December 2020

Can donor selection policy move from a population-based donor selection policy to one based on a more individualised risk assessment? Conclusions from the For the Assessment of Individualised Risk (FAIR) group

1. Executive summary and recommendations

For the Assessment of Individualised Risk (FAIR) steering group have taken an evidence-based approach to review whether the UK blood services could move to a more individualised blood donor selection policy. This work has focussed on behaviours associated with acquiring blood borne infections (BBIs) and using both epidemiology and behavioural science we have made recommendations as to donor eligibility. The work has focussed on men who have sex with men (MSM) and what changes could be introduced now as a move towards a more individualised donor selection policy.

The epidemiological review looks at the literature relating to higher risk sexual behaviours and markers of risk; observed data in current donors and risk factors, and survey data on behaviours and acceptability of questions in current donors. The behavioural work including focus groups and surveys of a range of stakeholders including donors, potential donors, staff, MSM and patients and assessment of reproducibility, acceptability and robustness of potential questions. The work also explored the concept of risk and how communication with current and new donors could ensure that donors understand the importance of donor selection in maintaining blood safety and protecting blood recipients from infection.

The current donor health check asks a number of general questions about donor health and specific questions about infection in the donor's partner. Questions relating to infection risk are asked of donors and risks in their partners including injecting drug use, paying for sex and for men, whether they have had sex with another man in the last 3 months. The donor selection guidelines for men who have sex with men were changed in 2017 resulting in a change from a 12 month to 3 month deferral from last sex with a man, (Northern Ireland made this change in 2020). There is no evidence that this change to donor selection policy has impacted on the safety of the blood supply in the UK.

Current blood safety measures include both donor selection and donation testing, over recent years the sensitivity of donation screening has improved with the introduction of smaller NAT pool sizes. Overall rates of infection in donors have decreased with the exception of syphilis where the rise in infections has mirrored that in the general population. There are a small number of reports of syphilis being transmitted by transfusion but these have been from whole blood or fresh plasma. There have been no reports of transmission in the UK.

Since the time of the last SaBTO review in 2017 a number of countries have reduced their time based deferral for MSM, including Canada, USA (3 months), and The Netherlands (4 months).

Considerations and recommendations for a more individualised risk-based donor selection policy are as follows:

1. A review of the current epidemiological literature and observed data in donors and the wider population has identified the following behaviours as having increased risk of acquiring BBIs through sex: a bacterial sexually transmitted infection (STI) in the last 12 months, chemsex, sex under the influence of drugs except cannabis and Viagra, multiple or new sexual partners. Analysis of psychometric data using principle components analysis showed that certain behaviours shared common covariance specifically: new sexual partner, multiple partners chemsex and recent STI diagnosis. People who reported one of these behaviours also had a higher probability of reporting one of the other behaviours too. However, it is acknowledged that these questions are open to impression management bias which will need to be managed. Questions related to behaviours with higher epidemiological risk have high reliability. These epidemiological higher risk questions map 100% onto the proposed gateway question. Those who score higher on the epidemiological higher risk factors perceive their risk of a future STI to be higher and therefore may be more likely to self-defer and not donate.
2. The group agreed that a more individualised risk-based approach should be taken to blood donor selection policy. The group explored how such an individualised risk approach could be applied to allow more men who have sex with men (MSM) to become donors. Specifically, this would result in a move from a population-based 3 month deferral for all MSM to a donor selection policy based on deferral of potential donors with higher risk behaviours associated with acquiring infections. It was acknowledged that this is the first step towards a donor selection policy entirely based on an individual assessment of risk.
3. Any current approach to a more individualised risk assessment must take into account the evidence but also what is practical given the current paper- based donor health check (DHC) system. Wales currently has an electronic system which is only used on session. Although all countries are exploring electronic donor health check systems, which may eventually allow completion ahead of session, this is not currently available.
4. This initial step towards a more individualised risk-based policy includes the introduction of gender neutral questions. Participants in the focus groups, and other stakeholders, were very keen that any changes to the donor health check should be communicated to current and new donors and that information was clear about the reason for this approach. There was also a recommendation to rename the DHC to emphasise that this is not only about donor health but also recipient safety.

5. The group recommends that two new questions should be asked of all donors reporting sex: 1) treatment for gonorrhoea or syphilis in the last 12 months and 2) history of chemsex in the last 3 months.
6. It was acknowledged that the current deferral for PrEP will remain in place. If the outcome of the review of national PrEP guidelines including impact on PrEP on HIV testing suggests that the current deferral could be removed a further recommendation to SaBTO will be made. It is recommended that JPAC should refer current PrEP selection criteria in September 2021.

   The current question asking about a partner's HIV status and donor eligibility should be reviewed considering current HIV treatment options and undetectable status.
7. Current questions relating to donor health, travel and partner risk should remain.
8. It is proposed that all potential donors who have ever had sex will be asked if they had a new sexual partner or more than one sexual partner in the last 3 months. If 'yes', donors will be asked if they had anal sex with their partner(s) regardless of whether they consistently used condoms. From this, donors who have had one sexual partner who was not new in the last 3 months are eligible to donate irrespective of gender, gender of partner or type of sex. This policy would mean that MSM in long-term partnerships would be eligible to donate. Donors who have had a new partner or more than one sexual partner in last 3 months are eligible if they had oral or vaginal sex, but not if have had anal sex with or without a condom.

   Other options were considered including asking all donors about condom use regardless of sexual behaviour if donors reported >1 or a new partner in the last 3 months, however this would result in significant donor loss including donors who are currently eligible.
9. The group also considered whether those donors who would be deferred under the proposed multiple/new partner/anal sex question could be retained if consistent condom use was reported. The psychometric work concluded that questions about condom use did not result in reliable responses compared to other behaviours. In addition there were concerns that more detailed questioning would be more difficult in a session environment due to limited privacy However, an electronic donor health check could potentially facilitate more detailed questions like these and it is recommended that future work should be undertaken to see how computer assisted donor health check could be implemented.
10. It is recommended that the new donor selection process should be piloted, this may be as a table-top exercise, prior to full implementation to ensure training materials and monitoring processes are appropriate.
11. An impact assessment should consider how the proposed questions would affect gay and bisexual men, women from minority ethnic groups and trans persons.

12. A number of recommendations have been made in terms of language used including use of risk versus safety, and ways of recruiting donors. In addition, the psychometric work supports the use of prompts prior to donation to remind donors to think about recent behaviours.
13. The process for managing deferrals should be reviewed to ensure that staff understand the reasons for deferral and can explain this to donors. In addition, it is recommended that the UK blood services review their communications to ensure that deferred donors are not thanked for their donation.
14. The group acknowledged that any implementation would need to take into account the current pressures due to the response to the COVID-19 pandemic.
15. A plan for implementation and evaluation should be devised. Recommendations for routine monitoring of infections, compliance with donor selection criteria and donor loss are made in this report. Syphilis screening should be maintained as a useful measure to of donor behaviour.
16. There is a concern that the questions themselves may deter new donors, especially questions about anal sex and the importance of communications with current and potential donors is acknowledged.
17. Patients have recommended that more should be done to make donors aware of the impact of donation on their lives, they are concerned that any change may result in a reduction in donors but trust the blood services to maintain the safety of the blood supply.
18. A number of developments for donor selection questions have been identified. As such a process for future proofing the recommendations should be developed such that any adjustments can be made effectively. The group was very clear that if accepted these recommendations are the first step towards a truly individualised donor selection policy and as such the donor selection guidelines should remain under regular yearly review by JPAC and SaBTO.

The data collection and analysis were carried out by the psychology team at the University of Nottingham: Professor Eamonn Ferguson, Dr Claire Lawrence, Dr Naomi Pierce and Erin Dawe-Lane; and the joint NHBT/PHE Epidemiology Unit: Katy Davison, Claire Reynolds, Joe Flannagan, and Zoe Gibney. Joe Flannagan provided the secretariat function for FAIR steering group with support from Tali Yawitch (NHBT/PHE Epidemiology Unit).

We would like to acknowledge all of the participants in the surveys and focus group, and the support of blood service staff and academic colleagues across the four nations.

2. Introduction

The safety and security of the blood supply is dependent on blood donor selection policies and blood donation testing. However, other issues that must be taken into consideration are donor motivations, understanding of, and compliance with, the donor selection criteria. Without appropriate donor engagement and compliance, the actual donor selection policies become irrelevant.

The donor selection criteria for behaviours related to sex were last reviewed by SaBTO in 2017 when donor selection criteria were changed for men who have sex with men (MSM) and commercial sex workers (CSW) from a 12-month to a 3-month deferral and permanent to 3-month deferral respectively. At the time this was a huge change based on analysis of the evidence that determined that this deferral period would be sufficient to ensure that any undiagnosed blood borne infections would be picked up by screening techniques. The UK blood services were some of the first to move to such a short deferral. The impact of the change on blood safety has been evaluated by monitoring infections in donors and associated risk factors. However, the impact on the numbers of MSM and CSW donating has not been evaluated as donors are not asked to identify as MSM or CSW but to report if they have had sex with another man or in exchange for money/drugs within the last 3-months.

The change to the donor selection criteria was introduced in England, Scotland and Wales from late 2017. Until very recently Northern Ireland maintained a 12-month deferral. Shortly after the deferrals were introduced the minister for public health urged NHSBT to look towards introducing a more individualised donor selection policy. Donor selection criteria related to sex falls within the remit of SaBTO and generally recommendations are made to ministers before a change is introduced. Since the 2017 change, a number of interested parties have continued to advocate for change to NHSBT and the other blood services to ensure that blood donation policies are both safe and non-discriminatory.

Analysis of data from 2018 showed no major impact on infection rates, therefore a funding request was made to the UK Forum following failure to attract external funding. This funding was to support a programme of work to look at a more individualised risk assessment. Funding was agreed in December 2018 for a piece of work to consider both behavioural and epidemiological aspects of moving to a more individualised risk assessment which could be introduced across the four UK blood services.

Once the initial discussions about the type of study required was nearing completion, a steering group was set up to take this work forward and to provide oversight and scrutiny of any chosen strategy. The group has a wide membership including both donor and patient representatives as well as interested parties from the main UK charities representing LGBTQ+ health issues.

The FAIR steering group was set up to provide input into the development, monitoring and delivery of a package of work relating to a more individualised risk assessment methodology for donor selection criteria (Appendix 1: FAIR steering group membership 2020).

3. Background

3.1. Donor selection and donation testing: current situation

Donor selection

Current donor selection guidelines can be found here www.transfusionguidelines.org. Since the SaBTO review finalised in 2017, MSM have been able to donate if it is more than 3 months since last sex.

Donor health check process

There are slightly different donor health check processes used across the UK based on a mixture of paper based and electronic forms. Although the form may be completed ahead of the session there is still discussion between donor and staff at session, and consent is taken on the day. Donors are asked to read a 'Welcome booklet' and answer a series of questions about their general health, social behaviours including sex, travel and long stay abroad. Some questions are asked only at the first donation whereas others must be asked at every donation.

Donors who answer yes to any question have a further discussion with one of the donation colleagues prior to their haemoglobin test.

Current testing and approaches to donor follow-up

Donation testing is based on a combination of serology tests on single donations and molecular tests for HCV, HIV and HBV which detect RNA or DNA and are carried out in pools. Currently, screening is carried out in a pool of 24. The size of the pool impacts on the sensitivity of the test. All molecular tests except for HCV RNA are additional to that required under the EU directive 2004/33/EU. Since 2009 the UK blood services have been using molecular tests for HIV, HCV and HBV which has resulted in increased sensitivity and associated reduced window periods for these infections. The current estimates for the infectious window period, when a virus may be infectious but not detected by current testing are as follows 4 days for HCV, 9 days for HIV and 30 days for HBV. However, this does not take into account other biological factors which may impact on detection or the non-infectious window. HEV virus is also screened for using NAT in pools of 24 or 16 depending on the blood service. (Appendix 2: Markers routinely tested for by UK blood services in 2020)

Additional testing

Other additional (discretionary) tests may be performed including the detection of antibodies to hepatitis B core antigen (anti-HBc), malaria (2002) and *Trypanosoma cruzi* (Chagas disease, 1998) and

nucleic acid testing (NAT) for West Nile virus (WNV, 2012). These tests are only performed if information given by the donor suggests that they may have been at risk for these infections. For example, Malaria or *T. cruzi* testing is performed where the donor reports a relevant travel history, residency in the epidemic area, or past infection. Donations confirmed positive for malarial antibodies are tested for malarial DNA by PCR. Additional testing indications can be found in the donor selection guidelines on the transfusion guidelines website:www.transfusionguidelines.org.

3.2.Surveillance of donors with markers of infection

When a marker of infection is detected in a blood donation, the donor is offered a post-test discussion, which may be held in a blood centre or more commonly by telephone. The donor is informed of their positive test results and the clinician explains what these test results mean and ascertains a likely source or risk factor for the infection, if possible. The clinician also discusses any infection control measures, testing and treatment of contacts and advises the donor that they will no longer be able to donate blood. Where appropriate, the donor is referred for specialist care.

Clinicians in blood centres in the UK (excluding Scotland) and Republic of Ireland pass anonymised information about infected blood donors to the Epidemiology Unit infected blood donor surveillance scheme using a standard electronic proforma. This information includes the characteristics of the infected donors (date of birth, gender, first part of postcode), details of their donating history (if any, with details of their most recent previous donation) and any behaviour that could be associated with the donor's infection. Infected donors are classified by the Epidemiology Unit as newly tested and previously tested for the marker they are found positive for according to detailed information provided by blood centres about all/any previous donations in the UK. Data from Scotland is supplied on an annual basis.

In recent years more effort has been made to ask donors about why they donated and why they did not comply with the donor selection guidelines in cases where they had a known infection or risk but did not disclose this. This is collected in routine surveillance and is an important part of monitoring the effectiveness of donor selection. Information on donor risk factors and compliance are reported in the annual NHSBT/PHE Epidemiology report [https://hospital.blood.co.uk/diagnostic-services/microbiology-services/epidemiology/] . The risk of a transfusion transmitted infection is rare. Each year this risk is estimated using observed donation testing data, in addition these estimates can be compared with known transfusion transmitted infections (TTIs). Surveillance of TTIs is a passive system and relies on reports made by hospital colleagues.

3.3.Transfusion transmitted infection surveillance

Blood centres in England, Wales and Northern Ireland report investigations of suspected transfusion-transmitted infections (TTIs) to the NHSBT/PHE Epidemiology Unit. For each report, information on the recipient, the recipient's infection, the implicated transfusion and findings of the investigation are provided using a detailed proforma. Blood centres in Scotland report all incidents to the Microbiology Reference Unit of the SNBTS, and the details and conclusion of each case are passed to the surveillance system annually. NHSBT/PHE Epidemiology Unit data are reconciled with the Serious Hazards of Transfusion (SHOT) and all blood service investigations with outcomes are included in the TTI chapter in the SHOT annual report [https://www.shotuk.org/]. The number of confirmed TTI incidents by years of transfusion in the UK is shown in Appendix 3: Transfusion transmitted infections, UK.

In recent years the majority of confirmed TTIs have been due to hepatitis E virus (HEV), however there have also been reports of occult hepatitis B transmissions; although not always possible to confirm due to low viral loads they appeared to be the likely source of infection in the affected patients. These occult hepatitis B transmissions are due to long standing chronic hepatitis B infections that may be missed on screening due to lack of HBsAg and low level of DNA in the sample being tested and circulating in the blood of the donor. This contrasts to acute hepatitis B virus infections, where potentially infectious donations may be missed due to the infection being recently acquired and in the window period. Any reduction in deferral times, or potential removal of deferral entirely, may result in an increased risk of window period infections if those donors newly eligible to donate have a recently acquired infection. Previous assessments of the impact of a change in donors deferral criteria regarding MSM have considered the impact on HIV residual risk. This has not been done here because given the very low due to a lack of appropriate data about incidence of HBV infections in the newly eligible population required for the modelling approach previously used.

3.4.International policy on blood donor selection regarding sex between men

EU Directive

Countries whose blood services are regulated under the EU directive interpret the donor selection criteria related to sexual behaviours in a number of ways. The European Union Directive 2004/33/EU states that there is a requirement for permanent deferral of 'persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood'; the definition of high-risk sexual behaviour is open to interpretation thus policies between countries can vary, and within countries there has been the potential for change.[1] The specific sexual behaviours

for which a deferral is deemed necessary will depend on the local epidemiology of HIV and other blood borne virus infections, the social and political influences within the country and the tests available for donation screening.[2] All countries apply a risk assessment to individual donors using a proforma and/or a face to face interview prior to donation; potential donors are asked about recent partners, and their viral status. Countries using gender neutral questions, ask about new or multiple partners.

Time-based deferral

Many countries first introduced a permanent deferral for men who have sex with men in the 1980s following the identification of HIV. Since then, a number have changed to a policy based on a period of time since last sex with another man (Table 3.1).[3, 4] Australia was the first country to introduce a 12-month deferral in 2000.[5] The UK, excluding Northern Ireland, was next to change to 12-months in 2011 with others following.[6] In late 2017, the UK, excluding Northern Ireland, was the first country to reduce the deferral further to 3-months since last sex between men (SBM), and Canada made the same change in 2018 (Northern Ireland changed in June 2020). To address the urgent need for blood in the US during the COVID-19 pandemic, the FDA in April 2020 revised several donor eligibility criteria for US blood services, this included reducing the deferral of MSM from 12-months to three.[1] A 3-month deferral has also been approved by the Australian regulators and is likely to be implemented at the end of 2020.[2] Three months remains the shortest time-based deferral worldwide, however 4-months has been adopted in Netherlands, France and Denmark.[7] Three months is based on the views of international peers that an interval of deferral should be at least twice the longest window period for the infection the supply is at most risk of, which for the UK is hepatitis B at 30 days, plus a precautionary 30 days.

Individualised risk assessment

Some countries in Europe have no specific deferral related to SBM. Italy, Spain, and most recently Hungary (2020), have policies based on sexual behaviours considered to be at higher risk regardless of partner gender. These include sex with a new partner, or multiple partners, and knowledge of a partner's risk behaviour. There are some key differences in the operation of blood centres for countries adopting this policy compared to those with time-based deferrals. Firstly, donors are interviewed face to face by a clinician to facilitate the more detailed questioning; there is no national blood service and the process is not well standardised across centres. Secondly, policies were introduced into law by government without formal risk assessment or analysis of the impact.

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[1] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-updated-guidance-address-urgent-need-blood-during-pandemic

[2] https://www.donateblood.com.au/sexual-activity-deferral-review

Italy changed from permanent deferral for SBM to sexual deferrals regardless of partner gender in 2001. Males and females are deferred for 4-months since sex with a new/occasional partner whose behaviour is unknown, or indefinitely for a usual/regular sex with multiple new partners. A study comparing HIV rates before and after the change showed no significant difference but were high in both first-time and repeat donors (12.3 per 100,000 and 3.8 per 100,000 in 2010) compared to many Northern European countries.[8, 9] Since 2015, all donors have a face to face interview in Italy in order to facilitate more effective selection, however, HIV rates remain high.[10] In 2018, HIV rate in first-time donors in Italy was 14.2 per 100,000.[3] In comparison in the UK HIV prevalence was 1.5 per 100,000 first-time donors.[4]

In Spain donors are deferred for 12 months for sex with more than one concurrent partner, or sex with an occasional partner. Published data to 2014 found HIV prevalence around 7.7 per 100,000, with levels only slightly lower in repeat donors. The authors reported rates similar to general population estimates, suggesting an ineffective selection policy.[11] In Russia, 'homosexual' deferral was deleted from the official order regarding medical examination of blood donors in 2008, and there is no documented deferral of MSM. In Poland donors are not asked specific sexual behaviour questions. [3]

[3] https://www.centronazionalesangue.it/node/90
[4] https://hospital.blood.co.uk/epidemiology-reports/

Table 3.1: Blood donor deferral relating to sex between men by country, June 2020

Country	Current deferral sex between men	Date of most recent change/ Other information
Argentina	None - unless 'high risk'	2015
Hungary	None - unless 'high risk'	2020
Italy	None or 4-months if new partner, or sex with occasional partner	2001
Russia	No documented deferral	2008
Spain	None or 12 m if > partner, or sex with an occasional partner	2005
UK	3 months	2017. Male and female donors with sexual partners with increased risk behaviours (Northern Ireland June 2020)
Canada	3 months	June 2019
USA	3 months	April 2020
France	4 months (whole blood)	2 April 2020 (review 2022)
Denmark	4 months	22 March 2020
The Netherlands	4 months	July 2019, to be applied to other risk behaviours (CSW, partner of MSM)
Japan	6 months	
Australia	12 months (3 months pending)	2000 - change to 3 months expected end 2020
Brazil	12 months	2004
Czech Republic	12 months	
Finland	12 months	2014
Germany	12 months	2017. Policy includes all increased risk partners, and heterosexual donors with >3 partners.
Hong Kong	12 months	2017
Malta	12 months	
New Zealand	12 months	2014
Republic of Ireland	12 months	2017
Sweden	12 months	2012
Israel	12 months (whole blood). No deferral* (Quarantined plasma)	*Since 2018, MSM accepted for frozen plasma quarantined for at least 4 months. Frozen plasma released for transfusion if donor retested negative at 4 months or more.
Austria	Permanent	12-months under review
Belgium	Permanent	
China	Permanent	
Croatia	Permanent	
Iceland	Permanent	
Lebanon	Permanent	

In Europe most countries blood donations are based on 100% unpaid volunteers although some countries give incentives such as Germany where paid leave from work is given.

France and Israel allow sexually active, single partner MSM to donate plasma for transfusion under a quarantine release scheme.[12, 13] Plasma is quarantined and released if subsequent donation is screen negative. Donors are actively followed up to return, however, the current return rate in Israel is low (30%).[14]

3.4.1. References

1 Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells. 2004.

2 Brailsford SR, Kelly D, Kohli H, et al.: Who should donate blood? Policy decisions on donor deferral criteria should protect recipients and be fair to donors. *Transfus Med* 2015; 25: 234-8.

3 Benjamin RJ, Bianco C, Goldman M, et al.: Deferral of males who had sex with other males. *Vox Sang* 2011; 101: 339-67.

4 Goldman M, Shih Y, O'Brien SF, et al.: Donor deferral policies for men who have sex with men: past, present and future. *Vox Sang* 2018; 113: 95-103.

5 Seed CR, Kiely P, Law M, et al.: No evidence of a significantly increased risk of transfusion-transmitted human immunodeficiency virus infection in Australia subsequent to implementing a 12-month deferral for men who have had sex with men (CME). *Transfusion* 2010; 50: 2722-30.

6 Department of Health Advisory Committee on the Safety of Blood TaOS: Donor Selection Criteria Review 2017. Available at https://www.gov.uk/government/publications/donor-selection-criteria-review, Department of Health and Social Care, 2011.

7 Pillonel J, Pelat C, Tiberghien P, et al.: The evolving blood donor deferral policy for men who have sex with men: impact on the risk of HIV transmission by transfusion in France. *Transfusion* 2020; 60: 525-34.

8 Raimondo M, Facco G, Regine V, et al.: HIV-positive blood donors unaware of their sexual at-risk behaviours before donation in Italy. *Vox Sang* 2016; 110: 134-42.

9 Suligoi B, Pupella S, Regine V, et al.: Changing blood donor screening criteria from permanent deferral for men who have sex with men to individual sexual risk assessment: no evidence of a significant impact on the human immunodeficiency virus epidemic in Italy. *Blood Transfus* 2013; 11: 441-8.

10 Liumbruno GM, Pupella S, Regine V, et al.: A new questionnaire to improve the effectiveness of pre-donation screening for sexual risk behaviors of HIV infection among blood donors in Italy. *Transfusion* 2015; 55: 91A.

11 Bes M, Piron M, Casamitjana N, et al.: Epidemiological trends of HIV-1 infection in blood donors from Catalonia, Spain (2005-2014). *Transfusion* 2017; 57: 2164-73.

12 Tiberghien P, Pillonel J, Toujas F, et al.: Changes in France's deferral of blood donation by men who have sex with men. *New England Journal of Medicine* 2017; 376: 1485-6.

13 Levy I, Olmer L, Livnat Y, et al.: Attitudes, perceptions and knowledge among men who have sex with men towards the blood donation deferral policy in Israel. *PLoS ONE* 2017; 12.

14 Moser AML, I.; Shalhavi, R.; Shmilo, C.; Shinar, E.;: Response of Men Having Sex With Men (MSM) to the New Nondeferral Blood Donations Policy in Israel-First Year Follow-Up. *Transfusion* 2019; 59: 1.

3.5.Markers of infection in UK blood donors

3.5.1. Key points

- There is a decreasing trend for HBV, HCV HIV and HTLV in donors with a current overall rate of 5.7 per 100,000 donations compared with an increasing trend for treponemal antibody (syphilis) in donors with a current rate of 5.6 per 100,000 donations as reported in 2019.
- Between 2018 and 2019 85 recent infections acquired within 12 months, were identified by screening UK blood donors, 15 were viral and 70 were syphilis.
- Of these 85 recent infections 60 (70%) were male and 58 (68%) were repeat donors Non-compliance was 16% (62/385) in all positive UK donors 2018-19 and 9% (8/85) in those with recent infections.
- As the MSM deferral period shortened to 3 months we saw reduced numbers of donors non-compliant to the MSM deferral; 2/15 of donors with recent viral infection and 12/70 with recent syphilis were reported as MSM during 2018-19, but only 4 were non-compliant to the 3-month rule. Under a 3m deferral we saw an increased proportion of past syphilis in MSM
- Syphilis screening is a useful monitor of behaviour and compliance.
- Donors donating to get a test for infection (test seeking) is rare, although may not be reported to the blood service.
- The estimated UK residual risk is highest for hepatitis B virus (HBV). Over the last 10 years, this has been around 0.7 per million donations and remained at this level following the change from a lifetime to 12-months deferral for MSM.
- HBV residual risk increased to 1.04 per million donations during 2016-2018. This peak was due to an increase in HBV incidence in 2018. Provisional estimates for 2017-2019 show this trend has not continued and analysis shows the peak was not associated with the policy change.

3.5.2. Summary of infections detected

The current knowledge of rates and numbers in UK blood donations provide a baseline data against which to monitor any change, including any change in types of infection, behaviour and non-compliance under any new system. The trends in infection in UK blood donors are shown in figure 3.1, excluding hepatitis E virus (HEV) which, although may be acquired through sex, has not been identified as a risk in UK donors to date [1]. Rates of markers of infection are higher in new donors whose donations comprise about 10% of all donations. However, overall the number of infections detected is usually low [2]. Most infections are longstanding chronic infections and detected by donation

screening as donors give blood for the first time. Recently acquired infections, those acquired within 12 months of donation, are identified by confirmatory testing markers and/or a negative previous donation together with information supplied by the donor at post donation discussion.

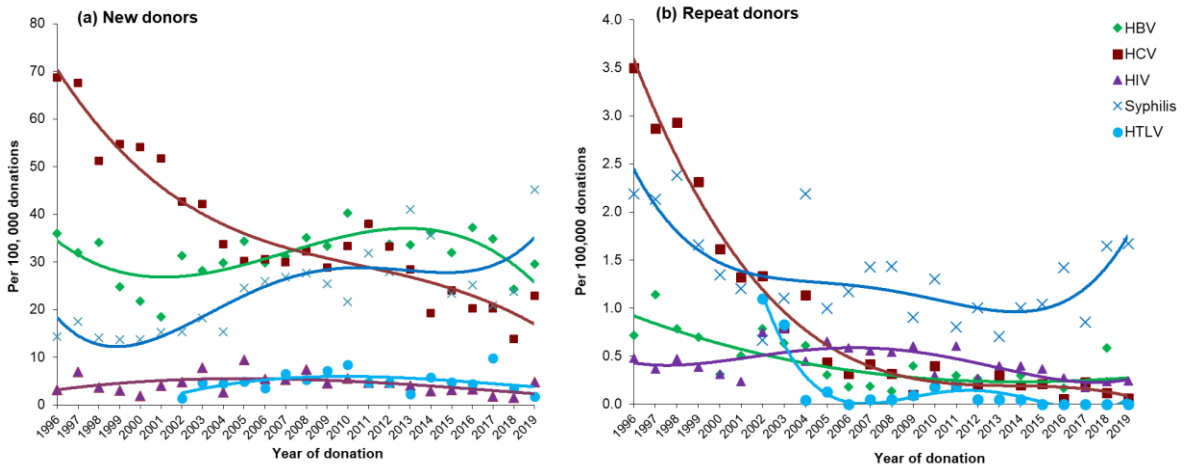


Figure 3. 1: The frequency of markers of HBV, HCV, HIV, HTLV and treponemes in blood donations from new (a) and repeat (b) donors collected by blood centres in the UK: 1996-2019 (note different scales)

In 2019, of 1.8 million donations screened, 50 were HBV positive (2 recent), 39 were HCV positive, 12 HIV positive (2 recent), 3 HTLV positive and 103 were positive for treponemal antibody of which 40 were likely recent syphilis infection (Table 3.2).

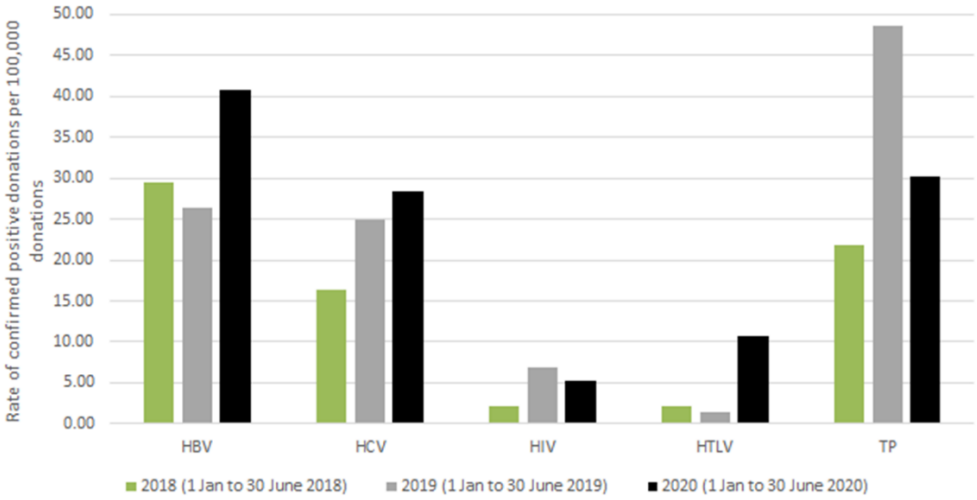
Table 3.2: Markers of HBV, HCV, HIV, HTLV and syphilis in UK donors,2019.

