UK Health Security Agency

NHS Blood and Transplant

Safe Supplies 2022: monitoring safety in donors and recipients

Joint working between NHS Blood and Transplant and UK Health Security Agency

Foreword

It gives me great pleasure to introduce the NHS Blood and Transplant (NHSBT) and UK Health Security Agency (UKHSA) Epidemiology Unit's annual review 'Safe supplies 2022: monitoring safety in donors and recipients.' This year we have produced eight infographics covering the Epidemiology Unit's programme of work which provides assurance of the safety of blood, tissues and organs across the UK.

Analysis of data from the surveillance schemes throughout 2022 show that the number of infections in donors remains low and few infections have been confirmed in recipients. Of note, the FAIR donor selection policy, introduced from June 2021, has not impacted on the safety of the UK blood supply with the chance of not detecting a recently acquired viral infection on routine screening remaining below 1 in 1 million donations. Under FAIR, gay and bisexual men who have sex with men in established relationships can give blood in the UK if no other deferral criteria apply. This gender neutral, more individualised approach to assess blood donation safety was a landmark change and led the way for other blood establishments around the world to move to a more inclusive policy.

During 2022 routine screening for antibodies to hepatitis B core was rolled out across the UK for blood donations in response to a review carried out by SaBTO, the Department of Health and Social Care's advisory committee on the safety of blood, tissues and organs. This has already had an impact on increased detection of potentially transmissible hepatitis B virus from donors with occult hepatitis B. Current surveillance systems allow post implementation monitoring of new tests and policy changes.

The unit is responsible for collating horizon scanning information to allow a risk assessment of potential emerging threats to the blood safety. In May 2022, this picked up the mpox outbreak and working closely with UKHSA colleagues informed a blood safety risk assessment concluding that the risk to recipients was minimised through pre-donation information to donors and existing mitigation steps.

Supporting the UK blood services in monitoring safety includes gathering evidence of transfusion-transmitted infections (TTIs), working in collaboration 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 lookback to the previous donations following a newly-identified infection in a repeat donor. In 2022, these investigations identified the first confirmed transmission of hepatitis B from a donor with occult hepatitis B infection (OBI) to two recipients in the UK. The transfusions occurred in 2021, prior to the introduction of hepatitis B core antibody testing. A 'near-miss' bacterial contamination event was reported where the affected unit was identified on visual examination, another patient who received an associated pack from the same donation remained well. Since FAIR was implemented, there have been no reported viral transmissions associated with this policy change.

Evidence of Creutzfeldt-Jakob disease (CJD) transfusion-transmission has been gathered through Transfusion Medicine Epidemiological Review (TMER) in collaboration with the National CJD Research and Surveillance Unit since 1997. TMER data have been key to assessing the risk of vCJD from the blood supply. Cases have been low in number and rarely linked to the blood supply. The most recent case of vCJD in 2016 was not found to be a blood donor. In 2018, the risk was downgraded such that plasma collection for manufacturing in the UK could safely be restarted. In 2022, both the US and Australia removed the deferral for people who had spent time in the UK during the years of the vCJD outbreak, 1980 to 1996.

In collaboration with Imperial College London, we continue to recruit to and manage the Human T-cell Lymphotropic virus (HTLV) National Register. Recruitment began after the introduction of blood donation screening in 2002 and identifies people without symptoms for long-term follow-up. Health information reported by participants in the 8th and most recent follow up at the end of 2022 showed onset of severe disease to be rare. Data from this register and the other surveillance systems across blood, tissues and organs are used to support wider public health policies and provide data about a generally healthy population.

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.

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Infection in blood donors, UK 2022

Excluding past HBV infection (see core antibody screening pages)

Good compliance with donor selection criteria leads to low number of positive donations

In 2022 approximately 950,000 whole blood donors made 1.8 million blood donations in the UK. All donations repeat reactive on screening were removed from the blood supply. Of the 1.8 million donations, 7.4% were made by new (first-time) donors. Of the whole blood donors, 52.9% were female and 28.4% were under 35 years old, rising to 52.9% under 35 years old in new donors. Ethnicity was not available for the whole of the UK, but white donors accounted for 91.6% of whole blood donors in England.

In 2022, there were 368 donations (1 in 4,700) confirmed positive for hepatitis E virus (HEV) RNA and discarded, similar to 2021. 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 271 donations (1 in 6,500) were confirmed to be positive for markers of other infections: 77 current hepatitis B virus infection (HBV) including 8 occult HBV, 30 hepatitis C virus (HCV) (15 or 50% with RNA detected), 9 HIV, 14 Human T lymphotropic virus (HTLV) and 142 syphilis with 42 syphilis cases assigned as acquired in the last 12 months, similar to 2021. One donor had both chronic HBV and syphilis markers. The confirmed positive donors were deferred from donating and referred for follow up care. The majority (223, 82%) of cases were in new donors, mainly longstanding infection and increased from January 2021 prior to FAIR introduction as shown in the bar chart. As in previous years, the majority of confirmed positive cases were male (76.4%), while 37.3% were under 35 years old and 56.1% were White.'

In confirmed positive donors, most reported good compliance with the FAIR individualised donor selection rules relating to sexual behaviour in place from 14 June 2021. 80% of confirmed positive donors were compliant and 20% non-compliant with donor selection criteria: 36 syphilis (16 GBMSM, 17 sex between men and women, 3 not known), 12 known viral cases, 6 injected drugs in the past. The overall proportions were similar to 2021 and 2020.

FAIR rules have not impacted on safety: residual risk remains below 1 in 1 million donations tested

The pre-donation selection questions reduce the chance of donors having very recent infections that screening might not detect.

The number of seroconverters detected over 3 years are used to estimate residual risk of not detecting HBV, HCV or HIV in the window period before the assays can detect very early infection. The residual risk of not detecting an HBV, HCV or HIV infection and releasing it into the blood supply currently remains at less than 1 in 1 million donations as shown in the graph.

Seroconverters are defined as cases with a recent negative donation. In 2022, 4 male donors had seroconverted including 1 non-compliant who injected non-prescribed substances (HIV) and 3 with multiple female partners (1 HIV and 2 HBV), of whom two reported travel to, or sex in Thailand (1 HIV, 1 acute HBV NAT yield). A further 4 were recent viral infections in new or lapsed donors including one GBMSM with HIV who was newly eligible under FAIR and 3 HBV cases reporting sex between men and women, 2 male, 1 female.

