NHS Blood and Transplant

NHSBT BOARD

Clinical Governance Report

28th November 2019

1. Status – Official

2. Executive Summary

There are two new Serious Incidents (SIs) within this reporting period**.**

- Serious Incident ODT INC 4278 – New Kidney and Pancreas Allocation Scheme. ODT's new planned Kidney and Pancreas (KP) allocation scheme which went live on the 11th September 2019. Seven days later concerns were raised by a liver Transplant Centre, in relation to the Liver Matching Run (LMR), which related to unexplained recipient exclusions from the LMR. Details of how many patients may have been affected are still being worked through.
- Serious Incident Filton Eye Bank QI15283, this incident involved problems with pre-cut Corneal Tissue. A surgeon reported that a cornea was thicker than it should have been. The surgeon undertook further manipulation of the graft themselves prior to transplantation but recipient experienced primary graft failure. Following investigation, a higher number of recipients than expected have also experienced graft failure during the time that the machine has been in use. The machine is no longer in use and the process suspended whilst investigations are ongoing.
- NHSBT has been engaged with the Care Quality Commission (CQC), for a number of years, regarding the services NHSBT provides and how this is best reflected in NHSBT's scope of registration with the CQC. Clarity on this has now been received. CQC have notified us that we will be subject to a Well Led CQC inspection in 2019/20
- The joint NHSBT/PHE team Epidemiology Report is the focus item below

3. Action Requested

The Board is asked to note the contents of the paper and discuss where relevant.

4. Overview of events in this reporting period

4.1 Serious Incidents (SIs)

There are two new SIs to report

ODT INC 4278: On the 11th September 2019 the new planned Kidney and Pancreas (KP) allocation scheme went live. Testing pre-implementation did not identify any issues or concerns with the release of the new scheme. However, on 18th September 2019 concerns were noted by a liver transplant centre with the Liver Matching Run (LMR). Immediate investigation took place and it was identified that there had been a piece of code in development for a future liver release, which had been introduced into the live environment inadvertently, without any testing (as it was not planned for release). The Route Cause Analysis (RCA) is now completed

and actions progressing to prevent recurrence. Three patients may have been impacted by this incident. The information has been given to the affected transplant centres and we are waiting their response.

Filton Eye Bank QI 15283**:** Historically individual surgeons cut corneal tissue using equipment in the hospital prior to specific ocular operations where this is required. NHSBT initially set up a service for pre-cutting corneas from Manchester Eye Bank but transferred this to the Filton Eye Bank in July 2019.

A surgeon reported that a cornea was thicker than it should have been, undertook further manipulation of the graft themselves but the recipient experienced primary graft failure. On investigation it was observed that the post cut thickness was greater than expected with NHSBT's equipment.

We have been informed of a total of 8 cases of primary graft failure, 4 patients with reduced visual acuity and 7 patients who have required additional interventions to reattach the graft.

These are expected complications of corneal transplantation and can occur despite optimal thickness. They are however more likely to occur if the tissue is too thick. The machine has been serviced by the manufacturer, has improved but is still performing sub optimally compared to the loaned machine. The service has been temporarily suspended and is being re-provisioned using alternative tissue with pre-cutting in theatre by the surgeon if required or utilising a pre-cutting service from another eye bank.

5. Care Quality Commission (CQC)

NHSBT, as a provider of health care services, is required to be registered with the CQC for the regulated activities it provides. This is a requirement of the Health and Social Care Act 2008. NHSBT has always been registered for three regulated activities:

- Diagnostics and screening procedures
- Treatment of disease, disorder or injury
- Management of supply of blood and blood-derived products

Following ongoing communication with the CQC regarding the scope of NHSBT's registration, clarification has been received and agreement about the scope of inspection agreed.

