UK Health Security Agency

NHS Blood and Transplant

Data sources and methods 2024

NHS Blood and Transplant and UK Health Security Agency

Contents

The aim of the NHS Blood and Transplant (NHSBT) and UK Health Security Agency (UKHSA) Epidemiology Unit is to monitor infections in blood, tissue and cell, and organ donors and recipients and to use this information to inform blood safety.

This document provides more detailed information on the data sources and methods used in each of the surveillance schemes run by the NHSBT and UKHSA Epidemiology Unit. It can be read in conjunction with the annual review.

The surveillance schemes can be modified to incorporate any changes to testing, such as the introduction of a new test, or when new data need to be gathered. These schemes are continually monitored to ensure high quality data is consistently collected.

Data is regularly published reports for different groups. The main reports include:

- monthly blood donation testing reports for UK Blood Services
- monthly confirmed positive donation dashboard for UK Blood Services
- monthly emerging infections report (EIR) for SACTTI/JPAC
- monthly and quarterly bacterial screening of platelets report for UK Blood Services
- quarterly confirmed positive donation report for Microbiology Services Clinical Group
- transfusion transmitted infections chapter in the Serious Hazards of Transfusion (SHOT) annual report
- blood donor sections for the UKHSA annual reports on HBV, HCV, HIV and syphilis
- annual residual risk estimates for Joint United Kingdom Blood Transfusion Services Professional Advisory Committee (JPAC)
- annual NHSBT/UKHSA review (all surveillance schemes)

The surveillance schemes are also described on the UKHSA website - Blood, tissue and organ donors: surveillance schemes

Donated blood, tissues and cells are collected by the UK Blood Services from volunteer adults who do not acknowledge any medical condition, travel history or behaviour that is known to be associated with an increased risk of blood borne infections. The donor selection guidelines are available on the Transfusion Guidelines website

Data are provided by the four UK Blood Services and the Republic of Ireland. For England this is NHS Blood and Transplant (NHSBT), for Northern Ireland this is the Northern Ireland Blood Transfusion Service (NIBTS), for Scotland it is the Scottish National Blood Transfusion Service (SNBTS), and for Wales it is the Welsh Blood Service (WBS).

UKHSA is an executive agency of the Department of Health and Social Care. It is responsible for planning, preventing and responding to external health threats, and providing intellectual, scientific and operational leadership at national and local level, as well as on the global stage.

Document last updated 20 October 2025.

Return to Table of Contents

Blood donor surveillance

Blood donor data is collected by the NHSBT and UKHSA Epidemiology Unit through two parallel schemes: blood donation testing and donors confirmed with markers of infection. Both surveillance schemes started in October 1995. The information is used to monitor donation testing reactive rates and blood donors with confirmed markers of infection. Additional denominator data providing more detailed information on the profile of whole blood donors making a donation by year is also gathered.

Blood donation testing

Background

Blood donations have been tested for infections since the 1940s when testing for markers of treponemes indicating syphilis (or other disease such as yaws or pinta that are also caused by Treponema) first began. Since then, screening for other blood-borne infections has been introduced as follows:

Hepatitis B virus (HBV)
Screening donations for hepatitis B surface antigen (HBsAg) began in 1972. HBV DNA testing began on 1 April 2009 in Filton as a by-product of the introduction of triplex nucleic acid test (NAT) testing. HBV DNA testing was subsequently introduced at Manchester on 10 August 2009 and Colindale on 3 December 2009, when all donations in England were HBV DNA tested. HBV DNA testing began on 27 April 2009 in the Republic of Ireland and 1 June 2009 in Wales. Scotland and Northern Ireland began HBV DNA testing on 22 March 2010. Hepatitis B core antibody (anti-HBc) testing was rolled out in 2022 across the UK: England (31 May), Northern Ireland (29 May), Scotland (5 April) and Wales (27 May) with the aim of screening all donors at least once as recommended by SaBTO to supplement current screening procedures. Scotland had capacity from the start to screen all current donors once, then donations from new and returning donors; Northern Ireland and Wales screen all donations; England's capacity to screen all donations increased with time with anti-HBs testing also performed; 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 reactive donation samples 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. Republic of Ireland had already been screening all donations for anti-HBc prior to 2022.

Human Immunodeficiency Virus (HIV)
Donation screening for antibodies to HIV (anti-HIV) began in 1985. Some England centres started using combined antigen-antibody screening for HIV (HIV Ag/Ab) in 2001 with all using HIV Ag/Ab by the end of 2005. Wales and Scotland started using HIV Ag/Ab in January and May 2005 respectively. Northern Ireland and Republic of Ireland Blood Transfusion Services introduced

combined Ab/Ag testing in 2011 and 2016 respectively. Although not mandatory, HIV RNA testing has been introduced as a by-product of duplex NAT and subsequently triplex assays. HIV RNA testing was introduced in Scotland and Northern Ireland in 2002 and some parts of England and Wales from November 2003 but did not become universal until 2007.