UK 2019		Donations	HBV	HCV	HIV	HTLV	Syphilis[1]	Total
New	n	165,809	49	38	8	3	75	173
	rate		29.6	22.9	4.8	1.8	45.2	104.3
Repeat	n	1,676,474	1	1	4	0	28	34
	rate		0.1	0.1	0.2	0.0	1.7	2.0
Total	n	1,842,283	50	39	12	3	103	207
	rate		2.7	2.1	0.7	0.2	5.6	11.2

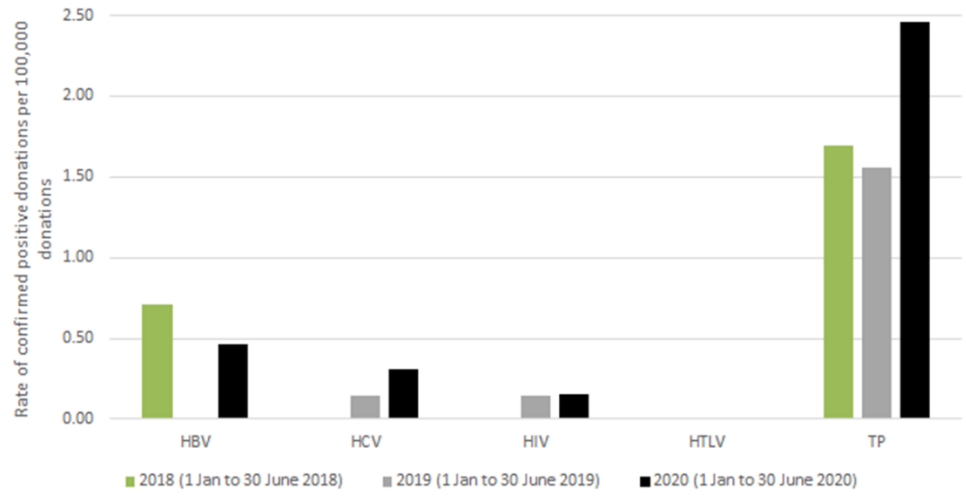
1. Syphilis includes those with past and treated infections as well as having the potential to pick up non-sexually acquired Treponema such as Yaws, rare in the UK.

Infections from new and repeat donors, from introduction of the donor selection guidelines until June 30th, 2020 are shown in Figure 3.2. The impact of COVID-19 has resulted in increased blood donation marketing for more male donors and BAME donors to donate blood to keep stocks up during lockdown. COVID-19 lockdown restrictions have also meant that some MSM were able to donate under current donation guidelines, however, we do not routinely collect data on sexual orientation.

Furthermore, people who had recovered from COVID-19 were called up, particularly males, to donate convalescent plasma from April 2020. During 2020 the preliminary data show rates of HBV, HCV and HTLV all went up in new donors while HIV rates were static. HCV and syphilis rates in repeat donors had gone up compared with the first 6 months of 2019, however this only equates to 2 repeat donors with HCV.



a) Donations from new donors



b) Donations from repeat donors

Figure 3.2: Rates of infection in donations from a) new and b) repeat donors England, January to June 2020 compared with the same time period for 2018 and 2019.

Infections in donors acquired through sex abroad are shown in Appendix 4: UK blood donors with markers of infection 2015-2019.

3.5.3. Impact of increased marketing during lockdown 2020

Of 87 positive donations to NHSBT between Jan and June 2020 we have information on 79 donors to date. 7 were CP donations, 5 in males, 6 in new donors and 1 lapsed donor: 4 syphilis, 2 HBV (longstanding) and 1 HCV likely of endemic origin in a new donor. Of 24 HBV cases, 19 were of endemic origin and likely longstanding. One acute HBV and a possible recent infection in a repeat donor were identified both female donors. Of 16 HCV cases the majority were white and 6 new donors reported a history of injecting drug use and 1 female lapsed donor had a partner who injected drugs. Of 3 HIV cases, all were male, 1 was MSM (expired deferral) and 2 heterosexual contact. Of 30 syphilis cases 20 were male, 7 reported MSM (3 expired deferral) and 16 reported heterosexual contact while source was not known for 7 (6 male) donors. Non-compliance appeared higher in the positive donors than usual, but only a small number were MSM described under section3.5.4. there is a suggestion from some positive donors that they felt the need for blood or convalescent plasma was greater than their past infection or that they felt their circumstances were safe.

3.5.4. Blood donors with recent infection by risk group

Recent infections identified in donors indicates recent higher risk behaviour. Recent viral infections, acquired within 12 months, feeds into the blood safety residual risk model as an indicator of how many HBV, HCV and HIV window period infections may not be detected but released into stock.

HIV rates are generally low and variable compared with HBV and HCV in new donors, but HIV has often been detected in greater numbers in repeat donors than HBV or HCV, indicating ongoing sexual risk in a subset of donors. Treponemal screening also detects past treated syphilis and endemic treponema such as yaws which is rare in UK donors, but there are increasing numbers of syphilis likely acquired within 12 months, again indicating ongoing sexual risk.

Infections in donors need to be seen in the context of the general population that donors are drawn from including knowledge of risk and opportunities for sexual health screening as well as being aware of and understanding the donor selection criteria.

The deferral period for MSM decreased from permanent to 12 months in 2011 to align with most other sexual deferrals and then all sexual deferrals were changed to 3 months in 2017. Overall, reducing the sexual behaviour deferral periods towards the end of 2011 and 2017 has not resulted in an increase in viral infection, in fact HIV has decreased. HIV diagnoses have also been declining in the

general population in England from 2014, particularly in MSM, with increased HIV testing [3] and low levels of acute HBV in the general population [4].

Meanwhile, syphilis, including recent infections has been increasing in both new and repeat donors, from around 2015. Infectious syphilis is also increasing in the general population, although still rare compared with gonorrhoea, providing an indicator of people in a risky sociosexual network [5]. Syphilis is not thought to be a TTI risk in the UK, with no reports of transmission to date, but is a useful monitor of increased risk behaviour and compliance with donor deferrals as HIV declines.

As per the overall trends above, the number of recent viral infections continues to decline in UK donors (Fig 3.3a), despite an increase in acute HBV in 2018 that was not continued in 2019. The number of recent syphilis infections is rising in UK donors (Fig 3.3b), mainly in male donors reporting heterosexual contact (see section 3.5.4). Of UK donors with recent infection reported MSM accounts for a low and variable number (fig 3.4). Of the low number of recent HIV cases, no males have reported SBM since 2015 in England but one donor in Wales with very recent HIV infection detected by NAT only, reported SBM in 2016 prior to the reduction in deferral to 3 months and one donor in Northern Ireland reported MSM 2018, again prior to their reduction to 3 month deferral.

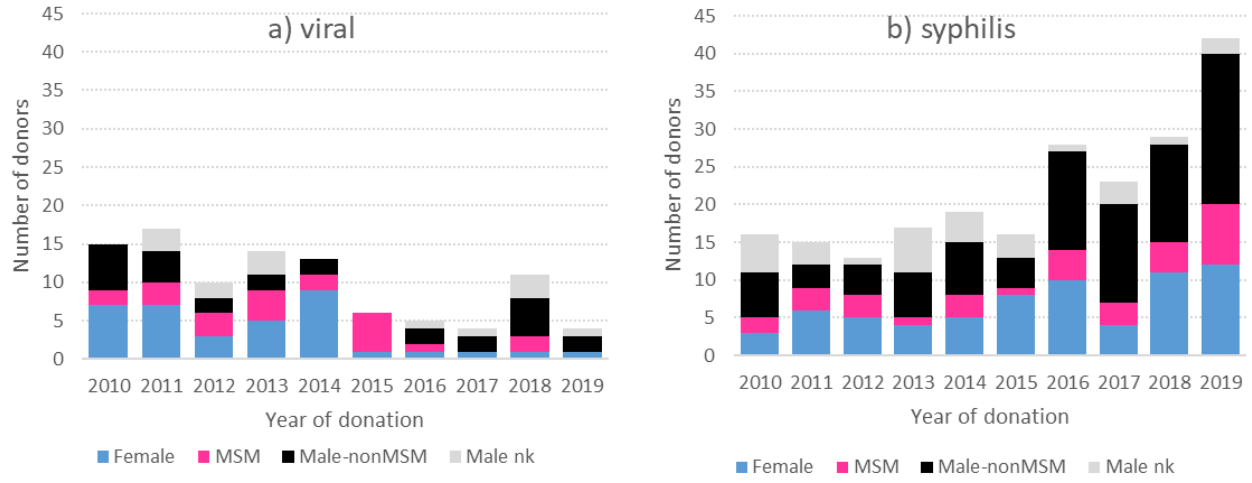


Figure 3.3: Recent viral (a) and recent syphilis (b) by reported risk group, UK 2010 – 2019

The number of positive MSM has increased in England (Fig 3.4) since the 2017 policy change. Syphilis has accounted for the majority of infections in MSM with the proportion of past infections increasing after 2017, and around 40% of infections treated This is similar to males and females reporting

heterosexual contact, where the proportion of syphilis that is past infection has remained at about 50% since 2016.

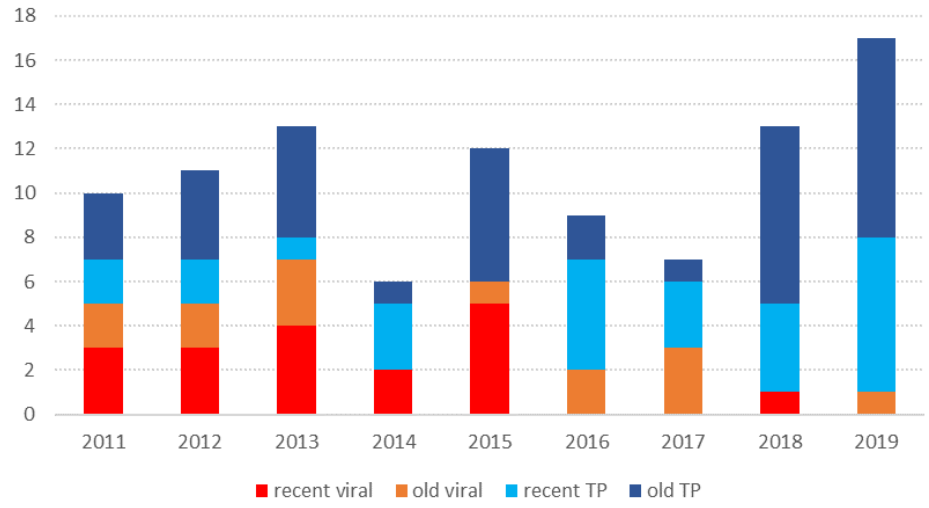


Figure 3.4: Positive donors where SBM self-reported by status of infection, England 2011-2019

3.5.5. Focus on syphilis – marker of higher risk sexual networks

Infectious syphilis is increasing in the general population in England (Figure 3.5). This increase is mainly among men who have sex with men (MSM,) accounting for 75% of cases in 2018, but also in heterosexuals with an associated increase in the identification of congenital cases. There is also evidence for infections in heterosexual identifying-MSM (HI-MSM), who are less likely to engage with services or be aware of their risk. [5]. Although syphilis is still rare compared to other bacterial STIs, acquiring syphilis is an indicator that the person is in a high risk sociosexual network whether they realise it or not. There is evidence for an increased risk of HIV in MSM who have had syphilis [6,7,8].

Between 2009 and 2018 over 18.6 million donations were screened by NHSBT, identifying 621 donors with *Treponema pallidum* antibody of which 155 (25%) were classified as having acquired syphilis within 12 months of the donation. Of these, 105 were also IgM positive indicating very recent acquisition. Estimated rates in MSM donors were about 10 times higher (25 per 100,000) than rates in non-MSM male (2 per 100,000) and female donors (0.8 per 100,000).

In the general population the higher rate in heterosexual males compared with females was thought to indicate heterosexual identifying-MSM (Figure 3.5), but the differential in donors is not so great at around 2:1 non-MSM males to all females (Figure 3.6).

However, a high proportion of all males did not disclose risk, 23 % (26/112) males could not (20) or would not (6) supply any information on how they acquired their infection. In donors, 22% (25/112) of males and 44% (19/43) of females reported a regular sexual partner.

Syphilis testing identified non-compliance with donor selection criteria among MSM, 14% (21/112) of males with recent syphilis reported sex between men (SBM), one was also HIV positive. Of these 21 men, 19 were within the deferral period and non-compliant including three with acute infection in 2018. Five reported a regular partner. Themes of acquiring syphilis infection in MSM donors were heterogenous and included: one-off contact, on/off contact, previous relationship (single by donation), long term partner, non-exclusive long-term relationship, used protection, no penetration, oral sex only, not been to GUM, been to GUM for routine test. Non-compliance reasons included: forgot, can't recall dates, in denial, stigma, felt safe, felt no different to heterosexuals.

Syphilis screening is identifying a small number of MSM who were donating non-compliantly in the belief that they are not at risk of infection or at least no riskier than heterosexuals, just as it identifies recent infection in heterosexual donors with a regular partner and donors who do not report any source of infection.

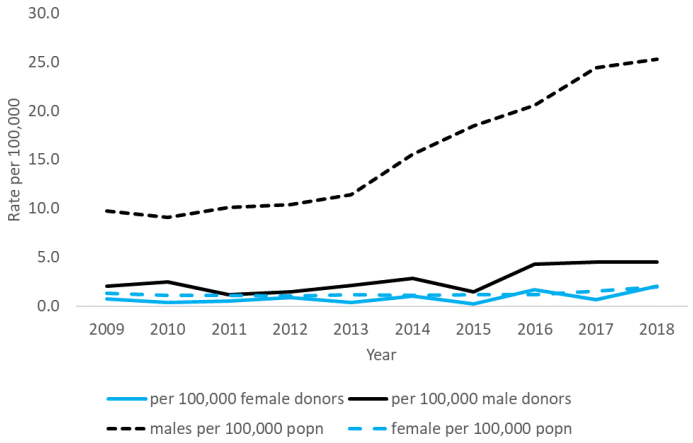


Figure 3.5: Rates of infectious syphilis in the general population by gender, compared with blood donors

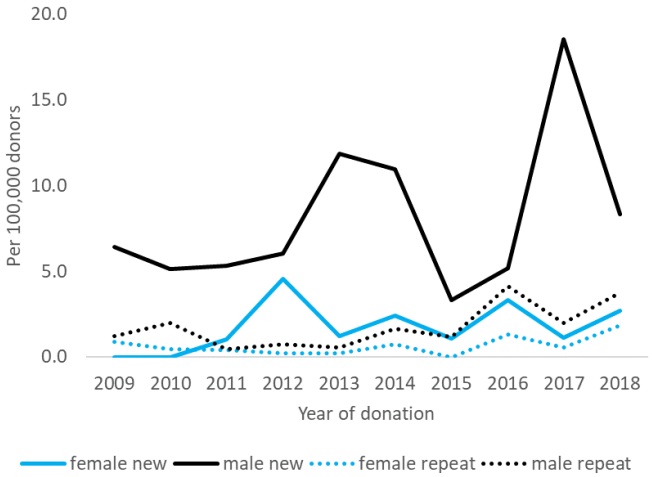


Fig 3.6: Rates of syphilis in blood donors by gender and first-time/repeat donors

3.5.6. Compliance with donor selection

The UK Donor Survey [9] conducted in 2014 showed that compliance with the lifestyle deferrals was high among negative donors, with over 99% fully disclosing information. In UK between 2018 and 2019 there were 385 donors with confirmed markers of infection (Table 3.3). Of these 16% (62) should have had a deferral applied if they had disclosed their history on session. Of those with an applicable deferral, over half, 35/62 had been treated for syphilis and a further 11 had known hepatitis. Eight males should have had the MSM deferral applied including three repeat donors. There were 85 donors with recent infection and of these 9% (8) should have had a deferral applied, 7 male and 6 repeat donors. Of those positive donors with a recent infection 15 had a viral infection of which only 2 reported an applicable deferral (MSM and endoscopy) both donors in Northern Ireland. Compliance in these donors with recent viral infection are looked at in more detail in section 7.3 to look at implications of FAIR.

Table 3.3: Compliance in UK donors 2018-2019

	Gender	New donor n (deferrable)		Repeat donor		All donors		% all
All positive	f	92	(6)	18	(2)	110	(8)	7.3
	m	215	(46)	60	(8)	275	(54)	19.6
		307	(52)	78	(10)	385	(62)	16.1
Recent positive	f	11	(0)	14	(1)	25	(1)	4.0
	m	16	(2)	44	(5)	60	(7)	11.7
		27	(2)	58	(6)	85	(8)	9.4

The proportion of positive MSM non-compliant to the known syphilis rule has increased, since the 3m deferral introduced (Fig 3.7) as presumably more MSM enter the donor population for the first time. See BEST data section 4.4 for estimates of MSM donating. The majority of known syphilis cases being in new donors with a past treated infection. The number of positive MSM reporting non-compliance to the MSM deferral decreased in 2018 and 2019 (Fig 4.4) with the shortening of the deferral period to 3 months. Infections seen in MSM non-compliant to the 3m deferral in 2018-2019 were syphilis and 1 acute HBV in a donor suspected of non-compliance. Of those who reported SBM more than 3 months ago i.e. expired, again most had syphilis infection and one HIV infection.

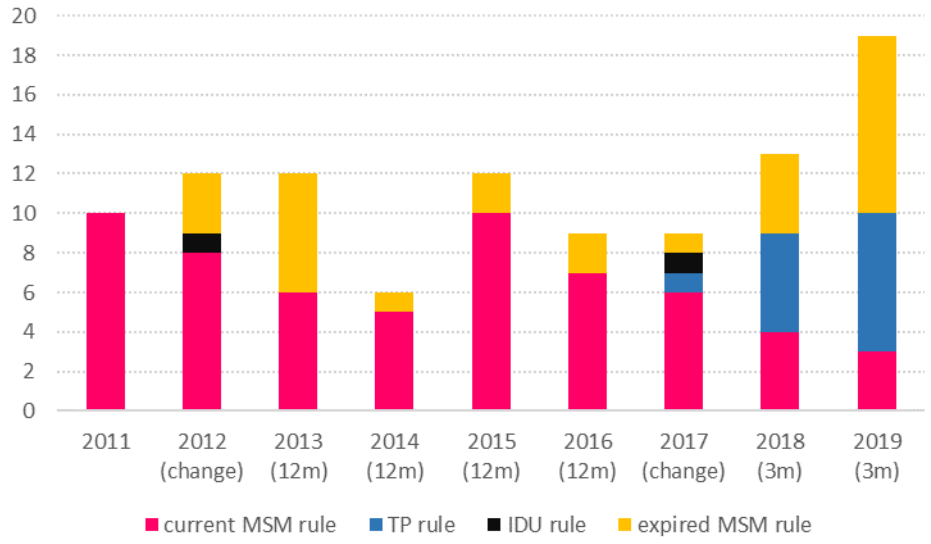


Figure 3.7: Non-compliance in positive donors reporting SBM, England 2011-2019

In 2020 (January to June) in England the proportion non-compliant was about double than in UK 2019 in both females and males and in new and repeat donors (Table 3.4). Again, about half of these were donors who if they had disclosed a history of infection would have been deferred. Only 4 were non-compliant to the MSM 3m deferral, 3 repeat donors, all with syphilis, 1 IgM positive. All four cited regular or monogamous partners.

Table 3.4: Compliance to all infections, England January to June 2020

	new		repeat		all		% all
f	15	(2)	10	(2)	25	(4)	16.0
m	43	(14)	11	(5)	54	(19)	35.2
all	58	(16)	21	(7)	79	(23)	29.1

Although compliance with the lifestyle deferrals was high, not being allowed to give blood was in the top four reasons for non-compliance. Data from the 2014 UK Donor Survey was analysed to look for motivating factors that might differentiate those non-compliant donors from compliant. A high proportion of non-compliant donors had donated to do a good thing or to help someone in need the same as compliant donors with or without a lifestyle deferrable behaviour.

Test seeking was significantly associated with non-compliance although only 8 (2.4%) of non-compliant donors reported test seeking compared with 15 (1.9%) of those with a history of a deferrable behaviour and 236 (0.4%) of donors without any deferrable behaviour. A low level of test seeking fits with self-perception of being at low risk being the main reason for non-compliance. Test seeking did not correlate to donors saying that they were at risk of HIV or hepatitis infection. That said, there may be unreported test seeking in positive donors and the blood services should seek ways to discourage test seeking highlighting: other more appropriate routes for testing, window period risk and the recipients.

3.5.7. References

1. Safe supplies: annual review. Annual review of the NHS Blood and Transplant (NHSBT) and Public Health England (PHE) Epidemiology Unit. https://www.gov.uk/government/publications/safe-supplies-annual-review
2. Reynolds C, Davison KL, Brailsford SR. Safe supplies: few infections in UK blood and tissue donors. Transfus Med. 2019 Aug;29(4):239-246. doi: 10.1111/tme.12576. Epub 2019 Jan 28. PMID: 30689250.
3. 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. https://www.gov.uk/government/publications/hiv-in-the-united-kingdom
4. Acute hepatitis B: national enhanced surveillance report January to December 2019. Health Protection Report Volume 14 Number 8 https://www.gov.uk/government/publications/acute-hepatitis-b-england-enhanced-surveillance-reports
5. Public Health England, 2019. Addressing the increase in syphilis in England: PHE Action Plan. https://www.gov.uk/government/publications/syphilis-public-health-england-action-plan
6. Desai S, Nardone A, Hughes G, Delpech V, Burns F, Hart G, Gill ON. HIV incidence in an open national cohort of men who have sex with men attending sexually transmitted infection clinics

in England. HIV Med. 2017 Oct;18(9):615-622. doi: 10.1111/hiv.12498. Epub 2017 Jan 27. PMID: 28127837.

7. Desai S, Burns F, Schembri G, Williams D, Sullivan A, McOwan A, Antonucci S, Mercey D, Hughes G, Hart G, Gill ON, Nardone A. Sexual behaviours and sexually transmitted infection outcomes in a cohort of HIV-negative men who have sex with men attending sexual health clinics in England. Int J STD AIDS. 2018 Dec;29(14):1407-1416. doi: 10.1177/0956462418789333. Epub 2018 Aug 16. PMID: 30114995.
8. White E, Dunn DT, Desai M, Gafos M, Kirwan P, Sullivan AK, Clarke A, McCormack S; PROUD study group. Predictive factors for HIV infection among men who have sex with men and who are seeking PrEP: a secondary analysis of the PROUD trial. Sex Transm Infect. 2019 Sep;95(6):449-454. doi: 10.1136/sextrans-2018-053808. Epub 2019 Mar 27. PMID: 30918121; PMCID: PMC6824743.
9. 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 Aug;25(4):265-75. Doi: 10.1111/tme.12236. Epub 2015 Sep 3. PMID: 26337860.

3.5.8. Residual risk of not detecting HBV, HCV and HIV by blood donation screening

The residual risk for UK blood donations is used to inform blood safety in terms of the risk that a potentially infectious hepatitis B (HBV) and C (HCV), and HIV donation is not detected by routine blood donation screening and is available for transfusion. Here we report residual risk estimates for the UK between 2009 and 2019, calculated for acute infections only, to assess the impact of the changes in the deferral regarding sex between men from 12-months to 3-months for all donors with sexual partners with potential increased risk behaviours at end of 2017.

The risk is usually described as the estimated residual risk per million donations tested, or as the estimated number of years of blood donation screening before a potentially infectious donation is not detected. It is not the estimated risk of transmission, since transmission will also depend on the amount of undetected virus in the component which may vary by type of components transfused and susceptibility of recipient for that infection. Residual risk is only calculated for HBV, HCV and HIV.

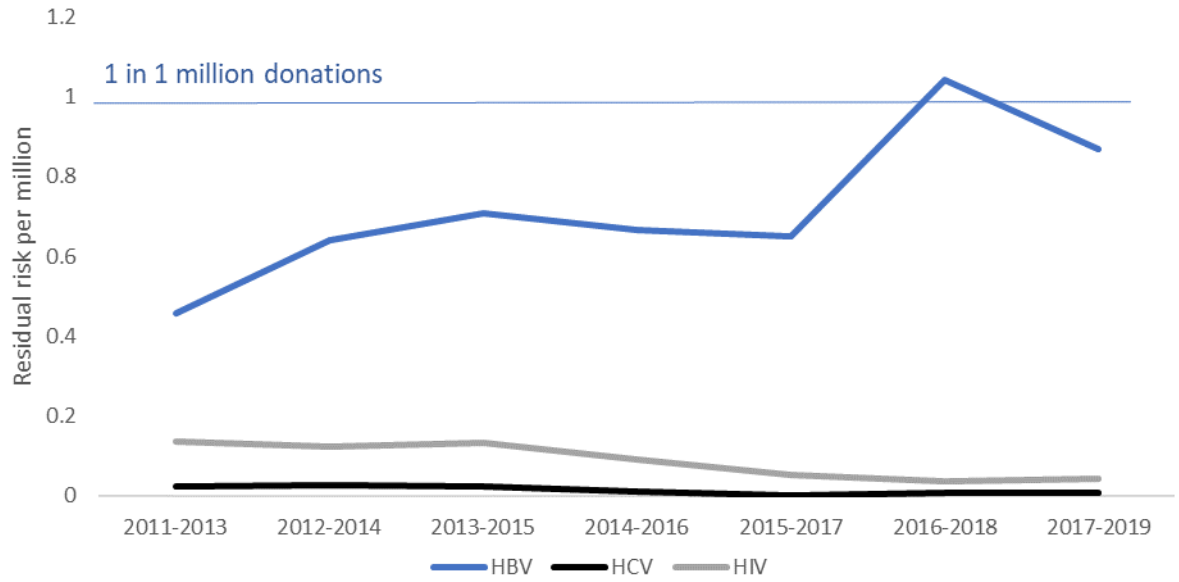
The calculations are made each year for the UK using a mathematical model. Currently the risk is calculated each year for the previous three years as the number of newly acquired infections found in blood donations per number of donors tested, or incidence, multiplied by the duration of infectious

window period of the assays. The infectious window periods included in the calculations since 2009 are for nucleic acid testing in samples of 24 donations at 30 days for HBV, 9 days for HIV and 4 days for HCV.

The 3-year estimates of residual risk for HBV, HCV and HIV are shown in figure 3.8. HBV risk is the highest and thus UK recipients are potentially at a greater risk of this virus than HIV or HCV. This is mostly due to HBV tests having the longest window period, combined with a higher level of estimated incidence. Over the last 10 years, HBV residual risk has generally been around 0.7 per million donations. This is less than the UK level considered tolerable by SaBTO in the risk tolerability model when donor selection was reviewed in 2017. Residual risk due to undetected HIV or HCV is considerably lower and values for both viruses are currently estimated to be less than 0.1 per million donations.

After the change to the 12-month deferral in 2011, there was initially a small decrease in HBV residual risk as the estimates fell to 0.5 per million donations for 2011-2013. Estimates for the first full 3-years post change during 2012-2014 increased back up to the steady level of 0.7 per million donations.
For the first estimates calculated after the change to the 3-month deferral at the end of 2017, HBV residual risk increased from 0.46 per million donations in 2015-2017 to 1.04 per million donations during 2016-2018. This peak was due to an increase in UK HBV population-level incidence 2018. Provisional estimates for 2017-2019 suggest this trend has not continued as estimates for HBV decreased to 0.87 per million. At current donation levels of approximately 2 million donations each year in the UK, it is estimated from these risk estimates that testing will *NOT* identify approximately two potentially infectious HBV window period donations every year. The residual risks for HCV and HIV, equate to one potentially infectious HCV window period donation every 76 years and one potentially infectious HIV window period donation every 12 years.

Figure 3.8: Residual risk of HBV, HCV and HIV per million donations tested in UK, 2009-2019



This increase in HBV residual risk is not thought to be related to the change in the donor selection guidelines relating to sexual behaviours given that in 2018 the rate of HBV in new donors continued to decline, and, from conversations with the incident donors, only one reported a sexual partner with increased risk behaviour. This donor was MSM and compliant with 3-month deferral. It is also important to note that the increase in HBV residual risk was based on the addition of a few incident donors on an already low number (3 in 2017 and 7 in 2018).

Note: the estimates for 2017-2019 are provisional as they are awaiting approval from the Joint UKBTS Professional Advisory Committee (JPAC). Once approved these estimates are published on the JPAC website as a position statement. https://www.transfusionguidelines.org/document-library/position-statements

3.6. UK general population epidemiology of HIV hepatitis B and C viruses and bacterial sexually transmitted infections

3.6.1. Key points

- HIV in the UK is declining, but gay, bisexual and other men who have sex with men remain disproportionally affected
- Hepatitis B virus occurs at a low prevalence, but acute hepatitis B is more common in people who have unprotected sex with multiple partners.
- People who inject drugs are the main risk group for hepatitis C, however testing at sexual health services had higher positivity rates among gay and bisexual men compared to heterosexuals
- Significant increases in gonorrhoea, chlamydia and syphilis may be due to better detection but are also driven by behavioural changes associated with increased sexual risk

Here the epidemiology of HIV, hepatitis B and C in the general population is described, including groups considered to be at higher risk of infection. For completeness data on gonorrhoea in the general population is included although this is not included in blood donation screening.

3.6.2. HIV

Diagnosed and undiagnosed HIV

HIV diagnoses in the UK general population is declining. In 2018, there were 4,453 people newly diagnosed with HIV, 3/4 of whom were male.[15] This represents a 28% decline from the number reported in 2015 and a 6% decline relative to 2017. Gay, bisexual and other men who have sex with men (MSM) remain the exposure group most at risk. The overall trend has been driven by the decline in this group, which decreased to 2,250 diagnoses in 2018, accounting for 58% of all diagnoses in males for that year. The steepest decline has been observed in gay and bisexual men resident in London (Figure 3.9). Combination HIV prevention (including treatment, pre-exposure prophylaxis and testing) is the principal explanation for the fall in HIV incidence, estimated to have begun in 2012.

