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Blood and Transplant

Donor selection and impact of FAIR within NHSBT

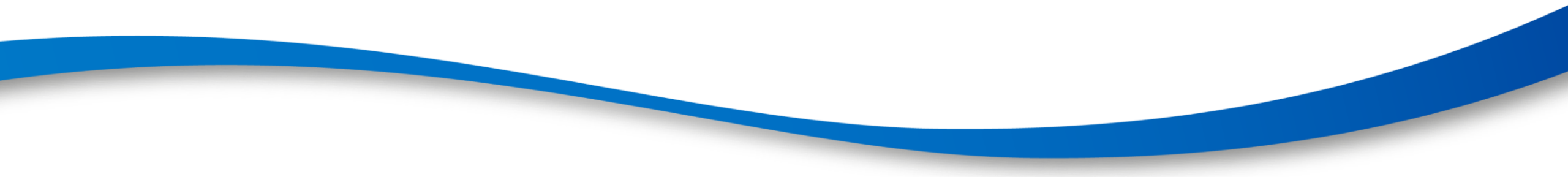
Dr Su Brailsford FFPH

Consultant in Epidemiology and Health Protection

IPFA/PEI 28th International workshop on surveillance and screening of blood-borne infections

Caring Expert Quality

Overview

- Donor selection in the UK
 - Preparing for implementation
 - Implementation of FAIR I/II
 - Impact of FAIR in England
- 
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Acknowledgements

- All the people who took part in the surveys and focus groups

• **Fair Steering group:** Naim Akhtar: NHSBT; Su Brailsford, Chair NHSBT; Katy Davison, Deputy Chair NHSBT/UKHSA Epidemiology Unit; Claire Reynolds NHSBT/UKHSA Epidemiology Unit; Eamonn Ferguson, University of Nottingham; Luke Foster, NHSBT; Joe Flannagan. Secretariat, NHSBT/UKHSA Epidemiology Unit; Stuart Blackmore, Welsh Blood Service; Angus Wells, Standing Advisory Committee on the Care and Selection of Donors (SACCSO); Josh Bradlow, Stonewall, Dan Costen, Freedom to Donate; Gareth Humphreys, NHSBT; Kat Davies, NHSBT; Stephen Bailey, NHSBT; Heli Harvala, NHSBT; Kat Smithson (previously Natasha Dhumma), National AIDS Trust; Paul Harvey, Donor representative; Gemma Room, Patient representative; Roanna Maharaj, Patient representative UK Thalassaemia Society; Michael Brady, Terrence Higgins Trust; Deborah McNaughton, Scottish National Blood Transfusion Service; Kathryn Maguire, Northern Ireland Blood Transfusion service

• **The psychology team at the University of Nottingham:** Eamonn Ferguson, Claire Lawrence, Naomi Pierce and Erin Dawe-Lane

• **UK Blood service implementation groups**

• **Colleagues at NHSBT/UKHSA Epidemiology Unit**

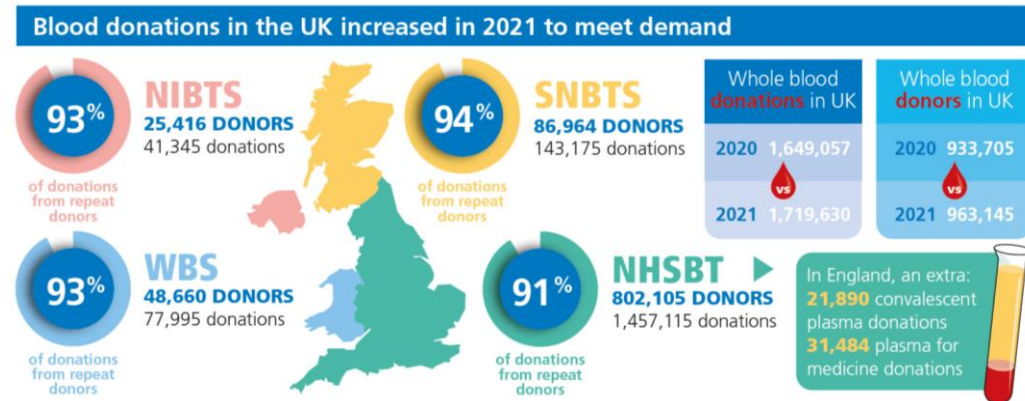


Donor selection in the UK

JPAC Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee

<https://www.transfusionguidelines.org/>

Whole blood donor demographics, UK 2021



GOV.UK

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

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation.