Hepatitis C virus (HCV)

Donation screening for antibodies to hepatitis C virus (anti-HCV) began in 1991. HCV RNA testing was introduced on a pilot basis in April 1999 and became a mandatory test carried out on all blood donations from 2002.

NAT pool sizes

UK pool sizes were 96 prior to 2000. For England and Wales between 2000 and 2009 pool sizes were 48. Pools of 24 were used as the triplex NAT was rolled out in 2009. Scotland used pool sizes of 96 between 1 July 1999 and 21 March 2010 after which pools of 24 were used. Republic of Ireland tested in pools of 8 until 27 April 2009 when singleton testing was used. NHSBT commenced NAT testing for Isle of Man on 24 July 2020 and Guernsey on 3 October 2023.

Human T-cell lymphotropic virus I and II (anti-HTLV)

Testing for antibodies to human T-cell lymphotropic virus I and II (anti-HTLV) was piloted in Scotland in 2000 and started UK-wide in 2002. Testing in the UK was conducted in pools until 2013 when singleton testing was implemented in England from 27 February 2013. Scotland switched to singleton testing in 2015, Northern Ireland in 2016 and Wales switched in 2018. Republic of Ireland used singleton testing from 2002. In January 2017, NHSBT tested donations from new donors and donations used for non leucodepleted blood components. From 5 April 2022 SNBTS also changed to testing new donors and donations used for non-leucodepleted products for HTLV. In addition, any repeat donors who advise of a sexual contact with a HTLV positive person since their initial HTLV test are tested. Every donation is tested for HTLV in Northern Ireland and Wales.

Table 1 - Anti-HTLV screening

	Pools 48 donations	Pools 24 donations	Single samples - all donations	Single samples - selected[1]	Assay(s) used
England	August 2002-March 2009	April 2009-February 2013	February 2013–December 2016	January 2017 onwards	2002–2013: Abbott Murex HTLV I+II 2013–2023: Abbott Prism HTLV-I/HTLV-II
Guernsey	N/A	N/A	March 2002 - February 2024 [Testing done by NHBST from March 2024 to the present]	N/A	2002-February 2013: ORTHO HTLV-I/HTLV-II November 2012-February 2013: DiaSorin Murex HTLV I and II February 2013-October 2015: Biokit Bioelisa HTLV-I+II November 2015-February 2024: Roche HTLV I/II Elecsys and Cobas
Isle of Man	N/A	N/A	October 2002-present	N/A	October 2002-March 2004: BIORAD HTLV-I NEW March 2004-September 2010: BioRad/Genlabs HTLV I/II ELISA October 2010-October 2016, December 2016-November 2020: Abbott Architect HTLV I/II November 2016: Abbott Prism HTLV-I/HTLV-II November 2020-present: Roche HTLV I/II Elecsys and Cobas
Northern Ireland	[NIBTS HTLV testing performed by Scotland between August 2002 – December 2012]	December 2012–March 2016	March 2016 onwards	N/A	December 2012–March 2016: Abbott Murex HTLV I+II March 2016-present: Abbott Architect HTLV I/II
Republic of Ireland	N/A	N/A	November 1996–February 2024	February 2024–present	November 1996–June 1997: Abbott Commander June 1997–September 2018: Abbott Prism HTLV-I/HTLV-II October 2018–present: Abbott Alinity s HTLV
Scotland	January 2000-February 2012	March 2012-February 2015	March 2015-March 2022	April 2022 onwards	January 2000–March 2015: Murex GE80/81 March 2015-February 2020: Abbott Prism HTLV-1/HTLV-II February 2020–present: Abbott Alinity s HTLV
Wales	[Until July 2009 testing performed by NHSBT]	July 2009 - October 2018	October 2018 - present	N/A	2009-October 2018: (pool testing): Abbott Murex HTLVI+II October 2018-present (individual testing) : Abbott Alinity s HTLV

[1] Donations from first-time donors and those used for non-leucodepleted components.

Hepatitis E virus (HEV)
Donation screening for HEV RNA was introduced in 2016 on a proportion of donations in order to supply HEV-screened components for specific patient groups. However, following review, the four UK blood services began universal HEV screening in 2017, with SNBTS and WBS starting in March 2017, NHSBT in April 2017 and NIBTS in May 2017, in pools of 24. WBS began individual donation NAT for HEV on apheresis platelets in November 2022, whilst SNBTS and NIBTS started from April 2024 and November 2024 respectively. Pooled platelets and red cells are still HEV screened in minipools of 16 in SNBTS and NIBTS, WBS continues to also test apheresis donations in single samples with pooled platelets and red cells screened in pools of 16. NHSBT tests all donations for HEV in minipools of 24.

NHSBT stopped collecting positive blood donor ID forms for HEV in August 2023 but still collects and stores donor demographic data in its donor management system PULSE.

Hepatitis A virus (HAV) and parvovirus B19
Scotland began screening all donations for HAV and B19 in pools of 96 from July 2024. NHSBT frozen stored Plasma for Medicine donations were also HAV and B19 tested in preparation for release to the fractionator (see Plasma section below).

