



## **Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)**

### **Donor Selection Criteria Report (2017) Version 2**

Published July 2017

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# 1. Executive Summary

- 1.1 The criteria that are used by the UK blood services to select blood donors on the basis of behaviours that may increase the risk of acquiring and transmitting blood borne infections (BBI) last underwent major review by SaBTO in 2011. That review led to a change in selection criteria for potential blood donors who are men who have sex with men (MSM). The selection criteria were changed from a permanent deferral to a twelve month deferral from last sexual contact in England, Scotland and Wales Blood Services in 2011, and by The Northern Irish Blood Transfusion Service in 2016. Another working group later reviewed the evidence base for selection of living and deceased donors of cells and banked tissues in the UK in relation to MSM behaviour. The SaBTO recommendation on Tissues & Cells on MSM Donor Selection review was published in July 2013.
- 1.2 Since the change in selection criteria for MSM the routine ongoing surveillance has shown that the risks of transmission of BBI have not increased. A large anonymised, unlinked survey of over 65,000 blood donors has been carried out since the last review to better measure donors understanding and compliance with donor selection criteria. There is high but not perfect concordance with the existing selection criteria. In addition, since that last review more comprehensive data is now available about the risk of acquiring BBI from a wide range of social behaviours. These data have been used to model the likely future concordance with selection criteria and the estimated risk of TTI (Transfusion Transmitted Infections).
- 1.3 Over the past two decades there have been a number of national and international judicial inquiries into the transmission of Human Immunodeficiency Virus (HIV) and hepatitis C virus (HCV) by blood and plasma products in the UK. A common theme of these judgements is the legal liability of Blood Services for harm caused by TTI. These legal proceedings attracted significant media and political attention and led to reputational damage and loss of trust in Blood Services and Government.
- 1.4 In November 2015 a review of donor selection criteria for MSM was announced by the then Public Health minister, Jane Ellison. In January 2016 SaBTO decided that this would be best done as part of a comprehensive review of donor selection criteria including other behaviours where there may be an increased risk of acquiring blood borne infections and thus potential to transmit to recipients of blood, tissues or cells. A working group was set up specifically to review the evidence base for donor selection, deferral and exclusion in the UK in relation to sexual behaviours that may increase the risk of acquiring specific blood-borne infections; HIV, hepatitis B virus (HBV), HCV and Syphilis. In addition, the group was asked to review the risk that these infections could be acquired following

procedures that involve piercing of the skin as well as flexible endoscopy, a procedure specifically covered by blood safety legislation.

- 1.5 The working group included SaBTO members, invited professional experts and representatives of stakeholder organisations. These included representatives of groups affected by the current selection criteria and patients who have diseases that are treated with multiple blood component transfusion. The first working group meeting was immediately followed by a public meeting which had been advertised to organisations and individuals who had made their interest in this issue known over the preceding months.
- 1.6 All Substances of Human Origin (SoHO) have a risk of transmitting infection to recipients of those substances. After considering the available evidence the working group decided to adopt the same level of tolerance of risk as was done in the 2011 review, i.e. the risk that a potentially infectious donation is not detected on routine screening due to a window period infection is less than one in a million donations. Consideration of other risks to recipients resulted in the Working Party recommending a more stringent criterion for potential donations from people who have injected drugs in the past.
- 1.7 The full report explores many relevant issues as listed in individual chapters, including; ethics, motivation, epidemiological data on BBI, international practice, the performance of tests for diagnosing BBI, and statistical modelling of the risk of TTI.

## **The Working Party recommended for blood donation:**

No deferral after:

- 1.8 Endoscopy, body piercing, acupuncture or tattooing carried out in UK
- 1.9 This would require a legislative change in respect of the deferral periods following endoscopy, body piercing and tattooing, or acupuncture by UK based qualified practitioners.

Three-month deferral after:

- 1.10 Endoscopy, body piercing, acupuncture, tattooing performed out of UK or non-commercial premises in the UK or for acupuncture, someone who is not considered a 'qualified practitioner'. As above, any change will require a change to the law.

- 1.11 Sex between men.
- 1.12 Sex with a person who has received money or drugs for sex.
- 1.13 Someone who has received money or drugs for sex (Sex will need to be defined in the Donor Selection Guidelines, recommend as physical anal, oral or vaginal sex).

Three-month deferral after:

- 1.14 Sex with a partner resident and sexually active in a high risk area.
- 1.15 Sex with a partner who was previously resident and sexually active in a high risk area for HIV/ AIDS and who has not been screened by the blood service.
- 1.16 Sex with a high-risk partner (ie with HIV, HBV, HCV, syphilis, HTLV, person who has received money or drugs for sex, person who has injected or been injected with non- medically prescribed drugs).

One Year deferral after:

- 1.17 Injection of not medically prescribed drugs.
- 1.18 Will require a legislative change.

### **The Working Party recommended for gamete donation:**

- 1.19 For sperm donor tested at donation and then five months with sperm released if negative. This will require a change in legislation;  
  
or
- 1.20 Sperm donor s tested at donation by serology, quarantine for 3 months, repeat serology and test by NAT, sperm released if negative;  
  
or
- 1.21 In exceptional circumstances with risk assessment and recipient consent, sperm donor tested at donation by serology and NAT, sperm released if negative.
- 1.22 For egg donation, donor tested by serology 2 months prior to donation, retested at start of medication by serology and NAT, donation released if negative.

## **The Working Party recommended for haematopoietic Stem cells (HSC) and tissue donation:**

### No deferral after:

- 1.23 Body piercing, acupuncture or tattooing carried out in UK
- 1.24 For donors with long term partners born in areas where HIV endemic and partner is tested negative

### Three-month deferral after:

- 1.25 Body piercing, acupuncture, tattooing performed outside of UK.
- 1.26 Sex with a partner resident and sexually active in a high risk area.
- 1.27 Sex with a partner who was previously resident and sexually active in a high risk area and who has not been screened.
- 1.28 Sex with a high-risk partner (ie with HIV, HBV, HCV, syphilis, HTLV, commercial sex worker, injecting drug user).
- 1.29 Sex between men.
- 1.30 Sex with a commercial sex worker.
- 1.31 Commercial sex work (receiving money or drugs for physical sex). Injection of not medically prescribed drugs
- 1.32 This deferral period may be reduced by doing individual risk assessment if the risk of acquiring an infectious disease may be outweighed by the risk of delaying a lifesaving transplantation.

### One Year deferral after:

- 1.33 Habitual use of intravenous drugs for addiction.
- 1.34 This can be reduced to 3 months supported by individual risk assessment together with single NAT testing and bacterial screening if the risk of acquiring an infectious disease may be outweighed by the risk of delaying a life-saving transplantation.

### Tissue and cell establishments:

- 1.35 In contrast to blood donation which is managed by the four UK blood services, there are many providers of tissues and cells. The establishments have to comply with EU Directive for donor selection and testing as a minimum requirement which does not require Nucleic Acid Testing (NAT) as a mandatory test. Non blood service establishments are advised to consider the SaBTO recommendations for suitability of application within their organisation taking into consideration of the testing algorithms used to screen donor samples for transmissible infections. It is recommended that a deferral period following a behaviour which may put a donor at higher risk of a Blood Borne Infection should be at least a minimum of two infectious window periods unless after risk assessment the recipient's clinical circumstances indicate that there is likely to be more harm from avoiding the cellular product/tissue than from transmitting an infection.

## 2. Background and Process

2.1 The criteria that are used by the UK blood services to select blood donors last underwent major review by SaBTO in 2011. That review was confined to the risk of transmission of blood borne infections (BBI) from men who have sex with men (MSM) and from commercial sex workers (CSW). The review led to a change in selection criteria for potential blood donors who are MSM from permanent to twelve months deferral from last sexual contact in all UK blood services. This change was adopted by services in England, Scotland and Wales in 2011 and by The Northern Irish Blood Transfusion Service in 2016. There was no change recommended to the selection criteria for commercial sex workers, people who had received money or drugs for sex, due to lack of evidence. Following the SaBTO recommendation, a working group reviewed the evidence base for selection of living and deceased donors of cells and banked tissues in the UK in relation to MSM behaviour. The scope of this review included haematopoietic stem cells (family and friends, unrelated donors and cord blood); pancreatic islets; hepatocytes; banked tissues (skin, cornea, heart valves, amnion, bone and tendon); and gametes and embryos for reproductive purposes (ie not for derivation of cell lines).

2.2 The SaBTO recommendation on Tissues & Cells on MSM Donor Selection review was published in July 2013. The products were divided into four groups for risk based assessments and recommendations for different tissues and cells.

Group 1: Haematopoietic stem cells, whether from family and friends, or unrelated adult donors, or from cord blood. This also includes related products from the same donor types eg donor lymphocytes, and virus-directed T cells.

2.3 For 'family and friend' donors: NO DEFERRAL.

2.4 Retain the individual risk/benefit donor assessment i.e. ensure documentation of MSM behaviour but place no specific restrictions regarding donation.

This represented no change in practice.

2.5 For unrelated donors joining a registry: NO DEFERRAL.

2.6 The MSM behaviour should be documented, to facilitate an in depth discussion should the donor be a potential match for a patient. This ensures that the practice of individual risk/benefit assessment prior to donation is continued.

For Anthony Nolan this represented no change in practice.

For the British Bone Marrow Registry and the Welsh Bone Marrow Donor Registry this represented a change from life time deferral.

2.7 For cord blood donors: NO DEFERRAL.

2.8 Allow donation with documentation of, but no restrictions regarding, MSM behaviour of the partner, and retain the individual risk/benefit assessment prior to use of the donation.

This represented a change in practice.

2.9 For Anthony Nolan this was a change from a lifetime deferral after sexual contact by the woman with a man who has ever had MSM behaviour.

2.10 For British Bone Marrow Registry this was a change from a 12-month deferral after sexual contact by the woman with a man who has ever had MSM behaviour.

Group 2: Pancreatic islets and hepatocytes: NO DEFERRAL.

2.11 Retain the individual risk/benefit donor assessment ie documentation of, but no specific restrictions regarding, MSM behaviour.

This represented no change in practice.

Group 3: Banked tissues (corneas, heart valves, amnion, bone, skin, and tendon)

Men: Allow donation 12 months or more after last MSM sexual contact.

Women: Allow donation 12 months after last sexual contact with a man who has ever had sex with another man.

2.12 This was represented a change from the lifetime deferral for both men and women, consistent with SaBTO guidance for blood donation.

Group 4: Sperm, eggs and embryos: NO DEFERRAL

2.13 Retain the individual risk/benefit donor assessment ie documentation of MSM behaviour, but no specific restrictions regarding donation.

This represented no change in practice.

- 2.14 The 2011 & 2013 reviews did not consider individuals with other risk behaviours who are deferred either permanently or for a specific period because they were considered at increased risk of transmitting BBI to recipients of blood or blood products and tissues and cells.
- 2.15 Since 2011 the donor selection criteria used by UK blood services, related to infection risk, have undergone a number of changes, principally to reduce the risk of transmission of infections that have emerged or become more widespread, for example Ebola and Zika viruses (see section 11).
- 2.16 Since the change in deferral status of MSM, routine ongoing surveillance has shown that the risks of transmission of BBI have not significantly changed (see section 11). A survey of over 65,000 blood donors presented to SaBTO in January 2016 demonstrated that there is a very high degree of concordance with the existing criteria, with few donors not adhering to the guidance. This is explored in more detail in section 7.
- 2.17 Over the past two decades there have been a number of national and international judicial inquiries into transmission of HIV and HCV by blood and plasma products. In the UK, the most important inquiries are those of Mr Justice Burton (2001), Lord Archer (2009) and Lord Penrose (2015). A common theme of these judgements is the legal liability of Blood Services for harm caused by TTI under (inter alia) the Consumer Protection Act 1987. These legal proceedings attracted significant media and political attention and have led to reputational damage and loss of trust in Blood Services and Government. The Penrose Inquiry led to public apologies from Scottish National Blood Transfusion Service, The First Minister of Scotland and the Prime Minister.
- 2.18 In November 2015 a review of donor deferral criteria for men who have sex with men was announced by the then Public Health minister, Jane Ellison. In January 2016 SaBTO discussed the nature of the review and decided that this would be best done as part of a comprehensive review of donor deferral criteria for diseases that can be transmitted sexually, although not exclusively via that route, and which could pose an infection risk to recipients of blood, tissues or cells. A working group was set up specifically to review the evidence base for donor selection, deferral and exclusion in the UK in relation to sexual behaviours that may increase the risk of acquiring specific blood-borne infections (HIV, HBV, HCV, Syphilis). In addition the group was asked to review the risk that these infections could be acquired following procedures that involve piercing of the skin as well as flexible endoscopy, a procedure specifically covered by blood safety legislation. This wider remit includes tattooing, body piercing, acupuncture and non-prescription parenteral drug use.

- 2.19 The working group had membership from SaBTO, invited professional experts and representatives of stakeholder groups. The members are listed in section 3. The stakeholder groups include representatives of groups that are affected by the current selection criteria and individuals representing groups who have diseases that are treated with multiple blood or blood product transfusion. The first working group meeting in April 2016 was immediately followed by a public meeting which had been advertised to groups and individuals who had made their interest in this issue known over the preceding months. At the first working group meeting thirty-three work streams were identified and a lead for each identified. Working group members were invited to participate in each area.
- 2.20 The working group has used the Alliance of Blood Operators safety framework as an aid to evaluate the implications of the recommendations. The working group's report will be presented to SaBTO in June 2017 who it is anticipated will make recommendations to the health ministers of the devolved administrations.

## 3. Remit and Terms of Reference

### Remit

3.1 The working group will: “review the evidence base for donor selection, deferral and exclusion in the UK in relation to social behaviours that may increase the risk of acquiring specific blood-borne infections (HIV, HBV, HCV, syphilis). In addition the group will review the risk that these infections could be acquired following procedures that involve piercing of the skin as well as flexible endoscopy, a procedure specifically covered by blood safety legislation. It will make recommendations to SaBTO on the most appropriate ways to maintain a safe and sufficient supply of blood, tissues and cells. The review will make recommendations as to whether current selection criteria are appropriate acknowledging that patient safety is paramount”.

Its remit includes:

1. Evaluating the evidence for selection and deferral policies;
2. Defining the infections of interest, both known and unknown;
3. Reviewing the epidemiology on blood borne infections
4. Assessing the performance of current testing procedures;
5. Estimating the residual risks for specific blood borne infections;
6. Reviewing relevant policies in other countries including individual assessment;
7. Assessing new evidence on donor behaviour and motivation and their impact on safety.
8. Evaluating the operational impact of any recommendations;
9. Making recommendations for disseminating the outcome of the review.
10. Ensuring that recommendations are in line with current legislation and relevant regulations.

## Terms of Reference

3.2 In formulating its advice, the working group will:

- take full account of the scientific evidence available, including the nature of uncertainties and assumptions used to reach conclusions;
- consider the impact of its advice on all stakeholders, including but not exclusively donors, patients, the UK blood services, the wider NHS, and the public
- take full account of the need to maintain the safety of blood, tissues and cells under the remit of the Precautionary Principle;
- aim to explore possible options to allow as wide a pool of donors as possible
- take account of views of interested parties on areas of concern, including concerns regarding discrimination, and address these as far as possible
- identify specific areas of research where further work is required to reduce uncertainty;
- be ultimately accountable to SaBTO
- not be addressing the selection criteria for solid organ donors

### Modus Operandi

1. The working group will meet on at least three occasions during the review.
2. A smaller sub-group or groups will meet on a regular basis (in person or by teleconference) to draft papers and assess the available evidence.
3. Papers will be circulated no later than 7 days prior to any ordinary meeting.
4. Administrative issues will pass to the SaBTO Secretariat who will also maintain a document library.

### For Information

5. Travelling expenses are payable for attendance at meetings in line with DH rates for individuals who serve on committees.
6. Members of the Working Group are asked to use public transport and to travel at standard rates.

[Insert title]

7. Receipts must be submitted with claims.

## 4. Current blood, tissue, cell and gamete donor deferral criteria

- 4.1 European Union (EU) law, UK Blood Safety and Quality Regulations (BSQR) and UK Tissue Safety and Quality Regulation (TSQR) set the minimum standards for donor selection. The World Marrow Donor Association (WMDA) guidance aims to provide minimum standards for unrelated adult haematopoietic stem cell donor registries to use in assessing the medical suitability of their donors. The purpose of WMDA is to provide globally harmonised medical assessment criteria which simultaneously protect the interest of donors whilst ensuring the safety of cellular products across international boundaries. Donor selection criteria are produced by The Joint Professional Advisory Committee (JPAC) of United Kingdom Blood Transfusion and Tissue Transplantation Services, usually taking advice from the Standing Advisory Committee (SAC) on Transfusion Transmitted Infections, and being written by SAC Care and Selection of Donors and SAC Tissues and Cellular Therapy Products (SAC TCTP). Advice is taken from SaBTO as appropriate. JPAC selection criteria apply to all UK donor services but individual services may operationalise them in different ways. Current WMDA guidance can be viewed here:[https://wiki.wmda.info/index.php?title=Main\\_Page](https://wiki.wmda.info/index.php?title=Main_Page) and current UK donor selection guidelines can be viewed here:  
<http://www.transfusionguidelines.org.uk/>
- 4.2 JPAC produce donor selection guidelines for 1. Whole Blood and Component Donors 2. Allogeneic Bone Marrow and Peripheral Blood Stem cells 3. Cord Blood 4. Deceased tissue donor and 5. Live tissue donors. The JPAC donor selection criteria are written so that they 'fail-safe'. There are two categories of deferral; Obligatory, the donors must not donate and Discretionary where a donor may donate often after a temporary deferral period and with the addition of extra tests such as hepatitis B anti-core antibody for blood donors with a recent history of piercing.
- 4.3 The EUTCD (EU Tissues & Cells Directive) requires that donors must be excluded unless justified by documented risk assessment if they have a "History, clinical or laboratory evidence of HIV, acute or chronic Hepatitis B (except in case of persons with a proven immune status), Hepatitis C, HTLV I/II, transmission risk or evidence of risk factors for these infections". Unlike the EU blood Directive (see Chapter 17), the EUTCD does not go into the details about risk factors for acquiring infections. It should be noted that anti-HBc antibody is a mandatory test for all tissue and cell donors.
- 4.4 Donor selection criteria are important in both ensuring the safety of both donors and underpinning the safety of donations.

## Tattoos and piercing, cosmetic procedures involving needles

4.5 'Piercing' events, where piercing includes tattoos, body piercing or acupuncture, are considered in the 'Exposure to risk of acquiring a transfusion-transmissible infection' section of the EU blood directive. This allows for a temporary deferral of 6 months following the piercing but this deferral may be reduced to 4 months provided a NAT test for hepatitis C is negative. The UK guidelines produced by JPAC for blood donors include derma-rolling, permanent and semi-permanent make-up, piercing and tattooing in this category. Botox and other cosmetic treatments involving needles are classified as complementary therapies. The UK criteria are more precautionary and donors must be deferred for 12 months from the piercing, however a discretionary deferral of 4 months from the event may be applied if a HCV NAT is negative and anti-HBc antibody is carried out. Where an additional test for hepatitis B is carried out donors may usually be accepted if a validated test for hepatitis B core antibody is negative or if the hepatitis B core antibody is positive and anti-HBs of greater than 100miu/ml has been documented.

For Tissue donors:

4.6 A similar deferral is used for tissue donors but anti-HBc is carried out for all tissue donors routinely. Tissue donors cannot donate if less than four months from last piercing and a validated hepatitis C NAT must be negative.

For Cell donors:

4.7 Obligatory: Must not donate if less than four months after last piercing

4.8 Discretionary: If it is less than four months since last body piercing there must be a discussion with the designated medical officer who will decide if the donor can be accepted following a document risk assessment and discussion with the transplant centre. A negative test for HIV, HCV and HBV is mandatory.

4.9 WMDA guidance on any acupuncture, body piercing, permanent or semi-permanent make-up or tattoo is in line with JPAC guidelines and described below:

Guidance at RECRUITMENT for adult volunteer donor and maternal donor (cord blood donation)

ACCEPTABLE

Guidance at CT/WORK-UP

ACCEPTABLE at the discretion of the requesting transplant centre, who should be informed where and when the procedure occurred.

Nucleic acid testing (NAT) for hepatitis B, C and HIV are recommended. Justification for guidance

There is a risk of transmission of blood-borne viruses, particularly hepatitis B and C, through the use of inadequately sterilised equipment used for tattoo, acupuncture and body piercings. A 4 month deferral is recommended from the date of the procedure, but this may be reduced by the transplant centre if it is thought that the risk of acquiring an infectious disease is outweighed by the risk of delaying transplantation.

4 months allows for the 'window period' between disease exposure and the earliest the disease may be detected by modern nucleic acid testing (NAT) assays.

## **Gametes & Embryos**

4.10 There are no specific deferrals for social risks specified for donors of gametes and embryos. Criteria for selection of these donors are described later in this chapter.

## **People who have any history of injecting non-prescribed drugs**

4.11 The EU blood directive states that there must be a permanent deferral for anyone with a history of injecting non-prescribed drugs IM or IV, including body building hormones and steroids. JPAC guidance applies to blood, tissues and cell donors, people must not donate if they have ever injected or been injected with drugs including body building drugs and injected non-prescribed drugs. WMDA guidance is less stringent but requires that potentially addictive drugs were not injected in the last 5 years.

[Insert title]

## **WMDA:**

Guidance at RECRUITMENT for adult volunteer donor and maternal donor (cord blood donation)

UNACCEPTABLE if injected drugs of addiction within the previous five years

UNACCEPTABLE if injected other non-prescription drugs, such as anabolic steroids, within the previous six months

Guidance at Commencing Treatment / WORK-UP

UNACCEPTABLE if injected drugs of addiction within the previous five years

If donor has injected androgenic steroid, or other non-addictive medications, then they may proceed at the discretion of the requesting transplant centre.

Justification for guidance

Use of non-prescribed injected drugs of addiction is associated with a considerably higher risk of transmission of blood borne infectious diseases.

Although case reports of transmission of hepatitis C have been reported in users of androgenic steroids have been reported, the exposure risk remains very low and such donors may proceed at the discretion of the requesting transplant centre.

## **Endoscopy**

- 4.12 The EU blood directive requires a temporary deferral of 6 months following endoscopy which can be reduced to 4 months if a NAT test for hepatitis C is negative. The JPAC blood donor selection guidelines require a 6 month deferral which can be reduced to 4 months if an anti-HBc test is carried out and is negative as well as a negative HCV NAT. Donors who have had an examination carried out using a rigid endoscope can be accepted.

- 4.13 Endoscopy is not a specific reason for deferral for tissue and cell donors in the EUTCD. Therefore there is no specific entry for endoscopy in JPAC guidelines for tissues and cells.

## **Complementary therapies including acupuncture and Botox**

- 4.14 The EU blood directive requires a 6 month deferral for acupuncture and botox therapies unless the procedures are carried out by a qualified practitioner using single-use needles. As with tattooing and piercing the deferral can be reduced to 4 months if HCV NAT is negative. In the UK donors may be accepted if the treatment was carried out by NHS staff on NHS premises, this includes GP premises; alternatively donors may be accepted if the procedure was carried out by someone on the qualified health care professional list outside the NHS (appendix C). Alternatively donors may be accepted after a 4 month deferral if, a validated test for hepatitis B core antibody is negative and HCV NAT is negative.
- 4.15 For tissues and cells the obligatory deferral is four months for therapies involving penetration by needles. The discretionary criteria of accepting donors without deferral apply if the therapy is carried out in the NHS or by registered health care professionals (similar to the blood donor selection guidelines). The WMDA guidance does not differentiate between acupuncture and body piercing.

## **Sexual behaviours**

- 4.16 The EU blood directive states that persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood should be deferred. The deferral should be appropriate to the risk posed by the behaviour although the directive does not give advice on this and it is left to individual countries to assess the local epidemiology and risk to the blood supply. JPAC seeks advice from SaBTO when a change to the sexual behaviour guidelines is required or SaBTO may themselves recommend a change to ministers.

## **JPAC guidelines below for blood donors.**

1. You must not donate if:

[Insert title]

You have ever received money or drugs for sex.

You must not donate for at least 12 months after sex (even if you used a condom or other protective) with:

- a) (If you are a man): another man.
- b) (If you are a woman): A man who has ever had oral or anal sex with another man, even if they used a condom or other protective. There are exceptions, so please ask.

You must not donate for at least 12 months after sex (even if you used a condom or other protective) with:

A partner who is, or you think may be:

- a) HIV or HTLV positive.
- b) A hepatitis B carrier.
- c) A hepatitis C carrier.
- d) A partner who has ever received money or drugs for sex.
- e) A partner who has ever injected, or been injected with, drugs: even a long time ago or only once. This includes bodybuilding drugs. You may be able to give if a doctor prescribed the drugs. Please ask.
- f) A partner who has, or you think may have been, sexually active, in parts of the world where HIV/AIDS is very common. This includes most countries in Africa. There are exceptions.

### **JPAC Tissue Safety Entry for Tissues & Cell donors:**

Obligatory: Information must be provided so that those at risk do not donate.

- e) You have ever received money or drugs for sex

**You must not donate for at least 12 months after sex (even if you used a condom or other protective) with:**

A partner who is, or you think may be:

- a) HIV or HTLV positive
- b) A hepatitis B carrier
- c) A hepatitis C carrier
- d) A partner who has ever received money or drugs for sex
- e) A partner who has ever injected, or been injected with, drugs: even a long time ago or only once. This includes bodybuilding drugs. You may be able to give if a doctor prescribed the drugs, please ask.
- f) A partner who has been, or you think may have been, sexually active in parts of the world where HIV/AIDS is very common. This includes most countries in Africa. There are exceptions.

**4a. For donors of haematopoietic progenitor cells, pancreatic islet cells or hepatocytes:**

- 4.17 There are no specific restrictions regarding donation after male-sex-with-male sexual contact, instead a documented individual risk/benefit donor assessment is required.

**4b. For donors of tissues/cells other than haematopoietic progenitor cells, pancreatic islet cells or hepatocytes:**

- 4.18 You must not donate for at least 12 months after sex (even if you used a condom or other protective) with:
- a) (If you are a man): another man.

b) (If you are a woman): A man who has ever had oral or anal sex with another man, even if they used a condom or other protective.

## **WMDA**

4.19 There are no strict definitions of high risk behaviours but include people having high risk sex with multiple partners, those who pay or are paid for sex and people from parts of the world where HIV has a high prevalence. Unprotected sex within a monogamous relationship is not necessarily seen as high-risk behaviour, regardless of whether it is a male homosexual relationship or not, if both partners remain monogamous during a set time-frame. However, a donor identified to be engaging in high-risk sexual behaviour may be acceptable at the discretion of the requesting transplant centre.

## **Assessment of gamete and embryo donors**

### Scope

4.20 This assessment relates to the donation, storage and use of sperm and eggs (gametes) and embryos for reproductive purpose in the UK. It also includes imported gametes and embryos that have been procured or created outside the UK and imported for reproductive purpose since such clinical procedures are all subject to regulation under the Human Fertilisation and Embryology Act (1990, amended 2008).

### Remuneration of Gamete Donors

4.21 In the UK, there is mixed economy provision of fertility treatment. The NHS pays for only 18% of donor gamete treatments. Most of this will include the 'purchase' of gametes from provider clinics.

4.22 Donors of sperm and eggs receive financial compensation for their donation. For sperm donors this limited to £35 per clinic visit and for egg donors the limit is £750.

### Clinical context

4.23 There are 75 licensed clinics in the UK that provide donor insemination treatment and 77 that provide IVF with donated eggs or sperm. HFEA data records that, in 2013, the number of sperm donors was 586. Of these, about 76% were UK donors and the remainder were imported donations. Imported donors must comply with

selection and screening procedures acceptable to the HFEA. Each recipient may have more than one insemination procedure during the course of treatment.

- 4.24 In 2013 there were 1,103 eggs donors.
- 4.25 The number of patients treated in 2010 with donated gametes or embryos was 975 (sperm), 1380 (eggs) and 269 (embryos).
- 4.26 For gamete and embryo donors there is a maximum of 10 family units that can be created using donations from the same donor.
- 4.27 The supply of donors is not limited by patient compatibility matching requirements but by the lack of donors. The UK supply was influenced by the removal of anonymity regulations.
- 4.28 Furthermore, the quality of the semen is important as only samples that retain good potential fertility after cryopreservation can be accepted.
- 4.29 Social and medical history information is obtained; some of which is made available to potential recipients so that they can choose their donor. There is a detailed discussion with the recipient about the donor that would include infection potential risks.
- 4.30 The recipients of gametes and embryos that are used for reproductive purposes will be healthy individuals for whom pregnancy would be appropriate. Treatments provided are potentially life-creating and there is therefore the additional consideration of the welfare of a child should vertical transmission of infection occur.
- 4.31 The HFEA review of egg and sperm donation in 2012-13 is available in [http://www.hfea.gov.uk/docs/Egg\\_and\\_sperm\\_donation\\_in\\_the\\_UK\\_2012-2013.pdf](http://www.hfea.gov.uk/docs/Egg_and_sperm_donation_in_the_UK_2012-2013.pdf).
- 4.32 Embryos undergo a culture period of up to 6 days before transfer. Any infection in the system at that stage is usually lethal to the embryo. If suitable for later transfer, the embryo can be cryopreserved, usually by vitrification in vapour phase or liquid nitrogen.

#### Donor deferral

- 4.33 There is no donor deferral in the UK that is based on social history. This is because it has been routine practice to cryopreserve and quarantine sperm for 6 months after the final donation. In practice, a clinic is unlikely to accept a sperm

[Insert title]

donor who may be at high risk of a new infection during the collection timescale because of cost implications.

## 5. Ethical Considerations

- 5.1 The donation of blood and other substances of human origin (tissues and cells) is a voluntary system. In contrast gamete donors may receive payment. Voluntary donations, such as that occurring in the NHS, has traditionally been regarded as an act of altruism; a gift to an unknown person who is in need. Such altruistic acts are regarded as morally praiseworthy. Recent evidence suggests that the factors that motivate people to donate blood within a voluntary system are in fact more complex. A meta-analysis of antecedents of blood donation behaviour and intentions found that the strongest correlations were with donor-related factors such as experience of donation, self-identity and anticipated regret at not donating (Bednallet al., 2013). It is likely that similar complexity of factors is associated with cell, tissue and gamete donation. Donation confers benefit on the donor as well as the recipient and a policy that excludes some people from an activity that is an acknowledged benefit to them must be justified. In the case of donation of substances of human origin this justification is grounded in the moral requirement to protect the health of donors and recipients (Brailsford et al 2015).

### Moral duties to recipients and donors

- 5.2 Those responsible for the collection, distribution, and provision of substances of human origin to patients who require them have a moral obligation to ensure that patients who are already vulnerable because of their condition are not put at unnecessary risk of harm as a result of receiving them. In the case of donation of gametes, there is also a moral obligation to protect any child born as a result of the donation from potential harm. However, there is also a moral obligation for the NHS as health care provider to aim to provide an adequate supply of these potentially life-saving substances to benefit patients.
- 5.3 In addition to its duty of care to patients in need of blood products and other substances of human origin, the health service also has a moral obligation to those who wish to donate. This includes an obligation to protect donors from harm but also an obligation not to unfairly discriminate against them. Respect for persons requires that we treat people equally unless there is a strong moral justification for not doing so.

## **Balancing moral duties**

- 5.4 The moral justification for discriminating against a potential donor is based on the moral obligation to protect others (or indeed the donor) from harm. For example, if donating blood would put the donor at risk of significant harm because they were already profoundly anaemic, then refusing to accept their donation would be morally justifiable. Similarly if the donor was known to have a blood borne virus that could seriously harm a recipient, refusal to accept donation would also be morally justified. The presence of infection and the associated high risk of harm to the recipient is a morally relevant difference that allows discrimination in respect of blood donation in these cases.
- 5.5 The empirical evidence that certain activities are associated with a higher risk of blood borne infections and the presence of a window period when such infections may not be detected in donated blood, may provide a justification for excluding specific groups of people from donating based on the risk rather than the certainty of a transmissible infection. This is the basis of current deferral criteria for blood donation and cell and tissue donation in the UK and internationally. However, the assessment and justification for treating donors differently on this ground relies on both empirical evidence of the risk and a moral judgement of whether the risk is sufficient to justify treating these donors differently (bearing in mind that no donation is risk free).

## **Acceptable risk sufficient to justify selection of donor groups**

- 5.6 Judgements about acceptable risk at an individual level are based on both empirical facts and personal values. Interpretation of risk at a population level must take account of the fact that individuals and groups will have different perceptions of, and tolerance for, risk. Risks are perceived as less acceptable if they are involuntary inequitably distributed and damage identifiable victims (Sjoberg, 2000). Risks of Transfusion Transmitted Infections (TTI) fulfil these criteria. Risk tolerance will depend on an individual's perception of a specific risk and how they weigh competing risks. For example, someone requiring a bone marrow transplant may accept a higher risk in relation to donation of haematopoietic stem cells because of the lifesaving potential of transplantation.
- 5.7 Policy makers must determine what level of risk is acceptable in order to ensure that there is an adequate supply of substances of human origin for those who need them. If the level of acceptable risk is set too low supplies will be insufficient and potential recipients will suffer serious, possibly fatal, harm. The supply of substances of human origin needs to be both adequate and safe to fulfil the duty to protect recipients from harm. A further moral consideration for policy makers is the obligation to use limited resources to provide health benefit to the whole

population. A strategy for donor screening that was very expensive to implement would have implications for health care funding in other areas.

- 5.8 Having agreed an acceptable level of risk of transmissible infection, there is still a question about how to ensure this standard is met while treating potential donors fairly. Individual risk assessment for each donor would be the least discriminatory approach but would need to satisfy the requirement of not breaching the acceptable level of risk.

