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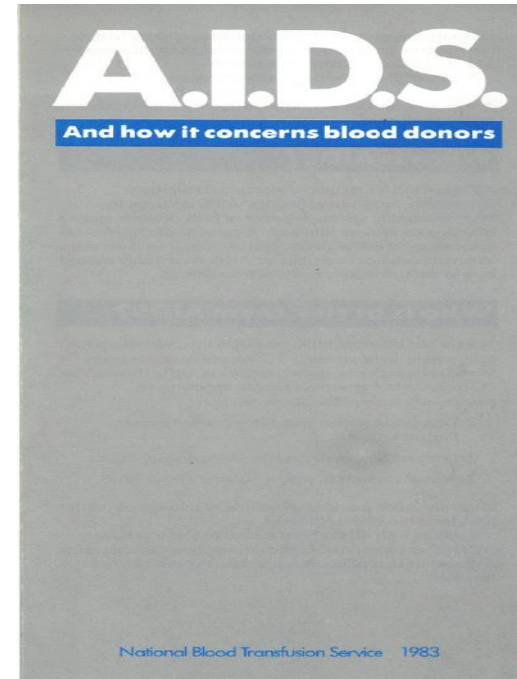
SaBTO, Sex and Safety-changes to the UK donor selection criteria

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NHS Blood and Transplant, UK

Overview

- Background to donor selection policy in the UK
- What happened since 2011
- Context for the review
- Knowns and unknowns
- Recommendations
- Implementation



Declaration of interests:

Member of DH advisory committee on safety of blood, tissues and organs (SaBTO).

These slides represent the views of the author

How are donor selection criteria made in the UK?

- Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
- Joint Professional Advisory Committee (JPAC)
 - <https://www.transfusionguidelines.org/>
- Four devolved administrations of England, Wales, Scotland and Northern Ireland

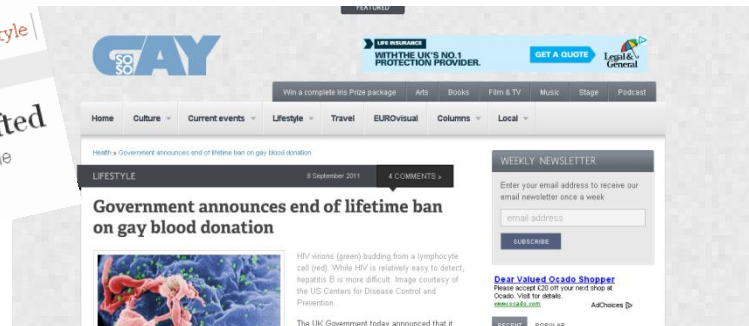
SaBTO, sex, blood safety and EU directive

Permanent deferrals

‘...of persons whose sexual behaviours puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood’

Temporary deferrals

‘persons whose behaviours or activity places them at risk of acquiring an infectious disease that may be transmitted by blood. Defer after cessation of risk behaviour for a period determined by the disease in question and the availability of appropriate tests’



2011 onwards

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



Donor Selection Criteria Review 2010



*Little NAT testing data for HBV
Only HCV NAT is mandatory*



CSW 

Over 12 months

**Compliance is key
to blood safety**

- 2011: change from permanent to 12 month deferral for men who have sex with men (MSM) and some other sexual deferrals
- Permanent deferral for commercial sex workers
- 2013: review of donor selection related to sexual behaviours for tissues and cells

Recommendations:

Evaluate impact of the change

Need for better understanding of donor compliance i.e. donor understands the rule and applies it correctly

Regular review

Evaluation and further work



UK infected donor surveillance

Pre AND post change – ongoing monitoring of infected new and repeat donors, all microbiological and clinical data:

- Recently acquired infections
- Source of infection
- Compliance
 - Reasons for non-compliance



UK Blood Donor survey

Post change - over 12 month, all eligible new and sample of repeat donors were invited via email to participate in anonymous online survey:

- Recent sexual behaviour
- Compliance
 - Reasons for non-compliance



Blood and Transplant

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SIGN OUR PETITION

Our belief is simple; those who wish to be able to donate blood, and can do so safely, should be able to donate blood.