New HIV diagnoses through heterosexual contact declined by 24% from 2,304 in 2015 to 1,550 in 2018. Over the last 10 years, the HIV epidemic among this group has diversified as the proportion among black African men and women declined, reaching 44% in 2018 (Figure 3.10).

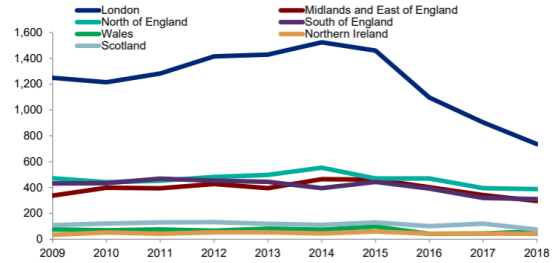


Figure 3.9: HIV in gay, bisexual and other men who have sex with men

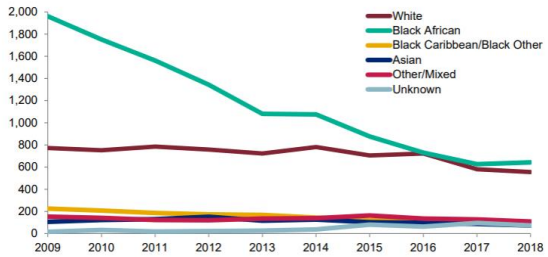


Figure 3.10: HIV in men and women who acquired their infection through heterosexual contact

Undiagnosed HIV in the UK is also declining.[16] Reducing the number of people who are unaware of their HIV status is important for public health but also for blood safety as people who think they might have, or have been diagnosed with HIV are asked not to give blood. In 2018, there was an estimated 7,500 people living with undiagnosed HIV, 4,000 were gay and bisexual men and 3,200 were heterosexual men and women.[17]

HIV testing and a risk prediction tool

PHE currently recommends HIV testing for individuals at continuing risk of infection. Gay, bisexual and other MSM should have an HIV test at least annually, or every 3 months if they are having unprotected sex with new or casual partners. Black African heterosexual men and women, and people born in countries where HIV is common, should also have an HIV test, and repeat this every year if having unprotected sex with new or casual partners from countries where HIV is common. In recent years, testing activity has continued to increase, largely driven by increased testing of gay and bisexual men. HIV test positivity in these groups has continued to decrease, falling from 1.2% in 2016 to 0.9% in 2017, reflecting both declining infection rates and changing testing routines.

Data collected by GUM clinics about people tested for HIV and other sexually transmitted infections has been used to identify individuals at increased risk of HIV to help prioritise care.[18] Using data from five clinics, estimated incidence of HIV was greater in MSM than heterosexual attendees. This demonstrated MSM at greatest risk were those with:

- at least one course of PEPSE in last year
- a bacterial STI in last year
- drug use in a sex context (chemsex).

3.6.3. Hepatitis B and hepatitis C

The UK is a low prevalence (<2%) country for hepatitis B virus (HBV), although levels are higher for certain groups of people such as those originally from high-risk countries, people who inject drugs and people who have unprotected sex with multiple partners. In 2018, there were 4,390 cases of HBV reported to PHE, 292 (4%) were confirmed as acute. HBV prevalence and incidence is likely to be an underestimate due to asymptomatic acute infections and undiagnosed chronic infections. Only a third of reports to PHE have a probable source of acquisition assigned:. among these approximately half report heterosexual exposure and 17% report sex between men. Reports of acute HBV made to PHE have been declining since 2011. [19] However, in 2015 there was some increase, likely caused by an outbreak in men who identified as heterosexuals but who had most likely acquired their infection from sex with another man .[20] Hepatitis B vaccine is recommended for individuals who change partners frequently, MSM, and male and female commercial sex workers although uptake may be variable[5] and information on the number of doses limited.

The UK is a country of very low prevalence (0.4%) of hepatis C virus (HCV). The number of laboratory confirmed reports of HCV in England between 2009 to 2018 increased by nearly 90%, with 16,216 reports of individuals testing positive in 2018. This increase is mostly due to increased testing. People who inject drugs are the main risk group, however testing at sexual health services had higher positivity rates among gay and bisexual men compared to other attendees (81 per 100,000 v 24 per 100,000).[21]

3.6.4. Syphilis

Since 2000 the epidemiology of syphilis and has changed significantly, influenced by behaviour change among MSM. Between 2008 and 2018, diagnoses increased by 162% (2,874 to 7,541) rising by 5.5% between 7,149 in 2017 and 7,541 in 2018. The increase in men, especially MSM has accelerated since 2013. In 2018, 75% of diagnoses of infectious syphilis were in MSM, after a 1.5% increase between 2017 and 2018. The rise in syphilis diagnoses in MSM is related to the increase in reported number of condomless anal intercourse partners, together with behaviours such as sex parties (group sex) facilitated by geospatial networking applications, such as GrindR, and 'chemsex'.[22]

[5] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/628602/Greenbook_chapter__18.pdf

3.6.5. Gonorrhoea

There were 56,259 diagnoses of gonorrhoea reported in 2018, a 26% increase relative to 2017. Since 2009, gonorrhoea diagnoses have risen by 249% (from 16,141 to 56,259), mostly due to increases among MSM. Between 2014 and 2018 there were large increases in diagnoses gonorrhoea (43%; from 18,568 to 26,574). The increase in gonorrhoea may be due to better detection of these STIs; it may also be driven by behavioural changes such as an increase in partner numbers and condomless anal intercourse, as well as, for some high risk MSM, 'chemsex' and group sex facilitated by geosocial networking applications.[23]

References

1 Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells. 2004.

2 Brailsford SR, Kelly D, Kohli H, et al.: Who should donate blood? Policy decisions on donor deferral criteria should protect recipients and be fair to donors. *Transfus Med* 2015; 25: 234-8.

3 Benjamin RJ, Bianco C, Goldman M, et al.: Deferral of males who had sex with other males. *Vox Sang* 2011; 101: 339-67.

4 Goldman M, Shih Y, O'Brien SF, et al.: Donor deferral policies for men who have sex with men: past, present and future. *Vox Sang* 2018; 113: 95-103.

5 Seed CR, Kiely P, Law M, et al.: No evidence of a significantly increased risk of transfusion-transmitted human immunodeficiency virus infection in Australia subsequent to implementing a 12-month deferral for men who have had sex with men (CME). *Transfusion* 2010; 50: 2722-30.

6 Department of Health Advisory Committee on the Safety of Blood TaOS: Donor Selection Criteria Review 2017. Available at https://www.gov.uk/government/publications/donor-selection-criteria-review, Department of Health and Social Care, 2011.

7 Pillonel J, Pelat C, Tiberghien P, et al.: The evolving blood donor deferral policy for men who have sex with men: impact on the risk of HIV transmission by transfusion in France. *Transfusion* 2020; 60: 525-34.

8 Raimondo M, Facco G, Regine V, et al.: HIV-positive blood donors unaware of their sexual at-risk behaviours before donation in Italy. *Vox Sang* 2016; 110: 134-42.

9 Suligoi B, Pupella S, Regine V, et al.: Changing blood donor screening criteria from permanent deferral for men who have sex with men to individual sexual risk assessment: no evidence of a significant impact on the human immunodeficiency virus epidemic in Italy. *Blood Transfus* 2013; 11: 441-8.

10 Liumbruno GM, Pupella S, Regine V, et al.: A new questionnaire to improve the effectiveness of pre-donation screening for sexual risk behaviors of HIV infection among blood donors in Italy. *Transfusion* 2015; 55: 91A.

11 Bes M, Piron M, Casamitjana N, et al.: Epidemiological trends of HIV-1 infection in blood donors from Catalonia, Spain (2005-2014). *Transfusion* 2017; 57: 2164-73.

12 Tiberghien P, Pillonel J, Toujas F, et al.: Changes in France's deferral of blood donation by men who have sex with men. *New England Journal of Medicine* 2017; 376: 1485-6.

13 Levy I, Olmer L, Livnat Y, et al.: Attitudes, perceptions and knowledge among men who have sex with men towards the blood donation deferral policy in Israel. *PLoS ONE* 2017; 12.

14 Moser AML, I.; Shalhavi, R.; Shmilo, C.; Shinar, E.;: Response of Men Having Sex With Men (MSM) to the New Nondeferral Blood Donations Policy in Israel-First Year Follow-Up. *Transfusion* 2019; 59: 1.
15 O'Halloran CS, S.; Nash, S.; Brown, A.; Croxford, S.; Connor, N.; Sullivan, A.K.; Delpech, V.; Gill, O.N.;: HIV in the United Kingdom: Towards Zero 2030. 2019 report. London, Public Health England, 2019.
16 Nash SD, S.; Croxford, S.; Guerra, L.; Lowndes, C.; Connor, N.; Gill, O. N.;: Progress towards ending the HIV epidemic in the United Kingdom: 2018 report. London, Public Health England, 2018.
17 England PH: Prevalence of HIV infection in the UK. *Health Protection Report* 2019; 13.
18 King C, Hughes G, Furegato M, et al.: Predicting STI Diagnoses Amongst MSM and Young People Attending Sexual Health Clinics in England: Triage Algorithm Development and Validation Using Routine Clinical Data. *EClinicalMedicine* 2018; 4-5: 43-51.
19 England PH: Acute hepatitis B: national enhanced surveillance report January to December 2019. *Health Protection Report* 2020; 14.
20 Shankar AG, Mandal S, Ijaz S: An outbreak of hepatitis B in men who have sex with men but identify as heterosexual. *Sex Transm Infect* 2016; 92: 227.
21 England PH: Hepatitis C in England 2020: working to eliminate hepatitis C as a major public health threat. www.phe.gov.uk, 2020.
22 England PH: Addressing the increase in syphilis in England: PHE Action Plan. 2019.
23 England PH: Sexually transmitted infections and screening for chlamydia in England, 2018 *Health Protection Report*; 13.

4. Epidemiology

4.1.Literature reviews

4.1.1. Does attendance at GUM help to inform whether an individual may be at higher risk of acquiring an STI?

Background and aim

People with health needs relating to sexual transmitted infections in the UK can access a range of services for testing and treatment including genitourinary medicine (GUM) or sexual reproductive health clinics, GPs, pharmacies and online facilities. Understanding the characteristics of service users can help to identify individuals potentially at increased risk, whether they have symptoms or not, or if they represent the 'worried well'. This review aims to identify and synthesize all available evidence about the demographics and characteristics of GUM attenders in the UK in order to inform the FAIR review of existing literature and data.

Review methodology

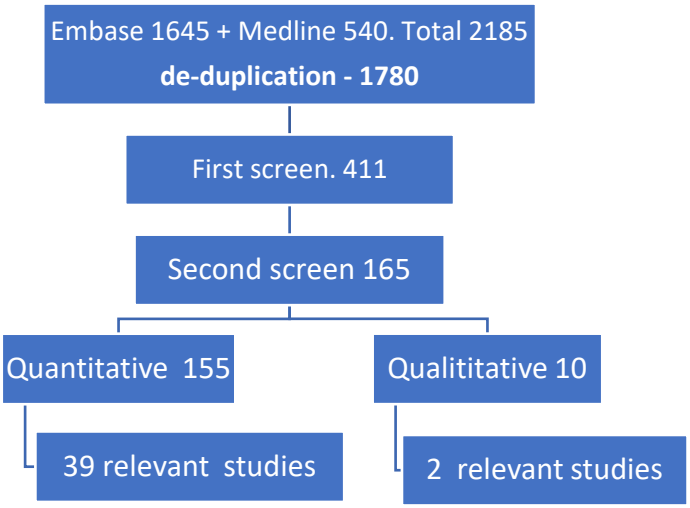
A literature search and initial screen was performed by PHE library services using Embase and Medline. Searches were limited to studies carried out in the UK and published between January 2000 and January 2020. Relevant articles were identified following review of titles and abstracts, studies were excluded for the following criteria: conference abstracts, quantitative studies with less than 100 subjects/samples, qualitative studies with less than 10 subjects, cost effectiveness studies, policy/process audit/standards of care, sti prevention, termination of pregnancy, female genital mutilation, sexual assault/domestic violence, children and adolescents, prisons, perinatally infected adults, cervical cytology, vulnerable adults, homeless, alcohol, PrEP, highly frequent attendees. Duplicates, where a study was reported in more than one journey with the same population and results were removed.

Remaining studies were categorised as quantitative or qualitative. A study was considered to be relevant after the second screen if the study was exploring characteristics and risks behaviour of attendees, or reason for attending GUM compared to GP/other service, or patients were worried well. Themes explored included attendance patterns, characteristics and sexual behaviour among attendees and testing for HIV/STI.

Results

The number of relevant studies identified is shown in Figure 4.1, and key findings from quantitative studies are shown in Table 4.1.

Figure 4.1: literature review flow diagram



Qualitative studies considered relevant - 2

- From 10 focus groups - evidence that GUM is the preferred choice of service for those with more complex sexual health needs. Perceived experience of staff was the key reason for attendance rather than general practice. The decision of where to test for STIs was also influenced by experience of testing, existing relationships with general practice, method of receiving test results and whether the patient had other medical conditions such as HIV.
- From conference proceedings - an analysis of self-perceived risk among 19 HIV negative MSM that found the majority identified as being at low risk of HIV despite some reporting inconsistent condom use and engaging in casual sex. Men did not judge their risk based on these behaviours and their context but on their intention to be safe and the relationships they were in.

Table 4.1: Quantitative studies considered relevant to the literature review (n-39)

Attendance patterns	Characteristics and sexual behaviour among attendees	HIV/STI testing among attendees
16 publications	14 publications	9 publications
6 key publications – (2 cross all 3 themes) [1,2, 3, 4, 5, 6]	2 key publications [7, 8]	2 key publications [5,9]
Key data sources: National Attitudes and Lifestyle Survey (NATSAL), online/paper questionnaire and GUM CAD, also NAZ project (sexual health for BAME community) Among non-attenders v attenders: higher rates unsafe sex, less likely to have symptoms, less likely to be MSM, similar rates STI. Increased attendance and reattendance with increasing age increased attendance over time, particularly in increased risk groups. Low rates attendance in Asian males, and Black Caribbean, Black African males and females. Low rates attendance in Central and Eastern European communities, high rates increased risk behaviour outside of community. Females less likely to attend than males. Trans people less likely to attend than cisgender, low uptake testing poor attendance in rural settings no evidence of 'worried well'.	Key data sources: National Attitudes and Lifestyle Survey (NATSAL), GUM CAD and AURAH (HIV negative MSM cohort) MSM condomless receptive anal sex and bacterial STI predictors of subsequent infection. MSM chemsex not common but increases risk of STI, also among het sex white males large population of with many partnerships, often casual, inconsistent condom use in het sex males and females, and MSM, importance of partner's behaviour identified. Male partnerships shorter than women's.	Key data sources: NATSAL, GUM CAD GUM surveys Increased testing over time, particularly in increased risk groups . Many who perceive themselves at risk did not report a test, including MSM. HIV incidence highest among MSM and black African het sex targeted testing required among black Africans, especially het sex. Ethnic difference in STI rates are not explained by sexual behaviour characteristics.

4.1.2. References

[1] Tanton, C., Geary, R. S., Clifton, S., et al. 2018. Sexual health clinic attendance and non-attendance in Britain: findings from the third National Survey of Sexual Attitudes and Lifestyles (Natsal-3). Sexually Transmitted Infections 94(4) 268-276.

[2] Mercer CH, Aicken CR, Cassell JA, et.al. 2013. Not so different after all? Comparing patients attending general practice-based locally enhanced services for sexual health with patients attending genitourinary medicine. International Journal of STD & AIDS, 01 Feb 2013, 24(2):106-111

[3] Bayley, J., Mesher, D., Nadarzynski, T., et al. 2018. Attendance of MSM at Genitourinary Medicine services in England: Implications for selective HPV vaccination programme (a short communication). Sexually Transmitted Infections 94(7) 542-544.

[4] McKeown, E., Doerner, R., Nelson, S., et al. 2012. The experiences of ethnic minority MSM using NHS sexual health clinics in Britain. Sexually Transmitted Infections 88(8) 595-600.

[5] Sonnenberg, P., Clifton, S., Beddows, S., et al. 2013. Prevalence, risk factors, and uptake of interventions for sexually transmitted infections in Britain: Findings from the National Surveys of Sexual Attitudes and Lifestyles (Natsal). The Lancet 382(9907) 1795-1806.

[6] Eccleston, K. & Richards, M. 2014. Sexual health in men who have sex with men in a rural setting: Is this a population at high risk of acquiring human immunodeficiency virus? HIV Medicine 3) 98-99.

[7] Desai, S., Burns, F., Schembri, G., et al. 2018. Sexual behaviours and sexually transmitted infection outcomes in a cohort of HIV-negative men who have sex with men attending sexual health clinics in England. International Journal of STD and AIDS 29(14) 1407-1416.

[8] Sewell, J., Cambiano, V., Miltz, A., et al. 2018. Changes in recreational drug use, drug use associated with chemsex, and HIV-related behaviours, among HIV-negative men who have sex with men in London and Brighton, 2013-2016. Sexually Transmitted Infections 94(7) 494-501.

[9] Aicken, C. R., Wayal, S., Blomquist, P., et al. 2019. Ethnic variations in sexual partnerships and mixing, and their association with STI diagnosis: findings from a cross-sectional biobehavioural survey of attendees of sexual health clinics across England. Sexually Transmitted Infections 17 17.

4.1.1. Literature review two: Risk of acquiring HIV/STIs associated with eight sexual behaviours

Key points

- There was very strong evidence for an association between a higher HIV/STI acquisition risk and:
    - Engaging in chemsex
    - Having a history of bacterial STI(s)
- There was strong evidence for an association between a higher HIV/STI acquisition risk and:
    - Increasing number of sexual partners
    - Less frequent condom use
    - Type of sex (specifically receptive and/or anal sex)
- There was no or very little evidence for an association between HIV/STI acquisition risk and:
    - GUM clinic attendance
    - Having a new sexual partner
    - Exclusivity
- The sparsity of evidence surrounding an association between acquisition risk and having a new sexual partner may be related to nuances around how studies defined/categorised new partners.

Introduction

A review of existing literature was conducted to look at the current evidence linking risk of acquiring HIV/STIs and eight pre-defined sexual behaviours. These pre-defined behaviours are based on current and proposed donor selection criteria following proposal by the BEST collaborative: sex on drugs (referred to as chemsex from here on), number of sexual partners, past history of bacterial STIs, attendance of Genito Urinary Medicine (GUM) clinics (or equivalent services), new sexual partners, condom usage, exclusivity, and type of sex (oral/vaginal/anal or insertive/receptive).

Review methodology

Initial searches for literature were carried out in Medline and Embase based on pre-defined search criteria (Appendix 5). The studies from these searches were then compiled and deduplicated before an initial screening was conducted using pre-defined exclusion criteria (appendix 2). A second screening was then carried out by looking at the studies in more detail to finalise the included studies.

In order to help assess the weight of evidence behind each sexual behaviour's link to HIV/STI acquisition risk, a scoring system was devised by which a score is applied to each included study (Table 4.2). This system is modified on the previous work of Brady et al. [1] Studies supporting a link between a particular sexual behaviour and risk of acquisition were identified and the scores from these studies

were added to give a total for that sexual behaviour. If a study identified multiple sexual behaviours were linked with risk this study's score was included in the counts for each of the sexual behaviours identified. This system allows for quantity of evidence and size of study (indicating increased reliability) to be taken into account. A large score for a sexual behaviour could indicate lots of smaller studies or a few larger studies supporting a link with acquisition risk, or a combination of the two. Any study assigned a score of three was classified as a key study. The devised scoring system was applied, counts for each sexual behaviour added up, and key studies identified.

Table 4.2: Scoring system for included studies

Score	Criteria
1	Study population of 50 to 199
	One study location & study population of 200 to 999
2	Multiple study locations & study population of 200 to 999
	One study location & study population of 1,000 to 4,999
3	Multiple study locations & study population of 1,000 to 4,999
	Study population of 5,000+

Results

Searches identified 3,027 studies which, after deduplication, equated to 1,645 unique studies (Figure 4.2). Out of these the first screening identified 392 studies and the second screening narrowed this down to 60 included studies. Reasons for exclusion were recorded on the second screening with not relevant (n=191), HIV positive study population (n=49), and being a purely prevalence/incidence study (n=25) were the most common reason for exclusion. There were 17 key studies identified.

Overall chemsex, number of partners, previous bacterial STI, condom usage, and type of sex had high scores and numerous key studies supporting a link to acquisition risk (Table 4.3). No studies were found linking exclusivity to acquisition risk and very few studies, none of which were key studies, were found linking having new sexual partners to risk.

The relationship between GUM attendance and risk of acquiring HIV/STIs was observed in five key studies. However, three of these showed a positive relationship (risk increased with GUM attendance) and two showed a negative relationship (risk decreased with GUM attendance). A score of -3 was assigned to studies showing a negative relationship producing an overall score of 3.

Figure 4.2: Literature review flow diagram

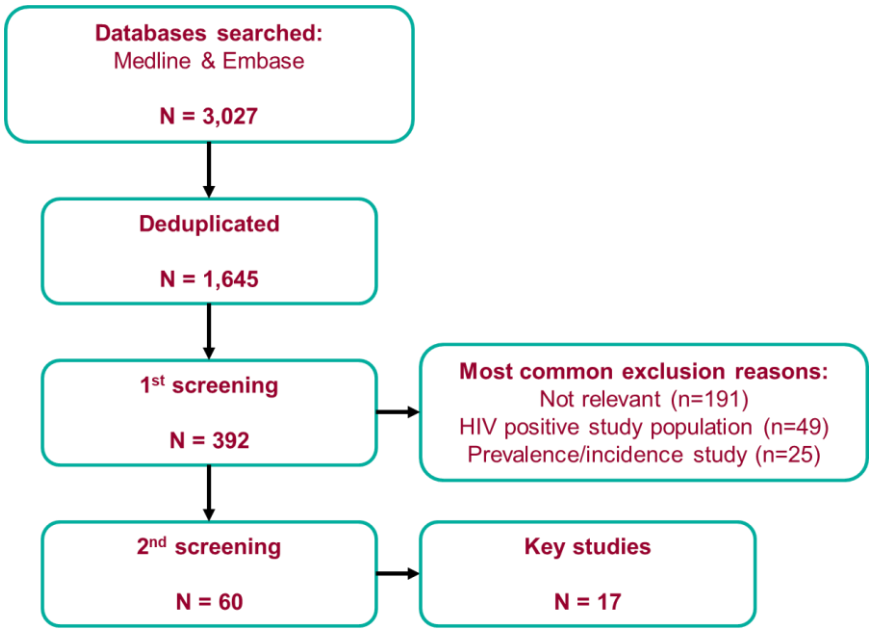


Table 4.3: Results of scoring system for each sexual behaviour, number of keys studies associated with each sexual behaviour and the study populations key studies were carried out in.

Behaviour	Score	No. of key studies*	Study populations of key studies
Chemsex	47	7	MSM
No. of partners	34	5	MSM
Previous bacterial STI	52	9	MSM, GUM clinic attendees, male sex workers
GUM attendance	3	1	GUM clinic attendees
New sex partner	3	0	N/A
Condom use	28	5	MSM, trans women, GUM clinic attendees
Exclusivity	0	0	N/A
Type of sex	25	4	MSM, trans women

**Many studies identified multiple behaviours associated with risk of HIV/STI acquisition, therefore this column adds up to more than the total number of key studies.*

MSM = Men who have sex with men

Discussion

Chemsex

Seven key studies supported a link between chemsex and HIV/STI acquisition risk [2, 3, 4, 5, 6,7,8]. One cross-sectional study and one cohort study looked at a range of drug use before/during sex, with the latter also including alcohol use [4, 8]. They found that participants engaging in chemsex had 2.14 (1.83-2.50) times the odds of having had a bacterial STI and 1.58 (1.09-2.29) times the odds of HIV acquisition respectively. One further cross-sectional study took place in six cities across Europe and

looked specifically at inhaled nitrate use at last sex among MSM [5]. It found those who had use inhaled nitrate at their last sexual encounter had 3.36 (1.98-5.70) times the odds of an undiagnosed HIV infection.

Some of the key studies did not specifically link drug use to sex but instead took use of drugs commonly used for chemsex, such as methamphetamine, gamma hydroxybutyrate (GHB)/ gamma butyrolactone (GBL) or inhaled nitrite, as their risk factor [3,6,7]. One of these studies allowed participants to define sexual performance enhancing drugs themselves [2].

Several of these studies found links between chemsex and other potentially high-risk behaviours such as sex with a person who injects drugs (PWID), unprotected anal intercourse (UAI), higher numbers of sexual partners, group sex and lower condom use [3,4,7]. These papers and others propose that the link seen between chemsex and HIV/STI acquisition risk is because chemsex increases the likelihood of several of these behaviours which leads to increased chance of acquisition.

Overall, there was very strong evidence of a link between chemsex and HIV/STI acquisition risk and hence be an appropriate question to be used to identify donors with higher risk of acquiring infection.

Number of partners

Five key studies were found that support a link between increased numbers of partners and increased HIV/STI acquisition risk [2,8,9,10,11]. One cohort study looked at high risk MSM across 47 US cities [2]. In an adjusted regression model this study found and those with 5-10 sexual partners and those with >10 partners in the past ix months had 1.8 (1.3-2.6) and 2.4 (1.7-3.3) times the odds of HIV acquisition compared to those with <5 partners. A cross-sectional study in MSM in New Zealand also looked at number or partners in the past six months but with STI diagnosis as the outcome [10]. It found significantly increased STI diagnosis for those with 6-10, 11-20, 21-50 and >50 partners compared to those with 1, and a general trend of increasing odds with increasing partner number was seen.

One cross-sectional study in MSM in London found very high odds with increasing number of partners but this looked specifically at number of partners who the participant had had UAI with, and so this is likely to explain the large odds ratios [9]. It found those with 2-5 UAI partners in the past year had 17.9 (15.4-20.9) times the odds of HIV acquisition compared to those with UAI 0-1 partners; for 6-10 partners this was 54.4 (33.3-88.8) and for >10 it was 69.8 (35.5-138.2).

Overall, there was strong evidence showing that as the number of sexual partners increased so did risk of HIV/STI acquisition. Therefore, this may be worth considering as part of a more individualised risk assessment for blood donors. However, there was no clear consensus across the studies as to how may partners over what time period is deemed as high risk but generally acquisition risk increased with increasing number of sexual partners in any time period.

Previous bacterial STI

Eight key studies were found that support a link between history of a bacterial STI and HIV/STI acquisition risk [2, 5,8,9,11,12,13,14,15]. It should be noted that studies looking at co-infection were not included, only ones using looking at historical STIs. Two cohort studies found participants who had a bacterial STI at the start of the study had an increased risk/rate of subsequent HIV acquisition, with one of these studies showing an HIV acquisition rate about three times higher; 7.2 (6.0-8.4) compared to 2.0 (1.7-2.3) [12,13]. A third cohort study of MSM attending GUM clinics across England, showed the same relationship but also looked at developing a subsequent bacterial STI [11]. It found those who had a bacterial STI at the start of the study had1.43 (1.17-4.26) times the odds of acquiring a subsequent bacterial STI.

Where studies did not use or did not only use baseline diagnosis as their metric but instead asked about STIs in a retrospective time period, all but one of them used 6 or 12 months as their time period [2,6,8,9,13]. Two studies looked at all STIs without specifying these had to be bacterial [3] [10]. Four studies found an association between acquisition risk and specific bacterial STIs such as gonorrhoea, chlamydia and syphilis [5,8,13,15].

Overall, there was very strong evidence showing a link between having a history of bacterial STI and subsequent HIV/STI acquisition. This link was shown when looking at a history of any bacterial STI or specifically a history of gonorrhoea, chlamydia and syphilis. This indicates a question on bacterial STI history is worth considering for inclusion in a more individualised risk assessment.

Condom usage

Five key studies found that decreased condom usage was associated with increased HIV/STI acquisition risk [2,8,10,16,17]. Out of these only two specifically looked at condom usage not in combination with the type of sex, these were a cross-sectional study of MSM in New Zealand and a case-control study on GUM clinic attendees in Northern Italy [10,17]. The former found those reporting low/medium condom use with casual partners had 1.7 (1.2-2,3) times the odds of reporting a bacterial STI in the past year and the latter found people reporting regular condom usage had 0.5 (0.4-0.5) times the odds of acquiring HIV compared to those reporting occasional or no use.

Most of the key studies identified combined condom usage and type of sex, e.g. condomless anal sex, condomless receptive sex, or condomless receptive anal sex, and compared these groups to those not partaking in these behaviours [2,8,16]. This means that the comparisons groups for these studies could be using condoms consistently and could not be engaging in these specific types of sex but not still using condoms. This makes it difficult to tease out where the risk if coming from in these groups.

The evidence for not using condoms and HIV/STI acquisition risk is strong but with potential limitations due to multiple studies combining condom usage and type of sex. A question on condom use may be worth considering for inclusion in a more individualised risk assessment but further research may be required to untangle the risk it poses with the risk from type of sex.

Type of sex

Four key studies were found that showed an association between type of sex and HIV/STI acquisition risk [2,8,10,16]. One cross-sectional study looked specifically at anal sex and found that those reporting anal sex in the past six months had 2.3 (1.3-2.7) times the odds of reporting a bacterial STI in the past year [11].

Other studies looked at anal sex in combination with condom usage which make it difficult to identify where the risk lay as discussed previously [2,8,16]. One such study found those having receptive UAI with a partner presumed to be negative had 1.92 (1.38-2.68) times the odds of HIV acquisition compared to those who didn't engage in UAI [9]. Furthermore, a study in MSM found an association between HIV acquisition and condomless anal sex and another study in MSM found HIV acquisition associated with receptive sex of any kind [2,16].

There's strong evidence for anal sex and/or receptive sex being linked to an increased chance of HIV/STI acquisition. However, since a lot of studies combine condom use and sex type further research may be needed to address this. Overall, asking about anal or receptive sex may be worth considering as part of a more individualised risk assessment.

GUM attendance

One key study was found that showed an association between HIV/STI acquisition risk and attending a GUM clinic [18]. However, this study did not compare GUM attendees to non-attendees but rather took a population of attendees and looked at who opted out of HIV screening. In a cross-sectional study conducted in The Netherlands it was found that heterosexuals opting out of testing had 1.85 (1.39-2.45) times the odds of having a history of STIs. Furthermore, it found that both heterosexuals and MSM who opted out had higher odds of having a current STI-related complaint; 1.98 (1.57-2.51) and 4.22 (2.43-7.33) respectively.

