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NHS Blood and Transplant

The FAIR approach to UK donor selection policy

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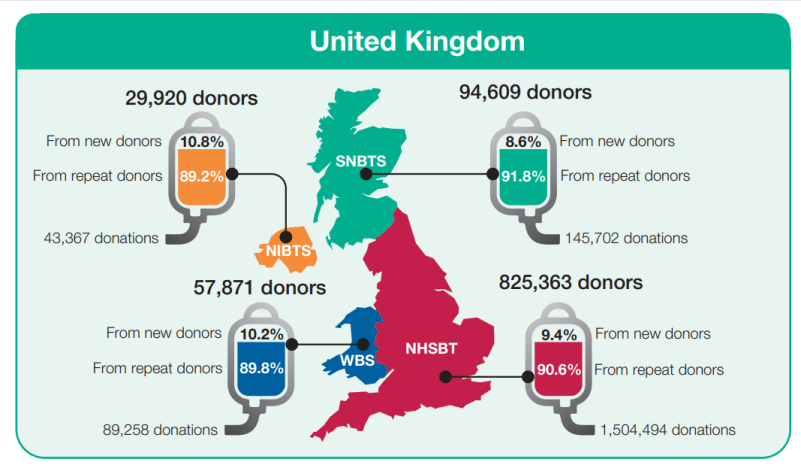
Background

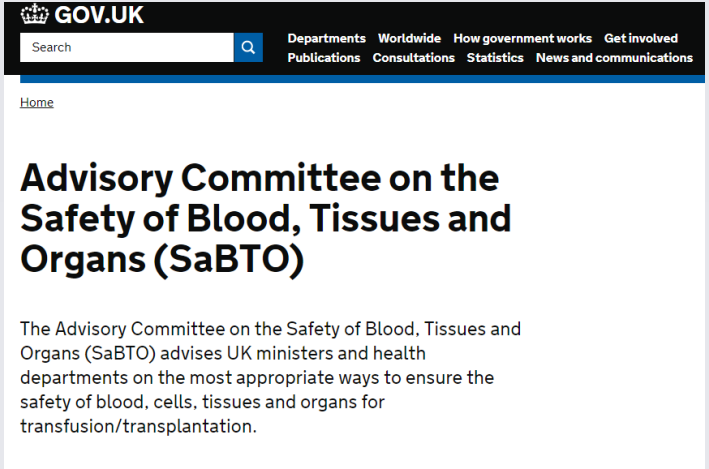
Health devolved to the four countries of the UK



Source: NHSBT/PHE Epidemiology Unit

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

https://www.transfusionguidelines.org/



Informing Policy: SaBTO approach

Implementation in England, Scotland and Wales November 2017 (NI 2020)

- MSM-change from 12 months to 3 months since last sex
- Commercial sex workers- change from permanent to 3 months
- Higher risk sexual partners-change from 12 months to 3 months

Request for more work on an individualised risk assessment

Blood, tissue and cell donor selection criteria report: 2017
www.gov.uk/government/publications/blood-tissue-and-cell-donor-selection-criteria-report-2017

Request for work

- Department of Health and Social Care continued to ask for work to be done
- Review impact of 2017 changes
- Initial discussions about epidemiological/psychosocial approach
- Money awarded by UK blood services to fund a research assistant

For the Assessment of Individualised Risk (FAIR)

FAIR (For the Assessment of Individualised Risk)

Aims:
-Explore if an assessment of individualised risk is possible
-If it is, explore what such an assessment would look like
-Maintain a safe blood supply

Challenges an assessment of individualised risk poses:

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

FAIR approach

- Steering group: UK blood service, University of Nottingham, charities and lobby groups. donor and patients
- Different approach to previous reviews of donor selection criteria
- Time based deferrals v different approach
- All donors not just MSM
- More focus on behavioural approach and donor understanding

