple as possible was recognised and it was felt that all temporary exclusions should be for the same time period.

It is important to emphasise that the exclusion period will relate to the most recent exposure, hence in practice where there is an on-going risk the exclusion will effectively become permanent.

4.3 A reduction in the exclusion period for temporary exclusions

It was agreed that the time period for temporary exclusion should be brought into line with international practice, currently believed to be 1 year. The two year exclusion currently operating was felt to be over cautious and difficult to justify. It is generally accepted that a prolonged antibody negative infectious state for HIV infection does not exist. The one year exclusion will comfortably exclude individuals in the window phase of HIV, Hepatitis B and Hepatitis C.

4.4The use of a "trigger clause" for individuals who feel they may need a test for hepatitis or an HIV antibody test or who feel that they may have placed themselves at risk

Studies of sexual behaviour have shown that a significant proportion of the young sexually active population will have had an HIV test or consider themselves in need of one. Unless specific risk activity had been undertaken, as defined in the leaflet, this should not result in exclusion. The move towards direct confidential medical assessment should facilitate this approach. A trigger statement has been introduced to alert donors who are uncertain to contact a doctor or nurse at the session.

Information is provided as to the availability of confidential testing facilities and national helpline numbers will be provided within the leaflet. This approach is

consistent with the absence of appropriate facilities for pre-test counselling at most blood donor facilities

4.5 Alteration to the wording of the "African" exclusion

This exclusion has been the source of much of the criticism raised in relation to the current leaflet. In this revision an attempt has been made to redefine the exclusion to reduce the negative impact on those affected whilst ensuring that safety is not compromised. Major concern has related to the apparent permanent exclusion of black Africans. This has been overcome by changing the exclusion to encompass individuals who have had sex with an individual of any race who has been sexually active in Africa in the last year. Whilst recognising that this may appear imperfect in epidemiological terms the exclusion is comprehensible, more acceptable to donors and should not result in any dimunition of the safety of the blood supply. This issue is further considered in section 5.2.5.1.

5. Rationale for Individual exclusions

In this section issues considered by the group are detailed. Information is provided, where necessary, to support the decisions that have been made. Additionally in some cases further information is provided to clarify the precise meaning of the exclusion, thereby hopefully leading to greater consistency in application.

5.1 Permanent exclusions

5.1.1 You should NEVER give blood if you, or your partner, are HIV positive

The permanent exclusion of individuals known to be HIV positive is self explanatory.

Partners of known HIV infected individuals are also included in this section since it was felt inappropriate to change this to a temporary exclusion. The term partner is likely to be interpreted as current partner, it is anticipated that the trigger clause asking donors who may have been at risk not to donate but to seek advice is likely to result in questions relating to historic relationships. Such cases will require careful individual assessment with a minimum exclusion of one year since the last exposure.

5.1.2 You should NEVER give blood if you carry the hepatitis B or C virus

This should result in permanent exclusion of donors.

Sexual partners have not been included here, since immunised partners of Hepatitis B infected individuals may be eligible. It is anticipated that the trigger clause relating to possible exposure, or for donors who feel they need a test for hepatitis, will result in requests for clarification. These will need to be carefully assessed on an individual basis in line with current donor selection guidelines.

5.1.2 You should NEVER give blood if you are a man who has had sex with another man, even safe sex using a condom

This should continue to result in permanent exclusion.

Within the UK this continues to be the main reservoir of HIV infection, with prevalence figures in the order of 10 -20% in some areas. Although the rate of increase may be less than that seen in heterosexually acquired cases the absolute number of new cases is higher.

A number of specific issues were considered in relation to this exclusion

(i) It was agreed that in this context sex refers to oral and/or anal penetrative sex.

(ii) It is recognised that safer sex reduces the likelihood of acquisition of blood borne infections. However in the context of penetrative sex the

potential risk of condom failure is such that it would be inappropriate to accept individuals on this basis.

(iii) Studies of sexual behavior have shown a significant level of isolated non-penetrative sex between adolescents or young men. This type of behaviour, so long as isolated, should not result in exclusion.

(iv)The issue of non penetrative safer sex in gay men is a difficult area which may require sensitive assessment of individual eligibility. Isolated episodes of non penetrative dry sex or mutual masturbation clearly carry a lesser risk than repeated episodes of "cottaging" . It may be felt appropriate to permit individuals who have undertaken risks of the former type to donate following a temporary exclusion period but this should only be considered following a thorough confidential assessment of individual cases.