## **Making an ethically justifiable policy decision**

- 5.9 The 2011 report of the Donor Selection Criteria Review (SaBTO 2011) recommended that in considering the deferral criteria for blood donation it was necessary to take into account the following:

- 'Evidence of the level of risk of transmission of a blood borne infection from the donation, that is the risk of a false negative test in screening
- Whether the level of risk is sufficient to justify treating some donors differently,
- Whether the parameters for defining the high risk donor group are fairly set (avoiding unnecessarily wide parameters for example lifetime deferrals, and justifying the agreed parameters for example the presence of a window period as justification of a specified deferral period),
- The feasibility, and resource implications, of setting narrower parameters such as individual risk assessment,
- Whether there is another reason to treat different donor groups differently, for example evidence of the effect of a change on the supply of blood and blood products for patients from specific ethnic backgrounds'.

- 5.10 These considerations apply equally to the donation other tissue, cells and gametes.

- 5.11 The requirement for fairness means that all potential deferral groups should be considered using the same criteria. To date most of the empirical evidence looking at risk and compliance has been in the MSM group. Fairness requires that evidence is also sought in relation to other groups so that consistent decision making processes can apply across all groups.

## The ethical importance of trust

5.12 The delivery of effective health care, including provision of substances of human origin, requires a high level of trust in the service from both recipients and donors. Loss of trust or failure to trust can have negative consequences. If excluded groups consider the reason for exclusion unfair or incorrect they are may not comply with the policy. Studies with donors who are MSM and do not comply with permanent deferral policies found that they are more likely to comply with a temporary deferral period, suggesting that when the justification is seen as reasonable or trustworthy compliance will improve (Grenfell et al 2011, Hughes et al 2015). Engendering and maintaining trust is more likely if those affected by the decisions have a voice in the process and if changes to policy are transparent and based on available evidence and publicly accepted values. Clear and effective communication with all groups will be important whatever the final recommendation. The need for trust and transparency in the area of donation of human tissue was highlighted in the Nuffield Council on Bioethics report: Human Bodies: Donation for medicine and research (2011). The report identified the importance of professional and relational values such as trust and respect as playing an essential part in creating and maintaining systems in which people will be willing to consider donation. This includes trust that systems are subject to good and responsible governance.

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## 6. Influences on altruism in general population and compliance with medical "rules"

- 6.1 Does a consideration of another's welfare ('altruism') influence our decisions to comply with general medical protocols (e.g., adherence to medicines, keeping appointments, take part in medical trials), as well as provide accurate information to a physician? We will explore the limited data on this. First we need to define what we mean by altruism in this context.
- 6.2 What do we mean by altruism in this context? From the perspective of evolutionary biology, an altruistic act is defined by increasing the Darwinian fitness (i.e., long-term survival and fecundity) of the recipient at a cost to the donor (West et al., 2011; Bshary et al., 2008; Sober & Wilson, 1988). However, in the context of medical decision making our concern is primarily with psychological altruism (motives for action: Sober & Wilson, 1988). Ferguson and Lawrence (2016: see also Ferguson 2015) define altruism in this context as either a preference for or ultimate desire to maximize the welfare (utility) of others, by reducing their suffering, at a personal cost, and without personal benefit. However, while in many cases people benefit from other's help, the helper often gains personally from helping (e.g., reputation as a good person, feelings of warm-glow: Ferguson 2015). Whether this personal gain is the primary motivation for helping is crucial in defining the act as purely altruistic (see Sober & Wilson, 1988). If some personal gain is the primary motive we may talk broadly of 'impure altruism' and if it is not 'pure altruism'.
- 6.3 With this in mind, we start by examining how altruistic motivations (pure or impure), preferences and traits are linked to compliance with medical rules.

### Altruism and Medicine

- 6.4 Without volunteers health services would struggle to meet and provide the levels of care and service they currently do. For example, volunteers provide (1) organs, cells and tissues for transplantation, (2) blood for transfusion, (3) participants for medical trials and experiments, (4) staffing for hospital radio, cafes, advice etc., (5) money and time to support medical charities, (6) staffing for patient and relative support groups, (7) vaccination uptake to meet herd immunity against the flu (Ferguson & Masser, in press). Many of these activities require that the volunteer

complies with medical screening questions (blood and organ donation, clinical trials) or comply with uptake requests (e.g., vaccination). People may also have to make decisions for the benefit of others (e.g., their relatives) where they have to put the welfare of others (and their wishes) ahead of their own. Below we look at the limited literature on how altruism may influence people's willingness to comply with medical directives.

## **Altruism and General Medical Compliance**

- 6.5 The literature is somewhat limited and we will focus on two areas that have received the majority of attention. Here the primary concern is with decisions that involve, to some degree, a consideration of the well-being of others. These decisions are either made on behalf of another's health (surrogate decision making) or require consideration of the relationship between one's own health and another's health (e.g., vaccination and temporal constraints).
- 6.6 **Surrogate Decision Making:** This involves making a decision on behalf of others (e.g., children, relatives). Altruism enters into this process through empathy, whereby the decision maker may have to put themselves in the position of the other person they are deciding for (the target), taking into account any known wishes of the target, and trying to maximize the target's well-being (which at times may be in conflict with advice from a physician or the decision maker's own perspective on the issue). A recent theoretical model (Tunney & Ziegler, 2016) suggests that this process contains biases. For example, the decision maker will, implicitly at times, be biased by self-regarding process. That is, the decision maker will not always be able to disentangle self- and other-regarding perspectives. This is less likely, the more the decision maker is empathic, accountable for their actions, familiar with the target and when the consequences are significant (Tunney & Ziegler, 2016). Thus, key social constraints – such as accountability and significance of consequences – are important for more impartial and reasoned decision making. If we think about this in the context of blood donation (as well as tissues and cells), then the donor needs to 'empathize' with the recipient of blood (or tissues and cells), as the decisions the donor makes influences the recipient directly. The donor may want to think of themselves as recipient, for example. Such increased 'empathy' with recipients may highlight the consequences of not providing accurate. This conjecture needs testing.
- 6.7 **Vaccination:** Vaccination involves a cost to the person being vaccinated (e.g., time, pain, potential side-effects) which will afford them some degree of immunity. The population, however, is only protected (herd immunity) once a large percentage (e.g., 80%) is vaccinated. However, the decision maker does not know

who else will get vaccinated. If 80% of others do, they do not need to. They can free-ride on the herd immunity provided by others and avoid any personal cost. Free-riding is the optimal strategy, as long as everyone else gets vaccinated. However, if everyone takes the free-riding option as herd immunity is not achieved. The structure of this decision is a classic social dilemma in game theory known as a public goods game (PGG). Furthermore, this whole decision is embedded in the fact that the vaccine itself will not be 100% effective, may carry side-effects (risks) and people's beliefs will differ with respect to the vaccine. So do people altruistically comply with a request to get vaccinated (winter flu vaccine, MMR) to help protect the population or tend towards free-riding?

- 6.8 Indeed, free-riding is a major problem for the success of vaccination programmes (see Meszaros et al., 1996; Hershey et al., 1994). Levels of free-riding increase with the perceived risks associated with vaccines (see Bauch & Earn, 2004) and the relative proportion of vaccine sceptics and believers in a population (see Shim et al., 2012). Imitation of others getting vaccinated may reduce free-riding to some degree (Bauch, 2005). Importantly, communicating the social benefits of vaccination (herd immunity) encourages people to express a preference to get vaccinated as long as the cost of being vaccinated (e.g., easy to get vaccination) is low (Betsch et al., 2013; see also Bauch et al., 2003). There are also effects of age. Younger age groups contribute more to herd immunity of the elderly than the elderly do.
- 6.9 Evidence further shows that when the positive effects of vaccination are focused on individual benefits, older participants are more likely to get vaccinated. But when positive effects of vaccination are focused on group benefits, then younger individuals are more likely to get vaccinated (Chapman et al., 2012). Loss framed messages (that empathize the cost of not getting vaccinated), are effective in encouraging vaccination relative to gain framed messages (that emphasise the benefits of getting vaccinated) (see Ferguson & Gallagher, 2007; Gerend & Shepherd, 2007; Gerend et al., 2008). Here again we see that social context is crucial to encouraging compliance with vaccination requests. Similarly social context is important in terms of blood donors' emotional reactions to blood donating (Clowes & Masser, 2012; Ferguson & Masser, in press; Masser, France, Himawan, Hyde & Smith, in press). This suggests that the social context of donation is important.
- 6.10 Temporal Altruistic Considerations: When considering their future health a substantial number of people (approx. 50%) taking into account the effect of their future health, not only in terms of their own well-being, but also its effect on their loved one's and friend's well-being (Krol et al., 2016). Two types of temporal health 'altruist' are defined: (1) 'longevity altruists' who wish to live as long as possible so as to avoid their close friends and relatives having to suffer grief and

(2) 'Quality of life altruists' who wish to avoid the burden of their ill-health on loved ones. These of course are not mutually exclusive. While both groups are motivated to comply (to live longer and avoid serious illness), the former may well want to live longer, at all costs, and may try more treatments and options.

## Personality and Medication adherence

- 6.11 Many factors influence non-adherence to completing a prescribed treatment regimen (e.g., memory, understanding, starting to feel better, side-effects of drugs, emotions). A recent meta-analysis showed that the personality trait of conscientiousness was a key predictor of medical adherence (Molloy, O'Carroll & Ferguson, 2014). The highly conscientious person is motivated not by altruism but by organizational and methodical skills which contribute positively to being able to comply and adhere to medication protocols. It has been shown that trait conscientiousness predicts sustained blood donor behaviour (Ferguson, 2004). This trait may help in organizing time and appointment to donate.

## Altruism and Deception

- 6.12 People may influence the outcome of their treatment by not complying with a course of treatment as prescribed. People may also influence the outcome of their treatment by not providing accurate information to their physician. This may be accidental (poor recall) or deliberate. When considering altruism, there is considerable evidence and theory to show that altruism and cheating/deception are intricately linked. For example, a heightened sense of compassion towards in-group members leads to in-group-serving dishonesty (Shalva, Carsten & De Dreu, 2014). Furthermore, people may be tactically dishonest (McNally & Jackson, 2013). We also need to detect cheats to avoid being exploited (ten Brinke, Vohs & Carney, 2016).
- 6.13 Importantly from the perspective of non-compliance. People might also be willing to tell small non-consequential lies (so called "White Lies"), if they believe this will help others. This brings into conflict two moral principles (helping others and telling the truth). Evidence shows that people who show altruistic preferences are less likely to tell a 'white lie' that helps both the altruist and the recipient but are more likely to tell a lie that helps the recipient but not the altruist (altruistic white lie) (see Bizziou-van-Pol et al., 2015). One reasonable hypothesis based on these findings, is that if pure altruism underlies blood donor behaviour then the altruistically

motivated donor may feel that they can tell a 'white lie' to be allowed to donate, as their donation will help others (the 'altruistic white lie'). The crucial question here is what donors (new and repeat) class as a 'small non-consequential lie'. At present we have no evidence to address this question directly? However, there is some indirect evidence with respect to MSM who wish to donate. When expressing reasons for non-compliance, MSM groups report: (1) feeling at low risk; (2) that the blood is screened anyway and that such screening is infallible; (3) that they always use safe sex: and (4) the frequency of sex with a man is very low (see Romeijn et al. 2016; Grenfell et al., 2011). In which case non-compliance maybe seen as non-consequential. However, as noted in Chapter 5 above MSM may be more likely to comply when a temporary deferral period is justification and seen as reasonable (Grenfell et al 2011). Thus good communication of the rationale for any deferral period that increases trustworthiness of the decision would appear crucial. Finally, people will also be more likely to be complaint if the costs of being non-compliant outweigh any benefits of being non-complaint (Zollman, Bergstrom & Huttegger, 2013). This again emphasizing the consequences to non-compliance for the recipient may be important also (see Surrogate Decision Making section above).

- 6.14 Summary: Altruistic preferences do enter into medical decision making when the decision involves others. Key factors in enhancing compliance seem to be greater empathy, accountability, a sense of the consequences of one's actions on others, trust that the compliance criteria are reasonably derived, and the social context in which the decision takes place. Altruist may also be willing to tell 'small non-consequential lie' if that helps another. However, what constitutes a small non-consequential lie in the context of blood donation is unknown.

## **Blood Donor Motivations and Compliance with Screening**

- 6.15 The above indicates that altruism is important to compliance with medical protocols. If altruistic motivations are going to influence compliance with screening in blood donation the crucial question is the extent to which blood donation is a purely altruistically motivated act. If it is, then non-compliance may be linked to telling 'small non-consequential lies', for example. However, recent work applying and synthesizing evidence from epidemiological, experimental psychology and behavioural economic suggests that blood donors are often motivated by 'impure altruism' (i.e., a mixture of wanting to help others but also feeling a sense of personal warm-glow from donating: Ferguson, 2015 for a review). However, it is acknowledged that other motivations such as donating: (1) to achieving goals, (2) because no-one else does (reluctant altruism), (3) to repay the transfusion serves for helping a loved one (reciprocity), (4) to get a health check, (5) to signal to

others that you are fit and healthy or (6) out of habit, all play a role in blood donation (see Bednall & Bove, 2011 for a review; Ferguson, 2015). Thus the effects of altruism on decision medical compliance may have less impact in blood donation.

- 6.16 However, the literature on motivations for non-compliance with screening, in MSM, suggests that this non-compliance is driven by other motives rather than altruism (see Romeijn et al.2016; Grenfell et al., 2011). Therefore, some of these other motivations may motivate the potential donor to be non-compliant about behaviours that would lead to deferral. If the potential donor wishes to display to others that they are a blood donor, as an indicator that they are fit and healthy, then they may be non-compliant. Those motivated to donate to get their blood screened may likewise be motivated to be non-complaint. While these types of motivations are expressed at a much lower frequency than altruism and warm-glow (Bednall & Bove, 2011), they still may be important determinants of non-compliance. Also the social context may be crucial. Donors often donate with others they know – as part of organized drives. A potential donor may not want to be seen to be deferred by their colleagues. Thus, if it is believed that a non-compliant answer is non-consequential, the potential donor may be non-compliant to avoid embarrassment. In the next chapter of this report (Chapter 7), we present some new data on this issue.

## **Medical Compliance and Motivation to Donated Cells and Tissues**

- 6.17 What motivation underlie cell and tissue donation. When asked to express their motivations potential sperm donors highlight a mixture of altruism, financial recompense, with actual donors citing warm-glow and investing in their own fertility as well as altruism, financial recompense (Van den Broek, Vandermeeren, Vandermeeren, Enzlin, Demyttenaere & D’Hooghe, 2013). Commercial egg donors cite a mixtures of altruism and financial gain and volunteer eggs donors primarily pure altruism (Purewal & van den Akker, 2010). Thus some of the biases that might result in non-compliance due to altruism may be observed in this context.
- 6.18 However, importantly, and unlike blood donation, there is also a choice phase to both sperm and egg donation. For example, a sperm donor has to be chosen from the 1000s on offer.
- 6.19 Thus, how men choose to signal their qualities is crucial and requires that the donor be honest in terms of the information they give to potential recipients. Such

signals are open to 'deception' as men will theoretically compete to show their genetic, phenotypic, psychological and social worth (Miller, 2007, Miller & Todd, 1998; Zahavi & Zahavi, 1997). It is crucial that the recipient can detect cheats in this context (ten Brinke, Vohs & Carney, 2016). The one study of sperm donors that has examined how men use the space on the donor web-pages to signal their health and fitness, fecundity, social preferences and so on (Bokek-Cohen, 2015). While physical characteristics are verifiable, traits like social preferences are less so. Similarly, it has been argued that it may be the case that being a blood donor is a way to signal your 'fitness' to attract a partner (Ferguson, 2015). Thus people may wish to be a blood donor to signal their health.

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## **7. Compliance and Motivation: evidence from the UK blood donor survey**

### **Introduction**

7.1 The UK donor survey, a large, anonymous, unlinked online survey of donors with a recent history of donation (Davison et al, 2015), revealed that overall, compliance with the lifestyle deferrals was high, more than 99%. However, one of the top four reasons for non-disclosure of a deferrable lifestyle behaviour was not being allowed to give blood. The motivations for giving blood among survey responders was analysed including compliant and non-compliant donors.

### **Methods**

7.2 Donors were asked why they came to give blood at their last donation choosing any reason that applied from a number of tick box options (Box 1) and were also given a free text option where they could expand on their reasons, or report another reason not covered by the tick boxes. These free text reasons were coded at the University of Nottingham according to a framework. The free responses were coded into 43 categories (many new e.g., “in memorial”, “known victim effect”) and subsequent reliability analyses conducted. The Kappa reliabilities were generally good-to-high. These were dummy coded and merged with the survey data on compliance and behaviour.

7.3 Comparisons were made between (1) the non-compliant donors and those without the reported behaviour and (2) between donors with the behaviour (compliant or not) to those without the behaviour using logistic regression in a data analysis and statistical software package (STATA).

### **Results**

7.4 Based on tick box responses and coded free responses.

- 395 non-compliant donors to UK-wide lifestyle deferrals (intranasal drug use deferrable in Northern Ireland only, so not included here).
- a further 461 donors who had a lifestyle deferrable behaviour but were deemed compliant based on timing or other explanation given by the donor.
- The most common motivation in over 70% of donors was “To do a good thing”, a pro-social act. There was no difference in those with a deferrable lifestyle behaviour compared to those without. This motivation was significantly more likely to be ticked by non-compliant donors compared with donors without the behaviour (78% versus 71%,  $p=0.009$ ). The difference was no longer significant after adjusting for age group.

Box 1: The question on motivation is shown below:

Why did you come to give blood the last time you donated?

Please choose all that apply

- To help someone in need
- I would rather not say
- To find out my blood type
- In response to an advert
- My friend(s) /workmates / family were going
- To get a blood test for infection
- My partner was going
- I was just passing / I had nothing else to do
- To do a good thing
- So my partner can give blood
- Not sure
- To feel good

Other, please specify

- The second most common motivation in nearly 70% of donors was “To help someone in need”, a purer altruistic motivation with no difference between the three groups.
- Wanting “To feel good” (warm glow) was ticked or mentioned by about a quarter of donors without a deferrable lifestyle behaviour. This proportion was slightly higher in those with a deferrable lifestyle behaviour at 28% ( $p=0.008$ ) but there was no significant difference when adjusted for age group and donor type (new/repeat/returning).
- Test seeking levels were low but significantly higher in those with a deferrable lifestyle behaviour compared to those donors without (1.8%) and slightly higher again comparing only non-compliant donors (2.4% versus 0.4%  $p<0.001$ ). Test seeking was still associated with non-compliance when adjusted for demographic variables. Only one out of eight non-compliant donors also answered “yes” to being at risk of HIV or hepatitis.
- About 6% attended their last session because workmates or family were going, many sessions being held in the workplace. There was no difference in those with or without a deferrable lifestyle behaviour.

### **Based on the coded free-responses only.**

- A small but significantly higher proportion of donors with a deferrable lifestyle behaviour gave because of direct reciprocity (7.8% versus 3.3%  $p=0.010$ ) or for “future protection”(7.8% versus 2.7%  $p=0.002$ ) compared with those without a lifestyle deferrable behaviour. This effect was still significant when demographic variables were added but was not different when comparing compliant with non-compliant donors. The category ‘all direct reciprocity’ reflects getting something back from donating (blood in the future) or donating because you have had a transfusion or nearly had one. The category ‘future protection’ is similar with the donor donating now to try and ensure there is blood in the future. Again the focus here is on self-protection and not necessarily regard for others. Those with deferrable lifestyle choices may feel particularly at risk of needing blood in the future or that their loved one’s might (future orientation). For example, a donor who had deferrable criteria in the past may have had a major change (e.g., had children) and may now feel a responsibility to donate to protect their children’s’ future. Those in the direct reciprocity category reflect paying the transfusion service back for a transfusion they had received (a deferrable criterion). Again the numbers of individuals are small.

7.5 Two examples of a donor giving for direct reciprocity/future protection highlight nicely the reasoning of donor in this group. Both donors had sex between men more than 12 months previously so the temporary MSM deferral no longer applied:

“I should not expect to receive blood if I do not give it [despite being able to]; wife pregnant so heightened awareness of need for blood for mothers and babies”

“it's the right thing to do - one day I might need a blood transfusion”

- A small but significantly higher proportion of donors with a deferrable lifestyle behaviour gave because of perceived need (7.0% versus 3.1%,  $p=0.02$ ). This small effect was still significant when adjusted for demographic variables. This may reflect a ‘moral’ motivation that blood donation is important and a need is not being met, so they need to donate. It may be that the need for blood is viewed as more important than compliance: It

is better to give than not as the blood is needed. This may reflect a lack of awareness in the group with deferrable behaviours about what happened to blood once donated. They may think it is ‘treated’ to be made safe.

- Non-compliant donors had not given any free text describing self-orientation or emotion- based motivations.

## Conclusions

- 7.6 Non-compliant donors had high levels of pro-sociality and purer altruistic motives the same as compliant donors with or without a lifestyle deferrable behaviour. This replicates findings in positive donors from the US where altruism was the most common reason for donating (Vahidnia et al 2016).
- 7.7 Test seeking, although at a very low level was the only significantly different motivator observed, in the tick box questions, in this survey by non-compliant donors compared with donors without a deferrable lifestyle behaviour. A low level of test seeking fits with the main reason for non-compliance reported as a self-perception of being at low risk. Furthermore, test seeking did not correlate to donors saying that they were at risk of HIV or hepatitis infection. Again these were small number. But nonetheless discouraging test seeking is an important goal of the service. One option here would be to highlight other more appropriate routes for testing.
- 7.8 As in other donors, non-compliant donors are subject to peer pressure through work, friends and family attending. This links with embarrassment being one of the top four reasons cited for non-compliance (although many of these non-compliant donors also have self-perceived low risk).

- 7.9 Giving so a partner could give, was cited by a slightly higher proportion of compliant donors with a deferrable lifestyle behaviour. However, this became non-significant when demographics were controlled ( $p=0.090$ ). While non-significant, this is still a trend and one that should be considered given the social nature of donation. The higher level of this motivation in donors with deferrable criteria may reflect the idea that those with partners who are donors are more aware of deferrable criteria and may not want their partners to know that they cannot give. These people may attend to donate, knowing they will be deferred, but happy to 'hide' this from their partner via the mechanisms of having their blood tested such as the policy of allowing partners to give a sample to prove their negativity in the case of donors with a partner who may have had sex in sub-Saharan Africa.
- 7.10 Future protection (and direct reciprocity) is seen to be higher in donors who had deferrable behaviours. This motivation reflects the idea that the donor is donating now to try and ensure there is blood in the future for themselves and others (usually loved ones) or the moral justification that 'to receive you should give'. Again a main focus here is on self-protect, as the other is usual kin (children). Thus, the donor may donate, with this reflecting a realisation that their kin may be more in need of blood in the future. Indeed, it may be the case that the donors who know they have deferrable behaviours justify to themselves donating as it for a greater good - their children.. This is speculative but could be explored empirically. However, again the numbers are small. Non-compliant donors gave no response on self-orientation (personal goals) or emotions, however, the numbers were too small for any real conclusions for the emotions. For goals it may be the case that the non-compliant donors have the goal to donate rather than make a specific target or goal.
- 7.11 Although donating as a protest against the MSM policy was not cited among motivations it was mentioned in free text reasons for non-compliance and in views expressed about the Donor Health Questionnaire (DHQ). Questions that are important here, however, are what would be the effect of changing the MSM policy on (1) perceptions of risk and (2) donor motivations?

## Overall

- 7.12 What does this tell us about non-compliance? Donating to get a test for infection emerged as a differentiator of compliance and deferrable lifestyle. This is a behaviour to be discouraged but is only reported by a very small numbers of individuals.

- 7.13 Two notions of moral justification were suggested about why donors with deferrable lifestyle behaviours were more likely to report the following motivations (1) blood is in short supply and an important and needed commodity and (2) I donate for future protection/reciprocity. We suggest, speculatively, that in the former case donors may reason that the 'need for blood outweighs any costs' and in the latter case that 'donating to protect my family/kin outweighs any cost'. If donors are making this type of cost-benefit judgement then they are weighting the personal benefits over the costs to others. This may reflect a mis-perception of what happens to blood when evaluating the cost ('blood is treated to make it safe. So it is OK to donate'). Thus the donor feels safe to donate – they believe they are not harming others – and indeed that donating blood is beneficial. Thus, this reasoning may lead to non-compliance. These speculations are empirically testable. If verified it would suggest that work is needed to re-educate potential and current donors around 'cost' in the cost-benefit judgements that are being made.
- 7.14 There was a trend that 'donating so your partner can give', was higher in those with deferrable criteria and thus may lead to non-compliance. While just a trend it is at this point probably worth exploring this further. For example, it has implications for campaigns where donor recruit new donors (who are likely to be partner or family or friends) may result in more deferrable donor turning up. This is a testable hypothesis.
- 7.15 In all the above caution in interpretation is needed as in many cases the numbers are small.

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## **8. Performance of tests for diagnosing BBI**

### **Laboratory screening by UK Blood Services**

- 8.1 The laboratory screening of donated products is necessary before their release to inventory for clinical use. Donations are screened for evidence of infection with a number of blood borne infectious agents using assays that detect specific markers of infection for each of the infectious agents. All donations collected in the UK are currently screened for markers of: HBV), HCV, HIV), and syphilis - mandatory screening. Only donations from first time donors and donations used to prepare non-leucodepleted products are screened for human T cell lymphotropic virus (HTLV). There are other infectious agents, or other markers of infection for a mandatory infectious agent, for which some donations are screened - additional or discretionary screening, determined either by additional specific donor risk or specific recipient needs, for example malaria testing due to recent travel; additional anti-HBc due to recent piercing.
- 8.2 The screening assays used include those that detect serological targets (antigens and antibodies) and those that detect molecular targets (viral nucleic acids), the combination of serological and molecular targets enhancing the overall sensitivity of the screening programme.
- 8.3 Donations which are initially reactive in any of the screening tests are retested and the repeat testing results are used to determine the fate of the donation. Blood donations which are still reactive on repeat testing are considered unsuitable for use and discarded. Non-blood donations which are still reactive on repeat testing may be considered suitable for release to inventory if confirmatory testing determines that the reactivity seen is non-specific and the donor is not infected. All screen repeat reactive donations are referred to the specialist reference laboratories that serve the UK Blood Services for confirmatory testing to determine if the screen reactivity reflects true infection in the donor or is non-specific.

### **Infectious agents**

- 8.4 This working group focused on the risk of transmission of the following four blood-borne infectious agents.

## HBV

- 8.5 Blood donations are screened for HBV surface antigen (HBsAg) and for HBV DNA. HBsAg screening is performed on individual donations, HBV DNA screening is performed on pools of 24 donations. Reactive pools are resolved to their individual component samples for re-testing.
- 8.6 Non-blood donations processed by UK Blood Services are screened as for blood donations except that molecular screening is performed on individual donations and with the inclusion of HBV core antibody (anti-HBc screening). Anti-HBc screening is a mandatory requirement for non-blood donations, but is only required for blood donations collected from donors with specific additional risk of exposure to HBV, specifically endoscopy and therapeutic/cosmetic procedures that pierce the skin. At this time donations which are screen negative for other HBV markers but which are anti-HBc reactive can be released to inventory if they have an anti-HBs level of at least 100 mIU/ml.

## HCV

- 8.7 Blood donations are screened for HCV specific antibody (anti-HCV) and for HCV RNA. Anti-HCV screening is performed on individual donations, HCV RNA screening is performed on pools of 24 donations. Reactive pools are resolved to their individual component samples for re-testing.
- 8.8 Non-blood donations are screened as for blood donations except that molecular screening is performed on individual donations.

## HIV

- 8.9 Blood donations are screened for HIV specific antigen and antibody (HIV Ag/Ab) in a combined assay, and for HIV RNA. HIV Ag/Ab screening is performed on individual donations, HIV RNA screening is performed on pools of 24 donations. Reactive pools are resolved to their individual component samples for re-testing.
- 8.10 Non-blood donations are screened as for blood donations except that molecular screening is performed on individual donations.

## Syphilis

- 8.11 Blood and non-blood donations are all screened for specific treponemal antibody (anti-Tp). Anti-Tp screening is performed on individual donations.

## Screening effectiveness

- 8.12 The overall effectiveness of the screening programme is determined by a number of factors. Although assay performance is the main factor, the means by which the assay is performed (the equipment used), and the overall quality management system all contribute to the accuracy and reliability of the overall screening outcomes.

## Assay performance

- 8.13 Overall assay performance can be measured in terms of sensitivity, ability to detect all infected cases, and specificity, ability not to signal with uninfected cases. However assay sensitivity and specificity are to a large extent mutually exclusive, as one increases the other decreases. Assay selection has to therefore balance the need for both high sensitivity, to ensure that all truly infected donors are detected, and high specificity, to ensure that non-specific reactivity is kept to a minimum.
- 8.14 The initial identification of assays appropriate and suitable for the infectious disease screening of donated products across the UK is the responsibility of the NHS Blood and Transplant (NHSBT) and SNBTS Kit Evaluation Groups. These groups undertake scientific evaluation of potentially suitable assays and maintain up to date lists of assays evaluated as suitable for screening. To avoid duplication and waste of resources these two groups work together and share evaluations and evaluation data. Sensitivity evaluation is performed to ensure that the manufacturer's performance claims are valid and to ensure that the assay performs equally as well with samples from a range of infected individuals including those from the donor population being screened. Assays for the same screening target are compared directly so that relative performance can be determined. The assays considered to be suitable for donation screening

represent those which give the best overall performance across assay design, analytical and clinical sensitivity, robustness and usability.

- 8.15 The operational screening laboratories are then able to use any assays from these lists, although over recent years there has been the move to full managed service agreements through competitive tendering with the complete serological screening package being provided by one supplier and the complete molecular screening package by another supplier.

## Equipment

- 8.16 A key part of ensuring consistency and reliability in assay performance and outcomes is the equipment that the assays run on. Across the UK the majority of donations are screened using dedicated 'closed' systems which are fully automated robotic systems and require minimal operator involvement outside of loading samples and reagents. These systems have the ability to scan sample and reagent barcodes, check reagent expiry dates, aspirate and dispense with accuracy and precision, and have process control at all stages. These mechanisms provide assurance that the assays have been performed correctly and that the results are reliable. In addition result data are transferred electronically to host IT systems removing the need for any transcription of data. The use of such systems has dramatically reduced the potential for errors within the screening process, a fundamental part of ensuring the safety of donated products.

## Quality Management System

- 8.17 The final factor in ensuring optimal performance of the screening programme is the laboratory Quality Management system (QMS). The increasing levels of regulation have resulted in comprehensive QMS in laboratories which cover all aspects of laboratory activities from supply of consumables and disposables to the release of results. Documentation has been standardised with comprehensive and specific SOPs with version control, and there is fully documented staff training and competency. Similarly to the impact of equipment, the QMS has also reduced the potential for human errors within the screening process.

## Window periods

- 8.18 Although the screening of donated products is performed to high standards producing accurate and reliable results, there is still the potential for an infected donor to donate a potentially infectious donation and for that donation not to be identified on screening - the residual risk associated with donated components.
- 8.19 Such residual risk results from one or all of a number of factors: error in the process, poor assay sensitivity, and a donation collected from a donor in the infection 'window period'.
- 8.20 However, in the UK today, given the high levels of control in the screening process, the main factor in the persistence of a residual risk (RR) is that of collecting a donation from a donor in the window period of infection.
- 8.21 The total window period is that period of time between an individual being exposed to the infectious agent and the first point at which the presence of the particular screening target becomes detectable. The window period is consequently determined by a combination of the biology of the infectious agent, the particular screening target utilised and the sensitivity of the assay for that target. There may be an initial period where the infection can neither be detected or passed on (non-infectious window period) this is estimated at 7 days for HIV, HCV and HBV. For hepatitis B expert opinion suggests that there is a longer period where the infection is unlikely to be detected but is at such low levels that it is unlikely to be transmitted. The non-infectious window period for HBV is estimated to be 15 days and this was used for estimating the residual risk as described below.
- 8.22 Current window periods have been determined, and the consequent residual risk calculated, for HBV, HCV and HIV (Table 1). The window periods used take into account the current use of both molecular and serological screening and the high levels of process control in use. At this time RR figures are only provided for HBV, HCV and HIV, RR figures for human T cell lymphotropic virus (HTLV) and syphilis are currently not officially calculated. As this working group had already indicated that syphilis is included in its remit, an interim RR analysis has been undertaken (Table 3). This analysis is based upon very limited data and has been undertaken to try to provide some idea of the relative risk of syphilis when compared against the formal NHSBT figures for HBV, HCV and HIV. To generate the RR figures the window period for syphilis has been estimated using published figures for the time period between exposure and first detection of syphilis antibodies; the maximum time period has been used. Considering the disease process and taking published data and figures from a GUM specialist specific treponemal antibody appears at any time from 9 to 90 days post exposure, but with an average of 21 days.

Although the timescale may be extended in some cases, the average of 21 days indicates that in most cases specific antibody appears within a few weeks of infection and a window period of four weeks would not be unreasonable.

## Window periods

8.23 Although there are published data which provide estimates of window periods which are used by many blood services to calculate their own RR figures, the actual window periods used by the UK Blood Services are determined by the specific screening algorithms used within the UK Blood Services. Currently these algorithms incorporate both serological and molecular screening for three of the infectious agents screened for:

HBV screening targets: HBsAg (serology) and HBV DNA (molecular)

HCV screening targets: HCV antibody (serology) and HCV RNA (molecular)

HIV screening targets: HIV antigen and antibody (serology) and HIV RNA (molecular)

Syphilis screening target: syphilis antibody

**Table 1 Estimated Infectious Window periods for HIV, HBV, HCV using serology and/or NAT and syphilis**

	HBV	HCV	HIV	Syphilis
Window period (days) – minimum pooled NAT1 with a pool size of 24	30	4	9	N/A
Window period (days) – minimum ID NAT1	21	3	5	N/A
Window period (days) – serology only <sup>4</sup>	66.8 (Ag)	59(Ab)	11 (Ag/Ab) 15 (Ab)	281

	HBV	HCV	HIV	Syphilis
Residual risk (1 per x million donations)	1.3	40.5	5.7	1.963
No. per million entering the blood supply	0.79	0.025	0.18	0.511

1. Kleinmann et al, Transfusion 2009

2. Determined from expert opinion of maximum expected time between infection and first appearance of syphilis specific antibody, range is 9-90 days with a mean of 21 days

3. does not take into account the reduced risk of transmission due to the temperature sensitivity of the syphilis bacterium

4. Values used for calculation of RR of HIV, HBV and HCV as approved by SACTTI

8.24 The current window periods, maximum expected time to the appearance of the first appearing screening target for each of the four infectious agents are shown in table 1.

