UK Health Security Agency

NHS Blood and Transplant

Safe Supplies 2023: Close monitoring of blood donations

Safe Supplies 2023: Close monitoring of blood donations

Foreword

I am very pleased to share with you the NHS Blood and Transplant (NHSBT) and UK Health Security Agency (UKHSA) Epidemiology Unit's annual review 'Safe supplies 2023: close monitoring of blood donations.' This year there are 6 infographics focusing on the Epidemiology Unit's work relating to the surveillance of infections in blood donors and transfusion recipients across the UK and providing assurance of the safety of the blood supply for recipients today.

During 2023, the Infected Blood Inquiry (IBI) heard final submissions and the Inquiry reported on 20th May 2024. Throughout the Inquiry we committed to assisting the Inquiry in its search for truth and justice for all and have apologised unreservedly for where the blood services of the past caused suffering. It is moving and humbling to hear and read the evidence of the Infected and Affected. The Inquiry report acknowledged that there have been major changes in donor selection, donation testing, infection surveillance and haemovigilance, however, we must continue to assure ourselves that our processes and procedures are still effective and ensure robust horizon scanning is in place.

During 2023, approximately 950,000 people aged 17 and above donated blood in the UK, 46% were men and 140,000 were first-time donors, including 8% of Asian heritage and 4% Black heritage individuals.

Almost 1.8 million blood and apheresis donations were screened, with 429 (1 in 4,164) confirmed positive for hepatitis E virus (HEV). Additionally, 287 donations (1 in 6,224) had evidence of current or past infection including HIV, hepatitis C (HCV), hepatitis B (HBV), Human T-lymphotropic virus (HTLV), and syphilis. Most positive donations came from first-time donors (72%), males (75%) and people of White ethnicity (59%).

From April 2022, the UK blood services began to routinely screen blood donations for Hepatitis B core antibody (anti-HBc) to reduce the risk of transfusion transmitted hepatitis B from donors with occult hepatitis B infection (OBI). This screening was in addition to routine Hepatitis B Surface Antigen (HBsAg) and pooled nucleic acid testing (NAT) for HBV DNA. Anti-HBc screening has significantly improved recipient safety, identifying 14 additional OBI cases in donors in 2023 that were not detected on pooled NAT screening alone.

The impact of For the Assessment of Individualised Risk (FAIR) policy as a more individualised approach to donor selection continues to be monitored. Under FAIR, the numbers of recent HIV, HCV, and HBV infections remain low and has had little impact on donor deferral at donation, there have been no reported viral transmissions associated with this policy change. There is some evidence of non-disclosure of information among positive donors, mainly related to past treated syphilis which is detected on screening. Research is ongoing to improve the questions asked during pre-donation checks and support donors in disclosing any relevant information pre-donation.

Surveillance data gathered throughout 2023 show that as in recent years the number of donors with markers of infections remain low and confirmed transfusion transmitted infections are rare. The estimated residual risk of not detecting a potentially infectious very early HIV, HCV, or HCV infection was calculated as less than 1 in 1 million donations tested.

The Epidemiology Unit is responsible for collating horizon scanning information to enable risk assessment of potential emerging threats and allow appropriate action to maintain a safe supply. In 2023, this resulted in actions taken by the Joint UK Blood Transfusion and Tissue Transplantation Service Professional Advisory Committee (JPAC) regarding the global spread of arboviruses, including local transmission of dengue and West Nile virus (WNV) in Europe.

Supporting the UK blood services in monitoring blood safety includes gathering evidence of transfusion transmitted infections (TTIs), working with the Serious Hazards of Transfusion (SHOT) scheme since 1996. Investigations into potential transmissions are initiated following a report from a hospital of a possible infection in a transfusion recipient, or via lookback to the previous donations following a newly identified infection in a repeat donor. In the UK in 2023, 140 suspected TTI cases were investigated, including 113 bacterial and 27 viral and parasitic incidents. No bacterial transmissions were identified, but probable transmissions of HEV and HBV were found in 2 recipients from transfusions in 2022. Confirmed 2023 transmissions included 1 malaria and 1 hepatitis A virus (HAV) infection. There were no transfusion transmissions identified by lookback.

It is 27 years since the Epidemiology Unit's surveillance schemes were first established in 1996. Over these years, there have been significant improvements in diagnosis and prevention of blood borne infections in the general population meaning fewer undiagnosed infections potentially entering the blood supply. Blood donation screening has seen a shift from serology-based assays to more advanced molecular methods, with a substantial reduction in window periods and other manufacturing advancements like enhanced traceability and reduced errors through barcoding and automation. This has resulted in a notable decrease in the number of infections detected in donors and the chance of undetected infections entering the blood supply. Supported by strategies to minimise transfusion, there are now very few incidents of transfusion transmitted infections expected or observed but as noted above we must remain vigilant for new and emerging risks.

As always, we are grateful to the thousands of donors and donor families who make transfusion and transplantation possible and help to save and improve more lives every year.

I hope you will find this year's report interesting and please do not hesitate to contact us (epidemiology@nhsbt.nhs.uk) if you require further information, or more detailed information which is available as a slide set.

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Safe Supplies 2023: Close monitoring of blood donations

Infections in blood donors, UK 2023

Excluding past HBV infection

Donor selection rules aim to allow as many donors as possible to give blood while maintaining the safety of the blood supply

950,000 volunteer donors aged 17 and above gave whole blood donations in 2023

46% **54%**

140,000 gave for the first time:

8% Asian heritage and **4%** Black heritage

63 positive donors not able to disclose information on donation:

46 treated syphilis
7 anal sex with new or multiple partners
3 known hepatitis
2 injected drugs and known hepatitis
2 injected drugs in the past
1 treated syphilis and taking preventative HIV medication
1 recent surgery (unrelated to infection)
1 partner may have injected drugs

1 of 5 seroconverters

was a regular apheresis donor whose partner may have injected drugs. They had not been able to disclose this information before donation. Early HIV infection was detected at their most recent donation. It is important to prompt regular donors about any changes since their last donation which may impact on recipient safety

Donor selection rules keep infection low, maintaining low chance of not detecting a very early infection