It has been confirmed that the regulated activity diagnostics and screening procedures no longer requires registration with the CQC. NHSBT's Statement of Purpose has been updated to reflect this change. This activity will continue to be regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Conversations have also taken place regarding Blood Donation (BD), activities and whether this should remain a regulated activity registered with the CQC. These talks have concluded with the CQC clearly stating the activity remains in scope and subject

to future inspections, commencing next year. The first inspections will be in Therapeutic Apheresis Services (TAS) and BD, followed by an inspection of NHSBT as an organisation. This will be a 'Well Led' CQC Inspection.

6. Risk Management Update

Clinical risk is being reviewed as part of the Strategic Risk Review being undertaken by the Risk Management Team. Clinical risks currently in the system, will be reviewed by their directorate owners and, as part of the restructure of the register, be moved to be child risks of the clinical strategic risk. The oversight of clinical risks at CARE will be through the clinical strategic risk, with detail of risk impacts coming from the reviewed child risks. Divisions and functions will have ownership of their relevant risks and will continue to review these at SMTs and divisional CARE committees.

7. Non – Clinical Issue (NCI) Report

Non-Clinical Issue (NCI) is NHSBT's managed service that enables donated materials that are unsuitable for, or surplus to, the clinical supply chain to be provided for approved non-therapeutic purposes. NCI charges approved customers for the provision of material. Actions have been undertaken which included a redesign of NCI procedures, to ensure compliance with the relevant codes of practice for the supply, use and storage of human material. NCI is operating in compliance with the Human Tissue Act 2004 (HTA) and Codes of Practice.

8. Report Focus - Safe Supplies 2018: Inform, Monitor, Progress
The Annual Review of the joint NHSBT/Public Health England Epidemiology Unit

The joint NHSBT/ Public Health England (PHE) Epidemiology team, set up in 1995, are responsible for the surveillance systems which report infections in blood, tissue, cell and organ donors across the UK and infections transmitted by blood transfusion. The unit has also run a large compliance and behaviour survey in blood donors in 2014, a travel survey in 2016 and collaborates with Nottingham University on donor behaviour and motivation, including work on BAME recruitment, and individualised donor selection policy. The unit is overseen by Dr Su Brailsford and comprises four epidemiology/public health scientists and a data manager.

Each year an annual review is published which in recent years has taken the form of infographics, data tables and graphs. Information can be found on the PHE website (https://www.gov.uk/government/publications/safe-supplies-annual-review) with links to the downloadable infographics, supplementary data and methods document on the hospitals website (https://hospital.blood.co.uk/epidemiology-reports).
Here we focus on the blood donation data:

Detailed information is available for blood donors donating in England, supplied to the joint unit by NHSBT. During 2018, 20% of donors in England were new donors providing 11% of all donations. The majority of these new donors were women (65%) and just over half aged under 35.

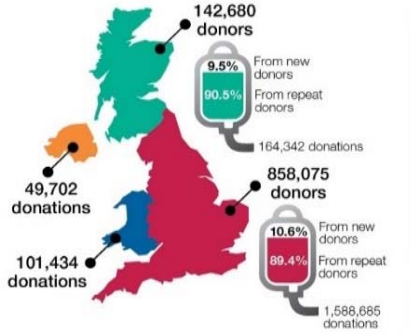
Safe supplies: Monitor, inform, progress

Joint working of NHS Blood and Transplant and Public Health England

NHS Blood and Transplant

Blood Donor Demographics 2018

- England needs **135,000** new donors per year to replace those who can no longer donate
- in 2018, **20.2%** of all donors in England were new donors (an increase from **17.3%** in 2017)



Donors must be:

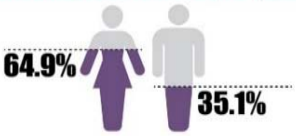
Between **17** and **66** years old

Over **70** and have given blood in the last two years

1 in 46 people aged **17-65** in England - donate

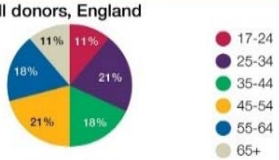
1 in 42 people aged **25-34** in England - donate