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

Safe Supplies 2022: monitoring safety in donors and recipients
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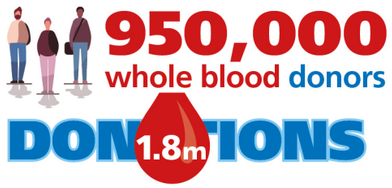
Infection in blood donors, UK 2022

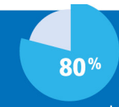
Excluding past HBV infection (see core antibody screening pages)

Good compliance with donor selection criteria leads to low number of positive donations



FAIR
Introduced from14 June 2021

In confirmed positive donors:
Good compliance with the FAIR individualised donor selection rules relating to sexual behaviour helping maintain safety



compliant, 20% non-compliant with donor selection criteria, similar to 2021:

36 treated syphilis
12 known viral cases
6 injected drugs in the past

Hepatitis E virus

In 2022, **368** donations **(1 in 4,700)** confirmed positive for HEV RNA and discarded, similar to 2021

Donors can return to donate after recovery from hepatitis E

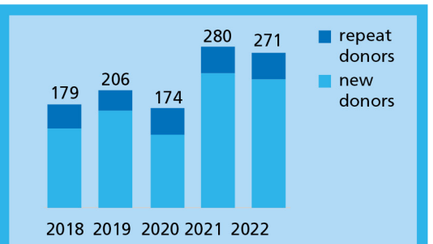
No specific donor selection rules for HEV, which is mainly foodborne in the UK

In 2022, 271 donations (1 in 6,500) confirmed positive and discarded, similar to 2021

130 viral: **77** HBV
30 HCV
9 HIV
14 HTLV

142 syphilis
(**1** dual HBV/syphilis)

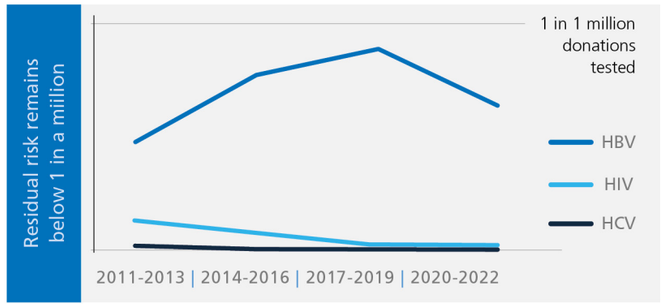
Donors are deferred



Majority of cases removed were new donors, mostly with longstanding infection, which increased from January 2021, low impact on safety

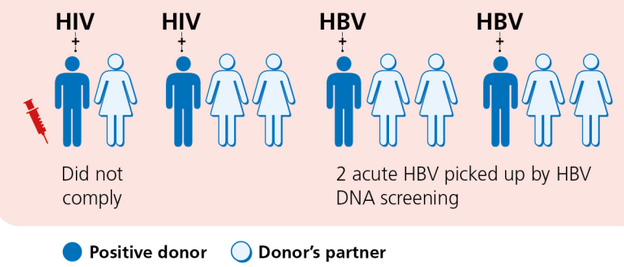
FAIR rules have not impacted on safety: residual risk remains below 1 in 1 million donations tested

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



Seroconverters are cases with a recent negative donation

In 2022, **4** donors were seroconverters for HBV, HCV or HIV compared with **3** in 2021 and **3** in 2020



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

Introducing hepatitis B core antibody screening of blood donations, UK 2022

The Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO) recommend the introduction of hepatitis B core antibody (anti-HBc) screening

All blood donations in the UK are routinely screened for hepatitis B surface antigen (HBsAg) on individual donations and a nucleic acid test (NAT) for hepatitis B virus (HBV) DNA on pools of 24 donations. In 2018, 2 probable transfusion transmitted cases of HBV in the UK were reported that were not picked up by routine screening. A person with occult hepatitis B infection (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 levels of anti-HBc (antibody to hepatitis B core antigen). The UK blood services introduced screening for anti-HBc in 2022 to mitigate the potential risk of OBI to the blood supply in the UK after recommendations from SaBTO's OBI working group to screen all donors at least once (https://www.gov.uk/government/publications/occult-hepatitis-b-infection-in-uk-blood-donors).

Donation screening rolled out for anti-HBc in 2022

Anti-HBc testing was rolled out for UK blood donations from April 2022. All anti-HBc repeat reactive donations are discarded and confirmatory HBV DNA testing is done on individual donation samples. The implementation strategy varied by country: Scotland began 5 April and had capacity from the start to screen all current donors once then donations from new and returning donors; Northern Ireland started screening all donations from 30 May; Wales started screening all donations from 27 May; England from 31 May. England's capacity to screen all donations increased with time; donations with repeat reactive anti-HBc and anti-HBs over 100 IU/L on screening were discarded without additional confirmatory testing; all screen anti-HBc reactives had confirmatory tests from March 2023; and functionality to allow screening of all donors once only rather than testing at every donation started from May 2023 in England.

By December 2022, the UK blood services had screened 643,671 donations for anti-HBc: Scotland identified 204 anti-HBc positive (0.26%); Northern Ireland 33 (0.13%); Wales 86 (0.17%) and England 1578 (0.32%) which includes 1175 unconfirmed anti-HBc repeat reactive donors with anti-HBs >100 mIU/ml (0.24%). In the UK, 5 OBI were identified via anti-HBc screening followed by detection of HBV DNA by individual confirmatory testing on 726 anti-HBc positive samples. 3 OBI were detected by existing routine pooled screening of all donations for HBV DNA. A further 5 OBI identified through large volume testing or archive sample testing as part of research. Of the anti-HBc confirmed positive donors deferred, 22% were from Asian donors, 14% from Black donors, 48% from White donors, 6% from the Mixed and other ethnic group and 10% where ethnic group was not known. This compares with 92% of whole blood donations made by White donors in England in 2022.

What does this mean for donors?

Deferrals disproportionately affect people born in HBV endemic areas. For donors anti-HBc positive without DNA it means that they had HBV in the past but there is no evidence of current infection. This is not significant to their current health, but they are deferred from donating. Donors who are anti-HBc positive without DNA are contacted with further information. Donors who are anti-HBc positive with DNA may be referred for further care on specialist advice.

What does this mean for recipients?

The introduction of anti-HBc screening has reduced the risk of HBV transmission from OBI. Lookback investigations of previous donations made by anti-HBc positive donors commenced in 2023.

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

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Introducing hepatitis B core antibody screening of blood donations, UK 2022

SaBTO recommend introduction of hepatitis B core (anti-HBc) screening

All donations screened for HBsAg on individual donations and HBV DNA by NAT on pools of **24** donations

Two cases of probable HBV transfusion transmissions from OBI reported in 2018. These were not picked up by routine screening.