8.25 The figures represent estimates of the time gap, in days, during which a recently infected individual may donate, be infectious and not be detected by the screening strategy currently in use within the UK Blood Service for each of these infectious agents.

## Overall effectiveness of laboratory screening

8.26 At this time, with the current donor selection and donation screening processes applied across the UK, there is no evidence of any systemic failure of the screening process to identify HBV, HCV HIV or syphilis infected donations, including those from donors with additional risk of acquiring HBV through clinical, therapeutic or cosmetic procedures.

## Window periods and residual risk: best practice - translating window period into deferral period

- 8.27 Within the context of donor/donation screening, the window period for an infectious agent is that period of time (days) during which a donor may donate but evidence of the infectious agent being present is not yet detectable; nonetheless the donation may still be infectious. Whilst the length of a window period can be estimated with reasonable accuracy, its length is not simply a function of test performance, it is a function of the screening strategy applied, and including both the donor selection process and the laboratory testing performed.
- 8.28 However to properly understand the significance of the window period it is helpful to convert the window period (time in days) into the corresponding risk of a window period donation being collected (residual risk figure, estimation of probability of collection of such a donation) and it being available for issue.
- 8.29 The UK Blood Services, through the joint NHSBT / Public Health England (PHE) Epidemiology Unit, produce annual figures for the residual risk (RR) of a potentially infectious hepatitis B virus, hepatitis C virus or human immunodeficiency virus window period donation entering the blood supply. The figures are based upon a number of factors, primarily the window period and incidence of infection (recently acquired infections) in the donors. These are estimates and include a number of assumptions, and it must be remembered that the confidence limits are very wide as there are only limited data available to generate the RR figures. The current published residual risk figures (using data from 2013-2015) are presented in Table 2. These figures are useful when considering the potential impact of any change.

**Table 2: Estimated risk (and 95% confidence interval) that a donation entering the UK blood supply is a potentially infectious HBV, HCV or HIV window period donation: 2013-2015**

Risk due to window period		HBV1	HCV2	HIV3
Number of potentially infectious window period donations in 1	All donations	0.79 (0.22 – 1.30)	0.025 (0.01 - 0.04)	0.18 (0.12 - 0.27)

Risk due to window period		HBV1	HCV2	HIV3
million donations	Donations from new	2.07	0.07	0.03
entering the blood	donors	(0.48 – 4.73)	(0.01 - 0.42)	(0.01 - 0.11)
supply (95% CI). This				
is equal to risk x	Donations	0.68	0.02	0.19
1,000,000	from repeat donors	(0.20 – 1.12)	(0.01 - 0.04)	(0.10 - 0.25)
Number of donations (millions) entering the blood supply before 1 of those donations can be expected to be a potentially infectious donation. This is equal to 1/(risk x 1,000,000)	All donations	1.3	40.5	5.7
	Donations from new donors	0.48	15.1	31.0
	Donations from repeat donors	1.5	47.6	5.3

1. HBV testing assumed all donations were tested for markers of HBsAg and HBV DNA using NAT with a window period of 30 days.

2. Anti-HCV testing and HCV RNA testing with a window period 4 days.

3. Combined HIV antigen/antibody testing and HIV NAT with a window period 9 days.

4. The risk due to WP amongst all donations was calculated as the weighted average of the risk amongst new and repeat donors, weighted according to the number of donations made from new and repeat donors. All molecular screening was performed on pooled samples of 24 donations.

8.30 The residual risk figures in table 2 are those for 2013 to 2015 and are updated annually and published by JPAC. The figures are primarily informative and comparative rather than definitive, the calculations being based upon the window

periods, the incidence of infection in donors and the inter-donation interval. However, the figures do help to put overall risk into perspective and do enable any changes to the screening process to be analysed to determine any incremental benefit likely to be obtained.

8.31 Alternatively these risks can be described as the estimated time period across which in theory one potentially infectious donation could be missed, assuming that annually 2.1 million donations are tested across the UK:-

1 HBV window period donation missed every 0.6 years

1 HCV window period donation missed every 19.3 years

1 HIV positive donation missed every 2.7 years

8.32 As stated above these figures are estimates which have been calculated using an internationally accepted and standardised approach but using limited data. These estimated figures clearly do not accord with the Serious Hazards of Transfusion (SHOT) data, the figures are cautious and reflect what is a combination of theoretical and actual risk, and do not take into account mitigating factors such as products not actually being issued to patients, recipients dying of their underlying condition prior to the development of any TTI, and the possibility of an unidentified TTI in a recipient.

## Use of window periods

8.33 If the estimated window periods are to be used to inform donor risk and consequent donor deferral periods for these four infectious agents, the length of the longest window period needs to be used as the minimum deferral period applied. However this does assume equal risk all four infectious agents, and the risk of transmission being the same from different components which is not the case.

8.34 It is also important to note that although a window period can be defined, any risk across the window period is not necessarily constant. The window period is a period of exponential growth in the level of circulating infectious agent, starting from nothing being present to sufficient appearing to be able to detect (end of window period), the probability of detection therefore also increasing exponentially through the window period as the amount of target present increases. On a practical basis this may not have much impact, but in considering the use of window periods to define deferral periods it could be considered that the window

periods quoted and used by many blood services may reflect the 'worst case' and therefore using the window period as the deferral period should provide sufficient 'safety' in respect of donors who may have been recently infected.

## **Risk of infection through sexual contact**

- 8.35 In the case of risk of infection through sexual contact, it could be argued that the minimum window period applied should be 90 days, to take into account risk of syphilis; a period which would then be sufficient to mitigate risk of the other transmissible infectious agents. In terms of window period alone syphilis presents the highest 'risk', although this is mitigated by the fact that the bacteria are very heat sensitive and die rapidly at temperatures below 12- 15°C. Any potential clinical risk is therefore very low and restricted to products which are not stored below this temperature range; currently these are platelets and granulocyte concentrates. This deferral period does not differentiate between sexual contact between both sexes or same sex, or the nature of the sexual contact.

## **Summary and Recommendations**

- 8.36 The length of the window period is a major determinant of the residual risk of a TTI. The longest average infectious window period for the infections being considered is for HBV at 30 days. International peers adopt an interval of at least twice the window period since the last "at risk behaviour" for the length of deferral before donation. We recommend a deferral interval of three months since last "at risk behaviour" as this is consistent with that practice and exceeds the longest interval for detection of syphilis.

## 9. Post donation processing

### Quality Monitoring Data

#### Background

- 9.1 Blood components are made from whole blood collection with the parameters defined below:

Whole Blood	Volume (mL)
Collection Volume	470
Anticoagulant	66.5
SAG-M	105
Hct	0.45
Red Cells	211.5
Plasma	258.5

- 9.2 Collections are processed into Red Cells, Platelets and Plasma.
- 9.3 Concentrated Red Cells units have 105mL of standard additive solution (SAGM) added to the packs.
- 9.4 Pooled platelets derived from whole blood (WB) are re-suspended in platelet additive solution (PAS) with a target of 30-40% plasma in the final component.
- 9.5 Apheresis platelets and plasma are collected as finished components by machine technology. Anticoagulant is 15% of the collected volume.
- 9.6 Plasma for patient groups born after 1st January 1996 is currently imported from Austria as a vCJD risk reduction measure. Plasma is sourced from both apheresis

and WB collections so the final plasma percentage will be 80-85%. The plasma is treated with methylene blue as a pathogen reduction measure which further reduces the risk of viral and bacterial transmission.

## Leucodepletion

- 9.7 Leucodepletion (LD) is performed on all blood components, other than those which are specifically designed to provide leucocytes i.e. pooled granulocytes and buffy coats. Blood is leucodepleted either by the use of leucodepletion filters or by machine technology for apheresis platelets and plasma. The residual white cell count is measured on a proportion of components by flow cytometry, and monitored by statistical methods.
- 9.8 Compliance with the Red Book is measured at two specifications:  $<1 \times 10^6$  per unit ( $>90\%$  compliance) and  $<5 \times 10^6$  per unit ( $>99\%$  compliance). The QM data has to provide 95% confidence that the specification has been met. The leucodepletion failure rate is simply the rate of failure (1:nnn) derived from the number of failures in the number sampled and tested.
- 9.9 The corrected residual risk (CRR) is calculated to define the risk to the patient of receiving a unit failing leucodepletion at a given specification. The calculation corrects for the number of units discarded as the leucodepletion failure has been detected. As the proportion sampled increases the CRR improves as the proportion untested has decreased. CRR at  $>1 \times 10^6$ /unit is provided below although units  $>1$  but  $<5$  are issued.
- 9.10 In the table below the leucodepletion failure rate are shown at  $>1 \times 10^6$  per unit,  $>5 \times 10^6$  per unit and  $>100 \times 10^6$  per unit to indicate the degree of leucodepletion failure.

## Processing, preservation and storage of Tissues:

- 9.11 The tissue grafts can be processed and stored as non-viable or viable (cryopreserved) grafts. Bone, tendon, decellularised dermis, irradiated skin, amnion and sclera are non-viable grafts, Heart valves, pericardium, arteries, skin, osteochondral, meniscus, cornea are viable grafts. In addition pancreatic islets are minimally processed, fresh, viable grafts infused without storage.

- 9.12 Femoral head donated by surgical donors is stored without additional processing or can be irradiated. Amnion donated by live donors is processed and stored. The tissues grafts donated by deceased donors are processed and stored with the exception of pancreatic islets.
- 9.13 Non-viable tissue grafts are processed where possible to deplete donor cell, blood and/or bone marrow contents. The processing steps may include physical processes, such as high pressure water jet, centrifugation or increased temperature up to 60°C, and chemical processes, including water washing or washing with solvents or detergents, depending on local protocols. Some types of non-viable tissue graft, such as bone, may also be terminally sterilised with gamma irradiation at an absorbed dose of 25-40kGy.
- 9.14 Viable grafts are decontaminated, followed either by cryopreservation by impregnation with a cryoprotectant and controlled freezing to <-135°C, or stored at normothermic temperatures for up to 28 days .
- 9.15 Decellularised grafts are terminally sterilised and stored at room temperature. Non-viable allografts are either freeze dried and stored at ambient temperature or frozen and stored in a freezer.
- 9.16 Viable grafts are cryopreserved and stored at <-135°C in the vapour phase of liquid nitrogen or using ultra low temperature freezers. The processing and storage conditions of tissue grafts may add to the safety to some extent.

## **Haematopoietic stem cells:**

- 9.17 Haematopoietic Stem Cells, whether sourced from Bone Marrow, Peripheral Blood Stem Cells collected by apheresis technology or cord blood, may undergo limited processing prior to cryopreservation. There may be additional processing on some occasions such as T-cell depletion or red cell reduction. The cellular processing steps do not reduce risk of transmission of blood borne infections.
- 9.18 Processing facilities must comply with the requirements of the EU Directives on Tissues and Cells, FACT-JACIE Standards and NetCord-FACT Standards. Processing should be performed according to written procedures and policies. Policies must be in place for the storage of all material whether or not destined for cryopreservation. Where donations of known virology or bacteriology positive material are stored, appropriate risk assessments ensuring adequate controls are in place must be completed. A secondary container, 'double bagging', must always be used to minimise cross-contamination between donations and to effectively

quarantine the unit.

## **Clinical procedures including sample processing for sperm, eggs and embryos**

### **Sperm**

- 9.19 The usual practice is that a donor will provide many semen samples over a period of several weeks so that sufficient sperm is stored to meet the potential clinical use of that donor. After the donation period is complete, the donor must return for repeat infection screening. Only when these tests are negative, is the donation released for use.
- 9.20 Semen samples are processed prior to storage to remove seminal plasma. This washing procedure reduces viral load. The prepared sperm are suspended in culture medium and cryopreserved in liquid nitrogen. The maximum storage period for a sperm donation is 10 years.

### **Eggs**

- 9.21 Eggs are donated usually immediately after collection and there is no quarantine period. The eggs are collected usually by transvaginal ultrasound guided aspiration. The eggs are separated from follicular fluid and are donated as single cells surrounded by their cumulus cells only. They are fertilised and cultured for up to 6 days before transfer. They may be cryopreserved as embryos for later transfer. More recently the technical procedures for cryopreservation of eggs has improved and some eggs e.g. for fertility preservation for autologous use, are now cryopreserved with acceptable outcomes.

### **Embryos**

- 9.22 Embryos that are donated are considered to be from two donors, the egg and the sperm unless one of the gamete providers is also the woman who intends to become pregnant or her cohabiting partner.
- 9.23 The calculation of residual risk in this report does not take into account processing steps.



[Insert title]

	NHSBT 2016 Jan-16 to Mar-16					NHSBT 2010 to 2016 Quarter 1					
	Component Type (%)	Volume of Unit (mL)	Hct (L/L)	Residual Plasma (mL)	Residual WBC Count (x10e6/U)	LD Failure Rate >1x10e6/U (1:nnn)	LD CRR >1x10e6/U (1:nnn)	LD Failure Rate >5x10e6/U (1:nnn)	LD CRR >5x10e6/U (1:nnn)	LD Failure Rate >100x10e6/U (1:nnn)	LD CRR >100x10e6/U (1:nnn)
Red Cells: Bottom and Top	32.0	259.8	0.566	6.2	0.27	199	211	1146	1215	7669	8128
Red Cells: Top and Top	68.0	304.1	0.587	16.4	0.32	165	169	1563	1603	71917	73722
Red Cells: All	100	289.9	0.580	13.1	0.30	171	176	1707	1759	20168	20778
Platelets: Apheresis	61.4	215.5		183.2	0.29	81	136	1211	2022	4058	6774
Platelets: WB Derived	38.6	296.1		106.0	0.33	58	67	716	833	>52963	>61672
FFP: Apheresis	0.5	283.5		241.0	0.30	209		>418		>418	
FFP: WB Derived	99.5	267.1		212.3							
FFP: MB Treated	100	227.1									

# 10. Safeguards against emerging infection

## Horizon scanning

- 10.1 To support the donor selection process it is essential that the selection process is targeted on donors who may be at risk of exposure to relevant infectious agents. In addition to the current mandatory infectious agents there is always the risk from other infectious agents, newly emerging as well as existing agents increasing in incidence or changing location. To ensure that the UK Blood Services are aware of such threats and, when necessary, can plan accordingly, JPAC has put in place an horizon scanning process that monitors for and identifies such threats.
- 10.2 The start point is the capture and analysis of relevant information to determine any significance to the UK Blood Services. On a monthly basis the joint NHSBT/PHE Epidemiology team collates notifications of disease outbreaks, incidents and other data related to emerging infectious disease activity. This monthly report is sent to the Chair and Secretary of the Standing Advisory Committee for Transfusion Transmitted Infections (SACTTI) who then review in detail and determine any possible risk to the safety of donated products; any risks identified are graded to determine if action is required and the urgency of any action. Risks are graded from 'Low risk' with no action required to 'Risk present' with the possibility of immediate action being required. Any specific risk identified by the initial assessment is then identified and recorded using a risk assessment tool which looks in detail at each risk identified to define more specifically the level of risk and potential actions available. Any action required, whether changes to country associated travel risk, inclusion of an additional 'risk activity' in the donor selection guidelines or response to the identification of a new infectious threat, are reported by the Chair of SACTTI to the Chair of the relevant Standing Advisory Committee, the Chair of JPAC and the JPAC Manager, the urgency of action being defined within the risk assessment and any subsequent discussions. If necessary ad hoc Standing Advisory Committee and/or JPAC meetings would be called to discuss the risk and determine broader actions needed, including escalation to DoH advisory bodies.
- 10.3 This approach has also put in place an effective mechanism for horizon scanning to identify possible infectious threats together with the ability to more objectively and consistently assess threats and act immediately if required. Although it is hoped that Blood Services generally are not constantly having to assess new infection threats, the UK Blood Service's horizon scanning system will ensure that such threats to the safety of donated products in the UK are identified and assessed in good time, allowing the appropriate measures, including informing the donor selection process, to be identified and implemented as soon as necessary. Recent emerging infections risks with implications for

door selection have included the spread of West Nile Virus and the emergence of Zika Virus.

- 10.4 There are tissues and cell establishments outside blood services in the UK. JPAC guidelines are widely available to non-blood service organisations. In addition European Centre of Disease Prevention & Control (ECDC) and competent authorities in European countries share alerts with competent authorities in the UK who disseminate the information to the regulated sectors.

# 11. Rate of BBI in UK blood donors

Markers of infection in donations from new and repeat blood donors.

## Data sources

11.1 Blood donor data is collected by the NHSBT/PHE Epidemiology Unit through two parallel schemes 1) blood donation testing and 2) the infected blood donors scheme. Both of these surveillance schemes started in October 1995. This information is used to monitor donations that are positive on initial screening which are then confirmed in the reference laboratory. Additional data providing more detailed information on the profile of all blood donors tested is also gathered.

## Blood donation testing

11.2 Blood donations have been tested for infections since the 1940s when testing for markers of treponemes usually indicating syphilis (or rarely yaws or pinta) first began. Since then testing for hepatitis B surface antigen (HBsAg), antibodies to HIV (anti-HIV), antibodies to hepatitis C virus (anti-HCV), HCV RNA, combined antigen-antibody for HIV (HIV Ag/Ab) and antibodies to human T-cell lymphotropic virus I/II (anti-HTLV) have been introduced. Although not mandatory, HIV RNA and HBV DNA testing has also been introduced (Figure1) as they were included in the newer duplex and subsequently triplex assays. Testing is described more fully in chapter 8.

## Additional tests

11.3 Additional tests may be carried out if a risk is reported by the donor. These include:-

- Anti-HBc where recent piercing, endoscopy or possible past hepatitis B is reported, four months must have elapsed since the 'risk'.

11.4 Additional tests related to travel, country of birth or long stay

- Antibodies to *Trypanosoma cruzi*

- Nucleic acid testing (NAT) for West Nile virus between May and November, where there is a relevant travel history
- Malarial antibody testing

**Figure 1. Timeline of introduction of microbiological tests for blood donations, UK**

1940s	1972	1985	1991	1999	2001	2002	2002	2009
Antibodies to treponemes	HBsAg	Anti- HIV	Anti- HCV	HCV RNA1	HIV Ag/Ab2	Anti-HTLV 3	HIV RNA4	HBV DNA5

1. HCV RNA testing was introduced on a pilot basis in 1999 and became a mandatory test carried out on all

2. NIBTS and Republic of Ireland use anti-HIV only.

3. HTLV testing was conducted by NHSBT in pools of 24 until 2013 when singleton testing was implemented. Scotland used pooled testing until 2015.

4. HIV RNA testing was introduced in Scotland and Northern Ireland in 2002 and in some parts of England.

5. HBV DNA testing began on 1 April in Filton as by-product of introduction of triplex NAT testing being phased in.

11.5 The rate of markers of infection has decreased over the years but rates have always been about fifty times higher in new donors. Any blood donor with markers of infection is permanently withdrawn. Infections detected in repeat donors usually reflect a newly acquired infection which may reflect an ongoing infection risk or a 'one-off' event since the last donation. However, occasionally low level reactions due to past infections may be detected in repeat donors due to a change in test, or an antibody reaction very close to the limit of detection.

**Figure 2 The rate of markers in blood donations made at blood centres in the UK, 1996-2015 in new donors**

Overall, the rate of markers for blood transmissible infections in the UK between 1996 and 2015 are higher in new donors than repeat donors.

Since 1996, the rate of HCV markers in blood donations at UK blood centres has decreased until 2006, where the rate of change then plateaus before decreasing further in 2013. Since 1996 and 2002, the rate of HIV and HTLV markers, respectively, in blood donations at UK blood centres have remained relatively constant. Since 1996, the rate of Syphilis and HBsAg markers in blood donations at UK blood centres have increased slightly.

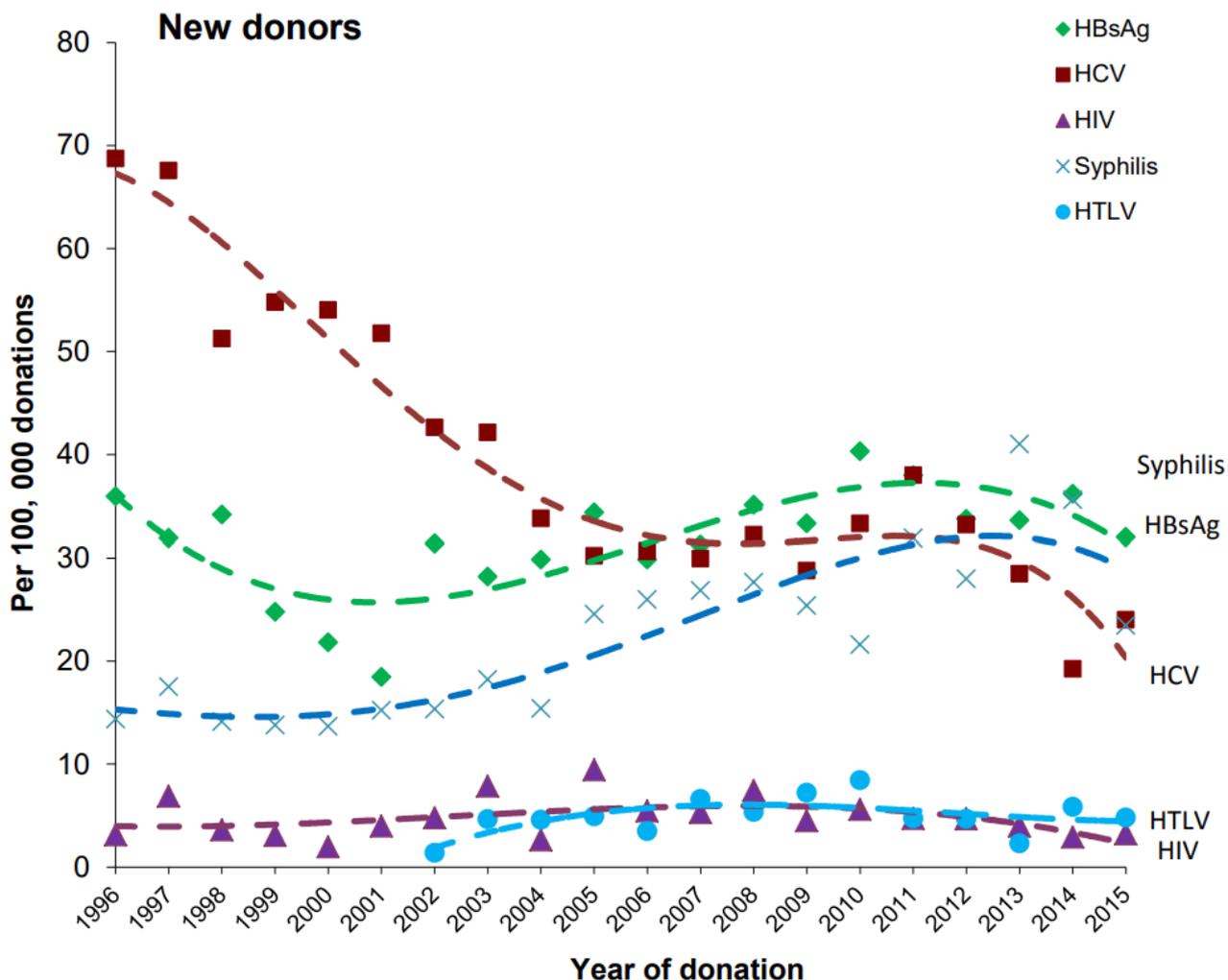
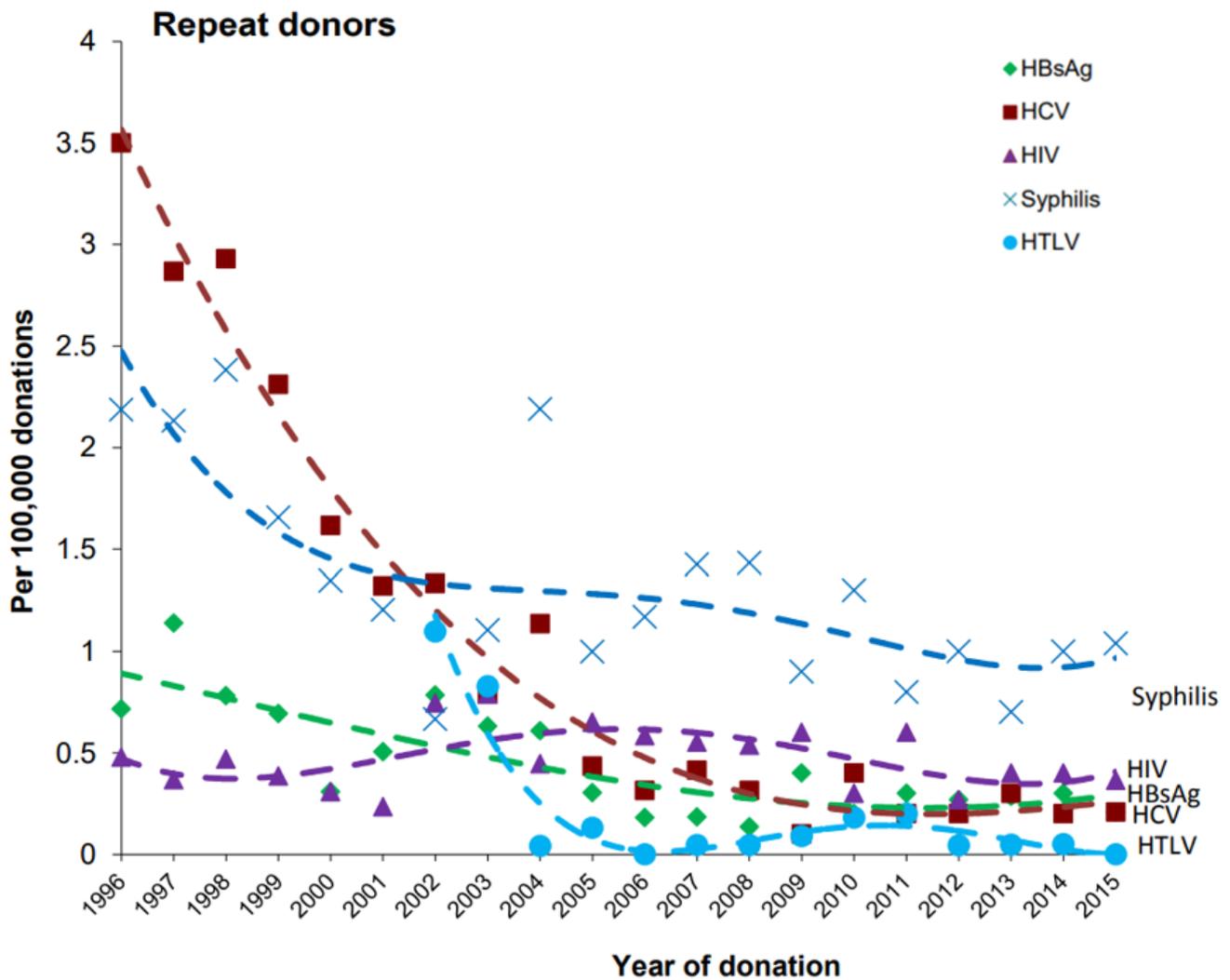


Figure 3 The rate of markers in blood donations made at blood centres in the UK, 1996-2015 in repeat donors (note different scale on y axis to Fig 2)

Overall, the rate of markers for blood transmissible infections in the UK between 1996 and 2015 are higher in new donors than repeat donors.

Since 1996, the rate of HBsAg, HCV, Syphilis and HTLV markers in blood donations at UK blood centres has decreased. Between 1996 and 2015, the rate of HIV markers in blood donations at UK blood centres has remained relatively constant.





## Data collection

- 11.6 Aggregate data on the number of blood donations tested and the number of donations that are positive for markers of infection are reported to the Epidemiology Unit donation testing scheme each month by the UK blood service's testing centres, for new and repeat donors. Disaggregate data on the number of donations confirmed positive is also reported in the same manner for centres outside England and by the NHSBT for centres in England.
- 11.7 The classification of new and repeat donors used in the Epidemiology Unit donation testing scheme is made by testing centres:
- 11.8 New donors: First time donors who were not known to have ever donated blood in the UK. New donors in the UK (excluding Scotland) may include 'lapsed' donors ie repeat donors who have not donated for more than three years. In Scotland, all lapsed donors are counted as repeat donors.
- 11.9 Repeat donors: For the UK (excluding Scotland, who include lapsed donors), donors known to have previously donated blood in the UK in the last three years are classified as repeat donors, although NOT all previous donations have necessarily been tested for all markers of infection (eg anti-HTLV testing was first introduced in 2002).
- 11.10 This classification of donations tested by new and repeat donors is used to estimate the frequency of infection and give an overview of the donations tested.

## Infected blood donors

- 11.11 When a marker of infection is detected in a blood donation, the donor is offered a post-test discussion. The donor is informed of their positive test results and the clinician explains what these test results mean and, where possible, ascertains a likely source or risk factor for the infection. The clinician also discusses any infection control measures, testing and treatment of contacts and advises the donor that they will no longer be able to donate blood. Where appropriate, the donor is referred for specialist care. Clinicians in blood centres in the UK (excluding Scotland) pass anonymised information about infected blood donors to the Epidemiology Unit infected blood donor surveillance scheme using two standard proformas. This information includes the characteristics of the infected

donors (date of birth, gender, first part of postcode), details of their donating history (if any, with details of their most recent previous donation) and any behaviour that could be associated with the donor's infection.

- 11.12 Infected donors are classified by the Epidemiology Unit as newly tested and previously tested for the marker they are found positive.
- 11.13 Newly tested: A donor who has not been previously tested for the marker under consideration by the blood transfusion services included in this surveillance.
- 11.14 Previously tested: A donor who has been previously tested for the marker under consideration by the blood transfusion services included in this surveillance.
- 11.15 Note: this classification differs to that used in the donation testing scheme and donor profile data sources (described above) where the donations are classified according to whether the donor has (or has not) donated blood in the last three years.
- 11.16 The classification of a seroconverters is made by the NHSBT/PHE Epidemiology Unit: Seroconverter: A previously-tested (within three years) donor whose previous donation is reliably documented as negative in comparable assays and is now positive.

## Donation process

- 11.17 NHSBT donors are encouraged to look at the information on [www.blood.co.uk](http://www.blood.co.uk) which gives information about behaviours which may result in deferral. All UK blood services have national call centres which can answer questions about selection criteria. Donors may decide to self-defer if they think they may not be eligible to donate blood. At each attendance UK donors are asked to read pre-donation information (specific to each UK service) which again explains the donation process, information about infection risks and what to expect post-donation. Donors then complete a donor health check (DHC), the Welsh Blood Service have recently introduced an electronic DHC but currently England, Scotland and Northern Ireland still use paper forms. The DHCs used by all 4 countries are very similar and ask the same questions in slightly different ways. However, Northern Ireland (NI) requires donors who have snorted drugs not to donate for 12 months. If a donor answers yes to any question the donation staff will ask them for more information on which to base their risk assessment.

11.18 Specific questions relating to sexual behaviours are asked by all UK Blood Services.

## **Post-test discussions**

- 11.19 At post-test discussion donors are asked about possible infection risks and information collated using a standardised electronic form (Appendix). The discussion will be informed by the infection and whether it appears to be a chronic or newly acquired infection.
- 11.20 Possible risk behaviours will be discussed including, for regular donors, the time of any risk exposures. Information is collated and published on an annual basis:- <https://www.gov.uk/government/publications/safe-supplies-annual-review>.
- 11.21 We have recently published on donor satisfaction with the post-donation discussion [Reynolds et al 2015]. In brief, a questionnaire was sent to 335 donors who had been notified by NHSBT during 2008 and 2009 of a positive result for HBV, HCV, HIV or HTLV. Using a five point scale participants were asked about their level of agreement or satisfaction with the initial notification letter and the subsequent post-test discussion with the NHSBT clinician. There was an overall 47.5% response rate with 58% of responders being satisfied with the initial notification letter. Scores for the post-test discussion were higher than the initial letter, with 90% of the 127 responders being satisfied. Overall, most donors were satisfied with the notification process, although scores were slightly lower for HTLV and HIV.

## **Epidemiology of infections in blood donors 2015**

### **HBV**

- 11.22 As in previous years, the majority (62/64, 97%) of HBV infections identified in donors were chronic, probably acquired abroad during childhood or at birth in, or to a mother from, an HBV endemic country. These infections were mostly associated with exposure in Africa, Asia, or Eastern Europe. For many donors, blood donation would have been the first time that they had been tested for HBV, although some had siblings or parents who they knew to be HBV positive. Two infections were classified as acute infections, one likely acquired through sex between men and one through sex between a man and woman.

## HCV

- 11.23 The largest demographic within the 49 HCV cases was new, white, male donors of UK and European origin. Of the 49, 9 (18%) were anti-HCV reactive but HCV RNA negative, indicating a donor with cleared infection (and therefore no transmission risk). Under the Blood Safety and Quality Regulations and EU Law a donation which tests positive on one of the screening tests cannot be released for transfusion.
- 11.24 The probable routes of infection were diverse, with the two most common routes in 2015 being infection associated with an endemic country and infection through other blood contact each making up 57% of new cases. There were only three cases where the donor reported injecting drug use, in addition, one donor reported snorting drugs in the past.

## HIV

- 11.25 There were 13 HIV cases in 2014: seven seroconverters, six within the last three years and six infected new donors. Five donors reported sex between men whereas the other eight declared sex between men and women and a likely risk for acquiring infection.

## T. pallidum (syphilis)

- 11.26 Markers of infection were found in people from a range of ethnicities and countries, but 56% (36/64) of these cases were probably transmitted by sex between men and women (SBMW). A further 13% were likely due to sex between men (SBM). The remainder were probably due to vertical transmission or due to unknown origin.