Table 2: Tests performed on blood donations within the UK blood services in 2024 by country

2024 blood services tested for	England	Guernsey	Isle of Man	Northern Ireland	Republic of Ireland	Scotland	Wales
HBsAg	yes	yes	yes	yes	yes	yes	yes
HBV DNA	yes	no	no	yes	yes	yes	yes
Anti-HBc	yes	no	no	yes	yes	yes	yes
Anti-HCV	yes	yes	yes	yes	yes	yes	yes
HCV RNA	yes	no	no	yes	yes	yes	yes
HEV RNA	pools 24	by NHSBT	by NHSBT	pools16 or singles for apheresis	singles	pools16 or singles for apheresis	pools 16 or single for apheresis
Combined HIV Ab/Ag	yes	yes	yes	yes	yes	yes	yes
HIV RNA	yes	no	no	yes	yes	yes	yes
Anti-HTLV	new and non-leuco depleted	yes	yes	yes	yes	new and non-leuco depleted	yes
Anti-treponeme	yes	yes	yes	yes	yes	yes	yes

In 2024, all donations were screened for HBV using HBsAg and HBV DNA screening performed in pools of 24 for the UK blood services (UKBS), and in singletons for Republic of Ireland

In 2024, all donations were screened for HCV using anti-HCV and HCV RNA screening performed in pools of 24 for UKBS, and in singletons for Republic of Ireland

In 2024, all donations were screened for HIV using combined HIV Ab/Ag assay and HIV RNA screening performed in pools of 24 for UKBS, and singletons for Republic of Ireland.

In 2024, donations were screened for HTLV antibodies as follows: anti-HTLV screening performed on new and non-leucodepleted donations in England and Scotland; anti-HTLV screening performed on all donations in Wales, Northern Ireland, Republic of Ireland, Guernsey and Isle of Man.

In 2024, all donations were screened for treponemal antibodies indicating syphilis including treated past infections as well as some non-sexually acquired treponemal infections such as Yaws and Pinta, rarely seen in the UK.

In 2024, all whole blood donations were screened for HEV RNA performed in pools of 24 for England, in pools of 16 for Northern Ireland, Scotland and Wales, and individually for Republic of Ireland. England screened apheresis donations in pools of 24 while individual apheresis donation samples were tested by Wales (from November 2022), Northern Ireland (from November 2024) and Scotland (from April 2024). Wales do not perform confirmatory testing for HEV RNA. England performed HEV RNA screening for the Isle of Man and Guernsey.

Jersey outsourced their donation testing in 2018 due to laboratory refurbishment and have not resumed reporting.

Plasma

In 2020 and 2021 the UK blood services collected convalescent plasma from recovered coronavirus patients for use in treatment trials. These donations were subject to the same screening and additional testing requirements as blood and apheresis donations with additional SARS-CoV-2 antibody testing. Donations in England were mainly collected via plasmapheresis.

NHSBT began collecting plasma for medicine (PFM) from April 2021. These PFM donations were subject to the same donation screening and additional testing requirements as blood and apheresis donations. Testing for Hepatitis A virus (HAV) and Parvovirus B19 began in March 2024 first on the frozen donations previously collected.

Additional testing

Other additional (discretionary) tests may be performed including the detection of antibodies to

hepatitis B core antigen (anti-HBc), malaria (2001) and *Trypanosoma cruzi* (Chagas disease, 1998) and nucleic acid testing (NAT) for West Nile virus (WNV, 2012). These tests are only performed if information given by the donor suggests that they may have been at risk for these infections.

Anti-HBc testing was previously performed for donations from donors reporting a recent piercing (for example acupuncture, ear, or body piercing and or tattooing), inoculation incident, flexible endoscopy, or history of jaundice or HBV infection. At the end of November 2017, anti-HBc testing ceased for donors with recent endoscopy, piercing and complementary therapies (for example acupuncture). All donors are now screened at least once for anti-HBc from April 2022 with further discretionary anti-HBc performed as required, such as donor reporting an uncertain history of HBV infection or exposure to someone with or recovered from HBV.

Malaria testing is performed where the donor reports a relevant travel history, residency or past infection. Donors are deferred for 4 months post-travel before testing up to 12 months (the deferral was shortened from 6 to 4 months in 2017). Donors are deferred for 4 months post residency before testing at any time. Donors are deferred for 3 years post treatment or malaria illness before testing at any time. Donations repeat reactive for malarial antibodies have been sent for confirmatory reference antibody testing since 30 August 2007. Donations confirmed antibody positive have been tested for malarial DNA by PCR from April 2010.

T. cruzi antibody testing was introduced in 1998. There is a 4-month deferral for rural travel, transfusion in South America or because they are of South American origin followed by testing. The deferral was shortened from 6 to 4 months in January 2021.

In 2012, WNV NAT testing of donations from donors returning from WNV affected areas was introduced in pools of 6 and replaced the temporary deferral of these donors. Wales began WNV testing in May 2024.Testing continues each year between 01 May and 30 November for affected areas as indicated in the Geographical Disease Risk Index.