Occult Hepatitis B infection (OBI)
- undetectable HBsAg in the blood
- may not detect low variable level HBV DNA
- detectable levels of anti-HBc

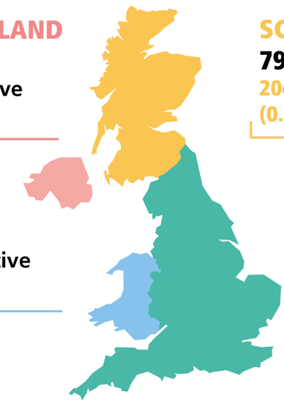
Anti-HBc screening introduced in 2022 to mitigate the risk of HBV transmission after recommendations from SaBTO to screen all donors for anti-HBc at least once

Donation screening rolled out for anti-HBc in 2022

Implementation strategy varied by country

All anti-HBc positive donations discarded

Confirmatory HBV DNA testing on individual donation samples



NORTHERN IRELAND
25,760 tested
33 anti-HBc positive (0.13%)

SCOTLAND
79,988 tested
204 anti-HBc positive (0.26%)

WALES
50,160 tested
86 anti-HBc positive (0.17%)

ENGLAND
487,763 tested
1,578 anti-HBc positive (0.32%)
Includes **1,175** screen core positive and anti-HBs >**100** discarded, anti-HBc reactivity not confirmed **(0.24%)**

643,671 donations screened for anti-HBc

726 confirmed anti-HBc positive donations discarded and donors deferred

Donors deferred

22% Asian
14% Black
48% White
6% Mixed/other
10% Not known

5 OBI detected via anti-HBc screening followed by routine confirmatory HBV DNA testing

3 OBI detected by existing routine pooled screening of all donations for HBV DNA

What does this mean for donors?

Deferrals disproportionately affect people born in HBV endemic areas

Anti-HBc positive without DNA:
- donor had HBV in past
- no evidence of current HBV
- not significant to current health
- donors contacted with information

Anti-HBc positive with DNA:
- donors may be referred for further care

What does this mean for recipients?

Better identification of donors with OBI so reduced risk of HBV transmission

Lookback investigations of previous donations made by anti-HBc positive donors commencing in 2023

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

Horizon scanning for emerging infections, UK 2022

Daily 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. Items are sent without delay if urgent. Good links to public health surveillance are crucial. Feedback helps refine EIR reports, and sources are reviewed annually.

Clear process for risk assessment and action
The monthly EIR is sent to the Joint UKBTS Professional Advisory Committee (JPAC) Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) for risk-assessment. SACTTI highlight whether further action is required by JPAC and its Standing Advisory Committees using the EIR and other sources such as alerts from the European Blood Alliance Emerging Infectious Disease Monitor group.

2022 actions included monitoring arbovirus spread and management of mpox outbreak
In 2022, a 28-day deferral was introduced for donors returning from areas in south of France affected by local dengue transmission.

Increased reports of yellow fever outbreaks led to a yellow fever flag being added to the 28-day tropical deferral for donors returning from countries with a risk of yellow fever.

Mpox is a viral illness transmitted through close personal contact but not thought easily transmissible within general populations. An mpox outbreak was identified in England from May 2022 cases almost exclusively among GBMSM. Following identification of the outbreak a blood safety risk assessment was carried out concluding that the risk to the blood supply is minimised by pre-donation information to donors, current FAIR selection criteria and donors reporting post donation illness.

Monitoring for mpox in the UK continues to inform blood safety
Prior to 2022, mpox cases were mainly reported in Africa where the virus is endemic. Limited spread within a family was seen in May 2021 after a case was imported to the UK from Nigeria. The risk to the general UK public was very low. Horizon scanning picked up an increase in outbreaks and cases in several countries in Africa in 2021. There was also published evidence from Nigeria of increasing risk of human-to-human transmission and of a switch to adult infection perhaps due to smallpox vaccination ceasing, and unexplained exports from Nigeria after the main outbreak peaked.

UKHSA raised the alert in May 2022 after another imported case to the UK from Nigeria was followed by an unrelated cluster of cases and subsequent transmission and outbreak among predominantly GBMSM, which had not been seen previously. UKHSA reporting helped to inform the blood safety risk assessment. By December 2022, mpox transmission had fallen significantly in the UK following implementation of a range of public health measures. There was little evidence of mpox cases in blood donors but monitoring continues for any increase in cases or change to transmission patterns in the general population to ensure blood safety.

For further information on the horizon scanning process see:
https://www.transfusionguidelines.org/document-library/position-statements

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 2022

Daily scanning for emerging infections

A monthly **Emerging Infections Report** (EIR) lists emerging infections with potential to affect the UK blood and tissue supply. A range of national and international sources are used. Items sent without delay if urgent.

Good links to public health surveillance are crucial

Feedback helps refine EIR reports

Clear process for risk assessment and action

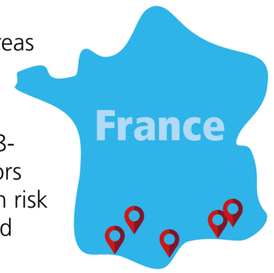
EIR sent to the JPAC Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) for **risk-assessment**

SACTTI highlight whether further action required by JPAC and its Standing Advisory Committees

2022 action: monitoring arbovirus spread, management of mpox outbreak

28-day deferral

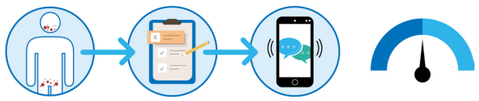
introduced for donors returning from areas in the south of France affected by local dengue transmission



Yellow fever flag added to 28-day tropical deferral for donors returning from countries with risk of yellow fever after increased reports of outbreaks

Mpox blood safety risk assessment

risk to blood supply is minimised by:
- pre-donation information to donors
- FAIR selection criteria
- donors reporting post donation infection



Monitoring for mpox in the UK informs blood safety

Monitoring in 2021

Prior to 2022, mpox cases were mainly reported in Africa

Limited spread in a family in May 2021 after a case imported to the UK from Nigeria: very low risk to UK public

Increase in outbreaks and cases in Africa in 2021

Evidence from Nigeria of increasing risk of human-to-human transmission and switch to adult infection perhaps due to smallpox vaccination ceasing

UKHSA raised the alert in May 2022

when imported case to the UK from Nigeria was followed by an unrelated cluster of cases mainly in GBMSM

UKHSA reporting helped inform blood safety risk assessment

By December 2022, mpox transmission had fallen significantly in the UK

Little evidence of mpox cases in blood donors but monitoring continues to look for any increase in cases or change to transmission patterns in the general population to ensure blood safety

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

Viral transfusion-transmitted infection (TTI) and lookback investigations, UK 2022

Transfusion transmitted infection (TTI) investigations
Investigations for possible viral TTI may be initiated when hospitals report a patient with a confirmed blood-borne virus infection with no obvious risks other than transfusion. These infections are often diagnosed and reported several months post-transfusion. Microbiological test results, date of transfusion(s) and component identification numbers are provided to support the investigation. If a TTI is suspected, donors of the implicated donations will be identified and where possible archive samples retrieved for testing. A donor may be asked for additional blood samples to assist with investigation. If the archived sample tests positive, the donor is informed of the results and referred as appropriate. Where possible, molecular typing of donor and recipient virus is used to confirm a transmission. Lookback investigations may be initiated if other, potentially infectious donations, are identified.

In 2022, of eight incidents investigated, seven were concluded as not TTI and one was the first confirmed HBV TTI from a donor with occult hepatitis B infection (OBI) in the UK. Sufficient virus was available for sequencing of both donor and recipient virus. The transfusion occurred in 2021, prior to the introduction of hepatitis B core antibody testing in 2022 following ministers' acceptance of a SaBTO recommendation. Despite this transmission, the overall risk of TTIs in the UK remains extremely low.

