FAIR II: An assessment of the evidence for the donor selection question asking about sexual partners who may have had sex in areas of the world where HIV is very common

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Recommendations

- 1. Complete removal of the question: In the last 3 months/since your last donation have you.....had sex with anyone who may ever have had sex in parts of the world where AIDS/HIV is very common (this includes most countries in Africa)? Or similar counterpart question in the UK blood services. Described here as HRP SSA.
- 2. To take effect at the same time as the FAIR deferral system in summer 2021, if practical to do so, thereby ensuring changes to the pre-donation selection questionnaire can be incorporated simultaneously.
- 3. No additional or new question post FAIR gateway is required.
- 4. Clear messaging for donors to prompt them to think before session about their current risk of infection via new and multiple partners, including sex overseas, and the importance of ensuring the safety of donations for recipients.
- 5. FAIR post-implementation monitoring to include information on donors reporting a partner who fits the HRP SSA description.

FAIR II steering group noted:

- a. FAIR deferrals will seek to remove those at highest HIV transmission risk: history of ano-genital bacterial STI, ChemSex, PrEP use, partner known to be positive for HIV or hepatitis, partner who injects drugs, partner who is paid for sex, or anal sex with new or multiple partners
- b. low estimated number of undiagnosed Black African heterosexuals in the UK (1,300) and England (1,200) combined with short HIV window period meaning risk of additional undetected infections extremely unlikely
- c. current non-compliance with, and difficulty in answering the HRP SSA question
- d. under the current deferral, a very small proportion of HIV positive donors report an HRP SSA partner, but although unlikely, it is not possible to confirm if the current deferral is solely responsible for such low numbers
- e. that although number of partners of potential donors who have attended to give samples and thus allow their partner to donate are small, anecdotally none have been identified as HIV positive
- f. more concern about the HBV risk given the longer window period, although current HBV screening under review as part of SaBTO occult hepatitis B work
- g. recent HIV or HBV in donors was reported after sex abroad in Thailand and Europe rather than Africa
- h. the addition of a new travel deferral for sex abroad would add unnecessary complexity, when the existing travel deferrals of one, four and six-months cover HIV (and many HBV) endemic areas and current risks of HIV are very low
- i. changing the question to cover all UNAIDS areas in new partners would require further change to the Geographical Disease Risk Index
- j. that they would like to see an estimate for what the risk is in new or multiple partners
- k. that reassurance should be provided for recipients that the safety of the blood supply will not be compromised
- I. the need for more Black African donors to supply rare blood types
- m. the negativity the HRP SSA question generates among the Black African community and the need for more inclusivity and equality.

Key findings

- 1. In the general population, the proportion of people living with diagnosed and undiagnosed HIV is higher in Black African heterosexual adults than in all heterosexual men and women but lower than in all gay and bisexual men.
- 2. There are estimated to be approximately 26,100 Black Africans living with HIV in England of whom 1,200 are undiagnosed.
- 3. Number of new HIV diagnoses have declined among all groups and estimates of incidence (recently acquired infection indicating ongoing transmission) in GBM have declined.
- Information on incidence is less well known for heterosexuals but again the estimated incidence was higher in Black African adults compared with all heterosexuals and lower compared with GBM in one study of sexual health service attendees.
- 5. The majority of Black African heterosexual adults diagnosed with HIV were born abroad, and it is estimated 40% of heterosexuals born abroad diagnosed with HIV acquired their infection in the UK in 2018 based on CD4 count and 30% of all newly diagnosed Black Africans based on an incidence estimate, indicating ongoing risk of acquiring HIV in the UK.
- 6. Around half of all heterosexuals are diagnosed late meaning there is potential to pass on HIV for at least 3 to 5 years before their diagnosis. This is slightly higher in heterosexual males especially Black African males (65%) compared with 33% in GBM.
- Acute HBV is rare in the UK and mainly reported as heterosexual contact with Black African or Black Caribbean individuals, comprising 7.1% of notified cases and Indian (5.4%) although ethnicity is not well recorded.
- 8. The screening assays may not detect a positive donation from a blood donor who has very recently acquired infection. The current risk of not detecting an HIV infectious donation is estimated as 1 every 12 years and 1 every 6 months for HBV.
- 9. Under the current deferral system, HIV NAT pick-ups in blood donations indicating very recent infection are very rare with 6 in total, two of whom who's only reported risk was a partner who may have had sex in sub-Saharan Africa, the last such case donated in 2008.
- 10. Under the current deferral system, donors reporting a partner who may have had sex in sub-Saharan Africa comprised 10% (5/49) of HIV positive donors between 2015-2019 while donors reporting sex between men comprised 27% (13/49) and other heterosexual contact comprised 53% (26/49).

- 11. Under the current deferral system, donors reporting a partner who may have had sex in sub-Saharan Africa comprised 8% (1/12) of donors with recently acquired HIV between 2015-2019 while donors reporting sex between men comprised 50% (6/12) and other heterosexual contact comprised 33% (4/12) of recent HIV infection.
- 12. Under the current deferral system, donors reporting a partner who may have had sex in sub-Saharan Africa comprised 0/17 recent HBV infections.
- 13. Non-compliance with the HRP SSA question was 0.2% in a 2014 UK blood donor survey with a further 1.25% who thought they were affected by the question, noting a very small number of Black African responders to the survey question.

Background

Following the FAIR report to SaBTO to remove the 3 month deferral for men who have sex with men and use a gateway question to identify all donors at higher risk, we agreed to set up a working group to look at the evidence for retaining a 3 month deferral for people who have had sex with someone who may ever have had sex in parts of the world where HIV/AIDS is very common. This includes a long-term partner. Any suggested change would need the agreement of SaBTO¹.

The current donor health check selection question in England asks:

In the last 3 months/since your last donation have you.....had sex with anyone who may ever have had sex in parts of the world where AIDS/HIV is very common (this includes most countries in Africa)?

The question will be referred to as Higher Risk Partner, sub-Saharan Africa (HRP SSA) in this document.

JPAC guidance² states that "HIV/AIDS is common in some areas of the world, and sexual activity with partners in these countries carries a risk of infection. This Index [Geographical Disease Risk Index (GDRI)] identifies the countries of Sub Saharan Africa to facilitate interpretation of the guidance. However, the health care professional should consider all other risks of HIV associated with travel and remember that this is not restricted to Sub Saharan Africa."

If the donor reports sexual activity with a partner who may have been sexually active in one of the countries listed as Sub Saharan Africa in the GDRI the donor is deferred for 3 months after last sexual contact with that partner. Donors affected by this question may be eligible if their partner is happy to come to a session and give a one-time sample for testing, this applies in England only.

The details of the rationale for the introduction of the HRP SSA question are not easily available but it is thought that there were concerns that a sexual partner who may have had sex in an area where HIV is very common ie high prevalence of 1% or greater (<u>Appendix A.1</u>) could have undiagnosed HIV and that this may be transmitted to the donor either via a new partner or a regular partner at any time. Although all blood donations are screened for HIV there is a risk that very recent infections will be missed. Donor selection aims to minimise recent infection in donors where possible in order to maintain blood safety. Current residual risk which is acceptable states that we would miss 1 infectious HIV donation every 12 years. The HBV residual risk is higher at 1 infectious HBV donation every 6 months or 1 in a million donations. This does not equate to transmission risk. The last proven HIV transmission in the UK was in 2002.

¹ Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee: <u>https://www.transfusionguidelines.org/about</u>

² https://www.transfusionguidelines.org/dsg/gdri/preliminaries/hiv-aids

Although the HRP SSA question applies to people of any ethnicity, we know from both anecdotal and research evidence of the de-motivating effect of the donor selection question on partners who may have had sex in Africa on potential and current Black donors³. The UK blood services need to recruit more Black donors to meet clinical needs and there is concern that the HRP SSA question could be a barrier to donation in Black communities. Reviewing the evidence to see if the HRP SSA deferral can be removed safely aligns with the equality, diversity and inclusion culture we are building at NHSBT. Evidence suggests we also need to better explain the rationale for deferrals which will have to remain for now.