Additional testing indications can be found in the donor selection guidelines on the Transfusion Guidelines website

Data collection

Aggregate data on the number of blood donations tested and the number of donations initially reactive is reported to the Epidemiology Unit donation testing scheme each month by the UK blood service's testing centres throughout the UK and the Republic of Ireland and via Scottish National Blood Transfusion Services (SNBTS) for Scottish blood centres. Disaggregate data on the number of donations repeat reactive with confirmatory testing results are also reported by centres outside England and by the NHSBT Microbiology Services surveillance team for centres in England.
The classification of new (first-time) and repeat donors used in the Epidemiology Unit donation testing scheme is made by testing centres. This classification of donations tested by donor type is

used in particular to estimate the frequency of infection and give an overview of the donations tested.

1. New donors are first-time donors who were not known to have ever donated blood to that UK blood service. New donors in the UK (excluding Scotland) and the Republic of Ireland may include ‘lapsed’ donors for instance repeat donors who have not donated for more than 2 years. In Scotland, all lapsed donors are counted as repeat donors.
2. Repeat donors for most UK centres (excluding Scotland, who include lapsed donors) and the Republic of Ireland, are donors known to have previously donated blood in the UK in the last 2 years, although not all previous donations have necessarily been tested for all markers of infection (for example anti-HTLV testing was first introduced in 2002).

Data on additional (discretionary) testing performed by NHSBT is reported monthly via the following sources:

1. Electronic Site report from Filton and Manchester testing centres
2. an electronic line listing of donations sent for anti-HBc testing along with screen results
3. an electronic list of the repeat reactive and confirmed positive malaria and *T. cruzi* cases from Microbiology Services surveillance
4. an electronic list of the reference results for samples sent for confirmatory anti-HBc testing from the Microbiology Service Laboratory (MSL)
5. characteristics of donors sent for confirmatory anti-HBc testing are collected via pro-forma from clinical teams and from PULSE

Blood donors with confirmed markers of infection

When a marker of current HBV (HBsAg or HBV DNA) (also anti-HBc in Northern Ireland and Wales), HBV, HIV, HTLV, syphilis, current malaria (DNA positive) is detected in a blood donation, the donor is offered a post-test discussion, which may be held in a blood centre or more commonly by telephone. The donor is informed of their positive test results, and the clinician explains what these test results mean and ascertains a likely source or risk factor for the infection, if possible. The clinician also discusses any infection control measures, testing and treatment of contacts and advises the donor that they will no longer be able to donate blood. Where appropriate, the donor is referred to the appropriate services for specialist care. Clinicians in blood centres in the UK and Republic of Ireland pass anonymised information about donors with confirmed markers of infection to the Epidemiology Unit using a standard electronic proforma. This information includes the characteristics of the donor (date of birth or age, gender, first part of postcode), details of their donating history (if any, with details of their most recent previous donation) and any behaviour that could be associated with the acquisition of markers of infection. Donors with confirmed markers of infection are classified by the Epidemiology Unit as newly tested and previously tested for the marker they are found positive for according to detailed information provided by blood centres about all or any previous donations in the UK.

The classification of donors as newly or previously tested is done by the NHSBT and UKHSA Epidemiology Unit:

1. a newly tested donor is one who has not been previously tested for the marker under consideration by the blood transfusion services included in this surveillance
2. a previously tested donor is one who has been previously tested for the marker under consideration by the blood transfusion services included in this surveillance

Note that this classification differs to that used in the donation testing scheme and donor profile data sources (described above) where the donations are classified according to whether the donor has (or has not) donated blood in the last 2 years.

The classification of a seroconverter is made by the NHSBT and UKHSA Epidemiology Unit as a repeat donor with confirmed marker of infection with either a previous negative donation within 1 year, or microbiological and or clinical evidence of recent infection AND a previous negative donation within 3 years.

Surveillance data is being continually updated as new or additional information is received. Therefore, some changes between reports may be identified. For example, the seroconverter definition was changed from previously tested within 3 years to within 1 year from 2016 onwards.

Infection status was assigned by the unit as recently acquired if there was a previous negative donation within 12 months, or if HBV NAT pick up and/or acute HBV is indicated by confirmatory tests, or if HIV NAT pick up, or HIV avidity test indicated recently acquired in the last 4 months or if HCV NAT pick up. For treponema, the clinical history was also reviewed, along with a previous negative donation within 12 months and/or IgM-positive result.

Convalescent plasma donors confirmed to have markers for infection were differentiated by a log number in order to be able to count them separately if required, CP for donations and CPS for samples. Similarly, plasma for medicine donors are differentiated by PFM in the log number.