Lookback investigations
Lookback investigations are considered when markers of infection are newly identified in a donation from a repeat donor. Lookback may also be required when a new screening test is introduced, such as the hepatitis B antibody testing implemented in 2022. All UK blood services keep archive samples of previous donations for at least three years. In a lookback, the sample of a donor's most recent previous donation is identified and tested for markers of infection that were not detected on routine screening. Investigations may be extended to all previous donations depending on the implicated virus. Any recipients identified as requiring lookback will be offered information about lookback, asked for consent for testing and followed up depending on the outcome of tests, usually via their medical practitioner. Lookback investigations have begun across the UK following introduction of anti-HBc screening.

In 2022, NHSBT identified eight positive repeat donors who required lookback investigations. 19 of the components investigated were transfused. 10 of the recipients were alive, 9 of whom were tested and one is still undergoing follow up. One recipient was positive for markers of HBV infection and confirmed by genetic sequence analysis to be from the same donor as discussed in the HBV TTI described above. Wales reported one HEV investigation where seroconversion in an apheresis donor was not detected by pooled screening. HEV screening is currently under review by SaBTO.

In the last five years of investigations there were eight confirmed or probable viral TTIs, identified through TTI or lookback investigations, three HEV and five HBV due to donors with OBI. The transfusions involved in these investigations took place between 2015 and 2021.
All investigations and outcomes are reported to SHOT and are available on the SHOT website - https://www.shotuk.org/

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

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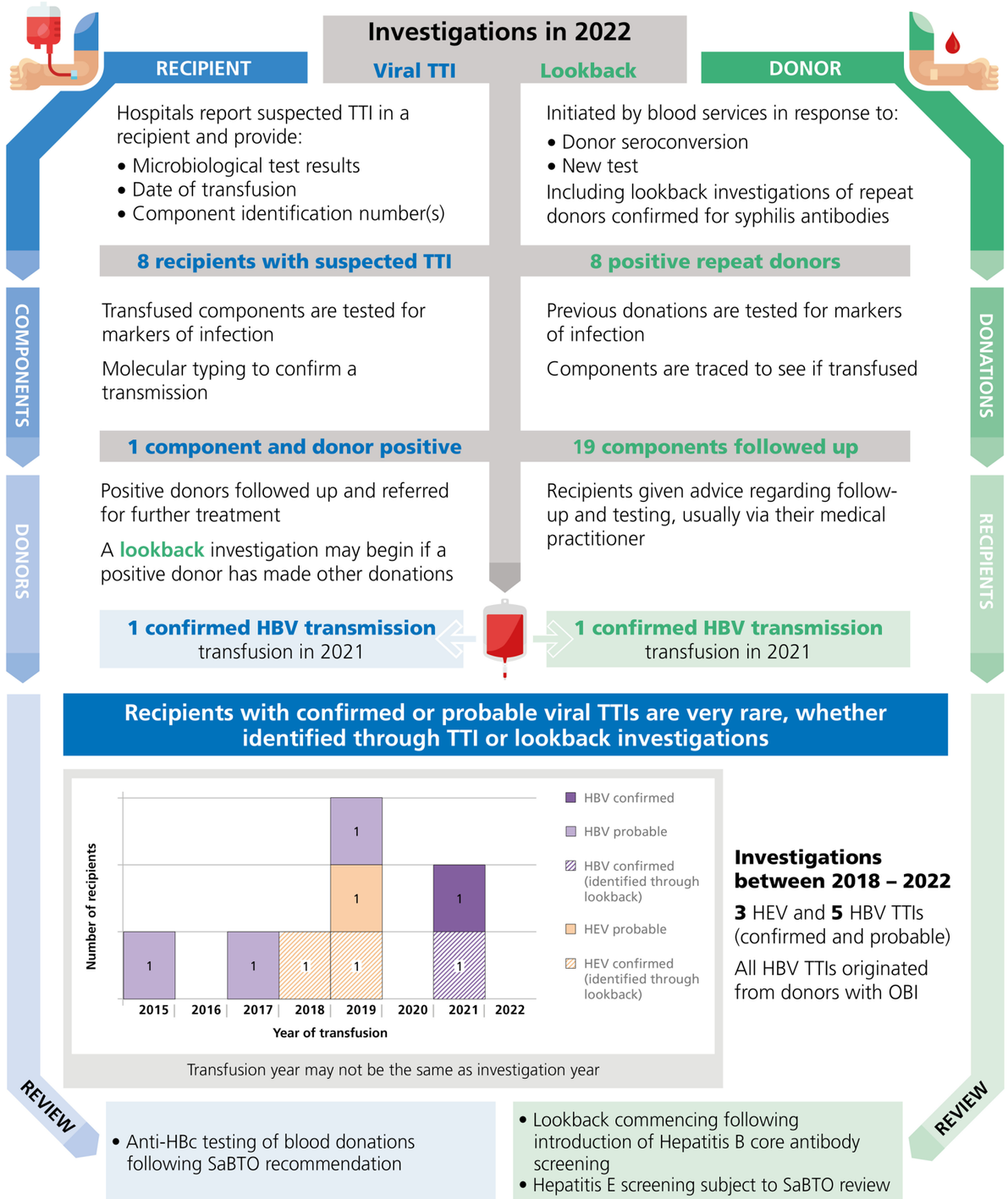
Viral transfusion-transmitted infection (TTI) and lookback investigations, UK 2022



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

Bacterial screening and bacterial transfusion-transmitted infections (TTI), UK 2022

Very low rates of bacterial contamination confirmed in platelets, with a small number of clinically relevant bacteria identified

Platelet donations have been screened for bacterial infections since 2011 in England, the last of the UK countries to introduce bacterial screening of platelets. Platelets can be collected by pooling four units derived from whole blood donations or as a single-donor apheresis unit. All four countries use a large volume bacterial culture technique for screening, with differences in the sampling of platelets. For apheresis platelets Scotland and Northern Ireland sample the donation pack, but England and Wales take samples after the split into multiple packs. In 2022, as in previous years, the confirmed positive (CP) rate in pooled platelets was slightly higher than those donated by apheresis. In England, 263,514 platelet components were screened, 47% were apheresis components and 27 (0.02%) were CPs, whereas 142 (0.1%) of pooled platelets were CP. Scotland screened 17,299 components. 36% were apheresis, with 3 (0.05%) CPs in apheresis and 11 (0.1%) CP in pools. Northern Ireland screened 5378 components. 64% were apheresis platelets, with 2 (0.06%) CP and 1 (0.05%) CP in pools. Wales screened 12,606 components, 43% apheresis platelets, 2 (0.04%) CPs and 5 (0.07%) CP in pools.