A potential reason for very little evidence being found is because this behaviour restricted to studies specifically looking at screening within a healthcare setting compared to not. For instance, a study by Ferrer et al. wasn't included because a healthcare setting wasn't specified [5]. However, it showed those who had had an HIV test in the previous year had greater odds of having undiagnosed HIV at the time of the study, although the opposite relationship was reported Dukers-Muijrers [18].

Overall, there's very little evidence to support GUM attendance being associated with HIV/STI acquisition risk and what evidence there is does not present a clear direction for their relationship. Therefore, including a question on GUM attendance in a more individualised risk assessment is not recommended, unless further research uncovers stronger evidence presenting a clear relationship between GUM attendance and acquisition risk.

New partners

No key studies were identified that showed a link between having a new sexual partner and HIV/STI acquisition risk however, two non-key studies were identified [19,20]. The first is a study in Australia which conducted interviews with MSM newly diagnosed with HIV and compared them to controls [19]. They found that few HIV infections occurred between men in long term sexual relationships and most occurred men in new sexual relationships. The second study was amongst adolescent women in the US and found that having had a new sexual partner in the previous 12 months was strongly associated with STI acquisition with 3.0 (1.6-5.7) times the odds [20].

The sparsity of evidence is potentially due to how studies may have defined a new partner. For instance, a study may have looked for associations with number of partners or self-defined casual partners instead of specifically asking about new partners. This seems likely given that many studies were found which looked at number of partners and several which referred to casual partners, as defined by the participant.

Based on this literature review there is insufficient evidence to support including a question on new sexual partners in a more individualised risk assessment. However, there is some evidence pointing towards an association between new partners and acquisition risk and, as mentioned, it's thought the sparsity of evidence may be due to how studies have categorised/defined new partners. With this in mind it may still be worth considering.

Exclusivity

No studies were found that linked exclusivity to HIV/STI acquisition. This is potentially because exclusivity was difficult to define or was defined by the study in terms of number of partners and so was categorised under this sexual behaviour instead. Some studies did refer to casual sex partners which could be interpreted as a substitute for non-exclusive. However, the opposite of a casual relationship is not necessarily an exclusive one and so conclusions about exclusivity can't be drawn from these studies. This difficulty in defining an exclusive relationship is one that may also cause problems if a question on exclusivity formed part of a more individualised risk assessment.

Because of the lack of evidence uncovered in this literature review including relationship exclusivity in a more individualised risk assessment for blood donors cannot be recommended. However, if further research uncovers evidence suggesting otherwise and the problem of defining exclusivity can be overcome then it may be worth considering.

4.1.2. References

[1] Brady OJ, Gething PW, Bhatt S, Messina JP, Brownstein JS, Hoen AG, et al. (2012) Refining the Global Spatial Limits of Dengue Virus Transmission by Evidence-Based Consensus. PLoS Negl Trop Dis 6(8): e1760. https://doi.org/10.1371/journal.pntd.0001760

[2] Ackers M-L, Greenberg AE, Lin CY, et al.: High and persistent HIV seroincidence in men who have sex with men across 47 U.S. cities. *PloS one* 2012; 7: e34972

[3] Rudy ET, Shoptaw S, Lazzar M, et al.: Methamphetamine use and other club drug use differ in relation to HIV status and risk behavior among gay and bisexual men. *Sexually transmitted diseases* 2009; 36: 693-5.

[4] Sewell J, Miltz A, Lampe FC, et al.: Poly drug use, chemsex drug use, and associations with sexual risk behaviour in HIV-negative men who have sex with men attending sexual health clinics. *International Journal of Drug Policy* 2017; 43: 33-43.

[5] Ferrer L, Furegato M, Foschia J-P, et al.: Undiagnosed HIV infection in a population of MSM from six European cities: results from the Sialon project. *European journal of public health* 2015; 25: 494-500.

[6] Katz DA, Dombrowski JC, Bell TR, et al.: HIV incidence among men who have sex with men after diagnosis with sexually transmitted infections. *Sexually Transmitted Diseases* 2016; 43: 249-54.

[7] Kohli M, Hickson F, Free C, et al.: Cross-sectional analysis of chemsex drug use and gonorrhoea diagnosis among men who have sex with men in the UK. *Sexual Health* 2019; 16: 464-72.

[8] Koblin, Beryl A[a]; Husnik, et al. Risk factors for HIV infection among men who have sex with men, AIDS: March 21st, 2006 - Volume 20 - Issue 5 - p 731-739 doi: 10.1097/01.aids.0000216374.61442.55

[9] Aghaizu A, Wayal S, Nardone A, et al.: Sexual behaviours, HIV testing, and the proportion of men at risk of transmitting and acquiring HIV in London, UK, 2000-13: a serial cross-sectional study. *The Lancet HIV* 2016; 3: e431-e40.

[10] Dickson N, Ludlam A, Saxton P, et al.: Self-reported STIs and sexual health checks in a cross-sectional study of gay and bisexual men in New Zealand. *Sexually transmitted infections* 2015; 91: 49-54.

[11] Desai S, Burns F, Schembri G, et al.: Sexual behaviours and sexually transmitted infection outcomes in a cohort of HIV-negative men who have sex with men attending sexual health clinics in England. *International Journal of STD and AIDS* 2018; 29: 1407-16.

[12] Llata E, Braxton J, Asbel L, et al.: New Human Immunodeficiency Virus Diagnoses Among Men Who Have Sex With Men Attending Sexually Transmitted Disease Clinics, STD Surveillance Network, January 2010 to June 2013. *Sexually transmitted diseases* 2018; 45: 577-82.

[13] Desai S, Nardone A, Hughes G, et al.: HIV incidence in an open national cohort of men who have sex with men attending sexually transmitted infection clinics in England. *HIV medicine* 2017; 18: 615-22.

[14] Fournet N, Koedijk FDH, van Leeuwen AP, et al.: Young male sex workers are at high risk for sexually transmitted infections, a cross-sectional study from Dutch STI clinics, the Netherlands, 2006-2012. *BMC infectious diseases* 2016; 16: 63.

[15] Kassler WJ, Zenilman JM, Erickson B, et al.: Seroconversion in patients attending sexually transmitted disease clinics. *AIDS (London, England)* 1994; 8: 351-5.

[16] Buchbinder SP, Glidden DV, Liu AY, et al.: HIV pre-exposure prophylaxis in men who have sex with men and transgender women: a secondary analysis of a phase 3 randomised controlled efficacy trial. *The Lancet Infectious diseases* 2014; 14: 468-75.

[17] Parazzini F, Cavalieri D'oro L, Naldi L, et al.: Number of sexual partners, condom use and risk of human immunodeficiency virus infection. *International journal of epidemiology* 1995; 24: 1197-203.

[18] Dukers-Muijrers NHTM, Niekamp AM, Vergoossen MMH, et al.: Effectiveness of an opting-out strategy for HIV testing: evaluation of 4 years of standard HIV testing in a STI clinic. *Sexually transmitted infections* 2009; 85: 226-30

[19] In Australia, Most HIV Infections Among Gay and Bisexual Men are Attributable to Sex with 'New' Partners. AIDS and behavior 21(8) 2543-2550.

[20] New sex partner acquisition and sexually transmitted disease risk among adolescent females. Journal of Adolescent Health 34(3) 216-223.

4.2.Risk of transmission by exposure route

The available data for risk of transmission of HIV through a range of sexual and other route has been systemically reviewed by Patel *et al.* and an estimate of risk of transmission per 10,000 acts calculated (Table 4.4). Unfortunately, similar data is not available for hepatitis B, although it would be expected that risks would be in the same order although it is known that for needlesticks hepatitis B is more easily transmitted than HIV.

Table 4.4: Estimated per-act probability of acquiring HIV from an infected source, by exposure route.

Exposure route	Risk per 10 000 exposures to an infected source	95% Confidence interval
Blood transfusion	9250	(8900–9610)
Needle-sharing injection drug use	63	(41–92)
Percutaneous needle stick	23	(0–46)
Receptive anal intercourse	138	(102–186)
Insertive anal intercourse	11	(4–28)
Receptive penile–vaginal intercourse	8	(6–11)
Insertive penile–vaginal intercourse	4	(1–14)
Receptive oral sex	Low	(0–4)
Insertive oral sex	Low	(0–4)

Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. Estimate of risk of transmission from sexual exposure to an HIV-infected partner assumes no condom use.

4.3. Sexually transmitted viruses with the potential transfusion transmissible risk that blood donations are not screened for in the UK

All UK blood donations are screened for markers of HIV and hepatitis B and C viruses (HBV and HCV, respectively), and markers of Human T-cell Lymphotropic Virus (HTLV) among donations from new donors. Donations found to be reactive are excluded from the supply to minimise transfusion risk. Here we consider some other sexually transmitted viruses circulating in the UK that blood donations are not screened for and could pose a potential transfusion transmissible risk. Consideration has been given to the impact of a change in the donor deferral criteria regarding sexual behaviours, particularly for MSM, and whether increased levels of these viruses among newly eligible donors could be expected.

Any virus with an asymptomatic blood-borne phase has the potential to be transmitted via transfusion. The likelihood of transmission will depend on the level in the donor population, as well as persistence of the virus in the blood component and the ability to cause infection by intravenous route. The potential for risk reduction or removal through donor selection, testing, storage or processing also needs to be considered. However, to be relevant to blood safety, the virus also needs to cause disease in the recipient, which may be more likely for immunosuppressed individuals receiving transfusions.

The characteristics of the viruses considered relevant to the FAIR review are summarised below (Table 4.5). The herpes viruses CMV, HSV 1 & 2, and HHV8 are known to be sexually transmitted via bodily fluids. There is evidence of increased seroprevalence for these among HIV negative MSM. Previous reviews of donor selection criteria related to MSM have reviewed the risk of HHV8 but to date there is no evidence that this is transmitted through transfusion. Both CMV and HSV are associated with severe disease in seronegative neonates, currently CMV screening is carried out on a selected group of donations for specific recipient groups as recommended by SaBTO. In addition, leucodepletion is routinely carried out as part of vCJD risk reduction measures but also gives addition risk mitigation of leucocyte associated viruses. There are already specific donor selection criteria for any acute infection and specific donor deferrals in place for donors with active HSV infection, information about sexually transmitted infections should be included as part of the Welcome folder and in any communications regarding a change to donor selection criteria. Despite the potential increased risk of some infections in MSM it should be acknowledged that although a time-based 3-month deferral has been in place for MSM since 2017, there has been no associated increase in reports of transfusion-transmitted infection.

Of most concern are those viruses with low endemicity in the UK but where specific sexual behaviours such as anal sex may contribute to outbreaks. Hepatitis A virus (HAV) infection is generally associated with contaminated food or water and has a low seroprevalence in the UK, however outbreaks have been associated with oral/anal sex among MSM. Since this outbreak guidelines have been updated it is recommended that all MSM attending sexual health clinics should be screened for HAV antibody and vaccinated if anti-HAV IgG negative although there may still be some regional variation HAV transfusion-transmitted infections has been reported in the UK, to date 4 transmission have been confirmed since 1996, most recently during an outbreak amongst MSM in 2016-2017 when a transmission was reported from platelet transfusion in 2017. In both cases the donors were compliant with the donor selection criteria. In the earlier transfusion-transmission, the donor reported symptoms within 2 weeks of donation which allowed immunoglobulin to be given to the recipient and resulted in a mild infection. It is possible that donors could remain asymptomatic. It is important that blood services remain vigilant for any outbreaks of infectious disease that may impact on blood safety. During the most recent hepatitis A outbreaks in 2016-2017 actions were taken to avoid taking donations in areas where they had been clusters of infection and public health agencies were asked to inform the blood services of any cases or contacts that were identified. Currently hepatitis A screening is not routine, however, any move to collect plasma for fractionation may result in the current screening status being reviewed.

Parv4, Human pegivirus (HPgV-1), human papillomaviruses (HPV) and polyomaviruses were also considered. There is some evidence of increased prevalence among MSM. Both PARV4 and HPgV1 are largely asymptomatic and although these viruses can be detected in blood there is currently no evidence to suggest that transfusion is a significant mode of transmission.

Table 4.5: Summary of sexually transmitted viruses with the potential transfusion transmissible risk that blood donations are not screened for in the UK

Virus	**Evidence for increased prevalence in newly eligible donor population**	**Likelihood of transmission via blood transfusion**	**Potential for risk reduction or removal**	**Impact if recipient exposed**	**Conclusions**
CMV Cytomegalovirus (Vyse *et al*. 2009, Bilsen *et al*. 2018)	Yes - increased prevalence among HIV negative low risk MSM v non-MSM male donors in Netherlands	Low in the presence of testing and LD although theoretical risk of cell free viraemia	High - LD, red cell cold storage, testing. PI possible (solvent-detergent, methylene blue)	Severe disease in immunocompromised and neonates	Current risk mitigation in place likely appropriate for any increase in incidence
Herpes simplex virus 1 and 2. (HSV-1, HSV-2)	Yes - increased prevalence among HIV negative MSM in England and Wales, and among low risk MSM compared to non-MSM male donors in Netherlands	Low in the presence of LD - but theoretical risk of cell free viraemia	High - LD, red cell cold storage. PI possible (solvent-detergent, methylene blue).	Severe disease in seronegative immunocompromised and newborns	Current risk mitigation in place likely appropriate for any increase in incidence
HHV-8	Yes - increased prevalence in MSM irrespective of HIV status. Increased prevalence associated with people originating from endemic countries	Low in the presence of leucodepletion (LD) - but theoretical risk of cell free viraemia	High - LD, red cell storage. PI possible (solvent-detergent, methylene blue). No appropriate test available	Clinical disease not documented via transfusion. Incidence of neoplasia including Kaposi's sarcoma increased in immunosuppressed	Current risk mitigation in place likely appropriate for any increase in incidence
Hepatitis A virus (HAV)	Yes - infections generally associated with travel to endemic countries however peak in 2017 among MSM. No recent data from UK blood donors	Low due to short viraemic phase, low concentration of virus in the blood, absence of a carrier state	High - donor deferral for recent jaundice/hepatitis in place. Also serological and molecular testing available if required. LD not effective. Not susceptible to PI	Any non-immune or immunosuppressed patient risk becoming infected. Vaccination and immunoglobulin could be offered to exposed patients (if known). Multi transfused could be offered vaccination.	Unlikely incidence in donor population would increase given virus characteristics and donor deferral in outbreak situation

PARV4	Yes - higher rates of infection are found in MSM. A study in UK blood donors 3 to 5% with IgG antibodies to PARV4, but no sample had detectable PARV4 DNA.	Low - although detected in whole blood and plasma no evidence of transmission via transfusion	No commercial assays available - inhouse possible e.g. NAT	No adverse outcome for infected individuals	No additional risk expected
Human pegivirus HPgV-1 (previously known as GBV-C, HGV) Scallan *et al*. 1998	Yes - HIV negative MSM 17% viraemic v 3% controls (low risk GUM attenders).	No evidence		No evidence that would cause a symptomatic infection, although major impact for HIV infected.	No additional risk expected
Papillomaviruses (Cladel *et al*. 2019)	Yes - MSM<45 immunised since 2018. MSM have higher rates of HPV infection and HPV-related disease including genital warts and anal cancer.	Virus detected in sexually naïve ,multitransfused children. Evidence of transmission via transfusion from animal models	Testing/PI	Not clear. Infections in animal models manifested in genital sites and vital organs. Could be many years after transfusion.	No additional risk expected
Polyomaviruses (HPyVs) (Kamminga et al. 2019)	Not sure. Common in general population, acquired in childhood, causing persistent infection. 5.4% Dutch donors virus detected.	Transfusion-transmitted HPyV infection has not been reported	PI not expected to be effective as non-enveloped. LD may be effective. Seropositive recipient may not be protective	Severe disease in immunocompromised and elderly recipients	No additional risk expected

PI – Pathogen inactivation, LD - Leucodepletion

4.3.1. References

To finalise

Cladel NM, Jiang P, Li JJ, et al. Papillomavirus can be transmitted through the blood and produce infections in blood recipients: Evidence from two animal models. *Emerg Microbes Infect*. 2019;8(1):1108-1121. doi:10.1080/22221751.2019.1637072

Kamminga S, van der Meijden E, de Brouwer C, Feltkamp M, Zaaijer H. Prevalence of DNA of fourteen human polyomaviruses determined in blood donors. *Transfusion*. 2019;59(12):3689-3697. doi:10.1111/trf.15557

Plunkett J, Mandal S, Balogun K, et al. Hepatitis A outbreak among men who have sex with men (MSM) in England, 2016-2018: The contribution of past and current vaccination policy and practice. *Vaccine X*. 2019;1:100014. doi:10.1016/j.jvacx.2019.100014

Scallan MF, Clutterbuck D, Jarvis LM, et al., Sexual transmission of GB virus C/hepatitis G virus*, J Med Virol*, 1998; 55: 203-8.

Van Bilsen WP, Zaaijer HL, Matser A, et al.: Infection pressure in men who have sex with men and their suitability to donate blood. *Topics in Antiviral Medicine* 2018; 26 (Supplement 1): 410s-1s.

Vyse AJ, Hesketh LM, Pebody RG: The burden of infection with cytomegalovirus in England and Wales: how many women are infected in pregnancy? *Epidemiol Infect* 2009; 137: 526-33. Beebeejaun K, Degala S, Balogun K, Simms I, Woodhall SC, Heinsbroek E, et al. Outbreak of hepatitis A associated with men who have sex with men (MSM), England, July 2016 to January 2017. Euro Surveill. 2017;22(5):30454. https://doi.org/10.2807/1560-7917.ES.2017.22.5.30454 PMID: 28183392

4.4. Acceptability of questions and potential risk behaviours in current blood donors: BEST surveys

4.4.1. Behaviour survey

Background

In 2019, an anonymous online survey of blood donors was undertaken which aimed to look at the levels of certain sexual behaviours in the English donor population. A link to the survey was sent via email by NHS Blood and Transplant's (NHSBT) Donor Insight team to roughly 3,500 new donors and 3,500 repeat donors, both randomly sampled and known to have donated within the previous two weeks. All 7,000 donors also received two reminder emails roughly 1 week and 2 weeks after the initial email. The survey questions can be accessed in Appendix 3.

Response rate

The overall response rate was 18.9% (1,311/6,949). Response rates were similar between males and females but were higher in older age groups, potentially leading to some age bias. 62% of respondents were female, 15% self-classified as new donors (classification may differ from NHSBT classification), 8% were 17 to 24, 18% were 25 to 34, 19% were 35 to 44, 23% were 45 to 54, 17% were 55 to 64, and 13% were 65+. These proportions are mostly similar to donor demographics in 2018 except for new donors which was 5% lower than donor population. [1]

Sex in the past 12 months

Table 4.6: Have you had sex with anyone in the past 12 months (including oral sex)? n=1,311

	Proportion (no.)
Yes	74.4% *(976)*
No	23.3% *(306)*
Prefer not to say	2.2% *(29)*

The 25 to 34-year-old group was most likely to have said yes with decreasing proportions in age groups above this. Six men declared they had oral or anal sex with other men at any time period, five were in the past three months indicating non-compliance with donor selection guidelines.

Exclusivity

Table 4.7: Do you believe your current relationship is exclusive (neither of you have sex with any other people)? n=932

	Proportion (no.)
Yes	89.6% *(835)*
No	3.4% *(32)*
Don't know	1.0% (9)
Not in a sexual relationship	5.7% (53)
Prefer not to say	0.3% *(3)*

Significantly more repeat donors said they were in an exclusive relationship, a difference which seems to relate to age. In general, with each age group there was an increasing proportion of respondents saying they were in an exclusive relationship from 67% (53) in 17 to 24 year olds to a peak of 96% (134) in the 55 to 64 age group. The slight decrease seen from the 55 to 64 year old to the 65+ age group seems to be partly due to this age group not wanting to disclose this information.

New sexual partner

5% (39) of respondents had a new sexual partner in the past three months and 9% (76) in the past 12 months. New donors were more likely to have a new sexual partner at all time periods.

Number of sexual partners

Table 4.8: How many different sexual partners have you had in the last… n=852, n=845 & n= 907 respectively

	3 months - % (no.)	6 months - % (no.)	12 months - % (no.)
0	27% (228)	25% (209)	23% (207)
1	71% (602)	70% (592)	68% (619)
2	1% (12)	3% (25)	4% (36)
3	0% *(4)*	1% *(7)*	2% (14)
More than 3	0% *(4)*	1% (10)	3% (27)
Prefer not to say	0% *(4)*	0% *(2)*	0% *(4)*

Across all time periods there was a general trend of having more sexual partners the younger the respondent was. New donors also tended to have more partners, which seems to be related to age.

Condom usage (including for oral sex)

Most responding, 85% (743/871), said they didn't use a condom every time they had sex in the past 3 months, 88% (736/835) in the past 6 months, and 91% (803/886) in the past 12 months. At each time period between 91% and 94% of those who didn't use a condom every time they had sex said they were in a relationship they believed to be exclusive.

Anal sex

Table 4.9: Have you had anal sex with anyone in the last… n=852, n=845 & n= 907 respectively

	3 months - % (no.)	6 months - % (no.)	12 months - % (no.)
Men only	3% (23)	3% (25)	6% (55)
Women only	2% (13)	3% (21)	3% (29)
Men and women	0% *(0)*	0% *(0)*	0% *(0)*
Didn't have anal sex	95% (774)	94% (756)	90% (761)
Prefer not to say	1% *(5)*	1% *(5)*	1% *(5)*

As age increased there was a trend of an increasing proportion of respondents not having had anal sex in the past 6 month or the past 12 months.

Overall, five men had anal sex with another man, all within the last three months indicating non-compliance. Of those respondents who had anal sex at each time period between 71% and 76% did not use a condom every time they had anal sex. Only one respondent had anal sex without a condom in the past 3 months who didn't consider themselves to be in an exclusive relationship.

Chemsex

Only 7 people engaged in chemsex in the past 3, 6 or 12 months, 1% of respondents at each time period. Two were male, five were female and all were repeat donors with ages from 25 to 70.

Bacterial STI

One respondent had been diagnosed with or received treatment for a bacterial STI in the past 3 months and one in the past 12 months. Both were female repeat donors in their 20's. This may include chlamydia.

4.4.2. Acceptability of questions survey

Background

In 2019, an anonymous online survey of blood donors was undertaken which aimed to find out how acceptable donors would find being asked questions on certain sexual behaviours as part of the donor selection process. A link to the survey was sent via email by NHS Blood and Transplant's (NHSBT) Donor Insight team to roughly 3,500 new donors and 3,500 repeat donors, both randomly sampled and known to have donated within the previous two weeks. This was a different donor population than those who received the behaviour survey. All 7,000 donors also received two reminder emails roughly 1 week and 2 weeks after the initial email. The survey participants were different to those in the behaviour survey. Questions are available to review in appendix 3

Response rate

The overall response rate was 17.8% (1,239/6,957). Response rates were similar between males and females but were higher in older age groups, potentially leading to some age bias. 66% of respondents were female, 18% self-classified as new donors (classification may differ from NHSBT classification), 9% were 17 to 24, 19% were 25 to 34, 19% were 35 to 44, 23% were 45 to 54, 20% were 55 to 64, and 10% were 65+. These proportions are all similar to the donor demographics in 2018.

Ever had sex

Table 4.10: Have you ever had sex (this includes oral sex)?

n=1,236

	Proportion (no.)
Yes	96% (1,186)
No	3% (39)
Prefer not to say	1% (11)

Results

The following question were framed under the text "Please rate how comfortable you would be answering questions on these topics in order to donate blood or platelets…"

Red text in table 4.11 indicates where the combined response of "completely comfortable" and "somewhat comfortable" is below 90% or when the response "would stop me from donating" is above 2%.

Table 4.11: Acceptability

	Completely comfortable	Somewhat comfortable	Somewhat uncomfortable	Completely uncomfortable	Stop me from donating	Total no.
Exclusivity	81%	12%	5%	2%	1%	1,239
No. partners	81%	9%	6%	3%	1%	1,239
New partner	84%	8%	5%	2%	1%	1,234
Anal sex	**65%**	**10%**	14%	7%	**3%**	1,234
Only oral sex	**67%**	**12%**	12%	6%	2%	1,231
Partner's gender	85%	7%	5%	2%	1%	1,229
Condom use	**78%**	**11%**	8%	2%	1%	1,229
Chemsex	**81%**	**8%**	5%	4%	2%	1,230
Previous bacterial STI	83%	8%	4%	2%	**3%**	1,228

Substantial differences seen

Any differences observed for each question based on gender, donor type (new or repeat), or age are described below.

Anal sex

Table 4.12: Whether you have had ANAL sex with anyone in the last 6 months.. n=411 & n=811 respectively

	Male - % (no.)	Female - % (no.)
Completely comfortable	74% (303)	61% (497)
Somewhat comfortable	8% (34)	12% *(94)*
Somewhat uncomfortable	9% (36)	17% (141)
Completely uncomfortable	5% (22)	8% (62)
Would stop me from donating	4% (16)	2% (17)

Only oral sex

Table 4.13: Whether you had ONLY ORAL sex (no vaginal or anal sex) in the last 6 months. n=409 & n=810 respectively

	Male - % (no.)	Female - % (no.)
Completely comfortable	74% (303)	63% (511)
Somewhat comfortable	11% *(45)*	15% (121)
Somewhat uncomfortable	9% (38)	13% (109)
Completely uncomfortable	4% (16)	7% (56)
Would stop me from donating	2% *(7)*	2% (13)

For most questions, there was a trend of increasing proportions of respondents answering "completely comfortable" as age increased i.e. older ages more comfortable with answering these questions. This ranged from an 11% difference between the 17 to 24 and 65+ age group for a question on new partners (76% vs 87%) to a 25% difference for a question on anal sex (51% vs 76%). However, this was often accompanied by a trend of decreasing proportions answering "somewhat comfortable" and "somewhat uncomfortable" as age increased. No trend was seen across age for "completely uncomfortable" or "would stop me donating" but the numbers are very small here. This was not the case for a question on gender of partner for which no age trend was seen.

Recall of sexual partners

99% said they could definitely recall the no. of sexual partners they had in the last 3 months

98% said they could definitely recall the no. of sexual partners they had in the last 6 months

97% said they could definitely recall the no. of sexual partners they had in the last 12 months

5. A Psychometric Approach to Developing Screening Tool

5.1.Key points

- The outcome of the psychometric work including surveys of the general population and donors in the UK, and surveys in Canada of MSM, patients and the general public together with interviews and focus groups in the UK with MSM, patient, staff and donors is briefly described below.
- Four sexual behaviour questions are identified as forming a coherent psychological cluster that picks up epidemiological higher risk behaviours (a previous bacterial STI, chemsex, a new sexual partner in the last 3 months and having more than one sexual partners in the last 3 months).
- Questions related to behaviours with higher epidemiological risk have high reliability.
- These epidemiological higher risk questions map 100% onto the proposed gateway question and together with an additional anal sex question would defer 9.3% of all new comers; 2.3% of those who reported having donated in the last 2 years potential donors and 7% of non-donors.
- Those who score higher on the epidemiological higher risk factors perceive their risk of a future STI to be higher and therefore may be more likely to self-defer and not donate
- The epidemiological higher risk factor has a small degree of impression management bias and this needs to be managed and suggestions are made as to how this may be done
- Issues concerning people's ability to accurately recall their behaviour are expressed. People may be biased in their assessment of accuracy as people rate their own recall accuracy as higher than others do. Interventions to enhance accuracy such as allowing people to use their mobile devices to look back on their previous 3 months activities are suggested
- There is a concern that the nature of the questions themselves may deter new donors, especially questions about anal sex.
- Intersectionality with ethnicity, sex and age needs to be considered.
- The perceived risk to patients from the change in policy is considered to be low.
- Time for staff training and donor education should be factored into any implementation plan.

5.2.Rationale

There is no single way to maintain the safety of the blood supply. Two main interlinked safety measures are: (a) testing of the blood donations and (b) accurate selection of safe donors. With a proposed change to individualized donor selection informed by donors' sexual behaviour, rather than sexuality, careful consideration is needed to: (1) select the most appropriate questions that are open to all, yet which identify those at higher infection risk accurately and reliably by minimizing error in measurement, (2) minimize unforeseen behaviour consequences such as increased deferral or self-deferral, or negative impact on other groups, (3) understand the perceived risks associated with a change and (4) manage the logistics of implementation. Understanding on all these fronts is vital to select the best questions to select and to inform communication about the change.

5.2.1. Psychometric Principles and Approach to Question Selection: Minimizing Error and Enhancing Accuracy

Since blood donation testing has a window period when new infections may not be detected, collection of blood from donors at low risk of blood-borne infection is central to this safety process. Therefore, we need to identify sexual behaviour questions that minimize error and maximize reliable and accurate reporting of sexual behaviours that are associated with both objective and subjective estimates of infection risk.

As such, a donor health check question should have the following psychometric properties. They should:

- be free from motivational biases or the extent of such biases known:

Two reporting biases are important here: *impression management* and *self-deception*. Impression management reflects a motivation to ***consciously*** respond in such a way that presents the person in the best light with respect to how they think others will view them. Self-deception is a ***non-conscious*** belief by the person that something is true of them, but that is not.

- be reliable in terms of the temporal stability of response patterns:

For a question to be reliable, people should provide the same answer to the same question, pertaining to the same time period, when asked to make these judgements twice one week apart. This is termed **test-retest reliability**.

- be psychometrically cohesive:

This means that any set of questions to be used as a potential screen for higher risk sexual behaviour should form a coherent psychometric factor or grouping. That is, people who answer YES to engaging in one particular sexual behaviour will also have a higher probability of answering YES to another in a

coherent manner. For example, those who report having a number of new sexual partners may also report a STI diagnosis, but be less likely to respond positively to a question about using a condom consistently. It is important to identify sexual behaviour questions that go together to identify higher risk behaviours as this will indicate their psychometric appropriateness as a sub-set of questions to be used as a screening tool. We examine this using **principal component analysis (PCA)** on reported sexual behaviours.

