SaBTO

Advisory Committee on the Safety of Blood, Tissues and Organs

Donor Selection Criteria Review

(April 2011)

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1 Executive Summary

Since 1985, men who have ever had oral or anal sex with another man (MSM) have been permanently deferred from donating blood in the UK. Similarly, individuals who have ever accepted money or drugs in exchange for sex are permanently deferred from donating blood. In 2006, a review of the permanent deferral of MSM found that there were insufficient data regarding compliance to determine the impact of any changes. Recently, data has become available on the level of compliance with the current donor deferral criteria. These data, together with advances in the testing and processing of donated blood, changes in the epidemiology of sexually transmitted infections (STIs) and improved scientific knowledge have prompted a review of donor deferral on the basis of sexual behaviour. This review focused on MSM and commercial sex workers (CSW), it did not include other sexual behaviour deferrals or the permanent deferral from blood donation of intravenous drug users.

The review noted that process improvements and automation have significantly reduced the chance of errors in blood testing such that the modelled risk of a HIV infectious donation being released into the blood supply is 1 per 4.4 million donations. The introduction of either a 12 month or a 5 year deferral would not significantly affect this figure if the number of non-compliant individuals remained unchanged. Under the current permanent deferral, it was shown that 11 % of MSM had donated blood since becoming ineligible, although the majority of non-compliers had not had a risk exposure (ie. oral or anal sex with a man) within the 12 months prior to donation. Upon investigation, non-compliers were shown to be supportive of a change to a 12 month deferral. For individuals exchanging money or drugs for sex, the prevalence and incidence of blood borne viruses was lower than in MSM. There was a clear difference between on-street and off-street sex workers, with populations of on-street sex workers having higher levels of blood borne viruses, a feature associated with increased injecting drug use. Injecting drug users, a population outside the scope of this review, are permanently deferred from donating blood.

In the UK population as a whole, where risk factors were reported for new diagnoses of blood borne viruses, heterosexual sex was the most commonly reported risk factor for both acute Hepatitis B infection (63 %) and human immunodeficiency virus (54 %) during 2009. The population with the highest risk of Hepatitis C virus (> 90 % of new diagnoses) was intravenous drug users.

2 Background and process

Blood services internationally employ a number of strategies to maintain safe supplies of blood and blood components. These strategies combine testing for selected known transfusion transmitted infections (TTIs) together with deferral from donation for those groups that are known to have increased prevalence and incidence of specific TTIs. Many of the current deferral criteria relate to specific sexual behaviours. Recipients of blood may be at some avoidable risk if individuals with these behaviours donate.

In the UK, the combination of donation testing and donor deferral has dramatically reduced the number of TTIs in recent years. The blood donor deferral criteria in relation to sexual behaviour, introduced in the early 1980s, were last reviewed in 2006 when the available evidence supported the existing measures and as a consequence no changes were proposed. It remains best practice to review the measures that are in place to ensure that they are safe, appropriate and supported by the most recent data available. There have been a number of incremental improvements in the ability to detect infection in donors and reduce the potential for transfusion transmission. These improvements are the result of scientific and technological advances in donation testing, notably i) Reduction of the window period through the introduction of nucleic acid technology (NAT) testing; ii) Effective use of Information Technology to reduce the number of human errors in the testing laboratory environment and product release errors; iii) Introduction of automated sample handling and tracking systems to reduce testing errors; iv) increased information surrounding compliance with the current deferral.

In addition to these technological advances and quality control there have been significant social, cultural and legal changes since 2001, which need to be considered when reviewing blood donor selection. The Equality Act 2010 prohibits discrimination on grounds of sexual orientation, but includes a provision which permits blood donor deferral if the refusal is a reasonable judgement made on the basis of available data.

In order to assess the impact of these changes, the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) established a Steering Group to review the current criteria for exclusion from blood donation based on sexual behaviour. The Terms of Reference for the Steering Group (See Appendix 1 for details) includes reviewing deferral criteria related to sexual behaviour which has the potential to put transfusion recipients at increased risk of TTIs and the

appropriateness of existing deferral criteria in the light of technological advances, specifically:

1. The appropriateness of continuing lifetime exclusion of men who have had sex with men (MSM);
2. The appropriateness of the continuing lifetime exclusion of individuals who accept money or drugs for sex (ie. Commercial Sex workers).

The recommendations made on the basis of this review take into account available scientific evidence on:

- The effectiveness of current testing strategies employed by the UK Blood Services;
- The differences in prevalence and incidence of TTIs between different risk groups;
- The level of compliance with current blood donor deferral and exclusion criteria;
- The risks associated with changing donor deferral and exclusion criteria, including any impact on the level of compliance;
- The impact on transfusion recipients.

Any proposed evidence based change to blood donor selection criteria is then based firmly on the effectiveness of screening, the safety of recipients, the reasonable treatment of donors and takes into account the current levels of compliance.

Although they formed part of the original Terms of Reference of the Steering Group, the review was not able to consider the 12 month deferral for individuals who had sex with partners from high risk endemic geographical areas. It was agreed that considering the deferral criteria for intravenous drug users (IDUs) was beyond the remit of this review, but that this issue should be considered at a later date.

3 The UK Blood Supply

3.1 The UK Blood Services

In the United Kingdom there are four Blood Services which operate well established centralised blood collection programs based on the principle of non-remunerated volunteer blood donors. NHS Blood and Transplant (NHSBT), responsible for the supply of blood to England and north Wales, is a Special Health Authority, reporting directly to the Department of Health as an "arm's length body" (ALB). The Scottish National Blood Transfusion Service (SNBTS) is part of NHS National Services Scotland. The Welsh Blood Service (WBS) is a division of Velindre NHS Trust and the Northern Ireland Blood Transfusion Service (NIBTS) is an independent, Special Agency of the Health and Personal Social Services in Northern Ireland.

3.2 Maintaining a safe and sufficient blood supply

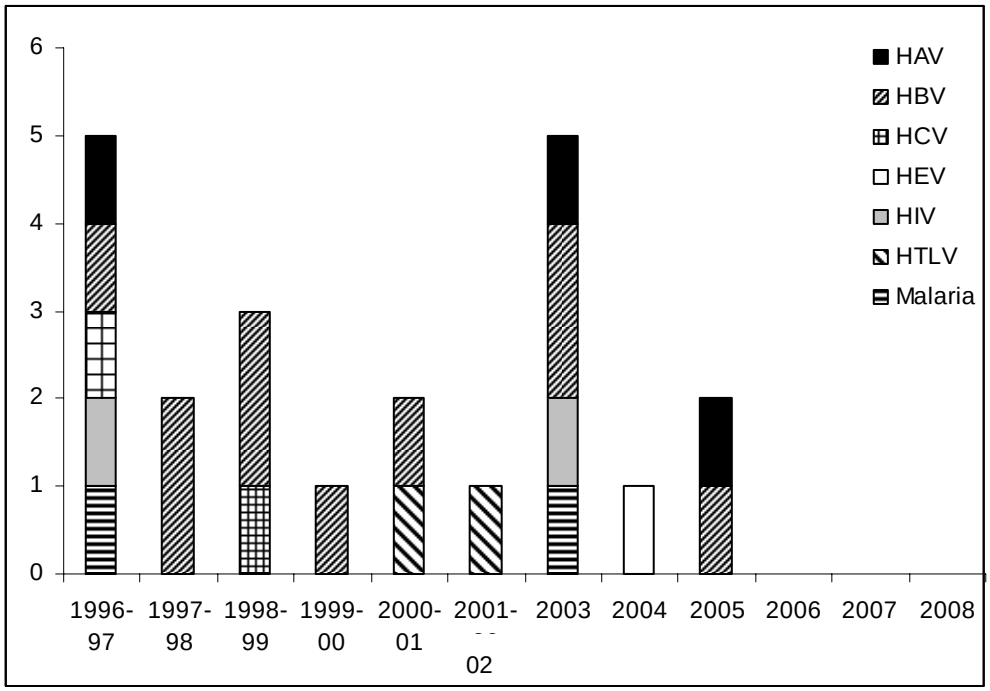
For nearly a century, the ability of blood and serum to transmit hepatitis has been well recognised. Post-transfusion hepatitis was a well recognised sequel to transfusion and led to the identification of hepatitis B and the introduction of the first screening test for a virus in the late 1960s. The emergence of blood borne infections such as non-A, non-B hepatitis (now known to be hepatitis C virus (HCV)) and Human Immunodeficiency Virus (HIV) during the 1970s and 80s and variant Creutzfeld-Jacob disease (vCJD) in the 1990s has had a profound effect on blood services policy and practice across the world. In the UK, the judgement of Justice Burton in the case of A v National Blood Authority (2001) in relation to legal action by blood recipients infected by HCV has had far reaching consequences for UK Blood services. This judgement considered infected blood to be defective under the Consumer Protection Act (CPA) and further considered the requirements for services to take action to reduce risk of infection even where the risk was theoretical or the risk reduction measure unproven. While there is an acceptance that no medical treatment including blood transfusion can have zero risk there is a clear legal requirement that it must be as safe as possible.

Appropriate donor selection and donation testing form the cornerstones of maintaining a safe blood supply. Blood donor selection has the dual aim of protecting the safety of the recipient and the safety of the donor. Effective donor selection should be applied by all blood establishments so as to identify those donors who do not fulfil the selection criteria to give blood either temporarily or permanently. Careful donor selection is essential for all donors regardless of whether they are a

first time, regular or returning donor. For most infections, the deferral period for blood donation is set for a given time after possible exposure, after which the donor could be expected to be no longer infectious (eg measles, chickenpox, West Nile virus/agents which are not routinely tested for in the UK) or to have developed a positive reaction in a screening test (for those infections which are tested for). All blood donor deferral criteria are subject to regular review and, with demand for blood forecast to increase, any recommendations for change must also consider the need to maintain a sufficient supply.

Additional details on the current process for screening and selecting blood donors is provided in Appendix 2 and details of the testing regimes in place in the UK Blood Services are provided in Appendix 3.

Figure 1: Number of viral and parasitic incidents by year of report and infectious agent



The effectiveness of the current measures at limiting transfusion transmitted infections is evidenced by data collected through the Serious Hazards of Transfusion (SHOT) national haemovigilance scheme. There has not been a confirmed case of blood-borne viral transmission since 2005 (Figure 1), including a number of infections that are not part of routine screening (eg hepatitis A). However, this is a passive surveillance system and relies on clinicians to report blood transfusion as a possible risk factor for a recipient's infection. The last confirmed HIV transmission was

reported in 2003, the recipient was traced and tested 15 months after the transfusion in 2002. This transmission pre-dates the use of HIV NAT as a routine screening test.

3.3 Recent risk reduction strategies

Globally there are active surveillance mechanisms in place for identifying and responding to threats to the safety of the blood supply. As a result of this active monitoring, and in response to threats to the UK Blood supply, decisions about the need to introduce new or remove old safety measures are made. In the UK, the recent blood safety agenda has been dominated by the need to mitigate the risk of transfusion transmission of vCJD. Measures that have been introduced to mitigate this risk include the importation of plasma for fractionation, importation of fresh frozen plasma for children born after 31st December 1995, universal leucodepletion of all blood components and exclusion of transfusion recipients from donating blood for allogeneic transfusion. In addition, blood services in the UK no longer collect plasma for fractionation as a further vCJD risk reduction measure. The main viral risk reduction strategy has been the progressive extension of NAT introduced in 2000 to HCV and HIV in 2005 and HCV, HIV and HBV (ie Triplex) in 2009.

3.4 Regulation of UK blood services

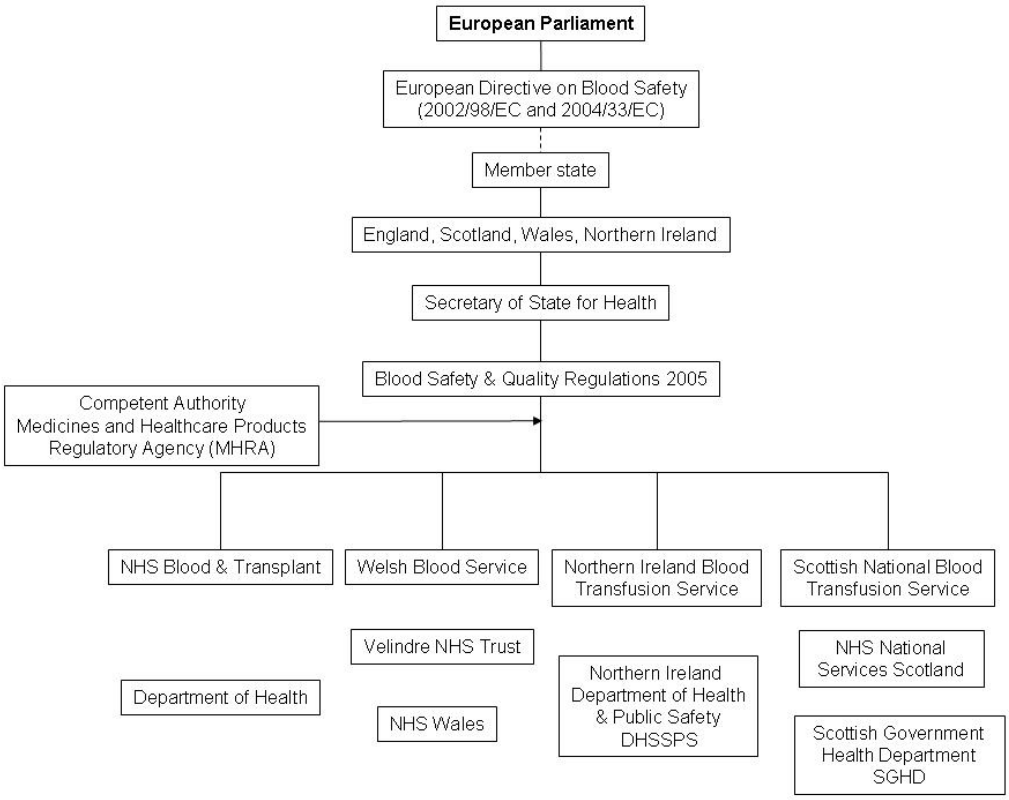
All European member states are obliged to take all the necessary measures to encourage voluntary and unpaid donation. In 2000, the Treaty of Amsterdam empowered the European Parliament to legislate on the quality and safety of organs and substances of human origin, including blood and blood derivatives. The result was the EU Directive on Blood Safety (2002/98/EC and 2004/33/EC) which lay down the *minimum* technical requirements for the medical selection and health assessment of blood donors. Individual member states may have additional guidance in relation to health assessment and more stringent donor deferral criteria than those required by Commission Directive 2004/33/EU. There is no requirement in European law for a permanent deferral of MSM. There is only a requirement for a permanent deferral of 'persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood'. But this is not further defined and different countries interpret this provision differently.