Donor profile

Information about individuals donating blood at NHSBT centres (England and north Wales to 1 April 2016) is stored on PULSE, the NHSBT computerised donor information database. Since 1996, this information has been available to the Epidemiology Unit via two sources:

1. NHSBT testing centres

Between 1996 and 2000, the number of donations made each month by gender and age group (17 to 24, 25 to 34, 35 to 44, 45 to 54, 55 years and over) for new and repeat donors was reported to the Epidemiology Unit by 7 of the 14 testing centres in England and north Wales. The breakdown from these centres was applied to the total number of donations tested by blood

centres in the UK (excluding Scotland) and Republic of Ireland each year to derive the distribution of donations by gender and age group.

2. NHSBT Donor Insight
Between 2001 and 2006, aggregate information about individuals donating blood was available from NHSBT Donor Insight (the Market Research and Analysis Department). This information included the proportion of donations made by new and repeat donors by gender, age group (as above) and ethnic group (Asian Other, Black African, Black Caribbean, Black Other, Chinese Indian or Pakistani or Bangladeshi, Mixed, White British, White Other, Other and Not Known). This proportion was applied to the total number of donations tested by blood centres in the UK (excluding Scotland) and Republic of Ireland each year to derive the distribution of donations by gender, age and ethnic group. The data from Market Research and Analysis between 2001 and 2006 were based on a random sample of approximately 1.5 million donation records stored on PULSE.

For 2007 to 2009, data extracts were received for the month of September. These extracts were a complete dataset of every donor who donated during that month at NHSBT. Data included gender, age, donation date, date of most recent previous donation, ethnicity, postcode and new or repeat status. Region was identified using the donor postcode and mapped to strategic health authority regions, to provide more detailed geographical information.

For 2010 onwards, a PULSE extract of all individuals donating during the full year was made available to the NHSBT and UKHSA Epidemiology Unit. These data were used to determine a gender, age, and ethnicity profile of all whole blood donors making a donation. As all blood donors are included these data are able to reflect accurately the characteristics of new and repeat blood donors. In 2021 the method was adapted to include a field for donation made to differentiate PFM from whole blood and apheresis donations.

For both 1 and 2 above, individuals were classified as new donors if they had donated blood for the first time ever or if more than 2 years had elapsed since their last donation.

The NHSBT statistics unit provided data on the CVP donations and samples given on a monthly basis by male and female donors and a total age group and ethnicity breakdown for April 2020 to March 2021.

The other UK blood services have provided denominator data from 2019 to include gender and age group. Scotland and Wales also provided ethnicity from 2023.Denominators used for donation testing are:

Monthly blood and apheresis donations tested by new and repeat donors. NHSBT data included CVP donations in 2020 and 2021 and are excluded from calculations of rates. NHSBT monthly donation testing data does not include PFM where collected by plasmapheresis.

For consistency in trends from 1996 to present we apply the demographic proportions of whole blood donors donating to the new and repeat donations tested denominator to give rates by gender and age-group.

CJD surveillance

Aims and process of CJD surveillance
TMER (Transfusion Microbiology Epidemiology Review) surveillance was a collaborative project with NCJDRSU in Edinburgh and UK Blood Services (UKBS), funded by Department of Health and Social Care (DHSC) until 31 March 2025, to look for evidence of CJD transfusion-transmission. The Unit will continue to coordinate lookback for CJD cases notified to the Unit via UKHSA.

The NCJDRSU notified the Unit of CJD cases (variant, sporadic or genetic cases) who may have donated blood. The Unit then coordinated UKBS search for a donor record and any units issued; in-date units were recalled. UKBS liaised with hospitals to search for recipients of issued units. Details were returned to the Unit who sent a list of recipients to NCJDRSU for flagging to identify any history of CJD in their death records. In the reverse search NCJDRSU notified the Unit of any CJD cases reported to have received a blood transfusion within the UK. The Unit coordinated UKBS liaison with hospitals to identify units received by a CJD case who had a transfusion. UKBS identified the donor(s) who provided the transfused units and sent a list of donors to the Unit for flagging by NCJDRSU. In both the main and reverse searches, a link was made if CJD developed in a recipient of a unit from or in a donor to a CJD case. The Unit recorded the outcomes of the searches.

3 clinical and 1 asymptomatic case of transfusion-transmitted variant CJD were identified through the TMER and 167 out of 213 higher risk individuals receiving blood from or donating to vCJD cases were notified with some requiring pre-surgical assessment (see Annex J). The vCJD transfusion-transmissions occurred prior to leucodepletion safety mitigation. No further links were made; the most recent vCJD case was in 2016 and not a donor. Another highly precautionary safety step is permanent deferral for blood transfusion recipients, not to be confused with the individuals at higher risk requiring pre-surgical assessment.

Key dates for CJD surveillance and safety measures

- 1997 - CJD surveillance in transfusion medicine began.
- 1996 – 1999 - CJD surveillance identified three recipients
- 1999 – leucodepletion and importing plasma to make plasma derived products, eg factor VIII.
- 2003 – first report of vCJD case linked by TMER to transfusion.
- 2004 – TMER links pre-clinical case to transfusion.
- 2005 – donors and recipients notified they are at risk of vCJD and followed up.
- 2006 – TMER links 2 vCJD cases to transfusions.
- 2014 – 2 recipients of fractionated plasma products and red cells found to have sporadic CJD. No causal link identified.
- 2016 – last report of vCJD case in the UK, not a donor.
- 2017 – Audit identifies extra sporadic CJD cases who were donors where family did not recall the person donating blood.