- have demonstrable construct validity:

People's self-reported estimates of their own **perceived risk** of future sexually transmitted infections should positively correlate with reporting engaging in riskier sexual behaviours as defined by the epidemiological evidence.

- have demonstrable external validity:

The sexual behaviour questions should be associated with demographics in a predictable and consistent manner;

- have individual and normative consistency for acceptability, accuracy and deterrence across stake-holder groups:

Questions should be seen (i) to be acceptable to be asked, (ii) not to actively deter people from wanting to donate blood and (iii) to be able to be accurately recalled. This needs to be consistent across stakeholders but also both individually and normatively. That is, when an ***individual*** is asked whether a question would deter them, if they find it appropriate and if they could accurately recall the behaviour, we should also examine the extent to which they believe this is also true for other potential donors. It may be that individuals are accepting of specific questions, but believe that others will not be (***normative perspective***), which may lead to overall concern about particular questions. Such a concern may be misplaced if individual and normative perceptions about the acceptability and deterrence value of questions are not aligned.

5.2.2. Minimizing Unforeseen Consequences and Identifying Benefits

Deterring (Costs) and Recruiting (Benefits)

Costs: Any change in policy can bring about uncertainty and lead to unforeseen consequence. Here one potential is that the new questions will increase deferral rates. This may happen in three ways.

Objective deferral: More people are deferred than previously – which may result in a safer system.

Self-deferral based on perceived risk: People may be more likely to self-defer, and decide not to become a donor, as they perceive themselves to be at higher risk based on their sexual behaviours – which again, may result in a safer system.

Self-deferral based on the nature of the questions: People may self-defer not because of their sexual behaviour, but because they do not like the types of question being asked. Thus, we need to understand more about questions which increase this form of deferral.

Benefits: There are two main benefits: attracting new/more donors and organizational reputational gains.

Attracting New/More Donors: A change in policy can attract more new donors. If this is the case, then advertising and communication about the change in policy may be met with more people deciding to donate and encouraging each other to donate blood.

Organizational Reputation Gains: If a change in policy to a system that is based on behaviour rather than sexuality perceived is more equitable and fairer, this should enhance the reputation of the organization and in so doing, potentially attract more new donors.

5.2.3. The perceived risks associated with a change

For a policy change to be considered acceptable to all stakeholders, we need to consider not only the objective risk, but also subjective perceptions of risk. Perceived risk is a good predictor of behaviour and, as such, we need to know if a policy based on asking all donors questions about their sexual behaviour increases or reduces perceptions of risk associated with the transmission of infections.

5.2.4. Logistics, Operational Considerations & Implementation

Finally, any policy change needs to be implemented, marketed and communicated. For any change to be successful careful consideration of these is needed.

Time Demands

Any change needs to consider the logistics of administering the new system. This includes: (1) allowing donor staff to administer the DHC with minimal additional time demands and with clear guidance relating to follow-up conversations with donors and deferral criteria and (2) consideration of the context (privacy issues) in which sensitive questions are asked of donors.

Implementation

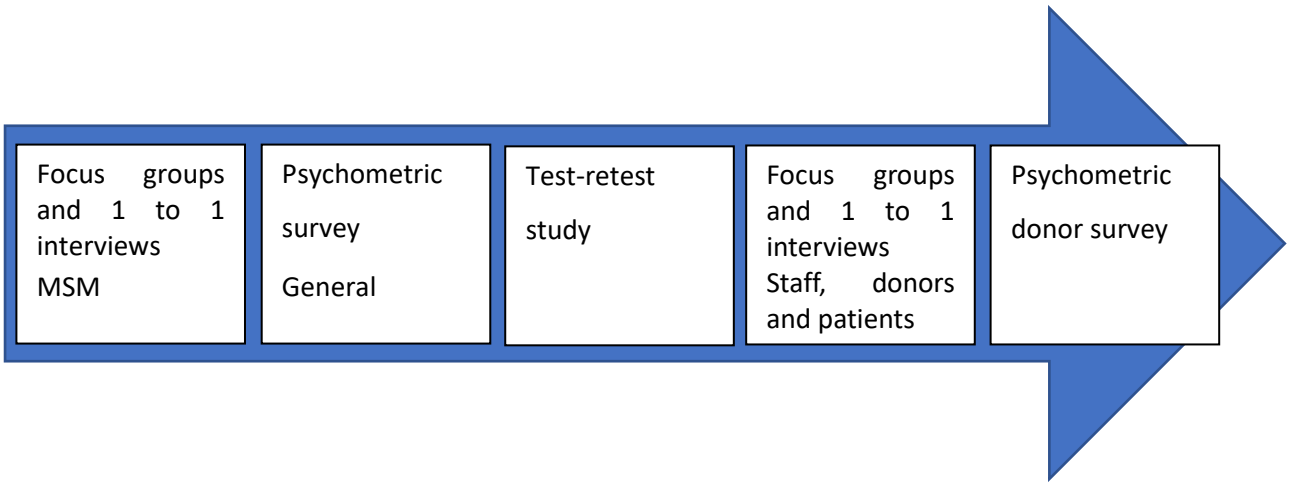
The nature of the change and its rationale needs to be communicated in a clear and effective manner.

5.3.Methodology

To address the objectives set out above, we used a mixed methods approach. We conducted two surveys in the UK (one with the general public and one with existing donors) and drew on data from a recent Canadian Blood Services (CBS) funded project – the SAFE project – in Canada. We conducted a test-retest study to explore the temporal stability of the sexual behaviour questions. We conducted a series of focus groups and interviews with MSM, donors, donor staff and patients (regular recipients of donated blood) to explore the issues examined qualitatively in the surveys in more detail. Thus, we were looking for triangulation between the quantitative and qualitative results. The time line for this separate parts of the psychometric/psychological aspect of this report are detailed in Figure 5.1 below and the detailed methodology given below that.UK

The survey methodologies are detailed below. Two surveys were funded by the project and took place in the UK and one funded by the CBS took place in Canada and the US.

Figure 5.1: Psychometric Studies Timeline



5.3.1. UK Surveys

Psychometric Survey 1:

General Population: This was conducted across staff and students at the Universities of Nottingham, Stirling and Bangor form Dec 2019 to Feb 2020. The survey was online and fully anonymous, and the link was sent to students in all schools across all faculties at Nottingham, to all staff and students in Bangor and psychology students in Stirling. The survey assessed sex, sexuality, donor status, ethnicity, the extent to which the participants had engaged in each of 11 targeted ***sexual behaviours/relationships*** (Yes/No) (see Table 5.1), the extent to which they felt they could **accurately**

recall the behaviour ("How accurate is your answer?, Complete guess, Pretty accurate, Completely accurate), if they felt that the question was ***inappropriate to ask*** ("Is this question inappropriate to ask? Yes/ No) and if being asked the question would deter them from donating blood ("Would being asked this question put you off donating blood? Yes, Quite Likely, Not very likely, No, Not sure). A series of questions on the absolute, relative and acceptable risk were also asked and standard indices of impression management and self-deception biases used.

Table 5.1. Sexual Behaviours in UK Survey 1 (general population) and UK Survey 2 (donors)

Survey 1: Reports of Individual Actual Behaviour	**Survey 2**: Perceptions of Normative Behaviour
Do you believe your current relationship is **exclusive** (neither of you have sex with other people)?	Do you believe your current relationship is **exclusive** (neither of you have sex with other people)?
How many sexual partners have you had in the last 3 months, including oral, anal or vaginal sex (please indicate the number)?	**How many sexual partners** have you had in the last 3 months, including oral, anal or vaginal sex (please indicate the number)?
Have you had any **new** sexual partners in the last 3 months?	Have you had any **new** sexual partners in the last 3 months?
Have you had ONLY **oral sex** in the last 3 months (AND no anal or vaginal sex)?	Have you had ONLY **oral sex** in the last 3 months?
Have you had **anal sex** in the last 3 months?	Have you had **anal sex** in the last 3 months?
Did you use any drugs (excluding Viagra and cannabis) before or during sex to improve your sexual experience in the last 3 months?	Did you use any drugs (excluding Viagra and cannabis) before or during sex to improve your sexual experience in the last 3 months?
Did you use **condoms** every time you had sex in the last 3 months (oral, anal or vaginal sex)?	Did you use **condoms** every time you had sex (including oral, anal or vaginal sex) in the last 3 months?
Have you **given** penetrative sex in the last 3 months?	Have you **given** penetrative sex in the last 3 months?
Have you **received** penetrative sex in the last 3 months?	Have you **received** penetrative sex in the last 3 months?
Have you been **diagnosed** with or been treated for gonorrhea, syphilis or chlamydia in the past **12 months**?	Have you been **diagnosed** with or received treatment for gonorrhea, syphilis or chlamydia in the past **12 months**?
In the last 3 months, have you taken **PrEP (**PrEP is a drug taken by people before sex that reduces the risk of getting HIV) or **PEP** (PEP is a treatment that can stop HIV infection after the virus has entered a person's body. It must be taken within 72 hours of exposure)?	Have you taken PEP in the last 3 months (PEP is a treatment that can stop HIV infection after the virus has entered a person's body. It must be taken within 72 hours of exposure)?
	Have you taken PrEP in the last 3 months **(**PrEP is a drug taken by people before sex that reduces the risk of getting HIV)

Psychometric Survey 2:

Blood donors: 60,000 current blood donors who met the inclusion criteria were randomly sampled in England, 10,000 in Wales, and 10,000 in Scotland. The link to the fully anonymous and unlinked initial survey in England was sent on the 27th of July and the reminder on the 10th of August. In Wales an initial 100 emails were sent on the 20th of July to check the system was working. The remaining emails were then sent out over the next 7 days, with the last initial mail out on the 7th of August (as well as an extra 1000 donors to compensate for any surveys that had bounced back). In Wales, the reminders were sent out from the 24th to the 28th of August. The survey in Scotland was initially set out on 23rd of July and the reminder on 7th August. As the last mail out was August 28th (in Wales), we closed the survey on the 4th of September. In this survey, we were specifically interested in assessing the normative component of recall accuracy, appropriateness and deterrent nature of each of the 12 target ***sexual behaviours/relationships*** (Yes/No) (see Table 5.1). There are 12 questions in this survey as we split the PrEP and PEP questions into two separate questions. These were assessed as follows:

Perceived **accuracy of recall** for the behaviour ("Please remember that we are **NOT** asking you to indicate how accurately **you** would be able to answer each question, **but how accurately you think other donors** would be able to answer each question?" Complete guess, Pretty accurate, Completely accurate).

Perceived ***appropriateness to ask*** ("Please indicate if you think this is an **appropriate** question to ask potential donors?" Yes/ No).

Perceived extent to which questions would **deter people** from donating blood (" Please indicate if you think that being asked this question prior to donating blood would **put people off** donating blood?" Yes/No).

A series of questions on absolute, relative and acceptable risk were also assessed and an index of impression management and self-deception biases.

Inclusion/Exclusion Criteria: Inclusion criteria were: aged over 18, both male and female, all donors registered to donate blood and who have donated in the last 2 years (this is how NHSBT defines a current active donor, those who have not donated for 2 years are archived as lapsed donors), had an email address registered with the blood services. Exclusion criteria were: sampled in other blood service research in the last 6 months, opted out of communications with the relevant blood service, email addresses shared by 2 or more donors and medical deferrals or screen positive donation testing results.

Reliability: Test-Retest Stability Study: We asked participants (N = 31) to recall twice (with a one week interval between) if they had engaged in the 12 target sexual behaviours/relationships over the same previous 12 month time window. This study took place February and March 2020 and was cut short due to COVID-19 restrictions.

5.3.2. Canadian Safe Project

(PI Prof Blaine Ditto McGill University, CI Prof Eamonn Ferguson, Nottingham University, Partners Dr Su Brailsford, Katy Davison & Claire Reynolds, NHSBT)

General Procedure

A targeted anonymous on-line survey of key Canadian stakeholders (patients groups, LGBTQ+ groups, professional and the general public via M*Turk*[6]) was conducted between April 2018 to April 2019, with the M*Turk* Canada sample recruited between September 21st 2018 and April 2019. An additional sample of the general US population was recruited through M*Turk* between December 3rd and 6th 2018 (see Figure 1). This resulted in a final sample of 841 with 96 patients, 228 self-identifying as LGBTQ+, and 72 as blood service / transfusion professionals.

*Measures***:** The survey asked questions about the following:

Perceived acceptable risk for the (then) current 12-month deferral policy and then for a proposed change to a 3 months deferral policy and eventually an individualized risk assessment. Moral beliefs were assessed using Haidt's Moral Foundation Questionnaire.

Trust was assessed both behaviourally, using an economic game, and psychometrically for general trust and trust in others to be honest about their sexual behaviour.

Fast and intuitive processing was assessed using the Cognitive Reflections Test.

A ***willingness to become or remain a blood donor*** question was used to see if policy changes had any negative effect of deterring current donors.

Political activism and standard background demographics, as well as self-defined sexual orientation, ethnicity and religion were assessed. We also assessed the perceived number of MSM who would donate under each policy, perceptions of safety and estimated risk of HIV entering the blood supply under each policy.

[6] This is an online tool to recruit members of the public to participate in research projects.

5.3.3. UK Focus Groups and Interviews with Key Stake Holders (MSM, Donors, Donor Staff and Patients)

The focus group/interview methodologies

MSM Focus Groups and interviews: The sample consisted of 23 self-identified men who have sex men, ranging in age from early twenties to late fifties. These were arranged through Stonewall, Terrence Higgins Trust and the University of Nottingham LGBTQ+ student and staff networks. There were 5 focus groups and 11 one-to-one interviews. Focus groups took place as follows: FG1 took place on the 8th August 2019 with 2 students – one psychology UG, one linguistics PhD. FG2 on the 29th October 2019 with 2 students, both undergraduates, early twenties, both identified as gay and one was a previous donor. FG3 took place on the 12th December 2019 with 2 students, both undergraduates in their early twenties, both from the UK and both identified as gay and both were previous donors. FG4 took place at Stonewall offices in London on the 22nd October with two men in professional roles, one was in their mid-fifties and one was in their mid-thirties. Both from were from the UK, with one in long term monogamous relationship, one single and sexually active. Both identified as gay and both were previous blood donors. FG5 took place at Nottingham University through the LGBTQ+ staff network on the 20th January 2019, with 4 men, all white UK/European, employed by university, with age ranges in the 20s - 50s. Two described themselves as having multiple partners (one in open relationship), and one as being in a monogamous relationship. Three of group were previous blood donors. There were 11 one-to-one interviews, all who identified as male and gay. Their ages ranged from 20s to 50s, with most having professional roles (law, data analysis, arts, education etc.). The interviewees were a mixture of single and both sexually active and not, married or in long-term relationships. Four had donated blood previously, usually before coming out/becoming sexually active. These were not audio-taped and notes were taken.

Staff and Donor Focus Groups: A focus group with staff in England took place in the North of England on the 6th of February 2020 and consisted of 13 staff members. A focus group with 7 staff in Wales took place on 20th of February 2020 and a focus group with 7 donors in wales took place on 20th of February 2020. Six one-to-one interviews took place across April and May 2020 with donors in Scotland (no staff). These were audio-taped and transcribed. Due to staff constraints Northern Ireland couldn't participate in the surveys or focus groups.

Patient Focus Groups: These have been organized through the UK Thalassemia Society and to date, 4 interviews have been completed. All participants were female. These were not audio-taped and notes were taken.

Focus Groups/Interviews Protocol:

Focus groups examined perceptions about the change to a behavioural assessment system and the pros and cons of that change, as well as a specific analysis of the 12 targeted behaviours. The full protocol is below.

MSM, Staff and Donor Focus Groups Schedule.

Existing thoughts about blood donation

Are you aware of the current deferral system for MSM?

(inform participants of the policy at this point)

How do you feel about this? Do you feel it is an important issue that needs to be addressed?

Blood donation behaviour.

Have any of you ever donated blood? (in the non-donor groups)

How long have you been blood donors? (in the donor groups)

Why do you donate blood? (donor groups)

Does the current system deter you from donating blood? (focus question especially for non-donors).

If the donor health check became more detailed in terms of its focus on sexual behaviours, would this deter you from donating blood? (focus question especially for donors and non-donors)

Does the idea of a more detailed donor health check based on sexual behaviour that would be given to all prospective donors be acceptable?

If yes why?

If no, what would need to be considered?

Views on Blood donation behaviour

Looking at the questions which are proposed, are there any specific questions that you feel are offensive, or that you would feel uncomfortable being asked in this context?

Are there any questions that you imagine others would feel were offensive or make them uncomfortable answering?

Are there any questions you feel should be included that are not, and are there any questions that you feel could be re-phrased or re-ordered to make them more acceptable?

Do you feel accuracy of memory might be an issue when recalling these behaviours?

What behaviours would you consider high / low risk in the context of blood donation with respect to getting an infection you can pass on. Please consider infections such as HIV, syphilis, hepatitis (B & C).

Checklist description

There are possible ways of contextualising or the donor health check. People will be asked to complete the donor health check as accurately as they can, and the reasons for this checklist will be given as:

(i) ensuring that you are safe to give blood and your donation is safe for a recipient to receive

(ii) ensuring you are safe to give blood and to maintain the safety of the blood supply

(iii) to ensure a more accurate risk assessment to reduce the risk to the blood supply

Or some combination or alternative. What are your thoughts?

Developing ways of encouraging blood donation

Given the proposed change to the checklist approach what factors do you think will encourage more people to give blood from your perspective?

Feedback element – Feeding back the group's main thoughts to the group for confirmation / amendment.

Additional questions & Debrief

Provide participants with the opportunity to ask any other questions, thank them for their participation and provide them with debrief.

Staff and Donor Interview schedule

Blood donation behaviour.

Have any of you ever donated blood? (in the non-donor groups)

How long have you been blood donors? (in the donor groups)

Why do you donate blood? (donor groups)

Does the current system deter you from donating blood? (focus question especially for non-donors).

Existing thoughts about blood donation

Are you aware of the current deferral system for MSM?

(Inform them all of the policy at this point)

How do you feel about this? Do you feel it is an important issue that needs to be addressed?

If the donor health check became more detailed in terms of its focus on sexual behaviours, would this deter you from donating blood? (focus question especially for donors and non-donors)

Does the idea of a more detailed donor health check based on sexual behaviour that would be given to all prospective donors be acceptable?

If yes why?

If no, what would need to be considered?

Views on Blood donation behaviour

Looking at the questions which are proposed, are there any specific questions that you feel are offensive, or that you would feel uncomfortable being asked in this context?

Are there any questions that you imagine others would feel were offensive or make them uncomfortable answering?

Are there any questions you feel should be included that are not, and are there any questions that you feel could be re-phrased or re-ordered to make them more acceptable?

Do you feel accuracy of memory might be an issue when recalling these behaviours?

What behaviours would you consider high / low risk in the context of blood donation with respect to getting an infection you can pass on. Please consider infections such as HIV, syphilis, hepatitis (B & C).

Questionnaire description

There are possible ways of contextualising or the donor health check. People will be asked to complete the donor health check as accurately as they can, and the reasons for this questionnaire will be given as:

(i) ensuring that you are safe to give blood and your donation is safe for a recipient to receive

(ii) ensuring you are safe to give blood and to maintain the safety of the blood supply

(iii) to ensure a more accurate risk assessment to reduce the risk to the blood supply

Or some combination or alternative. What are your thoughts?

Developing ways of encouraging blood donation

Given the proposed change to the questionnaire approach, what factors do you think will encourage more people to give blood from your perspective?

Feedback element – Feeding back the group's main thoughts to the group for confirmation / amendment.

Additional questions & Debrief.

Provide participants with the opportunity to ask any other questions, thank them for their participation and provide them with debrief.

Patient Interviews Schedule

Schedule

Existing thoughts about blood donation

Are you aware of the current deferral system for MSM?

(inform all participants of the current policy at this point)

How do you feel about this? Do you feel it is an important issue that needs to be addressed?

Views on Blood donation behaviour

Are there any questions that you imagine others would feel were offensive or make them uncomfortable answering?

Are there any questions you feel should be included that are not, and are there any questions that you feel could be re-phrased or re-ordered to make them more acceptable?

Do you feel accuracy of memory might be an issue when recalling these behaviours?

What behaviours would you consider high / low risk in the context of blood donation with respect to the potential donors having an infection they could pass on. Please consider infections such as HIV, syphilis, hepatitis (B & C).

Checklist description

There are possible ways of contextualising the donor health check. People will be asked to complete the donor health check as accurately as they can, and the reasons for this checklist will be given. For example:

(i) ensuring that the donor is safe to give blood and the donation is safe for a recipient to receive

(ii) to ensure a more accurate risk assessment to reduce the risk to the blood supply

Or some combination or alternative. What are your thoughts?

Are there any issues we have not covered that you think are important to note?

Developing ways of encouraging blood donation

Given the proposed change to the checklist approach what factors do you think will encourage more people to give blood from your perspective?

Feedback element – Feeding back the participant's main points for confirmation / amendment.

Additional questions & Debrief.

Provide participants with the opportunity to ask any other questions, thank them for their participation and provide them with debrief.

5.4. Results relating to the main psychometric analyses

5.4.1. Survey results

The tables below (Tables 5.2 to 5.4) detail the sample descriptives for the two UK surveys and the Canadian SAFE project.

Table 5.2: UK Survey 1 (general public)

Variable	Mean (SD) or N
Age	25.49 (10.2)
Gender	
Male	200
Female	532
Sexual Orientation	
Straight	487
Gay	48
Lesbian	14
Bisexual or Pansexual	145
Other	22
Organisation	
Nottingham	325
Stirling	63
Bangor	405
THT	2
Website	3
Donor Status	
Current Donor	191
Past Donor	279

Survey dates were December 2019 to February 2020.

Table 5.3: UK Survey 2 (donors)

Variable	England	Scotland	Wales (English)	Wales (Welsh)
Age	47.9 (14.7)	54.4 (8.2)	47.9 (14.7)	51.30 (13.7)
Gender				
Male	2421	668	1056	31
Female	4231	836	1474	37
Other	23	0	5	0
Prefer not to say	20	0	7	0
Sexuality				
Heterosexual	5882	1392	2273	61
Bi/Pan Sexual	317	20	87	1
Lesbian	87	3	21	2
Gay	71	8	14	0
Celibate/Grey Sexual	13	2	9	0
Prefer not to say/Other	144	27	58	3
Donor Status				
<1m	1544	279	396	13
2 – 12 month	4244	1087	1856	49
12m – 2years	546	104	226	4
> 2 years	259	12	21	1
Can't remember	32	2	17	0
Started	7966 (13.3%)	1782(17.8%)	3041	84 (31.24%)*
Completed 95%	5983 (9.97%)	1317 (13.17%)	2189	47 (22.36%)*

Heterosexual = heterosexual, straight and Cis. % = combination of Scottish, English and Welsh Surveys

Table 5.4: SAFE Project (general public, patients and sexuality)

Variable	Mean (SD) or N
Age	38.12 (13.23)
Gender	
Male	372
Female	532
Other	17
Prefer Not to Say	6
Sexual Orientation	
Straight	585
Mostly Straight	12
Gay	89
Bisexual or BiCurious	59
Other	68
Organisation	
Professionals	72
LGBTQ+	103
Patients (Other)	41
Patients (SCD, Anaemia & Thalassemia)	55
Canadian Public	312
US Public	258

It should be noted that for the UK donor survey (survey 2, Table 5.3) that there are a number of donors who identified as non-heterosexual. In England for example, about 6% of the sample of donors self defined their sexuality as Bi/Pansexual or Gay.

5.4.2. Psychometric Principles and Approach to Question Selection: Minimizing Error and Enhancing Accuracy

Below we detail the results relating to the main psychometric analyses.

Free from motivational biases or the extent of such biases known:

Table 5.5 details the association between impression management (IM) and self-deception (SD) bias and the reporting of sexual behaviours. Having had a new sexual partner, number of sexual partners, having had an STI and using drugs for sex were all negatively associated with impression management. As such, people who have a tendency to create or portray a positive image to others are likely to report fewer sexual partners, not having had a new partner, and are less likely to report having had an STI and having used drugs for sex. Thus, if these questions form part of any screening, further algorithmic procedures will be needed with their implementation to reduce the effect of such bias. These could also include 'normalizing and non-judging' the reporting of these behaviour as something that everyone does (especially new or more partners) and emphasising that the donor is not being judged. However, it should be noted that the effect sizes for these associations is small.

Reliable in terms of temporal stability of response patterns:

Table 5.5 also details the temporal stability of the sexual behaviour questions (last column). Reliability varies between -1 and +1 with +1 being perfectly stable and reliable. Of these behaviours, the consistent use of condoms for sex is the least reliably reported behaviour. The other questions are all reliably estimated.

Psychometrically Cohesion:

These analyses are reported in Table 5.6. We applied a principal components analysis (PCA) with oblique rotation.

The first component indicates that reporting having a new sexual partner, greater number of sexual partners, using drugs to enhance sexual behaviour and having a recent STI diagnosis all share common covariance. That is, people who disclose one of these behaviours have a higher probability of reporting the other 3 behaviours. These four questions all relate directly to a set of higher risk sexual behaviours as defined in terms of the epidemiological evidence. Therefore, we will name this coherent clustering of questions as 'epidemiological higher risk' behaviours. This clustering suggests which questions could be used to define and identify those more likely to be engaging in higher risk sexual behaviour, however, overall a positive response to these 4 questions is negatively associated with impression management (see bottom panel of Table 6). As such, people wanting to appear in a positive light

typically report fewer sexual partners, and are less likely to report having an STI, a new partner and engaging in chemsex. Thus, if used as a screen, this association needs to be acknowledged and mitigated (see section above “Free from motivational biases or the extent of such biases known”). However, the effect size of this association is small.

The 2nd component relates to giving penetrative sex and being less likely to receive penetrate sex and is not associated with impression management but is negatively associated with self-deception. We name it “Giving Penetrative sex”.

The 3rd component relates to having safer sex and comprises using a condom, having only oral sex and being less likely to report having anal sex. Therefore, we term this clustering of behaviours as ‘safer sex’ and it is uncorrelated with impression management or self-deception.

Table 5.5 Association with Response Bias, Reliability and Percentage by Donor Status (Survey 1)

	IM associations	SD associations	Yes		Accuracy		Inappropriate		Deter [Yes-Quite Likely]		
			Donor	Non-Donor	Donor	Non-Donor	Donor	Non-Donor	Donor	Non-donor	Reliability
Do you believe your current relationship is **exclusive** (neither of you have sex with other people)?	-.005	-.090*	66.3% (4.8% unsure & 33.7 not in a relationship)	55.6% (6.6% unsure & 37.9 not in a relationship)	95%	92.2%	23%	25.7%	4.8%	6.9%	V = .893*** (yes, no, not in a relationship)
How many sexual partners have you had in the last 3 months, including oral, anal or vaginal sex (please indicate the number)?	-.181**	.028	16.7% = More than one 57% = one	16.7% = More than one 57.8% = one	97.3%	95.4%	35.3%	34.1%	6.4%	8.9%	ρ = .964***
Have you had any **new** sexual partners in the last 3 months?	-.185**	-.003	21.9%	23.5%	98.9%	99%	21.4%	26.2%	1.6%	6.2%	ϕ = .667***
Have you had **anal sex** in the last 3 months?	-.069	.011	12.7%	15.6%	95.6%	96.9%	38.7%	34.9%	11%	17.2%	Constant
Have you had ONLY **oral sex** in the last 3 months (AND no anal or vaginal sex)?	-.095	.049	7.7%	5.2%	97.8%	97.5%	36.3%	30.9%	9.5%	12.7%	ϕ = 1.00
Did you use **condoms** every time you had sex in the last 3 months (oral, anal or vaginal sex)?	.044	-.027	28.1%	18.3%	95.4%	95.2%	22.6%	23.1%	3.4%	7.5%	ϕ = .558***
Drugs	-.209**	-.072	5.1%	4.5%	97.7%	98.1%	28.1%	22.7%	5.6%	8.3%	ϕ =.695***
PrEP or **PEP**	.039	.020	0%	1.1%	97.3%	99.6%	14.2%	18.5%	0.6%	4.9%	Constant
Have you **received** penetrative sex in the last 3 months?	-.072	-.066	57.7%	57.8%	99.4%	98.5%	22.7%	23.1%	5.1%	9.0%	ϕ =.844***
Have you **given** penetrative sex in the last 3 months?	-.068	-.112**	14.1%	19.6%	99.4%	96.3%	22.4%	22.4%	5.3%	7.3%	ϕ =.895***
Have you been **diagnosed** with or been treated for gonorrhea, syphilis or chlamydia in the past **12 months**?	-.111*	. 026	1.2%	2.4%	98.8%	97.6%	13.5%	18.2%	1.8%	6.4%	ϕ =.1.00
N (Range)	548-567	551-570	191-170	531-458	191-170	531-458	191-170	531-458	191-170	531-458	31

Notes: PrEP or **PEP**: In the last 3 months, have you taken PrEP (PrEP is a drug taken by people before sex that reduces the risk of getting HIV) or PEP (PEP is a treatment that can stop HIV infection after the virus has entered a person's body. It must be taken within 72 hours of exposure)?

Drugs = Did you use any drugs (excluding Viagra and cannabis) before or during sex to improve your sexual experience in the last 3 months? IM = Impression management, SD = Self-deception. * p < .05 ** p < .01, *** p < .001. Reliability = test-retest stability coefficient (f)varies from -1 to 1. Accuracy 0 = Complete Guess - Pretty Accurate, 1 = completely accurate. Inappropriate 1 = yes and 0 = no. **Deter** = 0 = no/not very likely, 1 = not sure, 2 quite likely/yes

Table 5.6: PCA with Oblique (oblique rotation)

Sexual Behaviour	Epidemiology Higher Risk (Episex Risk)	Giving Penetrative (Pen Sex)	Safer Sex
Number of Partners	.885		
New Partner	.826		
Drugs	.410		
STI Diagnosis	.334		
Given Penetrative Sex		.834	
Received Penetrative Sex	.386	-.772	-.435
Anal	.307		-.619
Condom Used			.539
Oral Only	.316		.538
Latent Factor Correlations			
Epi Risk	1		
Pen Sex	.071	1	
Safer Sex	-.164	.050	1
Eigenvalue	2.26	1.32	1.12
% Variance	25.15	14.68	12.49
N= 601			
IM	-.256** (n = 562)	-.004 (n = 562)	.051 (n = 547)
SD	-.004 (n = 565)	-.106* (n = 565)	-.002 (n = 550)

Note. IM = Impression Management, SD = Self-Deception

Construct validity

In UK survey 1, we asked participants to rate their ***Absolute Risk of Infection*** ['What do you think the chances are of acquiring a sexually transmitted infection in the next 3 months?' (0 = not at all at risk, 100 = completely at risk'), ***Optimistic Bias for Infection*** ['Compared to someone of the same age, sex, sexual orientation, to what extent do you think your sexual behaviour puts you at risk of a sexually transmitted infection?' (0 = much less risk, 50 = about the same, 100 = much greater risk] and ***Others' Accuracy of Recall*** ['To what extent do you feel that people answering these sexual behaviour questions will be able to recall their behaviour accurately?' (0 = not at all, 100 = definitely)].