³ Eamonn Ferguson BAME Report for NHSBT 2020, McKinsey Report 2020

Current HIV epidemiology in the UK from PHE HIV report 2019⁴

New diagnoses

There are two main groups in the UK who are disproportionately affected by HIV; gay and bisexual men (GBM) and Black African heterosexual men and women. We took Black African heterosexuals as a proxy for partners who may have had sex in sub-Saharan Africa in absence of better data on partners. Here we compare data in GBM, Black African heterosexual adults and other heterosexual or all heterosexual adults.

After a peak of new HIV diagnoses in the United Kingdom (UK) in 2014, a rapid decline has been observed. This decline was particularly marked among GBM where diagnoses fell by 35% from 3,480 in 2014 to 2,250 in 2018.

The number of new HIV diagnoses in people who acquired HIV heterosexually has almost halved over the past decade to 1,550 in 2018. The steepest declines were in London residents, in those aged 25 to 34 years, in persons of Black African ethnicity and those born abroad. Black African men and women accounted for 44% of new HIV diagnoses among adults who acquired HIV heterosexually in 2018, compared to 61% of new diagnoses in heterosexuals in 2009. Nearly half of all adults diagnosed in 2018 who acquired HIV heterosexually of high HIV prevalence compared with 63% in 2009. Most people diagnosed in 2018 and born in a high prevalence country were of Black African ethnicity. It used to be assumed that HIV had been acquired in country of birth but this is now known not to be the case. A CD4 back-calculation model is used to estimate country of infection in those born abroad. It is estimated that around 40% of heterosexuals born abroad diagnosed with HIV acquired their infection in the UK in 2018 with 332 (uncertainty range: 242 to 417) acquiring HIV after arrival to the UK and 489 (uncertainty range: 404 to 579) acquiring HIV before UK arrival. There has been a decline in infection in those born abroad in both infections acquired before and after arrival to the UK.

Test positivity among sexual health service attendees

The test positivity (Table 2) among sexual health service attendees additionally shows that being Black African and born in a high prevalence country carries higher risk than being born in a low prevalence area with 0.7% of Black Africans born in a high prevalence country testing positive, the same proportion testing positive as in GBM in general. While Black Africans born in a low prevalence country like the UK have the same low positivity as all heterosexual men and women of 0.1% (See also <u>Appendix A.2</u>). These data may not represent prevalence in non-SHS attendees, but is a useful comparison between attending groups.

⁴ O'Halloran C, Sun S, Nash S, Brown A, Croxford S, Connor N, Sullivan AK, Delpech V, Gill ON. *HIV in the United Kingdom: Towards Zero 2030. 2019 report.* December 2019, Public Health England, London. <u>https://www.gov.uk/government/publications/hiv-in-the-united-kingdom</u>

Table 1: Estimated number and prevalence of HIV in different adult risk groups, England 2018. Data taken from PHE 2019 & BHIVA 2020⁵

England 2018, adults 15 to 74 years	Est. living with HIV n	Est. undiagnosed n	undiagnosed n prevalence living with HIV	
GBM	45,200	3,600 (2,000-6,700)	88 per 1000	6.81 per 1000
Black African men and women	26,100	1,200 (900-1600)	36.6 per 1,000	1.65 per 1000
All heterosexual men and women	45,200	2,900 (2,200-4,700)	1.10 per 1,000	0.07 per 1000

Table 2: Test positivity at sexual health services, England 2018. Data taken from PHE2019

Test positivity at sexual health service (SHS), England 2018	Percentage		
GBM with ano-genital bacterial STI <12m	4.90%		
GBM	0.70%		
Black African Heterosexuals born in an HPC	0.70%		
Heterosexual Black African women	0.40%		
Heterosexual Black African men	0.30%		
Non-Black African Heterosexuals born in an HPC	0.20%		
Heterosexual men and women	0.10%		
Black African Heterosexuals NOT born in an HPC	0.10%		
Black Caribbean heterosexual men and women	0.10%		
HPC - high prevalence country			

HPC – high prevalence country

Late diagnoses

A late diagnosis is defined as a person who has a CD4 cell count <350 cells/mm3 within 91 days of their HIV diagnosis. People diagnosed late are likely to have been living with an undiagnosed HIV infection for at least 3 to 5 years and may have been at risk of passing on

⁵ These data on the general population are drawn from the PHE HIV report *HIV in the United Kingdom: Towards Zero 2030. 2019 report.* (Data to 2018) and BHIVA/BASHH/BIA Adult HIV Testing guidelines 2020 <u>https://www.bhiva.org/HIV-testing-guidelines</u> Note that PHE HIV data to 2019 is published but BHIVA uses 2018 data to give the undiagnosed prevalence and picture very similar for 2019 data.

HIV to partners if having unprotected sex. Overall, the proportion of late diagnoses in 2018 remained high at 43% (1,883/4,453). The number of late diagnoses has declined by 44% since 2009, especially in Black African men and women but is still high in heterosexual men and women (Table 4).

Table 4: Late diagnoses in general population,	UK 2018. Data taken from PHE 2019
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Diagnosed late, UK 2018	Men	Women
GBM	33%	
Black African heterosexual men and women	65%	47%
White heterosexual men and women	59%	49%

Estimates for those living with HIV infection

In 2018, the number of heterosexual Black Africans in England estimated to be living with HIV but unaware of their infection ie undiagnosed, continued to decline to 1,200. A Multi-Parameter Evidence Synthesis (MPES) model⁶ is used to estimate the total number of people living with HIV including those undiagnosed. Information on exposure group sizes, numbers diagnosed and in care, and HIV prevalence from prevalence surveys, and data on HIV testing in various groups, are synthesised to estimate the number of persons living with undiagnosed HIV. In the general population the rates of new diagnoses and estimated prevalence of people living with undiagnosed infection are highest in GBM. Black Africans have lower prevalence of living with HIV than GBM but higher than in all heterosexuals (Table 1).

Since HIV testing is cost effective at over 1 per 1000 undiagnosed infections, GBM and Black Africans are groups recommended for HIV testing in the BHIVA guidelines. To look at it another way, at a population level, it is estimated that 1 in 147 GBM are undiagnosed compared with 1 in 606 Black African adults and 1 in 10,000 for all heterosexual men and women.

Estimates of recent infections (incidence)

Recent infection or incidence tells us about current transmission among the population. The fall in underlying incidence of HIV infection has continued. In GBM, the number of incident infections has declined by 71%, from a peak of around 2,800 new infections in 2012 to 800 in 2018. The estimated number of newly acquired HIV infections among men who acquired HIV heterosexually halved from 550 in 2014 to 250 in 2017. Equivalent estimates for women who acquired HIV heterosexually were 450 and 350.

The first study⁷ to provide estimates of annual HIV incidence in England among heterosexual men and women of Black African ethnicity by using an HIV recency test on sexual health service attendees, estimated incidence in 2013 was 1.7 per 1000 for Black

⁶ Appendix 24, HIV in the United Kingdom: Towards Zero HIV transmissions by 2030 (2019 report– data to end 2018) - Appendix <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/965766/HIV_in_t</u> <u>he_UK_2019_towards_zero_HIV_transmissions_by_2030_appendix.pdf</u>

⁷ Aghaizu A, Tosswill J, De Angelis D, Ward H, Hughes G, Murphy G, Delpech V. HIV incidence among sexual health clinic attendees in England: First estimates for Black African heterosexuals using a biomarker, 2009-2013. PLoS One. 2018 Jun 20;13(6):e0197939

African heterosexuals, approximately four-fold higher than the 0.4 per 1000 in heterosexuals overall. HIV incidence was highest among MSM at 14.6 per 1000 (Table 3). Incidence could not be reliably estimated by country of birth as the numbers were small resulting in very wide and unstable variance estimates. GBM attending sexual health clinics in this study had approximately three-fold higher incidence than estimates among all GBM confirming that these sexual health clinic attendees are a higher risk group of HIV acquisition. The lack of data in Black Africans meant it was unclear whether incidence in Black African SHS attendees was different or higher than in non-attendees. It is likely that under these guidelines GBM will retest more than heterosexuals. Motivated and frequent testers have a higher probability of being diagnosed during the earlier stages of infection therefore potentially inflating the estimated incidence. The authors applied the 0.17% annual incidence estimate among Black Africans to the 67,337 who attended sexual health clinics in 2013 equates to 115 persons with incident infections. Using a CD4 backcalculation model and date of entry into the UK, authors estimated that approximately 500 Black African heterosexuals acquired their infection each year in the UK over the 5 years (equating to 30% of all newly diagnosed Black Africans). This gives some indication of current transmission in the UK at that time noting that this is 2013 data and likely to have declined since among all groups.