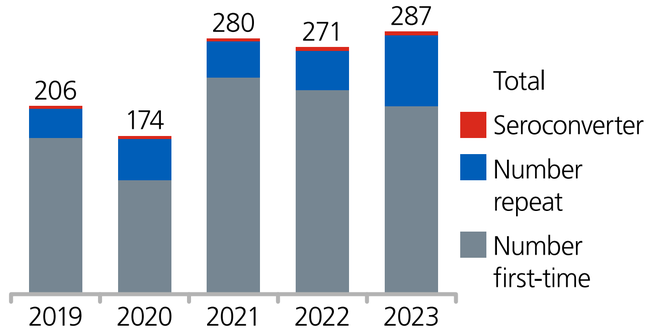
1,786,431
donations screened

92%
of donations from repeat donors

287 donations confirmed positive and discarded:

7 HIV
29 HCV
81 HBV (61 chronic, 16 occult, 4 acute)
10 HTLV
162 syphilis (46 recent)
includes **2** dual HIV/syphilis

72% (205)
positive donations from first-time donors, majority longstanding hepatitis B or C (97) or syphilis (73)



2023 saw increase in repeat donors deferred due to identification of longstanding or treated syphilis using a more sensitive test in England

Recent HIV, HCV or HBV is rare

1 acute HBV in first-time donor
5 repeat donors had a recent negative donation i.e. seroconverted 2 HIV 3 HBV (4 in 2022)

Recent HIV, HCV or HBV identified in donors help us estimate the chance of not detecting a very early HIV, HCV or HBV infection which has remained

below 1 in 1 million donations for **10 years**

Sources: data supplied to NHSBT/UKHSA Epidemiology unit by NHSBT, NIBTS, SNBTS and WBS.

Safe Supplies 2023: Close monitoring of blood donations

Infections in blood donors, UK 2023 (excluding past HBV infection)

Donor selection rules aim to allow as many donors as possible to give blood while maintaining the safety of the blood supply

In 2023 approximately 950,000 volunteer blood donors aged 17 and above gave a whole blood donation in the UK: 46% were made by men and 54% by women with 140,000 donors giving for the first time of whom 8% were Asian heritage and 4% Black heritage. All donors complete a questionnaire before they give blood which aims to keep recipients and donors safe, but we know that some donors are not able to fully disclose information before giving blood. Donors confirmed to have current or past infection on testing are contacted and the information from post-test discussion is closely monitored to ensure the donor selection process is working as expected. In the UK in 2023, 63 or 22% of the 287 donors confirmed with HBV, HCV, HIV, HTLV or syphilis later gave the clinical team information they had not disclosed before donating which would have resulted in them being deferred: 46 had been treated for syphilis, 7 had anal sex with new or multiple partners, 3 knew they had hepatitis, 2 injected drugs in the past, 2 injected drugs in the past and also knew they had hepatitis, 1 had been treated for syphilis and was taking preventive HIV medication, and 1 had undergone recent surgery (unrelated to their positive donation). One regular apheresis donor who seroconverted with early HIV infection should not have donated as their partner may have injected drugs but had not been able to disclose this information before donation. It is important to prompt regular donors about any changes since their last donation which may impact on recipient safety.

Donor selection rules keep infection low, maintaining low chance of not detecting a very early infection

In the UK in 2023, 1,786,431 blood and apheresis donations were screened. All those repeat reactive on screening were removed from the blood supply. In 2023, there were 429 donations (1 in 4,164) confirmed positive for HEV Ribonucleic Acid (RNA) and discarded, a small increase on 2022. Donors can return to donate after recovery from HEV. There are no specific donor selection rules for HEV as locally acquired cases in the UK are mainly foodborne. Some 287 donations (1 in 6,224) were confirmed to be positive for markers of other infections and discarded: 7 HIV, 29 HCV (17 (59%) with HCV RNA), 81 HBV (61 chronic, 16 OBI, 4 acute), 10 HTLV and 162 syphilis with 46 syphilis cases assigned as acquired in the last 12 months, similar to 2022 (42). Not counting past HBV infection or malaria, 2 donors had dual infections: HIV and past syphilis detected in first-time male donors in the 25 – to 34-year-old age-group. These donors were deferred from donating and referred for follow up care.

Repeat donors accounted for 92% of donations made but 72% (205) of positive donations were from first-time donors, mainly with longstanding hepatitis B or C (97), or syphilis (73). As in previous years, the majority of confirmed positive cases were male donors (75%, 215), while 27% (79) were under 35 years old and 59% (169) were White. During 2023 an increase was seen in repeat donors deferred for longstanding or treated syphilis after switching to a more sensitive assay in England. Recently acquired HIV, HCV or HBV infections remain rare in blood donors. In 2023 1 acute HBV was identified in a first-time donor while 5 repeat donors had seroconverted i.e. were negative for infectious markers at their previous donation, 2 HIV and 3 HBV compared with 4 seroconverters in 2022. One was not able to disclose information as described above while 5 of 6 were compliant, reporting sex between men and women, 4 with regular partners 1 with a new partner without anal sex. Recent HIV, HCV or HBV detections (and discard of the donations) allow us to estimate the chance of not detecting a very early HIV, HCV or HBV infection. This has remained below 1 in 1 million donations for the last 10 years.

Sources: data supplied to NHSBT/UKHSA Epidemiology unit by NHSBT, NIBTS, SNBTS and WBS.

Safe Supplies 2023: Close monitoring of blood donations

Hepatitis B core antibody screening of blood donations, UK 2023

Anti-HBc screening introduced in 2022 to mitigate risk of transfusion-transmission from OBI

Anti-HBc screening introduced in 2022 to mitigate the risk of HBV transmission after recommendations from SaBTO to screen all donors for anti-HBc at least once

OBI
- undetectable HBsAg in the blood
- may not detect low variable level HBV DNA
- detectable levels of anti-HBc

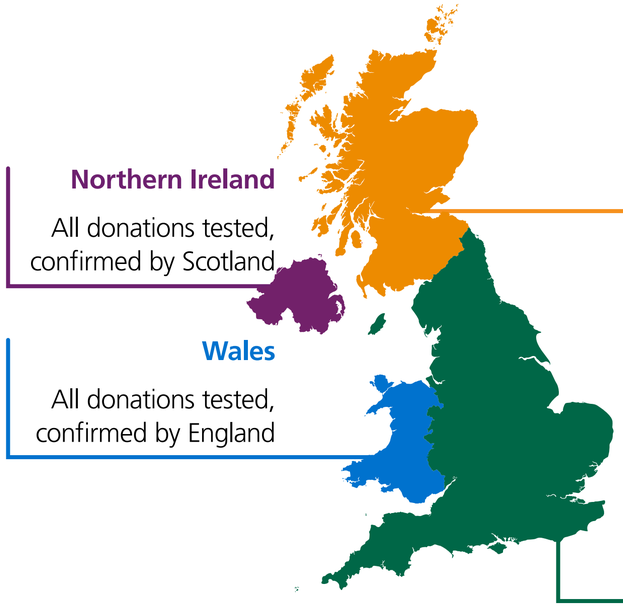
Testing began **2022**

All anti-HBc positive donations discarded.