[Insert title]

Table 1 Supplementary data including cumulative data and reported risk factors are available here <https://www.gov.uk/government/publications/safe-supplies-annual-review>. A summary of number of infections and risks for donations collected between 1996 and 2014 is shown below

	SBM		SBMW (high risk partner*)		SBMW (no reported high risk)		Drug-related		Endemic 1		Other2	
	No. cases	%	No. cases	%	No. cases	%	No. cases	%	No. cases	%	No. cases	%
HBV	12	6.0	56	10.8	85	11.5	6	0.9	682	71.5	216	23.1
HCV	8	4.0	172	33.2	35	4.7	651	97.7	94	9.9	687	73.4
HIV	126	63.0	149	28.8	132	17.8	5	0.8	3	0.3	7	0.7
HTLV	1	0.5	54	10.4	12	1.6	3	0.5	104	10.9	13	1.4
TP	53	26.5	87	16.8	477	64.4	1	0.2	71	7.4	13	1.4
Total infections	200	100.0	518	100.0	741	100.0	666	100.0	954	100.0	936	100.0
Mean age	34.7		39.3		40.2		39.2		33.9		39.4	
% Male	100.0		40.7		54.3		72.7		64.8		58.2	
% White	84.0		67.4		73.5		91.3		23.8		81.6	
% Born UK (where known)	88.3		61.9		68.2		85.6		18.5		65.9	
% Seroconversions	33.5		11.2		13.2		1.4		0.2		3.3	
Most common infection	HIV		HIV		HIV		HCV		HBV/HIV		HBV/HCV	

DONOR SELECTION CRITERIA REPORT JULY 2017 (VERSION 2)

	SBM		SBMW (high risk partner*)		SBMW (no reported high risk)		Drug-related		Endemic 1		Other2	
	No. cases	%	No. cases	%	No. cases	%	No. cases	%	No. cases	%	No. cases	%
% Recent infections <sup>3</sup>	44.5		12.4		28.5		1.4		1.3		4.1	
% Compliant	9.5		80.1		93.0		13.8		98.7		95.4	

partners here include PWID, MSM, person paid for sex and person who had had sex in sub-Saharan Africa.

1. Includes HTLV donors born in endemic countries with partners born in endemic countries.
2. Includes medical, tattooing, acupuncture, occupational, and other blood exposures.
3. Includes seroconversions in repeat donors and acute or recent infections in new donors.

[Insert title]

**Table 2** The number and rate of markers of HBV, HCV, HIV, HTLV and syphilis identified among blood donations from new and repeat donors and country of blood centres where donation was made: 2015 [Reynolds et al 2015 CA, Brailsford SR, Hewitt. Notifying blood donors of infection: results of a donor satisfaction survey (2015). Transfusion Medicine 2015 Dec 28. doi: 10.1111/tme.12268.

Country of blood centre	Donations tested			HBV			HCV			HIV			HTLV			Syphilis1			Total		
	New 2	Repeat 2	All	New 2	Repeat 2	All	New 2	Repeat 2	All	New 2	Repeat 2	All	New 2	Repeat 2	All	New 2	Repeat 2	All	New 2	Repeat 2	All
England	156,052	1,629,354	1,785,406	57	4	61	42	1	43	5	6	11	9	0	9	38	10	48	151	21	172
Rate3				36.5	0.2	3.4	26.9	0.1	2.4	3.2	0.4	0.6	5.8	0.0	0.5	24.4	0.6	2.7	96.8	1.3	9.6
Wales	7,314	71,124	78,438	1	0	1	3	0	3	1	0	1	0	0	0	1	2	3	6	2	8
Rate3				13.7	0.0	1.3	41.0	0.0	3.8	13.7	0.0	1.3	0.0	0.0	0.0	13.7	2.8	3.8	82.0	2.8	10.2
N. Ireland	6,248	50,859	57,107	0	0	0	0	0	0	0	1	1	0	0	0	1	2	3	1	3	4
Rate3				0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	1.8	0.0	0.0	0.0	16.0	3.9	5.3	16.0	5.9	7.0
Scotland	17,822	172,938	190,760	2	0	2	1	3	4	0	0	0	0	0	0	4	6	10	7	9	16
Rate3				11.2	0.0	1.0	5.6	1.7	2.1	0.0	0.0	0.0	0.0	0.0	0.0	22.4	3.5	5.2	39.3	5.2	8.4

DONOR SELECTION CRITERIA REPORT JULY 2017 (VERSION 2)

Country of blood centre	Donations tested			HBV			HCV			HIV			HTLV			Syphilis1			Total		
	New 2	Repeat 2	All	New 2	Repeat 2	All	New 2	Repeat 2	All	New 2	Repeat 2	All	New 2	Repeat 2	All	New 2	Repeat 2	All	New 2	Repeat 2	All
Total UK	187,436	1,924,275	2,111,711	60	4	64	46	4	50	6	7	13	9	0	9	44	20	64	165	35	200
Rate3				32.0	0.2	3.0	24.5	0.2	2.4	3.2	0.4	0.6	4.8	0.0	0.4	23.5	1.0	3.0	88.0	1.8	9.5
Republic of Ireland	10,237	132,898	143,135	0	1	1	1	0	1	0	1	1	0	0	0	1	2	3	2	4	6
Rate3				0.0	0.8	0.7	9.8	0.0	0.7	0.0	0.8	0.7	0.0	0.0	0.0	9.8	1.5	2.1	19.5	3.0	4.2
Channel Isles & I. of Man	517	4,926	5,443	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rate3				0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total	198,190	2,062,099	2,260,289	60	5	65	47	4	51	6	8	14	9	0	9	45	22	67	167	39	206
Rate3				30.3	0.2	2.9	23.7	0.2	2.3	3.0	0.4	0.6	4.5	0.0	0.4	22.7	1.1	3.0	84.3	1.9	9.1

[Insert title]

1. Treponema antibody testing detects both recent and past syphilis caused by the bacterium *T. pallidum*. It will also pick up diseases caused by other treponemes such as yaws caused by *T. pertenue* and pinta caused by *T. carateum*, endemic in some countries but both rare in the UK.
2. New and repeat donors classified according to records available to the blood centre and therefore new donors may include returning donors who have not donated within the previous three years for NHSBT. Numbers of donations reported here may differ slightly from new donors used in Table because different data sources were used.
3. Rate per 1000,000 donations (see data sources and methods).

The NHSBT/PHE Epidemiology unit also collates and analyses data on the numbers and types of infectious marker in tissue and cord blood donors donating to NHSBT and tissue and cell donors donating to SNBTS and NIBTS. Data can be viewed here <https://www.gov.uk/government/publications/safe-supplies-annual-review>.



[Insert title]

## 12. Rate of Transfusion-Transmitted Infections in the UK blood services

- 12.1 The NHSBT / PHE Epidemiology Unit acts as the national infections coordination for the Serious Hazards of Transfusion (SHOT) scheme (<http://www.shotuk.org/>). This is the United Kingdom's independent, professionally-led haemovigilance scheme and has been collecting and reporting since 1996. SHOT is a passive surveillance scheme and relies on clinical colleagues identifying and reporting suspected adverse events related to transfusion. The majority of suspected TTIs are reported to the English blood service (NHSBT). All reports are reviewed and where a TTI is likely, patients and donors will be followed up and where appropriate, additional testing of donors carried out. Approximately 100 bacterial and 20 viral possible TTI are reported to NHSBT every year. The numbers and types of confirmed reported viral and TTI are shown below in table 1.
- 12.2 Viral transmissions may be identified several years after the implicated transfusion and may be identified opportunistically when tests are carried out due to symptoms, due to another condition or prior to immunosuppression therapy. Bacterial transmissions are usually identified at the time of the transfusion or shortly afterwards as patients become significantly unwell over a short period of time.
- 12.3 No screening was in place for vCJD, human T cell lymphotropic virus (HTLV), hepatitis A virus (HAV), HEV or parvovirus B19 at the time of the documented transmissions. In both malaria transmissions, malaria antibody testing was not applicable at the time according to information supplied at donation
- 12.4 † The two HIV incidents were associated with window period donations (anti-HIV negative/HIV RNA positive) before HIV NAT screening was in place. A third window period donation in 2002 was transfused to an elderly patient, who died soon after surgery. The recipient's HIV status was therefore not determined and not included
- 12.5 †† In 2004 there was an incident involving contamination of a pooled platelet pack with *Staphylococcus epidermidis*, which did not meet the TTI definition because transmission to the recipient was not confirmed, but it would seem likely. This case was classified as 'not transfusion transmitted'
- 12.6 Same blood donor as one of the 1997 transmissions so counted as the same incident. § A further prion case died but transfusion was not implicated as the

cause of death. The outcome was assigned to major morbidity instead because although there was post-mortem evidence of abnormal prion proteins in the spleen the patient had died of a condition unrelated to vCJD and had shown no symptoms of vCJD prior to death.

**Table 1. Number of confirmed TTI incidents and number of affected recipients by year of transfusion in the UK between October 1996 and December 2015 (Scotland included from October 1998)**<https://www.shotuk.org/wp-content/uploads/SHOT-2015-Annual-Report-Web-Edition-Final-bookmarked.pdf>

Year of transfusion*	Number of incidents (recipients) by infection											Implicated component				
	Bacteria	HAV	HBV	HCV	HEV	HIV	HTLV I	Parvovirus (B19)	Malaria	vCJD/ prion	Total	RBC	Pooled platelet	Apheresis platelet	FFP	Cryo
Pre 1996	-	-	1 (1)	-	-	-	2 (2)	-	-	-	3 (3)	3				
1996	-	1 (1)	1 (1)	1 (1)	-	1 (3)	-	-	-	1 (1)	5 (7)	5	1		1	
1997	3 (3)	-	1 (1)	1 (1)	-	-	-	-	1 (1)	2 (2)	8 (8)	6	1	1		
1998	4 (4)	-	1 (1)	-	-	-	-	-	-	-	5 (5)	2	1	2		
1999	4 (4)	-	2 (3)	-	-	-	-	-	-	‡ (1)	6 (8)	5	3			
2000	7 (7)	1 (1)	1 (1)	-	-	-	-	-	-	-	9 (9)	1	5	3		
2001	5 (5)	-	-	-	-	-	-	-	-	-	5 (5)		4	1		
2002	1 (1)	-	1 (1)	-	-	1 (1) †	-	-	-	-	3 (3)	2	1			
2003	3 (3)	-	1 (1)	-	-	-	-	-	1 (1)	-	5 (5)	1	1	3		
2004	††	-	-	-	1 (1)	-	-	-	-	-	1 (1)	1				
2005	2 (2)	1 (1)	1 (1)	-	-	-	-	-	-	-	4 (4)	1	3			

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Year of transfusion*	Number of incidents (recipients) by infection											Implicated component				
	Bacteria	HAV	HBV	HCV	HEV	HIV	HTLV I	Parovirus (B19)	Malaria	vCJD/ prion	Total	RBC	Pooled platelet	Apheresis platelet	FFP	Cryo
2006	2 (2)	-	-	-	-	-	-	-	-	-	2 (2)		1	1		
2007	3 (3)	-	-	-	-	-	-	-	-	-	3 (3)	2	1			
2008	4 (6)	-	-	-	-	-	-	-	-	-	4 (6)		2	4		
2009	2 (3)	-	-	-	-	-	-	-	-	-	2 (3)	1		2		
2010	-	-	-	-	-	-	-	-	-	-	-					
2011	-	-	1 (2)	-	1 (2)	-	-	-	-	-	2 (4)	2			2	
2012	-	-	1 (1)	-	1 (1)	-	-	1(1)	-	-	3 (3)	2			1	
2013	-	-	-	-	-	-	-	-	-	-	-					
2014	-	-	-	-	2 (3)	-	-	-	-	-	2(3)	1			2	
2015	1(1)	-	-	-	2 (3)	-	-	-	-	-	3(4)		2	1		1
Number of Incidents	41	3	12	2	7	2	2	1	2	3	75					

# 13. International Practice

## Sexual deferrals

13.1 Countries covered by the EU direction interpret the donor selection criteria related to sexual behaviours in a number of ways. The specific wording in the directive talks about a deferral for 'persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood'. The specific sexual behaviours for which a deferral is deemed necessary will depend on the on the local epidemiology of HIV and other blood borne viruses, the social and political influences within the country and the tests available for donation screening (Brailsford et al, 2015). All countries apply a degree of individualised risk assessment taking into account recent partners, their viral status or, such things as multiple partners using gender neutral questions. Countries with no specific deferral related to men who have sex with men (MSM) include: Chile, Italy, Mexico, Poland, Portugal, Russia, Spain and Thailand (Benjamin et al, 2011; Keelan et al, 2014). In Europe most countries have 100% unpaid volunteers although some countries give incentives such as Germany where paid leave from work is given.

[http://www.who.int/bloodsafety/global\\_database/GDBS\\_Summary\\_Report\\_2011.pdf?ua=1](http://www.who.int/bloodsafety/global_database/GDBS_Summary_Report_2011.pdf?ua=1)

13.2 The South African National Blood Service uses an individualised approach advising potential donors that they can donate if they live a sexually safe lifestyle. Donors with a new sexual partner cannot donate for 6 months or if they have multiple sexual partners they will be permanently deferred (<http://www.sanbs.org.za/index.php/donors/new-donors/can-i-donate>). In addition to further protect the blood supply in South Africa individual NAT screening is used to reduce risk of failing to detect a very recent infection.

13.3 There are still a number of countries within Europe who maintain a permanent deferral for MSM and European Directorate for the Quality of Medicines EDQM continue to review the sexual deferrals at a European level (<https://www.edqm.eu/>). Donor selection criteria for MSM are described in Table X.

13.4 The UK Blood Services are all members of the Alliance of Blood Operators (ABO) (<https://www.allianceofbloodoperators.org/home.aspx>) which is a group of countries who work together to promote best practice, drive local improvement and exchange knowledge. The ABO includes the European Blood Alliance which represents countries within the European Union and the European Free Trade

Association, most of the major blood services within the USA, The Australian Red Cross and Canadian Blood Services. The US, Canada and Australia currently have a 12 month deferral in place for MSM. Australia has recommended a further reduction to 6 months but this was not agreed by their regulator (Clive Seed personal communication). Canadian Blood Services are in the process of commissioning work to carry out research to better understand different options including individualised risk assessment for donor selection

(<https://blood.ca/en/blog/2017-03/international-meeting-sets-research-agenda-changing-eligibility-msm-blood-donors>) whereas blood services within the United States of America have recently begun implementation of the change from a permanent to a 12 month deferral for MSM that was recommended by the Federal Drug's Administration (FDA) in December 2015.

**Table X Current and previous MSM selection criteria interval since sex with another man**

<b>Country</b>	<b>At time of last SaBTO review*</b>	<b>Current</b>	<b>Further information</b>
Argentina	Unknown	12 months	
Hungary	Unknown	12 months	
Australia	12 months	12 months	Regulator rejected a proposed further change to 6 months (personal comm. Clive Seed)
Brazil	12 months	12 months	
Czech Republic	12 Months	12 months	
Japan	12 months	12 months	Information on web suggests change to 6 month deferral but no good reference available
Finland	Permanent	12 months	1st January 2014 change
Sweden	Permanent	12 months	January 2012
UK	Permanent	12 months	NI to implement from September 2016
USA	Permanent	12 months	Expected to roll out through 2016
France	Permanent	12 months	Whole blood from July 2016- 4 month deferral following new sexual partner for plasma donors.

[Insert title]

<b>Country</b>	<b>At time of last SaBTO review*</b>	<b>Current</b>	<b>Further information</b>
The Netherlands	Permanent	12 months	December 2015
New Zealand	5 year	12 months	Change December 2014
Canada	5 years	12 months	Change in 2016 (?December)
Republic of Ireland	Permanent	12 month	Implemented January 2017
Lebanon	Permanent	Permanent	
Belgium	Permanent	Permanent	
China	Permanent	Permanent	
Croatia	Permanent	Permanent	
Denmark	Permanent	Permanent	
Germany	Permanent	Permanent	Ongoing discussions about change to 12 month deferral. Deferral introduced for new sexual partner
Hong Kong	Permanent	Permanent	Discussions ongoing re 12 M deferral
Iceland	Permanent	Permanent	
Israel	Permanent	Permanent	Recommendation made to change to 12 month deferral
Norway	Permanent	Permanent	
Slovenia	Permanent	Permanent	
Switzerland	Permanent	Permanent	
Turkey	Permanent	Permanent	

13.5 Recent symposia have been held in both the Republic of Ireland (ROI) and Canada to review and discuss the current blood donor selection criteria for MSM. These discussions were used, in part, to assist with a decision to recommend a

change from a permanent to a 12 month deferral for MSM in the ROI. Canada arranged a symposium to discuss current shortening deferrals but also to identify themes and issues for research streams prior to commissioning research. Current available data on donor selection and ongoing discussions of change to donor selection are discussed below.

## Australia

- 13.6 Australia was one of the first countries to change from a permanent deferral for MSM to a 12 month deferral in 2001. The current 12 month deferral has been shown to be effective with no confirmed transfusion transmitted infections since 1998 nor any significant change in HIV prevalence in male donors; the current HIV residual risk is below 1 in 1 million donations (<http://kirby.unsw.edu.au/surveillance/2016-blood-donors-surveillance-report>). A survey has been carried out of Australian blood donors to ascertain the level of compliance with a number of donor selection criteria including the MSM deferral (Seed et al, 2013, Lucky et al 2014). Overall compliance with donor selection criteria was high, of the 14476 responses from male donors 34 (0.23% , 0.16-0.33%) were non-compliant to the MSM deferral of whom 24 (0.17%) had had sex within 6 months of donation. Factors significantly associated with non-compliance included multiple partners, history of injecting drug use, perception of lack of privacy and preference for a computer-based questionnaire. A recent independent review has supported the continuing need for MSM deferral but supported a reduction to 6 months since last sex, however, this was rejected by the Australian regulator due to concerns about the increasing rate of HIV within the general population. Test used is individual NAT (Kiely et al 2014).

## Canada

- 13.7 Canada has taken a phased approach to changing the donor selection criteria, in part due to concerns of any impact of rates of BBI following the 'Tainted Blood' incident in Canada. Prior to making the change to a 5 year deferral modelling was carried out which predicted that an additional 10 HIV positive donors would be identified per year, however, similar to the UK experience these extra positive donations were not observed. A survey of donors under the 5 year deferral found the level of compliance to be high. The available evidence from Canada and other countries supported a change to a one year deferral which has been implemented by Canadian Blood services and Hema Quebec. Canada has recently put out a call for funding to support research applications investigating alternatives to the

current deferral. Concerns have been raised by a number of groups in Canada that the current deferral is disproportionate and the blood services believe that the negative feelings about this will result in a decrease in young donors coming forward to donate. NAT Testing is done in Canada on mini-pools of 6 (O'Brien et al, 2017).

## **Countries with an individualised gender-neutral donor selection criteria**

- 13.8 The two countries which have reported the impact of their individualised donor selection criteria are Italy and Spain. There is no peer-reviewed literature describing the Spanish situation but this has been presented at the recent ROI symposium.

### **Spain**

- 13.9 Spain does not defer on the basis of MSM risk but on sexual risk regardless of the gender of the sexual partner, an individualised sexual risk approach was introduced in 2005. The rates of HIV in the general population in Spain and across much of Southern Europe are higher than those in the UK. In recent years the rates of incident and prevalent infections in blood donors have been of concern with rates varying widely across Spain from 0.9/100,000 in Navarra to 22.8 per 100,000 blood donors in Canarias. This compares to the rate in UK blood services of 2.9 / 100,000 in new and 0.4 / 100,000 in repeat donors and suggests that the pre-donation screening for potential risk behaviours is not effective in selecting a low risk group. In the last ten years there have been two transmissions of HBV, however, neither were related to MSM. Given the ongoing increase in HIV positive donors there has been a call to either change to individual NAT screening from pool of 24 donor testing and to decrease the window period or alternatively reintroduce a 12 month deferral for MSM. In an attempt to decrease the HIV prevalence in new donors there is a focus on improved donor selection materials and communications to promote compliance and raise awareness of risk, an improvement to the understanding and therefore accurate completion of the donor health check questionnaire is also viewed as priority.

## Italy

- 13.10 The current selection criteria in Italy for sexual behaviours require donors to complete a pre- donation questionnaire and then have an individual face-to-face conversation with a physician to discuss the answers to their donor health questionnaire. Donors are assessed and accepted if thought to be of low risk, or categorised as having a risk behaviour or a high risk behaviour. Risk behaviours include one sexual partner whose behaviour is unknown, occasional sex with one person or occasional sex with someone with a BBI, donors in this last category are deferred for 4 months. High risk behaviours include usual sex with more than one partner, paid for or paying for sex, injection of non-prescribed drugs, usual sex with someone with an infection or sex with multiple partners, these behaviours have a permanent deferral. The impact of the current donor selection criteria has been compared with the previous MSM deferral. Infection surveillance data was available in 1999 from two thirds of blood centres, by 2009 this had increased to 100%. During 2009/10 the HIV incidence in blood donors was three times higher in returning male donors than females. Of the 218 HIV positive donors with a post-test discussion 25.5% reported a sexual risk more than 4 months ago, 28.5 % no risk and 36% with risk less than 4 months ago. The authors reported that there was no difference in the rates of HIV positive donors when comparing pre-change data from 1999 and 2009/10 although data from 1999 was less complete and HIV rates remained high (Suligo et al, 2013).
- 13.11 A more recent publication looked at the rate of infection in new and repeat donors who donated between 2009 and 2011. Rates of HIV in new donors ranged between 15.5 / 100,000 donors in 2009 and 13.4 / 100,000 in 2011. Repeat donors had lower rates of infection but rates were still high compared to the UK, the lowest rate of 3.8 / 100,000 in 2010 to 4.8 /100.000 in 2011. Higher rates were observed in repeat male donors compared with new donors. A third of repeat donors reported MSM behaviour within the last four months compared with 22% in first time donors. Those donors who were non-compliant reported a number of reasons for not declaring a risk, not realising that they had a risk was the most commonly reported reason for not disclosing (66.4%) compared with the donor's interpretation of it being a negligible risk (22.1%). The current pre-donation questionnaire failed to detect undisclosed risk in 1/3 HIV positive donors, most of whom were young, repeat donors who reported heterosexual behaviour (Raimondo et al, 2015).

## Countries in the process of changing (USA and France)

### USA

- 13.12 The final guidance on changes to MSM deferral from permanent to 12 months was issued by the FDA in December 2015 and the US blood services are in process of implementing the change. Prior to the change a number of studies were carried out to better understand compliance amongst US donors- the Blood DROPS studies. From the available data of current HIV transfusion-transmission risk (1 in 1.5 million donations) and observed MSM non-compliance (0.7 - 2.6%), it is clear that HIV prevalence in donating MSM is lower than has been previously modelled. Of those donors who were HIV positive 60% reported that they were, compared with 67% of HIV positive men in the general population reporting that they are MSM. A number of studies were undertaken to provide evidence for the change including both qualitative and quantitative studies. A small number of HIV-negative MSM who had previously donated blood and were happy to be interviewed were recruited about their understanding and opinions of the current selection policy (Hughes et al 2015). Of the 40 recruits the study 95% supported a change to the permanent MSM deferral with a range of donor selection criteria preferred from no deferral to a five year deferral. Interviewees thought that it would be useful to include additional questions about behaviours on the donor health check questionnaire to better assess risk behaviours. Although the men in the survey acknowledged that HIV rates are higher in MSM than the general population in US they considered themselves to be at low risk and one of their main justifications for their own non-compliance in giving blood was their own assessment of their risk as low. A larger survey (Custer et al 2015) invited male donors with e-mail addresses to complete a confidential online survey. Donors were asked about the current donor deferral policy, basic demographics, sexual history and compliance. A total of 3183 surveys were completed, 2.6 % (2.1-3.2%) reported donation after MSM sex. Of all male responders 6.8% reported at least 6 female partners and 0.3% reported at least 6 male partners in the last 5 years. There was evidence of non-compliance with the current MSM deferral, and half of those affected said that they would comply with a one year deferral (Custer et al, 2015).
- 13.13 A new donor health questionnaire has been designed to be used following the change in the MSM deferral, in addition a Transfusion transmitted infection monitoring system has been set up to monitor numbers of BBIs in how these infections relate to risk behaviours.

## France

- 13.14 At the Republic of Ireland symposium the recent changes to the French Donor Selection criteria were described. In France MSM have a disproportionate burden of HIV infection, HIV prevalence is 70 times higher in MSM than heterosexuals without any injecting drug risk with incidence being 115 times higher in MSM. Between 2011 and 13 there were 24 incident infections in blood donors with 15 declaring a MSM risk at post-test discussion. Compliance with the permanent deferral for MSM was estimated at 2.1%
- 13.15 During 2015 the French Ministry of Health organized extensive work, involving different stakeholders, such as health authorities, transfusion operators, patient and donor associations, and lesbian, gay, bisexual, and transgender rights organizations to review current MSM donor deferral. A large majority of stakeholders agreed that MSM could give blood, provided they have not had sex with men in the last 12 months before donation. However, several LBGT organizations felt that differing policies for MSM donors versus other donors was unjustified, while patient and blood donor associations considered that safety consideration mandated a precautionous approach. It was agreed that MSM who have had only one male partner in the four months before donating will be allowed to donate plasma. The plasma will be quarantined until return and testing of the donor between 2 and 6 months later. The deferral for whole blood donation will be 12 months since last sex with a man for MSM. Depending on the results of new implemented studies, as well as of other international studies, further reduction in the deferral period will be considered if no additional risks can be demonstrated. These donor selection criteria were implemented in July 2016. To date less than 100 donors have donated plasma more than once but all were HIV screen negative (personal communication Josiane Pillonel).

## Germany

- 13.16 Germany has had discussions about changing their current permanent deferral. Recently a new deferral has been introduced for men and women having sex with someone of the opposite gender for anyone with a new partner in the last 4 months. This has resulted in a 2% reduction in donors (personal communication Ruth Offergeld).

## **Other deferrals related to sexual behaviours**

- 13.17 Currently people who have received drugs or money for sex are not eligible to donate under the EU directive / BSQR. European countries who use an individualised gender neutral risk assessment, e.g. Italy, classify sex with multiple partners as 'high risk' resulting in a permanent deferral. In other ABO countries a similar deferral is in place.

## **People who have ever injected non-prescribed drugs (PWID)**

- 13.18 Injecting non-prescribed drugs is one of the behaviours with a permanent deferral in the EU directive. None of the blood services in the USA, Canada or Australia allow people who have ever injected non-prescribed drugs, e.g. steroids, to donate blood.

## **Acupuncture, Endoscopy, Tattooing and Piercing.**

- 13.19 The EU directive does not allow blood donations to be given by people with a recent tattoo or piercing or endoscopy, four months must have elapsed since exposure and a test for HCV RNA must be negative. People who have received recent acupuncture may donate if the person delivering the acupuncture practitioner is defined as a qualified practitioner as described by the relevant blood service. There are a range of deferrals applied by the other ABO members. In the US the American Red Cross accepts donor who have had acupuncture treatment as does Canada if single-use needles were used. Australia accepts donors with recent acupuncture if the acupuncture was carried out using sterile single-use needles or by a registered professional.
- 13.20 In the US donors with recent piercings may be accepted if single use needles were used, donors may also be accepted following tattoos if the tattoo was given in a state which regulates its tattoo parlours. Canada has a 3 month deferral in place for tattooing and piercing. Whereas in Australia donors cannot donate for 4 months following a tattoo or body piercing but can donate after 24 hrs following ear piercing.

13.21 It was not clear from the donor selection criteria whether the US or Canada accept donors following endoscopy, in Australia donors are accepted unless biopsies were taken in which case they are deferred for 4 months.

(Reference: Australian Red Cross website, Canadian Blood Services website, American Red Cross website).

# 14. Individual Risk Assessment for Blood Donors

## 1.0 Background

- 14.1 All donors undergo a degree of individual risk assessment by answering at each donation session a donor health questionnaire at which they self-report a number of activities that could increase the risk of BBI. This may be followed by an interview by a staff member to explore for example details of travel to areas where there is increased risk of BBI.
- 14.2 While the SaBTO recommendation in 2011 to relax the permanent exclusion of MSM to a time-based deferral was welcomed by stakeholders it was recognised for example that this did not enable monogamous sexually active MSM's to donate. In the intervening period, there has been increasing pressure from those affected by this rule for the UK blood services to implement a more 'individualised' risk assessment that would enable more MSM's to donate.
- 14.3 The Donor Selection Subcommittee, recognised the complexities in considering this issue and commissioned a workgroup to explore a more individualised risk assessment.
- 14.4 The remit of this subgroup of the SaBTO donor selection criteria working group is to examine the feasibility of using "individual" risk assessment as a tool to evaluate donors who may consider themselves eligible but fall within one or more of the groups that currently are regarded by the blood services as to be exposed to high risk of infections that may be transmitted by blood transfusion. These groups include the following:
- men that have sex with men (MSM)
  - people that have partners from high risk epidemiological areas such as sub-Saharan Africa
- 14.5 It is also noted that there is currently an All Party Parliamentary inquiry examining the present deferral of men that have had sex with and other man within the past 12 months.

## 2.0 International Experience

- 14.6 There are a number of countries where there is no specific exclusion for MSM and where donor selection is based on recent sexual history. This can be perceived as being more individual in that it defers all donors based on their answers to the same questions. However, these criteria would not appear to take into account the known epidemiological risk of the individual's sexual partners. The rate of HIV infection is between 40 and 70 fold more common in MSM compared to the heterosexual population. Data from the UK donor survey indicated that ~12% of male donors had a new sexual partner in the last year with ~2% having 3 or more new partners. Therefore, exclusion on the basis of recent new sexual activity could result in significant increases in deferrals with no safety gain. This could result in blood shortages.
- 14.7 In addition, the data from Spain and Italy indicate some matters for concern on this approach. In Spain and in Italy the rates of detection of HIV positives in both new and repeat donors are considerably higher than current levels in the UK. In Italy, more than 50% of HIV positives were detected were in repeat donors. Additionally, the data from Spain indicates that the most common risk for detecting HIV infection in both new and repeat donors were that they were MSM. Spain is actively considering the reintroduction of a time based deferral for sexual contact for MSM.
- 14.8 We have no knowledge of other countries that are able to rationally separate the whole MSM population based on epidemiology to enable more individual risk assessment.
- 14.9 Another area of international practice of interest that may help to contribute to the evidence base are the recent changes to policy in France. This proposes that MSM who have only had one sexual partner in the last four months can be accepted for source plasma. This plasma will be held in quarantine for a minimum of two months and only released on the basis of a second negative test.
- 14.10 While the collection for source plasma as not an option for the UK at the present time due to vCJD risk reduction measures, it may prompt the question of whether this was feasible for FFP and could be managed safely on current IT platforms. There would also be issues that would require MSM or other 'higher risk' cohort allowed to donate on this basis to be 'flagged' in our system that need particular consideration under data governance.
- 14.11 With respect to individuals that have long term relationships with people from sub-Saharan Africa and the risk needs to be assessed of the likelihood of the

relationship being unknowingly HIV or HBV discordant (with the infected person not being the donor) and the probability of the presenting donor being in the window period of one of these infections.

14.12 The estimated transmission risk as published on the Aidsmap website (<http://www.aidsmap.com/Estimated-risk-per-exposure/page/1324038/>) is shown in the table below. These figures also assume that the 'source partner' is always HIV-positive and unless stated without condom.<sup>1</sup>

1. Boily MC et al. Heterosexual risk of HIV-1 infection per sexual act: systematic review and meta-analysis of observational studies. *Lancet Infect Dis* 9(2): 118-129, 2009
2. Vittinghoff E et al. Per-contact risk of human immunodeficiency virus transmission between male sexual partners. *American Journal of Epidemiology* 150: 306-311, 1999
3. Del Romero J et al. Evaluating the risk of HIV transmission through unprotected orogenital sex. *AIDS* 16(9): 1296-1297, 2002
4. Townsend C et al. Low rates of mother-to-child transmission of HIV following effective pregnancy interventions in the United Kingdom and Ireland, 2000-2006. *AIDS* 22: 973-981, 2008
5. Baggaley RF et al. Risk of HIV-1 transmission for parenteral exposure and blood transfusion. *AIDS* 20: 805-812, 2006
- 6.

### Estimated HIV transmission risk per exposure for specific activities and events

Activity	Risk-per-exposure
Vaginal sex, female-to-male, studies in high-income countries	0.04% (1:2380)
Vaginal sex, male-to-female, studies in high-income countries	0.08% (1:1234)
Vaginal sex, female-to-male, studies in low-income countries	0.38% (1:263)
Vaginal sex, male-to-female, studies in low-income countries	0.30% (1:333)

Activity	Risk-per-exposure
Vaginal sex, source partner is asymptomatic	0.07% (1:1428)
Vaginal sex, source partner has late-stage disease	0.55% (1:180)
Receptive anal sex amongst gay men, partner unknown status	0.27% (1:370)
Receptive anal sex amongst gay men, partner HIV positive	0.82% (1:123)
Receptive anal sex with condom, gay men, partner unknown status	0.18% (1:555)
Insertive anal sex, gay men, partner unknown status	0.06% (1:1666)
Insertive anal sex with condom, gay men, partner unknown status	0.04% (1:2500)
Receptive fellatio	Estimates range from 0.00% to 0.04% (1:2500)
Injecting drug use	Estimates range from 0.63% (1:158) to 2.4% (1:41)
Needlestick injury, no other risk factors	0.13% (1:769)
Blood transfusion with contaminated blood	92.5% (9:10)

Sources: vaginal sex;<sup>1</sup> anal sex;<sup>2</sup> fellatio;<sup>3</sup> mother-to-child;<sup>4</sup> other activities.<sup>5</sup> See footnote

### 3.0 Can we assess the risk of a couple?

14.13 One consideration would be a clinically led assessment of donors who present to give blood together. Currently this would not be policy in the UK Blood Services due to donor confidentiality and information governance concerns. However, many donors who are affected by these deferrals find this frustrating and may consent to the sharing of information. This is particularly frustrating for donors whose partners have been sexually active in sub Saharan Africa where the partner is able to

donate after 12 month while the donor under assessment would in effect be permanently deferred.