Under current guidelines, there are a number of restrictions around who is able to donate blood. This includes a 12 month deferral criterion on those classed as MSM (Men who have sex with Men) and a complete blanket ban on anyone who has ever had sex for money or drugs or ever injected drugs. Scientific advances and new evidence means that such restrictions should be reconsidered in light of the urgent need to maintain our supply of blood. Excluding people who may be able to donate threatens a sufficient supply of blood, something 1 in 4 of us will rely on at some point in our life.

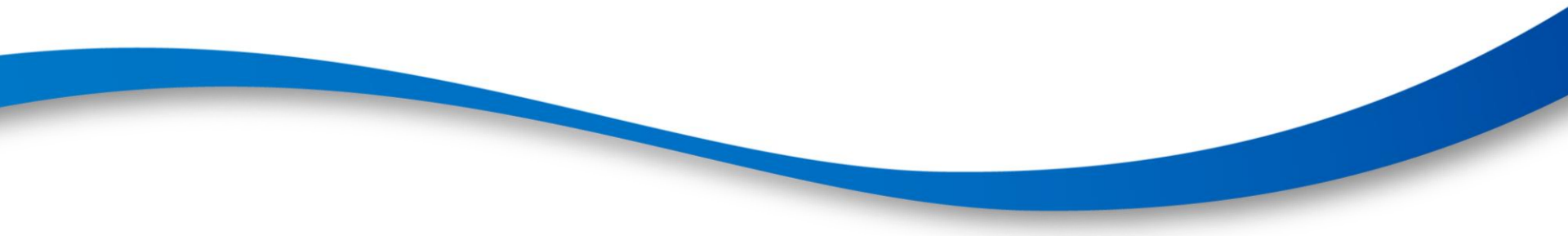
[SIGN OUR PETITION](#)

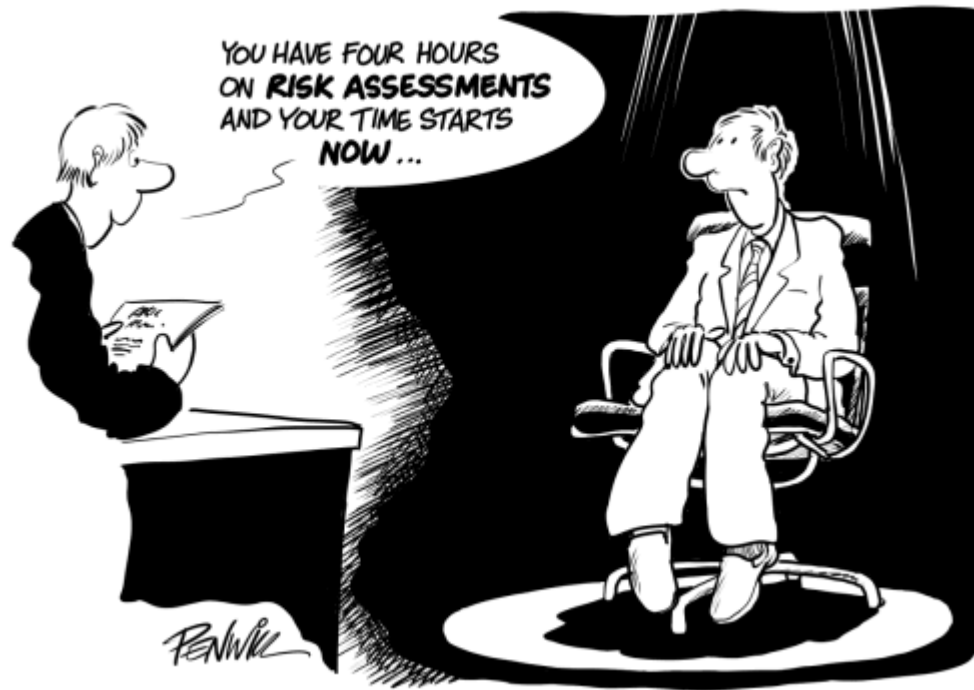
What happened in 2016?