Confirmatory HBV DNA testing on individual donation samples.

Assessment of anti-HBs level

Anti-HBc screening strategy differs by blood service



Northern Ireland

All donations tested, confirmed by Scotland

Wales

All donations tested, confirmed by England

Scotland

Testing each donor once

Confirmatory testing for all repeat reactives

England

Testing all donations as capacity increased, confirming repeat reactive with anti-HBs<100mIU/ml

March 2023: confirmatory testing for all repeat reactive

May 2023: Testing donors once

16 OBI identified and removed in 2023

UK 2023	Percentage anti-HBc positive	Confirmed Anti-HBs>100 mIU/ml	Confirmed Anti-HBs <100 mIU/ml
Donations from first-time donors	0.69%	499 (2 OBI)	473 (7 OBI)
Donations from repeat donors	0.15%	655 (1 OBI)	615 (6 OBI)

Anti-HBc screening impacts on donor diversity

approximately **1 million UK donations** screened for anti-HBc in 2023 with **0.23%** confirmed positive

Half of the 2,226 donors deferred with past HBV exposure had anti-HBs >100 mIU/ml. Work ongoing to see how these donors could be retained

Deferrals disproportionately affect people born in HBV endemic areas

Asian heritage:
30% anti-HBc positive Asian heritage **vs**
4% all whole blood donors Asian heritage

Black heritage:
22% anti-HBc positive Black heritage **vs**
2% all whole blood donors Black heritage

Anti-HBc screening improves safety for recipients

2 OBI detected by pooled HBV NAT screen

14 additional OBI detected by anti-HBc screening

Before anti-HBc testing
4 probable TTI and **1** confirmed TTI due to OBI

Since anti-HBc testing
0 HBV TTI identified to date

To date, lookback from anti-HBc screening has not identified any living recipients with current HBV

Sources: Data supplied to NHSBT UKHSA Epidemiology unit by NHSBT, NIBTS, SNBTS and WBS.

Safe Supplies 2023: Close monitoring of blood donations

Hepatitis B core antibody screening of blood donations

Anti-HBc screening introduced in 2022 to mitigate risk of HBV transfusion-transmission from OBI

The UK blood services introduced screening for anti-HBc in 2022 to mitigate the potential risk of transmission of hepatitis B from donors with OBI. This followed recommendations from the advisory committee on the Safety of Blood, Tissues and Organs (SaBTO) that all blood donors should be screened at least once for anti-HBc – (https://www.gov.uk/government/publications/occult-hepatitis-binfection-in-uk-blood-donors). A person with OBI is defined as having undetectable levels of HBsAg in the blood but with low and variable levels of HBV DNA which may not be detected by pooled screening, and with detectable anti-HBc. All blood donations in the UK are routinely screened for HBsAg on individual donations and HBV DNA by NAT on pools of 24 donations. Anti-HBc testing was rolled out from April 2022. All anti-HBc repeat reactive donations are discarded, antibody to hepatis B surface antigen (anti-HBs) levels are measured, and confirmatory HBV DNA testing performed on individual donation samples.

Anti-HBc screening strategy differs by blood service

Blood services of Northern Ireland (NIBTS) and Wales (WBS) test all donations with confirmatory testing performed by Scotland (SNBTS) and England (NHSBT) respectively. Scotland tested all donors once from anti-HBc implementation. England's capacity to screen all donations increased with time. Donations repeat reactive for anti-HBc with anti-HBs under 100 mIU/ml on screening were sent for confirmatory testing. All screen anti-HBc reactive had confirmatory tests from March 2023. Functionality to allow screening all donors once instead of testing every donation started from May 2023 in England.

16 OBI identified and removed in 2023

In donations from first-time donors 0.69% were confirmed positive for anti-HBc: 499 with anti-HBs level over 100mIU/ml, 2 with HBV DNA and 473 with anti-HBs level under 100mIU/ml, 7 with HBV DNA, 2 of the 7 were also picked up on the pooled NAT screen. In donations from repeat donors 0.15% were confirmed positive for anti-HBc: 655 with anti-HBs level over 100mIU/ml, 1 with HBV DNA and 615 with anti-HBs level under 100mIU/ml, 6 with HBV DNA. Four OBI were detected by concentrating the sample.

Anti-HBc screening impacts on donor diversity

Approximately 1 million UK donations were screened for anti-HBc in 2023 with 0.23% confirmed overall. This excludes 589 reactive with anti-HBs>100mIU/ml in England between January and March 2023 prior to confirming all reactive donations. There were 2,226 donors deferred with past HBV without DNA detected, half of whom had anti-HBs levels over 100mIU/ml and work is ongoing to see how these donors could be retained. These deferrals for past HBV exposure disproportionately affect people born in HBV-endemic areas with 30% of the deferred donors being of Asian heritage compared with 4% of all whole blood donors donating and 22% of deferred donors being of Black heritage compared with 2% of all whole blood donors donating.

Anti-HBc screening improves safety for recipients

An additional 14 OBI were identified and discarded through anti-HBc testing in 2023 compared with pooled HBV NAT screening which identified 2 OBI. Before anti-HBc testing began, there were 4 probable and 1 proven HBV transfusion-transmitted incidents due to OBI with 6 recipients affected. Since anti-HBc testing was introduced in 2022, there have been zero HBV TTI identified to the end of 2023. To date lookback of the repeat donors who are anti-HBc positive has not identified any living recipient with current HBV infection.