- 14.14 This approach sits in a regulatory grey area and it would be essential that donors consenting to 'paired' assessment fully understand the consequences should either partners become ineligible in future. While it is possible to procedurally undertake such protocols, it is likely that this would need to be clinically led as it would be difficult to envisage how this type of approach could operate with current staffing profiles and in the context of a collection session. SaBTO considered the proposal that donors in a relationship in a category where they would be deferred, such as MSM or donors whose partners have been sexually active in sub-Saharan Africa, could be tested together. Members raised issues of donor confidentiality, information governance and the need to consider how to handle the consequences of a positive test. The Committee decided that this was an operational matter and it would be for UK Blood Services to decide if this was a viable option for them to implement.

## **4.0 Evidence Base and Gaps**

- 14.15 The short life working group reviewed the available evidence including:
- Data from the Scottish Bar Study provided by Lisa McDaid
  - Natsal
  - UK Donor Survey
  - London MSM Study
  - European Online survey
- 14.16 It is recognised that some of the available evidence would not be representative of the overall MSM cohort or indeed the cohort of MSM who would present as blood donors and that the data would therefore be skewed. During 2016, PHE had been approached to see if they could undertake a study looking at the risk of acquiring HIV in MSM who were in civil partnerships or gay marriages but had at that time expressed concerns on being able to undertake a study with sufficient power to inform the revision of policy.
- 14.17 An issue for consideration is on-going surveillance mechanisms and how these could support this review. There needs to be consideration how we could obtain

the appropriate evidence and who should be responsible for its collation. It would not seem appropriate that this be a responsibility for the blood services and this may therefore have implications for the UK Public Health and Health Protection bodies in terms of resource and current surveillance mechanisms.

- 14.18 A brief summary of the 2014 data analysis comparing three cohorts of MSM from the Scottish bar study provided by Lisa McDaid is given below That indicates that the overall % positive is 4.6% compared to the 3.6% and 3.1% in the No Sexual Contact and Lower risk cohorts, respectively, while in the high risk cohort (representing 52% of the sample) the rate of HIV positive tests was 5.7%.

	Number	% of Sample	% HIV positive Saliva Samples	% Undiagnosed
No Sexual contact last 12 months	83	6%	3.60%	33%
Sexual contact last 12 months not high risk	553	41%	3.10%	23.50%
Sexual contact last 12 months high risk	703	52%	5.70%	37.50%
Total Group	1340		4.60%	34.40%

This potentially prompts consideration of what rate of prevalence would we consider a cohort to be at an acceptable level and what other factors should be considered in assessing donors as being at acceptable levels of risk.

## 5.0 Equality versus Access to Donation

- 14.19 It is essential that blood services meet their responsibilities under the Equalities regulations in force in the UK and Europe, however in the context of blood donation we need to consider whether this means treating all donors equally or designing protocols that treat donors differently but appropriately, in recognition of

individual factors and risk, to enable more equal access to donation. It is also important that we engage with stakeholder groups affected to explore the potential implications of this kind of more tailored and individual approach such as 'Paired' assessment discussed in 3.2.

## 6.0 Enabling Donation while Recognising Risk

14.20 Campaigners such as Freedom to Donate seek the complete removal of donor deferral for MSM on the basis of improved testing and increased rates of BBI in heterosexuals. This approach minimises the health inequalities including the frequency of BBIs between MSM and the non IVDU heterosexual population which continues to widen in the UK<sup>2</sup>. It is therefore extremely challenging to deliver change in the face of this observed increase risk against a background of perceived greater safety and reduced awareness of risk behaviours. This is particularly challenging given the legal judgements of Burton and more recently Penrose in Scotland.

7. 2Boily MC et al. Heterosexual risk of HIV-1 infection per sexual act: systematic review and meta-analysis of observational studies. *Lancet Infect Dis* 9(2): 118-129, 2009

8. Vittinghoff E et al. Per-contact risk of human immunodeficiency virus transmission between male sexual partners. *American Journal of Epidemiology* 150: 306-311, 1999

9. Del Romero J et al. Evaluating the risk of HIV transmission through unprotected orogenital sex. *AIDS* 16(9): 1296-1297, 2002

10. Townsend C et al. Low rates of mother-to-child transmission of HIV following effective pregnancy interventions in the United Kingdom and Ireland, 2000-2006. *AIDS* 22: 973-981, 2008

11. Baggaley RF et al. Risk of HIV-1 transmission for parenteral exposure and blood transfusion. *AIDS* 20: 805-812, 2006

12.

## 7.0 Operational considerations

14.21 Undertaking detailed donor selection in the context of a community blood collection environment where typically only portable screens separate donors can

be challenging in providing a safe and confidential space for donors to disclose sensitive information.

## 8.0 Stakeholder input

14.22 An early version of the paper on which this chapter was based had been shared with many LGBT stakeholders at a stakeholder event. The paper was welcomed but not many specific comments were made. Feedback from the (Blood Services) Care and Selection of Donors Committee raised questions on details of sexual activity and the likelihood of operational resistance to these questions. It was suggested to reframe the question as a hypothesis – What evidence would we need to identify a cohort of sexually active gay men who would safely give blood? For example, paired testing of partners could be introduced to provide further information.

## 9.0 Improving pre-donation self risk assessment

14.23 There has been some discussion around the potential benefits of developing a tool to allow donors to more accurately self-assess their sexual health risks in the days prior to donation that would potentially improve compliance and build awareness of how this contributes to blood safety. These could be developed on the basis of expert knowledge and be less reliant on an evidence base. However, the use of such tools can be fraught with difficulty and must be robustly evaluated. Despite this there may be considerable benefit in exploring the potential of such online tools to improve compliance in relation to sexual risk and promoting donor education.

- Summary
- Individualised Risk Assessment based on monogamy
- Donor selection criteria in relation to BBI risk are evidence based and consider epidemiology and other associate risk factors. This means that we at present broadly manage donor risk at a population level. In relation to MSM, this is contentious in that it regards men who have either oral or anal sex with other men as a homogeneous cohort and does not recognise the differences in risk behaviours and relationship status. This is especially contentious to potential donors in monogamous same sex relationships. We have failed to find a way to

practically separate a sub group of MSM who have oral and or anal sex but are at the equivalent BBI risk as heterosexually active blood donors.

- The workgroup have discussed this issue at length. and recognise that in reality this cannot be truly individual, as we cannot assess the potential donor's partner but that there is potential to make this more tailored to the individuals circumstances. This would require evidence that would enable us to segment the wider 'high risk' categories such as MSM and PWID to identify sub-cohorts that would be at lower risk. It is clear that at this time we do not have the evidence to support this approach and that we are currently unclear on how to obtain it.
- This is also contentious for donors in monogamous relationships with people in other 'high risk' cohorts such as PWID, or where partners have been sexually active in sub Saharan Africa. However the epidemiology of transmission of BBI in this group is different to that seen between MSM and is explored more fully in the summary chapter on modelling of TTI risk.

## **Summary Individualised Risk Assessment based on behavioural disaggregation**

- 14.24 Responses to the Gay Men's Sex Survey carried out in 2008 indicated that approximately 2 % of gay men exclusively practice insertive oral sex (<http://www.sigmaresearch.org.uk/gmss/>) If it is the case that insertive oral sex has a <1:1,000,000 risk of acquiring a BBI, whatever the serology of the partner it was considered whether the donor health questionnaire could ask a modified question that could separate out individuals for whom this was the only risk.
- 14.25 There is evidence from the guidelines for provision of HIV prophylaxis that insertive oral sex carries a low risk of HIV transmission. There is uncertainty around HBV and HCV and expert opinion was that there would be a risk of both HBV and syphilis transmission.
- 14.26 One issue would be whether such a change would result in blood services being able to accept only a small number of extra donors who would otherwise be deferred under the existing question and whether we would alienate larger number of donors by the more descriptive nature of the question who then decide not to donate or fail to return to donate. The working group could not form a concrete opinion on this question and it was not formally discussed at a minuted meeting

and there is to the best of our knowledge no data to guide the opinion. This issue was therefore referred to SaBTO (see page 98).

## **Tissues and Cells:**

- 14.27 This is no opportunity in blood donation to discuss possible risks relating to an individual donor with the patient's clinician to get informed consent from the recipient, but this is not uncommon in organ donation. For tissues and cells, the situation varies among products, with such discussions possible for potential recipients of stem cell transplantation and pancreatic islet transplantation, but not for recipients of banked tissues. The role of individual risk assessment is included in the recommendations for life-saving tissues and cells.

## 15. Modelling Summary

- 15.1 To estimate the effects of changes in selection criteria, models were developed to calculate the risk of a potentially infectious donation not being detected on screening in the UK in one year. These models combine data from several sources, including survey data of blood donors and the general population, to estimate the change in the number of donations from compliant and non-compliant donors following implementation of the revised selection criteria and the associated change in risk. It is important to understand that even if a potentially infectious donation is not detected on screening, it may not necessarily be issued and, even if it is, may not result in an infection in the recipient. As such, the modelled risks represent a highly precautionary estimate.
- 15.2 While extremely rare, there are a number of ways that a potentially infectious donation can enter the blood supply. The most significant of these is the residual window-period risk due to incident infections in the donor population. While false negative test results due to issues other than the window-period (such as assay sensitivity, or errors due to sampling, processing or issuing) may occur the overall impact of these on risk is considered to be minor in comparison with the window-period and so these are not included in the calculation. This approach is consistent with the standard methodology previously used to estimate the risk of a potentially infectious donation not being detected and the residual risks for HIV, HBV and HCV are published each year<sup>3</sup>.
- 15.3 Assuming donor selection criteria of 3 months for activities considered to be at higher risk of infection, the chance of an newly acquired (incident) infection being present in a donation depends on the donor engaging in higher risk behaviour in the preceding three months such that an infection exists, but cannot be detected as it is in the window-period. These donors would be considered as non-compliant with the selection criteria. Therefore any observed residual window-period risk associated with the behaviour will be solely due to donations from non-compliant donors who have engaged in the higher risk behaviour in the three months prior to donating (HRB<3m). For this reason, data relating to higher risk behaviour and compliance in groups of donors is used to model the risks of a potentially infectious donation being present in the blood supply chain.
- 15.4 Under the standard methodology, the residual window-period risk scales with both the total number of donations and the incidence of infection in the whole donor population. To account for the effect of the donor selection criteria on mitigating risk, the standard methodology has been modified to instead use the number of donations from non-compliant HRB<3m donors and the incidence of infection in this group. For deferrals due to sexual behaviour the incidence of HIV observed in the donor population is used and for deferrals due to drug use (including that of a

partner) HCV is used. While there may be a change in the risk due to other infections under the revised selection criteria, these infections have been chosen as they represent some of the main risks and will be indicative of the change in risk in the populations being modelled.

- 15.5 As mentioned earlier hepatitis B may be transmitted by sexual contact or injecting drug use and may be harder to identify in donations due to the long window period. In comparison to HCV and HCV, although data on incident infections in the general population is collected it is likely to represent significant underreporting, in part because the infection may be asymptomatic and cleared in 80% of healthy adult individuals. Due to the paucity of data HBV was not included in the residual risk models.
- 15.6 As the residual window-period risk is dependent on the number of non-compliant HRB<3m donors, it is important to understand how the compliance in the donor population will be affected by a change in the selection criteria. Due to the high level of uncertainty in the rate of compliance under the revised criteria, reasonable best- and worst-case estimates, based on observations of current compliance, are used to give a range of possible outcomes for the number of donations and associated risk: Under the reasonable best-case scenario the number of donations and incidence of infections in non-compliant HRB<3m donors is the same as currently observed, i.e. all current donors continue to donate and any additional donors are compliant with the selection criteria, and so the total overall compliance increases without changing the residual window-period risk; while under the reasonable worst-case scenario the number of donations and incidence of infections in non-compliant HRB<3m donors increases and so the total overall compliance decreases while the residual window- period risk increases.

3<http://www.transfusionguidelines.org/document-library/position-statements>

- 15.7 The expected number of donations from compliant and non-compliant HRB<3m donors before and after implementation of the revised selection criteria are modelled by combining compliance data from a survey on blood donors with the annual number of UK donations. These values are then scaled using survey data on the sexual behaviour and drug use of the general population. It is assumed that the sexual and drug behaviours of the general population are representative of the behaviour of the donor population (both compliant and non-compliant donors). The residual window-period risk is then calculated by combining the expected number of non-compliant HRB<3m donors with an incidence of infection calculated using historical surveillance data.
- 15.8 The results of the modelling can be seen in Table X and Y. It is estimated that the residual window-period risk of a potentially infectious donations not being detected based on these deferral changes would be between 0.18 - 0.66 per million

donations for HIV and between 0.04 - 0.10 per million donations for HCV. As even under the worst-case scenario implementing all selection criteria represents less than a 1 in a million risk to patients these changes are considered tolerable from the standpoint agreed by the SaBTO donor selection working group. Similar residual risk modelling was not carried out for tissue or cell donation, however, these risks calculated using blood donor data can be used to estimate the size and change in risk for other categories of donor.

**Table 1: Estimated number of additional donations and residual window-period risk of HIV under the best- and worst-case scenario (there is no change to risk under the best-case scenario) following implementation of different three month selection criteria. Note – the standard methodology was used to calculate the current residual window-period risk and this was then adjusted using the modelled change for each selection criteria. Even if a potentially infectious donation is not detected on screening it may not necessarily be issued and, even if it is, may not result in an infection in the recipient represent a highly precautionary estimate of patient risk.**

<b>Selection criteria implemented</b>	<b>Current</b>	<b>MSM4</b>	<b>HRP - MSM5</b>	<b>HRP - HEC6</b>	<b>HRP - BBV7</b>	<b>HRP - CSW8</b>	<b>All</b>
Number of additional potentially infectious donations not detected on screening per million donations	-	0 - 0.16	0 - 0.06	0 - 0.08	0 - 0.09	0 - 0.09	0 - 0.47
Total number of potentially infectious donations not detected per million donations screened	0.18	0.18 - 0.35	0.18 - 0.24	0.18 - 0.27	0.18 - 0.27	0.18 - 0.27	0.18 - 0.66
Average number of years until a potentially infectious donation is not detected (at 2.2 million donations per year)	2.5	1.3	1.9	1.7	1.7	1.7	0.7

4. a man who has ever had oral or anal sex with another man (with or without a condom)
5. a sexual partner who would be classed as an MSM
6. a sexual partner who has, or may have been, sexually active, in an HIV endemic country at any point in their lives (this includes most countries in Africa)
7. a sexual partner who has had a blood-borne virus at any point in their lives
8. a sexual partner who has received money or drugs for sex at any point in their lives

**Table 2: Estimated number of additional donations and residual window-period risk of HCV under the best- and worst-case scenario (there is no change to risk under the best-case scenario) following implementation of different three month selection criteria. Note – the standard methodology was used to calculate the current residual window-period risk and this was then adjusted using the modelled change for each selection criteria. Even if a potentially infectious donation is not detected on screening it may not necessarily be issued and, even if it is, may not result in an infection in the recipient represent a highly precautionary estimate of patient risk.**

<b>Selection criteria implemented</b>	<b>Current</b>	<b>PWID9</b>	<b>HRP - PWID10</b>	<b>All</b>
Number of additional potentially infectious donations not detected on screening per million donations	-	0 - 0.01	0 - 0.04	0 - 0.05
Total number of potentially infectious donations not detected per million donations screened	0.04	0.04 - 0.05	0.04 - 0.09	0.04 - 0.10
Average number of years until a potentially infectious donation is not detected (at 2.2 million donations per year)	10.4	8.4	5.3	4.8

[Insert title]

9. an individual who has injected non-prescription drugs at any point in their lives

10. a sexual partner who would be classified as a PWID

## 16. Options and Recommendations

### 1 SaBTO Safety Framework and the Alliance of Blood Operators (ABO) Risk-Based Decision Framework

- 16.1 The SaBTO Framework was developed in the first year of the Committee's operation (2008) and has been used to enable the Committee to make sure it considered the wider issues, such as legal, political, ethical, commercial and the impact of these on a particular working groups activity. The Committee had been discussing updating the SaBTO Safety Framework. The ABO Risk-Based Decision Framework (RBDF) has been developed recently and also seeks to formalise the process of approaching a safety issue and to make sure that all relevant inputs have been considered. It aligns closely with the risk assessment process, places strong emphasis on stakeholder participation and risk communication, and enables all aspects of the decision-making process to be captured transparently.
- 16.2 A presentation on the ABO RBDF was made to the group and it was noted that the working group had already completed steps in the Framework namely, problem formulation, risk characterisation and engagement strategy and had populated the Framework accordingly. It was also noted that the current review will be simultaneously looking at several strands and the Framework can accommodate this. The working group agreed that the ABO Decision Framework would be suitable for use for the Donor Selection Criteria review Risk assessment will be required for each strand where sufficient evidence is available. The Framework then leads into risk assessment for different policy options, in this case options for different donor selection criteria. Further details of the Framework can be found at <https://allianceofbloodoperators.org/home.aspx>.
- 16.3 For each of the donor selection criteria a summary of the outputs of the ABO Decision framework, including possible options is provided. The results of the modelling (done on blood donors), if available, are then presented followed by the working group's recommendation. The recommendations were then considered for tissues, cells and gamete donors.

## 2 Window period for Blood Borne Infections

- 16.4 Discussion with other international blood services has suggested that a deferral period following a behaviour which may put a donor at higher risk of a BBI should be at least a minimum of 2 infectious window periods. The data available for input into the models did not allow differentiation between a 2 or 3 month deferral period. Hepatitis B has an infectious window period of 30 days, however, there is also an initial period after acquisition which may last up to 15 days when the virus may not be detected but where virus levels may be too low to result in transmission. These values are used when estimating the residual risk of a potentially infectious donation being missed on screening. Given these data it would seem appropriate to recommend a deferral of at least 60 days to take into account two times the infectious window period of HBV plus the initial non-infectious period. The working group decided that a window period of 3 months would protect patients and be operationally feasible. Therefore, the options appraisal/modelling was only done for 3 months and not 2 months. The working group also decided that this should be applied consistently across all deferrals relating to acquiring a BBI unless there was reason to reconsider.
- 16.5 With the now established use of NAT testing for blood donation testing it was thought by the working group that the late window period of HBV infectivity would be detected by NAT. The working group acknowledged that 3 months was still precautionary but recognised that it would also give more protection against emerging infections although recognising that most recent risks from emergent viruses were related to travel.

## 3 Acupuncture

- 16.6 For an initial assessment of the risk it is reasonable to examine two extreme options for the deferral of donors, leave the donor deferral period unchanged and remove the deferral period. Both options assume that the current testing regime is unchanged so HCV, HIV and HBV NAT tests are performed on pools of 24 donors for blood donations.

Option 1: No change to the current deferral period for blood donation

- 16.7 Current selection criteria managed by Joint Professional Advisory Committee require a 12 month deferral from the date of exposure if not carried out in the NHS

or by a member on the list of 'qualified practitioners' (Appendix C) or a 4 months deferral if a HCV NAT test is negative and an anti-HBc test is carried out and is negative or, if positive anti-HBs is >100miu/ml.

Option 2: No deferral for donation for acupuncture carried out in the UK in a commercial registered setting with a 3 month deferral for non-UK and non- registered settings, for example, at home.

## **Preliminary risk assessment:**

- 16.8 Option 1: It is estimated that the current risk of not detecting HBV on screening due to a window period infection is 1.3 per million donations. This equates to 0.6 donations per year. Infectious window period is taken as 30 days. This risk estimate is highly conservative since there have been only 2 cases of transmission to 3 recipients in the period 2009-2014 after HBV NAT testing was introduced (3.5 cases expected). However it should be acknowledged that acute hepatitis B infection can be asymptomatic.
- 16.9 Option 2: The proportion of cases of HBV reported to PHE giving body piercing/tattooing/acupuncture as a risk factor has remained at around 2% per year for the period 2008-2012. If we assume, as a precaution, that 5% of the 0.6 donations per year could come from a donor who has contracted HBV from body piercing this leaves a transmission risk of 0.03 donations per year or 1 transmission every 33 years.

## **Recommendations**

- 16.10 The working group decided that there was a very low risk for acupuncture carried out in the UK in registered and regulated premises by appropriately trained individuals and recommended no deferral for UK based acupuncture practitioners, 3 months if done outside UK for blood donation. The working group thought that the current list of qualified practitioners should be extended.

## **Use of Hepatitis B (HBV) Anti-Core antibody testing for blood donations**

- 16.11 The working group discussed the current selection criteria for acupuncture, body piercing, tattooing and cosmetic procedures, which is 12 months or 4 months with negative nucleic acid test for Hepatitis C and a negative HBV anti-core antibody or if positive for anti-HB core with anti-HBs of 100iu/ml or greater. The rationale for including the HBV anti-core antibody is that during the recovery phase levels of the virus may be below detectable levels and so the antibody can act as a marker of continuing infection and possible low-level viraemia. The group discussed whether this provided a significant contribution to blood safety. The group agreed that it was difficult to quantify the difference between a 24 pooled NAT test for blood and the HBV serology test but felt that it was unlikely that the serology test provided significant extra protection from transfusion transmitted infections.
- 16.12 SaBTO further discussed the recommendation of the working group that Hepatitis B virus (HBV) anti-core testing be discontinued for blood donors who have had acupuncture, tattooing, piercing or similar cosmetic procedures. It was noted this is not required for other behaviours that could lead to HBV exposure and risk of acquiring infection. Of the 30,000 additional tests carried out annually, the majority of tests (29,000) were due to some type of skin piercing or endoscopy risk and did not result in any positives resulting from such procedures. Members considered whether this serological test done on a single blood donation would provide extra protection compared with a 24 pool nucleic acid test for HBV. This had not been studied directly but members were informed that the Irish Blood Service does HBV anti-core testing on all blood donations and has not found any positives after acupuncture, tattooing or piercing. Members agreed with the recommendation that HBV anti- core testing be discontinued for blood donors that have had acupuncture, tattooing, piercing or similar cosmetic procedures.

### **For Tissue and cell donors:**

- 16.13 The working group recommended that no deferral is required for tissues and cell donors if acupuncture is performed in the UK in registered premises. A 3 month deferral is recommended from the date of the procedure if performed outside UK. This may be reduced by doing individual risk assessment on risk benefit analysis. The working group noted that the risk of acquiring an infectious disease may be outweighed by the risk of delaying a lifesaving transplantation. It was also noted that anti-HBc is a mandatory test under EUTCD and carried out routinely on all donations. SaBTO agreed that anti HBc testing should be retained for all tissue and cell donors. NAT for HBV, HCV and HIV are recommended to inform risk assessment if not done routinely.

## 4 Tattooing, Body Piercing and Cosmetic Procedure

- 16.14 The donor selection working group initially proposed investigating two options, no deferral for body piercing/tattooing within the UK and a 3 month deferral for procedures done outside the UK. For the temporary deferral option consideration will also be given to the need to test for anti-HBc provided a NAT test is carried out for HBV. Removal of anti-HBc would allow the SNBTS and NIBTS, who currently do not perform anti-HBc testing, to reduce their current 12 month deferral period to align with other blood services. If the need for anti-HBc testing was retained then either a 12 month deferral option needs to be maintained or reduced to a period, say six months but still without the need to test for anti-HBc.
- 16.15 Feedback from the operational feasibility group was that having different selection criteria from within and outside the UK and further subdividing between licensed and unlicensed premises in the UK, although possible, would be difficult. Therefore, this group preferred retention of a single donor deferral interval for all donors.

Option 1: Reduction in the current deferral period for blood donation to 3 month without an HBV anti-core test for all body piercing/tattoo events (UK and worldwide)

Option 2: Reduction in current deferral period for blood donation and tissue donation to 3 months with an HBV anti-core test for all body piercing/tattoo events (UK and worldwide)

Option 3: No deferral for UK events only in a licensed premises, 3 month donor deferral period for non-UK activity or in a non-commercial setting.

- 16.16 It is likely that the residual risk, at least in the UK, will be tolerable (less than 1:1,000,000) for a no deferral period. However, operational concerns regarding the separation of licensed and unlicensed activity in the UK and less controlled practice outside the UK may impact on the overall tolerability leading to retention of a deferral period for all donors.

### Recommendation

- 16.17 The working group decided that for blood donation no deferral would be required if the procedure is done in UK licensed premises, 3 months deferral for procedure in a non-licensed or outside the UK.

- 16.18 Tissue and cell donors: No deferral for procedures in UK licensed premises, 3 months if non-licensed or outside UK is recommended. . SaBTO agreed that anti HBc testing should be retained for all tissue and cell donors.

## 5 People who inject drugs

The current deferral period for PWID is a permanent deferral for blood and living & deceased tissue donors

- 16.19 It is estimated that around 1% of persons in the UK had injected drugs at some point. For many of these individuals, particularly those who would want to volunteer as blood or living tissue donors, injection of drugs would reflect a past behavior for a period and not a continuing dependency.
- 16.20 Document (1) reports that between 2011 and 2015, 41 blood donors, all but 2 of them new donors) who were confirmed positive for a BBI after blood donation had injected drugs.
- 16.21 The UK blood donor survey found self-reported non-compliance in donors for prior injection of recreational drugs at (25/62959).
- 16.22 Document (3) reviews the complexities of the issues around permitting PWID to donate. The available data suggests that, for HCV at least, reducing the deferral period would be not lead to an increase in transmission provided that compliance remained high, in part due to the very short window period for HCV NAT. However, other factors are important and influence the risk to patient safety. These include bacterial infections, emerging infections and the protection of recipients from exposure to psychoactive drugs commonly used by PWID.
- 16.23 Compliance and relapse are also factors for consideration as are undiagnosed cases of HCV which may have a temporary, but significant, impact on the blood services.
- 16.24 It may be appropriate to allow potential blood & living tissue donors with an historical injecting drug use to be allowed to submit a sample for screening before being allowed to donate. Consent would be required from the donor meaning disclosure to staff on sessions unless some mechanism could be found to keep the process confidential. For tissue and stem cell donation this would be less

problematic. Development of an on-line pre-donation health questionnaire could improve confidentiality and facilitate a more detailed disclosure.

- 16.25 Consideration of a defined deferral period rather than the current permanent deferral would appear reasonable and proportionate to the risk.

### **Options under consideration would be:**

1. No change, permanent deferral for PWID
2. Reduce deferral period to 3 months in line with options being considered for sexual behavior
3. Reduce deferral period for a minimum period after last episode of drug use (6 to 12 months)

### **Recommendation**

- 16.26 The working group discussed the option that people who inject drugs (PWID), which highlighted the thinking behind revising the interim conclusion that the deferral for PWID could be changed, subject to legislation, to 3 months. Modelling of the residual window period risk found that the risk was lower than 1:1,000,000 which the working group had defined as tolerable. However, other concerns were raised, data demonstrated that there is evidence of a bi-modal distribution of PWID with those who have not injected for a year likely to have stopped injecting but those who have injected within 6 months likely to be continuing to inject. With little knowledge of the likely rate of compliance in PWID it was suggested that the deferral period for blood donation be reduced to 12 months and the working group supported this. This deferral would also be sufficiently long to reduce the risk of bacterial transmission transmitted infections as the risk of bacterial infection both at injection site and systemically is known to be higher in current PWID. The likelihood of such a risk in donors is probably low but currently we do not have evidence to prove or disprove this.

### **Tissue & Cell donors:**

16.27 For tissue and cell donors, a three month deferral is recommended if injected with non-prescribed use of performance enhancing drugs or cosmetic treatment. For habitual use of intravenous drugs for addiction, 12 month deferral is recommended. This can be reduced to 3 months supported by individual risk assessment together with use with single NAT testing and bacterial screening.

## 6 Commercial Sex Workers

The current deferral criterion for blood, living & deceased tissue donors is a permanent deferral from donation if the person has ever received money or drugs for sex.

- 16.28 Data for the number of current and past sex workers and the incidence of BBIs in this group are scarce.
- 16.29 Data was reviewed from two papers looking at all attendees of genitourinary medicine clinics in England in 2011, one for males and the other females. With the caveat that there may be significant under reporting, 0.4% of females and 0.08% of males attending the clinics were identified as sex workers. The rate of HIV infection in female sex workers was no different from other female attendees at 0.2%. Male sex workers were 3 times more likely to have HIV compared to non-sex workers at 3.7%.
- 16.30 Data from the UK Blood Services Donor Survey indicates that compliance with the existing selection criterion is high (non-compliance rate 0.05% females and 0.04% males).
- 16.31 The opinion of the donor selection working group is that changes to the testing methodology and sensitivity for blood borne infections mean that permanent deferral is not a proportionate response for this group.
- 16.32 The Terence Higgins Trust shared a recent online survey of sex workers concerning their knowledge and attitudes to blood donation. The working group agreed that the conclusions of report were broadly in agreement with the deliberations of the working group and would inform the recommendations on deferral of current and former sex workers and their clients.
- 16.33 Rates of HIV and syphilis are higher in current sex workers than in the general population so a deferral period is justified. The deferral period should be determined by the tolerability of the residual risk of transmission of a BBI and although HIV and syphilis are important for commercial sex workers the longer window period of HBV needs to be taken into account.. It would also be highly

desirable, for operational practicality, to align the deferral period with other deferrals for high risk sexual behavior.

### **Option under consideration would be:**

1. Reduce deferral period for a minimum period of three months.

### **Recommendation**

- 16.34 The working group noted that there was more evidence available than the previous SaBTO review, although data was still sparse. The working group thought that there was no reason to not use the 3 month deferral period based on the HBV window period. It was recommended that the deferral period should be 3 months for current and former sex workers and that a 3 month deferral period for clients of sex workers would be appropriate.

### **For Tissue and Cell donors:**

- 16.35 A 3 month deferral period after last sexual contact is recommended for sex workers and for clients of sex workers. This may be reduced by doing individual risk assessment considering risks and benefits of the transplant.

## **7 Men who have sex with men**

- 16.36 The working group noted the high level of interest in this deferral with the 12 month deferral being viewed by some in the LGBT community as discriminatory since heterosexuals can donate blood even if they have multiple partners. There is an All Party Parliamentary Group (APPG) currently examining this MSM donor selection issue which the Chair of the SaBTO working group made a presentation and which did provide input to the working group. The APPG is expected to report its findings later this year.
- 16.37 The donor selection review group has examined the evidence and modelled changes to the donor selection criteria for all MSM.

## Options under consideration would be:

Reduce deferral period for a minimum period of three months for blood and tissue donors

The existing policy for Haematopoietic stem cell donors and donors of pancreatic islets/hepatocytes would remain unchanged

## Recommendation

16.38 Modelling of the residual window period risk indicated that this would be lower than the 1:1,000,000 risk that the working group had defined as tolerable. The working group recommended that a 3 month deferral period be introduced for MSM i.e. 3 months since anal or oral sex with another man with or without a condom. For tissue donors (except pancreatic islets/hepatocytes) a deferral period of 3 months was also recommended.

## Further Discussion

16.39 The working group further discussed whether a change to the question on the donor health check with regard to the type of sexual activity would be supported. It was stated, for example that there is a low HIV risk from insertive oral sex as recognised in the clinical guidance for HIV prophylaxis. The working group was concerned about not seeing evidence on the other infections and the operational feasibility of such a change. Expert opinion obtained by the working group agreed that the HIV risk was low but that the risk for HBV and syphilis was probably significant. In addition, members of the operational implementation group raised the issue of the effect of more detailed description of sexual behaviour on donor's willingness to donate. SaBTO discussed this issue and Members agreed that the evidence that insertive oral sex was a safe practice with regard to blood donation had not been thoroughly examined and so SaBTO did not make a recommendation. Members also agreed that if further examination suggests that it may be a safe practice any changes to the donor health check should be trialled to understand the impact on existing donors.

## 8 High Risk Partners

- 16.40 The current deferral period for sex with a high risk partner is 12 months for blood donors and deceased tissue donors.
- 16.41 The specific deferral criteria under review include: women who have sex with MSM; sex with a partner resident or sexually active in a high risk area (usually defined as an area where there is a high prevalence of HIV including most of sub-Saharan Africa); sex with a partner who was previously resident in a high risk area and who has not been screened by the blood service; sex with a high risk partner, i.e., with a blood-borne infection (BBI), sex worker or injecting drug user.

### Options under consideration would be:

Reduce deferral period for a minimum period of three months for blood and tissue donors\*

\*The existing policy for Haematopoietic stem cells donors and donors of pancreatic islets/hepatocytes donors for partners of MSM would remain unchanged.

### Recommendation

- 16.42 Modelling of the residual window period risk estimated that this would be lower than 1:1,000,000 and a 3 month deferral was agreed for donors with a high risk partner. For donors with a high risk partner who had been tested for blood borne infections a removal of the deferral period was recommended.
- 16.43 Tissue and cell donors: No change required. To continue with current practice of accepting donors without deferral. This meets regulatory requirement. There is no specific deferral for endoscopy in EUTCD.

## 10 Gametes

### Recommendations:

16.44 In the following recommendations, the term “serology” refers to:

- a) HIV-1. 4th Generation assay testing (combined antibody / antigen) detection of HIV-1/HIV-2. The test should be validated with the UK anti-HIV 1 working standard, available from NIBSC (99/750 or equivalent)
- b) HCV. Anti-HCV or combined antibody / antigen detection using a test validated with the UK anti-HCV working standard (06/188 or equivalent), available from NIBSC
- c) HBV. Enzyme immunoassay for HBV surface antigen (HBsAg) and antibodies to HBV core protein (anti-HBc). The HBsAg assay should have a minimum sensitivity 0.2 IU/ml.
- d) Syphilis. Specific tests for anti-treponemal antibody using an assay validated with the Health Protection Agency (HPA) syphilis quality control preparation

16.45 NAT refers to direct detection of HIV-1/2, HCV and HBV virion DNA or RNA by PCR or other amplification methodology. HCV NAT testing has a mandatory minimum sensitivity of 5000 IU/ml. Minimum sensitivities for HIV-1 and HBV NAT should be comparable.

16.46 All the following screening options are acceptable practice.

### Sperm donation.

16.47 Option 1. Serology + quarantine

(this summarises the current approved SABTO recommendation. Note that, despite this evidence based recommendation, centres must currently still adhere to the legal requirement for 6 month quarantine of donor sperm unless testing by NAT in addition to serology.)

Serology test at donation; Quarantine for 5 months; repeat serology and release if negative.