- 5 years since last review
- Lobbying
 - Freedom to donate and others
 - Acupuncture
- Request from PH minister
- SaBTO set up donor selection working group
- Initial meeting early 2016, open meeting
- ‘Let’s talk blood donation’



Remit

- Behaviours associated with increased risk of acquiring infectious diseases: sex, drugs, piercing
 - Blood, tissue and cell donors
 - Stakeholders and terms of reference: LGBT groups, patient groups
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Review of data

- Epidemiology of blood borne infections in donors and general population
- Source of infections
- Testing and window periods
- Current levels of compliance
- International considerations

[Overview of the RBDM framework and Stage 1 - Preparation](#)

[Stage 2 - Problem Formulation \(Part 1\)](#)

[Stage 2 - Problem Formulation \(Part 2\)](#)

[Stage 3 - Participation Strategy](#)

[Stage 4 - Assessments](#)

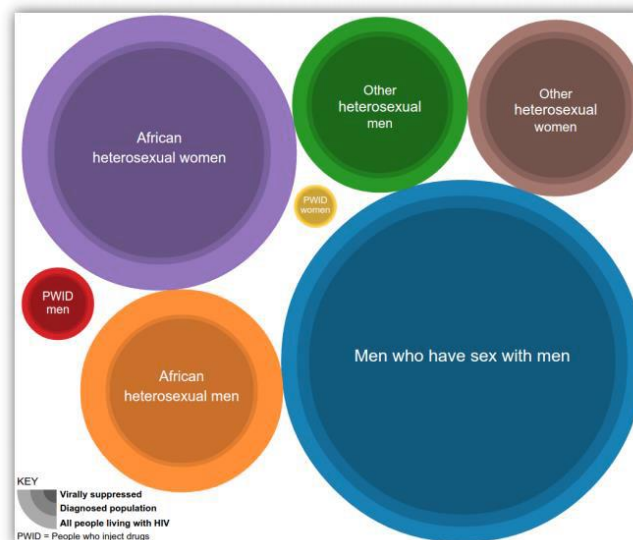
[Stages 5 and 6 - Evaluation and Decision](#)



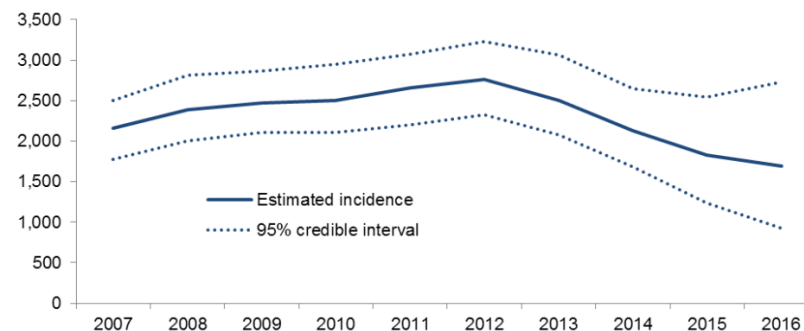
- ‘Tolerable’ residual risk of <1/million donations