The BHIVA guidelines only had evidence to recommend regular HIV testing for MSM with repeat testing in other groups triggered by the identification of individual behavioural risk factors, symptoms suggesting seroconversion, or the identification of indicator conditions. The guidelines cited a retrospective review of 31,469 heterosexual patients of a diverse range of ethnicities attending London sexual health services which found that of 4584 retested for HIV within 12 months of an initial negative test only one retested positive⁸.

Table 3: Estimated recent infection in attendees at sexual health services, England
2013. Data taken from Aghaizu et al. (2018) PLoS ONE 13(6): e0197939

England SHS 2013	Estimated incidence	95% CI
GBM	1.46%	(1.23-1.70)
Black African heterosexual men and women	0.17%	(0.05-0.30)
All heterosexual men and women	0.04%	(0.03-0.06)

Infections acquired abroad

Among UK-born men and women, HIV infections acquired abroad remained low and stable, below 100 diagnoses ie just below 1 in 5 of all new diagnoses if people previously diagnosed abroad are excluded (see <u>Appendix A.3</u>). Data from NATSAL shows that travelling away from home presents opportunities for new sexual partnerships, which may

⁸ Leber W, McMullen H, Anderson J et al. Promotion of rapid testing for HIV in primary care (RHIVA2): a cluster-randomised controlled trial. Lancet HIV 2015; 2: e229–235.

be associated with sexually transmitted infection (STI) risk⁹. The Mayisha study¹⁰ carried out in 1999, showed nearly half of Black African men and women travelled to their country of origin in the previous five years and 40% of men and 22% of women acquired a new sexual partner when abroad. An association between travelling to their country of origin and high sexual risk such as larger numbers of partners and history of a sexually transmitted infection diagnosis was also one of the findings. These NATSAL and Mayisha surveys demonstrate sexual transmission risk when abroad by travellers of any ethnicity to HIV endemic areas. They do not equate to HIV transmission.

Current HBV epidemiology in England in 2018

A total of 381 acute or probable acute cases of hepatitis B were reported for England in 2018. This gives an annual low incidence of 0.68 per 100,000 populations lower than the incidence of 0.80 per 100,000 population reported for 2017¹¹. Only 56 cases (14.7%) of the total acute or probable acute hepatitis B cases had their ethnicity recorded. Seventy one percent of the cases were White (an increase from 67% in 2017), followed by Black African or Black Caribbean (7.1%) and Indian (5.4%). As in previous years where known the commonest reported risk attributed was heterosexual exposure, implicated as the probable route of exposure in 55 (50.0%), compared to 54.8% in this category in 2017 (n=68). The incidence of acute hepatitis B continues to remain higher in males than females. This excess of male cases is partly explained by cases in GBM.

⁹ Tanton C, Johnson AM, Macdowall W, et al. Sex Transm Infect 2016;92:415–423. https://sti.bmj.com/content/92/6/415

¹⁰ Fenton KA, Chinouya M, Davidson O, Copas A, Mayisha research team. HIV transmission risk among sub-Saharan Africans in London travelling to their countries of origin. AIDS 2001; 15(11):1442±1445. <u>https://journals.lww.com/aidsonline/Fulltext/2001/07270/HIV transmission risk among sub Saharan Africans.17.as</u> <u>px</u>

¹¹ Acute Hepatitis B (England): annual report for 2018

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/877344/hpr3019_ ct-hbv18_V3.pdf

Infection in blood donors under the current deferral

Here we present data on observed HIV in blood donors under the current deferral. The original deferral as written in the transfusion guidelines is specific for HIV. We also present HBV data since this viral infection is also endemic in sub-Saharan Africa.

Residual risk

Current testing with NAT and Ag/Ab HIV has a window period of around 9 days, with a residual risk of 23 million donations tested before an HIV infectious donation is not detected, or one donation every 12 years, based on current data for 2017-2019¹². The model uses recent infections detected and the window period of the assays: the lower the number of recent infections the smaller the residual risk of releasing an infectious HIV donation. For 2017-2019, HBV has a higher residual risk of not detecting 1 infectious donation every 6 months because the window period is longer at 30 days.

Total number of HIV infections

In the UK, between 2015 and 2019 there were 49 HIV positive donors with five (10%) female white British donors reporting HRP SSA of which one donor had a recent infection described below (Table 5 and <u>Appendix A.4</u>). Four had acquired their infection in the UK and one in Africa. Just 1 of 49 HIV positive donors was of Black African ethnicity and born in Africa, a new female donor under 35 years old. No sexual contact was reported and there was no indication by avidity testing or clinical history that this was a recent infection. One Black Caribbean donor who was confirmed HIV serology positive/NAT negative reported a new female partner within 3 months and chlamydia infection.

Recent HIV infection acquired within 12 months of donation

A seroconversion, i.e. a change from a negative to a positive HIV result within 1 year of the donor's previous donation is concerning because of the potential for non-detection of the HIV infection in the previous donation.

Twelve of the 49 (24%) HIV positive donors had a recent HIV infection acquired within 12 months including 10 HIV seroconversions with one donor reporting HRP SSA risk: a female white British new donor reporting sex with 2 new partners from Africa although the timing of sexual contact was unclear the avidity results indicated recent infection. A further male white British new donor reported sex with new partners in Thailand, an HIV endemic area (See <u>Appendix A.1</u>).

We have reviewed data on HIV NAT pick-ups termed window period infections indicating extremely recent infection which could be viewed as near miss events. Six window period HIV infections were detected in the UK in the 23-year period between 1996 to 2019 (Table 4). Three of these were in White British donors with Black African partners, although one also had another possible risk factor. One was picked up on donation screening with a very early infection 2 weeks after unprotected sex with their regular partner of 7 months. We have not detected any HIV NAT pick-ups with reported HRP SSA risk since 2008.

¹² The estimated residual risk that a donation made in the infectious window period is not detected on testing: risks specific for HBV, HCV and HIV in the UK (2020) <u>https://www.transfusionguidelines.org/document-library/position-statements</u>

Year	Exposure	Туре	Ethnicity	Partner	Partner information
2004	GBM	Apheresis	white	no info	no info
2004	HRP	Repeat	white	new partner	Unprotected sex in the UK with a one-off partner from Nigeria 18 days before
2007	HRP/PFS	Repeat	white	regular partner HRP /new partner PFS	Partner of 18 months from Zimbabwe. Paid For Sex (PFS) using a condom about 19 days before
2008	HRP	New	white	regular partner	Partner of 7 months from Africa. One episode of unprotected sex 2 weeks before
2011	SEX	Repeat	mixed	new partners?	Sexual partners, no further info
2016	GBM/HET	New	white	regular partner HET/ new partner MSM	Married to a female who had recently had another partner and oral sex with male partner not known to him

Table 4: HIV NAT pick-ups in blood donors and exposure, UK 1999 to 2019

Table 5: HIV in blood donors, all and recent infection acquired <12months: key information, UK 2015-2019 (full table in <u>Appendix A.4</u>)

HIV UK 2015-2019	HIV all	HIV recent	% which are recent	% of recent infections
Total	49	12	24.5	
NAT pick up	-	1		8.3
Seroconversion	-	10		83.3
Black ethnicity	2	0	0.0	0.0
Born Africa	1	0	0.0	0.0
Acquired Africa	1	0	0.0	0.0
Risk group				
GBM	13	6	46.2	50.0
HRP SSA	5	1	20.0	8.3
Other heterosexual	26	4	15.4	33.3
Other/NK	5	1	20.0	8.3

Higher risk partner SSA trend

The proportion of HIV positive donors attributed to HRP SSA has decreased over time with HRP SSA being assigned as the possible risk in 24% of donors between 1996-2019 and a maximum of 50% (7/14) in 2000. In the last 5 years only 10% (5/49) of HIV positive donors were attributed to HRP SSA. Looking only at recent HIV infection, 14% (19/132) reported HRP SSA UK 1996-2019. There was a case reporting new partners in 2019 but prior to that no donor with recent HIV infection had reported HRP SSA since 2010. Of these 19 HIV positive donors with recent infection there were 6 who reported a regular partner who may have had sex in Africa as their only risk.