Justification:

The 'window periods' for HBV/HCV/HIV/Syphilis are 66.8/59/11/28 days based on serology alone. Thus, the quarantine period for cryopreserved semen and serology testing would be  $66.8 \times 2 = 133.6$  days. This has been rounded up to 5 months.

16.48 Option 2. Serology + NAT + quarantine.

Serology for HBV/HCV/HIV at donation; Quarantine for 3 months and repeat serology and test by NAT; release if negative.

Syphilis: there is no test by NAT for syphilis therefore a negative serology is required after the 3month quarantine period.

Justification:

Testing by NAT in some labs uses 'pooled' samples. Alternatively, individual testing can be done. The 'window periods' for HBV/HCV/HIV are different depending on this practice. For 'pooled' samples they are 30/4/9 days giving a recommended quarantine period of  $30 \times 2 = 60$  days (3 months). For 'individual' NAT they are 21/3/5 days giving a recommended quarantine period of  $21 \times 2 = 42$  days (2 months). By recommending 3 month quarantine we take the precautionary approach to avoid misunderstanding of laboratory procedures. In relation to Syphilis, both quarantine periods (2 and 3 months) are within the accepted 28day serology window period for syphilis.

16.49 Option 3. Serology + NAT + Deferral by history.

Note that this option is only considered to be relevant in exceptional circumstances as it is likely that most samples would be cryopreserved for practical considerations. The full donor assessment protocol including genetic testing would be likely to exceed the 3month quarantine period in 1.2. Nonetheless the following option could be appropriate if proceeded by an individual risk assessment and the recipient has given informed consent.

Deferral: An initial screening questionnaire is completed to identify and exclude potentially high risk donors (under preparation by the professional societies).

and

Serology and NAT tests for HBV/HCV/HIV. Serology tests for syphilis. If these tests are negative, the donation can be released.

**Justification:**

This recommendation provides for an extreme clinical situation where a delay in release of the donation would be clinically detrimental.

Since this protocol is based on the seroconversion rates used to inform blood donation procedures. The risk for infection transmission is most likely further reduced by the low risk process of insemination compared to intravenous transfusion.

## **Egg Donation**

### 16.50 Serology + NAT + Deferral.

There is currently no clinical imperative to require that donated eggs are cryopreserved and most donations are of non-cryopreserved eggs. An obligatory quarantine period is therefore not appropriate.

Given the clinical intervention that is required prior to actual donation, it is practical and appropriate to screen prior to the start of any intervention for the donor (e.g. medication or surgery) rather than at the point of donation.

Deferral: 2 months prior to donation, a screening questionnaire similar to that for sperm donors is completed to identify and exclude a potentially high risk donor.

and

Serology for HBV/HCV/HIV/Syphilis.

Start of medication: At the start of medication for the donor (about 3 weeks prior to the actual donation), serology and NAT tests for HBV/HCV/HIV and serology tests for syphilis. If these tests are negative, donation is released. If cryopreservation of donated eggs becomes the standard procedure, it would then be appropriate to implement the procedure in 16.48.

Justification:

The screening questionnaire and initial serology tests will exclude high risk donors and those who were not considered to have been high risk but were nonetheless infected.

Repeat screening after 2 months, will identify those who may have been infected at the initial screen but were within the window period.

Given that the egg donor will have been under clinical supervision during most of the 2 months from initial testing to donation, the risk of new infection to a low risk donor during this period is very low.

## 11 Surveillance

- 16.51 SaBTO emphasised the importance of maintaining effective surveillance in maintaining the safety of the blood, tissues, cells and gametes supply.

## 17. Legal Considerations

- 17.1 For some of the donor selection criteria there are mandatory deferral periods in the Blood Safety and Quality Regulations based on the Blood Directives. The working group has made its recommendations based on the best available evidence irrespective of the existence of mandatory deferral periods but recognises that implementation of these recommendations faces a legal barrier. The working group's recommendations will be provided to the European Commission as part of their current review of the Blood Directives, which may provide an opportunity to change donor selection criteria in EU law. In addition, any appropriate changes to the UK's Blood Safety and Quality Regulations following the UK's exit from the EU will be considered going forward.

<b>Policy</b>	<b>Mandatory period</b>	<b>Recommended period</b>
People who inject drugs	Permanent	1 year
Endoscopic examination using flexible instruments	6 months or 4 months if HCV NAT is negative	No deferral
Tattooing or body piercing	6 months or 4 months if HCV NAT is negative	No deferral for procedures done in licensed UK premises  3 month deferral for procedures done in non-UK or unlicensed premises

Acupuncture	6 months or 4 months if HCV NAT is negative unless performed by a qualified practitioner using sterile single-use needles	No deferral for procedures performed by a qualified practitioner with single use needles  3 month deferral for procedures don in non-UK non-qualified
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17.2 There may be some scope for changes in current practice for some of these donor selection criteria. Current JPAC guidelines for tattooing and body piercing, and for acupuncture is to defer for 12 months or 4 months with HCV NAT and HBV anti-core negative, these could be reduced to 6 months with no test without legislation. In addition, other practitioners could be added to the accepted JPAC list of “qualified practitioners” for acupuncture. For flexible endoscopy the deferral is 6 months or 4 months with HCV NAT and HBV anti-core negative so the time of deferral could not be changed.

## Tissue & Cell donors:

17.3 There is no prohibitive legal or regulatory barriers for implementing SaBTO recommendations for tissue and cell donors. The EUTCD requires that donors must be excluded if they have a “History, clinical evidence, or laboratory evidence of HIV, acute or chronic Hepatitis B (except in the case of persons with a proven immune status), Hepatitis C, HTLV I/II, transmission risk or evidence of risk factors for these infections” unless justified by documented risk assessment approved by the responsible person.

17.4 The review undertaken by SaBTO informs the justification for the risk based donor selection approach with available epidemiological data. The rationale for accepting donors with past Hepatitis B infection with or without anti HBs (Hepatitis B except in case of persons with a proven immune status) is supported by doing NAT testing on donors to rule out ongoing infection.

## **Legal considerations for gamete donation**

- 17.5 The EUTCD relates to practice within this scope. The Human Fertilisation and Embryology Authority (HFEA) is the Responsible Body for ensuring implementation of the Directive.

## **Regulatory considerations**

- 17.6 The procedures within the scope can only be provided by clinics in the UK that are appropriately licenced by the HFEA. Compliance with the Code of Practice provided by the HFEA is required and actions that do not comply may result in criminal charges.
- 17.7 The HFEA collects information on serious adverse events and reactions related to the donation of gametes and embryos. This includes an infection that resulted from gamete or embryo donation.

## 18. Communication of Outcome of the Review

- 18.1 Effective communication of any recommendations that UK Blood Services are instructed to implement will be critical to maintaining the ongoing safety of blood, tissues, cells and gametes. It will be important for messages to reach potential donors where donor selection criteria have changed so that they understand the new donor selection criteria and why the change has been made.
- 18.2 SaBTO secretariat, NHSBT communications team and DH press office are working together to produce a communications plan. In addition, other UK blood services and devolved administrations are also involved.

Key aims of the communications plan

- a) Reach all stakeholders with appropriate messaging
- b) Use stakeholder networks to increase spread of messages
- c) Ensure that the importance of compliance with donor selection is emphasised
- d) Maintain clarity and consistency of communications

## 19. Glossary

ABO	Alliance of Blood Operators
APPG	All Party Parliamentary Group
BBI	Blood Borne Infections
BSQR	Blood Safety & Quality Regulations
CSW	Commercial Sex Worker
DHQ	Donor Healthcheck Questionnaire
DNA	Deoxyribose Nucleic Acid
EDQM	European Directorate for the Quality of Medicines
EU	European Union
EUTCD	European Union Tissue & Cells Directive
FDA	Federal Drug's Administration
GUM	Genito-urinary Medicine
HBV	Hepatitis B virus
HBV anti-core	Hepatitis B virus anti-core serology test
HBsAg	Hepatitis B virus surface antigen
HCV	Hepatitis C virus
HFEA	Human Fertilisation and Embryology Authority
HIV	Human immunodeficiency virus
HTLV	Human T-cell lymphotropic virus
IVDU	Intravenous Drug Users
JPAC	Joint Professional Advisory Committee
LGBT	Lesbian Gay Bisexual Transgender

## DONOR SELECTION CRITERIA REPORT JULY 2017 (VERSION 2)

MSM	Men who have sex with men
NAT	Nucleic Acid Test
Natsal	National Survey of Sexual Attitudes and Lifestyles
NHSBT	National Health Service Blood & Transplant
PGG	Public Goods Game
PHE	Public Health England
PWID	Persons Who Inject Drugs
QMS	Quality Management System
RNA	Ribonucleic Acid
RR	Residual Risk
SaBTO	Advisory Committee on the Safety of Blood Tissues and Organs
SACTTI	Standing Advisory Committee for Transfusion Transmitted Infections
SBMW	Sex Between men and Women
SHOT	Serious Hazards of Transfusion
SLWG	Short Life Working Group
SNBTS	Scottish National Blood Transfusion Service
SOP	Standard Operating Procedure
TSQR	Tissue Quality & Safety Regulations
TTI	Transfusion Transmitted Infection
vCJD	Variant Creutzfeldt-Jakob disease
WP	Window Period

## 20. Appendices

### Modelling the risk of revised selection criteria for blood donors

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June 2017

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11 Department of Health

12 NHS Blood & Transplant/PHE Epidemiology Unit

## Glossary of terms

Men who have sex with men (MSM)	Men who have ever had oral or anal sex, with or without a condom.
People who inject drugs (PWID)	An individual who has injected non-prescription drugs at any point in their lives.
Commercial sex worker (CSW)	An individual who has ever received Money or drugs for sex.
Higher Risk Behaviour (HRB)	Behaviour associated with an increased chance of individuals having an incidence infection.
High Risk Partner (HRP)	A donor with a sexual partner who engages in higher risk behaviour.
High Risk Partner – People who inject drugs (HRP – PWID)	A donor with a sexual partner who would be classified as a PWID.
High Risk Partner – Men who have sex with men (HRP – MSM)	Women with a male sexual partner who would be classified as an MSM.

High Risk Partner – HIV endemic country (HRP – HEC)	A donor with a sexual partner who has, or may have been, sexually active, in an HIV endemic country at any point in their lives (this includes most countries in Africa).
High Risk Partner – Blood-borne virus (HRP – BBV)	A donor with a sexual partner who has had a blood-borne virus at any point in lives.
High Risk Partner – Commercial sex worker (HRP – CSW)	A donor with a sexual partner who would be classified as a CSW.
Compliant HRB	A donor who engages in higher risk behaviour but is compliant with the selection criteria.
Non-compliant HRB<3m	A donor who is not compliant with the Selection criteria and has engaged in higher behaviour (HRB) in the three months prior to donating. These donors contribute to the residual window-period risk associated with the HRB.

[Insert title]

Non-compliant HRB>3m

A donor who is not compliant with the selection criteria and last engaged in higher risk behaviour (HRB) more than three months prior to donating. These donors do not contribute to the residual window-period risk associated with the HRB.

Seroconversion in repeat donations

A positive repeat donor who had previously tested negative on routine testing within three years.

Eligible HRB population

The proportion of the general population who engage in HRB who could donate under the selection criterion.

Ineligible HRB population

The proportion of the general population who engage in HRB who could not donate under the selection criterion.

## Introduction

As part of the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) review of donor selection criteria, the Department of Health and experts from the NHS Blood & Transplant/PHE Epidemiology Unit were commissioned to produce risk modelling in support of the Alliance of Blood Operators (ABO) Risk-Based Decision Framework. It was agreed by the SaBTO donor selection working group that any change to the selection criteria that increased the risk to patients by more than 1 in a million is considered intolerable and so will be rejected.

To estimate the effects of changes in selection criteria, models were developed to calculate the risk of a potentially infectious donation not being detected on screening in the UK in one year. These models combine data from several sources, including survey data of blood donors and the general population, to estimate the change in the number of donations from compliant and non-compliant donors following implementation of the revised selection criteria and the associated change in risk. It is important to understand that even if a potentially infectious donation is not detected on screening, it may not necessarily be issued and, even if it is, may not result in an infection in the recipient. As such, the modelled risks represent a highly precautionary estimate.

While extremely rare, there are a number of ways that a potentially infectious donation can enter the blood supply. The most significant of these is the residual window-period risk due to incident infections in the donor population. While false negative test results due to issues other than the window-period (such as assay sensitivity, or errors due to sampling, processing or issuing) may occur the overall impact of these on risk is considered to be negligible in comparison with the window- period and so these are not included in the calculation. This approach is consistent with the standard methodology previously used to estimate the risk of a potentially infectious donation not being detected and the residual risks for HIV, HBC and HCV are published each year<sup>13</sup>. All revised selection criteria use a three month deferral of the last occurrence of higher risk behaviour to mitigate any window-period risk in compliant donors and so any additional risk will be due to window-period infections in donors who are non-compliant under the revised selection criteria.

Due to the high level of uncertainty in modelling donor compliance, reasonable best- and worst-case scenarios have been used to produce estimates, based on observations of current compliance, that give a range of possible outcomes for the change in risk associated with moving to the revised selection criteria. For deferrals due to sexual behaviour the incidence of HIV observed in the donor population is used and for deferrals due to drug use (including that of a partner) HCV is used. While there may be a change in the risk due to other infections under the revised selection criteria, these infections have been chosen as they represent some of the main risks and will be indicative of the change

[Insert title]

in risk in the populations being modelled. The list of selection criteria being reviewed and the risk being modelled can be seen in Table 1.

**Table 1 Current and revised deferrals and risk being modelled for selection criteria being considered in the SaBTO donor review**

<b>Selection criteria</b>	<b>Risk considered</b>	<b>Current deferral</b>	<b>Revised deferral</b>
PWID	HCV	Permanent	3 month
MSM	HIV	12 month	
HRP – PWID	HCV		
HRP – MSM	HIV		
HRP – HEC			
HRP – BBV			

Due to the lack of available data the change in residual window-period risk for CSW has not been modelled in this report.

13 <http://www.transfusionguidelines.org/document-library/position-statements>

## Methodology

As it represents the most significant risk of a potentially infectious donation entering the blood supply, this analysis will focus on the change in residual window-period risk of implementing the revised selection criteria. The residual window-period risk is due to the presence of an incident infection in a donation that cannot be detected on screening, as it is still in the window-period, but may be transmitted to a blood recipient. The use of donor selection criteria is, in part, intended to reduce this risk by deferring individuals whose higher risk behaviour (HRB) gives an increased chance of an incidence infection being present at the time of donation. As such, all risk calculations in this work are based on incident infections associated with the HRB of donors and, to simplify modelling, all such behaviours are considered independent.

Under all revised selection criteria it is proposed that the deferral period on HRB be shortened to three months as this represents the minimum period sufficient to mitigate the residual window- period risk in donors. This means that any infections donors have contracted due to higher risk behaviour should be detected by screening, as they are no longer in the window-period, and so not pose an increased risk to blood safety. Any additional residual window-period risk is then due solely to donations from non-compliant donors who have engaged in higher risk behaviour in the three months prior to donating (HRB<3m) as there is a chance that an infection exists in these donors but cannot be detected.

Using the standard methodology (see Appendix A), the residual window-period risk scales with both the total number of donations and the incidence of infection in the whole donor population. While this approach is valid if the selection criteria do not change, to account for the effect of the revised selection criteria on mitigating risk the standard methodology has been modified to instead use the number of donations from non-compliant HRB<3m donors and the incidence of infection in this group (see Appendix B). It is assumed that the total number of donations collected each year in the UK will remain the same following the implementation of the revised selection criteria and, as a precautionary assumption, that any additional donations from donors engaging in higher risk behaviour will replace those from the rest of the donor population.

To estimate the change in the residual window-period risk under the revised selection criteria the current and expected number of donations from non-compliant HRB<3m donors needs to be modelled in addition to the incidence of infection in this group. Under the current selection criteria the donor population being considered can be broken down

into three groups: compliant HRB donors; non-compliant donors who last engaged in higher risk behaviour more than three months prior to donating (non-compliant HRB>3m); and non-compliant HRB<3m donors. Of these three groups, only donations from non-compliant HRB<3m donors contribute to the additional residual window-period risk associated with the HRB. Under the revised selection criteria the situation is simplified and there will be only two donor groups: compliant HRB donors and non-compliant HRB<3m donors.

As the residual window-period risk is dependent on the number of non-compliant HRB<3m donors, it is important to understand how the compliance in the donor population will be affected by a change in the selection criteria. Due to the high level of uncertainty in what the rate of compliance will be under the revised criteria, reasonable best- and worst-case scenarios, based on observations of current compliance, are used to give a range of estimates for the change in associated risk:

**Reasonable best case scenario** – Under the reasonable best-case scenario the number of donations and incidence of infections in non-compliant HRB<3m donors is the same as currently observed, i.e. any additional donors are compliant with the selection criteria, and so the residual window-period risk remains the same. As non-compliant HRB>3m donors who are currently donating will become compliant under the revised selection criteria the total number of non-compliant HRB donors will decrease and so the total compliance increases.

**Reasonable worst case scenario** – In the reasonable worst case scenario the number of donations and incidence of infections in non-compliant HRB<3m donors increases. This causes the residual window-period risk to increase while at the same time the total compliance decreases. To model the increase in the number of non-compliant donations, the proportion of all HRB donations that are non-compliant remains the same under the revised selection criteria<sup>14</sup>, i.e. if the number of compliant donations were to double then so would the number of non-compliant donations. The increase in the incidence of infections is modelled by assuming that the observed number of seroconversions in repeat donors, used in the risk calculation for the non-compliant HRB<3m donors, follows a Poisson distribution and then using the upper bound of the 95% confidence interval to calculate the incidence.

A diagrammatic representation of the reasonable best- and worst-case scenarios can be seen in Appendix C.

## Sources of data

It is assumed throughout that the sexual and drug related behaviours of the donor population are representative of the general population as a whole and so data from the Third National Survey of Sexual Attitudes and Lifestyles (Natsal-3) [1] are used to model these behaviours. Data on the number of currently non-compliant donors (and compliant MSM donors) are derived from responses to the UK Blood Donor Survey [2]. Data on the prevalence of HIV in the general population was derived from the PHE HIV in the UK 2016 report [3] and UK population estimates from ONS 2015 figures. Surveillance data on the number of seroconversions in repeat donations, as well as additional data, were provided by NHS Blood & Transplant/PHE Epidemiology Unit.

## Current donations

To model the annual number of UK donations by age, gender, and type (new or repeat donor) data on the number of donations in 2015 in England provided by NHS Blood & Transplant (NHSBT) were scaled to match the 2.2 million donations expected in the UK each year. The expected number of annual annual donations by age, gender, and type can be seen in Table 2

14. It is important to understand that under current selection criteria non-compliant HRB donations include both HRB>3m and HRB<3m donors whereas under the revised selection criteria all non-compliant donations will be from HRB<3m donors.

**Table 2 Expected annual UK donations by age, gender, and type. Figures are derived by applying the distribution of donations in England (2015) to the 2.2 million annual donations expected across the UK.**

Age group	Male			Female		
	New	Repeat	Total	New	Repeat	Total
17-24	27,867	60,335	88,202	46,807	88,104	134,910
25-34	29,764	110,205	139,969	48,842	136,471	185,314
35-44	19,627	146,331	165,958	33,464	162,206	195,670
45+	25,724	678,859	704,583	34,145	539,426	573,570
Total	102,982	995,730	1,098,712	163,257	926,207	1,089,464

## Current risk

To calculate the residual window-period risk under the current selection criteria, the standard methodology (see Appendix A) was used with surveillance data provided by NHS Blood & Transplant/PHE Epidemiology Unit. The number of repeat donations was calculated by using the same NHSBT data as for the number of annual UK donations. The estimated current residual window-period risk for HCV and HIV can be seen in Table 3.

**Table 3 Current residual window-period risk for HIV and HCV in the UK calculated using the standard methodology (see Appendix A).**

	HCV	HIV
Surveillance period	2011-2015	2013-2015
Total donations (UK)	11,428,579	6,564,530
Number of seroconversions in repeat donors	16	24
Repeat donations	10,038,044	5,765,812
Incidence per 1,000,000 person-years in Repeat donations	3.19	8.32
Residual window-period risk per 1,000,000 New donations screened	0.11	0.04

	HCV	HIV
Residual window-period risk per 1,000,000 Repeat donations screened	0.03	0.21
Risk per million donations screened	0.04	0.18
Estimated positive donations not detected on screening each year	0.10	0.40
One donation not detected on screening every x years	10.4	2.5

## Outline methodology for reasonable worst-case scenario

To calculate the change in residual window-period risk for the reasonable worst-case scenario (as there is no change in risk under the reasonable best-case scenario) under each revised selection criterion the same basic methodology has been used:

- The number of currently compliant HRB donations is obtained either directly, using the UK Blood Donor Survey when available, or indirectly, by applying data from Natsal-3 survey to the number of expected annual UK donations;
- The number of currently non-compliant HRB donations is derived by applying the weighted values from the UK Blood Donor Survey to the number of expected annual UK donations;
- Data from the Natsal-3 survey are used to model the number of currently non-compliant HRB donations that would be from non-compliant HRB<3m donors;
- The number of future compliant HRB donations is estimated by using data from the Natsal-3 survey to predict the relative increase in the number of compliant HRB donors under the revised selection criterion;
- The number of future non-compliant HRB<3m donations is calculated by scaling all the current non-compliant HRB donations by the same increase in the number of compliant HRB donations;
- To calculate the change in risk under the revised selection criterion, the number of predicted future non-compliant HRB<3m donations is multiplied by the worst-case residual window-period risk associated with the HRB and the difference taken with

the current risk calculated in the same way but using the central estimate of the residual window-period risk (see Appendix B).

## Men who have sex with men (MSM)

### Donations

To calculate the number of donations from compliant and non-compliant MSM, the weighted number of valid responders<sup>15</sup> from the UK Blood Donor Survey was used for each age group and the values for new<sup>16</sup> and repeat donors calculated separately. Data from Northern Ireland has been excluded from the analysis as they have only recently changed to a one-year deferral in line with the other UK blood services. The proportion of new and repeat donors as well as the % non-compliance within the MSM group can be seen in Table 4 and Table 5 respectively.

**Table 4 Proportion of compliant and non-compliant MSM new donors in the UK Blood Donor Survey (values in 25+ have been combined). Note that the numbers of responders are non-integers as they are weighted values.**

Age group	All Male Responder	Compliant MSM		Non-compliant MSM	
		No.	% of male responders	No.	% of male responders
17-24	1,675.0	33.0	1.97% (1.36% - 2.76%)	14.0	0.84% (0.46% - 1.40%)
25-34	1,126.2	16.3	1.29% (0.89% - 1.81%)	4.9	1.26% (0.87% - 1.78%)
35-44	643.8	6.1		1.8	
45+	782.5	10.6		25.5	

Total	4,227.5	65.9	1.56% (1.21% - 1.98%)	46.2	1.09% (0.80% - 1.46%)
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15 excludes individuals who dropped out and did not respond

16 returning donors have been included under new donors

**Table 5 Proportion of compliant and non-compliant MSM repeat donors in the UK Blood Donor Survey (certain values have been combined). Note that the numbers of responders are non-integers as they are weighted values.**

Age group	All Male Responder	Compliant MSM		Non-compliant MSM	
		No.	% of male responders	No.	% of male responders
17-24	2,218.3	22.7	1.02% (0.65% - 1.54%)	28.5	1.29% (0.86% - 1.85%)
25-34	3,188.0	18.4	0.61% (0.44% - 0.81%)	22.5	0.71% (0.44% - 1.06%)
35-44	4,333.9	27.1		13.1	0.30% (0.16% - 0.52%)
45+	16,068.7	66.8	0.42% (0.32% - 0.53%)	18.3	0.11% (0.07% - 0.18%)
Total	25,808.9	135.0	0.52% (0.44% - 0.62%)	82.5	0.32% (0.25% - 0.40%)

To estimate the number of non-compliant donations from MSM who have engaged in sex between men17 (SBM) in the three months prior to

donating (non-compliant SBM<3m), weighted data from the Natsal-3 survey on rates of SBM in MSM18 were used (Table 6). Assuming that the relative proportions of MSM who have engaged in SBM in the last three months (SBM<3m) and in the last year (SBM<1y) is the same in the non-compliant MSM donor population as in the general population and that the chance an ineligible MSM donor will donate is independent of when the last engaged in SBM, the proportion of non-compliant donations that would still be ineligible under the revised selection criterion (non-compliant SBM<3m) can be calculated as:

$$\begin{array}{rclcl}
 \text{No. non-compliant} & = & \text{No. MSM general} & \times & \% \text{ ineligible MSM who} \\
 \text{MSM} & & \text{population} & & \text{donate} \\
 \text{donations [SBM<1y]} & & \text{[SBM<1y]} & & \\
 & & & & \\
 & = & & \times & \% \text{ ineligible MSM who} \\
 \text{No. non-compliant} & & \text{No. MSM general} & & \text{donate} \\
 \text{MSM} & & \text{population} & & 
 \end{array}$$

17 SBM is defined as oral or anal sex with another man with or without a condom

18 MSM individuals were identified by looking for male respondents who have ever engaged in oral or anal sex with another man

donations [SBM<3m]		[SBM<3m]	
% non-compliant MSM donations [SBM<3m]	=	No. non-compliant MSM donations [SBM<3m]	÷
	=	No. MSM general population [SBM<3m]	÷
	=	% MSM general population [SBM<3m]	÷
	=	(1 - % MSM general population [no SBM<3m])	÷
			(1 - % MSM general population [no SBM<1y])

So for all MSM the proportion of non-compliant SBM<3m donations would be  $(1 - 64.9\%) / (1 - 51.3\%) = 72\%$ . The calculated proportions for MSM of all ages can be seen in Table 7. To estimate the increase in the number of compliant MSM donations following the change to the revised selection criterion a similar calculation is performed to derive the relative increase in the current number of compliant MSM donations:

[Insert title]

$$\begin{array}{l} \text{No. compliant MSM donations} \\ \text{[no SBM<1y]} \end{array} = \begin{array}{l} \text{No. MSM general} \\ \text{population} \\ \text{[no SBM<1y]} \end{array} \times \begin{array}{l} \% \text{ eligible MSM who} \\ \text{donate} \end{array}$$

$$\begin{array}{l} \text{No. compliant MSM donations} \\ \text{[no SBM<3m]} \end{array} = \begin{array}{l} \text{No. MSM general} \\ \text{population [no} \\ \text{SBM<3m]} \end{array} \times \begin{array}{l} \% \text{ eligible MSM who} \\ \text{donate} \end{array}$$

$$\begin{array}{l} \text{Relative increase in compliant} \\ \text{MSM donations [no SBM<3m]} \end{array} = \begin{array}{l} \text{No. compliant MSM} \\ \text{donations [no SBM<3m]} \end{array} \div \begin{array}{l} \text{No. compliant MSM} \\ \text{donations [no SBM<1y]} \end{array}$$

$$= \begin{array}{l} \text{No. MSM general} \\ \text{population [no} \\ \text{SBM<3m]} \end{array} \div \begin{array}{l} \text{No. MSM general} \\ \text{population [no SBM<1y]} \end{array}$$

$$= \begin{array}{l} \% \text{ MSM general} \\ \text{population [no} \\ \text{SBM<3m]} \end{array} \div \begin{array}{l} \% \text{ MSM general} \\ \text{population [no SBM<1y]} \end{array}$$

This calculation assumes that the probability that an eligible MSM donor will donate is independent of the selection criterion. For all MSM the relative increase in compliant MSM donations would be  $64.9\% / 51.3\% = 1.27$  (see Table 7).

**Table 6 Natsal-3 data on the number of MSM who have not engaged in SBM in the last three months and one year. Note that the numbers of responders are non-integers as they are weighted values**

Age group	All Male Responders	No. MSM	% MSM	No SBM last three months		No SBM last year	
				No	%	No.	%
17-24	1,112.4	41.0	3.7%	20.4	49.9%	11.5	28.0%
25-34	1,374.5	71.5	5.2%	41.0	57.3%	33.3	46.6%
35-44	1,425.1	58.6	4.1%	35.7	61.0%	30.6	52.2%
45+	3,470.0	165.6	4.8%	121.5	73.3%	97.4	58.8%
Total	7,382.0	336.6	4.6%	218.6	64.9%	172.7	51.3%

**Table 7 Proportion of current non-compliant donations that are from men who have engaged in SBM in the three months prior to donating and the relative increase in compliant MSM donations under the revised selection criterion**

<b>Age group</b>	<b>% non-compliant MSM who have engaged in SBM in the last three months</b>	<b>Relative increase in compliant donations under the revised selection criterion</b>
17-24	70%	1.78
25-34	80%	1.23
35-44	82%	1.17
45+	65%	1.25
Total	72%	1.27

The proportion of compliant and non-compliant MSM donors (Table 4 and Table 5) were then combined with the annual number of UK donations (Table 2) and the proportion of currently non-compliant donations who engaged in SBM in the last three months (Table 7) to give the current annual MSM donations in the UK by compliance group (compliant, non-complaint SBM>3m, and non-compliant SBM<3m) that can be seen in Table 8 and Table 9.

**Table 8 Annual number of UK donations from MSM new donors by compliance group using central estimates under current one year selection criterion**

<b>Age group</b>	<b>Compliant</b>	<b>Non-compliant SBM&gt;3m</b>	<b>Non-compliant SBM&lt;3m</b>	<b>Total</b>
17-24	549	71	162	782
25-34	384	76	300	760
35-44	253	45	202	501
45+	332	115	210	657

Age group	Compliant	Non-compliant SBM>3m	Non-compliant SBM<3m	Total
Total	1,518	307	875	2,699

**Table 9 Annual number of UK donations from MSM repeat donors by compliance group using central estimates under current one year selection criterion**

Age group	Compliant	Non-compliant SBM>3m	Non-compliant SBM<3m	Total
17-24	618	236	540	1,394
25-34	667	157	621	1,444
35-44	886	81	362	1,329
45+	2,820	273	501	3,594
Total	4,991	747	2,023	7,761

The number of non-compliant SBM<3m donations under the revised three month selection criterion is calculated by assuming that the proportion of all MSM donations that are non-compliant under the revised selection criteria is the same as that currently. The number can then be calculated in the following manner:

$$\frac{\text{No. non-compliant MSM donations [revised]}}{\text{No. compliant MSM donations [revised]}} = \frac{\text{No. non-compliant MSM donations [current]}}{\text{No. compliant MSM donations [current]}}$$

$$\text{No. non-compliant MSM donations [revised]} = \text{No. compliant MSM donations [revised]} \times \frac{\text{No. non-compliant MSM donations [current]}}{\text{No. compliant MSM donations [current]}}$$

[Insert title]

$$= \frac{\text{Relative increase in compliant MSM donations [no SBM<3m]}}{\text{Relative increase in compliant MSM donations [no SBM<3m]}} \times \text{No. non-compliant MSM donations [current]}$$

$$= \frac{\text{Relative increase in compliant MSM donations [no SBM<3m]}}{\text{Relative increase in compliant MSM donations [no SBM<3m]}} \times (\text{No. non-compliant SBM<3m MSM donations [current]} + \text{No. non-compliant SBM>3m MSM donations [current]})$$

So for MSM repeat donations from donors in the 45+ age group this would be 1.25 x (273 + 501) = 966. The annual number of estimated non-compliant SBM<3m donations across the UK under the current and revised selection criterion can be seen in Table 10.

**Table 10 Annual number of UK donations from MSM SBM<3m donors under the current one year and revised three month selection criterion assuming a reasonable worst-case scenario**

Age group	Donations from New donors			Donations from Repeat donors		
	Current	Revised	Difference	Current	Revised	Difference
17-24	162	415	253	540	1,382	842
25-34	300	463	162	621	957	336
35-44	202	289	87	362	518	156
45+	210	405	195	501	966	465
Total	875	1,572	698	2,023	3,822	1,798

## Residual Window-Period Risk – HIV

The incidence of HIV infections, and so ultimately residual window-period risk, is calculated using historical data on the number of seroconversions in repeat donors associated with MSM. UK surveillance data on the number of seroconversions and total number of donations were provided by NHS Blood & Transplant/PHE Epidemiology Unit for the period 2013-2015. In this period there were 6.6 million donations in total and, extrapolating from Table 9, it is estimated that 23 thousand of these came from MSM repeat donors. The number of seroconversions associated with MSM, number of MSM donations by compliance group, and incidence per 100,000 person-years in repeat donors can be seen in Table 11, Table 12 and Table 13 respectively (see Appendix A and B for methodology).

**Table 11 Number of HIV seroconversions in repeat donors by MSM compliance group in the period 2013- 2015 across the UK**

<b>Age group</b>	<b>All MSM</b>	<b>Non-compliant MSM</b>	<b>Non-compliant SBM&lt;3m19</b>
17-24	1	1	1
25-34	2	2	1

19. Recent seroconversions (occurring in the past four weeks) were used as a proxy for seroconversions associated with non-compliant SBM<3m donors.

<b>35-44</b>	<b>4</b>	<b>3</b>	<b>3</b>
45+	3	2	2
Total	10	8	7

**Table 12 Number of repeat donations from by MSM compliance group in the period 2013-2015 across the UK**

<b>Age group</b>	<b>All MSM</b>	<b>Non-compliant MSM</b>	<b>Non-compliant SBM&lt;3m</b>
17-24	4,181	2,327	1,620
25-34	4,333	2,332	1,862
35-44	3,987	1,330	1,086
45+	10,782	2,322	1,502
Total	23,283	8,311	6,070

**Table 13 Incidence of HIV infections per 100,000 person years (95% confidence intervals) in repeat MSM donors by compliance group in the period 2013-2015 across the UK**

<b>Age group</b>	<b>All MSM</b>	<b>Non-compliant MSM</b>	<b>Non-compliant SBM&lt;3m</b>
17-24	48 (1 - 267)	86 (2 - 479)	123 (3 - 688)
25-34	92 (11 - 334)	172 (21 - 620)	107 (3 - 598)
35-44	201 (55 - 514)	451 (93 - 1319)	553 (114 - 1615)
45+	56 (11 - 163)	172 (21 - 622)	266 (32 - 962)
Total	86 (41 - 158)	193 (83 - 379)	231 (93 - 475)

As there is no statistically significant difference between the incidence of HIV infections across the different ages within each compliance group the totals are used. Comparing the central estimate and upper bound of the

95% confidence intervals, the incidence of HIV infections in the non-compliant SBM<3m donor group of 231 (93 – 475) per 100,000 person years is highest and so this is used for the residual window-period risk calculation under the current selection criterion (central estimate) and the reasonable worst-case scenario under the revised selection criterion (upper bound).