In England, of the 169 CPs, 79.3% of identified isolates were either Cutibacteria (71.6%) or *Staphylococcus saccharolyticus (7.7%)*, and unlikely to be of clinical significance, 10.7% were other skin flora, 5.3% mouth/throat flora, 1.8% other and 3% gut flora. Of note was identification of *Streptococcus pyogenes*, donor had a dental abscess and required treatment, and *Streptococcus gallolyticus*, which led to the donor being referred for gastrointestinal review.

Apheresis screening, England

Apheresis platelet donations are split into smaller volume packs and sampling for screening is done after the split. This gives a lower sample to volume ratio compared with sampling the index donation, consequently increasing sensitivity of screening. Of the 27 apheresis donations confirmed positive, 16 (59%) were positive in all splits and 11 (41%) were not positive in each split. This highlights the importance of sampling after the splitting process to increase sensitivity of detection.

Most recent bacterial transfusion transmitted infection was in 2015

Screening of platelet components cannot guarantee the absence of bacterial contamination. Packs are released for issue as 'negative-to-date', which can be before bacteria have multiplied sufficiently for detection on screening. Haemovigilance systems for bacterial TTI are passive, relying on clinical colleagues to suspect and report TTI. Since bacterial screening of platelets began, there has been one confirmed TTI in 2015 involving *Staphylococcus aureus*. In 2022, there were 113 suspected bacterial TTI investigations, none of which were proven. One further investigation was concluded to be a near miss. In the near miss, the pack was identified as visually abnormal prior to transfusion, bacterial screen negative but *Staphylococcus aureus* was identified on further culture. The associated pack had already been transfused but fortunately no adverse reaction was reported. This emphasises the importance of visual inspection of units prior to transfusion.

https://www.shotuk.org/wp-content/uploads/myimages/20.-Transfusion-Transmitted-Infections-TTI-2022.pdf

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

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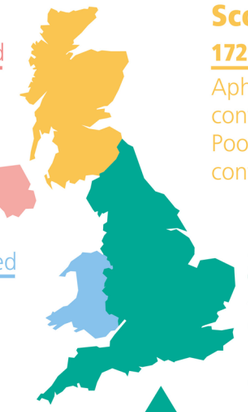
Bacterial screening and bacterial transfusion-transmitted infections (TTI), UK 2022

Very low rates of bacterial contamination confirmed in platelets, with a small number of clinically relevant bacteria identified

Northern Ireland
5378 components screened
Apheresis **64.3%**
confirmed +ve **2** (0.06%)
Pooled **35.7%**
confirmed +ve **1** (0.05%)

Scotland
17299 components screened
Apheresis **36.1%**
confirmed +ve **3** (0.05%)
Pooled **63.9%**
confirmed +ve **11** (0.10%)

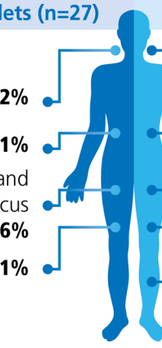
Wales
12606 components screened
Apheresis **43.0%**
confirmed +ve **2** (0.04%)
Pooled **57.0%**
confirmed +ve **5** (0.07%)



England
263514 components screened
Apheresis **47.3%**
confirmed +ve **27** (0.02%)
Pooled **52.7%**
confirmed +ve **142** (0.10%)

Apheresis platelet donations
Split into smaller volume packs.
Sampling each pack for screening increases chances of detecting very low levels of bacteria.
16: all split packs positive 59%
11: not all split packs positive 41%

Species identified from confirmed positive apheresis platelets (n=27)



Mouth/throat **22.2%**
Gut **11.1%**
Skin – Cutibacteria and *Staphylococcus* saccharolyticus **55.6%**
Other skin flora **11.1%**

Species identified from confirmed positive pooled platelets (n=142)
Mouth/throat **2.1%**
Gut **1.4%**
Skin – Cutibacteria and *Staphylococcus* saccharolyticus **83.8%**
Other skin flora **10.6%**
Other species **2.1%**

England data

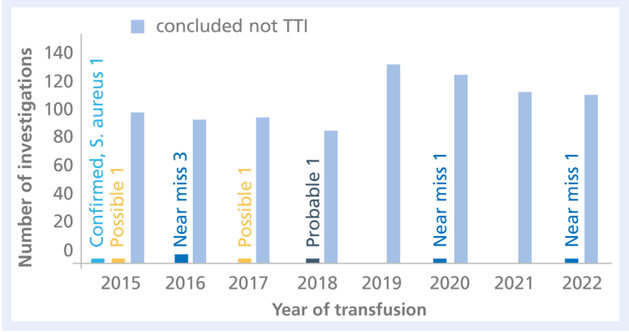
Species identified 12.4%
21 clinically relevant bacteria, and donors followed up

Most recent bacterial transfusion transmitted infection was in 2015

Since bacterial screening of platelets began in 2011, there has been **1** confirmed TTI in 2015 *(Staphylococcus aureus)*

A near miss incident is NOT a TTI: an infection in a component pack is identified before it is due to be transfused

For more details, see www.shotuk.org



2022 investigations

113 concluded not TTIs

1 near miss incident involving a unit of platelets identified via visual inspection. Other unit from the donation was already transfused with no adverse reactions

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

Creutzfeldt-Jacob disease (CJD) surveillance, UK 1997 to 2022

CJD surveillance in transfusion medicine ongoing since 1997

Aims and process

The Transfusion Medicine Epidemiology Review (TMER) is a collaborative project set up in 1997 and funded by the Department of Health and Social Care, between UK National CJD Research and Surveillance Unit (NCJDRSU) and UK Blood Services (UKBS) to look for evidence of CJD transfusion-transmission.

The NCJDRSU notifies UKBS of all CJD cases who are old enough to have donated blood or CJD cases reported to have received a blood transfusion within the UK. These can be variant, sporadic or genetic cases. UKBS search for a donor record and if they were a donor, if any units issued. In-date units are recalled. UKBS then ask hospitals to search for recipients of issued units. In the reverse search, the hospital identifies units received by a CJD case who had a transfusion. UKBS then identify the donor who provided the transfused units. UKBS send a list of recipients and donors to NCJDRSU for flagging. NCJDRSU are then notified of the cause of death. A link is made if CJD develops in a recipient of a unit from or in a donor to a CJD case.

2022 surveillance activity

In 2022 the NCJDRSU notified 79 sporadic CJD cases to UKBS, 71 for donor search to identify any recipients and 8 transfused cases for a unit search to identify the donors. No sporadic CJD cases have been linked to transfusion to date.

Variant CJD risk assessment downgraded followed by review of safety measures

Key dates for surveillance and safety measures

The TMER was set up in 1997 to look for evidence of CJD transfusion-transmission. The TMER identified that between 1996 and 1999, non-leucodepleted red cell units from 3 donors likely transmitted vCJD to 4 recipients: the links were made in 2003, 2004 and 2006 after three recipients developed confirmed vCJD and one pre-symptomatic recipient was identified at post-mortem. The implicated transfusions were prior to the introduction of leucodepletion in 1999 to mitigate the risk of vCJD. Other safety measures include importation of plasma for medicines from 1999; transfusion deferral introduced in 2004 for donors as additional risk-reduction as part of general vCJD prevention measures, with surgical precautions not usually required. Also, from 2004 plasma was imported for recipients born after 1 January 1996. The most recent vCJD case was notified to the UKBS in 2016 and was not found to be a donor.