Sources: Data supplied to NHSBT/UKHSA Epidemiology unit by NHSBT, NIBTS, SNBTS and WBS.

Safe Supplies 2023: Close monitoring of blood donations

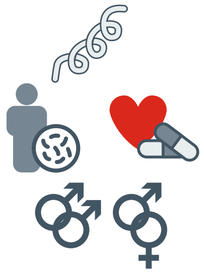
Monitoring donor selection, UK 2023

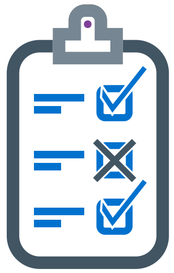
Close monitoring shows FAIR questions helped maintain safety of blood supply

From June 2021 FAIR questions to all donors:

- Ever had syphilis
- In the last 3 months have you:
  - had gonorrhoea*
  - used drugs during sex
  - had anal sex with a new or multiple partners

*Northern Ireland asks about partner with gonorrhoea





The blood services support donors to:

- postpone donation if appropriate
  – by providing prompts and information
- disclose information before donation
  – by providing inclusive confidential setting

Low number recent HIV, HCV or HBV detected maintains low chance of non-detection of very early infection

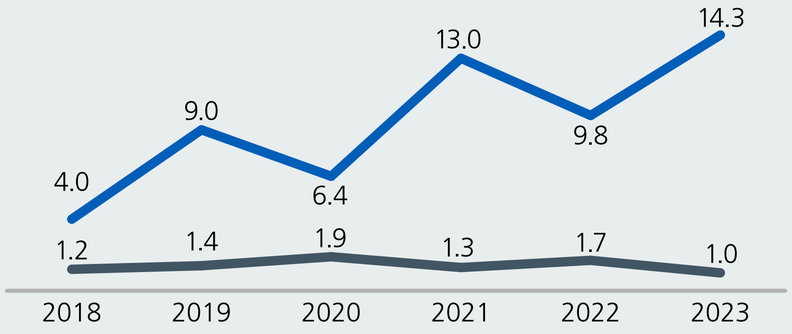
Recent infection		
2018 to 2020 3 month deferral	**2021 to 2023 FAIR**	**Newly eligible**
6 HIV	6 HIV	1
3 HCV	0 HCV	0
11 HBV	11 HBV	0
106 syphilis	130 syphilis	19

Recent infection less than 12m:

- informs chance of non-detection of very early HIV, HCV or HBV
- indicator of recent exposure

Recent HIV, HCV, HBV positive donations detected and discarded remain low

Chance of non-detection of an infectious HIV, HCV or HBV donation **less than 1 in 1 million**



Recent syphilis rate in first-time donors per 100,000 donations

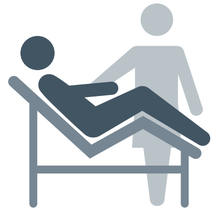
Recent syphilis rate in repeat donors per 100,000 donations

Recent syphilis increasing before FAIR introduced but lower level than in general population

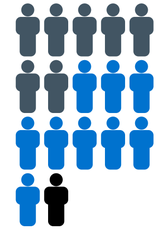
No increase in recent syphilis rates in repeat donors despite increase in longstanding syphilis detected by assay change

Low impact of FAIR at donation but some evidence of non-disclosure

NHSBT audit shows **9** donors deferred at donation because of FAIR for every **100,000 donations made**



Surveillance shows a further **17** positive donors with recent infection not able to disclose information to a FAIR question at donation or **1 per 100,000** donations



Didn't disclose:
7 anal sex with new or multiple partners
9 syphilis treatment,
1 syphilis treatment also taking HIV preventative medication

Further evidence sought by survey of donors

2024 survey to look at behaviour and understanding FAIR in donors with no evidence of infection

Sources: Data supplied to NHSBT/UKHSA Epidemiology unit by NHSBT, NIBTS, SNBTS and WBS.

Safe Supplies 2023: Close monitoring of blood donations

Monitoring donor selection, UK 2023

Close monitoring shows FAIR questions helped maintain safety of blood supply

From June 2021, donor selection in the UK changed to a more individualised selection policy asking gender neutral questions to all donors prior to each donation, using an evidence-based approach as advised by FAIR and recommended by SaBTO. The specific questions on sex between men were removed and replaced with a suite of questions to ask whether the donor had ever had syphilis (used prior to FAIR) or in the last 3 months had gonorrhoea, used drugs during sex or had anal sex with a new or multiple partners. Note that in Northern Ireland donors are asked if they had sex with a partner with gonorrhoea in the last 3 months.

It is important to enable donors to postpone their donation if appropriate and to disclose information at the donation session. Blood services can enable appropriate self-deferral and full disclosure by prompting donors to review their eligibility, providing information in various formats and by providing inclusive confidential settings to review the donor questionnaires.

Low number of recent HIV, HCV or HBV detected maintains low chance of non-detection of very early infection

Recent HIV, HCV or HBV infections acquired in the 12 months prior to a confirmed positive donation are used to estimate the residual risk of non-detection. Although syphilis is not thought to be a direct risk to the recipient in the UK setting, partly due to cold storage of red cells, it is seen as a useful monitoring tool indicating possible recent exposure to other blood-borne infections. Donations discarded due to recent HIV, HCV, or HBV infection remain low. Comparing the three-year periods before and after FAIR implementation i.e. 2018 to 2020 with 2021 to 2023 shows 6 HIV infections detected in both periods with 1 HIV infection identified in a newly eligible donor after FAIR was implemented. There were 3 HCV infections before and no HCV infections under FAIR and 11 HBV detected in both periods with none in newly eligible donors and 1 in a non-compliant donor. The chance of non-detection of a very early infectious HIV, HCV or HBV donation remains less than 1 in 1 million donations. Recent syphilis was increasing before FAIR was introduced but at a lower level than in the general population, suggesting donors were at lower risk. No increase was seen in recent syphilis rates in repeat donors despite increase in longstanding syphilis detected by assay change.