Applying the modified methodology (Appendix A and B) to the incidence of HIV infections and number of non-compliant SBM<3m donations (Table 10) gives an estimated risk of 0.12 and 0.48 positive donations not detected on screening each year under the current one year and revised three month selection criterion respectively. Taking the difference between these and adding it to the current residual window-period risk across all donations gives a total residual window-period risk under the reasonable worst-case scenario of 0.35 potentially infectious donations issued per million donations compared to 0.18 under the reasonable best-case scenario.

## People who inject drugs (PWID)

### Donations

Currently all PWID donors are non-compliant and to calculate the proportion of donations from these donors the weighted number of valid responders<sup>20</sup> from the UK Blood Donor Survey was used for each age group and gender (see Table 14).

**Table 14 Proportion of non-compliant PWID donors from the UK Blood Donor Survey**

Age group	Male	Female
17-34	0.06% (0.04% - 0.10%)	0.04% (0.02% - 0.07%)
35+	0.05% (0.03% - 0.08%)	0.03% (0.02% - 0.06%)

To estimate the number of non-compliant donations from PWID who have injected in the three months prior to donating (non-compliant ID<3m), adjusted data from the Natsal-3 survey on rates of injecting drug use were

[Insert title]

used. As data on the number of responders who injected in the last three months was not available, the four week rates were used as a proxy for three months (Table 15) due to the bimodal nature of the distribution 21.

**Table 15 Natsal-3 data on the number of PWID who have injected in the last four weeks**

Age group	Male			Female		
	No. PWID	No. injected < 4 weeks	% injected < 4 weeks	No. PWID	No. injected < 4 weeks	% injected < 4 weeks
17-34	42.9	6.2	14.4% (5.6% - 28.5%)	6.7	0.6	8.4% (0.0% - 52.5%)
35+	43.2	4.2	9.7% (2.8% - 22.6%)	17.0	6.2	36.3% (14.9% - 62.6%)
Total	86.1	10.4	12.1%	23.8	6.7	28.4%

20 excludes individuals who dropped out and did not respond

21 Drug use appears to be either historical (>1 year) or frequent (< 4 weeks)

			<b>(6.0% - 20.9%)</b>			<b>(12.0% - 50.4%)</b>
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Assuming that the rate of injecting drug use in the non-compliant PWID donor population is the same as same as in the general population, the number of non-compliant ID<3m donations can be calculated by by multiplying these proportions by the annual number of non-compliant PWID donations, obtained by by applying the proportions from Table 14 to the annual number of donations in Table 2, and can be seen in Table 16 and Table 17.

**Table 16 Annual number of donations from PWID new donors by last injection group using central estimates under current permanent deferral selection criterion**

<b>Age group</b>	<b>Male</b>		<b>Female</b>	
	Injected > 3 months	Injected < 3 months	Injected > 3 months	Injected < 3 months
17-34	31	5	34	3
35+	21	2	15	8
Total	52	7	49	12

**Table 17 Annual number of donations from PWID repeat donors by last injection group using central estimates under current permanent deferral selection criterion**

<b>Age group</b>	<b>Male</b>		<b>Female</b>	
	Injected > 3 months	Injected < 3 months	Injected > 3 months	Injected < 3 months
17-34	91	15	80	7
35+	389	42	153	87
Total	480	57	233	94

To calculate the annual number of compliant PWID donations if a revised three month selection criterion was implemented, data from the Natsal-3 survey was used to calculate the ratio of PWID to non-PWID in the general population (Table 18).

**Table 18 Ratio of PWID to non-PWID based on responses from the Natsal-3 survey. Note that the numbers of responders are non-integers as they are weighted values**

Age group	Male			Female		
	No. PWID	No. non-PWID	Ratio (per 1,000 non-PWID)	No. PWID	No. non-PWID	Ratio (per 1,000 non-PWID)
17-34	42.9	2,405.9	17.8	6.7	2,429.1	2.8
35+	43.2	4,660.4	9.3	17.0	4,886.8	3.5
Total	86.1	7,066.3	12.2	23.8	7,315.9	3.2

The ratio of PWID to non-PWID was then multiplied by the proportion of PWID who have not injected in the last three months (Table 15) and the annual number of non-PWID UK donations<sup>22</sup> to estimate the number of compliant PWID donations under a revised three month selection criterion. Based on the expert opinion of the NHS Blood & Transplant/PHE Epidemiology Unit, as the prevalence of factors, such as blood-borne viruses, that make an individual ineligible to donate blood are much higher in PWID than in the non-PWID population an additional factor of 48% was then applied to the estimated number of compliant PWID donations to account for the lower fitness to donate. The number of compliant PWID donations under the revised selection criterion can be seen in Table 19.

**Table 19 Estimated number of annual UK donations from compliant PWID donors under a revised three month selection criterion**

Age group	Male			Female			Total
	New	Repeat	Total	New	Repeat	Total	
17-34	427	1,263	1,690	120	282	401	2,092
35+	184	3,356	3,540	80	834	915	4,455
Total	611	4,619	5,230	200	1,116	1,316	6,546

As no compliant PWID donors exits under the current selection criterion, to calculate the annual number of donations from non-compliant ID<3m it is assumed that the proportion of the general population who are ineligible but donate under the revised selection criterion is the same as that for individuals who are eligible, i.e. someone who has injected in the last three months is just as likely to donate as someone who last injected more than three months ago. As such, the number of donations from non-compliant PWID donors is calculated so that the proportion relative to the total unadjusted donations from PWID individuals<sup>23</sup> is the same as the proportion who have injected in the last four weeks (see Table 15). The estimated number of donations from non-compliant ID<3m

22. Obtained by subtracting the numbers from Table 16 and Table 17 from the annual donations in Table 2.

23. The total number of compliant and non-compliant PWID donations without including the additional factor to account for fitness to donate in the compliant donors.

donors under the revised selection criterion and assuming a reasonable worst-case scenario can be seen in Table 20.

**Table 20 Estimated number of annual UK donations from non-compliant PWID under a revised three month selection criterion assuming a reasonable worst-case scenario**

Age group	Male			Female			Total
	New	Repeat	Total	New	Repeat	Total	
17-34	148	438	586	22	52	74	660
35+	41	743	784	85	886	972	1,756
Total	189	1,181	1,370	108	938	1,046	2,416

## Residual Window-Period Risk – HCV

The incidence of HCV infections, and so ultimately residual window-period risk, is calculated using historical data on the number of seroconversions in repeat donors associated with PWID. As a precautionary estimate, HCV seroconversions in repeat donors where the source is not known have also been included in the incidence calculation. UK surveillance data on the number of seroconversions and total number of donations were provided by NHS Blood & Transplant/PHE Epidemiology Unit for the period 2011-2015. In this period there were 11.4 million donations in total and, extrapolating from Table 16 and Table 17, it is estimated that 5.1 thousand came from PWID of which 2.8 thousand were repeat donations from male donors and 1.7 thousand were repeat donations from female donors. The number of HCV seroconversions in repeat donors, number of repeat donations, and incidence per 100,000 person-years in repeat donors can be seen in Table 21, Table 22 and Table 23 respectively (see Appendix A and B for methodology).

**Table 21 Number of HCV seroconversions associated with PWID and unknown sources in repeat donors in the period 2011-2015 across the UK**

<b>Age group</b>	<b>Male</b>	<b>Female</b>
17-34	1	1
35+	1	2
Total	2	3

**Table 22 Number of repeat donations from PWID donors in the period 2011-2015 across the UK**

<b>Age group</b>	<b>Male</b>	<b>Female</b>
17-34	556	458
35+	2,251	1,254

Age group	Male	Female
Total	2,807	1,712

**Table 23 Incidence of HCV infections per 100,000 person years (95% confidence intervals) in repeat PWID donors in the period 2011-2015 across the UK**

Age group	Male	Female
17-34	360 (9 - 2,005)	436 (11 - 2,431)
35+	89 (2 - 495)	319 (39 - 1,152)
Total	143 (17 - 515)	350 (72 - 1,024)

As there is no statistically significant difference between the incidence of HCV infections across the different ages for each gender, the total incidences are used for the residual window-period risk calculation under the current selection criterion (central estimate) and the revised selection criterion assuming a reasonable worst-case scenario (upper bound).

Applying the modified methodology (Appendix A and B) to the incidence of HCV infections and number of non-compliant ID<3m donations (Table 17 and Table 20) gives an estimated risk of 0.006 and 0.244 positive donations not detected on screening each year under the current permanent and revised three month selection criterion respectively. Taking the difference between these and adding it to the current residual window-period risk across all donations gives a total residual window-period risk under the reasonable worst-case scenario of 0.15 potentially infectious donations issued per million donations compared to 0.04 under the reasonable best-case scenario.

## High Risk Partner

### HRP rates in the general population

As limited data is available from the Natsal-3 survey, the proportion of individuals in the general population with a HRP has been calculated indirectly using data on the average number of heterosexual partners<sup>24</sup> and the prevalence of HRB in the general population. This assumes that HRB individuals will have the same sexual behaviour as the general population and that individuals in the general population are equally likely to have a HRP.

[Insert title]

The average number of heterosexual partners derived from the Natsal-3 survey over different periods can be seen in Table 24.

**Table 24 Average number of heterosexual partners over various periods derived from the Natsal-3 survey**

<b>Period</b>	<b>Male</b>	<b>Female</b>
3 months	0.87	0.75
1 year	1.36	1.07

24. Only heterosexual partners are considered as under a three month SBM deferral for MSM donors all compliant MSM donors will not have had any partner in the three months prior to donating

<b>lifetime</b>	<b>13.29</b>	<b>7.22</b>
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The probability that an individual has had at least one HRP is then given by:

$$\text{Probability of HRP} = 1 - (1 - \text{prevalence of HRB})^{\text{Number of partners}}$$

Using these probabilities, the number of compliant and non-compliant HRP donations under the current and revised selection criteria can be calculated in a similar way to that for MSM (see above).

## **High Risk Partner – MSM**

### **Donations**

To calculate the number of donations from non-compliant HRP – MSM female donors the number of valid responders<sup>25</sup> from the UK Blood Donor Survey was used. Due to the

small numbers, all ages and donor types were combined to give a total of 62.7 in 33,491.8 female responders who were

non-compliant representing a proportion of 0.19% (95% CI 0.14% - 0.24%). This gives 2.0 thousand non-compliant HRP – MSM donations each year of which 1.7 thousand are repeat and 0.3 thousand new donations.

The proportion of compliant HRP – MSM was modelled by using data from the Natsal-3 survey to calculate the proportion of males who would be classified as MSM but who are sexually active with females<sup>26</sup>. It was found that 3.0% (177.4 / 5,877.5) of males who had had sex with a woman in the last year would be classified as MSM. The average number of partners for women was then used to calculate the proportion of the female population who would be considered HRP – MSM donors but who had not had an MSM partner in the last year (17.2%). This proportion was then multiplied by the annual number of female donations to give 187.1 thousand compliant HRP – MSM donations each year of which 28.0 thousand are new donations and 159.0 thousand are repeat donations.

The number of current non-compliant HRP – MSM donations from donors who have had an MSM partner in the last three months (non-compliant HRP – MSM<3m) was estimated by calculating the proportion of females in the general population who have had an MSM partner in the last three months relative to all those who have had an MSM partner in the last year (70.0%). This proportion was then applied to the number of non-compliant HRP – MSM donations derived from the UK Blood Donor Survey to give 0.2 thousand new and 1.2 thousand repeat donations from non-compliant HRP– MSM<3m donors each year.

The increase in the number of annual compliant HRP – MSM donations under the revised selection criterion was calculated as the ratio of the estimated proportion of females who are HRP – MSM but have not had an MSM partner in the last three months to those who have not had an MSM partner in the last year (18.0% / 17.2% = 1.05). The number of annual non-compliant HRP – MSM<3m donations under the revised selection criterion was then calculated by applying this ratio to the total number of currently non-compliant donations. This gives the reasonable worst-case scenario for the

25. excludes individuals who dropped out and did not respond

26. This was defined as having had oral, vaginal or anal sex with a woman in the last year.

number of non-compliant HRP – MSM<3m donations under the revised selection criterion of 2.1 thousand of which 0.3 thousand are new and 1.8 thousand repeat donations.

## Residual Window-Period Risk – HIV

There has been only one recent (<4m) HIV seroconversion in a repeat donor observed in a non-compliant HRP – MSM<3m female donor in the period 2013-2015. Over this same period there would be an expected 3.6 thousand repeat donations from non-compliant HRP – MSM<3m donors. This gives an incidence of HIV infections of 54.9 (95% CI 1.4 – 306.1) per 100,000 person years.

Applying this incidence to the number of donations from non-compliant HRP – MSM<3m donors gives an estimated risk of 0.017 and 0.141 positive donations not detected on screening each year under the current one year and revised three month selection criterion respectively. Taking the difference between these and adding it to the current residual window-period risk across all donations gives a total residual window-period risk under the reasonable worst-case scenario of 0.24 potentially infectious donations issued per million donations compared to 0.18 under the reasonable best-case scenario.

## Commentary

The estimated number of compliant HRP – MSM donations seems very high compared to the number of non-compliant HRP – MSM donations that were identified by the UK Blood Donor Survey. It is likely that most women are unaware that their partners would be classified as MSM and so the real non-compliance rate may be significantly higher than modelled using the survey data. Due to the nature of the modelling, this will not have any effect on the estimated increase in residual window-period risk under the worst-case scenario.

31. excludes individuals who dropped and did not respond.

## High Risk Partner – BBV

### Donations

To calculate the proportion of donations from non-compliant HRP – BBV donors the number of valid responders<sup>27</sup> from the UK Blood Donor Survey was used. Due to the small numbers, all ages, genders and donor types were combined to give a total of 6.5 in

65,083.6 responders who were non-compliant representing a proportion of 0.01% (95% CI 0.00% - 0.02%). This gives 217 non-compliant donations each year of which 191 are repeat and 26 new donations.

The proportion of compliant HRP – BBV donors was modelled by using data from ONS and PHE HIV in the UK 2016 Report to calculate the proportion of individuals in the general population with HIV. Data from ONS estimated that there were 25.4 million males and 26.7 million females over the age of 17 in the UK in 2015. According to the PHE report, of the 25.4 million males 3.3% will be MSM leaving 24.6 million non-MSM males. It is estimated that 0.08% (19,550 / 24,573,334) of non-MSM males and 0.11% (29,870 / 26,689,674) of females have HIV (either diagnosed or undiagnosed). The average number of partners by gender was then used to calculate the proportion of the population who would be considered HRP – BBV donors but who had not had a BBV partner in the last year (females: 0.5%; males: 1.3%). This proportion then multiplied by the annual number of donations to give 5.4 thousand compliant HRP – BBV donations from female donors each year and 14.5 thousand compliant HRP – BBV donations from male donors of which 0.8 thousand and 1.3 thousand are repeat donations respectively.

The number of current non-compliant HRP – BBV donations from donors who have had a BBV partner in the last three months (non-compliant HRP – BBV<3m) was estimated by calculating the proportion of individuals in the general population who have had a BBV partner in the last three months relative to all those who have had a BBV partner in the last year (females: 69.7%; males: 64.3%). This proportion was then applied to the number of non-compliant HRP – BBV donations derived from the UK Blood Donor Survey to give 11 new and 64 repeat donations each year from non-compliant HRP – BBV<3m female donors and 6 new and 63 repeat donations from non-compliant HRP – BBV<3m male donors.

The increase in the number of annual compliant HRP – BBV donations under the revised selection criterion was calculated as the ratio of the estimated proportion of individuals who are HRP – BBV but have not had a BBV partner in the last three months to those who have not had a BBV partner in the last year (females: 0.5% / 0.5% = 1.05; males: 1.4% / 1.3% = 1.04). The number of annual non-

32. excludes individuals who dropped out and did not respond.

27. excludes individuals who dropped out and did not respond

compliant HRP – BBV<3m donations under the revised selection criterion was then calculated by applying this ratio to the total number of currently non-compliant donations. This gives the reasonable worst-case scenario for the number of non-compliant HRP –

[Insert title]

BBV<3m donations under the revised selection criterion of 114 from female donors, of which 17 are new and 97 repeat donations, and 113 from male donors, of which 10 are new and 102 repeat donations.

## **Residual Window-Period Risk – HIV**

There were no observed HIV seroconversions in all HRP – BBV repeat donors in the period 2013- 2015. Over this same period there would be an expected 383 repeat donations from non-compliant HRP – BBV<3m donors, 193 from females and 190 from males. This gives an incidence of HIV infections of 0 (95% CI 0 – 3,816) per 100,000 person years in female non-compliant HRP – BBV<3m donors and 0 (95% CI 0 – 3,889) per 100,000 person years in male non-compliant HRP – BBV<3m donors. Applying this incidence to the number of donations from non-compliant HRP – BBV<3m donors gives an estimated risk of 0 and 0.141 positive donations not detected on screening each year under the current one year and revised three month selection criterion respectively. Taking the difference between these and adding it to the current residual window-period risk across all donations gives a total residual window-period risk under the reasonable worst-case scenario of 0.27 potentially infectious donations issued per million donations compared to 0.18 under the reasonable best-case scenario.

## **Commentary**

It should be noted that these values only account for the proportion of HIV in the population, rather than HBV and HCV, and includes both diagnosed and undiagnosed individuals with the assumption that there is no difference in their sexual behaviour.

## **High Risk Partner – HEC**

### **Donations**

To calculate the proportion of donations from non-compliant HRP – HEC donors the number of valid responders

33. excludes individuals who dropped out and did not respond

28 from the UK Blood Donor Survey was used. Due to the small numbers, all ages, genders and donor types were combined to give a total of 114.6 in 62,502.5 responders who were non-compliant representing a proportion of 0.18% (95% CI 0.15% - 0.22%). This gives 4.0 thousand non-compliant HRP – HEC donations each year of which 3.5 thousand are repeat and 0.5 thousand new donations.

The proportion of compliant HRP – HEC donors was modelled by using data from the Natsal-3 survey to calculate the proportion of individuals whose last sexual partner was Black African as a proxy for a partner who is HEC. It was found that 1.5% of females (129.6 / 7,214.2) and 1.2% of males (80.6 / 6,703.2) last sexual partner had been Black African. The average number of partners by gender was then used to calculate the proportion of the population who would be considered HRP – HEC donors but who had not had a HEC partner in the last year (females: 10.5%; males: 13.4%). This proportion then multiplied by the annual number of donations to give 114.9 thousand compliant HRP – HEC donations from female donors and 145.9 thousand compliant HRP – HEC donations from male donors of which 97.7 thousand and 132.4 thousand are repeat donations respectively.

### **34. excludes individuals who dropped out and did not respond**

The number of current non-compliant HRP – HEC donations from donors who have had a HEC partner in the last three months (non-compliant HRP – HEC<3m) was estimated by calculating the proportion of individuals in the general population who have had a HEC partner in the last three months relative to all those who have had a HEC partner in the last year (females: 69.9%; males: 64.5%). This proportion was then applied to the number of non-compliant HRP – HEC donations derived from the UK Blood Donor Survey to give 209 new and 1.2 thousand repeat donations each year from non-compliant HRP – HEC<3m female donors and 118 new and 1.2 thousand repeat donations from non-compliant HRP – HEC<3m male donors.

The increase in the number of annual compliant HRP – HEC donations under the revised selection criterion was calculated as the ratio of the estimated proportion of individuals who are HRP – HEC but have not had a HEC partner in the last three months to those who have not had a HEC partner in the last year (females: 11.1% / 10.5% = 1.05; males: 13.9% / 13.4% = 1.04). The number of annual non-compliant HRP – HEC<3m donations under the revised selection criterion was then calculated by applying this ratio to the total number of currently non-compliant HRP – HEC donations. This gives the reasonable worst-case scenario for the number of non-compliant HRP – HEC<3m donations under the revised selection criterion of 2.1 thousand from female donors, of which 314 are new and

[Insert title]

1.8 thousand repeat donations, and 2.1 thousand from male donors, of which 190 are new and 1.9 thousand repeat donations.

## **Residual Window-Period Risk – HIV**

There was one observed HIV seroconversion in all HRP – HEC male repeat donors and one HIV seroconversion in non-compliant HRP – HEC female repeat donors in the period 2013-2015. Over this same period there would be an expected 402.7 thousand repeat donations from HRP – HEC males and 5.1 thousand repeat donations from non-compliant HRP – HEC female donors. This gives an incidence of HIV infections of 39.3 (95% CI 1.0 – 218.7) per 100,000 person years in non-compliant HRP – HEC<3m female repeat donors and 0.5 (95% CI 0.0 – 211.1) per 100,000 person years in non-compliant HRP – HEC<3m male repeat donors<sup>29</sup>. Applying this incidence to the number of donations from non-compliant HRP – HEC<3m donors gives an estimated risk of 0.012 and 0.198 positive donations not detected on screening each year under the current one year and revised three month selection criterion respectively. Taking the difference between these and adding it to the current residual window-period risk across all donations gives a total residual window-period risk under the reasonable worst-case scenario of 0.27 potentially infectious donations issued per million donations compared to 0.18 under the reasonable best-case scenario.

28 excludes individuals who dropped out and did not respond

## **High Risk Partner – CSW**

### **Donations**

To calculate the proportion of donations from non-compliant HRP – CSW donors the number of valid responders<sup>30</sup> from the UK Blood Donor Survey was used. Due to the small numbers, all ages and donor types were combined to give a total of 6.7 in 35,038.3 female responders and 58.0 in 30,044.4 male responders who were non-compliant representing a proportion of 0.02% (95% CI 0.01% - 0.04%) and 0.19% (95% CI 0.15% - 0.25%) respectively. This gives 2.3 thousand non-compliant HRP – CSW donations each

year of which 1.9 thousand are repeat male and 193 new male donations and 177 are repeat female and 31 new female donations.

The proportion of compliant HRP – CSW donors was modelled using data from the Natsal-3 survey to calculate the proportion of individuals who have ever paid for sex. It was found that 0.1% of females (10.5 / 7,319.1) and 10.4% of males (705.6 / 6,814.4) have paid for sex in their lifetime. Using the number of average lifetime partners these proportions were converted to the proportion of partners who would be CSW (females: 0.02%; males: 0.82%). The average number of partners by gender was then used to calculate the proportion of the population who would be considered HRP – CSW donors but who had not had a CSW partner in the last year (females: 0.1%; males: 9.3%). This proportion was then multiplied by the annual number of donations to give 1.5 thousand compliant HRP – CSW donations from female donors each year and 103.6 thousand compliant HRP – CSW donations from male donors of which 1.1 thousand and 92.1 thousand are repeat donations respectively.

The number of current non-compliant HRP – CSW donations from donors who have had a CSW partner in the last three months (non-compliant HRP – HEC<3m) was estimated by calculating the proportion of individuals in the general population who have had a CSW partner in the last three months relative to all those who have had a CSW partner in the last year (females: 69.7%; males: 64.4%). This proportion was then applied to the number of non-compliant HRP – CSW donations derived from the UK Blood Donor Survey to give 22 new and 123 repeat donations each year from non-compliant HRP – CSW<3m female donors and 124 new and 1.2 thousand repeat donations from non-compliant HRP – CSW<3m male donors.

The increase in the number of annual compliant HRP – CSW donations under the revised selection criterion was calculated as the ratio of the estimated proportion of individuals who are HRP – CSW but have not had a CSW partner in the last three months to those who have not had a CSW partner in the last year (females:  $0.1\% / 0.1\% = 1.05$ ; males:  $9.7\% / 9.3\% = 1.04$ ). The number of annual non-compliant HRP – CSW<3m donations under the revised selection criterion was then calculated by applying this ratio to the total number of currently non-compliant HRP – CSW donations. This gives the reasonable worst-case scenario for the number of non-compliant HRP – CSW<3m donations under the revised selection criterion of 219 from female donors, of which 33 are new and 186 repeat donations, and 2.2 thousand from male donors, of which 200 are new and 2.0 thousand repeat donations.

29. Note that upper limit for male donors was calculated using non-compliant < 3m seroconversions and donations for males

36. excludes individuals who dropped out and did not respond

## **Residual Window-Period Risk – HIV**

There were no observed HIV seroconversions in all HRP – CSW repeat donors in the period 2013- 2015. Over this same period there would be an expected 4.0 thousand repeat donations from non-compliant HRP – CSW<3m, 370 from females and 3.7 thousand from males. This gives an incidence of HIV infections of 0 (95% CI 0 – 1,996) per 100,000 person years in non-compliant HRP – CSW<3m female donors and 0 (95% CI 0 – 201) per 100,000 person years in non-compliant HRP – CSW<3m male donors. Applying this incidence to the number of donations from individuals who are non-compliant HRP – CSW<3m gives an estimated risk of 0 and 0.194 positive donations not detected on screening each year under the current one year and revised three month selection criterion respectively. Taking the difference between these and adding it to the current residual window- period risk across all donations gives a total residual window- period risk under the reasonable worst- case scenario of 0.27 potentially infectious donations issued per million donations compared to 0.18 under the reasonable best-case scenario.

## **High Risk Partner – PWID**

### **Donations**

To calculate the proportion of donations from non-compliant HRP – PWID donors the number of valid responders<sup>31</sup> from the UK Blood Donor Survey was used. Due to the small numbers, all ages, genders and donor types were combined to give a total of 36.3 in 62,081.7 responders who were non-compliant representing a proportion of 0.06% (95% CI 0.04% - 0.08%). This gives 1.2k non-compliant HRP – PWID donations each year of which 1.1k are repeat and 0.1k new donations.

The proportion of compliant HRP – PWID donors was modelled by using data from the Natsal-3 survey to calculate the proportion of individuals who have ever injected non-prescription drugs. It was found that 0.3% of females (23.8 / 7,294.7) and 1.2% of males (78.5 / 6,790.0) had injected non-prescription drugs. The average number of partners by gender was then used to calculate the proportion of the population who would be

considered HRP – PWID donors but who had not had a PWID partner in the last year (females: 6.9%; males: 3.8%). This proportion was then multiplied by the annual number of donations to give 75.7 thousand compliant HRP – PWID donations from

31. excludes individuals who dropped out and did not respond

female donors each year and 42.1 thousand compliant HRP – PWID donations from male donors with HRP – PWID of which 63.9 thousand and 37.4 thousand are repeat donations respectively.

The number of current non-compliant HRP – PWID donations from donors who have had a PWID partner in the last three months (non-compliant HRP – PWID<3m) was estimated by calculating the proportion of individuals in the general population who have had a PWID partner in the last three months relative to all those who have had a PWID partner in the last year (females: 69.8%; males: 64.3%). This proportion was then applied to the number of non-compliant HRP – PWID donations derived from the UK Blood Donor Survey to give 64 new and 361 repeat donations each year from non-compliant HRP – PWID<3m female donors and 36 new and 354 repeat donations from non-compliant HRP – PWID<3m male donors.

The increase in the number of annual compliant HRP – PWID donations under the revised selection criterion was calculated as the ratio of the estimated proportion of individuals who are HRP – PWID but have not had a PWID partner in the last three months to those who have not had a PWID partner in the last year (females:  $7.2\% / 6.9\% = 1.05$ ; males:  $4.0\% / 3.8\% = 1.04$ ). The number of annual non-compliant HRP – PWID<3m donations under the revised selection criterion was then calculated by applying this ratio to the total number of currently non-compliant donations. This gives the worst-case scenario for the number of non-compliant HRP – PWID<3m donations under the revised selection criterion of 639 from female donors, of which 96 are new and 543 repeat donations, and 630 from male donors, of which 58 are new and 572 repeat donations.

## **Residual Window-Period Risk – HCV**

There were two observed HCV seroconversions in non-compliant HRP – PWID male repeat donors and one recent (<4m) seroconversion in non-compliant HRP – PWID<3m female repeat donors in the period 2013-2015. Over this same period there would be an expected 2.9 thousand repeat donations from all non-compliant HRP – PWID male donors and 1.9 thousand repeat donations from non-compliant HRP – PWID<3m female donors. This gives an incidence of HCV infections of 106.2 (95% CI 2.7 – 591.5) per 100,000 person years in non-compliant HRP – PWID<3m female donors and

[Insert title]

139.3 (95% CI 16.9 – 603.5) per 100,000 person years non-compliant HRP – PWID<3m male donors<sup>32</sup>. Applying this incidence to the number of donations from individuals who are non-compliant HRP – PWID<3m gives an estimated risk of 0.014 and 0.105 positive donations not detected on screening each year under the current one year and revised three month selection criterion respectively. Taking the difference between these and adding it to the current residual window-period risk across all donations gives a total residual window-period risk under the reasonable worst-case scenario of

0.09 potentially infectious donations issued per million donations compared to 0.04 under the reasonable best-case scenario.

## **Overall change in residual window-period risk**

The results of the modelling can be seen in Table 25 and Table 26. It is estimated that the residual window-period risk of a potentially infectious donations not being detected based on these deferral changes would be between 0.18 - 0.67 per million donations for HIV and between 0.04 - 0.19 per.

32. Note that upper limit for male donors was calculated using non-compliant < 3m seroconversions and donations for males million donations for HCV under the revised selection criteria. As even under the reasonable worst- case scenario implementing all revised selection criteria represents less than a 1 in a million risk to patients these changes are considered tolerable from the standpoint agreed by the SaBTO donor selection working group.

**Table 25 Estimated number of additional donations and residual window-period risk of HIV under the reasonable best- and worst-case scenario (there is no change to risk under the best-case scenario) following implementation of different three month selection criteria. Note – the standard methodology was used to calculate the current residual window-period risk and this was then adjusted using the modelled change for each selection criteria. Even if a potentially infectious donation is not detected on screening it may not necessarily be issued and, even if it is, may not result in an infection in the recipient represent a highly precautionary estimate of patient risk.**

<b>Selection criteria implemented</b>	<b>Curr ent</b>	<b>MSM</b>	<b>HRP - MSM</b>	<b>HRP - HEC</b>	<b>HRP - BBV</b>	<b>HRP - CSW</b>	<b>All</b>
Number of additional potentially infectious donations not detected on screening per million donations	-	0 - 0.16	0 - 0.06	0 - 0.09	0 - 0.09	0 - 0.09	0 - 0.48
Total number of potentially infectious donations not detected per million donations screened	0.18	0.18 - 0.35	0.18 - 0.24	0.18 - 0.27	0.18 - 0.27	0.18 - 0.27	0.18 - 0.67
Average number of years until a potentially infectious donation is not detected (at 2.2 million donations per year)	2.5	1.3 - 2.5	1.9 - 2.5	1.7 - 2.5	1.7 - 2.5	1.7 - 2.5	0.7 - 2.5

**Table 26 Estimated number of additional donations and residual window-period risk of HCV under the reasonable best- and worst-case scenario (there is no change to risk under the best-case scenario) following implementation of different three month selection criteria. Note – the standard methodology was used to calculate the current residual window-period risk and this was then adjusted using the modelled change for each selection criteria. Even if a potentially infectious donation is not detected on screening it may not necessarily be issued and, even if it is, may not result in an infection in the recipient represent a highly precautionary estimate of patient risk.**

<b>Selection criteria implemented</b>	<b>Curr ent</b>	<b>PWID</b>	<b>HRP - PWID</b>	<b>All</b>
Number of additional potentially infectious donations not detected on screening per million donations	-	0 - 0.11	0 - 0.04	0 - 0.15

[Insert title]

<b>Selection criteria implemented</b>	<b>Curr ent</b>	<b>PWID</b>	<b>HRP - PWID</b>	<b>All</b>
Total number of potentially infectious donations not detected per million donations screened	0.04	0.04 - 0.15	0.04 - 0.09	0.04 - 0.19
Average number of years until a potentially infectious donation is not detected (at 2.2 million donations per year)	10.4	3.0 - 10.4	5.3 - 10.4	2.4 - 10.4

## References

- [1] Johnson, A., London School of Hygiene and Tropical Medicine. Centre for Sexual and Reproductive Health Research, NatCen Social Research, Mercer, C. (2017). National Survey of Sexual Attitudes and Lifestyles, 2010- 2012. [data collection]. 2nd Edition. UK Data Service. SN: 7799, <http://doi.org/10.5255/UKDA-SN-7799-2>
- [2] Public Health England (2015). UK blood donor survey. <https://www.gov.uk/government/publications/uk-blood-donor-survey-overview-and-findings>
- [3] Kirwan PD, Chau C, Brown AE, Gill ON, Delpech VC and contributors, Public Health England (2016). HIV in the UK - 2016 report. Available from: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/602942/HIV\\_in\\_the\\_UK\\_report.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/602942/HIV_in_the_UK_report.pdf)

## Appendix A – Standard methodology for calculating the residual window-period risk

Table 27 Standard parameters used for modelling different viruses.

	HIV	HCV
Inter-donation interval	0.5	0.5
Window-period (days)	9	4
Window-period (years)	0.025	0.011
Z-multiplier for new donations	0.17	3.16

The residual window-period (WP) risk is calculated using the following formulae. For each stratified age, sex, and policy group:

$$\text{Person years between repeat donations} = \text{Number of repeat donations} \times \text{Inter-donation interval (IDI)}$$

$$\text{Incidence per person year in repeat donations} = \frac{\text{Number of seroconversions in repeat donations}}{\text{Person years between repeat donations}}$$

$$\text{WP risk in repeat donations} = \text{Incidence per person year in donors} \times \text{Average length of WP in years}$$

$$\text{WP risk in new donations} = \text{Z multiplier} \times \text{WP risk in repeat donations}$$

To calculate the total residual window-period risk the weighted sum of the risks across each stratum is used:

$$\text{WP risk in all donations} = \sum \text{Fraction of all donations from strata} \times \text{WP risk in strata}$$

## Appendix B – Modified methodology for calculating the residual window-period risk

While the calculation of the residual window-period risk is correct if the distribution of donors is the same currently as in the surveillance period, the standard methodology requires modification to account for a revised selection criterion with different deferrals for higher risk behaviour donors.