The EU Directive is written into UK domestic law as the Blood Safety and Quality Regulations 2005 (BSQR), which came into force on 8 February 2005 and were fully implemented on 8 November 2005. The Secretary of State is responsible for the licensing and inspection of blood establishments, monitoring compliance by hospital

blood transfusion laboratories, and carrying out haemovigilance. The Medicines and Healthcare products Regulatory Agency (MHRA), by agreement with the Secretary of State, is the competent authority that oversees implementation and compliance with the regulations. The MHRA is empowered to give an order to "cease and desist" from activities in the event of an unsatisfactory report.

An overview of the regulatory environment relating to blood transfusion is shown in Figure 2. The UK blood services are accountable to their respective Health Department that may decide on policy matters not covered in BSQR. The UK Forum, which consists of the four national Medical Directors and the four Chief Executives of the blood services, together with observers, provides an informal structure to co-ordinate activities. In addition, The Joint Professional Advisory Committee of the UK Blood Services and the Health Protection Agency (JPAC), through its Standing Advisory Committees, provides expert advice to the UK blood services and produces the UK Guidelines for blood transfusion services. The Chair of JPAC reports to the UK Forum.

Figure 2: Regulation of the blood supply



4 Transfusion Transmitted Infections

4.1 Hepatitis B virus (HBV)

Hepatitis B virus (HBV) is a blood borne infection, transmitted parenterally by exposure to blood, perinatally from mother to child and horizontally by contact, often sexually, with an infected person. Depending upon the age when infection occurs, the infection may become persistent (termed a carrier state), commonly seen in infants, or be an acute self-limited infection, commonly seen in adults. It has been estimated that as many as 350 million people worldwide are chronic HBV carriers including some 180,000 people in the UK. The UK is considered an area of relative low prevalence (<2%) with an estimated prevalence for HBV carriage of around 0.3%.[1] Carriers, who may be asymptomatic and/or unaware of their infection, represent the most common source of HBV infection to others in the UK. Most HBV infection occurs in adulthood in the UK following intravenous drug use (IDU) or sexual exposure [2] and usually leads to a self-limited acute infection. Acute infection in adults is typically a mild illness without clinical symptoms, although there may be an acute hepatitis. Both hepatitis B and hepatitis C are notifiable diseases, ie there is a legal obligation to report all clinically and laboratory identified infections to the 'proper officer', usually the Health Protection Agency, to enable surveillance of and public health action for these cases. The case definition depends upon detection of hepatitis B surface antigen (HBsAg) and anti-hepatitis B core antigen IgM (anti-HBc IgM) in serum with or without compatible symptoms. There was a recognized fall in laboratory reports of acute hepatitis B infection in England and Wales from around 2000 in 1984 to 531 in 1992.[3] The observed decline is believed to be due to risk modification in response to the HIV/AIDS epidemic as well as improved vaccine uptake. Reports have remained stable between 400 to 900 cases per year until 2008.[4]

During 2007 national standards were introduced for the reporting of acute hepatitis B cases with the aim of improving the surveillance and public health follow-up of acute cases. However, risk exposure data is difficult to collect and may not be complete and therefore should be interpreted with caution. During 2009 a total of 597 acute hepatitis B cases were reported, an incidence of 1.15/100,000). Ethnicity was reported for 46 % of cases with the majority (59%) of these being reported as white. Numbers with exposure history have increased and of the 398 acute or probable acute cases reported to health protection units, risk factor information was available

for 226 (57%). Of these, 63 % reported heterosexual sex as a risk, 13 % IDU and 10 % MSM. There was a higher incidence in males than females for all age ranges.[5]

The prevalence of HBV carriers varies across the UK with elevated rates particularly in those migrating from countries with high HBV endemicity. The annual increase in HBV carriage has been estimated as high as 7,700 in the UK with 96% of chronic infections in migrants from high prevalence countries.[6] Many of these will be sexually active adults including women of child bearing age, however it is not known what proportion, if any of these are CSWs. The UK does not have a universal hepatitis B vaccination policy, hepatitis B immunisation is only recommended for those people at high risk of exposure due to occupational, health or lifestyle risks. Hepatitis B vaccine should be offered to those who change sexual partners frequently particularly MSM and both female and male CSW.[2]

Over the last decade the number of acute hepatitis B infections have remained stable despite an increase in the number of migrants from endemic countries. This would suggest that migration has had little impact on acute infections in the UK.[7] An increase in the prevalence of non-A genotypes has been observed which may increase the burden of disease through progression to chronic liver disease.

The risk of transfusion transmitted HBV is reduced by screening donors for plasma HBsAg and also by excluding those in whom there is perceived to be a risk of acute HBV infection. Although HBsAg is usually detectable in infected donors, individuals very early after infection (also known as early window infections) or very late in the clearance phase of the acute infection (late window infections) may have HBV DNA present in their plasma in the absence of detectable HBsAg. In the late clearance phase of long term carriage, persistence of HBV DNA can occur. This stage of the infection is referred to as “Occult Hepatitis B” (OHB) and is characterised by persistent low levels of circulating HBV DNA in absence of detectable HBsAg but the presence of anti-Hepatitis B core (anti-HBc) and occasionally low level anti-HBs. Blood donors with OHB may transmit infection,[8] however, the viral species are frequently genetically scarred with reduced replicative potential. The risk of infection has been further demonstrated to be even less from donors with OHB whose serum also contains anti-HBs.[9] Late acute and OHB donors could be identified by screening for anti-HBc but this is not considered cost effective in the UK. HBV NAT testing further reduces but does not completely remove this risk.[10] The introduction of HBV NAT testing in pools was not expected to increase the number of HBV infections detected in UK blood donors because of comparable sensitivity of existing single-sample sensitive HBsAg testing. Evidence from the first 20 months of testing

within NHSBT has, however, shown that a small number of acute (early and late window) infections and occult (chronic) infections have been detected by the use of pooled HBV NAT testing.

In addition to this, a recent study to detect HBV infection in US blood donors observed a more than double expected rate of HBV infection (1 in 410,540 donations) with NAT testing.[11] The frequency of non A2 infections observed in this group led the authors to speculate that current A2 vaccines might be less efficacious for the prevention of clinical disease in donors with non-A genotypes relative to A genotypes. Of particular relevance to this review was the observation that a number of the infections in donors with detectable plasma DNA never produced detectable HBsAg and represented infection in the face of vaccine induced pre-existent anti-HBs. This demonstrates that vaccine induced immunity may not be sterilising and that acute infections may occur which are difficult to detect, thus raising concerns about allowing individuals at risk of HBV infection with partial immunity to return to the donor panel. The viruses in these donors are unlikely to be heavily scarred and might be fully transmissible, however, compliance with a fixed period exclusion would negate this risk.

4.2 Hepatitis C virus (HCV)

HCV is a blood borne virus most commonly transmitted by parenteral exposure. Perinatal transmission from infected mother to child and horizontal transmission from sex with an infected person are less common. Acute infection with HCV rarely causes illness but more than half of individuals with acute infections become persistent carriers. It has been estimated that as many as 170 million people worldwide are chronic carriers of HCV including 185,000 in the UK.[12] The UK is considered an area of lower prevalence (0.4%) with the worldwide prevalence of chronic infection being 3%.[13] Chronic HCV infection is frequently asymptomatic and can be treated with pegylated interferon and ribavirin; efficacy of treatment varies with age and viral genotype. The Sentinel Surveillance of Hepatitis Testing Study between 2002 and 2008 observed that up to 90% of tested individuals had genotype 1 or 3 infection. The most common genotype 3a was detected in 38.6% of all patients tested. The next most frequent genotype 1a was detected in 23.2% of all patients and is of significance as genotype 1 is less responsive to therapy.

An increase in laboratory confirmed cases of HCV carriers has been observed in England and Wales from 241 in 1992 to 8,456 in 2008.[14] Although rates of diagnosis have increased, much of it due to increased testing, many HCV infections

remain undiagnosed. In the UK, IDUs are the main risk group with evidence to suggest that greater than 90% of new HCV infections occur in this group.[14] Furthermore, data from the Unlinked Anonymous Prevalence Monitoring Programme (UAPMP) survey in England reveal HCV prevalence in excess of 40% in IDUs. Enhanced Surveillance of Newly Acquired Hepatitis C (SNAHC) [15] infection in MSM show HCV infection continues to pose a risk with 56 new confirmed cases in the first 17 months of the study, 96% of these patients were already infected with HIV. A confirmed case of newly acquired HCV infection was defined as HCV antibody positive and a documented negative HCV antibody within the previous 36 months. Furthermore, an annual 20% rise of newly acquired HCV infections in HIV positive MSM has been observed in over 4 years of study.[16] Risk factors that have been proposed include traumatic sexual practices and recreational drug use that is non-IDU related.[17]

Evidence suggests that people who are non-white have greater morbidity and mortality from HCV-related end stage liver disease than white people in the UK. Outreach studies using sampling methods other than venesection have been employed to bring testing to these populations. Surveillance indicates that individuals from the Indian sub-continent are particularly at an increased risk of HCV infection reflecting the higher HCV prevalence in this region and demonstrating the impact of immigration from countries where healthcare-associated HCV may be common. These individuals are frequently unaware of their risk of liver disease, their infection and may present late with end-stage liver disease.

The risk of transfusion-transmitted HCV by chronic HCV carriers is reduced by screening for antibodies to HCV (anti-HCV), which are usually detectable in established infections. However, individuals who are recently infected exhibit a long window period (50-60 days) with a high level of plasma viraemia before seroconversion occurs. In the presence of immunosuppression [18] the window period may be extended. Viraemia in the absence of an antibody response can be detected by NAT testing or to a lesser extent presence of HCV core Ag in the plasma. The risk of transfusion transmitted HCV has been reduced by the greater sensitivity and specificity of 3rd generation anti-HCV tests which contain antigens from the HCV core genes and nonstructural 3, 4 and 5 genes. HCV RNA testing of mini-pools is advocated for routine screening of blood donations and became mandatory on all blood donations in the UK from 2002. Data since NAT testing was introduced indicate that acute seronegative infections in blood donors are rare and detected in 1 in 2 million donations, a far lower incidence than initially expected.

Currently, the majority of MSM donors with new HCV infection have HIV co-infection so these may additionally be excluded through HIV screening that has a shorter window period. A recently published systematic review and meta-analysis of the risk of window period HCV infection demonstrated that injecting drug users pose a 10-times greater risk than MSM.[19]

4.3 Human Immunodeficiency virus (HIV)

HIV is a blood borne virus most commonly transmitted through sexual intercourse with an infected person. It is also transmitted through parental exposure (injecting drug use, through sharing of drug-taking equipment) and vertically from infected mother to child. It has been estimated that approximately 33 million people globally are living with HIV, only a small proportion of whom have already developed acquired immunodeficiency syndrome (AIDS).[20] In the UK, exposure to contaminated blood products and to other hazards like tattoos piercings and needle-stick injuries have become very rare today. The risk with oral sex is very low but HIV transmission does occur, however, given the lack of data it is difficult to make summary estimates for the transmission risk through oral sex.

Once a person has been exposed to, and infected by, HIV there is usually a short incubation period of between one and four weeks before the person may develop a glandular fever like illness characterised by joint pains, malaise and sometimes an urticarial skin rash. The symptomatic phase of primary HIV infection is usually a mild and self-limiting illness prior to clinical latency with few or no symptoms. Many people may not be aware they have an HIV infection and the standard method to diagnose HIV is by a screening enzyme immunoassay (EIA) for HIV antibody in plasma. Correspondingly high levels of HIV viraemia and P24Ag can be detected at the time of seroconversion that reaches a stable state at a lower level after around 6 months.

Clinical latent HIV infection can proceed to symptomatic HIV disease, characterised by one of a number of opportunistic infections and tumours which are included in the AIDS case definition. This is associated with a fall in CD4+ T cell counts. The risk of AIDS defining illness increases particularly as the CD4+ T cell count decreases to less than 200 cells per µL. The progression to an AIDS-defining diagnosis can be delayed or prevented by antiretroviral treatment (ART).

Estimates of the disease burden in the UK can be derived in a number of ways. Serial estimates of the prevalence in selected populations has been through the UAPMP. In addition, the number of people accessing HIV-care is captured by the

Survey of Prevalent HIV Infections Diagnosed (SOPHID). During 2008 an estimated 83,000 people were living with HIV in the UK including both diagnosed (73%) and un-diagnosed cases. This gives a prevalence of infection of 1.3 per 1000 of the UK population. In 2008, 50% of the 61,213 cases reported as receiving care were believed to have been infected through heterosexual intercourse and 42% through sexual intercourse between men. There were 7,298 newly diagnosed cases with 67% of heterosexually acquired infections diagnosed in black Africans, with many of these infections being acquired abroad, principally from countries in sub-Saharan Africa. The majority of the 2,760 newly diagnosed MSM acquired their infection in the UK (83%). Just over half of those individuals living with HIV and accessing care in England live in London, which has a prevalence rate five times higher than the rest of the country. Transmission through injecting drug use and maternal child transmission each account for around 2 % of all infections.

Early studies suggested that female street sex workers had a low prevalence of HIV (0.9%) compared with other behavioural risk groups at the time.[21] In the period up to 2002 a further study in London showed a declining prevalence of STIs and no statistically significant change in HIV prevalence (1.1% in 1985-92, 1.5% in 1996-2002) while condom use for vaginal sex with clients increased to 98%.[22] However studies of street sex workers in Hackney and Bristol report poor general health together with evidence of other infections such as STIs and TB.[23, 24] That these problems are not caused by sex work alone is supported by the finding that street workers have higher rates of injecting drug use.[24] Recent surveillance data from Central London Action on Street Health (CLASH) indicates a prevalence of HIV of 0.4 % in a predominantly non-UK born off-street sex worker population seen at a sexual health outreach clinic, with other studies reporting comparable prevalence levels (1.1 %, Platt *et al*, in press).