Decision making

- FAIR report reviewed by SaBTO
- SaBTO made recommendations to ministers
- Accepted the recommendations and advised on timeline
- Written ministerial statement
- Announcement in parliament by SoS for health



<https://www.gov.uk/government/groups/advisory-committee-on-the-safety-of-blood-tissues-and-organs>

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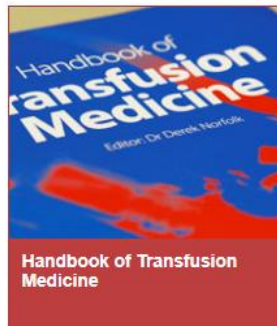
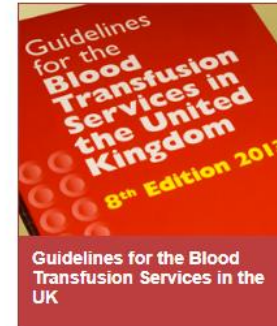
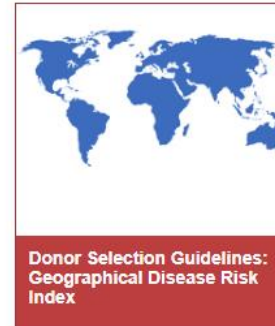
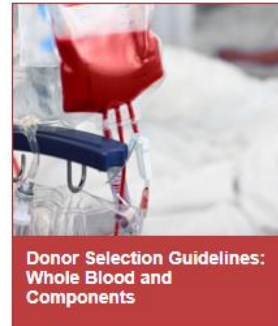
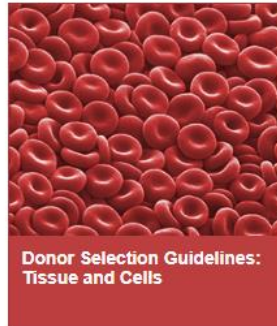
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Home / Donor Selection Guidelines / Whole Blood and Components / A-Z Search / Blood Safety Entry

Whole Blood and Components

A-Z Search

- Drug Index
- Latest Updates
- Version Information
- Preliminaries
- Introduction
- Document and Change Control
- General Principles
- Medication
- Inspection of the Donor
- Use of Alphabetical Listing

Appendices

- Appendix 1 - Estimated Blood Volume for Female donors (after Nadler) by height and weight
- Appendix 2 - Table of Immunizations
- Appendix 3 Maximum permitted Extra Corporeal Volume for component donors

Blood Safety Entry

Definitions:	Individual risk is based on the donor's sexual behaviour, including new partners and number of partners. Partner risk is based on sexual contact with a partner who may, at a population level, be at higher risk of acquiring infection, as described in this entry. Sexual contact is defined as oral, vaginal or anal sex. Anal sex is defined as penile-anal intercourse only. It does not apply to oro-anal sex or the use of sex toys. Chemsex is sex while using stimulant drugs taken for the specific purpose of enhancing sexual experience and reducing inhibitions. Chemsex does not refer to sex after using alcohol or recreational drugs for other purposes, nor the use of drugs such as Viagra or Cialis to treat erectile dysfunction.
Obligatory:	Information must be provided so that individuals at risk do not donate. The reasons for donor self-exclusion must be understood. 1. You must not donate if: You think you need a test for HIV/AIDS, HTLV or hepatitis. 2. You must never donate if: a) You are HIV positive or receiving treatment for HIV. b) You are HTLV positive

Blood Safety Entry:
No longer has specific
MSM entry



Challenges an assessment of individual risk can pose

Identifying

low and high risk sexual behaviours

Separating

out those with low risk behaviours using a series of questions

Acceptability

of such questions to current donors, potential donors and session staff

Reliability & accuracy

of people's answers to such questions

Practicalities

of asking such questions e.g. length of the DHC

Perceptions

people have of their own risk may not be accurate

New FAIR questions are to all donors



In the last 3 months, have you:

had gonorrhoea?
used drugs during sex?
had anal sex with a new or
multiple partners?