This can most easily be illustrated using the hypothetical example of the HIV risk in MSM going from a permanent deferral in the surveillance period to no deferral under the revised selection criterion. Assuming 100% compliance, there would be no MSM donors represented in the historical surveillance data and so newly eligible MSM donors would be associated with the same WP risk as non-MSM donors which is clearly not the case.

Assuming that a selection criterion with a three month deferral mitigates the residual window- period risk then to estimate the number of expected undetected positive donations the risk calculation should include only donors who have engaged in higher risk behaviour in the last 3 months (HRB<3m):

$$\begin{array}{l}
 \text{Undetected positive repeat donations} \\
 \text{Undetected positive new donations}
 \end{array}
 =
 \begin{array}{l}
 \text{WP risk in HRB<3m repeat donations} \\
 \text{WP risk in HRB<3m new donations}
 \end{array}
 \times
 \begin{array}{l}
 \text{Number of HRB<3m repeat donations} \\
 \text{Number of HRB<3m new donations}
 \end{array}$$

where:

$$\begin{array}{l}
 \text{Person years between HRB<3m repeat donations} \\
 \text{Incidence per person year in HRB<3m repeat donations} \\
 \text{WP risk in HRB<3m repeat donations} \\
 \text{WP risk in HRB<3m new donations}
 \end{array}
 =
 \begin{array}{l}
 \text{Number of donations from HRB<3m month donations} \\
 \text{Number of seroconversions in HRB<3m repeat donations} \\
 \text{Incidence per person year in HRB<3m donors} \\
 \text{Z multiplier}
 \end{array}
 \times
 \begin{array}{l}
 \text{Inter-donation interval (IDI)} \\
 \text{Person years between HRB<3m repeat donations} \\
 \text{Average length of WP in years} \\
 \text{WP risk in HRB<3m repeat donations}
 \end{array}$$

[Insert title]

The above calculation assumes that the HRB<3m and compliant donors are equally likely to donate, i.e. they have the same inter-donation interval.

Assuming that infections in the donor population are correlated to higher risk behaviour, the incidence per person year in HRB<3m repeat donations must be greater than or equal to that in all non-compliant donations. The incidence per person year in non-compliant repeat donations in turn must be greater than or equal to that across all donations. This gives the following inequality:

$$\begin{array}{ccccc} \text{Incidence per person} & \geq & \text{Incidence per person year} & \geq & \text{Incidence per person} \\ \text{year in} & & \text{in non-} & & \text{year in} \\ \text{HRB<3m repeat} & & \text{compliant repeat donations} & & \text{all repeat donations} \\ \text{donations} & & & & \end{array}$$

Due to the low rate of observed seroconversions in blood donors and the small number of donations from the HRB group, it is difficult to accurately estimate the incidence in the non-compliant HRB<3m donors. Using the above inequality, the incidence per person year in HRB<3m repeat donations approximated by using the maximum of: the incidence per person year in HRB<3m repeat donations; the incidence per person year in non-compliant repeat donations; and the incidence per person year in all repeat donations. Similarly, to calculate the upper 95% confidence interval on the incidence per person year in non-compliant HRB<3m repeat donations the maximum of the confidence intervals in the three possible incidences is used.

## **Appendix C – Diagrammatic representation of the reasonable best- and worst case scenarios used to estimate the range of residual window-period risk for higher risk behaviour (HRB) donors**

Current donors

5 x compliant HRB donors

5 x non-compliant HRB donors (4 x HRB<3m; 1 x HRB>3m)

% non-compliant HRB donors =  $5 / 10$

= 50%

Reasonable best-case

8 x compliant HRB donors

4 x non-compliant HRB<3m donors

Number of non-compliant HRB<3m donors same as under current selection criterion

[Insert title]

Reasonable worst-case

8 x compliant HRB donors

8 x non-compliant HRB<3m donors

% non-compliant HRB donors = 8 / 16

= 50% same as under current selection criterion

Key:

Compliant HRB donor

Modelled additional compliant HRB donor

Non-compliant donor who has engaged in HRB in the three months prior to donating (HRB<3m)

Modelled additional non-compliant donor HRB<3m

Non-compliant donor who last engaged in HRB more than three months prior to

donating (HRB>3m)

## Appendix 2

### The Alliance of Blood Operators Risk-Based Decision Framework

1. Acupuncture
2. Tattooing, body piercing and cosmetic procedures
3. People who inject drugs
4. Commercial sex workers
5. Men who have sex with men
6. High risk partners
7. Flexible endoscopy

### Assessment Question and Decision Requirements

Donor Selection Criteria: Acupuncture

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Clearly state the primary decision to be made so that it provides guidance on: areas where the assessments must focus to support a decision; the types of assessments required, and; the level of investigation required.

Be specific about the kind of information required and the level of detail required to inform the decision.

[Insert title]

The review will look at donor deferral periods in view of current evidence of transmission of BBI. The presumption is that the review would look to reduce or eliminate deferral periods based on residual risks for each considered option. Some options would require changes to blood safety regulations. Individual risk assessments could be tailored for particular risk behavior(s).

This appraisal will consider the deferral for acupuncture.

The work group has already produced documents to aid in the development of deferral options. These are:

- (1) Donor selection criteria related to body piercing, tattoos & acupuncture.
- (2) Markers of infection in donations from new and repeat donors
- (3) Rates of observed transfusion transmitted infections with current deferral rules
- (4) What is the performance of test for diagnosing BBIs and the window periods for those tests?

An overview of the current deferral criteria acupuncture is provided in document (1). Acupuncture is a common procedure and features as a deferral affecting repeat donors so may have a disproportionate effect on the donor base. It is likely that acupuncture carried out by practitioners in the UK is safe, using disposable, single use needles. This may not be the case for procedures carried out overseas.

There is no deferral for acupuncture carried out by UK Healthcare professionals, as a pragmatic definition of qualified practitioner under the BSQR guidelines. Many acupuncturists, in the UK belong to a professional body such as the British Acupuncture Council but others do not so it difficult to find a way to mandate professional standards to ensure that acupuncture is always carried out using single use needles. It is possible that a move statutory regulation would provide a way forward.

The BSQR does allow for donors to be accepted without deferral if the acupuncturist is registered but there is currently no recognized register. Acceptance of donors for donation without deferral would either require a change to the BSQR to either permit acupuncture from a non-registered individual or establish a register.

The assessment question is:

What is the risk of acquiring a BBI from acupuncture and is a deferral period justified and, if so, what should be the minimum deferral period

For an initial assessment of the risk it is reasonable to examine two extreme options for the deferral of donors, leave the donor deferral period unchanged and remove the deferral period. Both options assume that the current testing regime is unchanged so HBV, HIV and HBC NAT tests are performed on pools of 24 donors.

Further assumptions for the preliminary risk assessment are that the risk of transmission is the same from new and repeat donors and the risk to recipients is the same (in practice this may not be the case for example platelets are prepared from 4 donors pools). Acupuncture is carried out on licensed premises within the UK.

### **Option 1: No change to the current deferral period for blood donation**

Current rules managed by JPAC, 12 months from the date of exposure or 4 months if a HCV NAT test is negative and an anti-HBc test is carried out and is negative or, if positive anti-HBs is >100miu/ml.

### **Option 2: No deferral for donation for acupuncture carried out in the UK**

The decision process for these options would be to perform a blood safety risk assessment to determine the residual risk of transmission then feed the risk into the risk tolerance table to determine the outcome.

Dependent on the outcome, further options could be considered and assessed in the same way. The driver for further options would be a significant difference in the residual risk for the extreme two options so more intermediate options could warrant investigation. These could include a deferral period based on the longest window period for the most likely BBIs (HBV in this case) and/or different deferral periods for new and repeat donors, modified testing regimes. Some options may require additional risk assessments (operational, health economic etc).

### **Preliminary risk assessment:**

Option 1: It is estimated that the current risk of not detecting HBV on screening due to a window period infection is 1.3 per million donations. This equates to 0.6 donations per year. Infectious window period is taken as 30 days. This risk estimate is highly conservative since there have been only 2 cases of transmission to 3 recipients in the

[Insert title]

period 2009-2014 after HBV NAT testing was introduced (3.5 cases expected). However it should be acknowledged that acute hepatitis B infection can be asymptomatic.

Option 2: The proportion of cases of HBV reported to PHE giving body piercing/tattooing/acupuncture as a risk factor has remained at around 2% per year for the period 2008-2012. If we assume, as a precaution, that 5% of the 0.6 donations per year could come from a donor who has contracted HBV from body piercing this leaves a transmission risk of 0.03 donations per year or 1 transmission every 33 years. The next step would be to assess whether this is an acceptable risk and develop a risk matrix for patient risk.

A similar risk assessment would be required for recipients of stem cells & tissues.

An initial view would be that acupuncture, if carried out in the UK, is of low risk and removal of the deferral period could be considered (although requiring a change to the EU directive and BSQR).

## Assessment Question and Decision Requirements

Donor Selection Criteria: Body Piercing & Tattoos

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Clearly state the primary decision to be made so that it provides guidance on: areas where the assessments must focus to support a decision; the types of assessments required, and; the level of investigation required.

Be specific about the kind of information required and the level of detail required to inform the decision.

The review will look at donor deferral periods in view of current evidence of transmission of BBI. The presumption is that the review would look to reduce or eliminate deferral periods based on residual risks for each considered option. Some options would require changes to blood safety regulations. Individual risk assessments could be tailored for particular risk behavior(s).

The primary decision is to review the current temporary deferral of donors (blood, tissues and cells) for body piercing and tattooing. The surveys conducted by PHE indicate that there is a degree of non-compliance due to confusion about some elements of piercing and quite a high number of deferrals meaning donors are turning up to sessions and being turned away.

Current selection criteria for blood and components: Defer for 12 months or 4 months with negative NAT for HCV and anti-HBc negative unless anti-HBs >100mIU/ml.

The rationale for inclusion of the anti-HBc test is that during the recovery phase of HBV infection, levels of HBsAg may be below the level of detection so core antibody may be the marker of infection.

Current selection criteria for tissues: Defer for 4 months with negative HCV NAT. Anti-HBc test is mandatory for tissue donations and must be negative or, if positive anti-HBs >100mIU/ml.

The incidence of body piercing, and particularly tattooing is increasing in the UK. Current estimates are 9% of UK citizens have tattoos. In a 3 month period June-September 2014, 2.4% of blood donors were deferred for a piercing event in the last 4 months. The proportion of new donor to repeat donors was not given, nor the number of donors who returned after the deferral period. For deceased tissue donors, deferral will result in a lost donation.

The donor selection work group has produced documents to aid in the development of deferral options. These are:

- (1) Donor selection criteria related to body piercing, tattoos & acupuncture.
- (2) Markers of infection in donations from new and repeat donors
- (3) Rates of observed transfusion transmitted infections with current deferral rules
- (4) What is the performance of test for diagnosing BBIs and the window periods for those tests?
- (5) Donor selection operational feasibility report

The blood/tissue risk assessment will assume that the risk of transmission is the same for new and repeat donors and the risk to recipients is the same (in practice this may not be the case for example platelets are prepared from 4 donors pools). Body piercing / tattooing is carried out on licensed premises within the UK but anecdotal reports suggest that these activities do occur in unlicensed/ unregulated premises.

[Insert title]

Infection control for tattooing and body piercing outside the UK may be of a lower standard and this needs to be considered. There was also some concern about compliance even within the UK.

The donor selection working group initially proposed investigating two options, no deferral for body piercing/tattooing within the UK and a 2/3 month deferral for outside the UK. For the temporary deferral option consideration will also be given to the need to test for anti-HBc provided a NAT test is carried out for HBV. Removal of anti-HBc would allow the SNBTS and NIBTS, who currently do not perform anti-HBc testing, to reduce their current 12 month deferral period to align with other blood services. If the need for anti-HBc testing was retained then either a 12 month deferral option needs to be maintained or reduced to a period, say six months but still without the need to test for anti-HBc.

Operationally, there is a strong feeling that having different selection criteria from within and outside the UK and further subdividing between licensed and unlicensed premises in the UK, although possible, would be difficult. Therefore, retention of a donor deferral interval for all donors is preferred.

Furthermore, the requirement for anti-HBc testing needs further investigation. Currently, NAT testing for HBV is performed on pools of 24 for blood donors and there is concern that this may miss low levels of HBV in the recovery phase. This is less likely for deceased tissue donations as these are tested individually. The risk assessment would need to look at the evidence for this and determine the residual risk with and without anti-HBc testing.

Option 1: Reduction in the current deferral period for blood and tissue donation to 2/3 month without an anti-HBc test for all body piercing/tattoo events (UK and worldwide)

Option 2: Reduction in current deferral period for blood donation and tissue donation to 2/3 months with an anti-HBc test for all body piercing/tattoo events (UK and worldwide)

Option 3: No deferral for UK events only, retention of a donor deferral period for non-UK activity

Required for the decision process for these options is a blood safety risk assessment to determine the residual risk of transmission. Operational factors have been considered and deemed manageable although option 3 not preferred.

Preliminary risk assessment from figures provided in documents (1) & (3):

The current risk assessment for HBV for transmission during a window period is 1.6 per million donations for all donors. This equates to 0.7 donations per year. Window period is taken as 30 days. This risk estimate appears to be slightly pessimistic since there have been only 2 cases of transmission to 3 recipients in the period 2009-2014 after HBV NAT testing was introduced (3.5 cases expected).

The proportion of cases of HBV reported to PHE giving body piercing/tattooing as a risk factor has remained at around 2% per year for the period 2008-2012. A figure of 2% would not impact greatly on the risk. However, there may be significant underreporting of HBV.

It is likely that the residual risk, at least in the UK, will be tolerable for a no deferral period. However, operational concerns regarding the separation of licensed and unlicensed activity in the UK and less controlled practice outside the UK may impact on the overall tolerability leading to retention of a deferral period for all donors. Removal of the requirement for anti-HBc testing will depend on expert opinion which is being sought.

## Assessment Question and Decision Requirements

Donor Selection Criteria: Persons who inject drugs (PWID)

Instructions

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Clearly state the primary decision to be made so that it provides guidance on: areas where the assessments must focus to support a decision; the types of assessments required, and; the level of investigation required.

Be specific about the kind of information required and the level of detail required to inform the decision.

The review will look at donor deferral periods in view of current evidence of transmission of blood-borne infections (BBIs). The presumption is that the review would look to reduce or eliminate deferral periods based on residual risks for each considered option. Some options would require changes to blood safety regulations. Individual risk assessments could be tailored for particular risk behavior(s).

**This assessment will look at permanent deferral for people who have injected non-prescribed drugs, including steroids and tanning agents (PWIDs).**

The Blood Safety & Quality Regulations mandate permanent deferral so any change in policy would require change to the legal framework. The work group has already produced documents to aid in the development of deferral options. These are:

- (1) Permanent deferral for people who have injected non-prescribed drugs, including steroids (prepared for the review by Su Brailsford & Claire Reynolds)
- (2) What are the safeguards against emerging infections?
- (3) What do we know about injecting drug users?
- (4) Markers of infection in donations from new and repeat donors
- (5) Rates of observed transfusion transmitted infections with current deferral rules
- (6) What is the performance of test for diagnosing BBIs and the window periods for those tests?
- (7) The UK Blood Donor Survey 2013/14

**The current deferral period for PWID is permanent deferral for blood and living & deceased tissue donors**

The estimate provided in (1) for the numbers of PWID in the UK suggests that around 1% of persons in the UK had injected drugs at some point. For many of these individuals, particularly those who would want to volunteer as blood or living tissue donors, injection of drugs would reflect a past behavior for a period when younger and not a continuing dependency.

Document (1) reports that between 2011 and 2015, 41 blood donors, all but 2 of them new donors) who were confirmed positive for a BBI after blood donation had injected drugs.

The UK blood donor survey found self-reported non-compliance in donors for prior injection of recreational drugs at (25/62959).

Document (3) reviews the complexities of the issues around permitting PWID to donate. The available data suggests that, for HCV at least, reducing the deferral period to the window period for HCV would be not lead to an increase in transmission provided that compliance remained high. However, other factors are important and influence the risk to patient safety. These include bacterial infections, emerging infections and the protection of recipients from exposure to psychoactive drugs commonly used by PWID.

Compliance and relapse are also factors (see document 3) as is undiagnosed cases of HCV which may have a temporary, but significant, impact on the blood services.

It may to allow potential blood & living tissue donors with an historical injecting drug use to be allowed to submit a sample for screening before being allowed to donate. This option would be problematic given the existing stigma attached to drug use. Consent would be required from the donor meaning disclosure to staff on sessions unless some mechanism could be found to keep the process confidential. For tissue and stem cell donation this would be less problematic. Development of an on-line pre-donation health questionnaire could improve confidentiality and facilitate a more detailed disclosure.

Consideration of a defined deferral period rather than the current permanent deferral would appear reasonable and proportionate to the risk.

Stakeholder consultation and operational issues require consideration.

**Options under consideration would be:**

1. No change, permanent deferral for PWID
2. Reduce deferral period to 2/3 months in line with options being considered for sexual behavior

[Insert title]

3. Reduce deferral period for a minimum period after last episode of drug use (6 to 12 months)

### **Option 1: No change to the current deferral period for blood or tissue donation**

The incidence of HCV among PWID in the general population is higher than the general population. Document (1) table 1 indicates that around 50% of persons who have a history of drug use test positive for HCV (around 20% for use in the last 3 years). Compliance issues require consideration.

### **Option 2: Change deferral period to 2 or 3 months for blood or tissue donation**

This option would align with current changes being considered for sexual behavior including MSM and high risk partners. Although the existing data suggests that may not lead to a higher risk of transmission of current BBIs providing donor compliance is unchanged there remains concern about other factors as discussed above.

Separate tissue and blood risk assessments would be required. For tissue donations the benefit to patients in some circumstances could be more significant than other concerns.

### **Option 3: Change deferral period to a period between 6-12 months**

The risk assessments would be the same as option 2 above. An additional deferral period would allow for bacterial and emergent infections to be taken into consideration beyond the risk of transmission in the window period of BBIs within the scope of this review.

Other risk assessments such as stakeholder, health economic and donor risk are not considered necessary at this stage.

## **Assessment Question and Decision Requirements**

Donor Selection Criteria: Commercial Sex Workers

Clearly state the primary decision to be made so that it provides guidance on: areas where the assessments must focus to support a decision; the types of assessments required, and; the level of investigation required.

Be specific about the kind of information required and the level of detail required to inform the decision.

The review will look at donor deferral periods in view of current evidence of transmission of blood-borne infections (BBIs). The presumption is that the review would look to reduce or eliminate deferral periods based on residual risks for each considered option. Some options would require changes to blood safety regulations. Individual risk assessments could be tailored for particular risk behavior(s).

**This assessment will look at the deferral criteria for persons who for people who have received money or drugs for sex (commercial sex workers).**

The selection criterion for individuals who purchase sexual services is being reviewed along with other criteria for high risk sexual behavior.

The Blood Safety & Quality Regulations and Tissue Quality & Safety regulations permits donation after a cessation of behavior and the availability of appropriate tests. Any change in policy would not, therefore, require a change to the legal framework. The work group has already produced documents to aid in the development of deferral options. These are:

- (1) Recent peer-reviewed health literature on sex work in the UK (past 5 years), Grenfell & Platt, London School of Hygiene & Tropical Medicine
- (2) Markers of infection in donations from new and repeat donors
- (3) Rates of observed transfusion transmitted infections with current deferral rules
- (4) What is the performance of test for diagnosing BBIs and the window periods for those tests?
- (5) Window periods and residual risk: best practice translating window period into deferral period.

(6) The UK Blood Donor Survey 2013/14

**The current deferral criterion for blood, living & deceased tissue donors is a permanent deferral from donation if the person has ever received money or drugs for sex.**

Data for the number of current and past sex workers and the incidence of BBIs in this group are scarce.

Document (1) provides data from two papers looking at all attendees of genitourinary medicine clinics in England in 2011, one for males and the other females. With the caveat that there may be significant under reporting, 0.4% of females and 0.08% of males attending the clinics were identified as sex workers. The rate of HIV infection in female sex workers was no different from other female attendees at 0.2%. Male sex workers were 3 times more likely to have HIV compared to non-sex workers at 3.7%.

More studies are being conducted in this area.

The lack of data for this diverse group means that assessment of selection criteria will be partially based on the considered opinion of the donor selection working group rather than evidence with residual risks likely to have wide confidence limits. The available data indicates that commercial sex work is a complex area including both on and off-street workers with high numbers of migrant workers from outside the UK. It could be difficult to define high and lower risk activities for the assessment of selection criteria.

It would be reasonable to assume that off-street workers would have healthier lifestyles, lower rates of, drug use, higher condom use and lower rates of sexually transmitted disease and BBIs. They would also be more likely to regularly attend sexual health clinics. From a blood and tissue donation view is it also possible to assume that healthier and lower risk individuals are more likely to wish to donate blood or be living donors for tissues?

Document (6) indicates that compliance with the existing selection criterion is high (non-compliance rate 0.05% females and 0.04% males).

The opinion of the donor selection working group is that changes to the testing methodology and sensitivity for blood borne infections mean that permanent deferral is not a proportionate response for this group.

Rates of HIV and syphilis are higher in current sex workers than in this group than in the general population so a deferral period is justified. The deferral period should be

determined by the tolerability of the residual risk of transmission of a BBI and guided by the window period for HIV (possibly syphilis?). It would be highly desirable, for operational practicality, to align the deferral period with other deferrals for high risk sexual behavior.

Options under consideration would be:

1. Reduce deferral period for a minimum period of two months
2. Reduce deferral period for a minimum period of three months
3. Removal of deferral period (for comparison with options 1 & 2)

Risk assessments required: patient safety – determination of residual risk. Stakeholder consultation and operational issues require consideration.

## **Assessment Question and Decision Requirements**

Donor Selection Criteria: Men who have sex with men (MSM)

Clearly state the primary decision to be made so that it provides guidance on: areas where the assessments must focus to support a decision; the types of assessments required, and; the level of investigation required.

Be specific about the kind of information required and the level of detail required to inform the decision.

The review will look at donor deferral periods in view of current evidence of transmission of blood-borne infections (BBIs). The presumption is that the review would look to reduce or eliminate deferral periods based on residual risks for each considered option. Some options would require changes to blood safety regulations. Individual risk assessments could be tailored for particular risk behavior(s).

[Insert title]

20.1 This assessment will look at the deferral criteria for men who have sex with men (MSM).

Deferral criteria for women who have sex with MSM will be considered in the sex with high risk partner document

The current deferral period for MSM is 12 months for blood donors and deceased tissue donors. There is no specific deferral period for living tissue donors (haematopoietic progenitor cells, pancreatic islets cells or hepatocytes). This is managed by risk/benefit donor assessment and testing.

Any change in policy would not require a change to the legal framework.

The work group has already produced documents to aid in the development of deferral options. These are:

- (1) Markers of infection in donations from new and repeat donors
- (2) Rates of observed transfusion transmitted infections with current deferral rules
- (3) What is the performance of test for diagnosing BBIs and the window periods for those tests?
- (4) Window periods and residual risk: best practice translating window period into deferral period.
- (5) The UK Blood Donor Survey 2013/14
- (6) International comparisons
- (7) Individual risk assessment
- (8) Influences on altruism in general population and compliance with medical "rules"

A SaBTO working group on donor selection criteria produced a report in 2011 (SaBTO Donor selection criteria review, April 2011) looked at changing the permanent deferral of MSM from blood & tissue donation in the UK. The recommendation to introduce a deferral period of 12 months was adopted by the English, Scottish and Welsh blood services in 2011 and by Northern Ireland in 2016. There was no rise in the incidence of HIV in new or repeat UK donors as a result of this change in the period 2011-2015 (document 1).

The UK donor survey 2013/14 (document 5) indicated that compliance with this policy was high. However, the 12 month deferral is viewed by the LGBT community as discriminatory since heterosexuals can donate blood even if they have multiple partners. This argument has strengthened with the introduction of civil partnerships (2004) and same-sex marriage (England, Wales & Scotland, 2014) providing a community of MSM in committed relationships who may have a low risk of contracting blood borne infections and could safely donate blood and tissue. There is an All Party Parliamentary Group (APPG) currently examining this MSM donor selection issue and is expected to report this year. Compliance with the existing policy may decline if the APPG recommend changes.

The review group has looked at the operational feasibility of introducing individualized risk assessments to see if it is possible to identify MSM who could be assessed as low risk from their own, and their partner's, sexual behavior and found that this is not possible at the moment (document 7). Future developments with on-line pre- donation health checks, enabling a more detailed disclosure of sexual behavior may allow this.

The donor selection review group, taking into consideration that it is not currently possible to separate MSM into low and higher risk groups of BBIs as donors of blood and tissue, will examine the evidence and model changes to the donor selection criteria for all MSM. A move from the current 12 months to a shorter period will be examined. In consideration of the risk of transmission of a BBI to the recipient, primarily of HIV in the case of MSM, the critical period would be the window period when transmission may be possible but the virus remains undetectable by NAT. A reduction of the deferral period to 2/3 months would cover the window period for all the BBIs under consideration under this review.

As with all high risk groups a high vigilance for emerging infections is required to ensure the safety of blood and tissue supplies.

### **Options under consideration would be:**

1. Reduce deferral period for a minimum period of two months for blood and deceased tissue donors
2. Reduce deferral period for a minimum period of three months for blood and deceased tissue donors The existing policy for living tissue donors would remain unchanged

Risk assessments required: patient safety – determination of residual risk.

[Insert title]

Stakeholder consultation (including engagement with the APPG) and operational issues require consideration.

## **Assessment Question and Decision Requirements**

Donor Selection Criteria: Sex with a High Risk Partner

Clearly state the primary decision to be made so that it provides guidance on: areas where the assessments must focus to support a decision; the types of assessments required, and; the level of investigation required.

Be specific about the kind of information required and the level of detail required to inform the decision.

The review will look at donor deferral periods in view of current evidence of transmission of blood-borne infections (BBIs). The presumption is that the review would look to reduce or eliminate deferral periods based on residual risks for each considered option. Some options would require changes to blood safety regulations. Individual risk assessments could be tailored for particular risk behavior(s).

This assessment will look at the deferral criteria for sex with a high risk partner. The specific deferral criteria under review include:

Women who have sex with MSM

Sex with a partner resident or sexually active in a high risk area (usually defined as an area where there is a high prevalence of HIV including most of sub-Saharan Africa)

Sex with a partner who was previously resident in a high risk area and who has not been screened by the blood service

Sex with a high risk partner, i.e., with a blood-borne infection (BBI), sex worker or injecting drug user

**The current deferral period for sex with a high risk partner is 12 months for blood donors and deceased tissue donors.**

There is no specific deferral period for living tissue donors (haematopoietic progenitor cells, pancreatic islets cells or hepatocytes) for MSM, including female partners. This is managed by risk/benefit donor assessment and testing.

Any change in policy would not require a change to the legal framework.

The work group has already produced documents to aid in the development of deferral options. These are:

- (1) Markers of infection in donations from new and repeat donors
- (2) Rates of observed transfusion transmitted infections with current deferral rules
- (3) What is the performance of test for diagnosing BBIs and the window periods for those tests?
- (4) Window periods and residual risk: best practice translating window period into deferral period.
- (5) The UK Blood Donor Survey 2013/14
- (6) Donor section guidelines-sexual partner at higher risk of infection
- (7) Individual risk assessment
- (8) Influences on altruism in general population and compliance with medical "rules"

The UK blood donor survey 2013/14 (document 5 and discussed in document 6) indicated that some donors found questions on their partner's previous sexual behavior difficult to answer.

[Insert title]

The review group has looked at the operational feasibility of introducing individualized risk assessments. This is not possible at the moment (document 7). Future developments with on-line pre-donation health checks may allow this. It may also provide an opportunity for potential donors to ask their partners questions about their past behavior which could increase compliance.

Data from surveys and the modeling may provide some information on the prevalence of BBI in partners. Assuming that individuals are not within any high risk category themselves and subject to other deferral criteria, the primary risk of contracting a BBI from their partner within any given time frame is the rate of transmission of the infection through sexual contact. If it is low, then setting a reasonable time frame for a 'safe' deferral period could be difficult even with long term partners but the risk of a window period transmission would be low.

Conversely, highly efficient transmission rates would increase the risk of a window period transmission with new high risk partners. The transmission rates of BBIs will be affected by the use of 'safe-sex' methods such as use of condoms and modeling will be complex.

The existing evidence is that the 12 month deferral is working well. The donor selection criteria working group considered that 12 month deferral period should be reviewed to align with the review of options for MSM. Operationally, keeping the deferral periods for all the high risk behaviors aligned would be the preferred option.

Options under consideration would be:

1. Reduce deferral period for a minimum period of two months for blood and tissue donors\*
2. Reduce deferral period for a minimum period of three months for blood and tissue donors\*

\*The existing policy for living tissue donors for partners are MSM would remain unchanged  
Risk assessments required: patient safety – determination of residual risk.

Stakeholder consultation and operational issues require consideration.

## Assessment Question and Decision Requirements

### Flexible Endoscopy

Clearly state the primary decision to be made so that it provides guidance on: areas where the assessments must focus to support a decision; the types of assessments required, and; the level of investigation required.

Be specific about the kind of information required and the level of detail required to inform the decision.

The review will look at donor deferral periods in view of current evidence of transmission of BBI. The presumption is that the review would look to reduce or eliminate deferral periods based on residual risks for each considered option. Some options would require changes to blood safety regulations. Individual risk assessments could be tailored for particular risk behavior(s).

This assessment is for the deferral of blood donors after undergoing a medical procedure involving the use of a flexible endoscope. Under the BSQR there is a temporary deferral period for flexible endoscopes but not rigid endoscopes.

Deferrals may become more frequent following routine bowel cancer screening.

The working group have already produced documents to aid in the development of deferral options. These are:

- (1) Impact of endoscopy on blood donors (Prepared by Sue Brailsford for the review)

[Insert title]

(2) A proposal to remove endoscopy as a deferral criteria for tissue donors (SACTTI review 2008)

(3) A proposal to alter acceptance/deferral criteria under the BSQR, 2005 (SACCSO, 2014)

(4) Markers of infection in donations from new and repeat donors

(5) Rates of observed transfusion transmitted infections with current deferral rules

(6) What is the performance of test for diagnosing BBIs and the window periods for those tests?

The issue of deferral for flexible endoscopy is comprehensively reviewed in documents 2 and 3. There has never been a clear case of transmission of a BBI from a flexible endoscopy procedure in the UK and the epidemiological evidence suggests that the reasons for including endoscopy in the EU directive 2004/33/EC were flawed (reviewed in (2))

Further exploration of options is considered unnecessary as there is a consensus that flexible endoscopy is not a risk a transmitting BBI if carried out in an appropriate healthcare setting and is properly cleaned and disinfected. A request to change the BSQR and EU directives is required.

## **Appendix C JPAC donor selection guidelines- Acupuncture**

Donors may be accepted without deferral if procedure carried out by the following: If performed by a Qualified Health Care Professional registered with the

General Medical Council (GMC), Nursing and Midwifery Council (NMC), General Dental Council (GDC),

The General Chiropractic Council (GCC), The General Optical Council (GOC),

The General Osteopathic Council (GOsC),

The Health and Care Professions Council (HCPC) (which regulates Physiotherapists, Arts therapists, Biomedical Scientists, Chiropodists/ Podiatrists, Clinical Scientists, Dieticians,

Hearing Aid Dispensers, Occupational Therapists, Operating Department Practitioners, Orthoptists, Paramedics, Pharmacists, Practitioner Psychologists, Prosthetists and Orthotists, Radiographers, Social Workers in England and Speech and Language Therapists), accept.

‘JPAC considers statutory registration of practitioners to afford the best overall guarantee that blood donated by individuals who have undertaken complementary therapy is safe. In the absence of statutory regulation of complementary therapy, there is currently no single body to which all therapists are accredited, and so to continue with the approval of one or more organisations would necessarily mean that others, of possibly equal merit, were excluded from approval.

Voluntary registration with a non-statutory body cannot provide assurance as to how high the standards of an organisation's members are, or how diligent the non-statutory regulator is in enforcing them, or the practitioner in applying them. Practitioners who choose not to join a voluntary register are still able to practise legally and to use the relevant title, as will a practitioner who has been removed from the register by the registering body.

There is no way of policing the enforcement by voluntary associations of the standards they require of their members as the organisations are not subject to supervision by the Council for Regulatory Healthcare Excellence (CHRE). Nor is there currently any external, independent

consideration of "fitness to practise" cases referred to voluntary regulators. While statutory regulation cannot guarantee the absence of risk, its primary aim is to deliver enhanced safety and public protection. Statutory "protection of title" means that donor centres can safely assume that a person who practises in the name of the registered profession is actually registered.’

## Appendix 3

### Members of the Donor Selection Criteria Working Group

Member	Affiliation
Yusef Azad	National Aids Trust
Nick Baker	GMFA
Su Brailsford	Epidemiology and Public Health (SaBTO member)
Moira Carter	SNBTS Care and Selection of Donors
Akila Chandrasekar	Tissue specialist (SaBTO Member)
Katy Davison	Epidemiologist Public Health England/NHSBT
Eamonn Ferguson	Professor of Health Psychology
Stephen Field Medical Director	Welsh Blood Service Medical Director now Irish Blood Service
Richard Gilson	Genito-urinary medicine specialist
Matthew Hodson	LGBT Consortium
John James	Sickle Cell Society
Alan Kitchen	Microbiologist NHSBT
Ruby Lake	Patients Association
Gail Mifflin	NHSBT Medical and Research Director
Elaine Miller	Thalassaemia Society
Alison Murdoch Fertility	Specialist (SaBTO Member)
Chas Newstead (Chair)	Renal Physician, now retired (SaBTO member) Alex Phillips Terrence Higgins Trust
Anne Slowther	Ethicist

**DONOR SELECTION CRITERIA REPORT JULY 2017 (VERSION 2)**

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Emergency Preparedness & Health Protection Policy Directorate/Health Protection Policy Team

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