The risk of transfusion transmitted HIV has been reduced by improved screening using 4th generation EIA assays that detect HIV antibody/antigen. In addition, early HIV infection can be detected by p24 antigen specific assays however these have lower sensitivity compared to HIV NAT testing of mini-pools which was introduced in the early 2000s. Individuals in the early stage of HIV infection (window infections) without detectable HIV antibody/antigen may transmit infection, however HIV NAT testing reduces the window period to nine days.

A summary table of the data for HIV, HCV and HBV is presented in Table 1, with further information on the epidemiology of HIV contained within Appendix 5.

Table 1: Risks reported for newly identified HCV, HBV and HIV infected individuals in England 2009 in the general population.

	MSM	Heterosexual sex[1]	IDU
Acute HBV[2]	10 %	63 %	13 %
HCV	[3]		>90 %
HIV	42 %	54 %[4]	2.6 %

Figures represent the percentage of new diagnoses per risk group. [1]Proportion of those diagnosed that are CSW not known; [2]96 % of chronic infections are identified in migrants from high prevalence countries; [3]96% of new HCV diagnoses in MSM are in individuals already positive for HIV; [4]67 % of cases acquired through heterosexual sex are in Black Africans. (For hepatitis B, these are acute cases with reported risks rather than newly diagnosed chronic infections).

4.4 Human T Lymphocytic virus

Human T-cell Lymphotropic virus I (HTLV-I) is a retrovirus that is endemic in certain parts of the world including Japan, sub-Saharan Africa, and the Americas.[25] HTLV can be transmitted parenterally by blood transfusion, horizontally by sex and perinatally from mother to baby by breastfeeding.[26] Infection with HTLV-I may lead to disease in ~5 % of cases. Associated diseases include HTLV-I myelopathy and adult T-cell leukaemia/lymphoma (ATLL), however, currently little is known about disease progression in the UK. HTLV-II is prevalent in injecting drug users and some American Indian populations.

Concerns were raised in the 1990s that HTLV may be transmitted by blood transfusion and as a result of studies to define the prevalence of infection and inferred risk,[27] testing of mini-pools for HLTV was introduced into the UK blood services in 2002. Although the numbers of infected donors is low these still present a potential risk for transmission. Seroprevalence studies in pregnant women have revealed a prevalence of 0.033% in women born in the UK, however, rates are higher in women born overseas (eg Caribbean (1.64 %); Central and West Africa (0.31 %)).[28] An increased risk of infection in women may reflect the relative efficiency of male to female sexual transmission.[29]

Other than for donation screening, anti-HTLV is not a routine test and is usually only tested for clinically in patients with symptoms suggestive of HTLV, their relatives and sexual partners. Diagnosis of HTLV-1 associated myelopathy/tropical spastic paraparesis (HAM/TSP) is dependent upon a number of clinical and laboratory criteria including detection of HTLV-1 antibody or antigen in blood and CSF. The detection of HTLV-1 proviral load in CSF has been proposed as a new criterion for the diagnosis of HAM/TSP. A study observed that the blood/CSF ratio of HTLV-1 proviral load corresponded to clinical infection or asymptomatic carrier state.[30]. A higher HTLV-1 proviral load has been observed as a risk factor for clinical infection.[31] A greater HTLV load may increase the rate of transmission from male to female sexual partners.[32] However, host factors may be more important than virus-specific factors in HTLV transmission.[33] The possible future role of HTLV viral or proviral load testing in reducing transfusion transmitted HTLV infection and its impact on particular donor populations is uncertain.

The HPA Centre for Infections collects data on all individuals who test positive for HTLV in the UK. Since the introduction of blood donation testing in 2002, 137 infected donors have been identified. A significant percentage of donors reported heterosexual sex as the most likely risk for acquiring HTLV infection whereas other risks related to mother to infant transmission or country of birth. During 2009 a total of 23 anti-HTLV positive donors were detected in the UK, of these 36 % were UK born and the majority of Black Caribbean ethnicity.[34]

4.5 Additional Infectious agents

A number of additional infections can be transmitted through sexual intercourse which may lead to a viraemia capable of transmission through blood transfusion. In addition to the viruses mentioned above, Hepatitis A Virus (HAV) and Human herpesvirus type 8 (HHV8) may also be transmitted. HAV is an enterically transmitted picornavirus which causes acute hepatitis A. Outbreaks amongst MSM have occurred related to sexual behaviours, but most infections result from exposure to contaminated food or water. Hepatitis A has an incubation period of around six weeks and is associated with a short plasma viraemia for a week before and the week after the onset of jaundice.

HHV8 is a gammaherpesvirus commonly found in some tropical countries; there is a higher prevalence in MSM (26% in those who are not HIV-infected) and people from countries in sub-Saharan Africa. It is easily transmitted by saliva and is probably best not thought of as a sexually transmitted infection. The level of virus in peripheral

blood of a healthy infected person is likely to be low and serology is poor at this point in time. Detection by PCR is at best insensitive in the healthy uninfected person. This alone suggests that transfusion associated infection is unlikely.

Another STI which has seen a resurgence in recent years is Syphilis caused by *Treponema pallidum*. The UK Blood Services have been screening for antibodies to treponemes since the 1940s. The current test will detect both current and past infection. During the 1980s and early 1990s the number of syphilis cases remained low, however, since 1997 there has been an increase in cases year-on-year with a number of outbreaks detected. Many of these outbreaks have been seen within the MSM community and it is reported that almost three-quarters of cases reported by GUM clinics are in MSM. Anyone with a positive test for syphilis, even if due to a previously treated infection, is permanently excluded from donating blood.

4.6 Transfusion risk from new/currently unknown infections

The international blood services are alert to the possibility of the emergence of a previously unidentified infectious agent and the potential for transfusion-transmission of this agent. Of particular concern are infectious agents that are asymptomatic for long periods of time but still transmissible, as is the case for HIV. When HIV was first discovered in the 1980s it was predominantly associated with homosexual men and as no rapid test was available all MSM were excluded from donating blood. Concern has been expressed by some commentators that a new sexually-transmitted infection could emerge in a similar way and that any change to MSM deferrals should take this into account.[35]

Since 1980 over 25 new infectious agents have been identified. These new and emerging infections may arise due to changes in an existing infectious organism, organisms emerging in a different geographic area, an infectious agent being identified as the cause of a known disease or by an old infection re-emerging. Over the last decade, both West Nile Virus (WNV), a vector-borne disease, and vCJD have emerged as transfusion-transmitted infections resulting in new deferral guidelines and the introduction of a range of safety measures.

WNV is transmitted by the *culex* mosquito, being acquired by feeding on infected birds and horses and then passing the virus into a human host. The disease was first identified in 1937, and was seen sporadically around the world, however, WNV is now endemic throughout parts of Europe (excluding the UK) and the US.[36] Transfusion-transmission of WNV was identified in the US in 2002, resulting in both Canada and the US introducing WNV NAT testing of donations in 2003. Currently

the UK has a specific deferral for people returning from areas where WNV is endemic to prevent transmission from asymptomatic donors

vCJD was first identified in humans in 1996, it is a type of transmissable spongiform encephalopathy caused by a prion. vCJD results in a rare, fatal degenerative brain disease which affects younger adults (median age 28 yrs). To date 170 cases of vCJD have been identified in the UK with three cases of the disease transmitted by blood transfusion. An additional transfusion recipient did not develop symptoms but had evidence of prion infection on post-mortem examination. There is currently no screening test available for vCJD, however, a number of processes have been put in place to reduce the risk of transmission including deferral of certain donors who are thought to be most at risk of infection by a prion and ceasing the use of UK plasma for fractionation. Several systems that remove infectious vCJD prion are available, effective in animal models and safe. These have not yet been implemented as they have not been tested clinically in humans. There is no evidence of sexual transmission of vCJD.

Sexual transmission is not the only potential route of new infections and may not be the route of the next emerging infection. As such, unknown TTIs come from a variety of sources and therefore it may not be appropriate to base deferrals for the unknown on just one possible route of infection. In addition since the emergence of HIV in the 1980s both laboratory and clinical surveillance systems have improved and the international health systems are able to react faster to developing outbreaks.

4.7 Epidemiology of infections in current UK donor population

A joint NHSBT/HPA infection surveillance unit was established in 1996 to collect information on the numbers of blood donors with markers of infection and possible risk factors associated with these infections. This information on possible risk factors is used to inform donor selection.

At this point, it is important to differentiate between incident and prevalent infections. Incident infections can be identified because a donor who has previously tested (within 10 years) as negative by reliably comparable assays is subsequently found to be infected. These individuals are classified as seroconverters by the Epidemiology Unit.[10] Incident infections can be missed due to the window period and the possibility exists that a recent donation occurred during this period. The risk of such a transmission will increase with shorter times between donations and an underestimation of incidence is likely as previous samples are needed to confirm seroconversion. Prevalent infections should be detected and appropriately de-

selected by the current blood donation system, however there remains the potential for lack of detection of infection for technical reasons.

Although new donors contribute to approximately 11 % of the 2.5 million UK donations, they comprise over 80 % of all donations with markers of infection. The majority of these infections are prevalent infections, often acquired many years previously eg hepatitis B acquired in childhood. Of greater concern for the UK blood services are new markers of infections in repeat donors as this suggests the donor has recently become infected due to a previously unidentified or undisclosed behavioural risk. During 2009 a total of 335 donations (overall frequency 13.2/100,000 donations) tested positive for one of the TTIs for which testing is mandated (Figure 3). The frequency of markers of infection in donations from UK blood donors has decreased year-on-year since surveillance began in 1996 by an average of 3.2% each year ($p<0.001$). This reduction is greater in repeat donors (8.25 % per year, $p<0.001$).

Hepatitis B was the most frequently detected marker of infection during 2009. HBV NAT testing was introduced in England in April 2009 and six acute hepatitis B infections were detected in repeat donors in England during 2009, four by HBsAg and two by NAT testing. HTLV I/II was the least frequently detected marker although frequency has increased since 2008. The number of new donors testing positive for syphilis has been increasing by approximately 6 % each year; however, there has been an ongoing decrease in repeat donors. The majority of these syphilis infections are past infections but 22 acute infections were identified in 2009. The number of HIV positive donors remains low but has increased each year since 1996 with a current rate of infection of 1/100,000 donations. Cumulative data for all markers is shown in Figure 3.

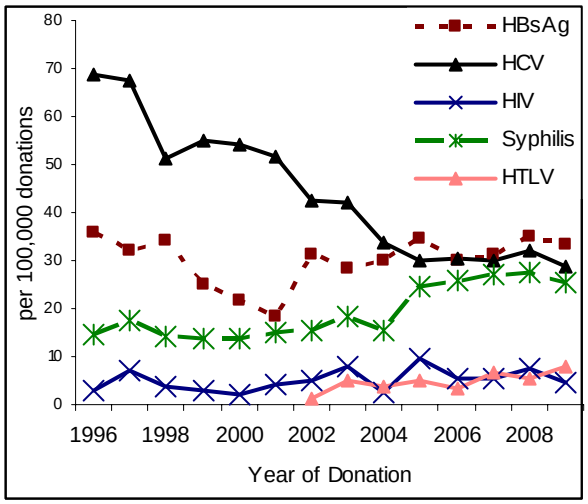
The mean age of infected donors was associated with the type of infection. HTLV infected donors tended to be older (mean age 45 years) whereas HIV positive donors were younger (33 years). Males account for 64 % of all infected donors and are most likely to be positive for markers of infection with the exception of HTLV where 80% of infected donors are female. It is not known, however, what proportion of these women are CSWs. This higher frequency of infections in males was most notable for hepatitis B and has been so since 2002. A similar trend of positive male donors has been observed for syphilis since 2005. The UK blood donor population is predominately white (97%), however, only approximately 66 % of infected donors were white with half of infected donors born in the UK. It was noted that donors

positive for HCV, HIV or syphilis tended to be white and UK born whereas HTLV and HBV positive donors were more likely to be non-white and non-UK born donors.

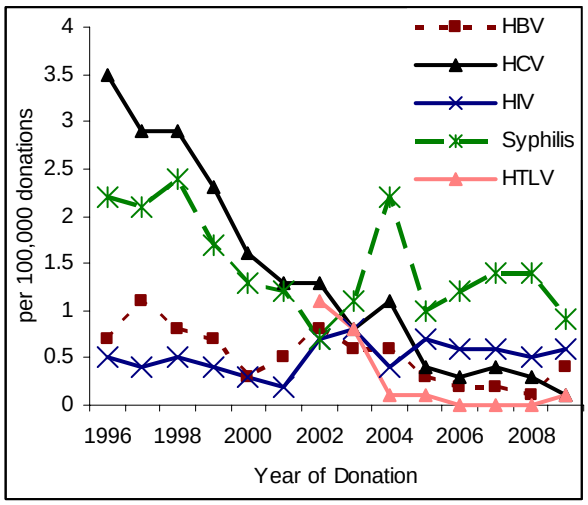
Figure 3: The frequency of markers of HBV, HCV, HIV, HTLV and syphilis in blood donations in the UK

(Note different scales for new and repeat donors)

a) New donors



b) Repeat donors



* HTLV testing began in 2002

4.8 Behavioural profile of blood donors with infection markers

All blood donors whose blood tests positive for one of the markers of infection are contacted by letter and invited to discuss their results with one of the blood service clinicians. A standardised surveillance form is used to collect information on risk factors including such factors as place of birth, possible behavioural risks and previous donation

history. Risk factor information was complete for 75 % of donors during 2009. A summary of donor characteristics, by infection, is given in Table 2.