FAIR Methods

February 2019

March 2020

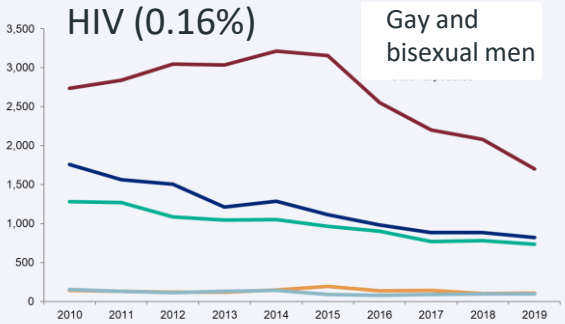
October 2020
Final report

Steering group

Epidemiology	Behaviour	Psychosocial
Blood borne infections • general population • blood donors	• Literature reviews • Survey of behaviours in donors	• Surveys of non-donors/donors: individual behaviours • Survey of donors: normative behaviour • Test-retest study • Focus groups/interviews

Epidemiology - viruses

General population



HBV (<2%)

- Unprotected sex with multiple partners

HCV (0.21%)

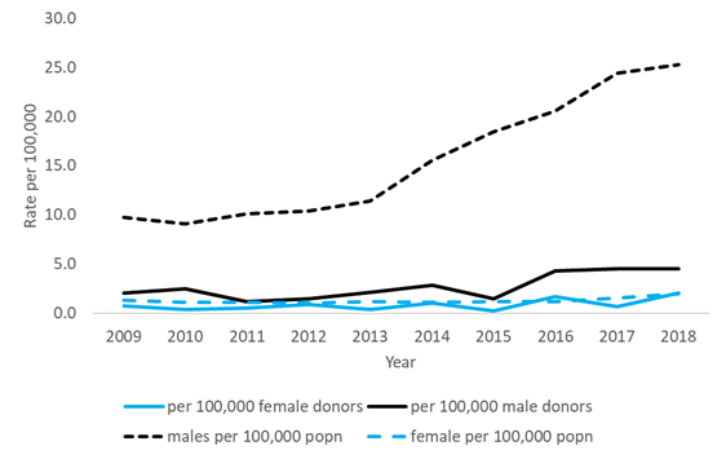
- People who inject drugs

Blood donors

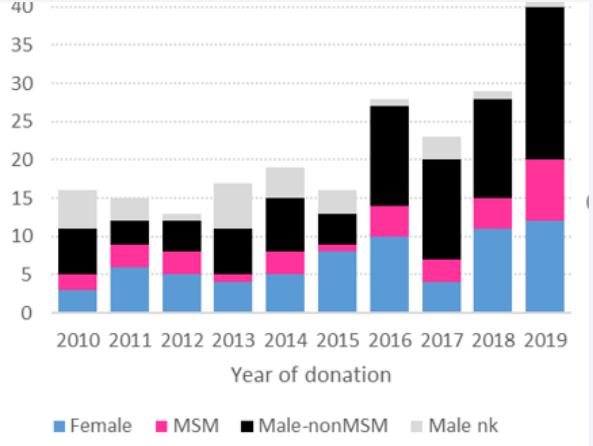
- Decreasing trend HBV, HCV HIV and HTLV
- 2019 - 5.7 per 100,000 donations
- Last 10 years, UK residual risk highest HBV at around 0.7 per million donations

Epidemiology - syphilis

General population and donors



Recent infections in donors



Increased risk sexual behaviours

Literature review (17 key studies)
Association between behaviour and HIV/STI acquisition

Strength of evidence	Behaviour
High	Chemsex
	Bacterial STI
Medium	Number of sexual partners
	Less frequent condom use
	Type of sex (specifically receptive anal sex)
Low/none	Clinic attendance
	New sexual partner
	Exclusivity

Donor survey (BEST)
Extent of behaviours in current donor population

1,311 responses (19%)

<5% reported increased risk behaviours

Low rates of deferrals expected

Psychosocial surveys

- **UK university staff/students 2019-2020**
- Individual's response
- N=732 (500 donors)

Test – retest 2020 (N=31)

UK donors 2020
Responses of others
N=12,873 (16%)

11 sexual behaviours: accuracy, appropriateness, intention to donate

Psychometric analysis

4 sexual behaviours statistically clustered: *STI diagnosis, Chemsex, new and number of partners*

- Reliably reported, associated with self-reported higher risk of infection and impression management bias
- Low and acceptable risk to patient safety
- Perceived accuracy of recall was reported as high

Focus groups and interviews with key stakeholders

MSM
5 focus groups
11 interviews

Donors
1 focus group
6 interviews

Staff
2 focus groups

Recipients
4 interviews

Thoughts about blood donation. Donor behaviour. Donor health check. Ways to encourage donation.