1990-2012

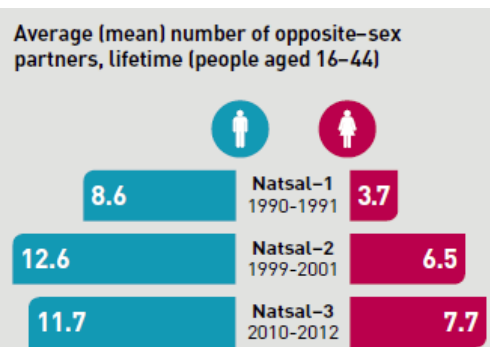
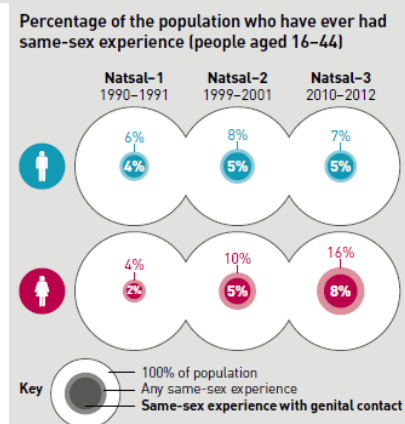
- Increase in lifetime number of partners
- Increase in same-sex sex
- Increase in HIV diagnosis & sexual health clinic attendance



Estimates of HIV incidence in gay and bisexual men: England, 2007 to 2016



<https://www.gov.uk/government/collections/hiv-surveillance-data-and-management>



<http://www.natsal.ac.uk/home.aspx>

Blood donors UK, 2016

Mainly repeat

Mainly from new

42 million

UK adult population
Aged 17-66 years old



Donor selection

- used to screen out people who may harm themselves or the blood supply if they donate
- leads to a low rate of infection in donors

2 million

blood & platelet donations



All screened for HBV, HCV, HIV, HTLV and syphilis

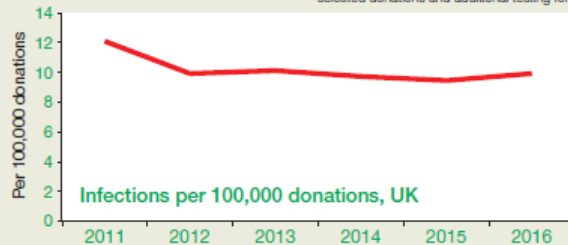
200 infections detected*



(mainly chronic) and removed from the blood supply to ensure safety

*Data presented here excludes HEV testing on selected donations and additional testing for travel

9 of 10 past/chronic endemic country
past sexual contact
past injecting



Recent viral infections, acquired in the 12 months prior to donation, are rare

5 recent viral infections detected

2 HIV, **4** Males
3 HBV, **1** Female

33 Median age

3 repeat donors
2 new donors

3 acquired through sex between men and women

1 sex between men
1 unknown source

3 compliant with donor selection criteria

2 unknown/incomplete information

Rate of HBV, HCV, HIV, HTLV and syphilis UK per 100,000 donations

	Donations tested			HBV			HCV			HIV			HTLV			Syphilis ¹		
	New ²	Repeat ²	All	New ²	Repeat ²	All	New ²	Repeat ²	All	New ²	Repeat ²	All	New ²	Repeat ²	All	New ²	Repeat ²	All
Total UK Rate ³	182,582	1,825,026	2,007,608	68	3	71	37	1	38	6	5	11	8	0	8	46	26	72
				37.2	0.2	3.5	20.3	0.1	1.9	3.3	0.3	0.5	4.4	0.0	0.4	25.2	1.4	3.6