- 2018 - UK vCJD risk assessment was downgraded after the vCJD outbreak was smaller than originally predicted.
- 2019 - UKBS stopped importing plasma for recipients born after January 1996.
- 2021 - Plasma for Medicine collection re-started in the UK.
- 2025 – specific Department of Health funding ceases, necessary surveillance continues.

Return to Table of Contents

Transfusion Transmitted Infections

Blood centres in England, Wales and Northern Ireland report investigations of suspected transfusion transmitted infections (TTIs) annually to the NHSBT and UKHSA Epidemiology Unit. For each report, information on the recipient, the recipient's infection, the implicated transfusion, and findings of the investigation are provided using a detailed proforma. Blood centres in Scotland report all incidents to the Microbiology Reference Unit of the SNBTS, and the details and conclusion of each case are passed to the surveillance system annually. NHSBT and UKHSA Epidemiology Unit data is reconciled with the Serious Hazards of Transfusion (SHOT) and all blood service investigations with outcomes are included in the TTI chapter in the SHOT annual report.

Definition of a transfusion-transmitted Infection
A report of an infection suspected to be due to transfusion was classified as a TTI if the following criteria were met at the end of the investigation:

- the recipient(s) had evidence of infection following transfusion of blood components, and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection

AND

Either at least one component received by the infected recipient was donated by a donor who had evidence of the same infection.

Or at least one component received by the infected recipient was shown to contain the agent of infection.

These may be identified because of infection in the recipient where transfusion is the suspected source, and a post-transfusion infection reported to the Blood Services. Alternatively, an infection in a recipient may be identified from lookback investigations which are initiated when a donation from a repeat donor is identified as having markers of infection. Archive samples are retrieved for retrospective testing, which may find a previous donation to also be positive but with markers of infection below the detection level of routine screening. In this case further work will be carried out to identify recipients.

An incident should NOT be reported if:

- the incident involved HCV, HIV or HTLV in recipients who had received transfusions in the UK prior to routine testing (September 1991 for anti-HCV, October 1985 for anti-HIV, August 2002 for anti-HTLV)
- the incident involved HTLV in a recipient identified through the HTLV National Lookback

- the incident involved a transfusion outside UK
- the incident was identified as part of the HEV study

Please note

1. the blood services are rarely able to conduct follow-up investigation of all untested donors implicated in post-transfusion HCV or HIV incidents, and these cases do not contribute to knowledge of the current infection transmission risks of blood transfusions
2. any post-transfusion HTLV infections identified through the HTLV National Lookback are excluded but will be collated, analysed, and published elsewhere, as was done previously with HCV 'lookback'

Data is published annually in the SHOT Annual Report, the UKHSA's Health Protection Report and in the NHSBT and UKHSA Epidemiology Unit annual review. The SHOT Annual Reports can be found on the SHOT website.

Lookback Investigations

Lookback investigations are initiated by the Blood Service in England when repeat donors are found to be newly positive for a marker of infection. This can be either due to donor seroconversion, post donation information or introduction of new test. These investigations involve reviewing donor history, retesting archive samples and tracing components, and tracing and testing recipients, where appropriate.

Return to Table of Contents

Bacterial screening of platelets

Platelets may be manufactured as pooled platelets from whole blood donors (a platelet pool from four donors) or as apheresis platelets where between 1 and 3 apheresis platelet packs may be manufactured from one component donor.

Bacterial screening of platelets first started in Northern Ireland in 2000, followed by rollout in 2002 in Wales and in 2003 in Scotland. NHSBT was the last of the UK blood services to introduce bacterial screening of platelets, testing of apheresis platelets began in February 2011 at Manchester, Bristol on 15th May 2011 and Colindale on 22nd May 2011. Screening of pooled platelets commenced at Bristol on 22nd May 2011, Colindale on 26th June 2011 and Manchester on 6th July 2011.

The BacTALERT culture system is used for bacterial screening across all four services but with slightly different sampling methods (see Table A). A surveillance system was put in place within NHSBT in 2011 to report the number of confirmed and indeterminate reactions each month and bacterial species on a quarterly basis.

NHSBT introduced the use of Platelet Additive Solution (PAS) for pooled platelets in 2015; by the end of June 2015 all pooled platelets were manufactured in PAS.