Low impact of FAIR at donation but some evidence of non-disclosure

NHSBT audit shows 9 donors deferred at donation because of FAIR for every 100,000 donations made. Surveillance shows a further 17 positive donors with recent infection had not been able to disclose information relating to a FAIR question at donation equating to 1 in 100,000 donations. Of the 17 donors, 1 repeat donor had acute HBV and 16 donors had recent syphilis. Of these 17 donors, 3 reported anal sex with multiple partners, 4 reported anal sex with new partners, 10 reported syphilis treatment including 1 also taking preventative HIV medication or Pre-exposure prophylaxis (PrEP). Of the 17 donors 12 were repeat donors, all were male with a median age of 30 years (range 24 to 36 years) giving a median of 2 donations (range 1 to 8) under FAIR; 4 started donating after FAIR was introduced. These routine surveillance data in positive donors who have been removed from the donor pool, indicate that there are donors donating who may be at higher risk of blood-borne infection compared with other donors.

Further evidence is being sought by a survey of donors in 2024 to look at behaviour and understanding of FAIR in the wider donor pool.

Sources: Data supplied to NHSBT/UKHSA Epidemiology unit by NHSBT, NIBTS, SNBTS and WBS.

Safe Supplies 2023: Close monitoring of blood donations

Transfusion transmitted infections and lookback investigations, UK 2023

TTIs are rare, but it is important to highlight to recipients the small but potential chance of infection

Recipient initiated TTI investigations – UK*

- hospitals report suspected TTI
- infection or reaction in transfusion recipients
- investigation of blood components received

→ 140 cases investigated

→ 113 suspected bacterial → **No transmissions**

→ 27 suspected viral and parasitic

→ **2 probable transmissions**
1 HEV (transfusion in 2022)
1 HBV from OBI donor (transfusion in 2022)

→ **2 confirmed transmissions**
1 malaria (transfusion in 2023)
1 HAV (transfusion in 2023)

Donor initiated lookback investigations of repeat donors identified with infection – England*

- after seroconversion, post-donation information or introduction of new test
- donor history reviewed
- archive samples retested
- components traced and recipients tested

→ 15 donors identified for lookback (1 EBV, 3 HEV, 4 OBI, 7 syphilis)

→ 42 components transfused
38 recipients identified

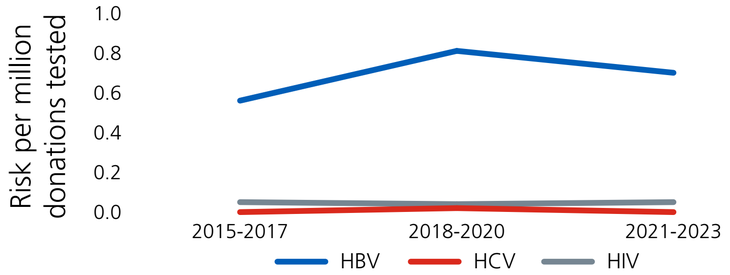
→ 16 recipients tested (22 recipients not tested – deceased)

→ **No transmissions. Lookback investigations continue for repeat donors with newly identified OBI**

Estimates of residual risk of non-detection of acute HBV, HCV and HIV have been below 1 in 1 million for 10 years

Residual risk estimate – the number of seroconverters detected over 3 years, are used to estimate the residual risk of not detecting HBV, HCV or HIV in the window period before assays can detect very early infection

Infectious window period in days
HBV NAT and HBsAg – 30 days
HCV NAT and Anti-HCV – 4 days
HIV NAT and HIV Ag/Ab – 9 days



The highest chance of non-detection is for very early HBV. Based on 1.8 million donations per year, the estimates suggest testing would not detect between 1 and 2 potentially infectious HBV

*data for TTI investigations covers the UK, and lookback investigations covers England only.
All investigations and outcomes reported to SHOT, reports available on the SHOT website https://www.shotuk.org. Sources: Data supplied to NHSBT/UKHSA Epidemiology unit by NHSBT, NIBTS, SNBTS and WBS.

Safe Supplies 2023: Close monitoring of blood donations

Transfusion transmitted infections and lookback investigations, UK 2023

TTIs are rare, but it is important to highlight to recipients the small but potential chance of infection

Suspected transmission investigations are initiated when hospitals report a suspected TTI, either as a result of an infection or a reaction in transfusion recipients and involve investigation of the associated blood components.

In the UK in 2023, 140 suspected cases were investigated, including 113 bacterial and 27 suspected viral and parasitic incidents. No bacterial transmissions were identified from these investigations. Probable transmissions were identified in 2 recipients including 1 HEV infection, and 1 HBV from a donor with OBI, both from transfusions given in 2022. Confirmed transmissions were identified in 2 recipients, including 1 malaria and 1 HAV infection, both from transfusions given in 2023.

Lookback investigations are donor initiated when repeat donors are identified with markers of infection. Lookback investigations are triggered after donor seroconversion, post-donation information supplied by a donor or following the introduction of a new test that detects previously undetectable infection. Investigations involve reviewing donor history, retesting archive samples, tracing components, and tracing and testing recipients. In England in 2023, 15 donors were identified for lookback investigations including 1 Epstein-Barr virus (EBV), 3 HEV, 4 OBI and 7 syphilis infections. Tracing identified 42 components that were transfused, and 38 recipients were identified. Recipient testing was conducted for 16 recipients who were alive, 22 recipients were not tested as they were deceased, no transmissions were identified. Lookback investigations continue for repeat anti-HBc positive donors with newly identified OBI.

Estimates of residual risk of non-detection of very early HBV, HCV and HIV have been below 1 in 1 million for over 10 years

The number of seroconverters detected over 3 years, is used to estimate the residual risk of not detecting HBV, HCV or HIV in the window period before assays can detect very early infection. The latest infectious window period estimation is 30 days for HBV NAT and HBsAg, 4 days for HCV NAT and Anti-HCV and 9 days for HIV NAT and HIV Ag/Ab.

The highest chance of non-detection is for very early HBV. Based on 1.8 million donations per year, the estimates suggest testing might not detect between 1 and 2 potentially infectious HBV.

All investigations and outcomes are reported to SHOT; reports are available on the SHOT website https://www.shotuk.org.

Sources: Data supplied to NHSBT/UKHSA Epidemiology unit by NHSBT, NIBTS, SNBTS and WBS.