In those donors reporting a risk, heterosexual sex was given as the most likely route of infection by 37 % of all infected donors. It was the main reported risk for acquiring HIV and syphilis. However a small percentage of donors who reported a heterosexual risk had had a high risk partner (8 %) ie IDU, or history of MSM or commercial sex. Just over half of those with a heterosexual risk reported sex in the UK as a risk with a further 10.0% reporting sex in HIV/AIDS endemic countries and 18.9% reported sex abroad in other areas. Of the 356 HIV infected donors reported between 1996 and 2008, 71 % were white and 55% were born in the UK. Of those identifying sex as a risk, 29% were MSM and 44% (n=157) heterosexual. Of the 157 heterosexual donors, twenty identified their partner as 'high risk' as described above. Of the remainder, 87 thought they had acquired their infection in the UK and 50 abroad. Of the 137 HTLV positive donors, 28 % (n=39) identified heterosexual sex as the most likely risk. Thirty-six of the 39 were women and only one of the three male HTLV positive donors reported sex with a male as a likely risk factor. Evidence regarding non-compliance with the exclusion of individuals who have accepted drugs or money for sex is not available.

Between January 2005 and December 2010, 139 donors tested positive for HIV, of these 62 were seroconversions (61 repeat donors and one new donor who only tested positive using NAT testing). During this period approximately 12 million donations were collected. Of these donors, 43 identified heterosexual sex as the likely risk factor and 17 males reported sex with another man. Where heterosexual sex was identified as the risk factor, six donors reported sex in the UK with no other risk factors, 17 reported possible high risk sex and 17 reported sex with a partner who may have had sex in a country endemic for HIV. Thirty two of the sero-converting donors would have been excluded from donating had they declared the risk factors at the time of donation.

Between 1996 and 2010, of the 4,672 marker positive donors identified, 88 reported paying for sex (PFS) or having a partner who paid for sex or worked as a CSW. Some of these 88 individuals reported multiple risk factors. The majority were new donors (84 %, n = 74) and male (91 %, n = 80). Nine were HIV positive, 13 had chronic HBV infections, 46 were HCV positive, 1 HTLV positive and 19 tested positive for treponemal antibodies. Only one of these 88 donors, who was female and tested positive for HCV, revealed a history of having worked as a commercial sex worker. However, this information was self-declared and this risk is not usually discussed as part of the post-test discussion.

The NHSBT/HPA epidemiology unit also collate data on reasons for non-compliance from infected blood donors. During 2009, 30 donors did not disclose information on their donor health check that would otherwise have resulted in either temporary or permanent deferral from donation. This was more common in new donors (76%). Most donors thought that the question did not apply to them (16/21 with reasons).

Table 2: Infected donations from donors who should not have donated 2009, UK (excl. Scotland)[1]

	No. of donations by infection (seroconverters)							
Deferral reason	**HBV**	**HCV**	**HIV**	**HTLV**	**Syphilis**	**All markers**	**%**	**Co-infections**
MSM (donor or their partner)	1	0	6(5)	0	0	**7**	***21.9***	
IDU (donor)	0	15	0	1	0	**16**	***50.0***	1 HCV/HTLV
Transfusion after 1986 or outside selected areas	0	1	0	0	0	**1**	***3.1***	
Heterosexual contact with partner who may have had sex in high prevalence country	2(1)	0	2(2)	0	0	**4**	***12.5***	
Known status or previous jaundice	3	1	0	0	0	**4**	***12.5***	
Recent piercing	0	0	0	0	0	**0**	***0.0***	
Total	**6 (1)**	**17 (1)**	**8 (7)**	**1**	**0**	**32**	**100.0**	31 donors, 32 infections
Number of donations with marker of infection	97	74	24	22	88	305		
% of donations by marker that should not have been donated	***6.2%***	***23.0%***	***33.3%***	***4.5%***	***0.0%***	***10.5%***		
Cumulative total: 1996-2008	24 (6)	494 (16)	140 (76)	4	85	747 (98)		732 donors, 747infections-15 co-infections
Number of donations with marker of infection	1165	1823	311	134	1049	4482		
% of donations by marker that should not have been donated	***2.1%***	***27.1%***	***45.0%***	***3.0%***	***8.1%***	***16.7%***		

1. SNBTS do not provide data to us on donor selection criteria assessed against reported risk exposures and are hence excluded from this table.

n.b: In 2009, 24.7% of donors had incomplete follow-up where no risk was identified for their infection and risk information could not therefore be assessed against donor selection criteria. These figures are therefore likely to underestimate non-compliance with donor selection criteria. For the period 1996-2008, incomplete follow-up was 28.6%.

5 Sexual behaviour under review

Under the Terms of Reference of this review, the evidence base for donor deferral and exclusion in the UK in relation to sexual behaviours will be assessed. The sexual behaviour under review includes men who have sex with men and commercial sex workers.

5.1 Men who have sex with men (MSM)

The National Survey of Sexual Attitudes and Lifestyles (NATSAL) is a British survey conducted first in 1990, repeated in 2000 (and currently being undertaken again beginning in 2010). In NATSAL 1990, 13,765 people aged 16 to 44 were interviewed compared to 11,161 in the 2000 survey.[37] In the 2000 survey, 5.4 % of men reported ever having sexual intercourse (oral or anal sex, or any other genital contact) with another man. Of these men nearly half (44.7%) had only ever had one partner of whom 23.4 % had had anal sex and 69.1 % oral sex. Over half (52.6%) of the men with a history of only one partner had not had any male sexual contact at all in the last 5 years and 61.5 % none in the last year.

Further analysis of those men who had any male sexual contact in the past year (including those with just one partner) showed that this group comprised 2.1% of all men in the survey in 2000 (0.8 % in 1990). Four in ten of these men (40.1 %) reported only one sexual partner in the past year, and 22.3% had had no male partner in the last four weeks. The distribution of number of partners was highly skewed with a median of 2 and mean of 8 partners in the past year. Two thirds (67.7 %) had had a new partner in the past year, 40.5 % in the past 4 weeks.

Estimates of the proportion of MSM attending a GUM clinic in the last year range from 18.6% (NATSAL) to 41.7% in the Gay Men's Sexual Health Survey, a community based survey of MSM conducted in London, Brighton and Manchester.[38]

5.2 Commercial sex workers (CSW)

There is limited data on the number of commercial sex workers in the UK, however in 1999 the DH estimated there were 80,000 in England and Wales. By definition CSW, both male and female have multiple sexual partners with whom they exchange sex for money or other goods or services. Sex work can be categorised as on-street and off-street, but within the latter is a wide variety of commercial structures associated

with different patterns of partner change, use of condoms and other risk behaviours such as drug and alcohol use. Differences between on-street and off-street sex workers include a higher prevalence of both drug use and blood borne infections among on-street sex workers, but the groups are not mutually exclusive.[24, 39] Long-term commercial sex workers will usually have worked in more than one setting.[40] In general, commercial sex workers, both male and female are at increased risk of STIs, but for some this is linked more to un-protected sex with non-paying casual or regular partners or injecting drug use, than it is to sex with paying clients. Men who sell sex are also at increased risk of HIV, but this risk is not directly linked to sex work.[41]

There are limited data on how a previous history of being a sex worker relates to future risk behaviours and future health. The evidence is suggestive of two populations of sex workers, one who are IDU (this group is strongly associated with onstreet sex work and a range of health and other problems) and a larger group who are not. A cohort study in London confirmed the expected medical consequences of STIs, drug and alcohol misuse acquired during or associated with a career in sex work. [40] These include the risk of pelvic inflammatory disease and infertility related to bacterial STIs, and to chronic infections including hepatitis B and C. However, the relation between health problems and sex work is complex, and despite the longitudinal nature of this study causation could not be determined. In this longitudinal study it was recognised that the women followed up would not be representative of sex workers in general or even the baseline cohort but would over-represent those who had continued to work in the industry, those living in London and those with ongoing health problems. The longitudinal study found that prejudice towards the sale of sex and legal penalties marginalised sex workers both during and after their time in the industry, with this burden of disrespect and the associated difficulties faced when hiding a history of sex work contributing to health problems. There is no evidence, however, that commercial sex work is associated with a continuing risk of blood borne viruses after sex work ceases above that attributable to other recognised behavioural risks such as continuing drug use. These factors, and other diseases such as tuberculosis, would themselves lead to exclusion from blood donation.

There is more data on the clients of sex workers, which suggests that there has been an increase in men paying for sex. The NATSAL 2000 survey reported 1.3 % of men paid for sex in the previous 12 months, 4.2 % in the previous 5 years and 8.8 % in their lifetime. A study from a Glasgow sexual health clinic found 10% of patients reported having ever paid for sex and 4.3% of these men had paid men for sex.[42]

Of those who reported paying for sex, 51% had done so whilst abroad. Sex with a CSW abroad was twice as likely to have been unprotected, compared to sex with a CSW in the UK. NATSAL noted that it was difficult to identify the clients of sex workers as a distinct group and these men were from a range of ages, social classes and ethnic groups. An Australian study looking at the impact of various sexual behaviours on the risk of a donation taking place during the HIV infectious window period found that clients of sex workers were a relatively low risk group.[43]

6 Donor deferral criteria in relation to sexual behaviour

6.1 European practice

In Europe, Commission Directive 2004/33/EU legally requires blood services to permanently exclude anyone whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood. A 2009 European Blood Alliance (EBA) survey of 23 blood services reported that 20 countries defer MSM permanently (or since 1977) and 3 countries (Latvia, Spain and Italy) defer on a temporary basis. For Latvia a temporary deferral is used if indicated by an individual assessment. For Spain a deferral of at least 6 months operates after a change of partner (heterosexual or MSM), with permanent deferral for individuals with multiple sex partners (more than one). In Italy, a deferral of 4 months from the risk behaviour operates for multiple partners or change in regular partner. Most, but not all, EBA countries permanently exclude sex workers as donors.

In 2010, the European Committee on Blood Transfusion of the Council of Europe established a subordinate ad-hoc group aimed at monitoring current practices and defining a harmonised approach to establishing rules for donor deferral linked to risks attributable to sexual behaviour. The outcome of this review is expected in 2011.

6.2 Practice outside of Europe

The USA and Canada have retained a lifetime (or since 1977) deferral for MSM. In Australia, Argentina, and Japan, a 12-month deferral operates for MSM, and in South Africa 6 months. In 2008, a review in New Zealand led to a reduction in the deferral period from 10 to 5 years after last MSM activity. The review conducted in New Zealand also led to a reduction of the deferral period for sex workers to 12 months and for sex workers from countries outside New Zealand to 5 years. Details of the current deferral periods for MSM are shown in Table 3.

Table 3: Current deferral periods for MSM

Country	Current Deferral	Comment
ASIA PACIFIC		
Australia	Deferred for 12 months	Changed in 2006/7.
Hong Kong	Deferred for an indefinite period	
Japan	Deferred for 12 months	Date of change unknown
New Zealand	Deferred for 5 years	Changed in 2008

Singapore	Permanently deferred	
NORTH AMERICA		
United States	MSM since 1977 permanently deferred	The US FDA reaffirmed its position in 2007. In doing so it indicated 'a willingness to consider new approaches to donor screening and testing, provided those approaches assure that blood recipients are not placed at increased risk of HIV of other transfusion transmitted disease'.
Canada	MSM since 1977 permanently deferred	Canadian Blood Services reviewed their exclusion and remained with the permanent deferral of MSM from 1977 (2007)
EUROPE		
Austria	Permanently deferred	
Belgium	Permanently deferred	
Denmark	Permanently deferred	
Finland	Permanently deferred	Referred to the Parliamentary Ombudsman in 2006. No change in policy.
France	Permanently deferred	The ABC newsletter published 8 September 2006 indicated that the French Minister of Health announced that 'the blanket prohibition on blood donation by gay men will end soon'. However, there is no evidence on either the EFS or AFSSAPS websites of any change in policy.
Germany	Permanently deferred	
Ireland	MSM ever having oral or anal sex (even with a condom) permanently deferred	
Italy	National policy is to exclude on basis of 'risky behaviour'.	In place since at least 2001. All donors are interviewed by a doctor. The interpretation of 'risky behaviour' is unclear and inconsistently applied. At least some centres continue to exclude MSM.
Netherlands	Permanently deferred	
Norway	Permanently deferred	
Portugal	Permanently deferred	
Spain	No specific exclusion of MSM	In the late 1990's a move was made from excluding homosexual men to excluding people with promiscuous sexual behaviour from donating blood. A 12 month exclusion exists for anyone who has had more than one sexual partner in the last 12 months.
Sweden	Permanently deferred	During 2006 the Swedish National Board of Health and Welfare considered a proposal to reduce the deferral period to 6 months. Following consultation they decided to leave the permanent deferral in place.

Switzerland	MSM since 1977 deferred.	
United Kingdom	MSM ever having oral or anal sex (even with a condom) permanently deferred	The United Kingdom Blood Transfusion Services reviewed their behavioural exclusion criteria in 2006 and have remained with permanent deferral following analysis of infections detected in blood donors over the period 1995-2006.
AFRICA		
South Africa	MSM deferral for 6 months (oral or anal sex with or without a condom)	Changed from 5 years in 2006 (individual sample HIV NAT screening in place).

For all EBA countries, mandatory testing of donations follows the minimal standards set out in the EU Directive, however, local differences in practice exist and additional testing over and above that covered by the Directive is known. A difference in prevalence of TTIs between countries is known. These differences may influence changes to deferral period, for example, New Zealand and South Africa have reduced the deferral period for MSM, but both use single sample NAT testing for HIV, HBV and HCV.

6.3 Current UK sexual behavioural donor deferrals

In the UK the current deferral and exclusion categories for sexual behavioural risk are given in Table 4.

Table 4: Current behavioural deferrals for blood donation in the UK

	Behavioural Risk	Duration
1	Sex with a Sex Worker	1 Year
2	Accepting money or drugs for Sex	Permanent
3	Sex with an Intra-venous drug user (IVDU)	At least 1 year after last sexual contact
4	Sex with anyone who may ever have had sex in parts of the world where HIV/AIDS is common	At least 1 year after last sexual contact
5	Sex with anyone infected by HIV, Hepatitis B or C	At least 1 year after last sexual contact
6	Females who have sex with a man who had sex with a man	At least 1 year after last sexual contact

7	Anyone who thinks they may be HIV positive	1 Year
8	Men who have ever had oral or anal sex with a man (MSM)	Permanent

In addition to these sexual behaviour deferrals, anyone who has a history of intravenous drug abuse is permanently deferred from donating blood.