We created unit weighted scores for each of the component of sexual behaviour derived from the PCA reported in Table 6 (we summed the 4 question for the 'epidemiological higher risk' component, the 2 for the 'giving penetrative sex' component and the 3 for the 'safer sex component with anal sex

reserve scored). In Table 5.7 we correlate responses to these risk questions with summed PCA components. As can be seen those who report more of the behaviours on the *Epidemiology High Risk* component rate themselves at greater absolute risk of infection and being less optimistic about being infected. Thus, while the mean absolute perceived risk of infection is low (11.45) those who with more behaviours on the *Epidemiology High Risk* component see themselves as a higher risk. Similarly, while the mean on the Optimistic Bias for Infection is low suggesting that people on average are optimistically biased (i.e., see themselves on average as at lower risk than others of their age, sex, and sexual orientation), those who report more behaviours on the *Epidemiology High Risk* component are less optimistically biased. Those disclosing more behaviours on the *Safer Sex* component are more optimistically biased. Thus, these associations show that the sexual behaviour components that assess higher and lower behavioural clusters are related to perceived risk of infection and bias. Therefore, people are sensitive to the objective risk associated with these behaviours when assessing their own subjective risk. Thus, people may self-defer based on how they perceive their level of risk.

Table 5.7: Association between Perceived Personal Risk and Sexual Behaviour Component

	Absolute Risk of Infection	Optimistic Bias for Infection	Others' Accuracy of Recall
PCA Factors	M = 11.45 (SD = 17.35)	M = 25.97 (SD = 25.13)	M 63.09 (SD = 20.63)
Epidemiology High Risk	.413*** (n = 444)	.528*** (n = 466)	.032 (n = 616)
Giving Penetrative sex	.040 (n = 443)	.045 (n = 465)	-0.99 (n = 618)
Safer Sex	-.083 (n = 436)	-.136** (n = 456)	-0.65 (n = 600)

Note. ** p* <.001, ** p < .01, * p < .05

Qualitative Triangulation

The idea that perceived risk is an important dimension to consider in term of all groups is also seen in the quotes below.

"You know if you are in, like, a homosexual relationship and you have a partner, it's not like you are in a high-risk situation." [donor]

"There is increasingly rates of infection in the heterosexual population as well as the MSM population" [staff]

"Personally, I feel that if men have been in a stable relationship with the same partner for the last 3 months, then they should be allowed to donate" [staff]

"But, now, I mean … you have like men who have sex with men and gay men getting married, being with the same partner for 10 years, who are probably at less risk than a heterosexual person, who is engaging in risky behaviour on a regular basis." [donor]

External validity

Table 5.8 provides the associations between the components of sexual behaviour derived in Table 5.6 and participants' self-defined sexual orientation in Survey 1.

Table 5.8. Predicting Sexual Behaviour Components from Sexuality

	Poisson	Under-Dispersed Poisson	
	Epidemiology High Risk	Giving Penetrative sex	Safer Sex
Sexuality			
Gay	0.28*	-0.26**	-0.35**
Lesbian	-0.19	-0.20	0.16
Bi/Pan Sexual	0.19*	0.05	-0.05
Constant	0.19***	0.35***	0.13***
N	594	614	604

Note. ** p* <.001, ** p < .01, * p < .05

The results show that participants who self-define as gay are more likely to report more behaviours on the *Epidemiology High Risk* component and fewer on the *Giving Penetrative sex* component.

Individual and normative consistency for acceptability, accuracy and deterrent across stake-holder groups:

Table 5.9 provides the results for perception of accuracy, potential to deter and perceived (in)appropriateness of the sexual behaviour questions and Table 8 provides the normative results from survey 2.

Table 5.9 shows that, in general, donors and non-donors felt that they could accurately recall the behaviours (92.2-99.6%). Apart from the PReP/PeP and STI questions, 1/5th to a 1/3rd felt that the remaining questions were inappropriate and that the anal sex question had a high potential self-deferral due to the nature of the question. The normative results (Table 8) are consistent with the individual results (Table 5.9). This is especially the case for the anal sex question, which was seen as normatively the most likely to put people off donating blood, also. In terms of inappropriateness across both surveys, anal sex, oral sex, number of sexual partners and receiving penetrative sex were seen as the most inappropriate.

Table 5.9: Percentage by Region on Normative Perceptions (Survey 2)

	Accuracy (Completely Accurate)			Appropriate (No)			Put people off (Yes)		
	England	Scotland	Wales (English)	England	Scotland	Wales (English)	England	Scotland	Wales (English)
Do you believe your current relationship is **exclusive** (neither of you have sex with other people)?	45.4% (5959)	49.5% (1313)	48.1% (2175)	18.3% (5736)	16.6% (1251)	13.7% (2094)	29.2% (5539)	31.0% (1210)	29.8% (2012)
How many sexual partners have you had in the last 3 months, (including oral, anal or vaginal sex)	68.2% (5893)	70.4% (1306)	68.4% (2152)	38.2% (5703)	33.9% (1241)	32.8% (2072)	57.1% (5544)	58.2% (1204)	51.1% (2006)
Have you had any **new** sexual partners in the last 3 months?	85.3% (5892)	86.4% (1296)	85% (2143)	17.5% (5720)	16.9% (1246)	16.7% (2083)	35.4% (5554)	38.6% (1206)	32.8% (2013)
Have you had **anal sex** in the last 3 months?	86.8% (5863)	88.5% (1299)	87.4% (2133)	30.4% (5717)	25.8% (1248)	24.1% (2074)	62.7% (5542)	63.4% (1198)	54.9% (2009)
Have you had ONLY **oral sex** in the last 3 months?	79.9% (6567)	81.0% (1290)	81.2% (2135)	37.3% (5711)	35.0% (1239)	30.4% (2076)	52.8% (5533)	53.9% (1196)	43.4% (2003)
Did you use **condoms** every time you had sex (including oral, anal or vaginal sex) in the last 3 months?	59.6% (5878)	62.1% (1291)	59.9% (2132)	17.7% (5718)	16.8% (1241)	15.9% (2071)	32.6% (5530)	36.2% (1200)	28.7% (2006)
Drugs	70.7% (5864)	72.1% (1295)	71.4% (2128)	28.4% (5705)	27.6% (1241)	24.6% (2075)	57.4% (5541)	56..0% (1199)	49.9% (2011)
PReP	85.2% (5847)	84.0% (1293)	86.6% (2123)	12.4% (5693)	14.1% (1240)	11.7% (2069)	36.2% (5518)	42.3% (1198)	32.0% (1996)
PeP	85.6% (5841)	83.4% (1290)	85.7% (2120)	11.8% (5702)	13.5% (1243)	11.4% (2071)	36.9% (5516)	42.1% (1196)	33.4% (2003)

Have you **received** penetrative sex in the last 3 months?	84.8% (5858)	84.2% (1290)	87.2% (2117)	30.6% (5702)	30.0 (1241)	26.1% (2065)	42.8% (5518)	48.6% (1195)	37.3% (2002)
Have you **given** penetrative sex in the last 3 months?	85.2% (5852)	84.5% (1287)	86.8% (2127)	30.7% (5694)	29.4% (1241)	26.0% (2064)	41.9% (5521)	47.5% (1196)	35.8% (1998)
Have you been **diagnosed** with or received treated for gonorrhea, syphilis or chlamydia in the past **12 months**?	85.1% (5859)	86.0% (1296)	85.9% (2128)	8.2% (5701)	9.2% (1244)	9.0% (2070)	39.5% (5519)	43.2% (1195)	36.4% (2005)

***Notes*:** PrEP Have you taken PrEP in the last 3 months (PrEP is a drug taken by people before sex that reduces the risk of getting HIV) PEP Have you taken PEP in the last 3 months (PEP is a treatment that can stop HIV infection after the virus has entered a person's body. It must be taken within 72 hours of exposure)? Drugs = Did you use any drugs (excluding Viagra and cannabis) before or during sex to improve your sexual experience in the last 3 months? Accuracy 0 = Complete Guess - Pretty Accurate, 1 = completely accurate. A**ppropriate** 1 = yes and 0 = no. **Deter** = 0 = No, 1 = Yes. The Welsh data is for the English version of the survey only as there were some concerns about the direct translation of accuracy in Welsh.

With respect to perceived accuracy, there is an interesting difference between the individual self-reported behaviours and the normative assessments. The reported accuracy for individual self-reported behaviours was higher than the normative assessments. This indicates that while people think they can accurately recall their own sexual behaviour, they believe others cannot and this is especially so for the perceived accuracy with respect to exclusivity of relationships.

Qualitative Triangulation: Accuracy, Appropriateness and Deterrence

The finding relating to accuracy, appropriateness and potential to deter are also seen in the qualitative findings. While the quotes are from donors and staff, the same issue were raised by patients and MSM but those interviews were not audio recorded.

Motivated Dishonesty (Impression Management)

"I wonder that some people don't feel comfortable talking about such personal things and would potentially be encouraged to lie and I think, you know, when you are talking about how many sexual partners have you had and how many of those are new, if people maybe had a lot of sexual partners but are uncomfortable talking to, because you do obviously have to do the face to face part after that, going in and having that discussion about, you know, what might be considered a lot of sexual partners, they might not be willing to be honest about some of these, I do wonder" [donor]

" I mean my first thing was like 'do you believe your relationship is exclusive', 'no I'm having an affair', I mean do you answer honestly, they see your wedding ring… what if you come in as a couple" [donor]

"They (donors) are not truthful, you ask them where they've been, they won't tell us because they think that they will be deferred for 4 months" [staff]

"I mean we have honesty being an issue every moment don't we? I mean in regard to their symptoms; we know for a fact that they'll tell us something and we can call the RN in and they'll change the story." [staff]

"I wonder if they would also, have the potential to not want to tell the truth on there just because they are so keen to donate blood…if they are so desperate to donate and help they might think oh I will just say no to everything" [Donor]

Recall Accuracy (Memory failures)

"if you ask somebody just generally, they probably wouldn't necessarily have any idea what they've done, especially if you have had multiple partners". [staff]

"If it's been a drunken night out isn't it, people are not going to remember, are they?" [staff]

"I think it depends on how much you have sex, I mean I wouldn't struggle, but maybe if you are having multiple experiences every few days I don't know." [donor]

"I suppose any sexual activity if there is going to be alcohol or drugs involved. It's going to affect number of partners, new partners, whether a condom was used or not, any drugs where involved, potentially what sort of sex happened, all those things could be confused or someone might not be aware of them, but that would apply to anyone, not just men who have sex with men." [donor]

Inappropriateness/Uncomfortable

"I wouldn't feel uncomfortable asking any of them" [staff]

"I personally wouldn't feel uncomfortable with any of these" [donor]

"unfortunately, yes, you are going to upset some people, but it is the nature of the job because at the end of the day it's about protection." [staff]

"yeah probably, I'd say in the age of like 40+, might be, I mean it probably depends I think my parents wouldn't be bothered, but I guess a lot of people who are of an older generation might find it a bit invasive" [donor]

*"yeah actually reading some of the sort of questions beforehand, I did think they are very personal. Ermm *laughs*" [donor]*

"But they could definitely make people feel more uncomfortable, of what's happening, whose reading, is like the nurse or whoever it is she's going to speak to, do they see all the answers to our questions?" [donor]

Potential to Put People Off Donating

"It wouldn't deter me from it at all." [donors]

"I'm not sure if it would deter people because, overall, if you want to give blood, you want to give blood" [donors]

"there are still quite conservative and you know, in long term marriages and things like that so they would probably think 'oh my god, I'm not going there again', because they could be asking me that kind of question. [staff]

"If the risk is going to be applied to everybody, then it means that we would actually be having to defer, potentially, heterosexual people because people are having sex with people of the same sex." [staff]

"well exactly, with the deferral rate, it would just be interesting to… if everybody were to ask these questions, it would be interesting. I think that we would be deferring lots of heterosexual donors" [staff]

"really it depends on the questions being asked, because it could put a lot of people off, if they are having to disclose such intimate details and obviously how you ask those questions…" [donor]

"people might sort of think, 'well, you didn't want my blood for the last like thirty years and now all of a sudden you are struggling, no I'm alright'." [donor]

The Potential Questions.

There were a number of concerns expressed about some specific questions.

Anal sex

"So, …, saying whether you have had anal sex. Maybe not putting anal in like bold, maybe just put it underlined." [donor]

Exclusivity

"I think question C is something that I'd sort of picked up on, which was saying whether you believe your current relationship was exclusive and neither of you have sex with other people, ermm, it was the word believe that sort of stuck with me, errm, because I think generally if you are in an exclusive relationship and you think you are, then you believe it. So, to be asked if you believe you are, it's sort of a bit odd" [donor]

"the one about exclusivity, I sort of think that if there is something that might carry any doubt in someone's mind about whether there relationship is exclusive and then the questions is saying 'well do you believe that your relationship is exclusive', it might just niggle away." [donor]

Giving/Receiving Penetrative Sex

"… saying whether you are the giver or receiver of penetrative sex, so to me is that asking generally have you given or received penetrative sex, or is it asking to clarify which one? So, were you the giver or the receiver? "yeah, I think, I think maybe, rather than being, some people might read that as being 'yes, I was the giver or receiver of penetrative sex', rather than 'yes I gave' or 'yes I received', or both, mhmmm." [donor]

"I'm not sure about … the terminology of giver and receiver, it sounds, I don't know, it doesn't sound very clinical. But then, I don't know if there is actually clinical terms than giver and receiver it sounds a bit rough. It might be that it is best wording available, but yeah, it does seem that, it kind of jarred when I read it, I think" [donor]

"yes, because one of my friends, he will, his partner doesn't want to receive it, so, do you know what I mean, his partner is the giver and he is the bottom… so umm, that is how they, you know, define it isn't it, maybe we should use those terms" [staff]

"So, maybe the elderly, the older community. It might feel a bit intrusive perhaps."

Chemsex

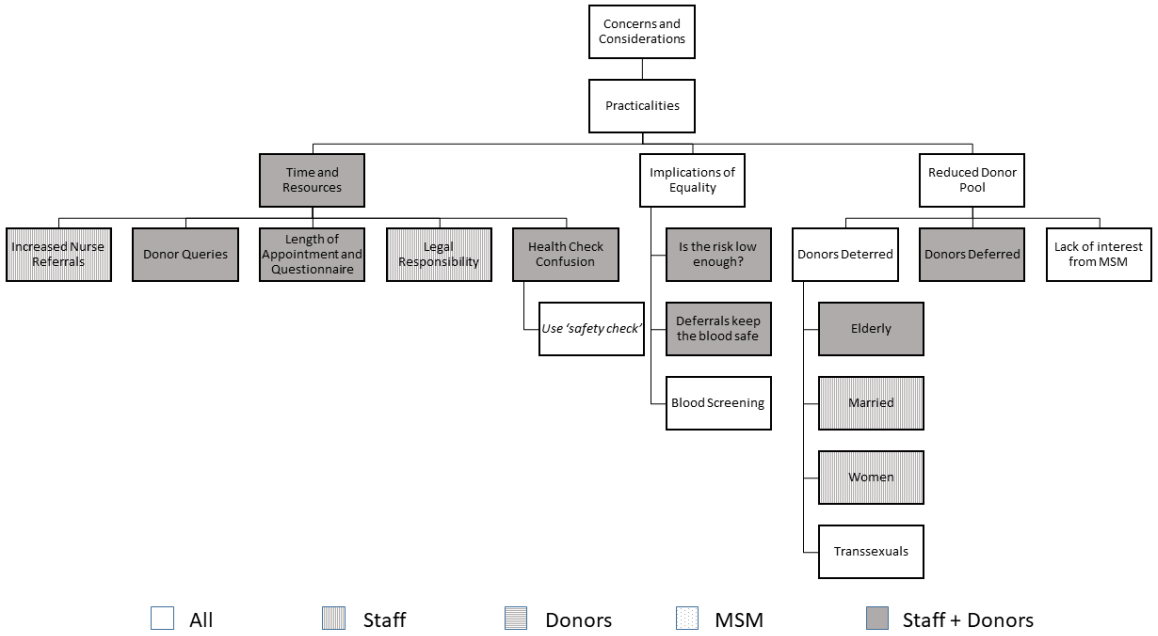
*"… I think, saying if you took any drugs, then specifically excluding Viagra or cannabis before or during sex… I mean… does alcohol count? Because that is a drug that you might take to feel like you are improving your sexual experience *laughs*. I'm not quite sure what I am suggesting there with that question, but there is something there about the use of the term drugs that automatically excludes alcohol, that perhaps shouldn't or if it does, it too." [donor]*

Consistency in Condom Use

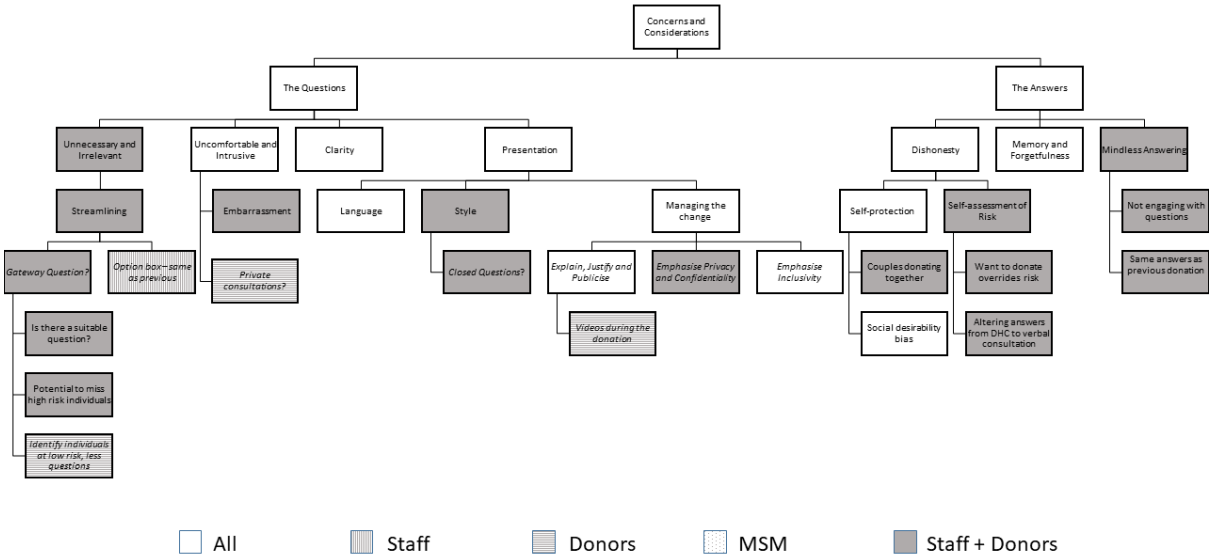
"have you practiced safe sex, every time you have had sex in the last 3 months, both you and your sexual partners, rather than condom because there are other forms of contraceptive." [donor]

The two thematic maps below summarize all the qualitative work for MSM, staff and donors relating to costs and concerns with a change to a new policy.

Thematic Map: Concerns about Practicalities



Thematic Map: Concerns about Questions and Answers



Minimizing Unforeseen Consequences and Identifying Benefits

Table 5.10 shows the correspondence (in terms of ranked position percentage of yes/yes-quite likely responses) between survey 1 (individual consequences) and survey 2 (normative consequences). There is a good degree of correspondence (ρ= .80). That is, the same rank order is seen, regardless of whether questions were asked in terms of whether they would put the respondent off donating, or whether they believed other people would be put off donating. As can be seen, the anal sex question is the most likely to deter people from donating, followed by the question about oral sex, number of sexual partners, receiving penetrative sex and chemsex all in the top 5. These are also some of the questions highlighted in the qualitative work as potentially problematic. The questions on chemsex and number of sexual partners that form part of the *epidemiological high-risk* component are also likely to be seen as potentially leading to a higher self-deferral rate.

However, this would mean that if these questions were selected for inclusion in the DHC, clear communication to the public, donor staff and potential donors about the change and why these questions have been chosen is critical. Crucially, the management of social media is very important if negative or fake new stories are circulating. Managing people's expectancies about what they are likely to be asked, and why, is key.

Table 5.10: Sexual Behaviours Order by deter for Survey 1 (it would put me off) and Survey 2 (it would put people off)

ρ= .80	Survey 1	Survey 2
Have you had **anal sex** in the last 3 months?	1	1
Have you had ONLY **oral sex** in the last 3 months (AND no anal or vaginal sex)?	2	4
How many sexual partners have you had in the last 3 months, including oral, anal or vaginal sex (please indicate the number)?	3	2
Have you **received** penetrative sex in the last 3 months?	4	5
Drugs	5	3
Have you **given** penetrative sex in the last 3 months?	6	6
Do you believe your current relationship is **exclusive** (neither of you have sex with other people)?	7	11
Did you use **condoms** every time you had sex in the last 3 months (oral, anal or vaginal sex)?	8	10
Have you been **diagnosed** with or been treated for gonorrhea, syphilis or chlamydia in the past **12 months**?	9	7
Have you had any **new** sexual partners in the last 3 months?	10	9
PrEP or **PEP**	11	8

Notes: PrEP or **PEP**: In the last 3 months, have you taken **PrEP (**PrEP is a drug taken by people before sex that reduces the risk of getting HIV) or **PEP** (PEP is a treatment that can stop HIV infection after the virus has entered a person's body. It must be taken within 72 hours of exposure)? **Drugs** = Did you use any drugs (excluding Viagra and cannabis) before or during sex to improve your sexual experience in the last 3 months?

Benefits: Encouraging others to Donate: Policy, Donor Status and Sexuality Effects (Survey 1)

We examined the extent to which people would be willing to encourage others to donate blood under the people current system and the proposed system on a scale form 0 = not at all, 100 = very much so.

In terms of the **current policy** participants were asked:

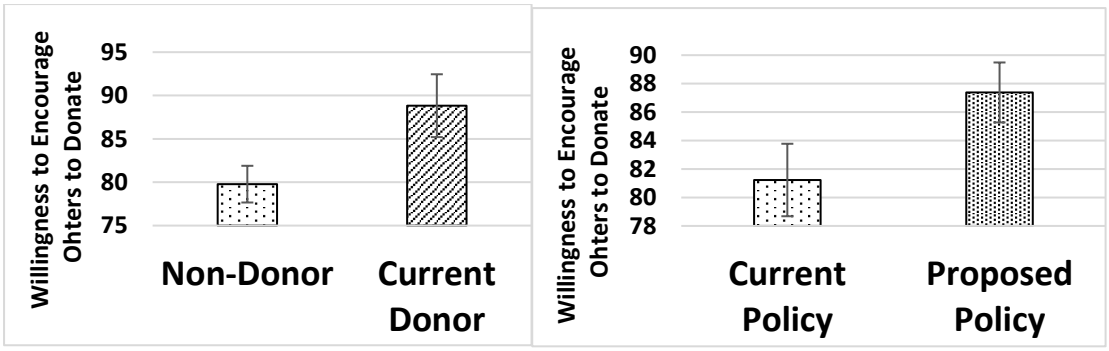
"Under the current system (men who have sex with men are not permitted to give blood for three months after any sexual activity (regardless of whether condoms are used or not), to what extent are you willing to encourage others to donate blood?"

In terms of the **new policy** they were asked:

"Under an alternative system where all potential blood donors have to answer the sexual behaviour questions as part of a donor selection criteria, to what extent would you be willing to encourage others to donate blood?"

We also explored how these perceptions varied by **sexuality** (heterosexual vs LGBTQ+) and **donor status** (current donor vs non-current donors: defined as having donated in the last 2 years).

A 2 (policy: current vs new) by 2 (sexuality: heterosexual vs LGBTQ+) by 2 (donor status: current vs non-donors) repeated measures ANOVA showed significant main effects for donor status ($F_{(1, 554)}$ = 17.94, p = .000), and policy ($F_{(1, 554)}$ = 34.59, p = .000) as well as a significant interaction between sexuality and policy ($F_{(1, 554)}$ = 10.76, p = .001). Such that current donors were overall more likely to encourage others to donate, and respondents were more likely to do so under the change to the proposed new policy (Figs 5.2 and 5.3).

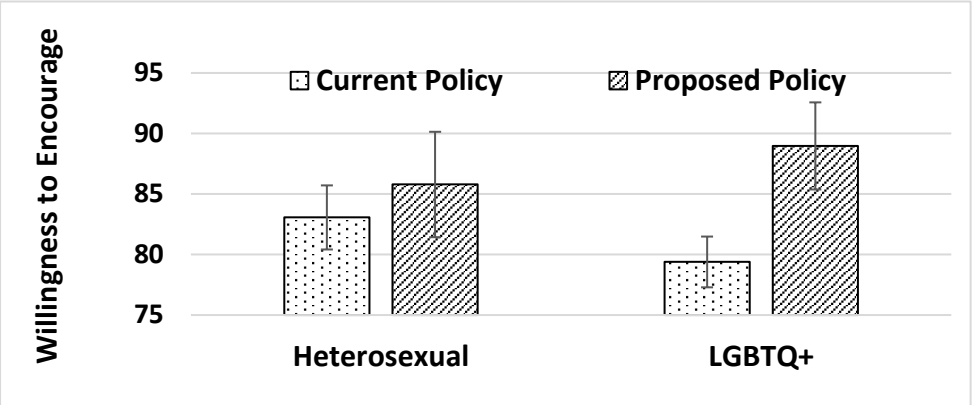


Figures 5.2 and 5.3. Willingness to Encourage other to donate as a function of Donor Status and Policy Change. (error bars = 95%CIs).

These finding suggest that a positive media campaign that focuses on the change of policy in terms of its equality and inclusiveness would be effective.

The interaction (Figure 5.4) shows that for those who identify as heterosexual, the change in policy has no significant effect on the extent to which they would encourage others to donate, but for those

who self-define as LGBTQ+, the change in policy would significantly increase the likelihood that they would encourage others to donate. Again, media campaigns that directly communicate this change of policy to people from the LGBTQ+ community may be especially effective.



Figures 5.4. The interaction of sexuality by policy on willingness to encourage others to donate. (error bars = 95%CIs).

Qualitative Triangulation on Benefits

Qualitative triangulation above detailed some of the costs in term of losing donors. Here, we focus primarily on the reported benefits of the change in policy.

Increased Equality and Fairness

"I suppose it's easier if it's quite a small-scale operation that's trying to do the best it can, what it can get, you don't want to increase the risk factors of contaminating the blood supply, especially considering the massive scandal that happened in the 70's, you do not want that to ever happen again. So, it's easier to go, 'well if we just exclude these people it is less likely to happen and we'll just continue struggling on', but it's good that we are now potentially looking at allowing other people coming in and give blood, because they are not actually as high risk as we initially thought." [donor]

"a lot of people from their community find it discriminatory and it fuels quite unhelpful stigmas and stereotypes, which is still damaging when you've got pretty much everyone in the world saying 'yeah equal rights' and legalising this and that, but then saying 'oh you can get married, you can do all of this, but, you can't give blood'… it doesn't really make a lot of sense." [donor]

"The point is that everybody is asked the same questions, so that it is fair" [staff]

"Rather than MSM questions and heterosexual questions, it'll be sexual health in general, which is more better than dividing people." [staff]

"I would say yes, just to make it equal for everybody. So at least then, for that person who you would potentially give that questionnaire to, does not feel discriminated against. So, like, everybody has the same set out questions. [donor]

"That is actually much more inclusive isn't it, because it is actually down to risk of behaviour." [staff]

"I think it is probably quite important because things are a bit different now. It is not a straightforward as men who have sex with men like people are a bit more fluid, they sleep with lots of different people, especially young people. So, I think it is quite important that it is updated." [donor]

Attracting New Donor Groups

"*I think it would probably encourage more from the younger generations" [staff]*

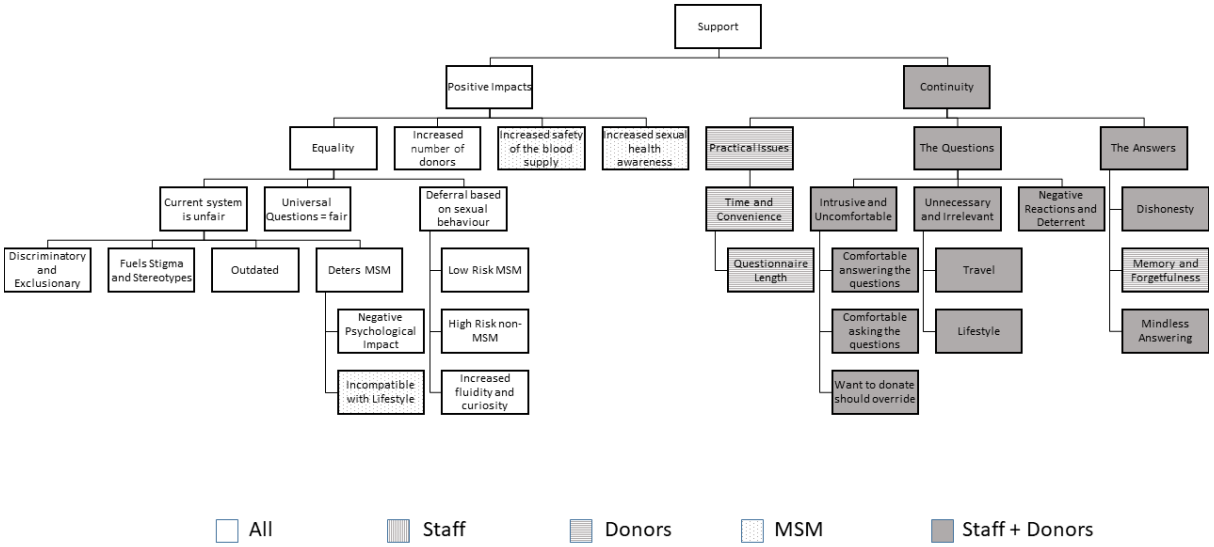
"yeah, I mean there is a whole group of people who are unable to give blood and we need all the blood that we can get, especially, if we can get it and get it safely." [donor]

"I think it is acceptable as long as there is demonstrable evidence that this is actually useful for us to generate more blood for people I think, you know, and a significant proportion more." [donor]

"I guess by changing that, even if you don't get whatever, all the generations changing their mind, what you are doing, you are then opening yourself up for younger, or a new generation of people who don't have that same stigma… so, while that might not change things overnight in terms of there is a whole new group of people who you immediately start getting, you are building a longer pipeline." [donor]

The thematic map below summarizes the qualitative work with MSM, donors and staff details the perceived benefits/support for the policy change.