NHSBT produces and screens the largest number of platelets of the four services. Platelets are held for a minimum of 36 hours' post-donation before being sampled. An 8ml sample is inoculated into an aerobic and an anaerobic bottle and placed on the BacTALERT system. If samples are negative after a minimum six-hour incubation, the associated platelet donation can be released as negative-to-date. Platelets are released to stock with a seven-day shelf life since time of donation; prior to the introduction of bacterial screening platelets had a five-day shelf life. Table A shows the sampling volumes and incubation conditions used for the four UK blood services

Table 3: Bacterial screening methods used by the UK blood services

Country	Time of sampling (hours)	Volume sampled (mls)	Apheresis sample	Time at release (hours)	Length of screening
England	36	2 X 8	Post-split	6	Day 7
Northern Ireland	36	16	Pre-split	6	Day 7
Scotland	36	2 X 8	Pre-split	6	Day 7
Wales	36	2 X 8	Post-split	12	Day 7

Please note:

- Screening methods in Wales changed mid-2018 from testing on day 1 and day 4 to testing on day 2 only

BacTALERT uses a colourimetric system that detects change in pH. A decrease in pH results in an initial reactive report. In some cases, units will have already been transfused. All associated units will be recalled, and the BacTALERT bottle and any associated packs will be re-tested, and a result released. Platelet donations are reported as confirmed positive if both the initial screen bottle and the index and or at least 1 associated pack is positive, and the same organism is identified in both. An indeterminate positive result is reported if bacteria are detected in only the initial screen bottle plus no index or associated packs are received or no index packs are received and there's no growth in any associated pack. For indeterminate negative packs, there is no growth from the initial reactive bottle, but a negative result cannot be confirmed because the index pack is not available. Units are confirmed negative if no organism is isolated from the initial reactive bottle and the index pack.

Bacteria isolated from the pack and the bottle are identified to the species level and an assessment will be made of any significance to the donor's health. If a unit has been transfused the transfusion laboratory is notified and asked about any reaction in the recipient.

Return to Table of Contents

Tissue and cord blood donor surveillance

The NHSBT and UKHSA Epidemiology Unit tissue and cell donor scheme collects information on tissue and cord blood donations tested by NHSBT. Living tissue donors give surgical bone (femoral heads) when undergoing elective primary hip replacement and generally have only 1 opportunity to give. Deceased tissue donors give bone, skin, heart valves, corneas, and tendons and are generally older than blood donors; those tested by NHSBT have been included in this scheme since 2012.

Donations tested by NHSBT

Data collection

Testing for the following mandatory markers of infection is carried out: on antibodies to HIV, HCV, HTLV and treponema; HBsAg and anti-HBc; HBV, HCV and HIV nucleic acid testing (NAT; singletons, triplex). Although not mandatory, donations are also tested for HEV RNA. Disaggregate data on the number of donations tested for mandatory markers of infection, as well as data on additional testing for malaria and *T. cruzi,* are extracted from PULSE (the NHSBT national donor database) on an annual basis. Donations are classified according to donor type (cord blood, living surgical bone or deceased donors [the latter including cornea donors]). The information extracted includes product or component type donated (for instance femoral head, left knee etc.) and gender and date of birth of the donors. Ethnicity of these donors is not currently recorded on PULSE and is therefore not available. Some data for stem cell and amnion donors are available but information is limited, thus these donors are not fully integrated into the surveillance scheme and are not reported upon.

Changes to testing

- there have been several changes to tissue and cord blood donor testing within NHSBT since surveillance began in 2001. HCV, HIV, HBV and HEV NAT (on single samples NOT pools) have been introduced for different donor types at different times
- Cord Blood Donors: HIV NAT and HCV NAT introduced in November 2003. HBV NAT since April 2009. HEV NAT since October 2017
- Deceased Donors: HIV NAT and HCV NAT since 2001. HBV NAT since September 2008. HEV NAT since October 2017

Surgical Bone Donors: Triplex HBV, HCV, HIV NAT since September 2008 (Note: A small number of surgical bone donors require two serology samples [initial and 6-month] where there is insufficient sample for NAT. Any follow-up samples are excluded from the count of number of

donors tested, as they do not represent new donors). HEV NAT on pooled samples since October 2017

Anti-HBc testing has been mandatory for all tissue and cord blood donors since 2006 under EU Commission Directive 2006/17/EC.

Donors with markers of infection

Follow-up or risk exposure information is received for living surgical bone donors and, where possible, cord blood donors whose donations had markers of infection. As for blood donors, these donors are contacted and asked to telephone the blood centre to discuss their results. The post-test discussion commonly takes place over the telephone and, as for infected blood donors, a behaviour history is sought. For infections detected among deceased donors, an assessment is made to see if any family member or other individual is likely to be at risk before the donor's family is contacted. Risk exposures are not requested for deceased donors. These data are reported to the tissue and cell surveillance scheme by NHSBT clinicians using standard proformas.

Return to Table of Contents

Deceased organ donor surveillance

Data collection

Organ donor data are provided for the UK from the UK Transplant Registry (UKTR) and provided by NHSBT Organ Donation and Transplantation (ODT). The data includes donor characteristics, cause of death, reactive test results, and a description of organs donated, and organs transplanted. This information is collected by the NHSBT and hospital staff and submitted to the UKTR either by paper or electronic form.