Safe Supplies 2023: Close monitoring of blood donations

Horizon scanning for emerging infections, UK 2023

Horizon scanning for emerging infections

A monthly **EIR** lists emerging infections with potential to affect the UK blood and tissue supply. A range of national and international sources are used. Urgent items sent without delay for review

Good links to public health surveillance are crucial

Feedback helps refine EIR reports

Clear process for risk assessment and action

EIR sent to the JPAC SACTTI for **risk assessment**

SACTTI highlight whether further action required by JPAC and its Standing Advisory Committees including changes to donor selection or donation testing

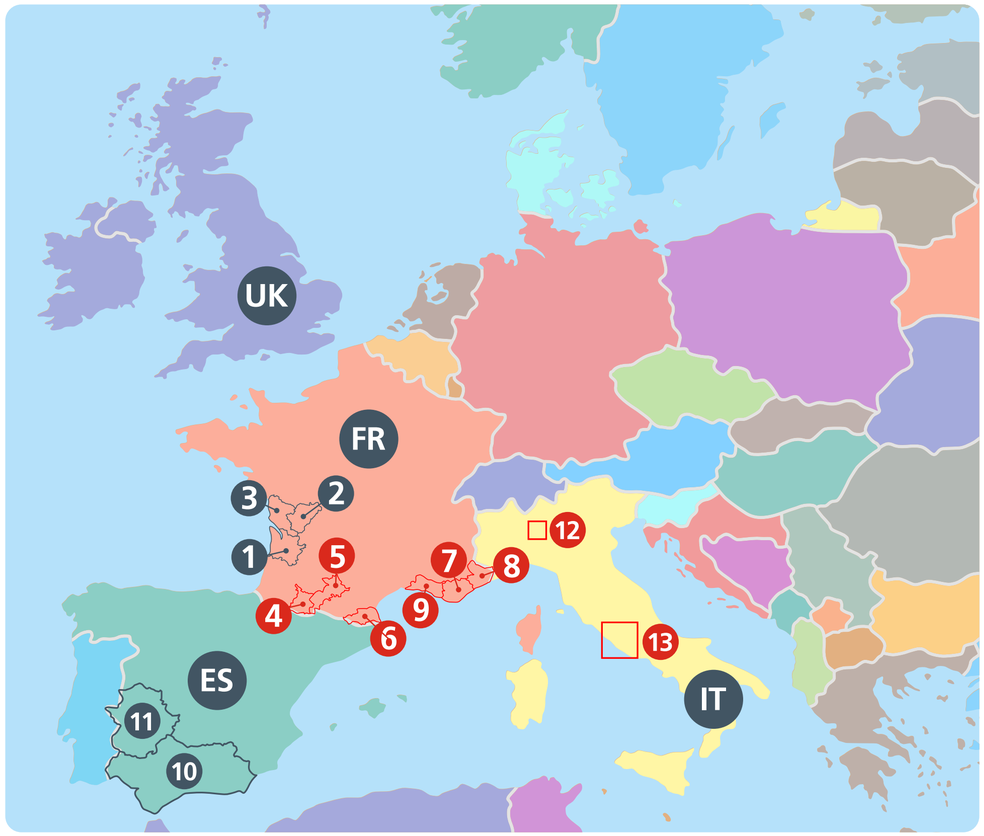
Actions in 2023 centred on observation of global spread of arboviruses, including local transmission of dengue and WNV in Europe

UK:
Close monitoring of **Usutu virus**

Increased complexity to areas requiring testing or deferral

France (FR):
Seasonal **WNV** testing in donors extended to **1 Gironde** then **2 Charente** and **3 Charente-Maritime**

Year-round 28-day **dengue** deferral for donors returning from, **4 Hautes-Pyrénées**, **5 Haute-Garonne**, **6 Pyrénées-Orientales**, **7 Var**, and **8 Alpes-Maritimes** applied 2022, extended to **9 Bouches-du-Rhône**



Spain (ES):
Seasonal **WNV** testing for donors returning from **10 Andalusia** extended to **11 Extremadura**

Italy (IT):
Seasonal **WNV** testing replaced by year-round 28-day **dengue** deferral for donors returning from the provinces of **12 Lodi**, **13 Latina** and **Rome**

WNV testing at highest level seen since testing started in 2012

>60,000 (3.6%) blood donations tested for WNV by England and Scotland 2023, all negative and available for release

For more information: www.transfusionguidelines.org

EIR Sources include: UKHSA EpiIntel reports; European Centre for Disease Prevention and Control (ECDC) communicable disease threat reports, Program for Monitoring Emerging Diseases (ProMED) outbreak and news alerts, peer-reviewed literature.

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Horizon scanning for emerging infections, UK 2023

Horizon scanning for emerging infections

The Epidemiology unit produces a monthly Emerging Infections Report (EIR); a horizon scanning list of outbreaks, emerging and re-emerging infections with potential to affect the UK blood and tissue supply. A range of national and international sources are used. Urgent items are sent to named individuals without delay for review. Good links to public health surveillance are crucial. The sources are reviewed annually, and stakeholders are regularly asked for feedback to refine the reports produced.

Clear process for risk assessment and action

The monthly EIR is sent to JPAC Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) for risk-assessment. Using the EIR and other sources such as alerts from the European Blood Alliance Emerging Infectious Disease Monitor group and other public health sources, SACTTI highlight whether further action is required by JPAC and its Standing Advisory Committees. Such actions may include changes to donor selection or where available, additional donation testing.

Actions in 2023 centred on observation of global spread of arboviruses, including local transmission of dengue and WNV in Europe

In the UK, close monitoring of Usutu virus continues with a small number of wild and captive birds testing positive since 2020. As of November 2023, no human cases of Usutu virus have been reported in the UK [Human Animal Infections and Risk Surveillance group (HAIRS) risk assessment www.gov.uk/government/publications/hairs-risk-assessment-usutu-virus/hairs-risk-assessment-usutu-virus.

The spread of dengue and WNV in Europe has brought increased complexity to testing or deferral decisions. Seasonal WNV testing has been extended to donors returning from France in the last 28 days, initially extended to Gironde and then Charente and Charente-Maritime. A year-round 28-day dengue deferral was applied in 2022 for donors returning from, Hautes-Pyrénées, Haute-Garonne, Pyrénées-Orientales, Var, and Alpes-Maritimes and was extended to Bouches-du-Rhône in 2023. Donors returning from Spain in the last 28 days require seasonal WNV testing with affected areas extended from Andalusia to Extremadura. Donors returning from Italy in the last 28 days usually have seasonal WNV testing but in the areas of Lodi, Latina and Rome this was replaced by a 28-day dengue deferral in 2023.