Key dates for risk assessment and review

In 2018, the UK vCJD risk assessment was downgraded after the vCJD outbreak was smaller than originally predicted at 178 cases with no vCJD TTI after 1999. In 2019 the UKBS stopped importing plasma for recipients born after January 1996. In 2021 plasma for medicine collection re-started in the UK following the Medicines and Healthcare products Regulatory Agency (MHRA) review of safety of UK plasma for manufacture of immunoglobulins, with albumin added in 2023.

In 2022 both the Food and Drug Administration (FDA) in the United States and the Australian Red Cross Lifeblood announced the removal of their blood donor deferral for people who had spent time in the UK between 1980 and 1996 with the FDA also removing the deferral for people who have received a transfusion in the UK since 1980. A SaBTO working group was set up to review UK CJD measures and is awaiting the outcome of the appendix study.

https://www.nhs.uk/conditions/creutzfeldt-jakob-disease-cjd/
https://www.cjd.ed.ac.uk/projects/transfusion-medicine-epidemiology-review-tmer

Sources: data supplied to NHSBT UKHSA Epidemiology Unit by NCJDRSU, UK blood services and UK hospitals

Safe Supplies 2022: monitoring safety in donors and recipients
Joint working between NHS Blood and Transplant and UK Health Security Agency

Creutzfeldt-Jacob disease (CJD) surveillance, UK 1997 to 2022

CJD surveillance in transfusion medicine ongoing since 1997

Aims and process

The Transfusion Medicine Epidemiology Review (TMER) is a collaborative project between UK National CJD Research and Surveillance Unit (NCJDRSU) and UK Blood Services (UKBS) to look for evidence of CJD transfusion-transmission

NCJDRSU notifies UKBS of CJD cases, variant, vCJD or sporadic, sCJD or genetic, gCJD

UKBS search for a donor record and if any units issued, in-date units recalled

Hospitals search for recipients of issued units

UKBS send list of recipients and donors to NCJDRSU for flagging. NCJDRSU then notified of cause of death

Hospital identifies units received by a CJD case who had a transfusion

UKBS identify donor who provided transfused units

Link made if CJD develops in a recipient of a unit from or in a donor to a CJD case

2022 surveillance activity

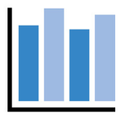
79 sporadic CJD cases notified to UKBS:
71 for a donor search to identify any recipients
and **8** transfused cases for unit search to identify the donors

No sporadic CJD cases have been linked to transfusion to date

Variant CJD risk assessment downgraded followed by review of safety measures

Key Dates:

Surveillance and safety measures



Risk assessment and review

1997	**TMER set up to look for evidence of CJD transfusion-transmission**
1996 to 1999	Non-leucodepleted red cell units from **3** donors transmit vCJD to **4** recipients: links made in 2003, 2004, 2006 when recipients diagnosed with vCJD
1999	Introduction of leucodepletion to mitigate risk of vCJD Importation of plasma for medicines
2004	Transfusion deferral for donors as an additional risk-reduction measure Plasma imported for recipients born on or after 1 January 1996
2016	Most recent vCJD case notified to UKBS, not found to be a blood donor
2018	UK vCJD risk assessment downgraded: the vCJD outbreak was smaller than predicted at **178** cases with no vCJD TTI after 1999
2019	UKBS stop importing plasma for recipients born after January 1996
2021	Plasma for medicine collection re-started in the UK following MHRA review
2022	USA and Australia among others remove their UK residency donor deferral and USA also remove transfusion deferral SaBTO working group set up to review UK CJD measures

Sources: data supplied to NHSBT UKHSA Epidemiology Unit by NCJDRSU, UK blood services and UK hospitals

The Human T-cell Lymphotropic Virus (HTLV) National Register in collaboration with Imperial College Healthcare NHS Trust, UK 2022

Donation screening: an opportunity to establish the UK's HTLV National Register, the first of its kind in Europe

HTLV is uncommon in the UK, with increased risk associated with birth in an endemic country. People with HTLV are expected to have a 5% to 10% chance of developing severe disease such as Adult T-cell leukaemia/lymphoma (ATLL) or HTLV Associated Myelopathy (HAM), but data are lacking from non-endemic countries like the UK. Anti-HTLV screening of blood, tissue and cell donations began in 2002, and identified people without symptoms. These donors with HTLV were identified by the blood services and invited to participate in the HTLV National Register to inform public health about onset and progression of HTLV associated disease. Other people affected by HTLV attending HTLV specialist clinics were also invited. The HTLV National Register is a collaboration between UKHSA, NHSBT and Imperial College, London. It is the first prospective study of its kind in Europe.

Recruitment to the HTLV National Register began in 2003

Recruitment by clinical staff at blood services and HTLV specialist clinics began in July 2003. Initially this included adults with HTLV at different stages of disease, along with close contacts and other people without HTLV. However, from 2013 recruitment focused on symptom-free adults with HTLV to understand more about disease progression. With consent, clinical staff report participant's details of diagnosis, clinical history, and demographics. Participants are asked to complete a baseline health questionnaire, and a follow up questionnaire every 2-3 years. The first follow up was in 2005, and the last, follow up 8, was in 2022.

So far 293 people affected by HTLV have taken part including 128 donors

Since July 2003, 293 people have consented to participate; 128 donors with HTLV, 9 recipients of blood transfused before screening and 156 clinic attendees. Most participants have HTLV-1 (n=254); 13 have HTLV-2, 3 HTLV type undetermined and 24 were without HTLV. Three quarters are female (74%), 43% are Black Caribbean, and the mean age of participants is 49 years. By the end of 2022, 241 participants remained on the register, 33 participants had died, and 12 were lost to follow-up or requested no further contact. None of the deaths were known to be associated with HTLV. Recruitment of people with HTLV and without symptoms continues.

Participants providing health information in up to 8 follow-ups showed onset of severe disease to be rare

Responses to baseline health information has been provided by 72% of participants, and 64% have returned at least 1 of 8 follow-up questionnaires. A total of 190 participants with HTLV infection who were asymptomatic at recruitment have returned 658 questionnaires. Their responses across 1638 person years of follow up indicate that onset of HAM-like symptoms to be rare at 1%, and overall, their self-perceived quality of life assessed using standardised questions was good.