Recent data from the Scottish National Blood Transfusion Service on the frequency of donor deferral at donation sessions indicates that, from a total of 199,061 attendances in 2010, sixty two attendees were deferred due to the current MSM lifetime deferral. The data also show that two attendees were not able to donate because of a past history of accepting money or drugs in exchange for sex and forty three were deferred due to a past history of injecting drug use.

6.4 Rationale for donor deferral

The original advice given to MSM was to not give blood to guard against transmission of the causative agent for AIDS.[44] Deferral for MSM has additionally been justified by a theoretical reduction in transmission of known but untested or unknown infection. Most established infections with HBV, HCV and HIV are detected by the current tests in practice with a high degree of sensitivity. There is, however, a "window period" (WP) where infection will not be detected in the initial stages of infection. Viral replication can now be tested for at an earlier stage by NAT testing prior to the presence of detectable levels of viral antigen and/or antibodies reflecting the host immune response. The average window period for the major blood borne viruses (BBV) is shown in Table 5.

The window periods can vary and will be different in cases of atypical infection, immunocompromised patients and new or different virus variants. A donation received during the window period could still be capable of transmission to recipients despite being undetectable. Furthermore, there is evidence of HBsAg negative donations with HBV DNA potentially below detectable levels that are capable of HBV transmission by transfusion.[45] The risk of this transmission is significantly lower in the late than early WP as it is reduced by screening for antibodies to hepatitis B core antigen (anti-HBc).[46]

Table 5: Estimated average window period for Blood Borne Viruses (BBV)

Virus	Assay	Estimated Average Window Period (days)
HBV	HBsAg	66.8
	HBV DNA	38.3
HCV	Anti-HCV	59
	HCV RNA	4
HIV	Anti-HIV	15
	Antigen/antibody	11
	HIV RNA	9
HTLV	Anti-HTLV	45

From Safe Supplies testing the nation Report for 2009 http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1287146241976

7 Risk and blood donation

7.1 Residual risk associated with existing blood supply

The risk of an infectious donation being issued is calculated each year for blood donations in the UK. Due to the number of blood transfusions carried out each year it is not possible to follow up each one individually. The UK blood services rely on the national haemovigilance system for reporting of any potentially transfusion-transmitted infections (SHOT; http://www.shotuk.org/) and as with many other countries the risk of an infectious unit being issued for transfusion is calculated using a residual risk model. The current model used in the UK is a modified version of that of Soldan and Sinka (2003) and is based on current prevalence of infections, window period for each marker, incident infection calculated from repeat donors who seroconvert between donations and inter-donation interval (the incidence/window-period model).[44]

There are a number of possible reasons for an infectious donation entering the blood supply which are taken into account in the model. The most significant of these risks relates to window period donations. Even with the most sensitive tests these types of infections will still be missed on screening as tests are not 100% sensitive so there is a risk of a false negative test result. The risk of an error occurring in testing or issue due to wrongly labelling a sample is very small but these risks are included in the model.

Table 6 shows the residual risks for 2009 based on data collected between 2007-2009. Although the introduction of nucleic acid testing has greatly reduced the window period since the early 2000s this still provides the majority of the risk within the model. As in previous years a greater risk was observed for first time donors as compared with repeat donors.

Based on these residual risk estimates and a total of 2.5 million donations processed and tested within the UK each year, we estimate that testing will NOT identify approximately two HBV infectious donations every year, one HCV every 33 years, one HIV every two years, and one HTLV I every seven years.

Table 6: Estimates of frequency of HBV, HCV, HIV and HTLV I infectious donations issued per million donations tested, UK: 2007-2009.

Risk due to	HBV[1]	HCV[2]	HIV[3]	HTLV I[4]
Window period Donation				
Per million	1.39	0.01	0.19	0.04
All causes				
All donations	1.50	0.01	0.20	0.06
Donations from new donors	5.23	0.06	0.27	0.29
Donors from repeat donors	1.10	0.01	0.19	0.03

[1] *HBsAg testing (window period of 66.8 days, test sensitivity of 99.9%, an error frequency of 0.1%) . HBV NAT rolled out since April 2009; estimates weighted accordingly*

[2] *Anti-HCV testing and HCV RNA testing on pools (window period 4 days, combined test sensitivity of 99.995%, dual error frequency of 0.1% squared).*

[3] *Anti-HIV testing (window period of 15 days, test sensitivity 99.9%, error frequency of 0.1%), or an HIV combined antigen/antibody testing (window period 11 days, test sensitivity 99.9%, error frequency of 0.1%), or HIV RNA testing (window period 9 days, a combined test sensitivity of 99.995% and a dual error frequency of 0.1% squared). Overall estimates are weighted accordingly.*

[4] *Anti-HTLV testing (window period of 45 days, test sensitivity of 98%, error frequency of 0.1%).*

7.2 Are the current risks acceptable?

Blood services are required to provide the safest possible products but no transfusion can ever be totally free of the risk of TTIs. The potential for TTIs in the UK, particularly of viruses, remains low.[47] Table 6 shows the estimates of frequency of HBV, HCV, HIV and HTLV I per million donations tested. Resilience in blood transfusion requires anticipating threats,[48] and blood services anticipate these threats and reduce the risks in transfusion through using low risk donors, using good manufacturing practices, ensuring appropriate clinical use of blood products, and haemovigilance.[49]

Risk is “the probability that an adverse event occurs during a stated period of time or results from a particular challenge”.[50] Risk assessment takes account of likelihood of an adverse event occurring, and the consequences/impact of the adverse event.

Using these two factors a risk rating can be produced eg low, medium, high, or very high.

An acceptable risk could be described as a low risk but it should not be assumed that a smaller risk is necessarily more acceptable.[51] Risks are less acceptable if they: are involuntary; inequitably distributed; inescapable; unfamiliar or novel; man-made rather than natural; cause hidden and irreversible damage; pose a danger to small children, pregnant women or future generations; damage identifiable victims; are poorly understood; and if they are subject to contradictory statements.[52] Risk perception is complex [53] and consequently, there is probably no single acceptable level of risk with regard to TTIs.

8 Reasons to consider change

There are a number of reasons why considering a change to the current donor deferral criteria in relation to sexual behaviour is timely. These include:

- Advances in donation testing and handling
- Changes to legislation
- Societal changes
- Recent information on compliance

8.1 Advances in donation testing and handling

Great improvements in donation testing have been implemented since the last review of blood donor selection in relation to sexual behaviour. All UK blood services currently use a triplex HIV/HCV/HBV NAT assay on pools of samples. This test is used despite the fact that only HCV NAT testing is mandatory. The assays that are currently in use conform to GMP (Good Manufacturing Practice) requirements, are fully automated and use positive sample identification. Each sample bears a unique bar code number, linking the sample to the donor/donation records. All tests use automated data handling, with IT links between all key instrument groups and the core IT systems. The position of any sample on the test run is positively identified using bar codes. Automated handling reduces the risk of system error in the testing process: IT links ensure that the correct samples are identified as reactive, and requiring repeat testing, or as repeatedly reactive, and therefore unsuitable for use.

All samples are tested once with the screening assay: negative results are recorded and passed to the core IT system. Reactive samples are selected for duplicate repeat testing. If both duplicate tests are negative, the result is negative. Samples with negative results on all assays are suitable for issue (subject to other requirements). The core IT system prevents the issue of repeatedly reactive donations, and those with no resolved result recorded.

With these safeguards, the estimated risk of an HIV infectious unit entering the blood supply through a window period donation not detected by current testing regimes (estimated window period 9 days, test sensitivity 99.9%) is 1 in 5.8 million donations, whereas the risk due to all causes (window period plus error) 1 in 5.38 million donations.

There has been no documented transmission of infection attributed to an error in testing since an HCV transmission in 1996. This incident resulted from human error, relating to repeat testing of a sample which showed initial reactivity in the HCV antibody screening assay. If HCV NAT testing had been in place, the error in the HCV antibody repeat testing would have been detected. None of the handful of HIV transmissions in the UK has been through errors of testing: all have been window period cases and occurred prior to 2002 and prior to the introduction of HIV NAT screening. While many experts believe that the parameters used for error in the residual risk calculations may be over-estimates for the UK, and observations suggest that errors are much less frequent than calculated, parameters are consistent with those used in other blood services.

The UK blood services use pools of samples for NAT screening. Currently, 24 donation samples are pooled and subjected to testing. If the pool tests reactive, then further testing is carried out to identify which of the 24 donations has caused the reaction. Pooled testing is the preferred option for operational, logistic, and financial reasons in areas where the chance of having an NAT reactive but serological test negative donation ("NAT only", usually a window period donation) is small. Although pooling will result in "dilution" of any NAT reactive sample with 23 negative samples, this is not a problem in practice. In cases where there is established (prevalent) infection, the infection should be detected in both serology and NAT screening tests; even if the NAT test failed to detect infection, the serology test would. In the case of "window period" donations, the viral load is usually sufficiently high for the sample to be detected as reactive in the pool test. Thus, both prevalent and incident infections would be expected to be detected.

In the UK there has been no documented example of failing to detect a "NAT only"/window period donation in a pooled NAT test, where it has subsequently been shown that an individual NAT test would have detected the infection. Lookback on the last negative donation from donors who subsequently are found to be infected (seroconversion) for any of the markers is carried out as routine within the UK blood services. For HIV and HCV infections, the last negative donation, tested by serology and pooled NAT, is retrieved and tested by single sample NAT. In no case has the previous negative donation (by serology and pooled NAT) been shown to be NAT reactive by single sample NAT. In countries where seroconversions are more common, and where there is therefore a greater risk of a "window period" donation detectable by NAT testing alone, then single sample NAT testing may be considered necessary for routine blood donation screening in order to pick up all incident

infections. This is the case in New Zealand and South Africa, where the major concern is HBV and HIV respectively.

For HBV, the available evidence suggested that introduction of the HBV element of the NAT assay in the UK would have no impact on detection of HBV infected donations, since the HBV NAT assay in pools of 24 samples was expected to be no more sensitive that the routine HBsAg assay carried out on single samples. In practice, in the first year of use of the triplex NAT assay within NHSBT, four HBV infected donations were detected only in the pooled NAT assay: the HBsAg assay was negative. One of these was an early acute hepatitis infection, one was a late acute infection, and two were “occult” chronic infection, consistently HBsAg negative.

For all infections except for hepatitis B, routine blood donation screening includes an antibody assay. This means that infection, once established, will continue to be detected in routine screening assays. In the case of hepatitis B, routine screening consists of an antigen assay (HBsAg), which is mandatory, and an HBV NAT assay (in the triplex NAT test) which is not mandatory. Although there are mandatory tests for detecting HBV infection, for example anti-HBc, they are not mandated for use in the UK. It is important therefore, that the deferral period after possible exposure or risk is set to take account not only of the fact that a donor may be incubating hepatitis B and be in the early infectious stage prior to developing a positive screening test(s) but also may be in the late infectious stage when HBV DNA is disappearing from the circulation. At this stage, a donor sample may test negative in the screening tests but still have sufficient circulating virus to transmit infection through a blood transfusion. Thus, to take account of hepatitis B infection, donor deferral must be set long enough for any donor to have undergone an infection and completely cleared the infection from the circulation, before allowing a subsequent donation. A deferral period of 12 months is considered sufficient to allow for the complete clearance in a recovered individual. Those individuals who do not recover from hepatitis B infection will be detected in the HBsAg assay.

8.2 Changes to legislation

Issues of blood donation regulation are covered by a number of legal provisions in the UK. It has been clear for some time that blood components are 'products' for the purposes of the Consumer Protection Act 1987 and the European Directive behind it on products liability (85/347/EEC). The key legal judgment is that of Mr Justice Burton in *A and Others v the National Blood Authority and Others*. This successful case was brought on behalf of 114 persons infected with Hepatitis C following blood

transfusions between 1988 and 1991. This judgment confirmed a 'strict liability' test based on the legitimate expectations of the public as to the safeness of the 'product'.

The national and international legal requirements in relation to blood donation and its safety must, however, also be read in the light of the Equality Act 2010, which consolidates a number of pieces of pre-existing anti-discrimination legislation including the Equality Act (Sexual Orientation) Regulations 2007. The Equality Act 2010 prohibits discrimination on grounds of sexual orientation by a public service provider (s29), and then at Schedule 3 para 13 states:

"Blood services

13 (1) A person operating a blood service does not contravene section 29 only by refusing to accept a donation of an individual's blood if—

(a) the refusal is because of an assessment of the risk to the public, or to the individual, based on clinical, epidemiological or other data obtained from a source on which it is reasonable to rely, and

(b) the refusal is reasonable.

(2) A blood service is a service for the collection and distribution of human blood for the purposes of medical services.

(3) "Blood" includes blood components."

Paragraph 13 provides that it is not unlawful for a person operating a blood service to refuse to accept someone's donation of blood provided they have reliable evidence that accepting it would put the public or the individual donor at risk and that such a refusal would not be unreasonable.

8.3 Societal changes

Much of the concern and opposition around the current lifelong deferrals for blood donation are based on a sense that they are discriminatory and reflect prejudice and stigma. The radical changes in both the legal and social consideration of same sex relationships reflect a society less accepting of perceived unfairness or discrimination. Furthermore, blood donation is positioned, for example in campaigns for more donors, as an important act of social responsibility and solidarity. The exclusion of MSM thus conveys, it is claimed, a marginalising message at odds with the emphasis on the Lesbian, Gay, Bisexual and Transgender (LGBT) community being a fully accepted part of society.

These social developments may also mean that gay men are themselves less willing to accept being 'lumped together' as a single risk category irrespective of their own

sexual behaviour and risk-taking. It has been claimed that a blanket ban on any man who has ever even once had oral or anal sex, however safe, with another man undermines confidence in safer sex messages. It should be noted that there has also in the last thirty years been the growth and development of a strong international sex workers' rights movement. Whilst issues of the criminalisation or legalisation of sex work remain hotly contested, there is a widely held conviction that there are rights, such as the right not to experience discrimination, which sex workers have and should enjoy, and this has a bearing on the lifelong deferral of those ever having been paid for sex, even if they do not enjoy the legal protections of the Equality Act 2010 in the same way that MSM do in relation to blood services.