For more information on JPAC change notifications and position statements see: www.transfusionguidelines.org/document-library

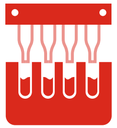
WNV testing was at the highest level seen since testing started in 2012

More than 60,000 or 3.6% of blood donations were tested for WNV by blood services in England and Scotland in 2023. These were all negative and donations available for release.

EIR Sources include: UKHSA EpiIntel reports; European Centre for Disease Prevention and Control (ECDC) communicable disease threat reports, Program for Monitoring Emerging Diseases (ProMED) outbreak and news alerts, peer-reviewed literature.

Safe Supplies 2023: Close monitoring of blood donations

Then and now

									
	UK-wide surveillance schemes to monitor safety and inform policy	HIV in the general population	Donor deferral for GBMSM	Donation screening	HIV, HCV or HBV positive donations removed from blood supply	Recent infections in repeat donors (seroconverted within 1 year)	Infectious window periods (days)	Estimated risk of missing an infectious HIV, HBV or HCV in the window period	TTIs reported in SHOT by year of transfusion
1996	Just set up	A third of cases undiagnosed HAART introduced	Permanent since 1983	Serology HIV, HCV, HBV, syphilis	445 donations 15.7 per 100,000	3 HIV 2 HCV 4 HBV (England)	HIV 15 HCV 59 HBV 80.5	HIV 0.13 in 1 million HCV 0.37 in 1 million HBV 1.43 in 1 million	6 1 HIV (3 recipients), 1 HCV 1 HBV 1 HAV 1 variant CJD 1 bacteria
2023	Nearly 30 years of data 4 donor selection policy reviews Horizon scanning	94% of cases diagnosed Treatment as prevention	GBMSM deferral removed, individualised since 2021	Serology HIV, HCV, HBV, HTLV, syphilis. NAT HIV, HCV, HBV, HEV. Bacteria	118 donations 6.6 per 100,000	2 HIV 0 HCV 3 HBV (UK)	HIV 9 HCV 4 HBV 30	HIV 0.05 in 1 million HCV 0 in 1 million HBV 0.7 in 1 million	2 1 malaria 1 HAV

Notes on data: HIV general population data from AIDSMAP & UKHSA; Risks estimated using 1996 to 1997 and 2021 to 2023 surveillance data, 1996 window periods and risks taken from Soldan et al 2005 Eurosurveillance; TTI taken from SHOT annual report TTI chapter. Risks and TTI data based on surveillance data supplied to NHSBT/UKHSA Epidemiology Unit by NHSBT, NIBTS, SNBTS and WBS.

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Then and now

1996

In 1996, UK-wide surveillance schemes to monitor infection in blood donors and transfusion recipients were just being set up to provide assurance of safety and inform policy decisions. In the general population around a third of HIV cases remained undiagnosed and highly active antiretroviral therapy (HAART) was just being introduced. Donor selection criteria included a permanent deferral for gay, bisexual and other men who have sex with men (GBMSM) introduced in 1983 in response to the spread of HIV but then as now, not everyone was able to fully disclose information when they gave blood. Donation screening was based on serology and carried out for HIV, HCV and HBV and syphilis with 445 donations positive for HIV, HBV and HCV or 15.7 per 100,000 donations detected and discarded. Nine of these were recent infections in repeat donors, 3 HIV, 2 HCV, 4 HBV (England data). The infectious window periods of the tests at that time were 15 days for HIV, 59 days for HCV and 80.5 days for HBV. There was a low risk of errors in the manufacturing process which at this time was largely automated and computerised. The estimated residual risk of non-detection of an infectious HIV, HCV or HBV in the window period (reflecting the epidemiology and window periods) was 0.13, 0.37 and 1.43 per million donations respectively. Hospital transfusion committees existed and were trying to help reduce unnecessary transfusions. SHOT had been established in 1996 and the English Blood Service was starting to work with the Public Health Laboratories Service to make TTI reporting more routine. In 1996 there were 6 TTIs reported and confirmed, 1 HIV resulting in transmission to 3 recipients, 1 HCV, 1 HBV, 1 HAV, 1 variant Creutzfeldt-Jakob disease (vCJD) and 1 bacterial TTI.

2023

In 2023, the UK-wide surveillance schemes for monitoring blood safety and informing policy have been in place for nearly 30 years informing 4 major donor selection policy reviews and including horizon scanning for emerging infection threats to the safety and sufficiency of the blood supply since 2007. In the general population 94% of HIV cases are diagnosed with people using preventative HIV medicine. Blood donor selection policy has evolved over time and from June 2021 changed to a more individualised policy via gender-neutral questions based on evidence of safety allowing some GBMSM to donate. Donation screening now includes NAT for HIV (from 2002), HCV (from 1999), HBV (from 2009) and HEV (from 2016) with anti-HBc testing introduced in 2022 to detect OBI. In 2023, there were 118 HIV, HCV or HBV positive or 6.6 per 100,000 donations and 5 were recent infections in repeat donors, 2 HIV, 0 HCV, 3 HBV (UK data, 1 HIV and 2 HBV in England). The infectious window periods of the tests have been reduced by NAT to 9 days for HIV, 4 days for HCV and 30 days for HBV. With barcoding for traceability, the extremely low chance of manufacturing errors are now excluded from the residual risk estimates. Leucodepletion introduced in 1999 is one of the safety measures designed to minimise vCJD but also has additional risk reduction benefits including the risk of HTLV transmission. For the 3-years 2021-2023, the residual risk of non-detection of infectious HIV or HBV was 0.05 and 0.7 per million donations. As no HCV seroconversions were detected during 2021-2023, HCV risk was estimated to be zero. Since we cannot test for everything and the overall risk is not zero, patient blood management aims to minimise transfusion where possible.

In 2023 there was 1 malaria and 1 HAV TTI. During 2023 the IBI hearings completed, and the final report (20th May 2024) is available on the IBI website (www.infectedbloodinquiry.org.uk). The blood services and wider NHS are currently reviewing the recommendations and preparing for implementation.