The most recent information provided by participants in follow up 8 included views on potential HTLV antenatal screening to reduce the risk of vertical transmission. There have been no surveys regarding the acceptability of screening, and this information was sought to inform the latest HTLV antenatal screening review. Among 99 respondents, 95% indicated their support for screening despite acknowledging this could cause moderate anxiety. However, responders were not representative of pregnant people so this may not reflect the views of people who would be potentially affected by screening.

https://view-health-screening-recommendations.service.gov.uk/htlv/

Sources: The HTLV National Register

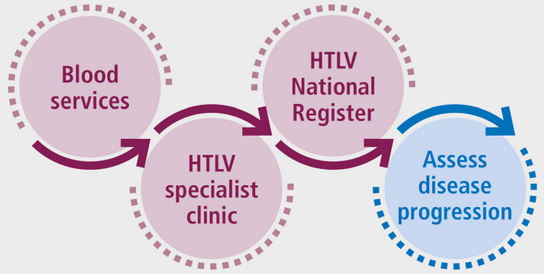
Safe Supplies 2022: monitoring safety in donors and recipients
Joint working between NHS Blood and Transplant and UK Health Security Agency

The Human T-cell Lymphotropic Virus (HTLV) National Register in collaboration with Imperial College Healthcare NHS Trust, UK 2022

Donation screening: an opportunity to establish the UK's HTLV National Register, the first of its kind in Europe

HTLV National Register

A unique cohort to inform public health



- HTLV is uncommon in the UK
- **5-10%** chance of developing severe disease: ATLL or HAM
- Blood donations screening introduced in 2002 identifying people without symptoms
- Donors with HTLV, and HTLV specialist clinic attenders invited to participate in the HTLV National Register

Recruitment to the HTLV National Register began 2003

- Consent for clinical staff to give details of diagnosis, clinical history, and demographics
- Participants self report health and wellbeing information
- Follow-up every 2-3 years

Follow Ups

1st in 2005	2nd in 2007	3rd in 2010	4th in 2013	5th in 2015	6th in 2017	7th in 2019	8th in 2022

293 people affected by HTLV have taken part

Blood services — **128** donors with HTLV:**116** donors HTLV-I, **11** donors HTLV-2, **1** type undetermined, **5** recipients with HTLV and **4** recipients without

HTLV clinics — **137** with HTLV: **133** HTLV-I, **2** HTLV-2, **2** type undetermined and **19** close contacts without HTLV

74% female Mean age 49 years

43% Black Caribbean

Participants providing health information in up to 8 follow-ups showed onset of severe disease rare

Self reported health information collected

Responses to baseline questionnaires

72%

Responses to at least **1** follow up questionnaire

64%

190 asymptomatic participants with HTLV

Provided **658** baseline or follow up questionnaires approximating to **1638** person years of follow up

- Onset of HAM symptoms rare **(1%)**
- Self perceived quality of life was good

Follow up 8 asked for views on HTLV screening in pregnancy

To inform antenatal screening review

- **99** respondents, **95%** indicated their support despite acknowledging this could cause moderate anxiety
- Responders were not representative of pregnant people

HTLVregister@ukhsa.gov.uk for further information

Sources: The HTLV National Register

Deceased organ donor surveillance in the UK and tissue surveillance in England, 2022

Deceased organ donor surveillance, UK 2022

Organ donation increased in 2022 but not back to pre-pandemic levels

After a comprehensive assessment of the donor's health and clinical history, 81% of the 1744 consented to donate became actual donors (1413) with at least one organ retrieved. 95% of actual donors became utilized donors (1345) with their organ(s) transplanted. There was a small increase in organ donation from 2021 to 2022 with 2% more people consented, 5% more actual donors and 6% more utilised donors. Organ donation is continuing to recover from the disruption of the COVID-19 pandemic in 2020, before which there were over 2000 deceased organ donors consented each year.

Consented donors are tested for pathogen reactivity

Blood samples from potential consented donors are tested for markers of infection. Before an organ is retrieved, donors are tested for: hepatitis B virus surface antigen (HBsAg); combined antibody and antigens for HIV; and antibodies to hepatitis B core, hepatitis C virus (HCV), human T cell lymphotropic virus (HTLV), *Treponema pallidum* (syphilis), *Toxoplasma gondii, cytomegalovirus* (CMV) and Epstein-Barr virus (EBV). All potential consented donors are tested for SARS-CoV-2 RNA in respiratory specimens. After donation, hepatitis E virus (HEV) RNA testing occurs. Depending on exposure risk criteria, including travel history, some donors are tested for antibodies to malaria, *Trypanosoma cruzi*, and West Nile Virus (WNV) RNA. Hepatitis B virus (HBV), HCV and HIV nucleic acid testing (NAT) depend on initial reactivity from hospital-based testing and history of increased risk behaviour.

In 2022, 1744 donors were screened. The most detected markers were for CMV (799) and EBV (1567), both circulate widely in the general population. Of the other main viruses screened for, HCV was the most common (19). There were also 2 HIV, 6 HBV, 2 HTLV and 5 HEV reactive results. No donor-derived transmissions were documented in this period.

Living and deceased tissue and cord blood donor surveillance, tested by NHSBT 2022

NHSBT manage living and deceased tissue donors, and cord blood donors to a similar protocol as blood donors. The 3-month deferral of people with increased risk sexual partners including MSM remained in place in 2022, and testing is by individual NAT.

Living tissue donors give femoral heads when undergoing elective primary hip replacement and generally have only one opportunity to give. In 2022, 372 people donated surgical bone with 3 positive for markers of infection. There were 11 positives over the last five years (2018 to 2022), approximating to a rate of 521 per 100,000 donors which was 4.3 times the rate in new blood donors.

Deceased tissue donors give bone, skin, heart valves, corneas, and tendons and are generally older than blood donors. In 2022, there were 2236 donors and 15 were positive for markers of infection. There were 59 positives over the last five years (2018 to 2022), approximating to a rate of 419 per 100,000 donors which was 3.4 times the rate in new blood donors.

Cord blood collection targets ethnically diverse populations around London to ensure a diverse supply. Donors are expected to have been routinely screened for markers of HBV, HIV and syphilis, and sometimes HCV, during antenatal testing. In 2022, there were 90 cord blood donors. No cord blood donor was found positive for markers of viral or syphilis infections, however, 2 were positive for malaria. Over the 5 years from 2018 to 2022 there were 3 HBV and 3 syphilis positives, approximating to 296 per 100,000 donors which was 2.4 times the rate in new blood donors. There was no evidence of recently acquired infections. Syphilis antibodies detected likely reflected past infections; they gave low reactivity on testing, likely below the cut-off for antenatal screening.

Sources: Data supplied to NHSBT UKHSA Epidemiology unit by Organ Donation and Transplantation

Safe Supplies 2022: monitoring safety in donors and recipients
Joint working between NHS Blood and Transplant and UK Health Security Agency

Deceased organ donor surveillance in the UK and tissue surveillance in England, 2022

Deceased organ donor surveillance, UK 2022

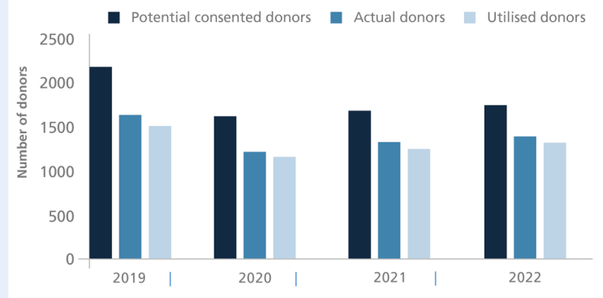
1744
Potential consented

1413 (81%)
Actual

767 (54%)
Brain stem death

646 (46%)
Circulatory death

1345 (95%)
At least one organ transplanted



Organ donation increased in 2022, but not back to pre-pandemic levels in 2019.