9 Evidence to support or refute a change in deferral criteria

9.1 Modelling studies estimating the effects of changes in deferral criteria

A small number of studies have looked at the potential impact of changing blood donor selection criteria, however, the majority of these relate to changes to MSM deferrals and do not consider other potential 'high-risk' groups. A recent review by Vamvakas[54] argued that there are other infection risks within the blood transfusion services such as exposure to numerous donors ie pooled platelets and donations from first time donors which have not be scrutinised in the same way as MSM deferrals. The author argued that a consistent approach to safety is required when considering donor deferral.

The published modelling studies have estimated the residual risk of an infected blood donation being issued both due to a window period donation being missed and to a false-positive result or a positive result being mistakenly issued following an administrative error. The literature relating to donor deferral mainly considers the risk of HIV infection although one study also looked at the impact of a change to deferral criteria and the risk of an increase in HIV and HBV transmission.[55]

Modelling work carried out in Australia took a different approach looking at the impact of various sexual behaviours on the risk of a donation taking place during the HIV infectious window period.[43] The study looked at a range of sexual behaviours: MSM, heterosexual sex, women who have sex with men from high risk countries, men who have sex with female sex workers and injecting drug users. The model used risk of transmission, frequency of sexual intercourse and prevalence of HIV to calculate the proportion of donors likely to be in the window period at time of donation. MSM were calculated to be at the higher risk but women having sex with men from high-risk countries were also at greater risk than the other populations. Currently both of these sexual behaviours have a 12 month deferral period in Australia and the authors concluded that if donors comply with the 12 month deferral criteria then the risk of a window-period donation is minimal.

In the UK between 2003 and 2008, the probability of an infectious HIV blood donation not being detected by current testing methods was estimated as 1 in 4 million donations, however the true value could be as low as 1 in 8.3 million or up to 1 in 2.2 million donations. Both Germain et al [56] in Canada and Soldan and Sinka [44] in the UK calculated the residual risk of HIV infection using 1 and 5 year deferral criteria for MSM. The risk of a window-period infection was important in both these models. These two models used different estimates of test errors and false-negative results,

the errors used in the UK model being higher due to no HIV NAT testing being used at the time. It should be remembered that these models also make assumptions about the number of MSM who would decide to give blood if donor deferral was changed.

Germain et al calculated that if a 12 month deferral was put in place then an additional 1 infected unit would be issued from every 136,000 new MSM donors; ie a change from 1:1 million to 1:925,000 infected donation with an estimated increase of 1.3% in donations. Soldan and Sinka looked at a number of different scenarios for the UK: the current permanent MSM deferral, a 12 month deferral and no deferral for MSM adjusting compliance to 100% and using the current compliance at that time.[44, 57] Using prevalence and incidence data from 1996-1998 the current HIV residual risk was calculated as 1 per 5.3 million donations for MSM (approximately one infection every two years), for a 12 month deferral this increased to 1 per 1.32 million donations (two per year, 66 % increase in risk) and with no MSM deferral to 1 in 0.95 million (between two and three per year, 458 % increase in risk). The model was also used to assess the residual risk of HIV infection in heterosexual donors who had had sex with someone who had been sexually active in a high risk area for HIV, this residual risk was calculated as 1 per 6.5 million.

This UK modelling work has recently been reanalysed by Davison *et al* (*In press*) to take into account changes in testing, most recently the introduction of HIV NAT and the change in estimated prevalence of undiagnosed HIV infection in MSM. This study looks at the residual risk of a HIV infectious donation being released into the blood supply between 2005 and 2007 for a 5 year deferral period. The new model requires an estimate of the number of MSM with and without undiagnosed HIV and has recently been repeated for a 12 month deferral period (Davison *et al*, *in preparation*). For fixed period deferrals of either 12 months or 5 years, any incident infections would be due to non-compliance as both are much greater than the current HIV window period whereas an increase in prevalence could have an impact on the number of false-negative reactions and donations erroneously released as negative. Due to the multiple data sources used in this model the direction of change and relative size of risks are more robust measures than the point estimates.

The data for 12 months, 5 years and no deferral are shown in Table 7. A 5 year deferral was estimated to result in a 0.4 – 7.4 % increase in HIV infectious donations being released for transfusion. For a 12 month deferral the increase was 0.5 – 9.9 depending upon the scenario. The modelling suggests that the length of the deferral period is less important than compliance with the rule, with 100 % compliance with

either a 12 month or a 5 year deferral reducing the risk by 30 %. The difference in the increase in risk between a 12 month and 5 year deferral was very small unless incidence increased as a result of non-compliance of MSM to the criterion. In terms of the additional risk expected due to the newly eligible MSM, the minimum and maximum increases observed under the different scenarios (0.001 and 0.022 expected extra HIV infectious donations per million) would equate to one additional HIV infectious donation every 455 and 21 years, respectively.

It is of note that these data are based on past observations and since 2007, improvements have been made to HIV blood donation testing. These improvements reduce the length of the WP and if it is assumed that all donations were tested using NAT techniques in minipools (rather than the 56% that were tested this way during 2005 – 2007), the infectious WP would reduce from 10 days to 9 days. Under these circumstances, the estimated HIV risk with no change in incidence/non-compliance would have been reduced by approximately 14 % to 0.195 per million donations.

In a more recent model Anderson et al used a probabilistic simulation approach to assess the risk of an infectious donation being released for transfusion in the US.[55] This study looked at failures in processing and issues considering the effect of a 12 month or a 5 year deferral for MSM. The risks of a failure in blood testing ie a falsely negative result and a contaminated component being falsely released were considered. The risks associated with a window period donation were not considered as it was considered that a 12 month deferral period (assuming compliance) would exclude the possibility of any donor having a window period donation. The model estimated that a 5 year MSM deferral could result in an additional 0.03 HIV infected and an additional 0.004 HBV infected units being released and a 12 month deferral in 0.18 additional HIV infected units and an additional 0.019 HBV infected units per year. In both scenarios, the increased risk arises through an increase in the number of prevalent infections whilst error rates remain unchanged. This would be expected to decrease after the first year of introduction of new donor deferral criteria as new donors with prevalent infections were detected and excluded from further donation.

Table 7: Estimated frequency of HIV infectious donations being released into the blood supply under current and alternative scenarios England and Wales 2005-2007

	X per million donations	1 per X million donations	% change baseline incidence
Lifetime exclusion MSM (current)	0.227 (0.157 – 0.318)	4.41	-
Accept MSM >5 y No change in incidence/non-compliance	0.228 (0.168 – 0.306)	4.39	0.4
Accept MSM >5 y incidence/non-compliance increase in line with prevalence	0.244 (0.180 – 0.321)	4.10	7.4
Accept MSM >5 y incidence/non-compliance decreased to zero	0.161 (0.111 – 0.228)	6.23	- 29.3
Accept MSM >12 months No change in incidence/non-compliance	0.228 (0.168 – 0.306)	4.38	0.5
Accept MSM >12 months incidence/non-compliance increase in line with prevalence	0.249 (0.181 – 0.322)	4.01	9.9
Accept MSM >12 months incidence/non-compliance decreased to zero	0.161 (0.111 – 0.228)	6.22	- 29.1
Accept all MSM	0.287	3.48	26.5

9.2 Data from countries who have changed their deferral criteria

A small number of countries including Italy and Spain have a donor deferral system that defers donors on the basis of 'high-risk sexual behaviour' over the previous 12 months. Italy changed its donor selection guidelines in 2001. Prior to this time all MSM were permanently deferred but the current deferrals relate to both heterosexual and homosexual 'high risk sexual behaviours' based on the number of sexual partners. There have been few reports of the impact of this change on donor infections. Velati and coworkers reported briefly on the impact in the Lombardy region of Italy which collects 500,000 donations per year, approximately 20 % of all Italian donations.[58] Data were collected on donations between 1997 and 2005 when 130 donors were identified as HIV infected. The authors identified high risk heterosexual behaviour as the main risk factor for HIV and concluded that the change in deferral criteria had not impacted on numbers of HIV infected MSM donors. This report had limited data and therefore should be interpreted with caution. Another study looking at the epidemiology of HIV in blood donations in Europe and specifically Italy reported an increase in the prevalence of HIV in Italian blood donations. An increase in HIV was noted prior to the 2001 change in deferral so this may not be as a consequence of the change in deferral but suggests that there may be some other issues eg compliance with the specific deferral.[59] There are few data available on the impact of the changes in Spain and Italy and the collection of these data is complicated by the fact that neither Spain or Italy have country-wide, national blood transfusion services. In the absence of this data, it is not possible to model the impact of sexual behaviour based deferral policies based on the risk of transfusion transmission. In addition, the current collection model employed by the UK Blood Services does not support conducting individual behavioural risk assessments prior to blood donation. Finally, studies suggest that the introduction of extensive donor health check questionnaires regarding sexual history will lead to a loss of existing donors. As a consequence of these factors, the review group excluded a sexual behaviour based deferral at this moment in time.

A recent publication by Seed et al looked at the impact of changing the lifetime deferral for MSM in Australia to a 12 month deferral period, this change was introduced in a stepwise fashion throughout Australia being completed in 2006.[60] There was an assumption that a change to the MSM deferral criteria would lead to an increase in HIV positive donations. The prevalence of HIV infection in blood donors did not change significantly post implementation of the deferral change, however, a small but non-significant increase was seen in a particular area of Australia. Although

a similar increase had been noted in the general population it appears that the increase in these incident infections in blood donors was due to non-compliance with the deferral criteria. All five HIV-positive MSM donors identified post deferral change were non-compliant ie donated within 12 months of last sexual experience. Therefore the increase in HIV numbers was due to non-compliance rather than a failure of the deferral criteria.

9.3 Compliance with deferral criteria

As discussed earlier, compliance remains a key issue when considering any change to deferral criteria as non-compliance may lead to an increase in undetected window-period infections. The Department of Health requested the Health Protection Agency to commission a piece of work to look at blood donor compliance, the study used a mixed methods approach using a random location 'Omnibus' survey of 1,028 men who have ever had any sexual experience with a man (MSeM), and 3,914 men and women in the general population. The survey was followed by qualitative research with a sample of 30 'compliers' and 'non-compliers' with the current lifetime MSM donor exclusion. The results of this study have recently become available.

In this study, 3.2% of all men reported as MSeM. Nearly half had ever had oral or anal sex with a man and a quarter had done so in the past 12 months. In addition, 11% of MSM had given blood since becoming ineligible and 2.5% had donated in the past year. 'Non-compliers' were more likely to identify as straight and less likely to have had oral or anal sex with a man in the past 12 months. Predominant reasons for ineligible donation were categorising oneself as low risk, or discounting sexual experience that barred donation. Others included conviction that screening safeguarded blood; misunderstanding of the rule; the need for secrecy around sexual history; and rarely, resentment over inequity of the deferral.

Just a quarter of MSeM were aware that experience of oral or anal sex with a man barred blood donation. A third considered that only unprotected sex prohibited donation. In the general population sample, 8 in 10 recognised the Blood Service's key concern as being the safety of blood and 4 in 10 considered the lifetime MSM deferral excessive. In this study, MSM participants rarely considered blood donation to be an individual right but there was a strong belief in the right to fair treatment for all potential donors.

The study also examined views on revisions to the MSM deferral, with the preference being an individual risk assessment but this was recognised as complex, expensive and difficult to administer in a donation session. A 12 month deferral (since last sex

with a man) was preferred to a 5 year equivalent, and would newly confer eligibility to 46% of MSM survey respondents. This study was not able to predict fully the effect of a revised MSM deferral on compliance. However, almost all qualitative interview participants (all currently compliant with the lifetime MSM exclusion) maintained that they would comply with a 5 year and a 12 month MSM deferral, particularly if provided with sufficient information on the rationale for the exclusion.

9.4 Impact on transfusion recipients

It is necessary to consider the impact of changes to donor selection criteria upon patients, particularly in those who are multi-transfused. This document provides a synopsis of changes in infection risk following alterations to the donor deferral criteria and has asked the question "what is an acceptable level of risk for the patient, the blood service and the general population?" It is clear with multiple transfusions that the risk of TTIs is additive. In order to determine an acceptable level of risk in all patients one must factor in the ongoing additive risk for the multi-transfused patient.

Changes to the current donor selection criteria may also impact upon the number of donors and hence availability of components for patients. A reduction in the current life-long exclusion of MSM donations may lead to an increase in donors. The UK Blood Services do not collect robust data on how many donors attending a donation session are excluded due to MSM and it is not possible to determine how many of these men would have been eligible to donate blood or how many additional men would have attended to donate blood if the exclusion period was reduced.

The recent review of the New Zealand donor deferral policy recommended a reduction in the MSM exclusion. However in order to provide a consistent recommendation based upon prevalence of HIV the exclusion period for individuals who have lived in countries with a high HIV prevalence was increased. This review of the UK donor selection criteria also considers possible approaches to protect the donated blood supply from the risk associated with HIV acquired through heterosexual activity, with particular emphasis on risks associated with sexual exposure with people in or from geographic areas of high prevalence.

An increase in the exclusion period which is currently 12 months for individuals who have had heterosexual sex with someone who has been sexually active in geographic areas with a high HIV prevalence combined with the current exclusion for 12 months following visiting a malarial endemic area may impact upon the availability of Rh and Kell compatible units. Although, for malarial endemic areas this can be reduced to 6 months as malarial testing can be used if the visit was between 6 and

12 months before the time of donation. NHSBTs Guidelines on the "Provision of Red Cell Transfusion Support for Transfusion Dependent Patients" state that "*Due to the diversity of RBC antigenic make up among different individuals, multi-transfused patients are likely to be exposed to many allogenic RBC antigens. Exposure to foreign RBC antigens is more likely when there are racial differences between blood donor population and the recipients, [61] such as in Sickle Cell Disease patients receiving blood from European Caucasian donors. 30% of transfusion dependent patients are reported to have developed RBC antibodies.[62, 63] Most antibodies that develop post transfusion are within the Rh and Kell systems.[64, 65] Patients who do not develop Rh or Kell antibodies are less likely to develop other antibodies".* Hence the provision of Rh and Kell compatible units in multi-transfused patients reduces the risk of allo immunisation which in itself further limits the availability of compatible RBCs.