It is hoped that the above will clarify the stance that the services should take in relation to this exclusion. Given the sensitivity that this exclusion engenders it is felt inappropriate to publicise the precise interpretation of the exclusion. This information may however be of value in the assessment of individual cases.

5.1.3 You should NEVER give blood if you have injected yourself with drugs, even once

This should continue to result in permanent exclusion.

Injecting drug users are a significant reservoir of a number of blood borne infections, including, HIV, HBV but particularly HCV. Data from the PHLS AIDS Centre shows a prevalence of 2% HIV infection in IVDUs without symptoms. Studies of donors found to be HCV antibody positive have shown that in excess of 50% have a history of IVDU on close questioning

5.1.4 You should NEVER give blood if you have ever worked as a prostitute

This should continue to result in permanent exclusion

Within the UK the prevalence of HIV infection in this group is approximately 1%, and there is often an association with injecting drug use.

5.2 Temporary exclusions

5.2.1 You should not give blood FOR A YEAR after sex with a man who has had sex with another man(and you are female)

This risk in epidemiological terms is identical to heterosexual sex with an African. This is based on the level of HIV infection in the community at risk. This should continue to result in deferral, but the period of exclusion will be brought in line with geographical heterosexual exposure.

5.2.2 You should not give blood FOR A YEAR after sex with a prostitute

This should continue to result in temporary exclusion.

In some parts of the country there is close link between prostitution and injecting drug usage. There is some evidence that men who have had contact with a prostitute are also more likely to have had sex with another male (Dr A. Johnson personal communication). Male prostitutes are also more likely to be bi-sexual. This may therefore be seen as a surrogate for high risk activity.

5.2.3 You should not give blood FOR A YEAR after sex with anyone who has injected themselves with drugs

Within the UK the level of HIV infection in the injecting drug user population is lower than that in many African countries, it is therefore appropriate that this should result in temporary as opposed to permanent exclusion.

This change brings this exclusion in line with the exclusion for sexual partners of individuals known to be infected with hepatitis C.

5.2.4 You should not give blood FOR A YEAR after sex with anyone with haemophilia or a related blood clotting disorder who has received clotting factor concentrates

This should continue to result in temporary exclusion.

This approach is in line with current FDA requirements.

It is recognised that currently available factor concentrates can be considered to be virologically safe. It was noted that virus inactivated products have only been available for approximately 10 years. Individuals treated prior to the availability of such products may represent a risk of other infections, although it was acknowledged that the number of haemophiliacs in this group is very small.

5.2.5 Heterosexual exposure overseas

5.2.5.1 AFRICA

You should not give blood FOR A YEAR after sex with anyone, of any race, who has been sexually active in Africa* in the past year. This is because the main route of HIV infection there is now heterosexual sex.

*** apart from Morocco, Algeria, Tunisia or Egypt**

This should continue to result in temporary exclusion.

Heterosexual exposure in Africa remains the most frequent identified risk in relation to second generation heterosexual acquisition of HIV, this relates to situations where infection has resulted from sex between men and women and the partner is not known to have a "high risk of infection" e.g. IVDU, Bisexuality, haemophilia. The prevalence of HIV infection in some cities in sub-Saharan Africa is as high as 40% and the evidence is that the prevalence is increasing rapidly in countries such as South Africa. Obviously countries are not uniformly affected but a pragmatic approach needs to be taken in deciding to undertake donor deferral on a geographic basis.

The issue can also be looked at from the perspective of the experience in the UK of HIV infections reported in persons "probably" infected in countries where heterosexual transmission is common and prevalence is high. Data from the PHLS AIDS Centre indicates that 73% of AIDS cases and 76% of HIV infections reported in persons infected through sex between men and women and who did not report a sexual partner with a high risk of infection were in persons probably infected through sex between men and women in African countries. Furthermore in reported AIDS cases 64% of those acquired abroad were in persons from the "black" ethnic group. These points are important in understanding the rationale behind the proposed exclusion.

It is recognised that at present individuals from African countries do not donate frequently in the UK and therefore that the primary aim of this exclusion should be to identify travellers who may have put themselves at risk whilst overseas. Thus the exclusion focusses on individuals who have had sex with someone who has been sexually active in Africa during the past year. The wording of the exclusion will also effectively exclude sexual partners of Africans who are temporarily resident within the UK.