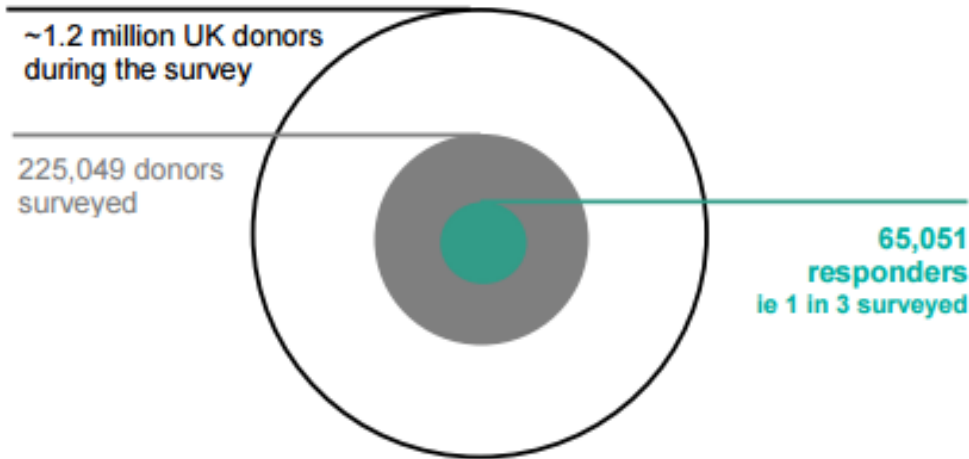
Estimated *residual risk* 2013-2015 UK

Virus	Window period (days)	RR (95% CI) per million	Time to detection (years)*
HBV	30	0.79 (0.22-1.30)	1 per 0.6 yrs
HCV	4	0.025 (0.02-0.04)	1 every 19.3 years
HIV	9	0.18 (0.06-0.10)	1 every 2.7 years

* Assume 2.2 million donations per year in UK

NAT in pool of 24 since 2009

UK Blood Donor Survey



Personal & sensitive information on 65,000 donors

A broad range of donors

Compliance with the DSG of interest exceeded 99.3%

Deferral

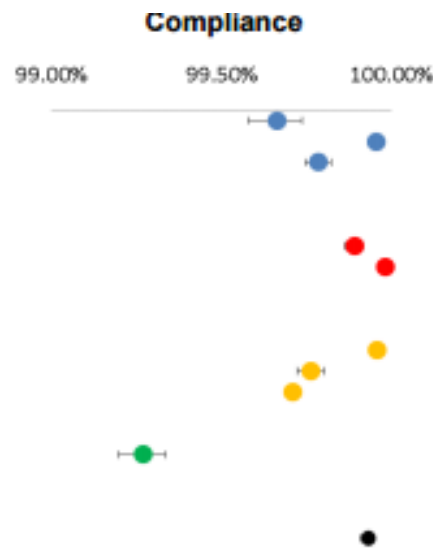
Paid for sex
Sex between men
Sex with a high risk partner

Injecting drug use
Intranasal drug use

Travel < 12 months
Travel < 2 months
Long stay

Piercing

Hepatitis/jaundice



TRANSFUSION MEDICINE
Official Journal of the British Blood Transfusion Society



ORIGINAL ARTICLE

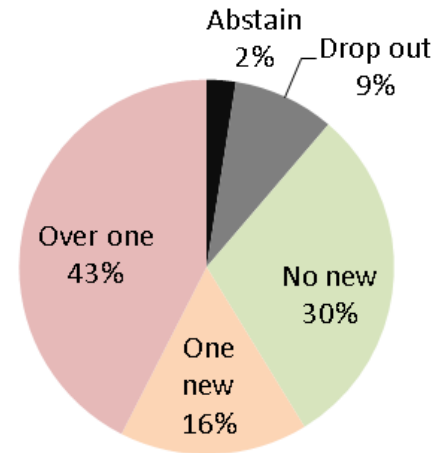
Getting personal with blood donors – the rationale for, methodology of and an overview of participants in the UK blood donor survey

K. L. Davison ✉, C. A. Reynolds, N. Andrews, S. R. Brailsford,
on Behalf of the UK Blood Donor Survey Steering Group

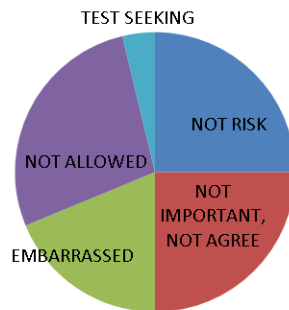
First published: 03 September 2015 | <https://doi.org/10.1111/tme.12236> | Cited by: 4