If no - you can donate



MSM questions were removed
from 14 June for England,
Scotland and Wales and
14 August for Northern Ireland

The HIV endemic area partner
question was removed by the
end of 2021 across the UK

Main Themes	Sub-Themes
Trust in Donors	Trusted and Generous Donors – Not just saving lives, but giving a life
	Trust donors to Self-Defer
Intersectionality	Sensitivity to culture, ethnicity, sex and politics
Donor-Recipient linkage	safety to recipients

Implementing the policy change

- Stakeholder engagement continued
- NHSBT managed implementation as a project
 - *new donor messaging/comms*
 - *'check you can give' tool*
 - *new donation safety check form*
 - *new consent procedures*
 - *staff training and FAQs*
- Marketing co-branded with stakeholders



Donation Safety Check for New and Returning Donors

The following questions must be completed by all potential blood donors. We realise that some questions may appear intrusive, but your answers will be treated with absolute confidentiality. Please answer all questions to the best of your knowledge to ensure your own safety and that of any potential recipient of your donation. If you are uncertain of any answer or answer 'Yes' to any question, please call the donor helpline on 0300 123 23 23 or visit www.blood.co.uk to check if you are eligible to donate. Please use blue or black ballpoint pen to complete this form.



Blood and Transplant

No	Question	DT CODE	Yes	No	Staff
1	Are you taking any prescribed medicines or tablets or other treatments (except HRT, the pill or other birth control)?		☐	☐	
2	Have you ever tested positive for HIV, or do you think you may be HIV positive?		☐	☐	
3	Have you ever had sex with anyone with Human T Cell Lymphotropic Virus (HTLV) or anyone who has ever had viral haemorrhagic fever (including Ebola)?		☐	☐	
4	Have you ever had jaundice or hepatitis, or do you think you may have hepatitis now?	J	☐	☐	
5	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)?		☐	☐	
6	Have you ever had or been treated for syphilis or gonorrhoea?		☐	☐	
7	Have you ever been told that you should not give blood?		☐	☐	
8	Have you ever seen a doctor with any complaints about your heart, or had any other serious illness?		☐	☐	
9	Have you ever had any medical investigations, tests, operations or alternative therapies?	S/E	☐	☐	
10	Have you ever received a blood or blood product transfusion?	T/R	☐	☐	
11	Have you or anyone in your family had Creutzfeldt-Jakob Disease (CJD)?		☐	☐	
12	Were you treated with growth hormone before 1985?		☐	☐	
13	Did you have brain surgery or an operation for a tumour or cyst in your spine before August 1992?		☐	☐	
14	Have you had fertility treatment, or had IVF for any other reason since 1980?		☐	☐	
15	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?		☐	☐	
16	In the last 7 days have you taken any aspirin, painkillers, anti-inflammatories, or taken any other medicines or tablets that you have bought yourself?		☐	☐	
17	In the last 2 weeks have you had any illness, infection or fever, or do you think you have one now?		☐	☐	
18	In the last 4 weeks have you been in contact with anyone with an infectious disease?		☐	☐	
19	In the last 8 weeks have you had any immunisations, vaccinations or jabs (including smallpox)?		☐	☐	
20	In the last 8 weeks have you been in contact with anyone who has had a smallpox vaccination?		☐	☐	



	In the last 3 months have you...	DT CODE	Yes	No	Staff
21	...had sex with anyone who has had syphilis, gonorrhoea, hepatitis, or anyone who is HIV positive?		☐	☐	
22	...been given money or drugs for sex?		☐	☐	
23	...had sex with anyone who has ever been given money or drugs for sex?		☐	☐	
24	...had sex with anyone who has ever injected drugs?		☐	☐	
25	...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?		☐	☐	
26	...used drugs during sex (excluding erectile dysfunction drugs or cannabis)?		☐	☐	
27a	...had sex with a new partner, or had sex with more than one partner?		☐	☐	
27b	If 'Yes' did you have anal sex?		☐	☐	

Monitoring the initial impact

Widespread media coverage – ‘landmark day’

LGBT+ community featured on national and local news

Strong international interest – Spain’s media also extensively covered Xavier and Oscar’s story

4,596 registrations on implementation day – 3,000 more than the week before

Positive feedback from staff on internal/external comms and social media



NHS
Blood and Transplant

Now more people than ever can save lives

Save a life
Give blood

Blood donation rules have now changed

For more information please visit:
blood.co.uk/fair or scan the QR code



Stonewall

NATIONAL AIDS TRUST

FREEDOM TO DONATE

TERRENCE HIGGINS TRUST

NHS

Landmark change for Black African heritage donors

Save a life
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Blood donation rules are now more inclusive

Find out more at blood.co.uk/fair or scan the QR code below



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Saving lives through bone marrow blood & organ donation

ONE VOICE NETWORK

SICKLE CELL SOCIETY

TERRENCE HIGGINS TRUST

FAIR II: higher risk partner from HIV endemic area

- New FAIR steering group set up met Feb/Mar 2021.
- In the last 3 months/since your last donation have you.....had sex with anyone who may ever have had sex in parts of the world where AIDS/HIV is very common (this includes most countries in Africa)?
- Data in Black African heterosexuals used as a proxy for the partner risk: low number estimated undiagnosed (900-1600).
- In donors, current question thought ineffective, low HIV residual risk, few HIV cases due to HRP SSA.
- Complete removal of question with FAIR deferrals in place.