The exclusion may be challenged by epidemiological purists. If an individual is at risk of transmitting HIV then the risk is clearly independent of the duration of residence within the UK. This point was carefully considered during the design phase of the leaflet. However given the epidemiological evidence identified above and recognising the extreme sensitivity of the African exclusion it was decided not to extend the exclusion to include all sexual partners of individuals who have ever been sexually active in Africa. The proposed exclusion is not significantly different to that used in the current leaflet and it is considered that the reduction in exclusion based on sexual activity in the last year as opposed to last two years will not result in a dimunition in the safety of the blood supply.

It is recognised that this particular exclusion had been the cause of significant criticism of previous versions of the leaflet. The need to carefully consider the precise wording of the exclusion was recognised and this was a specific issue reviewed during the field testing of the leaflet. Interestingly it was apparent during the field testing that most donors and potential donors interpreted the current exclusion as a permanent ban on sexually active Africans, extended by inference to include all Africans. The proposed wording within the new leaflet will hopefully overcome this problem.

The possibility of extending the list of countries which were covered by the exclusion was also considered. It was however decided that unless there was good epidemiological data to support this that other countries should not be included. This is further considered in section 5.2.5.2.

A number of specific issues were identified in relation to this leaflet. Some of these were considered during the field testing of the leaflet.

(i) The desirability of including the phrase 'of any race' within the exclusion clause. This was generally perceived as helpful and reduced the level of anxiety that this was a racial exclusion, i.e. directed at black Africans. Interestingly a vocal minority objected to this on the grounds that it introduced a racial element where none existed. It was decided on the basis of the research to maintain this phrase in the exclusion.

(ii) The exclusion does not apply to individuals who have visited Africa with their regular partner and had sex with them. The aim is to exclude 'new or non-regular partners' .

(iii) The exclusion does not apply to couples who have previously been resident in Africa but who have lived in the UK for some time. Individual discretion will be required in considering the eligibility of such individuals. Many of the problems that have occurred in relation to this exclusion relate to this area and a sympathetic approach will be needed in dealing with such cases.

(iv) The continued use of a geographical exclusion which focusses solely on Africa remains sensitive, particularly so with groups such as the CRE. It will be particularly important to ensure that staff at donor sessions are adequately briefed to answer questions in relation to this exclusion. An explanatory leaflet explaining the background to the exclusion will be produced by the SAC on donors for use at sessions.

5.2.5.2 OTHER COUNTRIES

(i) Thailand

The level of infection in the general population in Thailand is of increasing concern, and a number of cases have now been reported in the UK from this source. The nature of the sex industry in Thailand often disguises the nature of prostitution. Data was provided by Dr Noone on the number of cases reported to the PHLS AIDS Centre up to June 1994 where HIV was acquired by heterosexual intercourse by Country. The data indicates that sub-Saharan Africa remains the major source of such infection and does not justify highlighting Thailand as a specific problem. There has not been a significant increase in the

number of cases reported from Thailand with approximately 4 to 8 reports per year over the last 3 years. This contrasts with figures in excess of 100 for many sub- Saharan African countries.

Data from the PHLS AIDS Centre indicates that a number of European countries have been identified as the likely source of a greater number of cases of heterosexually acquired HIV than has Thailand. It is recognised that the situation will require to be carefully monitored but that at this stage the available data does not support specific identification of Thailand as a risk.

(ii) India, Caribbean, Brazil

The level of risk in these countries was considered in view of increasing concern relating to the level of heterosexual acquisition of HIV. During 1994 CDSC received no reports of HIV infection acquired in India, 1 from Pakistan and 11 from Caribbean countries. It was agreed that this data did not support specific identification of these countries. The situation will need to be carefully monitored.

5.3 Issues considered by the group which were not introduced as specific exclusions

A number of new potential exclusions were considered . The main ones are identified below. It was considered that the effectiveness of the leaflet may be diminished if too many potential exclusions are identified. This might distract attention away from the key exclusions which are felt to be important in maintaining a safe blood supply. It was therefore agreed that additional exclusions should only be added to the current list if clear evidence of relevance can be identified.

5.3.1 Individuals who have had multiple heterosexual partners

This should not result in exclusion unless specific risks identified within the leaflet are admitted.

The absence of an exclusion relating to promiscuous heterosexual individuals has been raised as a concern from a number of quarters, particularly in relation to reports of increasing heterosexual acquisition of HIV infection. This issue was carefully considered by the group.

(i) Studies of sexual behaviour undertaken in the London area have revealed that the concept of promiscuity is ill-defined and relative in nature. It was felt inappropriate to base an exclusion on a number of sexual partners in a given timescale.