The impact upon donors and component availability following changes to the current donor selection needs to be considered in addition to the risk of TTIs. It is critcal that the differing perceptions of risk need to be taken into account in risk communication.[66] Patients will focus on TTIs (however rare), and will probably have a lower risk tolerance than donors.

9.5 Ethical issues

The donation and use of blood and blood products within the UK health care system is in essence a moral enterprise. Donation is seen as an altruistic act, a gift to an unknown person who is in need, and such altruism is regarded as morally praiseworthy. Those responsible for the collection, distribution, and provision of blood and blood products to patients who require them have a moral obligation to ensure that already vulnerable patients are not put at unnecessary risk when receiving blood.

In addition to its duty of care to patients in need of blood products, the health service also has a moral obligation to those who wish to donate blood. This includes an obligation to protect donors from harm but also an obligation not to unfairly discriminate against them. Any difference in treatment of donors should be based on morally relevant and justifiable reasons. These reasons are likely to be based on the recipient-related moral considerations of minimising harm from the transfusion and ensuring an adequate supply of blood to respond to the current need. One morally relevant reason for treating different individual donors, or groups of donors, differently would be their likelihood of transmitting a blood borne virus in their donation, and thus their likelihood of harming a potential recipient. It seems clear that preventing

donors who are known to be infected with HIV, HBV, HCV and other blood borne viruses from donating is morally permissible and indeed morally required. Their blood would in any event be discarded following testing if found to be positive for these infectious agents. The presence of infection is a morally relevant difference that allows discrimination in selecting out these people as blood donors compared to the rest of the population.

Given the obligation to minimise harm and therefore reduce risk from transfusion, 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, it may be morally permissible to exclude specific groups of people from donating based on the risk rather than the certainty of a transmissible infection. This is the basis of current exclusion and deferral criteria for blood donation in the UK and other countries. 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). Thus in considering the deferral criteria both within groups (changing the period of deferral for MSM) or across groups (differences between MSM and heterosexual contacts of someone from geographical areas with a high prevalence of HIV) it will be necessary to take into account:

- Evidence of the level of risk of transmission of a blood borne infection from donated blood,
- Whether the level of risk is sufficient to justify treating donors differently,
- Whether the parameters for defining the high risk donor group are fairly set (avoiding unnecessarily wide parameters),
- The feasibility, and resource implications, of setting narrower parameters,
- 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 racial backgrounds.

The delivery of effective health care, including provision of blood and blood products, requires a high level of trust in the service from both recipients and donors. 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.

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11 Appendices

Appendix 1: Terms of Reference

ADVISORY COMMITTEE ON THE SAFETY OF BLOOD, TISSUES AND ORGANS

BLOOD DONOR SELECTION STEERING GROUP

The Remit and Terms of Reference

Background

Currently, men who have ever had sex with men (MSM) are excluded from donating blood for life. In addition, women who have had sex with MSM are deferred for 12 months after such sexual contact, as is anyone who has had sex in countries where AIDS/HIV is common.

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) has committed to review the current blood donor deferral and exclusion criteria in relation to specific sexual behaviours. This review will be conducted by a SaBTO working group composed of representatives of interested stakeholders.

Remit

The working group will "*Review the evidence base for donor deferral and exclusion in the UK in relation to sexual behaviours and make recommendations to SaBTO on the most appropriate ways to ensure the safety of the blood supply.*"

Its remit includes:

1. Evaluating the evidence base for deferral and exclusion policies;
2. Defining the infections of interest, both known and unknown;
3. Reviewing the epidemiology on transfusion transmitted infections (TTIs);
4. Assessing the performance of current testing procedures;
5. Determining the residual risks for specific TTIs;
6. Reviewing relevant policies in other countries;
7. Evaluating the operational impact of any recommendations;
8. Recommendations for disseminating the outcome of the review.

Terms of Reference

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;
- identify specific areas of research where further work is required to reduce uncertainty;
- take account of the discriminatory nature of any policies;
- consider the impact of its advice on all stakeholders in the blood supply chain, including but not exclusively donors, patients, the UK blood services and the wider NHS;
- take full account of the need to maintain the safety of the blood supply under the remit of the Precautionary Principle;
- be ultimately accountable to SaBTO.

Modus Operandi

All members of the working group will sit on the Steering Group which will meet on at least two occasions during the review. A smaller writing group will meet on a monthly basis (in person or by telecon) to draft papers and assess the available evidence.

Administrative issues will pass to the SaBTO Secretariat who will also maintain a document library.

Travelling expenses are payable for attendance at meetings in line with DH rates for individuals who serve on committees. Members of the Blood Donor Selection Steering Group are asked to make every effort to use public transport where possible, rather than taxis, and to travel at standard rates. Receipts must be submitted with claims.

Papers will be circulated no later than 7 days prior to any ordinary meeting.

Appendix 2: Donor selection guidelines, tools and processes in the UK

The provision of donor selection guidelines has several benefits, including:

- Consistency of decision making between staff members
- Minimises unnecessary deferral
- Improves safety
- Ensures that donors have their deferral reason explained clearly and accurately.

These benefits can be further increased by the use of good training materials and programs and the use of assessment tools to ensure competency. The directive requires that all staff undertaking this task be regularly trained and assessed for competency.

Format of the donor selection guidelines

The donor selection guidelines are available in two formats

- As a PDF file
- As an Offline Browser

The use of the browser platforms is recommended and promotes rapid and accurate use of the guidelines by permitting the use of synonyms as key words (eg allergy or hay fever to find the entry on hypersensitivity). An additional benefit of electronic formats is that they are easier to update rapidly and in a controlled manner. Additionally this information, or simplified extracts of it, can be made available on the website to allow donors access to accurate selection information.

The donor selection process: four major steps

The donor selection process consists of four major steps which are closely interlinked:

- Pre-donation information and advice
- Donors health questionnaire
- Donor interview
- Donor health assessment.

It is important to note that all four steps must be taken every time a donor presents him/herself for donation. The need to positively identify the donor prior to health assessment and donation is extremely important in ensuring safety, and the collection systems should be designed to make certain that the donor's identity is

confirmed at key stages in the donation process. Additionally, the donor's contact details must be clearly recorded by the blood establishment.

The following paragraphs aim to outline the four major steps in effective donor selection and identify key elements of good practice.

Pre-donation information and advice

Pre-donation information and advice are considered to be of paramount importance to the whole process of optimal donor selection and help to minimise unnecessary deferrals. It also helps to ensure that donors do not come to harm from donation and the ensuing components made from their donation are unlikely to harm any recipient.

The EU Directive defines the information and advice that should be provided to the blood donor in advance of the donation to enable them to make an informed decision about whether to donate or not. This information should be accurate and explicit and written in simple language to allow donors to fully understand the issues surrounding blood donation, including:

- The need for honesty
- Potential risks of donation
- The need to protect the recipient
- Common reasons for deferral
- The tests conducted on donation
- The donation process.

This information can be delivered in a number of formats:

- Verbally in the form of counselling
- Written leaflets via mailings
- Electronic formats on website.

The provision of this clear, concise information enables the donor to decide whether to self defer, ie to decide before donation that they are not eligible to donate. Additionally, blood establishments should consider alternative formats for pre-donation information such as versions in other languages, or formats for donors with special requirements such as Braille or audio for visually impaired donors, or video with titles or sign language for those with impaired hearing.

Whilst self-deferral should be promoted, donors should also be encouraged to communicate their reasons for self-deferring to the blood service. This ensures that

their understanding of the selection criteria are sound and allows the service to maintain accurate records in relation to donor health and risk factors.

It is essential that donors have several opportunities to withdraw from donation discreetly. The provision of adequate information in advance of donation is highly effective in achieving this aim. It is considered general good practice to offer the donor the opportunity to leave the session without question at any time. This becomes particularly important when dealing with risk factors and behaviours which may result in the transmission of blood borne infections.

Donor health questionnaire

When a donor has decided to come to a blood collection session on the basis of the pre-donation information and advice, he or she will be asked to fill out a health questionnaire. The questions included in the health check should serve to identify any infection risk to the patient resulting from the donor's history of medical conditions, lifestyle, sexual behaviour or travel. If a donor does not meet the eligibility criteria, he or she will be deferred: either temporarily or permanently.

Format

The donor health-check must be in a self-completion, tick box format. This should be written in clear and simple language to promote effective communication and understanding. The questions should be unambiguous and progressive, triggering additional questioning as appropriate to identify underlying reasons for deferral and ensure that the full relevant medical history is obtained.

Donor interview

Following completion of the health-check the donor should be interviewed by an appropriately trained and qualified health care professional. The format and extent of questioning may differ depending on the donor status. New or lapsed donors may be subject to additional questioning and more intensive interview with greater focus on blood safety and behavioural risks.

Donor health assessment

If the information collected from the donor by the questionnaire and interview indicate no reason for deferral, a health assessment is carried out to further confirm the donor's physical eligibility to donate. Generally, the following parameters are assessed:

- Haemoglobin level
- Weight, by asking the donor to confirm that they are at least 50kg.

Additional testing may also be in place for other products or components such as:

- Protein levels (for apheresis plasma donors)
- Platelet levels (for apheresis platelet donors).

Commission Directive 2004/33/EC defines the minimum haemoglobin level for females and males and requires the use of a validated method for measurement. Most member states use a capillary sample for this measurement however others use a secondary spectrophotometic test system to check the result on a venous sample. One EU blood establishment does not test Hb on session, but uses the result from the sample taken at the previous donation. Additionally, most blood establishments enforce a minimum weight for blood donation.

The Commission Directive 2004/33/EC requires that the health assessment should be conducted by a qualified health professional. The definition of 'qualified health professional' may differ between member states, but requires that they are appropriately trained and assessed for competency to undertake Donor Health Assessment and that this training must be regularly updated.

Donor consent or declaration

When a donor has completed the four steps of donor selection - pre-donation information and advice, donor health questionnaire, donor interview and donor health assessment - the donor signs the donor questionnaire, which is countersigned by the responsible staff member conducting the medical history interview. This particular action confirms that the donor:

- has read and understood the educational material provided
- has had an opportunity to ask questions and receive satisfactory responses
- agrees to the testing of their donation and that a sample will be archived
- grants informed consent to proceed with the donation process
- assumes responsibility that the information provided is true to the best of his/her knowledge.

Donor comprehension

Throughout the donor selection process there is a need to ensure that the donor can demonstrate that (s)he understands the process - this is pivotally important in securing blood safety. There is general acceptance that blood establishments should not use third party interpreters in the donor assessment or consent process - this is explicitly forbidden in some member states. There are, however, options to facilitate

communication between the blood service and donors with communication issues resulting from reading difficulties, language barriers or disability. These can include:

- Provision of materials in alternative formats such as large print, audio, Braille, video material with subtitles or sign language
- Provision of materials in alternative languages
- Provision of glasses
- Assisted completion by a member of blood service staff.

These options are there to facilitate comprehension and improve communication but it is important that the donor can clearly demonstrate comprehension during this process otherwise the donation should be declined.

The use of materials in multiple formats must be rigorously quality controlled to ensure consistency across the versions used.

Donor confidentiality

During the health assessment process and completion of the health check and the health assessment process, it is important that there is an appropriate level of donor confidentiality and that the session layout should promote donor confidentiality. Additionally, management and storage of donor documentation on the blood donation session should support donor confidentiality.

This can be supported by offering some of the following options:

- Allowing the donor to complete the health check at home or online
- Provision of private booths for interview and screening
- The use of folders or clipboards designed to avoid the donor being overlooked
- Background music on session to prevent donors being overheard
- The use of sound proofing materials in partitions
- Appropriate distances between screening booths.

The need to respect adequate privacy and confidentiality is particularly important in small communities and workplace collection environments where donors are more likely to know each other leading to social community pressure to donate when it may not be appropriate.

Appendix 3: Blood Donation Testing

Certain tests are performed on all blood donations within the UK and are mandatory (laid down by the Secretary of State or equivalent or in the BSQR). Additional tests are performed on all donations but are not mandatory. These have been introduced by the blood services but could be discontinued at any time at their own discretion. The EU Directive (and BSQR) lays down that each donation of blood must be tested in conformity with the basic testing requirements and any additional tests which may be necessary for specific components, types of donors or epidemiological situations. The tests which **must** be performed are specified as:-

i. Hepatitis B (HBsAg);

ii. Hepatitis C (Anti-HCV);

iii. HIV 1 and 2 (Anti-HIV 1 and 2).

At August 2010, the tests outlined below were in use within the four UK blood services.