Jessica Elgot
Chief political
respondent
jessicaelgot
1 Oct 2021 06:00

'Discriminatory' questions on sexual activity in sub-Saharan Africa to be removed for donations in England



Current donation rules mean many black African donors and their partners have been unable to donate blood. Photograph: NHS Blood and Transplant/PA

Ministers will remove questions on sexual activity in sub-Saharan Africa for



as around blood donation are being overhauled (stock photo) Image: Getty Images/iStockphoto

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England to remove 'discriminatory' hurdle for blood donors

Question about sexual activity in sub-Saharan Africa to be removed from donation form.



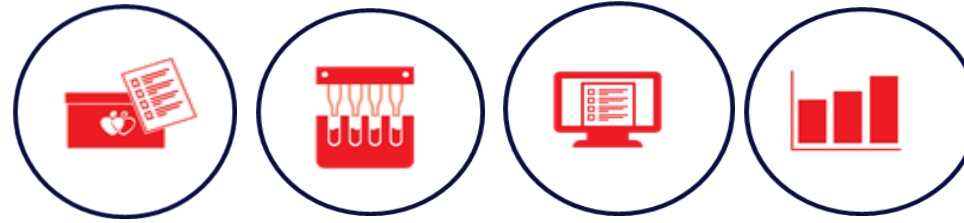
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Post implementation monitoring

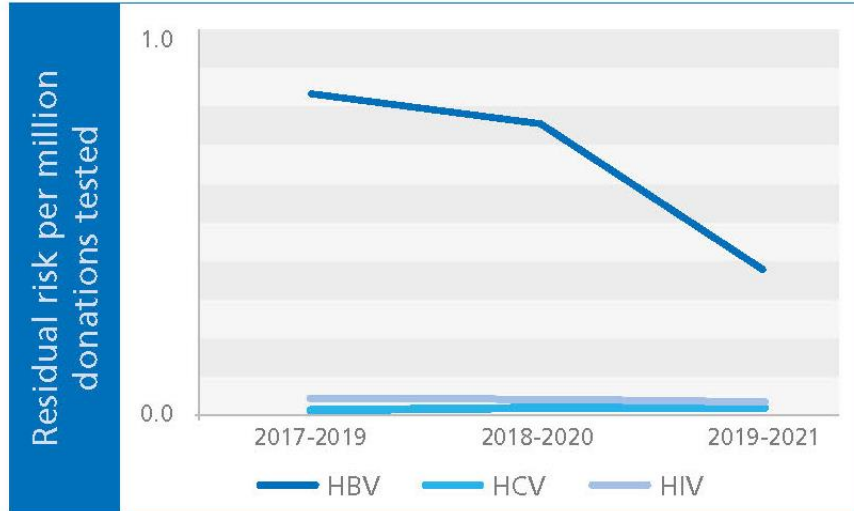


Monitoring



- Clinical/microbiology team regular review
 - *> 1 acute or recently acquired viral infection and/or > 2 recently acquired syphilis infection each month would warrant further review including risk factors and compliance*
- Enhanced NHSBT surveillance
- UK surveillance to estimate incidence, prevalence and residual risk
- On session survey of who is attending and views on FAIR
- 12 month review to UK Blood Services and SaBTO

Viral safety of the supply is maintained



Residual risk is the chance a very recently acquired infection may not be picked up on screening and enters the supply

The latest UK estimates for 2019 to 2021 include 6 months post-FAIR are lower than the previous estimates for 2018 to 2020 and 2017 to 2019 suggesting no impact on viral safety

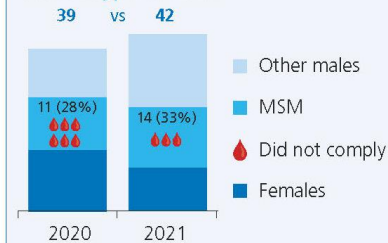
In 2021 there were no viral transmissions reported to SHOT