(ii) Exclusion based on new sexual partners would result in the unnecessary loss of too many donors.

(iii) There is little hard evidence that supports the contention that there is a marked increase in the level of heterosexually acquired HIV infection, other than that which relates to risks identified in the leaflet.

(iv) The possibility of using recent sexually transmitted infections as a surrogate marker for promiscuity is discussed below.

5.3.2 Recent sexually transmitted infection

This will not be identified as a specific risk within the leaflet, although it will continue to result in exclusion as identified in the MAD guidelines.

The feasibility of using a history of sexually transmitted infection as a marker of the high risk lifestyle was discussed. Appropriate infections were considered to be Gonorrhea, Non Specific Urethritis and Chlamydia. However

(i) It was felt that this would result in the unnecessary loss of a significant number of donors.

(ii) The efficiency of such an exclusion in identifying at-risk individuals was questioned. Data resulting from the unlinked anonymous surveillance programme was reviewed but no firm conclusions could be drawn .

(iii) The possibility of focusing on gonorrhea alone was considered. No firm data was identified to support the link between gonorrhea and HIV. It was noted that gonorrhea results in a year long exclusion within the current donor selection criteria and in view of the absence of a clearly

established link it was decided not to formally include this within the leaflet.

5.3.3 Sexual partners of multitransfused individuals

Given the current level of perceived risk from transfusion in the UK it was agreed that these individuals did not require to be excluded

6. Concluding comments

The new Blood Safety leaflet outlines the key exclusion categories which will be used to assist in the maintenance of a safe Blood supply within the UK. A number of alterations from the current leaflet have been introduced . It will be necessary to brief staff within the service in relation to the new exclusion criteria to ensure that they are consistently applied and also to ensure that staff are able to answer questions from donors

Appendix 1

BLOOD TRANSFUSION AND HIV - International Perspective

COUNTRY EXCLUSION	USA	FINLAND	AUSTRALIA	SAC RECOMMENDATION
1. Individuals known to be infected with HIV	PERMANENT	PERMANENT	PERMANENT	PERMANENT
2. Men who have had sex with other men	PERMANENT	PERMANENT	PERMANENT	PERMANENT
3. Individuals who have ever injected themselves with drugs.	PERMANENT	PERMANENT	PERMANENT	PERMANENT
4. Men or women who have ever worked as prostitutes.	PERMANENT	1 YEAR	PERMANENT	PERMANENT
5. Individuals who have had sex with a prostitute	1 YEAR	1 YEAR	PERMANENT	1 YEAR
6. Women who have had sex with a bisexual male	1 YEAR	1 YEAR	PERMANENT	1 YEAR
7. Sexual partners of individuals who have injected drugs.	1 YEAR	?PERMANENT	PERMANENT	1 YEAR
8. Sexual partners of individuals believed to be HIV positive	1 YEAR	PERMANENT	PERMANENT	1 YEAR
9. Sexual partners of haemophiliacs	1 YEAR	N/A	PERMANENT	1 YEAR
10. Individuals who have had gonorrhoea	1 YEAR	N/A	6 MONTHS	1 YEAR
11. Heterosexual exposure in sub-Saharan Africa.	N/A	N/A	N/A	1 YEAR

Appendix 2

Key contributors to the new Blood Safety leaflet

1. Standing Advisory group on Donor Selection (UKBTS/NIBSC)

Dr Virge James	Consultant Haematologist NBS Sheffield (Chairperson)
Dr Frank Boulton	Medical Director NBS Southampton
Dr Peter Flanagan	Clinical Director NBS Leeds
Dr George Galea	Medical Director Aberdeen and NE Scotland BTS
Dr Patricia Hewitt	Deputy Director NBS Colindale
Dr Philip Minor	NIBSC
Mrs Mairi Thornton	National Donor Services and PR Manager Manager SNBTS
Dr Tim Wallington	Medical Director NBS Bristol

2. Expert epidemiological advice

Dr Ahilya Noone	Consultant Epidemiologist CDSC Colindale
Dr Anne Johnson	Senior Lecturer Academic GU Unit UCH/Middlesex.

3. Leaflet design

Commisioned by DoH

Undertaken by Redhouse Lane Communication Ltd
1a Avery Rd London W1X 9HS

4.Research and field testing

Commisioned by Central Office of Information

Undertaken by Cragg Ross and Dawson Ltd
18 Carlisle Street London W1V 5RJ.