Gender of new donors, England

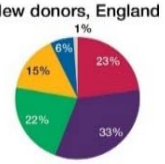


Age

All donors, England



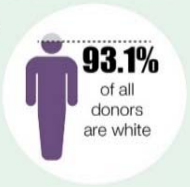
New donors, England



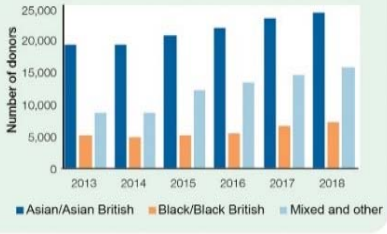
New donors are younger than repeat donors

Ethnicity of all donors, England

- more BAME (Black Asian and minority ethnic donors) donors are needed as some blood conditions that are treated with transfusions most commonly affect BAME individuals
- BAME donors are more likely to be a match for BAME recipients



Number of BAME donors by year



Data source: Data supplied to the NHSBT/PHE Epidemiology Unit by NHSBT, WBS, NIBTS & SNBTS and NHSBT Donor Insight

Safe supplies: Monitor, inform, progress

Joint working of NHS Blood and Transplant and Public Health England

NHS Blood and Transplant

Blood donors, UK 2018

- donor selection leads to a low rate of positive donations
- used to screen out people who may harm themselves or the blood supply if they donate

1.91 million donations screened

602 confirmed positive donations discarded (2017 totals)

10.6% new donors | **89.4%** repeat donors | **93.1%** white donors

Excluding HEV, most of the infections were detected in new donors

HBV (63)	HCV (39)	HIV (6)	Syphilis (54)	HTLV (17)
59	30	7	77	7

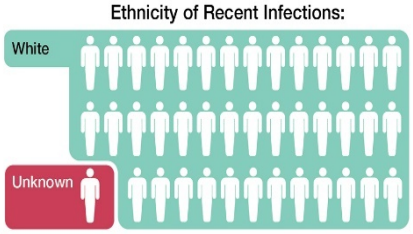
Probable Exposure	HBV	HCV	HIV	Syphilis
Sex between men and women	3		2	23
Sex between men (MSM)	1		1	4
No exposure identified	2	1		2
Blood contact possible	1			
Totals (2017 totals)	**7 (3)**	**1 (0)**	**3 (1)**	**29 (23)**

40 recent infections

Acquired within 12 months – suggests current risky behaviour

9 New | **31** Repeat

Ethnicity of Recent Infections:



Risk to the blood supply lies in recent infections

- highest rate of recent infections in 35- 45 year olds
- 6 donors did not apply donor selection correctly (non-compliant)

HEV

422

Universal screening for HEV came into effect in April 2017

- no specific donor selection for HEV ~ HEV usually clears in healthy individuals
- donors are allowed back to donate after 6 months
- rare blood types may be allowed back earlier