Partners providing a sample to NHSBT

The current system in England may allow donors with a partner from SSA to donate if their partner is willing to attend the session to give a blood sample. Anecdotally, the clinical team do not recall any partner tested under this system being HIV positive although a small number of partners have been found to have current HBV and HTLV infections.

Data for 2020 shows that 60 donors gave a sample and were then barred from donating. Samples were given for various reasons such as previous non-specific reactivity for example. Of these, one 28-year old female from Kenya had given so her male partner could donate and was tested negative. The records showed that the donor had been donating non-compliantly for some time before declaring his partner after he lapsed and returned in 2020. However, there will also be partners who have become blood donors themselves so their donor partner can donate and are not identified here. Other countries defer without an option for partner testing. There were around 50 and 16 deferrals on session annually in Scotland and Wales respectively (Personal communications, Lorna McLintock and Stuart Blackmore)

HBV infection

In the UK, between 2015 and 2019 there were 307 HBV positive donors. Most of these were chronic infection likely acquired in country of origin either at birth or in childhood, 59 of whom were born in Africa (Table 6 and Appendix A.5). We would expect to pick up longstanding infections through donation testing. There are some infections termed occult which may be missed on screening and these are being addressed via proposed changes to testing. Again, the main concern for blood safety would be to the partner acquiring a new HBV infection which was missed on testing.

Recent HBV infection

A small number,17/307 were recent HBV infections acquired within 12 months including 14 HBV seroconversions which included 3 HBV NAT pick-ups. None of these donors with recent infection reported HRP SSA although three had had sex in Thailand. One repeat Black African female donor born in the UK had an acute HBV infection after sex with a new white British male partner. One new male of Black African ethnicity, born Africa was assigned as acute but had no identified risks and may have reflected a reactivation. One female reported a regular Indian partner who had visited India and developed jaundice. Two of the NAT pick-ups had sex abroad with new female partners of Asian ethnicity one in Thailand and the second in Spain, the second case also had a new partner in the UK. The third NAT pick-up was in a female donor with no available information on partner.

HBV UK 2015- 2019	HBV ALL	HBV RECENT	% which are recent	% of recent infections
Total	307	17	5.5	
NAT pick up	-	3		
Seroconversion	-	14		
Black ethnicity	71	2	2.8	11.8
Born Africa	70	1	1.4	5.9
Acquired Africa	59	0	0.0	0.0
Risk group				
GBM	2	2	100.0	11.8
HRP SSA	0	0	0.0	0.0
Other Heterosexual	21	10	55.6	58.8
Other/NK	284	5		

Table 6: HBV in blood donors, all and recent infection acquired <12m: key information, UK 2015-2019 (full table in <u>Appendix A.5</u>)

Sex abroad

Although the guidance identifies countries in sub-Saharan Africa it does recognise that there are other risks associated with travel. Other areas are also identified by UNAIDS as high prevalence (See <u>Appendix A.1</u>).

Most recent infections in blood donors are sexually acquired. Sex abroad is a travel risk among all travellers but potentially more risky in those travelling to endemic areas. Although around half (14/29) of the recent HBV or HIV infections between 2015-2019 were acquired in the UK, sex in Thailand comprised 14% (4/29) of HIV and HBV recent infections (Table 7).

Although we know that Black Africans are travelling to see friends and family we do not see recent and only 1 longstanding HIV infection in donors that were acquired in Africa, even once deferral periods are up. None of the recent infections acquired via sex abroad were acquired in Africa, perhaps because of good compliance to the HRP SSA rule, but also possibly because of travel deferrals for malaria. None of the recently acquired infections were via sexual contact in Jamaica another area where HIV is very common.

However, the HRP SSA question is concerned with risk to the donor where a partner has had sex abroad in an endemic area. One of the compliant HIV positive donors reporting HRP SSA said their partner had travelled to Africa. However, we have no data on travel in

donor's partners to put this in context or where the partner had travelled without the donor. As donors noted in the 2014 survey, they trusted their partner but hadn't asked to be sure.

Table 7: Number of recently acquired infections (<12m) in blood donors, looking at area sexually acquired, UK 2015-2019

Number	Recent infection	Sexually acquired	Sex UK	Sex Thailand	Sex Europe	Sex other	Country nk
HBV	17	11	6	3	2	0	0
HCV	1	0					
HIV	12	11	8	1	2	0	0
Syphilis	135	123	101	1	5	2	14

Of the 5 acute HBV infections acquired abroad, 2 were NAT pick up acquired in Thailand and Spain. It was just over 28 days since last heterosexual contact in Thailand.

A donor survey in 2016 indicated 0.87% (206/23701) of responders said they had sex abroad with someone new in 2015 (ie up to 18 months prior to the survey), 16 (0.07%) with someone who usually lived in Asia and 7 (0.03%) with someone who usually lived in Sub-Saharan Africa.

Impact of travel deferrals

Travel deferrals should delay donors from donating immediately after travel to ahigh prevalence country as they coincide with 4 month deferrals for travel to malaria areas, and 3 years for previous malaria infection, 6 month deferrals for viral haemorrhagic fever areas (eg where Ebola outbreaks occurring) and 1 month deferrals for all other tropical areas.

Travel deferrals have a large impact on Black donors in England despite additional testing shortening the malaria deferral to 4 months. National Call Centre data showed that over 20,000 malaria deferrals were advised annually pre-session. Data from 2015 showed that White donors had the lowest proportions of deferral, with 15% of donors of Indian ethnicity, 10% of Pakistani ethnicity donors and 8% of Black African donors advised to defer presession. In Scotland there is no additional testing for malaria. We may need to explain the rationale better where deferrals have to remain for now. Malaria is not necessarily seen as an important infection in those from endemic countries and donors may not realise transfusion transmission in the UK has resulted in patient fatality.

Other blood services

Endemic area- South Africa National Blood Service¹³

Selective use of donations based on donor race-ethnicity reduced the residual HIV risk from 34 per million in 1998 to 26/million donations but was deemed unethical. Consequently, in 2005 South African National Blood Service eliminated race-ethnicity– based collection policies and implemented individual-donation nucleic acid testing (ID-NAT). Prospective blood donors complete a donor questionnaire that examines donor health (to protect the donor) and risk behaviour (to protect the patient) prior to donating blood. Positive responses to risk behaviour questions such as "Are you HIV positive?"; "In the past 6 months, have you had sexual contact with more than one person?"; and "In the past 6 months, have you started having sexual contact with a new sexual partner?" will prohibit blood donation at this time, eliciting a temporary deferral from blood donation until the "risk behaviour" has ceased.

The table below compares the South African experience where HIV is very common and they have ID NAT testing with the data for England.

Number	South Africa 10 yr (2005-2015)	UK (2010-2019)
% living with HIV	18%	0.23% in 2018 E
Incidence	0.91/100py	1.8/100py in GBM attending GUM EW 2016. 0.17% in Black African heterosexuals attending GUM E 2013
Donations per year	800,000	2 million
NAT testing	Individual	Pools of 24
Window period	3 days	9 days
HIV positive	15,702 (0.2%)	134 (0.0006%)
HIV NAT pick ups	481 in 7,736,202 donations ie 62 per million	2 in 21,549,669 ie 0.1 per million
Residual HIV risk	13.4 per million RBC transfusions in 2015	0.04 per million donations tested 2017-2019
Transfusion transmission	1 confirmed case of TT HIV 2005- 2015	Last confirmed TT HIV 2002

	Table 8: HIV in South	h African blood servio	e compared with UK
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¹³ Vermeulen et al. Assessment of HIV transfusion transmission risk in South Africa: a 10-year analysis following implementation of individual donation nucleic acid amplification technology testing and donor demographics eligibility changes. Transfusion. 2019 Jan;59(1):267-276.