Thematic Map for Benefits/Support for the Change in Policy



Perceived Risks to Patents

Across Surveys 1 and 2 we asked participants the following questions about perceptions of absolute risk to patients from the proposed change in policy.

Risk to Safety: To what extent do you think that the safety of patients in the UK would be put at risk if all donors were assessed in terms of their previous sexual behaviour, rather than on their sexuality? (0= Not at All Put at Risk, to 100= Completely

Risk Policy Change: If the UK policy were to change to using a donor health check of this type (that focused on every donor's sexual behaviour), what do you feel the level of infection risk to a patient receiving blood would be? (1 = no risk, 2 = small risk, 3 = a large risk, 4 = a very large risk, 5 = an extremely large risk)

Acceptable Risk: To what extent do you think this risk is acceptable? (0 = Unacceptable, to 10 = Acceptable)

Safe System: Do you think it is possible to have a completely safe system of blood donation where the chance of acquiring an infection from blood transfusion is zero?" (0 = yes, 1 = no).

The results are shown below in table 5.11 as function of sex, sexuality and country. The first thing to note is that the majority think a zero risk, purely safe system is not possible, and that the risk is general low to small and acceptable. There is little variation by sex, but some variation by sexuality with those who self-define as Bi/Pan/Bi-curious, Lesbian or Gay rating the risk as generally lower and more acceptable. Those who completed the English version of the Welsh survey rated the risk as slightly higher and the level of acceptable risk as lower. As variation is small in terms of what is seen in absolute terms, on a new policy that is perceived to be of low risk to patients.

Perceptions of Relative Risk to Patients from an Infection as a Function of the Policy Change and Sexuality (Survey 1)

In Survey 1 we examined a direct comparison of perceived risk to patients from an infection by asking participants to consider the current system and rate the risk, and then to consider the new proposed system and consider the risk from 0 = no risk at all and 100 = completely at risk.

In terms of the **current policy** participants were asked

"Under the current system, where men who have sex with men are prohibited from giving blood for 3 months after any sexual activity, to what extent do you think patients receiving blood transfusions in the UK are at risk of being infected with viruses such as HIV or hepatitis?"

In terms of the **new policy** participants were asked

"If UK policy were to change to using a donor health check whereby all potential donors were initial asked about their sexual behaviour prior to being allowed to donate blood or not, to what extent do

you think patients receiving blood transfusions in the UK are at risk of being infected with viruses such as HIV or hepatitis?"

We also explored how these perceptions of risk varied by **sexuality** (heterosexual vs LGBTQ+).

A 2 (policy: current vs new) by 2 (sexuality: heterosexual vs LGBTQ+) repeated measures ANOVA showed a significant effect for sexuality ($F_{(1, 522)} = 8.77$, $p = .003$) and policy ($F_{(1, 522)} = 26.10$, $p = .000$) but no significant interaction between the two ($F_{(1, 522)} = 2.29$, $p = .131$). LGBTQ+ participants perceived the risk (Mean = 20.00, 95% CI = 17.17, 22.85) as significantly lower than heterosexual participants (Mean = 25.14, 95% CI = 23.26, 27.01) and the new proposed policy (Mean = 20.43, 95% CI = 18.60, 22. 26) was perceived generally to be a lower risk than the current system (Mean = 24.71, 95% CI = 22.77, 26.66).

Table 5.11 Predicting Indices of Perceived Patient Risk and Safety (Survey 2: Donors)

	Survey 2 (Donors)				Survey 1 (Public)	
	OLS			Logistic	OLS	Logistic
	Risk to Safety	Risk Policy Change	Acceptable Risk	Safe System	Risk Policy Change	Safe System
	M= 22.56 (SD = 22.63)	M = 1.98 (SD = 0.46)	M = 5.95 (SD = 3.47)	No = 6692 (76.7%) Yes = 2030 (23.3%)]	M= 2.13 (SD = 0.61)	No = 427 (71.5%), Yes = 170 (28.5%
	B	B	B	OR	B	OR
Sex						
Female	0.81	0.02	-0.73***	0.75***	0.12	1.40
Other	-8.89	-0.05	1.27	1.13	-0.411	0.39
Prefer not to say	1.71	0.001	-1.89	1.55	----------	----------
Sexuality						
Bi/Pan/Bi-curious	-5.77***	-0.09**	1.33***	1.26	-0.18**	1.03
Lesbian	-7.76**	-0.11*	1.54***	1.17	-0.16	1.17
Gay	-11.86***	-0.11*	1.53***	0.75	-0.16	0.91
Celibate/Grey Sexual	0.72	0.05	0.61	0.88	----------	----------
Other/Not Say	6.92***	0.05	-0.98**	0.62*	----------	----------
Age	0.21**	0.003***	-0.03***	1.01***	-0.00	1.01
Country						
Wales (English)	1.54*	0.004	-0.43***	0.96	----------	----------
Scotland	0.08	-0.02	0.32	0.99	----------	----------
Wales (Welsh)	-1.73	0.06	-0.36	0.80	----------	----------
Constant	11.10***	1.83***	7.88***	2.25	2.09***	1.51
R^2	.03	.01	.04	.016	.05	.018
N	6,788	7,741	7,236	7,752	560	561

Note. *** p < .001, ** p < .01, * p < .05. **Risk to Safety:** To what extent do you think that the safety of patients in the UK would be put at risk if all donors were assessed in terms of their previous sexual behaviour, rather than on their sexuality? 0= Not At All Put At Risk, to 100= Completely. **Risk Policy Change**: If the UK policy were to change to using a donor health check of this type (that focused on every donor's sexual behaviour), what do you feel the level of infection risk to a patient receiving blood would be? (1 = no risk, 2 = small risk, 3 = a large risk, 4 = a very large risk, 5 = an extremely large risk). **Acceptable Risk:** To what extent do you think this risk is acceptable? (0 = Unacceptable, to 10 = Acceptable).**Safe System:** Do you think it is possible to have a completely safe system of blood donation where the chance of acquiring an infection from blood transfusion is zero?" (0 = yes, 1 = no).

Perceptions of Acceptable Level of Infection Risk as a Function of the Policy Change and Patient Status (Canadian SAFE project Data)

We examined perceptions of acceptable risk (1 = no risk at all, 2 small but acceptable risk, 3 = medium risk, 4 = large risk, 5 = a very large risk, 6 = an extremely large risk) when a participant considers:

- a 12 month deferral for MSM

"Given that MSM are allowed to donate blood 12 months after having had sex with another man, what do you feel the infection risk to patients is?" (which was the policy in Canada at the time)

- a change to 3 months deferral

"If MSM are allowed to donate blood 3 months after having had sex with another man, what do you feel the infection risk to patients is?"

- a change to sexual behaviour based approach

"If MSM are allowed to donate blood after practicing safe sex, what do you feel the infection risk to patients is?

We explore how these perceptions of risk varied by **patient group** (non-patient, patient receiving blood regularly or patient not receiving regular blood, LGBTQ+) controlling for sexuality using a 3 (patient group) 3 (policy) repeated measures ANCOVA. A significant main effect for policy ($F_{(2, 1050)}$ = 15.24, p = .000) was observed, such that all 3 policies were around the acceptable level of risk, with the 12 month policy rated as slightly lower risk (mean = 2.030) and the 3 month and behavioral policy slightly higher at 2.282 and 2.255 respectively but both close to the score of 2 for a small but acceptable risk.

5.4.3. The Patient Perspective (Interviews)

When we interviewed patients, a number of consistent themes emerged.

Trusted and Generous Donors – Not just saving lives, but giving a life

The patients all acknowledge, at the start and though out the interviews, their gratitude to the immense generosity of blood donors, who they perceived a very trusted, responsible, humble, benevolent and altruistic. Without their generosity the patients indicated that they, as people with a long-term need for blood, would not have had a life. The sentiment was that the blood donors were not just *saving lives* but giving people with long-term need for blood *a life*. This central theme of the importance of the donor influenced how the patients thought about the change in policy: they did not want donors to be put off donating blood because the questions are upsetting. One interviewee expressed how they would not be here today if it was not for donors. Patients did not want to put donors off donating but also realised that the safety to the patient required some donor screening.

Self-Deferral

The patients trust donors and suggest that if they were better educated about their health, sexual behaviour and other factors that might mean that they could be putting others (recipients of blood) at risk they would self-assess / self-screen and not donate.

Increased Fairness and Equality

Patients saw the current system was unfair and discriminatory and that a move to a more equitable and fair system was a justifiable and good thing.

Issues with Specific Questions.

Patients highlighted a number of specific questions were highlighted as particular problematic in term of privacy and appropriateness.

a. **Chemsex:** They felt that this could be seen as judgemental – making assumptions about donors' sexual behaviours. Also, it was mentioned that there was a need to remind people that the police will not be informed about drug use as this, otherwise people may not be honest about this.
b. **Anal and Oral sex:** These were seen as too specific and likely to make people feel uncomfortable by having to disclose intimate information. Also questions about oral and anal sex are both very culturally sensitive question and in many religions they are told not to engage in these behaviours. Therefore, it was suggested that there was a need to ensure confidentiality both verbally and physically (arrange

the room/booths so that people cannot be over-heard) especially with respect to cultural sensitivities.

c. **Partner faithfulness**: This was also raised as a concern in terms of whether people could actually ever know if their partner was faithful and as such would never be able to answer this accurately. People may answer this in all honestly but still be inaccurate. They think they are in an exclusive faithful relationship, but they are not.
d. **Giving and Receiving of Penetrative Sex**: What these terms meant was seen as unclear.

Intersectionality: Sensitivity to culture, ethnicity, sex and politics

The idea of intersectionality was raised by a number of the interviewees. In particular, issues around the intersection with **ethnicity**. This was expressed at a general level about asking about sexual behaviour, as it may not be acceptable in certain cultures to discuss sexual behaviours with others. Specifically, oral and anal sex were both described by patients as very culturally sensitive questions and in some faiths, people are told not to engage in these behaviours at all. The intersection with **sex** was also raised, with women more likely to be put off by answering questions that may be seen to stereotype them as promiscuous. The intersection with **age** was also highlighted. Specifically, it was felt that the younger generation may be OK with questions about anal sex but not the older generation. Finally, the influence of **political opinions** and beliefs were raised with those from a conservative political background may be less accepting of these questions.

Accuracy: Honesty and Memory Failures

Issues of accuracy of recall of behaviours was also highlighted. There was concern about people being dishonesty. Specifically people can have selective memory, particularly if they are trying to protect themselves or are embarrassed about the sexual behaviour being discussed. The use of drugs and alcohol, as was having multiple sex partners, were also highlighted as potential causes of people not being able to recall their sexual behaviour, as was having multiple sex partners. It was, therefore, suggested that if a person cannot recall any of the sexual behaviours listed, given that it is only in the last 3 months, they should be screened out.

Identify the best Sub-set of Questions

It was suggested that one question with sub-sections – i.e. In the last 3 months, have you had… (a) anal sex, (b) oral sex, (c) given penetrative sex, (d) received penetrative sex – would be more succinct and less intrusive.

Implementation

Patient trust and respect donors and the implementation ideas they suggested were design to remain and not put off donors if there were a change to the new policy. The follow details the types of implementation and communications suggested.

a. **Education and Rationale for the Change**. It was suggested that publicising/explaining the rationale behind the sexual behaviour questions and allowing donors time to digest this information before they come into donor centre, would feel less intrusive and result in donors feeling less uncomfortable. Educating donors (giving them all the information and rationale) and in particular, asking them a shorter list of questions, would be beneficial, otherwise it seems like the blood service does not trust them, which might deter people.

b. Donor-Recipient Linkage. The idea expressed here is that there are 2 people in the equation (donor and recipient). A more person-centred approach that highlights the relationship between the donor and the recipient was seen as potentially very helpful and likely to reduce any dishonesty. Patients emphasized that it was important to let donors know that blood is used for many different process, and that for patients who need blood long-term that this not just *saves their lives but gives them a life*. Thus, making the donor-recipient link stronger and salient was important to patients and the opportunity for parents to thank donors was something that would be welcomed.

c. Carer-Donor Matching. Drawing on the ideas of intersectionality it was suggested that the donor carer and donors were matched on grounds of sex, age and ethnicity. A female donor, for example, may feel more comfortable being asked about anal sex by a female carer.

d. Schools and start young: It was suggested to start teaching children at a younger age (secondary school) about blood donation, to make sure people know from a young how vital and important blood donation is.

e. **Mobile Unit:** Finally, it was suggested that convenience is such a big factor in donor recruitment that bringing back the mobile units to visit place of work and education would help increase the number of donors.

Implementation Ideas and Concerns.

In addition to the ideas expressed by the patients, the following implementation ideas were mentioned by MSM, donors and staff

Training and Time Constraints.

As these quotes show it was felt that training is needed, but that there is a critical issue of making sure any change does not add significantly to the time needed to process the donor.

"you know I do think that these questions, if they were going to be brought in, we would have to have some training on it" [staff]

"I guess ermm, would there be sort of extra training, and how the staff, they've always been amazing when you do the face to face, but just how sensitively these questions will be dealt with when you have to go through the form because these are very personal questions to talk about with a stranger." [donor]

"We've got 5 minutes to screen em', get em' out and on the bed, there's time constraints". [staff,]

"I still think we have to bear in mind that if you are there to give blood and it's the middle of the afternoon, so you probably have a limited amount of time to give blood" [donor]

"I appreciate that that is difficult to co-ordinate, but for me it is a logistics thing. If you make it easier for me, I will do it every 12 weeks without fail, and that's… yeah by all accounts that is definitely the top thing for me is convenience and ease of arranging it." [donor]

Gateway and Algorithm

As these quotes show it was felt that a gateway question would be useful and potentially help address the time constraint issue.

"but, what questions could you use to separate out high and who is low risk in the first place, to then go on and ask those questions?" [staff]

"Also, I think it should have a sort of a gateway question because what if somebody's has never had sex, if there is no relevance, after A, if there is no relevance then they'll just be answering no all the way down." [staff]

Mobile Phones as an Aide Memoire

To help circumvent some of the problems of memory and recall donors could use their mobile devices to look back over the previous 3 months.

"young people use the diary on their phone now…it even tells you the time, a young girl got her diary last time she was with me and she couldn't remember" [staff]

Target Younger donors

Targeting young donors who may be more receptive to the new system was seen as a potential avenue.

"I feel like from my experience, advertisements that I've seen have been like older people, I mean not everyone, but a lot of the people are 30's, 40's or 50's. I think there should be a bit more advertisement with early 20's and in different scenarios. Like, I guess like that gives examples that all people can give blood." [donor]

Emphasize Equality and Inclusivity

As these quotes show it was felt that emphasizing inclusivity and equality would be beneficial and this is supported by the quantitative analysis that people would be more willing to recruit others to donate under the new proposed policy.

"I suppose you would make the argument of, that in the past perhaps they have been ruled out from this when you didn't really want to, and it was for peoples safety, but you are really taking steps to try and reduce the exclusivity there, and then increase inclusivity, which is quite a popular buzzword at the moment as well…I think that is the angle that you should go for." [donor]

"…it could be something even like, changing the logo, obviously there is financial isn't there, but rebranding it, so you've got the rainbow or whatever… to make it a little bit. Yeah, that people recognise actually you know what we are working together." [donor]

Safety to Recipient

As with the patients, these quotes highlight the importance of making sure that the safety of the recipient of blood is highlighted in any communications.

" I think it's the message you are putting across about giving and receiving blood." [donor]

"… it is about you as well and that the recipient is safe" [donor]

"…. It talks about the recipient; it talks about the person who is actually going to be getting the blood. I think if you want to get an emotion from someone then that it the best one, because people who are there to donate blood are there to do it for someone else" [donor]

Sensitivity and Privacy

As these quotes show ensuring that these questions can be asked sensitively and with privacy will be crucial for the acceptance of a policy change.

"…we've actually got families that all come in together, there has been scenarios where you know, we've had to discuss difficult topics, they've got into the booth and somebody might change an answer… I mean, that question, is your current relationship exclusive, that might be a contentious question" [staff]

"…perhaps, there should be a section where we say, if you would like to discuss this, you know, there will be a private space" [staff]

Information and Context

It was also felt that adding a clear rationale why these questions have been added was important for the success of a policy change.

"… there should be kind of contextualising around adding these questions to the donor questionnaire and I just wondered what was going to be alongside something that you'd get with your form to put, ermm, a more generic thing of 'this is why we are asking these questions' and obviously with that, so sort of tagline about that." [donor]

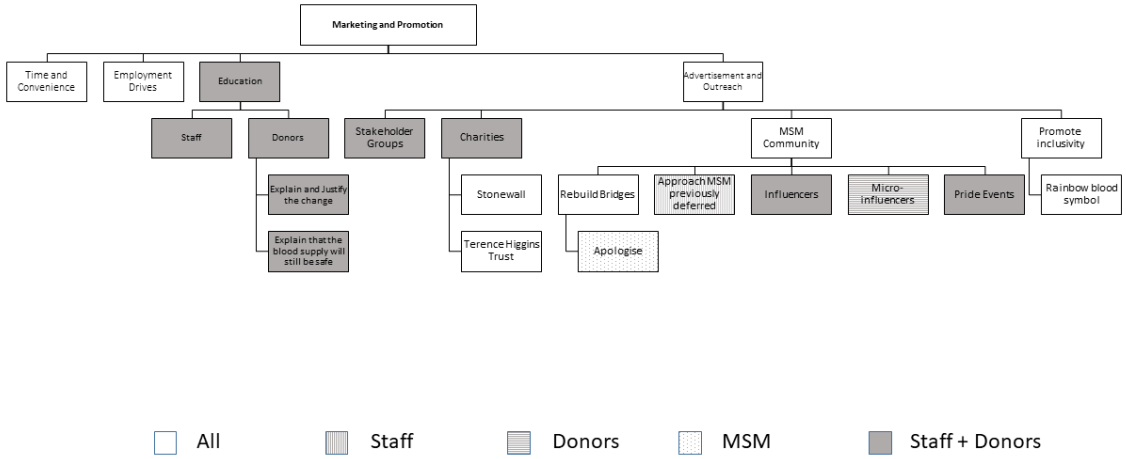
"maybe statistics around why, why these kind of things are asked, so that people aren't feeling really targeted as such by it, it's for a reason that we are asking you this."[donor]

"As long as people can see, ok there is a really good reason, here is the numbers, here is the figures, this means this many more people can give blood and that's a good thing, you know" [donor]

"but maybe also if there was information available to people about why these questions need to be asked, because some of them, you might just get really put off, like , 'why does someone need to know that, I've never been in a high-risk group before', but if it's in that pamphlet or if there is a link available like when you sign up to give blood, in the text message, you can read about why you are going to ask those questions, you would feel more comfortable answering them, which ever group you might fall into, because, like I would read some of them and think, I'm sure plenty of people answer yes to these and give blood now, why is it suddenly maybe going to put them into a high risk group." [donor]

The thematic map below that summarizes all the qualitative work for MSM, staff and donors for marketing and promotion highlights other potential avenues such as engaging more with MSM charities and stakeholder groups, attending pride and working with MSM influencers.

Thematic Map of Marketing and Promotion Ideas form Staff, Donor and MSM Qualitative work



5.5. Opinions of donation staff from an English city centre donation centre

5.5.1. Summary

Session staff are keen for a change to the deferral for sex between men, if questioning is straightforward and safety is maintained. An initial gateway question is preferred, and clear definitions plus clear limited answers are required throughout. The importance of compliance is recognised by staff and changing the focus from 'donor health' to 'patient safety' was suggested to improve this. A 'pop up' donor session was suggested to trial any changes to the DHC before implementation.

Background. A northern English city centre donor centre was chosen for a more in depth session with donation staff. The donor centre city centre workers, university staff and students and a wider population from the surrounding area. Donors attend for pre-booked appointments or walk-ins when available. Before donation, the Donor Health Check (DHC) form is completed by the donor and signed at the centre in the presence of a donor carer. A decision as to whether the donor can donate is made by the donor carer based on their responses to the DHC questions. This may be referred to a nurse if further questions are required, or if the donor requires further clarification of the reason for deferral. In February 2020, a workshop with centre staff was undertaken by the FAIR working group to assess the practical issues of asking donor deferral questions regarding sexual behaviour as alternatives to the current 3-month deferral for sex between men. Views on solutions to problems with the questions and ways to facilitate successful implementation were also collected.

The workshop. For the workshop, there were 12 carers and nurses plus a staff member from NHSBT Clinical Support Team. Staff were split into two groups, with a roughly even distribution of carers and nurses, and guided discussions were had about the idea of a more individualised risk assessment with an example of such an assessment used to facilitate conversation. Afterwards the groups reconvened to compare views and for an overall summing up of the outcomes.

Table 5.12 Framework for and summary of the workshop

1. Gateway question? Yes – Ask Q2. No – donate.
Liked the idea of gateway questions so not everyone had to be asked the more details questions. Suggested that a gateway question should let most people at session through. Asked their feelings about a gateway question being on the topic of oral/anal sex between men (SBM) with or without a condom within last 3 months (on DHC). Some staff felt this could be asked on DHC to all donors and would be more appropriate to do so than current question on sex between men.

Some staff felt this was too like the current question and so would still come with the same issues.
2. Have you taken any drugs ex Viagra/cannabis before/during oral/anal sex to enhance sexual experience in the last 3 months? Yes – defer. No - q 3
Comfortable to ask this question face to face but would want clear definitions on what drugs referring to and why it matters. Potential issues flagged around the many names of drugs. Some discussion around if sex on alcohol/while being drunk should be included here too. Happy to defer if responded YES.
3. Have you been diagnosed or received treatment for gonorrhoea/syphilis/chlamydia in last 12months? Yes – defer. No - q 4
Comfortable to ask this question face to face and happy to defer if someone responded YES. Suggestion that some people may have been diagnosed with an STI but may not remember which one. If "STIs" was used instead of specifying just three then potential issues discussed around definitions of STIs. Comment that donors are currently asked about doctor's appointment/diagnoses but they don't think everyone considers GUM clinicians when asked this, this question could ensure they do.
4. Have you had sex with a new or casual partner within last 3 months? Yes – defer. No - q 5
Some felt less comfortable to ask as thought it should be asked to all donors. Also require clear definitions of new and casual and the relevance of the question, several thought defining new or casual would be very tricky and potentially time consuming.
5. How many sexual partners have you had oral/anal sex with or without a condom within last 3 months? One – donate. >1 – defer
Thought recall would be difficult. Would they need reference points to help recall – unless it was 1 or more to defer. Preferred two answer options instead of reporting the number e.g. 1 or >1. Concerns this question could take too long.

Feedback from staff was good overall and they felt an assessment similar to the above would be feasible if refined (Table 5.12). Session staff were very comfortable to ask all the questions, their concern was that some donors may not be comfortable responding. It was felt that all donors should be asked the gateway question for a more equal process, and that would practically improve the selection process and save time. Suggested that the gateway question should be one that most donors get through. There was a strong message that answers should be as straightforward as possible (yes/no) as any grey areas would lead to more time being required per donor and more referrals to

the nurse. A ‘pop up’ donor session for was suggested to trial any changes to the DHC before implementation.

They felt it was very important to understand all the definitions and the reasons for deferral, and that they were comfortable explaining these to donors. They felt appropriate training would help with this and said that with training they would feel comfortable deferring donors after any of the five example questions should they need to. There were suggestions about question order swap Q5 for Q2.

Some staff had concerns over accurate disclosure by donors if questions were asked face to face. Staff felt that that donors thought the DHC was to assess their health for their own benefit, and not that of patients. Staff felt that changing the title of the DHC could facilitate more accurate disclosure to questions. Staff experience was that once donors have arrived on session they do not want to be deferred and are very disappointed if they are. Suggestion that this may impact on their answers and that we should do as much as we can to avoid this happening on session.

The time it would take to go through the questions was of concern. Very keen for the deferrals to be ‘out there’ to have as few at session deferrals as possible.

Very few staff had deferred a donor based on sex between men questions. The more common experience of sexual deferrals was for the sub-Sahara Africa question. Also reported that they knew donors did not read the questions. The member of staff from the clinical support team, i.e. specialist staff who receive queries from the donation staff when they are complex donor histories or when the donor selection criteria are not clear reported difficulty and upset explaining the rationale for the deferral of sex between men to men in a single partner relationship with a man.

6. Current donor health check form - NHSBT example

Currently all donors are given information to read at the time of donation, in NHSBT this is called The Welcome Pack. This gives information about the donation process, donation screening and donor selection rules. Donors are sent information prior to donation and encouraged to look at the blood service website to check their eligibility before attending the donation session. The four UK services all use slightly different forms, but all based on the current donor selection criteria. All donors must complete a donor health check form and give written consent, different forms are used for new and returning donors.

Table 6: Current donor health check for new NHSBT donors

	Are you taking any **prescribed** medicines or tablets or other treatments (except HRT for the menopause, the pill or other birth control)?
	In the last 7 days have you taken any **additional** medicines or tablets including any you have bought yourself?
	In the last 7 days have you seen a doctor, dentist, dental hygienist or any other healthcare professional or are you waiting to see one?
	In the last 2 weeks have you had any illness, infection or fever or do you think you have one now?
	In the last 4 weeks have you been in contact with anyone with an infectious disease?
	In the last 8 weeks have you had any immunisations, vaccinations or jabs (including smallpox)?
	In the last 8 weeks have you been in contact with anyone else who has had a smallpox vaccination?
In the last 3 months have you	
	…had sex with anyone who has had Syphilis or anyone who is HIV positive?
	…been given money or drugs for sex?
	…had sex with anyone who has ever been given money or drugs for sex?
	…had sex with anyone who has ever injected drugs?
	…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)?
	…taken Pre-Exposure Prophylaxis (PrEP) / Truvada for prevention of HIV or have you taken or been prescribed Post-Exposure Prophylaxis (PEP) for prevention of HIV?
	Male donors only; In the last 3 months have you had oral or anal sex with a man, with or without a condom?
	Female donors only; In the last 3 months have you had sex with a man who has ever had oral or anal sex with another man, with or without a condom?
In the last 12 months have you	
	…had your ears, face or body pierced, had a tattoo or any cosmetic treatment that involved piercing your skin?
	…had acupuncture?
	…been exposed to someone else's blood or body fluids eg through a needle prick or bite or broken skin?
	…shared a home with a person with Hepatitis?
	…had sex with anyone with Hepatitis?
	Have you ever tested positive for HIV or do you think you may be HIV positive? Have you ever had sex with anyone with Human T Cell Lymphotropic Virus (HTLV)? Have you ever had Hepatitis or think you may have Hepatitis now?
	Have you ever injected yourself or been injected with illegal or non-prescribed drugs including body-building drugs or cosmetics or injectable tanning agents (even if this was only once or a long time ago)?
	Have you ever had or been treated for Syphilis?
	Have you ever been told that you should not give blood?

	Have you ever seen a doctor with any complaints about your heart or had any other serious illness?
	Have you **ever** had any hospital investigations, tests, operations or alternative therapies?
	Have you ever had Jaundice?
	Have you ever received a blood or blood product transfusion?
	Have you or anyone in your family had Creutzfeldt-Jakob Disease (CJD)?
	Were you treated with growth hormone before 1985?
	Did you have brain surgery or an operation for a tumour or cyst in your spine before August 1992?
	Female donors only; Have you had fertility treatment or had IVF for any other reason since 1980?
	In the last 12 months have you been outside the UK (inc. business trips)?
	Were you born or have you ever lived or stayed outside the UK for a continuous period of 6 months or more? If 'yes' have you been outside the UK since then?
	Have you ever had malaria or an unexplained fever which you could have picked up while travelling or living or working abroad? If 'yes' have you been outside the UK since then?
	Have you ever visited Central America, South America or Mexico for a continuous period of 4 weeks or more?
	Were you or your mother born in Central America, South America or Mexico?

7. Potential questions to support a more individualised donor selection policy

7.1. Rationale

Based on literature and current risks identified in blood donors with markers of infection the following higher risk sexual behaviours were identified. In addition these correlated well with psychometric data and are therefore proposed as potential basis for questions to identify individuals at higher risk of acquiring BBIs.

- Chemsex: use of drugs to enhance sexual experience- excluding use of Viagra and cannabis and alcohol
- Bacterial sexually transmitted infection in last 12 months-specifically syphilis and gonorrhoea
- More than one partner and/or new partners within the last 3 months
- Specific sexual behaviours – anal sex
- Inconsistent condom use

7.2. Current and potential new questions - options

The risk behaviours listed above formed the basis of potential questions to be asked to donors irrespective of gender, and here they are considered in combination as options A, B and C (Table 7.1). It is proposed to only ask these questions to donors who have ever had sex.