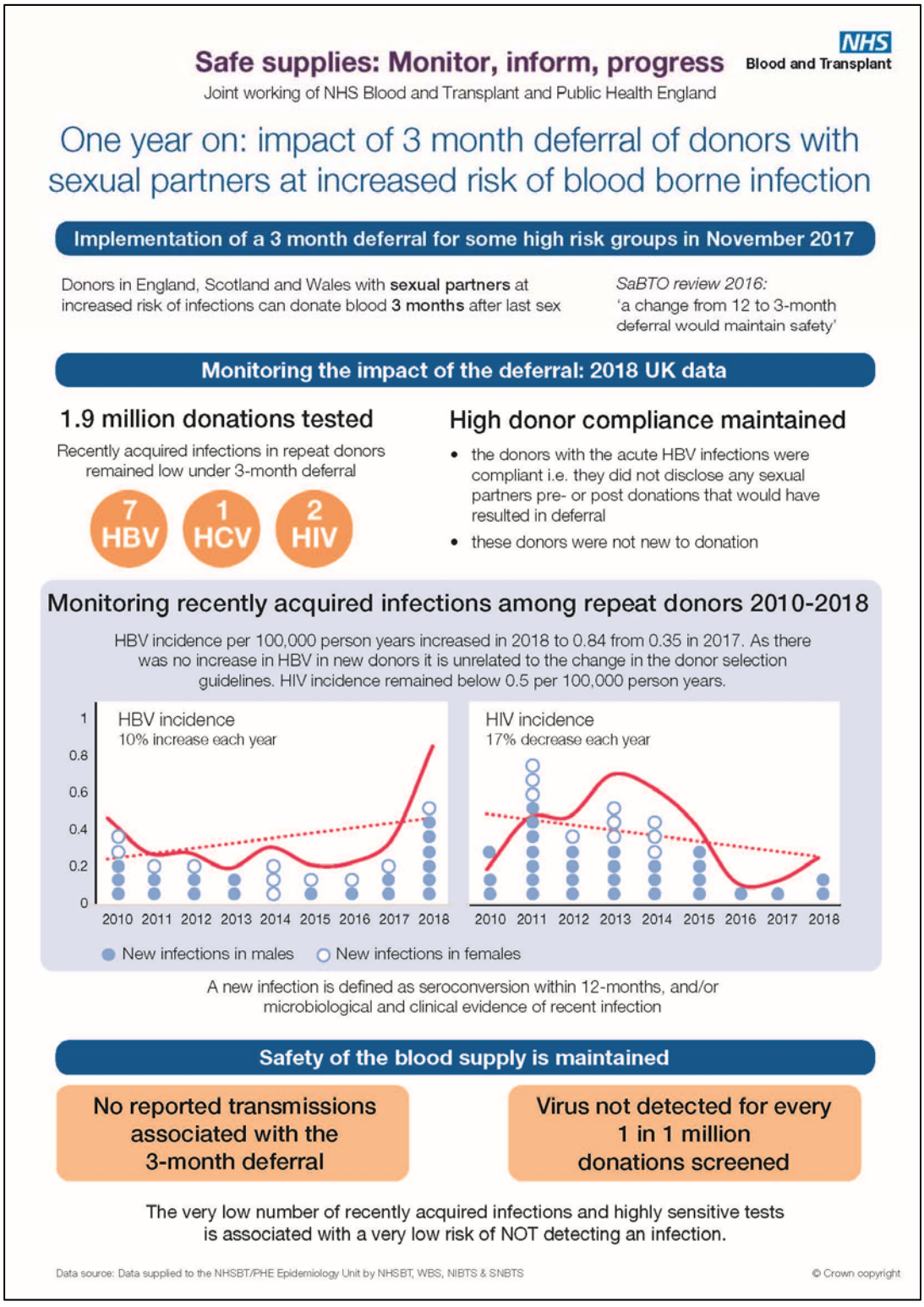
Non- compliant donors

4 MSM

1 Known infection | 1 Endoscopy

Data source: Data supplied to the NHSBT/PHE Epidemiology Unit by NHSBT, WBS, NIBTS & SNBTS

This method of collecting and analysing data also provides evidence for the success or otherwise of policy changes and evidence to inform future policy work. The impact of the recommendations to reduce the deferral to 3 months for higher risk sexual behaviors, implemented by NHSBT in November 2017, has been reviewed a year after this change. Current surveillance data suggest that these changes have not resulted in an increase in non-compliant donors or an increase in recently acquired infections due to a known deferrable risk factor.



In addition, this team:

- Contribute to and write the SHOT chapter on transfusion transmitted infections
- Contribute to policy work through JPAC and SaBTO
- Calculate estimated risks of an infectious donation entering the blood supply in the UK
- Work with PHE colleagues to monitor new and emerging infections which may impact on the blood supply
- Are working with the Canadian Blood Service to establish evidence to support an individual risk assessment policy for blood donors in higher risk population groups

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