2021 Annual review

- **Viral safety maintained** – chance of not detecting a window period HBV, HCV or HIV remained < 1 in 1 million donations.
- 3 recent infections 2021
- No reported viral transmissions in 2021

Recent syphilis remains low; good compliance with partner rule

Recent syphilis cases



No evidence of increase in higher risk sexual activities

8 MSM with recent syphilis were newly eligible to donate due to FAIR

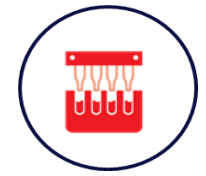
Transfusion transmitted syphilis has not been identified in the UK setting since surveillance began

33%

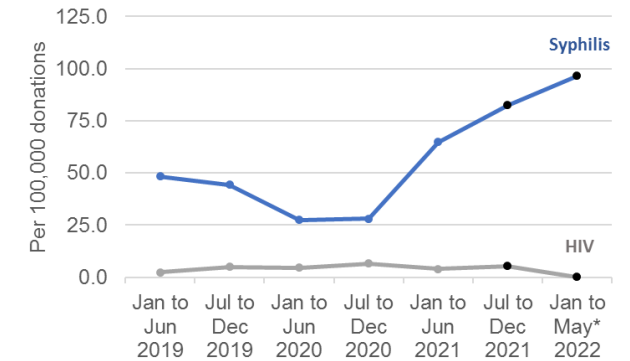
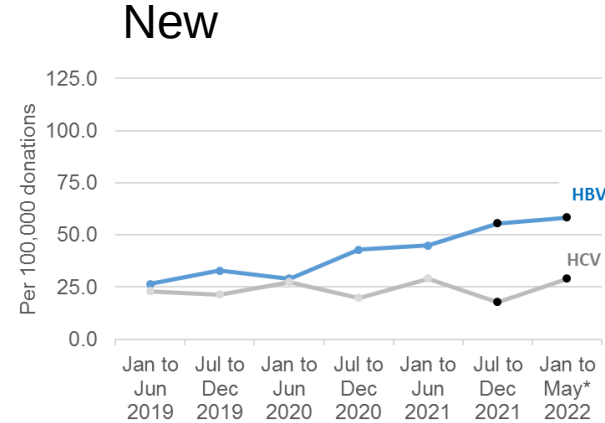
of donors with past syphilis were treated and were not eligible to donate

Post implementation monitoring, UK

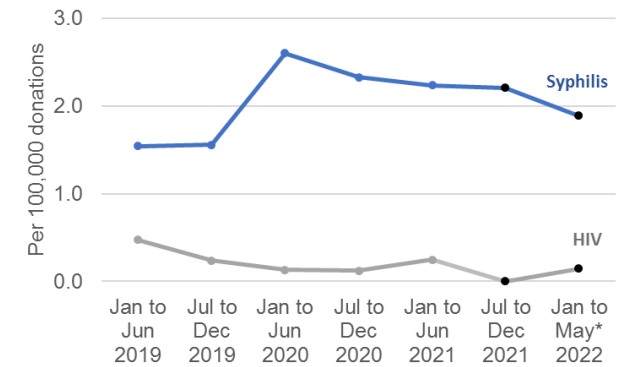
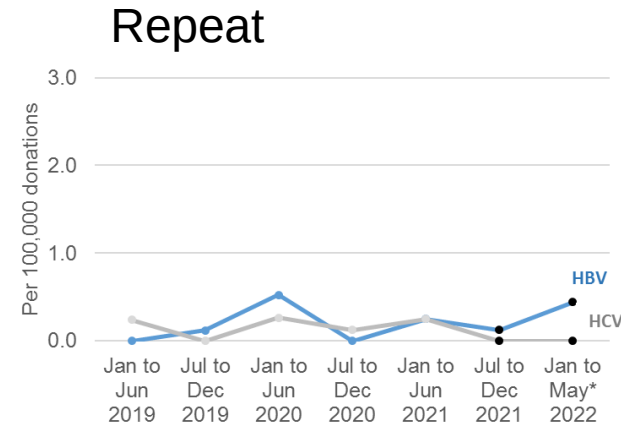
Routine surveillance - donations testing and clinical monitoring



- **New donors** - HBV and syphilis at increased level began before FAIR; chronic HBV, past treated syphilis. HCV and HIV lower and more stable.