Non-compliant MSM: partners and reasons

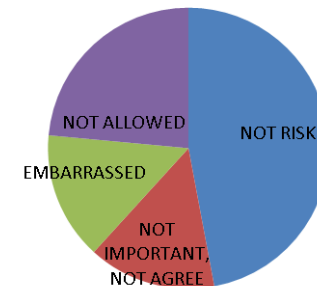
Non-compliant MSM, new partners 12 months n=76



Reasons: 1 or more new partner



Reasons: No new partner



Motivations, ethics and safety

- Altruistic motivations
 - Similar in compliant and non-compliant
 - ‘Justify’ the need to donate as it is so important
 - Very small numbers test-seeking
 - Fairness
 - Equity
 - Engendering and maintaining trust
 - voice in the process
 - transparent and evidence-based
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Individualised risk assessment

- Experience in other countries
- Specific sexual behaviours
- Specific subgroups
 - Number of partners
 - Multiple partners
 - Condoms and other protectives



Insufficient evidence for individualised risk assessment
Review risks associated with 3 month deferral

Estimating residual risk

- Residual risk calculated from
 - Number of donations from non-compliant donors
 - Incidence in this population
- High level of uncertainty best case and worst case

Estimates of residual risk for HIV under new selection criteria

Current	Current Risk	MSM	High Risk Partner MSM	High Risk Partner CSW
Additional not detected	-	0-0.16	0-0.06	0-0.09
Total not detected	0.18	0.18-0.35	0.18-0.24	0.18-0.27
Years until not detected	2.5	1.3-2.5	1.9-2.5	1.7-2.5

Per million donations screened

SaBTO

Advisory Committee on the
Safety of Blood, Tissues and Organs



Donor Selection Criteria Review 2016

What is minimum safe period that tests would be expected to detect infection?

Rate of infections in donors / Ethics / Legal /

Modelling new rates / International practice



NO DEFERRAL
if UK based practitioner
Subject to law

CSW ✓

Over
3 months



Over
12 months
Subject to law

 the patients association



Shaping attitudes.
Challenging injustice.
Changing lives.



**Work towards individualised
risk assessment**

SaBTO

Advisory Committee on the
Safety of Blood, Tissues and Organs

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

Donor Selection Criteria Report (2017)

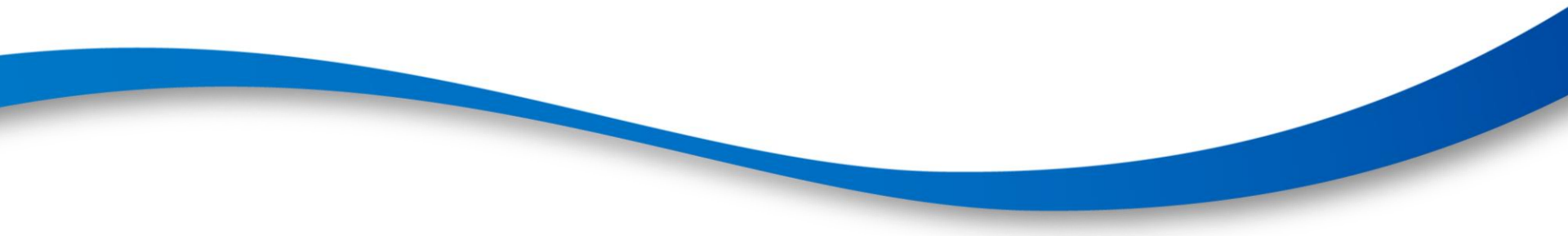
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/635174/SaBTO_donor_selection_criteria_report.pdf

Accepted by government

- **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**
 - **Past drug use**
 - **Blood borne infection**
 - **Sex in areas where high rates of HIV**