Non-endemic area- Netherlands

Sanquin currently have a deferral in place similar to our current deferral.

4-month deferral after:

- leaving an HIV-endemic area to live in the Netherlands
- sexual contact with persons who live in a HIV-endemic country
- sexual contact with a person who was born in a HIV-endemic country, unless this 'endemic' person has been living in the Netherlands for more than 4 months and has a documented HIV-negative test result.

What is an acceptable level of risk and how do we define this?

The low risk we calculate under the current blood safety protocols is acceptable, as the number of non-detected, potentially infectious donations estimated to not be detected is tolerated in terms of safety. However, these estimates have a high level of uncertainty because of the very low number of incident infections upon which they are based. This uncertainty is typically reported within a range (95% confidence interval). Any change in the estimate of risk consequent to a change in policy should remain acceptable if it is within this range – however, in practice this may be a difficult message to communicate particularly if the estimated risk is shown to double.

Residual risk can only be modelled where there is information on incidence. FAIR did not, therefore, use residual risk modelling but triangulated evidence from behaviours leading to transmission in the general population, epidemiology and behavioural insight into the acceptability and effectiveness of the questions. Appropriate messaging to avoid deferral on session and close monitoring of infections and compliance in donors will also be key.

Reliability of the answers we get to any questions on sexual behaviour

We know that donors are donating non-compliantly ie without declaring their partner risk, from positive donors and a 2014 survey¹⁴, where 130/65,439 donors said they had a partner who may have had sex in Africa but had not reported it at session, giving an adjusted compliance of 99.79% (95%CI 99.75-99.82%). Most of these donors were in England and applying this proportion to the NHSBT donor population of 901,700 that year equates to around 1,800 donors donating with an HRP SSA partner and not declaring it. The majority (95) had a regular partner which leaves 0.05% (35/65,439) non-compliant with a new partner, equating to about 450 donors to NHSBT. However, there were a further 220 donors donating compliantly who said yes to having a partner who fit the HRP SSA description. Of these 599, 39 had disclosed this at session and the majority of the others (343) didn't

¹⁴ Davison KL, Reynolds CA, Andrews N, Brailsford SR; UK Blood Donor Survey Steering Group. Getting personal with blood donors - the rationale for, methodology of and an overview of participants in the UK blood donor survey. Transfus Med. 2015;25(4):265-275.

think their partner had really been at risk of HIV but couldn't be 100% sure. Sixty-three donors didn't know their partner well enough to be sure and 17 donors thought their partners might have been at risk, one saying they had gone for STI testing afterwards and two relying on donation testing. Altogether, 949 (1.45%) of donors may have had a partner who fitted the HRP SSA description.

It is unlikely we know new partners so well. In the literature review for FAIR, no key studies identified a link between having a new partner and HIV/STI risk. The lack of data is thought to be due to how studies have defined new partner, for example as casual partner, and thus a precautionary approach was taken to consider at increased risk to a regular partner.

In FAIR surveys, the anal condom use question was less reliable than other questions.

Estimates of how many additional HIV positive donors we might expect by removing the deferral completely

It is possible that by removing the HRP SSA question additional HIV positive donors are identified among the newly eligible population. To determine how many are expected relies on knowing the size of the newly eligible population and the rate of HIV among them. As these data are not routinely available, we have considered data about HIV detected in current HRP SSA donors, along with data about undiagnosed HIV in Black African and non-Black African heterosexuals as the main populations affected. Three scenarios giving rise to additional HIV positive donors are considered, and an estimate of the number is made. For each scenario there are many assumptions and thus these estimates probably represent the upper end of the scale.

HIV in current HRP SSA donors:

In a 2014 survey 1.45% of donors reported a partner for whom they knew or were not sure the HRP SSA question applied with 0.2% non-compliant ie did not report their partner at session. Applying these proportions gives an annual rate of HIV seen in all donors reporting HRP SSA of 0.007% (1/14,616) or approx. 1 in 14,000 donors and 0.02% (0.4/2,016) or 1 in 5,000 non-compliant donors based on 2 HIV positive donors non-compliant to the HRP SSA question in 5 years, 3 others were compliant (Table 9). Overall there was an annual mean of 1 HIV positive in 100,000 donors based on 49 HIV positive in 5 years.

Annual data	Total donors	New donors	Repeat donors
Annual Donors UK	1,008,000	166,000	842,000
HRP SSA Q applies to 1.45% (2.15 new/1.18 rpt)	14,616	3,569	9,936
HRP SSA non-compliant at 0.2% (0.29 new/0.16 rpt)	2,016	488	1364
Mean annual HIV Positive donors reporting HRP SSA	1	0.4	0.6
% all HIV positive donors reporting HRP SSA compliant or not	0.007%	0.011%	0.006%
Mean annual number positive and non-compliant*	0.40	0.2	0.2
% of non-compliant donors to the HRP SSA Q who were positive	0.02%	0.04%	0.01%

Table 9: HIV in current donors reporting HRP SSA

*one donor was counted as likely non-compliant here as timing on partner not available but avidity testing showed likely acquired within 4 months.

Three scenarios giving rise to additional HIV positive donors are proposed as:

Scenario 1: currently we estimate that 0.5% of the Black African population in England are donating blood. If all the 1,300 undiagnosed Black Africans living with HIV had been subject to the HRP SSA 3m deferral and started donating at current black African donor rate of 0.5% this would equate to 6-7 people donating with undiagnosed infection which may be prevalent or incident.

Scenario 2: If incidence in Black African donors was 0.17% and the Black African donor population doubled then in 3,500 newly eligible donors we would expect 6 incident infections. However, this estimate of incidence was based on SHS attendees in 2013 and would be expected to be lower in non-attendees and lower given declining incidence and number of new diagnoses.

Scenario 3: We could assume at the top end of the scale that all those heterosexual adults living with undiagnosed HIV had a donor partner (Table 10). If they have vaginal sex 3 times a month with a transmission rate of 8 or 4 HIV transmissions per 10,000 penile-vaginal sex acts for receptive and insertive acts respectively then we can estimate how many HIV infections we could expect. For the donors reporting heterosexual contact with a non-Black African partner we excluded sex abroad. In the 1,800 heterosexuals excluding Black African adults using these assumptions we estimated 39 transmissions to their partner but we only observed an average of 4 HIV positive donors per year who reported heterosexual transmission that was not abroad and not with a Black African partner ie an 11-fold reduction in total HIV and a 97-fold reduction in recent HIV infections. In donors with Black African partners we currently see 26 and 130-fold lower total and recent HIV infections than what would be expected. But if the HRP SSA deferral was removed and assuming the same fold reduction as seen in other heterosexuals then we might see 2-3

(26/11) total HIV infections per year and 1 recent infection every 4 years. Note that there are higher numbers and prevalence of GBM and Black African heterosexual adults living with undiagnosed and diagnosed transmissible HIV. Even using these numbers does not introduce more than 6 new infections per year.

In reality all 3 scenarios could partially apply. The estimated range could be 0 to 6 incident infections per year. The higher risk appears to come from scenario 2 where the assumptions are out of date and may not hold true in donors who are asked not to donate if they think they could be at risk of HIV. Those heterosexuals currently donating appear to be at lower risk for HIV than in the general population. Removing the HRP SSA deferral would allow those people in regular partnerships who currently find it more difficult to donate to donate assuming all other deferral criteria met.

We have not included a scenario for donors having sex in Sub-Saharan Africa as these donors would be subject to 4 or 6-month travel deferrals.

Table 10: Scenario 3, assume all heterosexual adults living with undiagnosed HIV are partners of a blood donor

Assumptions and Estimates	Black African heterosexuals	Heterosexuals excluding Black African
N living with undiagnosed HIV in the UK ¹	1,300	1,800
Sex 3 times per month = X acts per year ²	46,800	64,800
8 or 4 transmissions per 10,000 acts ³	26	39
Donors with:	Black African heterosexual partner	Heterosexual partner UK excluding Black African
Annual mean number of HIV positive donors observed ⁴	1	4
Mean annual number recent infections in donors ⁴	0.2	0.4
X fold lower in all infections	26	11
X fold lower in recent infection	130	97

1 O'Halloran et al. HIV in the United Kingdom: Towards Zero 2030. 2019 report. December 2019, Public Health England, London.