- **Repeat donors** – rates HBV, HCV and HIV low and stable. Very few recent viral infections post-FAIR. Proportion of recent syphilis in MSM unchanged.



Monitoring acceptability and compliance



University of Nottingham - Behavioural Evaluation

- 3 studies – surveys and focus groups of donors, non-donors, MSM, recipients, and staff.
- Increased numbers of MSM, positive interactions in centres, no significant operational issues, well received.
- Some safety concerns expressed by recipients, public awareness low, the needs of polyamorous groups not addressed.



Future work – NHSBT/UKHSA Epidemiology Unit

- Large scale compliance survey.
- An assessment of on-session deferrals (pre-donation questionnaire).

Additional virological safety monitoring

A. Other viruses? Prevalence study in progress.

B. Increase in HIV pre-exposure prophylaxis (PrEP) use? Sub-optimal adherence can lead to HIV viral suppression/delayed seroconversion.

The extent of undeclared PrEP use in blood donors (*Heli Harvala and colleagues*).

Donors using PrEP asked to defer for 3 months.

Sample of donations from positive male donors pre and post FAIR (n=350).

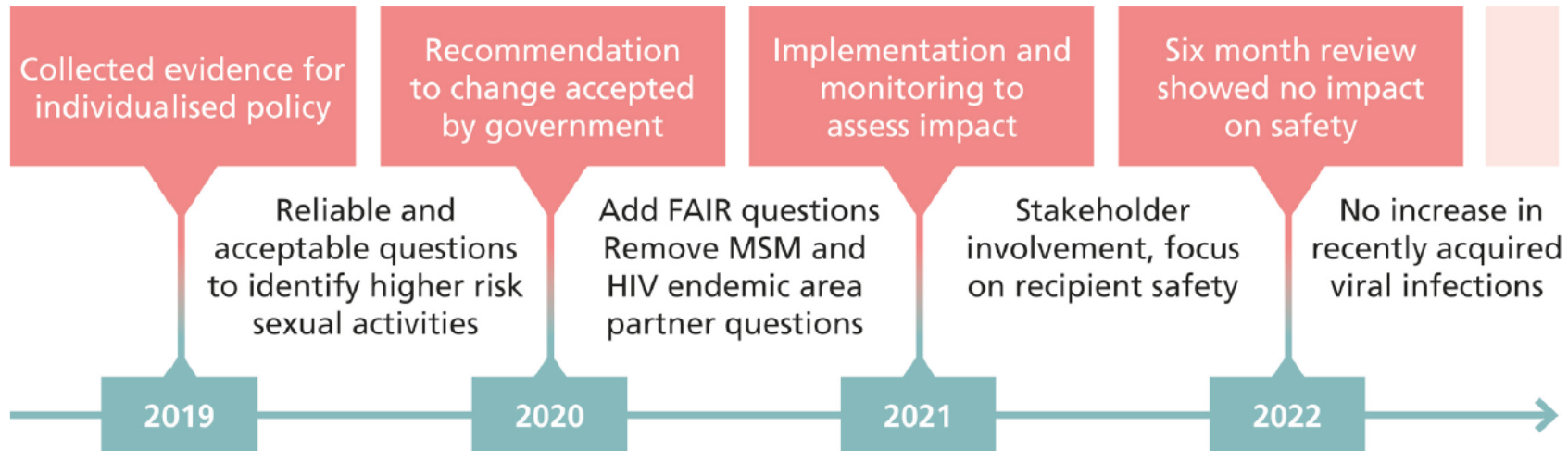
Anonymous testing for evidence of PrEP

Recent PrEP use ~5%, no evidence of increase post FAIR. Higher in MSM (7.8%), donors who have not declared their risk (12.5%) or participated to the post-donation discussion (20%) and low in heterosexuals (1.3%).

Non-compliance appears unchanged.

Summary

Working collaboratively towards the FAIR policy for blood donation



Summary

- Using an evidence based approach, FAIR was able to recommend a more individualised risk based donor selection policy to SaBTO
- For the first time, psychosocial research provided key evidence to inform the new policy
- Implementation has included an emphasis on recipient safety, clearer messaging around the rationale, and has encouraged donors to think about their recent sexual activities before donating
- Impact is being closely monitored and may inform future policy reviews
- Stakeholder engagement has been key throughout
- Evidence of wider impact beyond donor selection – FAIR is a more inclusive approach to donation

<https://www.blood.co.uk/news-and-campaigns/news-and-statements/fair-steering-group/>