Four month deferral for piercings, tattoos, endoscopy

Permanent deferral for people who have used drugs ever

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Implementation and review

- Launch by Equalities Minister July 2018
- Implementation in England, Scotland and Wales November 2018
- Request for more work on an individualised risk assessment
 - Lower risk behaviours
 - Lower risk groups
 - Qualitative work
 - Operational considerations



Summary

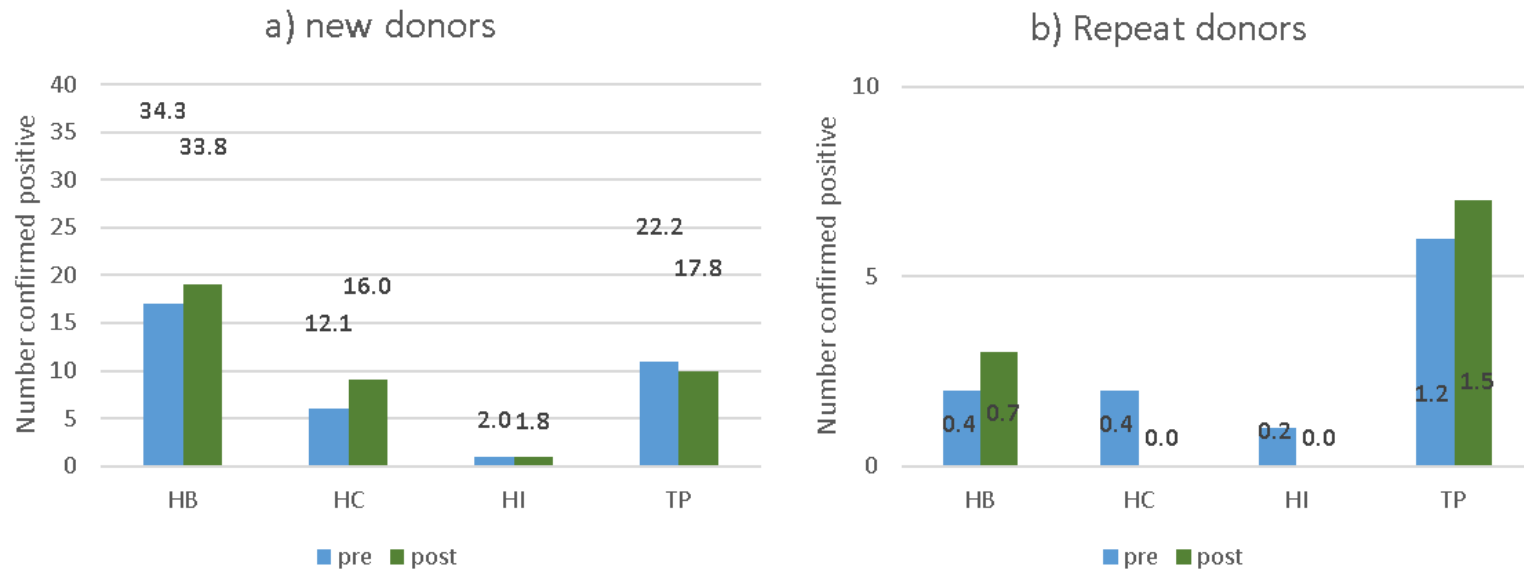
- Review of donor selection guidelines resulted in recommendations to change to 3 month deferral since exposure
 - ABO risk decision making framework used in reviewing and agree tolerable risk
 - Changes were received well by most
 - Request for further work and further changes
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Acknowledgements

- Past and present members of the joint NHSBT/PHE Epidemiology Unit
- Donor Survey Steering Group
- SaBTO working group
 - Eamonn Ferguson
 - Chas Newstead



Comparison of number and rate all donors: NHSBT pre and post change to donor selection



Pre=Dec16-Mar17

Post=Dec17-Mar18

Rate given above number bar as per 100,000 donations