Test	Methodology	Requirement	Originator	Date of Instruction
HBsAg	single sample testing	Mandatory	EU Directive/ BSQR	1972
Anti-HCV	single sample testing	Mandatory	EU Directive/ BSQR	1991
HIV 1 and 2[1]	single sample testing	Mandatory[2]	EU Directive/ BSQR	1985
Anti-HTLV	24 sample pool	Mandatory	Secretary of State	2002
HBV/HCV/HIV (Triplex NAT test)	24 sample pool	Mandatory[3]	Secretary of State	2000 (HCV) 2009 (Triplex)
Treponema Pallidum Haemagglutination test[4]	single sample testing	Mandatory	Secretary of State	1940s

[1] Combined antibody/antigen test except NIBTS, which is planning introduction in 2010/2011

[2] Anti-HIV 1 and 2 only, not antigen

[3] Only HCV NAT is Mandatory. Confirmed in February 2007, following review by MSBTO

[4] Or equivalent

Appendix 4: The number and frequency of markers of HBV, HCV, HIV, HTLV and syphilis[1] identified among blood donations made to blood centres by new and repeat donors[2] and country where donation was made: 2009

		No donations			HBV			HCV			HIV			HTLV			Syphillis[1]			All markers[3]		
2009		newly tested[2]	repeat tested[2]	all tested	NEW	REPEAT	ALL	NEW	REPEAT	ALL	NEW	REPEAT	ALL	NEW	REPEAT	ALL	NEW	REPEAT	ALL	NEW	REPEAT	ALL
England	Number	242,943	1,863,966	2,106,909	87	7	94	65	2	67	11	11	22	19	2	21	61	17	78	243	39	282
	Frequency/100000 donations				*35.8*	*0.4*	*4.5*	*26.8*	*0.1*	*3.2*	*4.5*	*0.6*	*1.0*	*8.2*	*0.1*	*1.0*	*25.1*	*0.9*	*3.7*	*100.0*	*2.1*	*13.4*
Wales	Number	9,660	90,898	100,558	1	0	1	6	1	7	1	0	1	1	0	1	4	1	5	13	2	15
	Frequency/100000 donations				*10.4*	*0.0*	*1.0*	*62.1*	*1.1*	*7.0*	*10.4*	*0.0*	*1.0*	*10.4*	*0.0*	*1.0*	*41.4*	*1.1*	*5.0*	*134.6*	*2.2*	*14.9*
Northern Ireland	Number	7,027	56,797	63,824	1	1	2	0	0	0	1	0	1	0	0	0	4	0	4	6	1	7
	Frequency/100000 donations				*14.2*	*1.8*	*3.1*	*0.0*	*0.0*	*0.0*	*14.2*	*0.0*	*1.6*	*0.0*	*0.0*	*0.0*	*56.9*	*0.0*	*6.3*	*85.4*	*1.8*	*11.0*
Scotland	Number	31,562	228,365	259,927	8	0	8	13	0	13	0	2	2	1	0	1	5	2	7	27	4	31
	Frequency/100000 donations				*25.3*	*0.0*	*3.1*	*41.2*	*0.0*	*5.0*	*0.0*	*0.9*	*0.8*	*3.2*	*0.0*	*0.4*	*15.8*	*0.9*	*2.7*	*85.5*	*1.8*	*11.9*
UK	Number	291,192	2,240,026	2,531,218	97	8	105	84	3	87	13	13	26	21	2	23	74	20	94	289	46	335
	Frequency/100000 donations				*33.3*	*0.4*	*4.1*	*28.8*	*0.1*	*3.4*	*4.5*	*0.6*	*1.0*	*7.2*	*0.1*	*0.9*	*25.4*	*0.9*	*3.7*	*99.2*	*2.1*	*13.2*

1. Treponema antibody testing detects both recent and past syphilis caused by the bacterium *T.Pallidum*. It also detects diseases caused by other treponemes such as yaws caused by *T. pertenue* and pinta caused by *T. carateum*, endemic in some countries but rare in the UK.

2. New and repeat donors classified according to records available to the blood centre and therefore new donors will include lapsed donors for all countries except Scotland.

3. There were six coinfections (UK excl Scotland): one HBsAg Carrier/*T.pallidum* in a new female donor; one HBsAg Carrier/*T.pallidum* in a new male donor, one HCV/*T.Pallidum* in a repeat male donor, one HTLV/HBsAg carrier infection in a new male donor, HCV/HTLV infection in a new male donor and one HTLV/*T.Pallidum* infection in a new female donor.

4. This includes five donors who were HBV NAT positive and HBsAg negative.

Appendix 5: Epidemiology of HIV in the UK

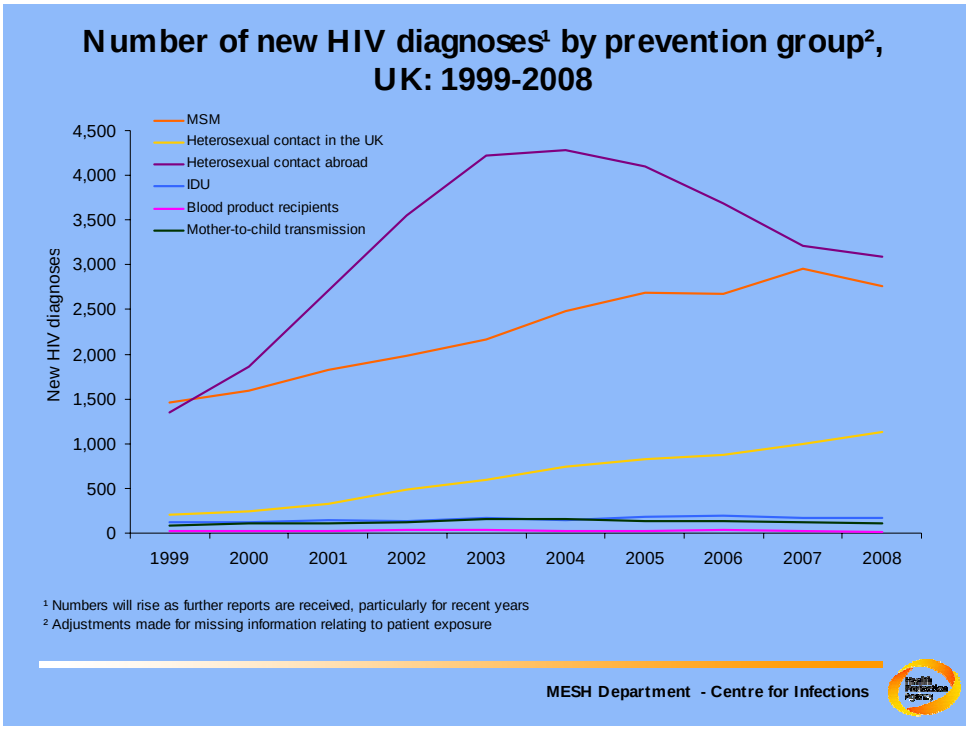
Data on the epidemiology of HIV in the UK is available from a number of sources. The Unlinked Anonymous Prevalence Monitoring Programme (UAPMP) survey includes 16 GUM clinics; eight in London, one in Scotland and seven elsewhere in the UK. The samples are unlinked from any patient identifiers, to maintain anonymity, but it is recorded whether the patient is already known to be HIV positive (previously diagnosed infection) or if they test positive on that occasion. UAPMP data from 2008 of previously undiagnosed HIV infections, which includes both those tested and diagnosed on the day and those who remain unaware of their status, shows that the prevalence was higher in MSM (3.1 %; 291/9,473) compared with heterosexual attendees (0.35%; 322/92,694). Prevalence was higher in heterosexual females (0.4 %) than in heterosexual males (0.32 %). Among heterosexuals HIV was more common in people born in sub-Saharan Africa (2.1 %; 118/5,721) compared with those born in the UK (0.18 %; 126/67,751) or elsewhere (0.42 %; 80/19,222). The proportion of infections in those unaware of their status has been falling and was 23% in 2008, although this is likely to be an overestimate because it is known that some patients who are aware of their status choose not to disclose it when attending a GUM clinic. A second source of prevalence data for HIV is from routine testing in antenatal clinics, where uptake of testing was 93% in 2008. Overall 1 in 486 women in antenatal clinics in England and Wales were HIV infected in 2008. There is a higher proportion of HIV infected women in London (1 in 268). Outside of London, prevalence has increased from 0.11% in 2004 to 0.15% in 2008. The highest prevalence was in women born in Sub-Saharan Africa (2.4%) compared with a prevalence of 0.05% in UK born women in 2008. Additional prevalence data is available from populations sampled outside GUM and other healthcare settings. In the Gay Mens Sexual Health Survey, which recruits men in bars and clubs the prevalence of HIV was between 8.6% and 13.7%. One third of infected individuals were apparently unaware of their status.[38] In this study, 18.7% of HIV negative men and 37% HIV positive men reported having unprotected anal intercourse in the last year. A cross-sectional community based survey in Black Africans living in the UK (MAYISHA II) reported an HIV prevalence of 14% of respondents, with 66% of the infections being previously undiagnosed. As with other studies, the majority of black Africans with HIV were from East and Sub-Saharan Africa and acquired their infection abroad.

The number of new diagnoses since 1999 is shown in Figure 4. A total of 6,630 new cases of diagnosed HIV infection were reported in 2009, 4,400 in men and 2,230 in

women. The annual number of new diagnoses has been decreasing since 2003. It is estimated that 54 % of these new cases were acquired heterosexually and 42% by men having sex with men. Data on new diagnoses of HIV suggests that the numbers of new and undiagnosed infections among Black Africans in the UK is decreasing, however, a similar trend is not seen in MSM.

In some groups, particularly MSM, an increasing proportion of cases occur in individuals who have tested negative in the past allowing a better estimate of the date of infection. Until recently this was the only way to determine the date of infection but developments in laboratory testing make it possible to identify most early infections, even in the absence of documented seroconversion. Preliminary data from the HPA using the Recent Infection Testing Algorithm (RITA) showed that in the first 6 months of 2009, 1 in 5 cases in MSM and 1 in 10 heterosexually acquired infections that were newly diagnosed had been acquired within the previous 6 months.

Figure 4: Number of new HIV diagnoses by prevention group



In the future, the total number of diagnosed cases of infection may increase because of further measures taken to reduce the proportion of undiagnosed cases. There are several initiatives designed to achieve this, particularly to reduce late presentations. If successful these will improve the survival of individuals because they can be

offered antiretroviral therapy to prevent disease progression. It will also result in an increase in the overall proportion of the HIV infected population who are on treatment and virologically suppressed, reducing the risk of onward transmission. Initiatives include wider offering of HIV testing, outside of the GUM clinic setting, such as opportunistic point of care testing (POCT) in Emergency departments, general medical admission units and out-patient clinics. Combined with changes in treatment guidelines, which recommend that treatment is started at higher CD4 counts, these measures will reduce the average infectiousness of the HIV-infected population. There are also experimental proposals to offer even earlier treatment with the primary aim of reducing infectivity (by full suppression of HIV viral load) but these are unlikely to be widely adopted or have a population level effect in the next 5 years.[67] Although incident HIV infections continue to contribute to the increase in prevalent cases, the largest effect has been from improved survival with antiretroviral therapy, and from new arrivals in the UK with infection acquired abroad.

The age distribution of patients with HIV infection is changing. While new infections are occurring at all ages, there has been a trend towards an older age of infection. In the UK Register of HIV Seroconverters, an open cohort study, the median age of seroconversion has increased from 28 years up to 1996, to 33 in 2004-6.[68] This is then added to the ageing of the existing cohort, now that long-term survival is the norm.

Appendix 6: List of Abbreviations

ABC	America's Blood Centers
AFSSAPS	Agence française de sécurité sanitaire des produits de santé
Ag	Antigen
AIDS	Acquired Immunodeficiency syndrome
ALB	Arms length body
Anti-HBc	Anti-Hepatitis B core
Anti-HBs	Anti-Hepatitis B surface
ART	Anti-retroviral treatment
ATLL	Adult T-cell leukaemia/lymphoma
BBV	Blood-borne virus
BSQR	Blood Safety and Quality Regulations
CPA	Consumer Protection Act
CSW	Commercial sex worker
DNA	Deoxyribonucleic acid
EBA	European Blood Alliance
EC	European Community
EEC	European Economic Community
EFS	Etablissement Français du Sang
EIA	Enzyme Immunoassay
EU	European Union
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
GUM	Genito-urinary medicine
HAV	Hepatitis A virus
HBsAg	Hepatitis B surface antigen

HCV	Hepatitis C virus
HEV	Hepatitis E virus
HHV8	Human herpes virus 8
HIV	Human Immunodeficieny Virus
HPA	Health Protection Agency
HTLV	Human T-lymphocytic virus
IDU	Intravenous drug user
IT	Information Technology
JPAC	Joint Professional Advisory Committee
LGBT	Lesbian, gay, bisexual and transgender
MHRA	Medicine and healthcare regulatory authority
MSeM	Men who have had a sexual experience with a man
MSM	Men who have sex with men
NAT	Nucleic Acid Technology
NATSAL	National Survey of Sexual Attitudes and Lifestyles
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
PALS	Patient Advice and Liaison Service
PCR	Polymerase chain reaction
PDF	Portable document format
POCT	Point of care testing
RBC	Red blood cell
Rh	Rhesus
RITA	Recent Infection Testing Algorithms
RNA	Ribonucleic acid
s29	Section 29

SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SHOT	Serious Hazards of Transfusion
SNAHC	Enhanced Surveillance of Newly Acquired Hepatitis C
SNBTS	Scottish National Blood Transfusion Service
SOPHID	Survey of Prevalent HIV Infections Diagnosed
SSA	Sub-saharan Africa
STI	Sexually Transmitted Infection
TTI	Transfusion Transmitted Infection
UAPMP	Unlinked Anonymous Prevalence Monitoring Programme
UK	United Kingdom
US	United States
vCJD	Variant Creutzfeld-Jacob disease
WBS	Welsh Blood Service
WNV	West Nile virus
WP	Window period

Appendix 7: Review Group Members

Group/Organisation	Individual	Notes
SaBTO Member	Professor Deirdre Kelly	Chair of Steering Group
National Aids Trust	Dr Yusef Azad	Director of Policy and Campaigns
NHSBT/HPA	Dr Su Brailsford	Epidemiology/Health Protection
Gay Men Fighting AIDS	Carl Burnell	Chief Executive
UK Blood Services (Operational)	Dr Moira Carter	SNBTS
GUM Specialist	Dr Richard Gilson	Senior Clinical Lecturer
UK Blood Services (Clinical)	Dr Patricia Hewitt	NHSBT
Stonewall	Ruth Hunt	Deputy Director of Public Affairs
Consultant Paediatrician	Dr Baba Inusa	
SaBTO Member	Dr Harpreet Kohli	Epidemiologist/Public Health
UK Thalassemia Society	Elaine Miller	
Sickle Cell Society	Dr Asa'ah Nkohkwo	Nationwide Adviser, Comprehensive Care
Terrence Higgins Trust	Sir Nick Partridge	Chief Executive
Haematologist	Dr Susan Robinson	
PALS	Cat Scott	PALS Officer, Brighton and Hove
Ethicist	Dr Anne Slowther	Associate Professor
Virologist	Dr Stephen Winchester	Virology Registrar
ADVISORS		
Health Protection Agency	Katy Davison	Epidemiologist
London School of Hygeine and Tropical Medicine	Pippa Grenfell	
Health Protection Agency	Professor Richard Tedder	Virologist
SECRETARIAT		
NHSBT/Department of Health	Dr Nicholas Watkins	Review Coordinator
Department of Health	Dr Beatrix Sneller	SaBTO Secretary