2022 v 2021
+2% consented
+5% actual
+6% utilised

Consented donors are tested for certain markers of infection

Before donation:
- HBsAg and HIV antigen
- Antibodies to: HIV, hepatitis B core, HCV, HTLV, *Treponema pallidum* (syphilis), *Toxoplasma gondii*, CMV and EBV
- SARS-CoV-2 RNA in respiratory samples

After donation:
- HEV RNA
- Criteria dependent: malaria, *Trypanosoma cruzi* antibodies, and West Nile virus RNA
- Additional: HBV, HCV and HIV NAT

Number of documented transmissions in 2022: **0**

Living and deceased tissue and cord blood donor surveillance, tested by NHSBT 2022

NHSBT manage living and deceased tissue donors, and cord blood donors to a similar protocol as blood donors. The 3-month deferral of people with increased risk sexual partners including MSM remained in place in 2022, and testing is by individual NAT.

Living surgical bone
Low in number, rarely positive for markers of infections

2022
1 HCV, **1** HBV and **1** syphilis positives

2018 to 2022
11 positives
521 per **100,000**
4.3 x rate of virus and syphilis in new blood donors

Deceased tissue
Donors are donating bone, skin, heart valves, corneas, and tendons

2022
6 HBV, **2** HCV, **1** HEV and **6** syphilis positives

2018 to 2022
59 positive
419 per **100,000**
3.4 x rate of virus and syphilis in new blood donors

Cord blood donors
Ethnically diverse population targeted

2022
90 donors
No viral or syphilis positives

2018 to 2022
3 HBV and **3** syphilis
296 per **100,000**
2.4 x rate of virus and syphilis in new blood donors

Sources: Data supplied to NHSBT UKHSA Epidemiology unit by Organ Donation and Transplantation

UK Health Security Agency

NHS Blood and Transplant

Publications

Peer review publications and awards from the NHSBT/UKHSA Epidemiology Unit, 2022

Harvala H, **Reynolds C**, Ijaz S, Maddox V, Penchala SD, Amara A, Else L, **Brailsford S**, Khoo S. Evidence of HIV pre-exposure or post-exposure prophylaxis (PrEP/PEP) among blood donors: a pilot study, England June 2018 to July 2019. Sex Transm Infect. 2022 Mar;98(2):132-135.

Saeed S, Uzicanin S, Lewin A, Lieshout-Krikke R, Faddy H, Erikstrup C, Osiowy C, Seed CR, Steele WR, **Davison K**, Custer B, O'Brien SF; Surveillance Risk Assessment and Policy (SRAP) Sub-group of the Transfusion Transmitted Infectious Diseases Working Party of the International Society of Blood Transfusion. Current challenges of severe acute respiratory syndrome coronavirus 2 seroprevalence studies among blood donors: A scoping review. Vox Sang. 2022 Apr;117(4):476-487.

Ferguson E, Dawe-Lane E, Khan Z, **Reynolds C, Davison K,** Edge D, **Brailsford SR**. Trust and distrust: Identifying recruitment targets for ethnic minority blood donors. Transfus Med. 2022 May 2.

Reynolds CA, Yawitch T, Hewitt PE, Harvala H. Blood donor notification of variant Creutzfeldt-Jakob disease risk: Lessons in communicating donor deferral and risk.Transfus Med. 2022 June 24.

Harvala H, **Reynolds C**, Fabiana A, Tossell J, Bulloch G, **Brailsford S,** Blackmore S, Pomeroy L. Lessons learnt from syphilis-infected blood donors: a timely reminder of missed opportunities. Sex Transm Infect. 2022 Jun;98(4):293-297

Harvala H, **Reynolds C, Brailsford S, Davison K**. Fulminant Transfusion-Associated Hepatitis E Virus Infection Despite Screening, England, 2016-2020. Emerg Infect Dis. 2022 Sep;28(9):1805-1813

O'Brien SF, Drews SJ, Lewin A, Russell A, **Davison K**, Goldman M; International Society for Blood Transfusion, Transfusion Transmitted Infectious Disease Working Party, Surveillance, Risk Assessment & Policy Sub-group. How do we decide how representative our donors are for public health surveillance? Transfusion. 2022 Dec;62(12):2431-2437.

Awards

Susan Brailsford, Katy Davison, Claire Reynolds and Eamonn Ferguson on behalf of FAIR Steering Group. NHS Blood and Transplant Executive Team's Global Impact Award - NHSBT's Together Awards

Susan Brailsford Kenneth Goldsmith Award for original research within the field of blood transfusion together with contributions to blood transfusion in general – British Blood Transfusion Society

Ruth Wilkie Margaret Kenwright Award for individuals under 40 with the highest scoring abstract in their chosen category – British Blood Transfusion Society

Katy Davison, Claire Reynolds, Nick Andrews and **Susan Brailsford** on behalf of UK Blood Donor Survey Steering Group. Best paper Prize in Vox Sanguinis – International Society of Blood Transfusion.

Glossary

Anti-HBc	Antibody to hepatitis B core antigen, also referred to as hepatitis B core antibody
CJD	Creutzfeldt-Jacob Disease
DNA	Deoxyribonucleic acid
EVB	Epstein-Barr virus
EIR	Emerging Infections Report
FAIR	For the Assessment of Individualised Risk
GBMSM	Gay and bisexual men who have sex with men
gCJD	Genetic Creutzfeldt-Jacob disease
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HEV	Hepatitis E virus
HIV	Human immunodeficiency virus
HTLV	Human T-cell lymphotropic virus
JPAC	Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee
MHRA	Medicines and Healthcare products Regulatory Agency
NAT	Nucleic acid testing
NCJDRSU	National Creutzfeldt-Jacob Disease Research and Surveillance Unit
NHSBT	NHS Blood and Transplant
OBI	Occult hepatitis B infection
PTR	Post transfusion reaction
RNA	Ribonucleic acid
SaBTO	Advisory Committee for the Safety of Blood, Tissues and Organs
SACTTI	Standing Advisory Committee on Transfusion Transmitted Infections
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
sCJD	Sporadic Creutzfeldt-Jacob disease
SHOT	Serious Hazards of Transfusion
TMER	Transfusion Medicine Epidemiology Review
TP	*Treponema pallidum*
TTI	Transfusion-transmitted infection
UKBS	UK Blood Services
UKHSA	UK Health Security Agency
vCJD	Variant Creutzfeldt-Jacob disease
WNV	West Nile virus