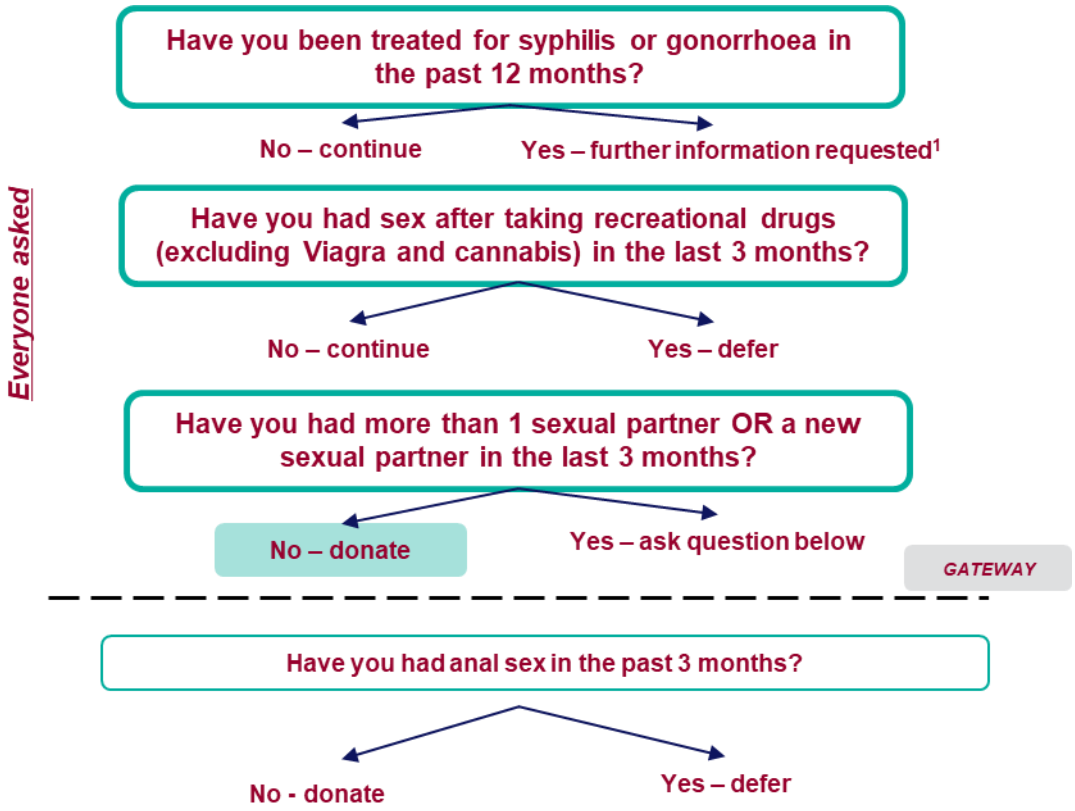
Table 7.1: Options for deferral questions

Current	A	B	C
	Ever had sex	Ever had sex	Ever had sex
-	Chemsex	Chemsex	Chemsex
Deferral Syphilis ever	Syphilis ever Treated for Syphilis or gonorrhoea in last 12 months	Syphilis ever Treated for Syphilis or gonorrhoea in last 12 months	Syphilis ever Treated for Syphilis or gonorrhoea in last 12 months
Questions about higher risk partners only	New partner or more than one partner in last 3 months	New partner or more than one partner in last 3 months	New partner or more than one partner in last 3 months
3 months deferral for higher risk sexual behaviours	New partner or more than one partner in last 3 months + anal sex	New partner or more than one partner in last 3 months + inconsistent condom use	New partner or more than one partner in last 3 months + anal sex with inconsistent condom use

The steering group considered each of these options, but based on evidence presented in this report, it was agreed that option A was the most appropriate to recommend, however, women who have sex with women would not be deferred. From BEST survey data, option B gave rise to an estimated 4.4% deferral of donors (see Figure 7.1 below) including donors currently selected and apparently low risk. Option C would allow donors who had anal sex with consistent condom use to donate; while this is recognised as a lower risk behaviour it was considered difficult to implement on session given concerns around confidentiality but will be kept under review. Currently none of the UK blood services have a truly electronic donor health check form which would allow donors to compete questions pre-donation and get further information about eligibility and reasons why they may not be eligible. Currently some donors complete a paper form ahead of donation and then discuss any issues at the donation centre. In static sites these discussions take place in rooms, however, in mobile sessions these are more likely to be in curtained area, whilst every attempt is made to make this confidential some people are concerned about privacy. Under these circumstances the number of additional personal questions that can be asked in a session environment are limited. All UK blood services are working towards electronic donor selection processes which would enable more questions about specific behaviours to be asked.

In addition, the psychometric work found that consistent condom use was the behaviour which had the least reliable reporting and therefore may not be a result in accurate answers with difficulties in recall. The questions included in option A agreed for FAIR are shown in the algorithm below (Figure 7.1).

Figure 7.1: Algorithm for FAIR questions in option A



[1] The donor will be asked additional questions: For past syphilis – permanent deferral. For past gonorrhoea – 3-month deferral. Note: new donors are asked an additional question about if they have EVER had syphilis, if yes they will be permanently deferred

7.2.1. Proposed donor health check - new donor

A potential new DHC is shown below with the new gateway question about multiple and or new sexual partners in the last three months (Table 7.2). The questions are grouped to reflect timing with some of the permanent deferral questions grouped at the top of the DHC. The layout of the DHC is the responsibility of the individual blood services however recommendations can be made about how questions should be grouped and which questions could inform the FAIR approach. Psychological data suggests recall may be increased by using reminders about dates and encouraging donors to think about this prior to arrival at session perhaps by giving a date in the donation session about 3 months.

The donor selection guidelines will be updated by JPAC if these recommendations are accepted

The steering group also discussed some of the questions which will remain include the question ‘in the last 3 months have you had sex with anyone is HIV positive’. It is recommended that the

donor selection guidelines should be updated to allow donation whose partners are taking treatment for HIV and have undetectable levels of virus under the following discretion:

'Accept if: sexual partner has been on treatment for at least 6 months and has an undetectable viral load'

There is good evidence that people with undetectable levels of HIV are highly unlikely to transmit the virus via sex. [1,2,3]

References

1. Rodger A et al *Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner is Using Suppressive Antiretroviral Therapy* JAMA 2016;316(2):171-8
2. Rodger A et al *Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multi centre, prospective, observational study* Lancet 2019 Jun 15;393(10189):2428-2438
3. Mujugira A et al *HIV Transmission Risk Persists During the First 6 Months of Antiretroviral Therapy* J Acquir Immune Deficiency Syndr 2016 Aug 15; 72(5): 579 - 584

Table 7.2: Proposed 'donor health check' form for new donors with FAIR questions included

Have you ever..	..been told that you should not give blood?
	seen a doctor with any complaints about your heart or had any other serious illness?
	ever had any hospital investigations, tests, operations or alternative therapies?
	Ever been treated for syphilis
	ever tested positive for HIV or do you think you may be HIV positive?
	had jaundice or Hepatitis or think you may have Hepatitis now?
	injected yourself or been injected with illegal or non-prescribed drugs including body-building drugs or cosmetics or injectable tanning agents (even if this was only once or a long time ago)?
In the last 12 months have you	…had your ears, face or body pierced, had a tattoo or any cosmetic treatment that involved piercing your skin?
	…had acupuncture?
	…been exposed to someone else's blood or body fluids eg through a needle prick or bite or broken skin
Have you ever	…
	had sex [oral, anal or vaginal]. If no skip to question X
	had sex with anyone with Human T Cell Lymphotropic Virus (HTLV)?
	Been treated for a sexually transmitted infection excluding Chlamydia
In the last 3 months	
	…had sex with anyone who has had Syphilis, Hepatitis or anyone who is HIV positive?
	…been given money or drugs for sex?
	…had sex with anyone who has ever been given money or drugs for sex?
	…had sex with anyone who has ever injected drugs?
	…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)?
	…taken Pre-Exposure Prophylaxis (PrEP) / Truvada for prevention of HIV
	Used drugs during sex excluding Viagra or cannabis
	Had more than one sexual partner or a new sexual partner
	Are you taking any **prescribed** medicines or tablets or other treatments (except HRT for the menopause, the pill or other birth control)?
	In the last 7 days have you taken any **additional** medicines or tablets including any you have bought yourself?
	In the last 7 days have you seen a doctor, dentist, dental hygienist or any other healthcare professional or are you waiting to see one?
	In the last 2 weeks have you had any illness, infection or fever or do you think you have one now?
	In the last 4 weeks have you been in contact with anyone with an infectious disease?
	In the last 8 weeks have you had any immunisations, vaccinations or jabs (including smallpox)?
	In the last 8 weeks have you been in contact with anyone else who has had a smallpox vaccination?
	In the last 3 months or have you taken or been prescribed Post-Exposure Prophylaxis (PEP) for prevention of HIV?
	Have you or anyone in your family had Creutzfeldt-Jakob Disease (CJD)?
	Have you ever received a blood or blood product transfusion?
	Were you treated with growth hormone before 1985?
	Did you have brain surgery or an operation for a tumour or cyst in your spine before August 1992?
	Female donors only; Have you had fertility treatment or had IVF for any other reason since 1980?
	In the last 12 months have you been outside the UK (inc. business trips)?
	Were you born or have you ever lived or stayed outside the UK for a continuous period of 6 months or more? If 'yes' have you been outside the UK since then?

7.3.Impact of proposed questions on number of donors

The likely impact on the overall number of donors has been considered in terms of the expected number of newly eligible donors and the number of current donors who would be deferred under the new criteria. It was estimated that 1.4% and 4.4% of donors would be deferred under option A and B respectively. Estimates were higher using general population survey data to assess eligibility of potential donors.

To derive an estimate of the number of newly eligible MSM, it was assumed if between 50% and 65% of MSM would be eligible to donate under option A, and 2% of eligible MSM would donate, then between 11.6K and 15.1K MSM in England, and 13.2K and 17.2K MSM in the UK could donate.

7.3.1. The estimated number of newly deferred donors

The number of donors who were likely to be deferred under options A and B of the proposed selection criteria were estimated using data from the BEST study of donors (n=1262) and the general population surveys (n=693). The questions from BEST are shown in Appendix 6. For both populations of potential donors, the percentage deferred was estimated and compared between the two populations. For the BEST survey of current donors, the proportion deferred was estimated by gender, donor type (new and repeat and age groups 17-34 and 35 plus. These proportions were applied to the total number of NHSBT donors in 2019.

- The deferral options:

  Option A: bacterial STI <12 months or chem sex<3 months, or more than 1 sex partner/new sex partner and anal sex <3 months

  Option B: bacterial STI <12 months or chem sex<3 months, or more than 1 sex partner/new sex partner and inconsistent condom use.

From the survey of donors, option A would give rise to 1.4% deferral of donors, this increased to 1.9% among new donors (Table 7.4). Option **B** deferred 4.4%, increasing to 7.1% among new donors. These may be an overestimate as respondents in the BEST survey were asked about all bacterial STIs including chlamydia. From the general population surveys, the overall estimated deferral rates were, as expected, much higher than in the donor survey at 9.3% for option A and 16.2% for option B (Table 7.5). However, when this is broken down by current donor and non-donor then for option A the deferral rate is 2.3% for current donors and 7% for non-donors and for option B it is 4% for current donors and 12% for non-donors. Thus the deferral rate for those identifying as current donors in the general population survey is mirrors that for donors in the BEST survey (Table 7.4).

When the deferral rates were applied to NHSBT donors, it was predicted that 13,170 donors in 2019 would have been deferred under option A, with the highest rate of deferral (5.3%) in male new donors aged less than 35 years, and the greatest number of donors deferred (3902) among female repeat donors aged less than 35 years (Table 7.6). This is very much a worst-case estimate.

Table 7.4: Estimated deferrals for option A and option B from BEST survey

Option A	Counts	deferral at each Q in sequence	sequential deferral	sequential eligible	Option B	Counts	deferral at each Q in sequence	sequential deferral	sequential eligible
Eligible responders (complete age, gender, donor type AND answered sex question)	1262		0	1262	Eligible responders (complete age, gender, donor type AND answered sex question)	1262		0	1262
bacterial sti	5	5	5	1257	bacterial sti	5	5	5	1257
sex on drugs	6	5	10	1252	sex on drugs	6	5	10	1252
gateway	60	0	10	1252	gateway	60	0	10	1252
gateway and anal	9	8	18	1244	gateway and condom	45	45	55	1207
deferral%				**1.4%**	**deferral%**				**4.4%**

Table 7.5: Estimated deferrals for option A and option B from the general population survey

Option A	Counts	deferral at each Q in sequence (blood donors)	sequential deferral (blood donors)	sequential eligible	Option B	Counts	deferral at each Q in sequence (blood donors)	sequential deferral (blood donors)	sequential eligible
Eligible responders (complete age, gender, donor type AND answered sex question)	693		0	693	Eligible responders (complete age, gender, donor type AND answered sex question)	693		0	693
bacterial sti	13	13 (2)	13 (2)	680	bacterial sti	13	13 (2)	13 (2)	680
sex on drugs	31	28 (9)	41 (11)	652	sex on drugs	31	28 (9)	41 (11)	652
gateway	86 (24)	0	41	652	gateway	86	0	41	652
gateway and anal	24	24 (5)	65 (16)	628	gateway and condom	71	71 (17)	112 (30)	581
deferral %				**9.4% (2.3%)**	**deferral %**				**16% (4%)**

Table 7.6: the estimated number of NHSBT donors deferred for option A by gender and age for new and repeat donors

			survey data				NHSBT donors 2019			
Option A			Defer	Not defer	Total	defer %	total donors	estimated number deferred	(95%CI)	% deferred donors
male	new	<35	1	18	19	5.3%	32771	1725	(197.0 - 11072.8)	13%
male	repeat	<35	1	69	70	1.4%	70905	1013	(135.5 - 7007.8)	8%
male	new	35 plus	0	24	24	0.0%	24216	0		0%
male	repeat	35 plus	5	342	347	1.4%	228203	3288	(1365.6 - 7824.5)	25%
female	new	<35	2	93	95	2.1%	50481	1063	(259.4 - 4149.1)	8%
female	repeat	<35	5	144	149	3.4%	116271	3902	(1615.4 - 9165.4)	30%
female	new	35 plus	0	63	63	0.0%	32750	0		0%
female	repeat	35 plus	4	491	495	0.8%	269766	2180	(816.3 - 5772.8)	17%
total			18	1244	1262	1.4%	825363	13170	(8130.3 - 21877.3)	100%

7.3.2. The estimated number of newly eligible donors

The number of newly eligible donors estimated was limited to the expected number of MSM who could come to donate under option A. This would include MSM with no more than one longstanding (>3 months) or no partners in the last 3 months, and MSM with new or multiple partners in the last 3 months but had only had oral sex with these partners. In the absence of any data about the extent of each of these behaviours in MSM in the general population, an assumption was made that between 50% and 65% of MSM would be eligible to donate under option A. This was based on the observation from the UK blood donor survey in 2014 that 2/3rd of MSM donors had between 1 and 2 sexual partners in the last 12 months. The number of MSM who would donate was then calculated for England and the UK based on the ONS estimate that 3% of males identify as gay, bisexual or other sexuality that was not heterosexual, and the 2% male donor rate. This gave rise to an estimate of 11.6K and 15.1K in England, and 13.2K and 17.2K in the UK of MSM who would be eligible to donate blood (Table 7.7).

Table 7.7: expected number of MSM who would donate in England and UK

	England	UK
ONS - number males aged 17-70 general population 2019	38771955	44182569
ONS - 3% males identify as gay, bisexual or sexuality other than heterosexual 2018	1163159	1325477
Assumption - 50% MSM eligible under option 1	581579	662739
Assumption - 65% MSM eligible under option 1	756053	861560
Actual estimated number MSM who donate @2% male donor rate with 50% eligible	11632	13255
Actual estimated number MSM who donate @2% male donor rate with 65% eligible	15121	17231

7.3.3. Impact of proposed donor selection criteria on blood donors with recent viral infections UK 2018-2019

In two calendar years following the 3-month deferral in place in England, Wales and Scotland, 3.7 million donations were made in the UK with 385 confirmed positive and removed. Of these, 15 positive donors were identified as having viral infections acquired within 12 months: 9 acute HBV, 1 HCV NAT pick up and 5 HIV (2 dual syphilis).

Table 7.8 shows compliance in these 15 donors to the current and potential FAIR system. Five were non-compliant to sexual behaviour deferrals while four males did not report any obvious risk. Of two donors reporting sex between men (SBM), one with HIV, was non-compliant to the 12-month deferral in Northern Ireland, which may, depending on the timing of their new partner be identified by the new FAIR gateway option if compliance is improved. Of 8 reporting SBMW, two compliant donors could go through the Gateway question but would only be newly deferred by FAIR options, if they had anal sex: one was a HBV NAT pick up who had used condoms, one with HIV was swinging with regular partners. The wording of the gateway question and communication on risk to recipients needs care to encourage disclosure.

Only one of the 9 acute HBV cases identified between 2018 and 2019 would potentially be picked up through FAIR options and then only if anal sex practiced. FAIR gateway questioning does not necessarily reduce the risk from acute HBV in donors with a regular partner or having vaginal sex. Numbers are usually very small but vary from year to year.

The issue of not knowing your regular partner has an infection or is at risk of infection remains and evidence is lacking for how it would change under FAIR gateway questioning. Not knowing your regular partner risk currently manifests in acute HBV and syphilis (see below).

Table 7.8: Recent viral infection and compliance, UK 2018-2019

Current deferral	Rule	FAIR option	Infection	Description
Knowingly non-compliant?	SBM-3m	No change	HBV acute	repeat male donor, regular male partner but reported last had sex more than 12 months ago, however, no other obvious risks reported to account for recent infection.
Knowingly non-compliant	SBM-12m	May become compliant?	HIV	repeat male donor, 6 donations since Oct 2016. One new partner and one regular partner in previous 12m, non-compliant under current NI donor selection criteria

Knowingly non-compliant	SBMW HRP SSA	No change	HIV	repeat female, 2 new HRP SSA partners timing unclear, sero-illness 2-4m prior to donation
Knowingly non-compliant	SBMW HRP PFS	No change	HIV/TP	new male, avidity likely 4m, regular partner, new partner(s) likely paid for 12m abroad
Unknowingly non-compliant	SBMW HRP HBV	No change	HBV acute	repeat female, 2 years since last donation, regular partner of 2 years (now known to have chronic HBV)
Compliant	SBMW	No change	HBV acute	repeat male, 3m since last donation, regular female partner of 2.5 years. Partner had new partner 5-6m previously.
Compliant	SBMW	No change	HBV acute	new male, regular female partner 3m, both from Romania, other risk?
Compliant	SBMW	No change	HIV	repeat male, 2 new female partners Thailand 6m, no condom, sero-ill 5m prior to donation, avidity likely 4m
Compliant	SBMW	Newly deferred?	HBV NAT pick up	repeat male, 3m since last donation, 2 new female partners 3m, condoms yes (unsure if fell off or damaged)
Compliant	SBMW	Newly deferred?	HIV/TP	repeat male, avidity likely 4m, regular female partner no sex contact, other new? partner 3m, regular sex with female swingers
Knowingly non-compliant?	Endoscopy	No change	HBV acute	Repeat male NI. Endoscopy not relevant to timeframe of infection but would have been deferred if declared. Forgot to declare – regular donor didn't read questions carefully. Recent dental treatment only other risk reported. No partners in the last 12m.
No risk reported	Not known	No change	HCV NAT pick up	Repeat male 55 years plus.
No risk reported	Not known	No change	HBV acute	Repeat male 55 years plus. Wife only sexual contact.
No risk reported	Not known	No change	HBV acute	Repeat male 55 years plus. Single.
No risk reported	Not known	No change	HBV acute	New male 25-34 years (query reactivation). Female partner of 10 years.

Looking at the period covered by the 3 month deferral only, during calendar years 2018-2019, there were 181 blood donors in the UK confirmed positive for *Treponema pallidum* antibodies, 53 with acute infection and IgM positive, 17 were not IgM positive but based on history were thought to have acquired their infection within 1 year and 111 with either past infection or where timing of infection could not be assigned.

Of these donors, 39 or 21.5% mostly with past infection knew that they had had syphilis in the past and did not disclose this at the time of donation i.e. were non-compliant to the syphilis ever rule.

Communication around the syphilis deferral needs strengthening and re-introducing on the regular donor DHC.

If a gateway question was applied to all donors who had had sex in the last three months then 34 donors would have potentially disclosed sex with more than one partner or a new partner in the last 3 months (Table 7.9). It is not known how many of these would be deferred on the anal question. However, this only accounts for 27/53 donors with acute syphilis. Another 26 donors with acute syphilis had not reported any recent partner change or multiple partners and would not be deferred unless they answered yes to one of the other lifestyle questions. Current deferrals do not identify everyone at risk of syphilis, and FAIR gateway options would not identify everyone at risk of syphilis. We do not expect FAIR to reduce syphilis in donors and we may expect to see more syphilis if more MSM enter the donor pool and if infectious syphilis continues to rise in MSM and heterosexuals.

Syphilis screening could be used to monitor compliance to the FAIR questioning and remove those donors who are in higher risk networks.

Table 7.9: Syphilis in blood donors UK 2018-2019

	ACUTE		1 YEAR		PAST/NK		TOTAL	
Syphilis total	53	29.3	17	9.4	111	61.3	181	100.0
Treated (applicable known infection)	**0**	**0.0**	**1**	**5.9**	**38**	**34.2**	**39**	**21.5**
MSM	0	0.0	1	5.9	12	10.8	**13**	7.2
HET	0	0.0	0	0.0	14	12.6	**14**	7.7
HRP	0	0.0	0	0.0	1	0.9	**1**	0.6
NK	0	0.0	0	0.0	9	8.1	**9**	5.0
Not known or treated	**53**	**100.0**	**16**	**94.1**	**73**	**65.8**	**142**	**78.5**
MSM	7	13.2	3	17.6	12	10.8	**22**	12.2
HET SEX	45	84.9	12	70.6	40	36.0	**97**	53.6
NK/non-sex	1	1.9	1	5.9	23	20.7	**25**	13.8
HRP	0	0.0	0	0.0	0	0.0	**0**	0.0
GATEWAY: >1/new partner 3m	27	50.9	2	11.8	5	4.5	**34**	**18.8**
MSM	3	5.7	0	0.0	0	0.0	**3**	1.7
M HET	15	28.3	2	11.8	3	2.7	**20**	11.0
F HET	9	17.0	0	0.0	2	1.8	**11**	6.1
Abroad	3	5.7	1	5.9	0	0.0	**4**	2.2

7.3.4. Positive donors with potential recent infection in England 2020: Preliminary data

Two new donors reported MSM with HIV avidity awaited (both reported new partner 4-6m, 1 had seroconversion illness 5m prior) so no deferral applied either under current system or under FAIR.

Three male donors with 3 recent syphilis, reported MSM, 2 IgM+. Two were non-compliant under current system but would become compliant under FAIR as they only reported regular partners, one was IgM+. A third was compliant under both current system and FAIR as last partner was 7-12m ago, and although treated for red patch, not diagnosed as syphilis.

One repeat female donor was found to have acute HBV and should have been deferred for the HRP SSA rule as they had a new partner who may have had sex in Africa within 3 months of donating.

Two female donors with recent syphilis IgM+ either had a regular partner or last partner 7-12 months ago and therefore compliant under both current and FAIR systems.

7.4. Donor selection criteria that will require ongoing review

Currently certain donor selection guidelines are enshrined in law in the Blood Safety and Quality Regulations and at the current time cannot be changed. For example, potential donors who have ever injected, or been injected with non-prescribed drugs are excluded. Other donor selection criteria can be changed if suitable evidence is available to assess the impact of such a change. Donor selection guidelines that remain in place within a more individualised risk assessment policy include the 3-month deferral for use of antiviral treatment as post exposure (PEP) or pre-exposure prophylaxis (PrEP) to prevent HIV infection.

Both PrEP and PEP are very positive advances in HIV prevention, when taken as prescribed, they pose specific issues when it comes to blood donation. Whilst HIV acquisition is rare in individuals prescribed PEP or PrEP, the use of antiretrovirals at or soon after infection can delay the time it takes for the infection to be confirmed. All blood donations are tested for HIV and recent use of HIV PEP or PrEP may either temporarily suppress the virus below detectable levels and / or delay the production of antibodies detected in HIV testing and hence the 3-month deferral period will have to remain in place. This means that anyone who has taken PrEP or PEP in the previous three months cannot donate blood.[1,2]

It is known that antiviral treatment causes HIV-infected individuals to express modified markers of infections (likely as a result of decreased viral levels in body), in some cases leading to undetectable HIV RNA by NAT assay and undetectable serological screening results. However, it is known that if antiviral treatment is discontinued in these cases, rebounding viraemia can be detected in weeks to months time, indicating their potential to transmit HIV infection to transfusion recipient given the large volume of blood transfused (i.e. 250ml to 500ml per pack of blood). Similar observations have been made in individuals on PrEP, impacting our current ability to identify these donors via current blood donation screening. If someone who is using PrEP becomes HIV infected either just before starting PrEP or whilst taking PrEP as a result, for example, of poor adherence the virus will, initially, be suppressed to levels not detectable by testing and the production of antibodies detected by HIV testing is likely to be delayed and atypical. However, international work is ongoing to identify more sensitive donation testing for HIV (such as individual NAT testing) or to eliminate this risk in other ways such as via pathogen inactivation (although not yet available for red cells or whole blood).

Undetectable levels of the virus may still be infectious through blood transfusion. Although there is little data on viral loads coinciding with PEP or PrEP usage that could result in a transfusion-transmitted infection, transfusion is a much more effective means of transmission than any sexual behaviour. The urgent need to investigate the extent of PrEP usage among blood donors and its risk

to blood recipient has been highlighted by the recent studies demonstrating PrEP use in 0.6% first-time male donors [against their donor selection criteria] and by survey in 5% of MSM in US. [3] The 3-month deferral is a precautionary measure because there are limited data currently available on this topic. Further data are being collated in the USA and, in the UK, the BHIVA / BASHH PrEP guidelines are currently undergoing a review which will include a focus on the data on HIV testing in the context of HIV acquisition whilst on PrEP which will hopefully contribute towards future policy evaluation.

We understand there is a lack of public awareness on the potential impact of PrEP on HIV testing, and hence we recommend further information is shared as part of the communication strategy following the implementation of the new deferral format. The effect of PrEP in the context of HIV testing will be further reviewed as more data becomes available.

1. Donnell D et al. The effect of oral *preexposure prophylaxis* on the progression of HIV-1 seroconversion. AIDS 2017 Sep 10;31(14):2007-2016. https://journals.lww.com/aidsonline/Fulltext/2017/09100/The_effect_of_oral_preexposure_prophylaxis_on_the.13.aspx
2. Elliott T et al Challenges of HIV diagnosis and management in the context of pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), test and start and acute HIV infection: a scoping review. Journal of the International Aids Society 2019. https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.25419
3. Custer B, Quiner CA, Haaland R, et al. HIV antiretroviral therapy and prevention use in US blood donors: A new blood safety concern. *Blood*. 2020 July 9.

8. Implementation and monitoring

8.1. Pilot and implementation

If recommendations are accepted, it is likely that the four UK blood services will be encouraged to implement the new process as soon as possible following direction from the devolved administrations. Initial discussions have been held to explore whether the new process should be piloted and explore what would need to be in place ahead of implementation. One of the issues that needs to be acknowledged if a change is required in the next few months is the ongoing COVID-19 pandemic and the pressure on the UK blood services to both maintain whole blood stocks whilst increasing the numbers of convalescent plasma donors. The blood services are also recruiting and training new staff to support the increased donation activity whilst being aware that any 'second wave' of COVID-19 may result in increased sickness within staff and decline in donors.

Originally it had been hoped to pilot the new process at one donation centre, possibly in England, this will be explored but it may be difficult to carry out a real-life pilot under the current pressures. Therefore it was suggested that a table-top approach could be used to walk through the process, this would include testing out various scenarios i.e. donors with a range of risk factors; which could also be tested out on staff and also used as training materials.

Before implementation the JPAC donor selection guidelines would need to be updated and new donor health check forms designed and printed as appropriate. Accompanying information both printed and digital would also require updating prior to any roll-out. Stakeholders were keen that any likely changes to questions over the next few months should also be included in the health check redesign and print run to prevent further retraining and reprints. The Welsh blood service would need to plan time for changes to their eProgesa system which requires IT input.

As already noted in feedback from focus groups and other members of the group it is very important that the rationale for the changes is clear and that donation staff are able to explain the reasons for selection and deferral clearly to both new and current donors. Training will focus on this new approach to donor selection and the reasons for the change

It was noted that a communications plan was required both for current and potential new donors but also for the wider public across a range of media. The support of other members of the steering groups including the charity and lobby groups would be helpful in messaging.

8.2.Monitoring

Post implementation monitoring is required to :

1) ensure that the new donor selection criteria do not have any unforeseen consequences
2) monitor both acute and chronic infections in new and regular donors
3) monitor complaints relating to new questions
4) develop ways to monitor overall deferrals
5) develop a post-implementation survey for donors

It is recommended that over the first few months of the any new donor selection guidelines the numbers and rates of infections in new (and regular) donors are monitored as close to ‘real-time’ as possible. It is expected that there will be an increase in prevalent, previously undiagnosed infection, in the short term. A change in such infections is usually observed whenever newly eligible donors join the donation pool, this has been observed in our convalescent plasma donors during 2020. More importantly would be any change in the number of new acute infections observed post implementation which would suggest that the donor selection criteria are not selecting low risk

donors. It is recommended that numbers of new infections are monitored every two weeks with particular attention paid to risk factors. These could be reviewed monthly by a subgroup of the UK Microbiology Services Clinical Group who could raise any concerns regarding rates of infection to the individual medical directors. It is recommended that the services decide on a rate of infection in new donors that is acceptable and if this rate is exceeded further review of the selection process will be required.

Current donor systems are not easy to interrogate although changes in donor numbers and attendance patterns can be reviewed. Deferral data are available but lacks detail about the reason for deferral. To better understand the impact of any change and behaviours, motivations and compliance in both new and regular donors it is recommended that an anonymous and unlinked donor survey is designed and run 4-6 months after implementation. In addition, complaints data should be regularly reviewed to ensure that the new process has not had an adverse impact on previous donors and potential donors who have been put off by the new questions.

The overall impact of the change should be reviewed 12 months after implementation.

9. Communications

The steering group has a communications representative who has provided updates to the media and other interested parties as the work has progressed. A communications strategy is being prepared ahead of any recommendation and holding lines are in place. A number of suggestions were made by the participants in the focus groups and these will be considered in the communications strategy. Depending on when any implementation occurs there may be a need to communicate with both whole blood donors and potential plasma donors. A wide range of channels will be used including social media.

Colleagues within donor marketing with be asked to support activities to inform donors of the new guidelines and market donation to those people previously ineligible. Members of the steering group representing LGBT+ charities will also be approached to support this.