Qualitative analysis
Issues relating to accuracy, appropriateness, potential to deter and benefits triangulated with the psychometric findings

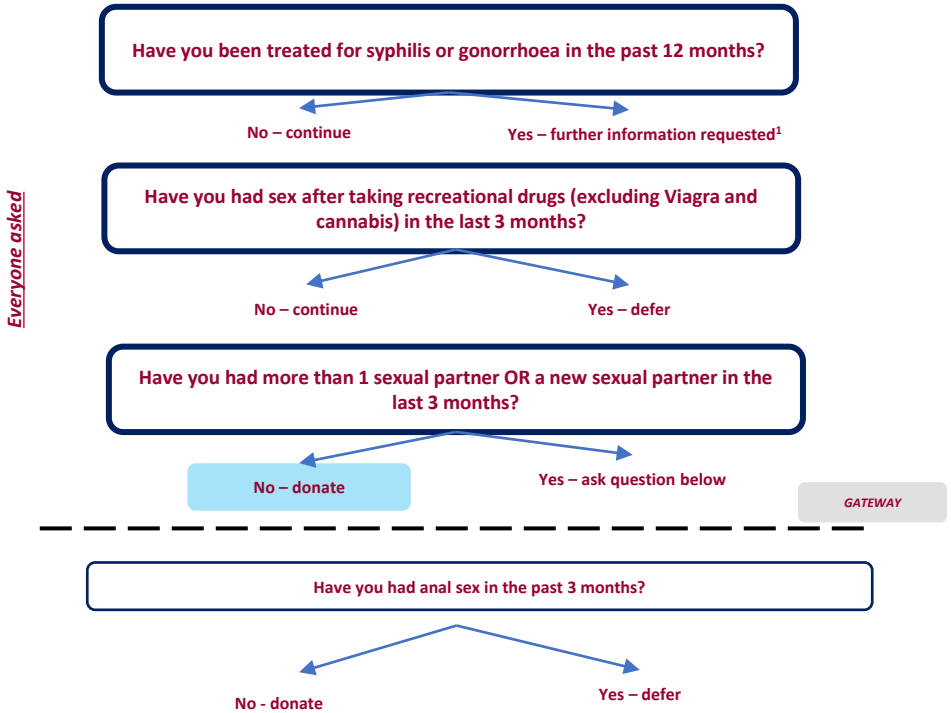
- Accuracy – safety for patient/communicate risk
- Deterrent – anal sex
- Benefit – more equitable and inclusive (attracting new donors)

Patient views

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

Steering group recommendations

Proposed changes



[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

Other Considerations

Potential impact on current donors
- estimated impact on donor loss

PrEP/PEP deferral remains in place
- Awaiting national review on impact of PrEP on testing

Importance of pre-donation information and marketing
- ‘prepare to donate’

- Evaluation and review

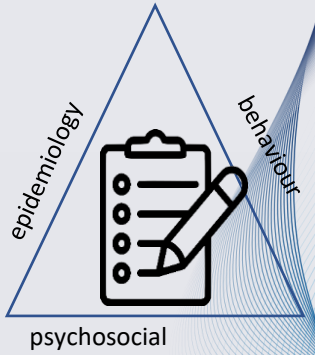
Recommendations

- SaBTO made recommendations to ministers to approve
- Recommended post-implementation monitoring
- Noted the importance of staff training and donor engagement
- Committed to assess impact at 12 months

- **December 14th announcement made by government**
- **Working towards implementation in June 2021**

Summary

- Epidemiology revealed low levels of blood borne infections in general and donor populations
- Behaviours associated with specific behaviours were used to formulate a policy to identify increased risk individuals
- Psychological analysis found cohesion of questions regarding epidemiological high risk behaviours and the acceptability, reliability and accuracy of responses
- SaBTO recommendation that the FAIR approach should be implemented, go live expected June 2021



Acknowledgments

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