2 NATSAL median number of sex acts is 3/month - Wellings et al. Changes in, and factors associated with, frequency of sex in Britain: evidence from three National Surveys of Sexual Attitudes and Lifestyles (Natsal). BMJ. 2019 May 7;365:I1525. <u>https://pubmed.ncbi.nlm.nih.gov/31064762/</u>

3 Receptive penile-vaginal 8 per 10,000 acts, Insertive penile-vaginal 4 per 10,000 acts estimated for male and females then combined to give a total. Patel et al. Estimating per-act HIV transmission risk: a systematic review. AIDS. 2014 Jun 19;28(10):1509-19.

4 Mean annual number of HIV infection in donors reporting heterosexual contact with Black African partner or other heterosexual partner UK 2015-2019 from NHSBT/PHE database. Recent infection defined as acquired within 12 months.

Is the HRP SSA deferral valid under FAIR?

Under the current deferral system, we have seen few recent HIV infections where the reported exposure was higher risk partner from sub-Saharan Africa (HRP SSA) although we know from a 2014 survey that there are a small number of donors who are not compliant to the deferral criteria.

Under the new FAIR system a more individualised donor selection policy will be introduced resulting in donor selection questions being gender neutral and new deferrals for behaviours which either are markers of increased risk of acquiring a blood-borne-infection (BBI) or may impact on the ability of current tests to identify a BBI in the donation samples.

Under FAIR, deferrals will apply for people reporting:

- previous ano-genital bacterial infection (syphilis ever, gonorrhoea 3m)
- taking preventative medication for HIV (3m)
- chem sex (3m)
- being paid for sex (3m)
- partner who has ever been paid for sex (3m)
- partner who has ever injected non-prescribed drugs (3m)
- partner who may ever have had sex in parts of the world where AIDS/HIV is very common (this includes most countries in Africa) (3m)
- partner who has a BBV (3m)
- partner who has HTLV (3m)

If one new or multiple partners within 3m donors answer a question on anal sex:

• anal sex with new/multiple partners 3m

For example, if you had anal sex with a new partner in the last 3 months we would defer you. This means, *unless a deferral above applies* anyone can donate with:

- a regular partner of more than 3m
- new or multiple partners within 3m but only vaginal or oral sex
- no partners within 3 months (as before)

Therefore, GBM with a regular partner will be allowed to donate without a deferral under FAIR if they meet all the criteria but a person whose partner who may ever have had sex in parts of the world where AIDS/HIV is very common would be deferred or asked to bring in their partner for testing if the question stays.

Post-implementation monitoring

The FAIR donor selection policy will be implemented across all four UK blood services in the summer of 2021. Post-implementation monitoring is required to ensure there are no unforeseen consequences on either the safety or supply of blood.

To do this, several processes will be in place. These include adapting well established surveillance/monitoring and other information systems to monitor changes in the number and type of infections confirmed among donors and unexpected changes in the number of donors, as well as developing new research and monitoring systems. This new work includes further work on virological markers and PrEP and a survey of the characteristics of people donating under FAIR with respect to gender and sexuality, and their views about donation.

Data will be reviewed at regular intervals, and the overall impact of the change will be reviewed 12-months post implementation. These reviews will aim to identify whether the FAIR criteria are effective in maintaining a safe supply, or if any changes are required. This could include changes to the messaging and training around the delivery of the new selection policy. As a worst case, if FAIR is assessed post implementation to be negatively impacting on safety then donor selection may be taken to revert to a 3-month deferral for individuals with sexual partners with increased risk behaviours.

Options for the HRP SSA deferral considered by FAIR II steering group:

1. Keep the question

- a. change wording &/or explain rationale?
- 2. Remove deferral for regular partners/keep for new partners
 - a. narrow to new partners born in areas where HIV common?
 - b. specify both SSA and Thailand?
- 3. Remove the question

The following tables on pages 27 and 28 shows pros and cons for each option.

Epidemiology considerations in general population					
Кеер	Remove for regular	Remove completely			
Could be justified if HIV transmission via sex between men more likely in first 3 months of relationship than in heterosexual men and women	GBM with a regular partner will be allowed to donate without a deferral under FAIR if they meet all the criteria (GBM <i>overall</i> have higher level undiagnosed HIV than Black African adults and are recommended for regular testing)	Other FAIR deferrals may cover those at higher risk of HIV transmission– eg bacterial STI, chem sex, anal sex with multiple or new partner(s) What constitutes higher risk of HIV in people with Black African partners <i>extra</i> to that covered by FAIR?			
The number of people diagnosed late and were at risk of passing on HIV to partners if having unprotected sex is still high in heterosexual men and women >50% compared with GBM 33% (Condom use is an unreliable safety question for blood donation)	UK prevalence of undiagnosed HIV infection highest in GBM <i>overall</i> (1 in 147), lower in Black African adults (1 in 606), lowest in all heterosexual men and women (1 in 10,000)				
Black African men and women accounted for 44% of new HIV diagnoses among adults who acquired HIV heterosexually in 2018 4-fold incidence in Black African heterosexuals compared with all heterosexuals in 1 study in SHS	No evidence that regular HIV testing needed in Black Africans: only 1/4584 retested for HIV within 12 months of an initial negative test retested positive among heterosexual patients of a diverse range of ethnicities attending London sexual health services Raised incidence is from a low starting point	Low incidence in heterosexuals			
Nearly half of all adults diagnosed in 2018 who acquired HIV heterosexually were born in a high HIV prevalence country (HPC)	The current deferral Q reflects sexual transmission risk in HIV endemic area We could attempt to simplify the Q to new partner born in HPC– BUT we haven't tested this for effectiveness or acceptability. It could be a prompt to think about risk -if donors know if their new partner was born in the UK vs born in SSA for example				

Evidence based on infections in blood donors under the deferral					
Кеер	Remove for regular	Remove completely			
		Very low residual risk of HIV			
If low number of HIV positive donors reporting HRP SSA is just due to HRP SSA deferral	If low number of positive donors reporting HRP SSA is due to other deferrals or good knowledge of status in general population We know donors not declaring partners	If low and declining number of positive donors reporting HRP SSA is due to good knowledge of status in general population and compliance to donor selection			
HIV NAT pick up in 2008 in a donor with a regular HRP SSA partner of more than 3 months	2019 case of recent HIV where donor reported HRP SSA in new partners, NAT pick up in 2004 where donor reported HRP SSA in new partners	HRP SSA as a source of infection has been declining in donors perhaps with better awareness of status in the general population			
Anecdotally, HBV and HTLV have been identified in regular HRP SSA partners coming forward to give a sample so that their partners may donate	Anecdotally, we have not identified HIV in regular HRP SSA partners coming forward to give a sample so that their partners may donate				
Will donor messaging about new partners help donors assess their own risk?	Removes need for regular partners to give a sample (NHSBT) Less likely to know HIV status of a new or one-off partner Can be asked after gateway, removes Q for many donors, may not need to go on DHC	Best option for improving trust among Black donors Higher risk behaviour including anal sex with a new partner is covered already			

Appendices

A.1 List of countries where HIV prevalence is 1% or greater, 2018, UNAIDS

* Country of birth where 10 or more people were diagnosed with HIV in the UK in 2018

Africa

Angola*, Benin, Botswana*, Burundi, Cameroon*, Central African Republic, Chad, Cote d'Ivoire*, Djibouti, Equatorial Guinea, Eswatini, Ethiopia*, Gabon, the Gambia, Ghana*, Guinea*, Guinea-Bissau, Kenya*, Lesotho, Liberia, Malawi*, Mali, Mauritius, Mozambique, Namibia*, Nigeria*, Republic of the Congo*, Rwanda, Sierra Leone*, South Africa*, South Sudan, Togo, Uganda*, United Republic of Tanzania*, Zambia*, Zimbabwe*

Latin America and the Caribbean

Antigua and Barbuda, Bahamas, Barbados, Belize, Guyana, Haiti, Jamaica*, Panama, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago

Europe Ukraine

Asia

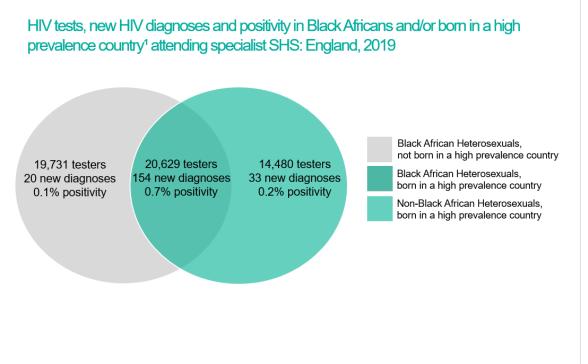
Thailand*

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attach ment_data/file/857480/HIV_in_the_UK_2019_towards_zero_HIV_transmissions_by_20 30_appendix.pdf

A.2 HIV in the UK (2019 data showing same results as 2018 data)

https://www.gov.uk/government/statistics/hiv-annual-data-tables

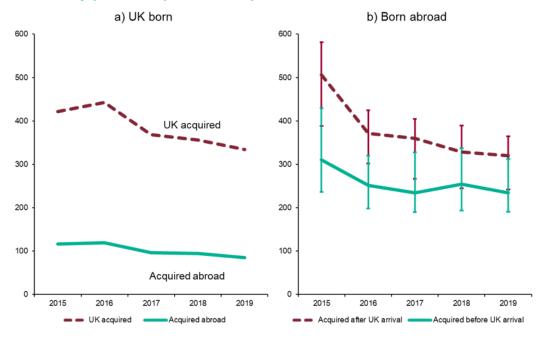
1664 Heterosexual diagnoses 2018	White Het sex		Black African Het sex	
Total	605	38%	683	44%
Region of birth recorded	585		667	
UK	398	68%	24	4%
Europe	143	24%	14	2%
Africa	17	3%	625	94%
Rest	27	5%	4	0%
Late diagnosis				
CD4 count at diagnosis	505		562	
CD4<350	269	53%	309	55%



¹ High diagnosed HIV prevalence country: Country of birth where HIV prevalence is 1% or greater among residents aged 15 to 59 years.

49 HIV in the United Kingdom: 2020 Slide Set (version 1.0, published 3 November 2020)

A.3 HIV in the UK https://www.gov.uk/government/statistics/hiv-annual-data-tables



Estimated number of new diagnoses among heterosexual men and women¹ by probable place of acquisition: UK, 2015 to 2019