Sources: Data supplied to NHSBT/UKHSA Epidemiology Unit by NHSBT, NIBTS, SNBTS and WBS. Notes on data: HIV data from AIDSMAP & UKHSA; Risks estimated using 1996 to 1997 and 2021 to 2023 surveillance data, 1996 window periods and risks taken from Soldan, Katherine, K. Davison, and B. Dow. "Estimates of the frequency of HBV, HCV, and HIV infectious donations entering the blood supply in the United Kingdom, 1996 to 2003." *Eurosurveillance* 10.2 (2005): 9-10.; TTI taken from SHOT annual report TTI chapter

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Peer review publications and awards of the NHSBT/UKHSA Epidemiology Unit, 2023

Rosadas C, Harvala H, **Davison K,** Taylor GP. **HTLV-1 screening of blood donations: We are systematically missing opportunities.** Br J Haematol. 2023 Sep;202(6):1220-1223.

Maddox V, **Reynolds C,** Amara A, Else L, **Brailsford SR,** Khoo S, Harvala H. **Undeclared pre-exposure or post-exposure prophylaxis (PrEP/PEP) use among syphilis-positive blood donors, England, 2020 to 2021.** Euro Surveill. 2023 Mar;28(11):2300135.

Knight C, Andreani J, Garrett N, Winter M, Golubchik T, Breuer J, **Reynolds C, Brailsford SR,** Harvala H, Simmonds P. **Absence of detectable monkeypox virus DNA in 11,000 English blood donations during the 2022 outbreak.** Transfusion. 2023 Apr;63(4):690-695.

Ferguson E, Bowen S, Lawrence C, Starmer C, Barr A, **Davison K, Reynolds C, Brailsford SR. Communicating the move to individualized donor selection policy: Framing messages focused on recipients and safety.** Transfusion. 2023 Jan;63(1):171-181.

Gates S, Ijaz S, Baklan H, Washington C, **Brailsford S,** Zambon M, Harvala H. **Investigating Blood Donors With Postdonation Respiratory Tract Symptoms During the Wild-Type, Delta, and Omicron Waves of the Coronavirus Disease 2019 Pandemic in England.** Open Forum Infect Dis. 2023 Oct 5;10(10):ofad499.

Fu MX, Simmonds P, Andreani J, Baklan H, Webster M, Asadi R, Golubchik T, Breuer J, Ijaz S, Ushiro-Lumb I, **Brailsford S,** Irving WL, Andersson M, Harvala H. **Ultrasensitive PCR system for HBV DNA detection: Risk stratification for occult hepatitis B virus infection in English blood donors.** J Med Virol. 2023 Oct;95(10):e29144.

Vassallo R, Kamel H, Goel R, Al-Riyami AZ, Al Muharrmi Z, Jacquot C, Ramirez-Arcos S, Khandelwal A, Goldman M, Hands K, McLintock L, Mitchell H, Wendel S, Scuracchio P, Fachini R, Pettersson SM, Bengtsson J, **Brailsford SR,** Tossell J, Amorim L, Lopes ME, Pêcego M, Germain M, Renaud C, Morley SL, So R, Townsend M, Hopkins C, Harritshoej LH, Erikstrup C, Gosbell IB, Levin MH, Dennington PM, Dunbar N. **International Forum on Management of Blood Donors with Culture-Positive Platelet Donations: Summary.** Vox Sang. 2023 Nov;118(11):997-1003.

Maddox V, Vallely P, **Brailsford SR,** Harvala H. **Virological safety of the UK blood supply in the era of individual risk assessments and HIV PrEP.** Transfus Med. 2023 Oct;33(5):372-378.

Neuberger J, **Brailsford SR,** Mallinson G, Murphy MF, Simmonds P. **Challenges for the maintaining the microbiological safety of the UK blood supply.** Clin Med (Lond). 2023 Mar;23(2):151-156.

Awards

British Blood Transfusion Society's Margaret Kenwright Award for individuals under 40 with the highest scoring abstract in their chosen category, 2023:

Process and progress: a five-year focus on viral transfusion-transmitted infection investigations in the UK, 2018-2022.
C Davison, **K Davison,** H Harvala, **S Brailsford.**

FAIR blood donation selection policy supported low risk of mpox transmission among donors in England, 2022.
R Wilkie, **C Reynolds, K Davison,** H Mohammed, S Brailsford.

Serious Hazards of Transfusion (SHOT) Annual Conference 2023, Best Poster award:

Process and progress: a five-year focus on viral transfusion-transmitted infection investigations in the UK, 2018-2022.
C Davison, **K Davison,** H Harvala, **S Brailsford.**

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Glossary

anti-HBc : Antibody to Hepatitis B Core Antigen
anti-HBs : Antibody to Hepatitis B Surface Antigen
DNA : Deoxyribonucleic acid
ECDC : European Centre for Disease Prevention and Control
EIR : Emerging Infections Report
FAIR : For the Assessment of Individualised Risk
GBMSM : Gay, Bisexual, and other Men who have Sex with Men
HAIRS : Human Animal Infections and Risk Surveillance group
HAART : Highly Active Antiretroviral Therapy
HAV : Hepatitis A Virus
HBV : Hepatitis B Virus
HBsAg : Hepatitis B Surface Antigen
HCV : Hepatitis C Virus
HEV : Hepatitis E Virus
HIV : Human Immunodeficiency Virus
HTLV : Human T-cell lymphotropic Virus
IBI : Infected Blood Inquiry
JPAC : Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee
mIU/ml : milli-international units per millilitre
NAT : Nucleic Acid Testing
NIBTS : Northern Ireland Blood Transfusion Service
NHSBT : NHS Blood and Transplant (England)
OBI : Occult Hepatitis B Infection
PrEP : Pre-exposure prophylaxis
ProMED : Program for Monitoring Emerging Diseases
RNA: Ribonucleic Acid
SaBTO : Advisory Committee for the Safety of Blood, Tissues and Organs
SACTTI : Standing Advisory Committee on Transfusion Transmitted Infections
SNBTS : Scottish National Blood Transfusion Service
SHOT : Serious Hazards of Transfusion
TTI : Transfusion-Transmitted Infection
UKHSA : UK Health Security Agency
vCJD : Variant Creutzfeldt-Jakob disease
WBS : Welsh Blood Service
WNV : West Nile Virus