1 - excludes people who were previously diagnosed abroad

18 HIV in the United Kingdom: 2020 Slide Set (version 1.0, published 3 November 2020)

Total491224.5NAT pick up-1Seroconversion-10Seroconversion-10GenderMale311135.591.7Female1815.68.3DorotypeNew2428.316.7Repeat25936.075.0Age0.0Age-range18-7128-60-Ethnicity2428.3Median age391025.683.3Asian5120.08.3Black200.00.0Other200.00.0Nk100.00.0String31412.933.3Europe6233.316.7Asia2150.08.3Africa100.00.0Nk7571.44.17Acquired infectionUK29827.666.7Europe5240.016.7Asia100.00.0Other100.00.0Nk29827.666.7Europe5240.016.7Asia133.38.3Africa100.0		HIV ALL	HIV RECENT	% which are recent	% of recent infections
Seroconversion10GenderMale311135.591.7Male311135.591.7Pemale311135.591.7Pemale315.68.3Donor typeNew2428.316.7Repeat25936.075.0Age-range18-7128-6075.0Median age3742.577EthnicityWhite391025.683.3Asian5120.08.3Black200.00.0Nk100.00.0Nk31412.933.3Europe6233.316.7Asia31412.933.3Africa100.00.0Nk2987.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Nk9111.18.3Africa13646.250.0Risgroup13646.250.0HR other313.625.0HR Pother3120.08.3Other3120.08.3Africa1	Total	49	12	24.5	
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Donor typeNew2428.316.7Repeat25936.075.0Age25936.075.0Age18-7128-6010Age-range18-7122-583.3Median age3742.583.3Ethnicity1025.683.3Motion5120.08.3Asian510.00.0Other200.00.0Other200.00.0Nk100.00.0Storn12.933.316.7Europe6233.316.7Asia100.00.0Other200.00.0Other200.00.0Other200.00.0Other200.00.0Other200.00.0Other200.00.0Nk733.38.3Africa100.00.0Other524.0.016.7Mix911.18.3Africa100.00.0Other100.00.0Hir Solution11.18.3Africa1333.61.0Hir Solution12.08.3<	Male	31	11	35.5	91.7
New2428.316.7Repeat25936.075.0Age25936.075.0Age87128-60Median age3742.5Ethnicity942.5White91025.683.3Asian5120.08.3Black200.00.0Other200.00.0Other200.00.0Nk100.00.0Stan121.933.3Europe6233.316.7Asia2150.08.3Africa100.00.0Other200.00.0Nk7571.441.7Acquied infection100.00.0UK9827.666.7Europe5240.016.7Asia100.00.0Nk9111.18.3Africa100.00.0Other23.33.38.3Africa13.650.0HR SA23.43.650.0HRP SA5120.08.3HRP Other313.650.0HRP SA110.00.0HRP SA510.	Female	18	1	5.6	8.3
Repeat 25 9 36.0 75.0 Age 25 0.0 Age-range 18-71 28-60	Donor type				
Age 18-71 28-60 Median age 37 42.5 Ethnicity 99 10 25.6 83.3 Asian 5 1 20.0 8.3 Black 2 0 0.0 0.0 Other 2 0 0.0 0.0 Nk 1 0 0.0 0.0 Born UK 31.4 4 12.9 33.3 Europe 6 2 33.3 16.7 Asia 2 1.1 50.0 8.3 Africa 1 0 0.0 0.0 Nk 7 5 7.6 66.7 Europe 5 2 40.0 16.7 Asia 1 33.3 8.3	New	24	2	8.3	16.7
Age-range18-7128-60Median age3742.5Ethnicity91025.683.3Asian5120.08.3Black200.00.0Other200.00.0Other200.00.0BornUUK31412.933.3Europe6233.316.7Asia200.00.0Other200.00.0Other100.00.0Other200.00.0Other31412.98.3Africa100.00.0Other200.00.0Nk7571.441.7Acquired infection2240.016.7UK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other0K9111.18.3Biskgroup3333HRP SA5120.08.3HRP other3120.08.3Other3120.08.3Other3333Other3333 </td <td>Repeat</td> <td>25</td> <td>9</td> <td>36.0</td> <td>75.0</td>	Repeat	25	9	36.0	75.0
Median age3742.5EthnicityWhite391025.683.3Asian5120.08.3Black200.00.0Other200.00.0Nk100.00.0BornUU00.0Burope6233.316.7Asia2150.08.3Africa100.00.0Other20.00.00.0Africa100.00.0Nk7571.441.7Acquired infectionU0.00.00.0UK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other9827.666.7Europe5240.016.7Asia313.38.3Africa100.00.0Other913.38.3Africa100.00.0Other933.38.3Africa100.00.0Other113.38.3Africa100.00.0Other1111Asia510.08.	Age				0.0
Median age3742.5EthnicityWhite391025.683.3Asian5120.08.3Black200.00.0Other200.00.0Nk10.00.00.0Born12.933.3Europe6233.316.7Asia2150.08.3Africa100.00.0Other200.00.0Other200.00.0Nk757.441.7Africa100.00.0Nk23.38.33.3Africa13.38.33.3Minope23.316.73.3Africa100.00.0Nk23.11.18.3Africa31.18.3Africa1000.0Other91.18.3Africa133.45.0Africa133.65.0Africa13.65.0Africa13.65.0Africa13.65.0Africa51.65.0Africa33.65.0Africa33.65.0Africa13.65.0Africa5	Age-range	18-71	28-60		
White391025.683.3Asian5120.08.3Black200.00.0Other200.00.0Nk100.00.0BornUU33.316.7UK31412.933.3Europe6233.316.7Asia2150.08.3Africa100.00.0Other200.00.0Other200.00.0Nk757.44.7Acquired infectionU0.00.016.7UK29827.666.7Europe5240.016.7Asia313.38.3Africa100.00.0Other000.016.7Europe513.38.3Africa10.00.010.0Other00-10.0BM13646.250.0HRSA5120.08.3HRP other3120.08.3Other100.010.0		37	42.5		
White391025.683.3Asian5120.08.3Black200.00.0Other200.00.0Nk100.00.0BornUU33.316.7UK31412.933.3Europe6233.316.7Asia2150.08.3Africa100.00.0Other200.00.0Other200.00.0Nk757.44.7Acquired infectionU0.00.016.7UK29827.666.7Europe5240.016.7Asia313.38.3Africa100.00.0Other000.016.7Europe513.38.3Africa10.00.010.0Other00-10.0BM13646.250.0HRSA5120.08.3HRP other3120.08.3Other100.010.0	Ethnicity				
Black200.00.0Other200.00.0Nk100.00.0BornUK31412.933.3Europe6233.316.7Asia2150.08.3Africa100.00.0Other200.00.0Nk7571.441.7Acquired infectionUK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other9111.18.3Africa13646.250.0Risk group131.625.0HRP SSA5120.08.3HRP other3120.08.3Other100.00.0	White	39	10	25.6	83.3
Other200.00.0Nk100.00.0Born	Asian	5	1	20.0	8.3
Nk100.00.0BornUK31412.933.3Europe6233.316.7Asia2150.08.3Africa100.00.0Other200.00.0Nk7571.441.7Acquired infectionUV40.016.7UK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other0-11.18.3Risk groupU11.118.3GBM13646.250.0HRP SSA5120.08.3HRP other3120.08.3Other100.00.0	Black	2	0	0.0	0.0
BornUK31412.933.3Europe6233.316.7Asia2150.08.3Africa100.00.0Other200.00.0Nk7571.441.7Acquired infectionUK29827.666.7UK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other0111.18.3Africa13646.250.0BM13646.250.0Het Sex23313.625.0HRP Other3120.08.3Other100.00.0	Other	2	0	0.0	0.0
UK31412.933.3Europe6233.316.7Asia2150.08.3Africa100.00.0Other200.00.0Nk7571.441.7Acquired infectionUK29827.6Europe5240.016.7Asia3133.38.3Africa100.00.0Other0-1011.18.3Africa13646.250.0BM13646.250.0Het Sex23313.625.0HRP Other3120.08.3Other100.08.3Other100.08.3	Nk	1	0	0.0	0.0
Europe 6 2 33.3 16.7 Asia 2 1 50.0 8.3 Africa 1 0 0.0 0.0 Other 2 0 0.0 0.0 Nk 7 5 71.4 41.7 Acquired infection UK 29 8 27.6 66.7 Europe 5 2 40.0 16.7 4.33 Africa 1 0 0.0 0.0 0.0 Other 5 2 40.0 16.7 4.33 3.3 8.3 Africa 1 0 0.0 <	Born				
Asia2150.08.3Africa100.00.0Other200.00.0Nk7571.441.7Acquired infectionUK29827.666.7UK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other00-Nk9111.18.3Risk groupU13646.250.0Het Sex23313.625.0HRP SSA5120.08.3HRP other3120.08.3Other10-0.0	UK	31	4	12.9	33.3
Africa100.00.0Other200.00.0Nk7571.441.7Acquired infectionUK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other0-Nk9111.18.3Risk groupGBM13646.250.0Het Sex23313.625.0HRP other3120.08.3Other10.0.0	Europe	6	2	33.3	16.7
Other200.00.0Nk7571.441.7Acquired infectionUK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other0-111.18.3Risk group111.18.3GBM13646.250.0Het Sex23313.625.0HRP SSA5120.08.3Other10-0.0	Asia	2	1	50.0	8.3
Nk7571.441.7Acquired infectionUK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other00-Nk9111.18.3Risk groupGBM13646.250.0Het Sex23313.625.0HRP other3120.08.3Other10-0.0	Africa	1	0	0.0	0.0
Acquired infectionUK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other00-1Nk9111.18.3Risk groupUUR13.625.0Het Sex23313.625.0HRP SSA5120.08.3Other100.00.0	Other	2	0	0.0	0.0
UK29827.666.7Europe5240.016.7Asia3133.38.3Africa100.00.0Other00-1Nk9111.18.3 Risk group 13646.250.0Het Sex23313.625.0HRP SSA5120.08.3Other10-0.0	Nk	7	5	71.4	41.7
Europe5240.016.7Asia3133.38.3Africa100.00.0Other00-Nk9111.18.3 Risk group GBM13646.250.0Het Sex23313.625.0HRP SSA5120.08.3HRP other3120.08.3Other10-0.0	Acquired infection				
Asia3133.38.3Africa100.00.0Other00Nk9111.18.3Risk group-GBM13646.250.0Het Sex23313.625.0HRP SSA5120.08.3HRP other310.00.0	UK	29	8	27.6	66.7
Asia3133.38.3Africa100.00.0Other00Nk9111.18.3Risk group-GBM13646.250.0Het Sex23313.625.0HRP SSA5120.08.3HRP other310.00.0	Europe	5	2	40.0	16.7
Other00-Nk9111.18.3Risk groupGBM13646.250.0Het Sex23313.625.0HRP SSA5120.08.3HRP other3120.08.3Other100.0		3	1	33.3	8.3
Nk9111.18.3Risk group </td <td>Africa</td> <td>1</td> <td>0</td> <td>0.0</td> <td>0.0</td>	Africa	1	0	0.0	0.0
Risk group GBM 13 6 46.2 50.0 Het Sex 23 3 13.6 25.0 HRP SSA 5 1 20.0 8.3 HRP other 3 1 20.0 8.3 Other 1 0 0.0 0.0	Other	0	0	-	
GBM13646.250.0Het Sex23313.625.0HRP SSA5120.08.3HRP other3120.08.3Other100.0	Nk	9	1	11.1	8.3
Het Sex23313.625.0HRP SSA5120.08.3HRP other3120.08.3Other100.0	Risk group				
HRP SSA5120.08.3HRP other3120.08.3Other100.0	GBM	13	6	46.2	50.0
HRP other 3 1 20.0 8.3 Other 1 0 0.0	Het Sex	23	3	13.6	25.0
Other 1 0 0.0	HRP SSA	5	1	20.0	8.3
	HRP other	3	1	20.0	8.3
Nk 4 1 25.0 8.3	Other	1	0		0.0
	Nk	4	1	25.0	8.3

A.4 HIV in blood donors, all and recent infection, UK 2015-2019

A.5 HBV in blood donors, all and recent infection, UK 2015-2019

	HBV ALL	HBV RECENT	% which are recent	% of recent infections
Total	307	17	5.5	
NAT pick up	-	3		
Seroconversion	-	14		
Gender				
Male	230	13	5.7	76.5
Female	77	4	5.2	23.5
Donor type				
New	286	3	1.0	17.6
Repeat	21	14	66.7	82.4
Age				
Age-range	17-70	21-61		
Median age	34	50		
Ethnicity				
White	115	13	11.3	76.5
Asian	89	1	1.1	5.9
Black	71	2	2.8	11.8
Other	28	0	0.0	0.0
Nk	4	1	25.0	5.9
Born				
UK	31	8	25.8	47.1
Europe	87	4	4.6	23.5
Asia	91	0	0.0	0.0
Africa	70	1	1.4	5.9
Other	3	0	0.0	0.0
Nk	25	4	16.0	23.5
Acquired infection				
UK	20	8	40.0	47.1
Europe	67	3	4.5	17.6
Asia	76	3	3.9	17.6
Africa	59	0	0.0	0.0
Other	3	0	0.0	0.0
Nk	82	3	3.7	17.6
Risk group				
GBM	2	2	100.0	11.8
Het Sex	18	10	55.6	58.8
HRP SSA	0	0	0.0	0.0
HRP other	3	0	0.0	0.0
Other	241	1	0.4	5.9
Nk	43	4	9.3	23.5