Consented donors are tested for pathogen reactivity

Before an organ is retrieved, blood samples from potential consented donors undergo mandatory testing for hepatitis B virus surface antigen (HBsAg), combined antibody and antigen for HIV; and antibodies to hepatitis B core (Anti-HBc), HCV, human herpes virus 8 (HHV8), HTLV, *Treponema pallidum* (Syphilis), *Toxoplasma gondii*, cytomegalovirus (CMV) and Epstein-Barr virus (EBV). After donation, HEV RNA testing occurs.

Markers of infection are not necessarily barriers for transplantation

Confirmatory results of initial reactive tests may not always be available at the time of translation, but specialist advice and informed patient consent may allow transplantation to proceed without results if the benefits are deemed greater for the recipient then the risk of infection. HBV, HCV and HIV nucleic acid testing (NAT) is conducted based on initial reactivity from hospital-based testing and history of increased risk behaviour, to inform post-surgical management of the recipient. Additional criteria for screening of malaria, *Trypanosoma cruzi*, and West Nile Virus (WNV) RNA include country of birth, transfusions whilst abroad and travel to affected areas.

Return to Table of Contents

Risk estimates for whole blood donations

The estimated risk that a whole blood donation entering the UK blood supply is potentially infectious for HBV, HCV or HIV, but not detected on screening because the donation is made during the infectious 'window period', is calculated annually for a rolling three-year period. This statistical process combines information about tests in use by the UK blood services, the infection itself, and data on characteristics of blood donors and donations to produce a point estimate for each infection. An infectious donation may not be detected if a blood donation is made during the infectious 'window period'. This is the period early in the course of infection when the tests in use will not detect the marker of infection. It is also possible that a false negative test result may arise because of issues relating to assay sensitivity other than window period or a blood donation may be erroneously issued as negative due to a sampling, processing, or issuing error. The contribution of these latter two elements is thought to be extremely small and is no longer estimated because of uncertainty around these values.

The estimates for HBV are for acute infections only and do not consider risk due to occult HBV. Hepatitis B core antibody screening for blood donations was rolled out across the UK in 2022 in response to a review carried out by SaBTO. This has already had an impact on increased detection of potentially transmissible hepatitis B virus from donors with occult HBV, which have been removed from the blood supply.

HEV residual risk estimates are not routinely calculated. This is primarily because of uncertainty of the duration of the WP and the fluctuating incidence of HEV in the donor population This means that the relevance of the traditional incidence WP method across 3-years, as used here for HBV, HCV or HIV, would be questionable for HEV. However, HEV risks have been calculated elsewhere for apheresis and whole blood donors in England between 2016-2020[1].

[1] 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

The model used for HBV, HCV and HIV combines data collected in a number of the surveillance schemes. The data required includes:

- number of whole blood donations tested (from new and repeat donors),
- number of whole blood donors with confirmed markers of infection, by marker (for new and repeat donors),
- number of seroconverting donors. The classification of a seroconverter is made by the NHSBT and UKHSA Epidemiology Unit as a repeat donor with confirmed marker of infection with either a previous negative donation within 1 year, or microbiological and or clinical evidence of recent infection AND a previous negative donation within 3 years. This is taken as 3-years to allow for archive testing to confirm absence of infection (archives

kept for up to 3- years in England). If more than 3-years, the donor is considered lapsed and for the purposes of RR calculations is categorised as a new donor.
- inter-donation interval (IDI) for all donors, taken from NHSBT Donor Insight department data

Parameters used in the model include:

- window period: from expert opinion and literature
- blood donor and donation characteristics: blood donor surveillance, NHSBT's Donor Insight department data

The window period risk is calculated as the incidence multiplied by the length of the window period and multiplied by one million. This gives an estimate of the number of potentially infectious donations in one million whole blood donations entering the blood supply. Incidence in repeat donors is calculated as the number of observed seroconversions divided by the number of person years exposed, which is estimated from the number of donations from repeat donors multiplied by the average inter-donation interval (IDI) in years. The IDI is created by calculating the difference in days between each donation and the most recent previous donation by the same donor. The average of all these differences is then taken. New donors who returned within the year to donate were excluded, as were donations with IDIs greater than 730 days (two years). Incidence in new donors is derived by adjusting the repeat donor incidence by the relative difference in acute or recent infections among the two groups.

Each year, 95% confidence intervals for the point estimates are calculated by a simulation approach. The same calculation of risk was repeated 1000 times each time using a different set of parameter values. Assumed sampling distributions were intended to reflect the degree of uncertainty in incidence, in average window period length and all other uncertainties in the calculation of the risk of a window period donation. From the resulting 1000 different estimates of risk, we then selected the 2.5 percentile and the 97.5 percentile as the lower and upper limits of a 95% confidence interval.

Parameters and estimates are reviewed annually by the NHSBT and UKHSA Epidemiology Unit. They are then approved annually by the joint UK Blood Transfusion and Tissue Transplantation Services Joint Professional Advisory Committee (JPAC) Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI).

Return to Table of Contents

Emerging infections

The Emerging Infections Report (EIR) produced by the NHSBT and UKHSA Epidemiology Unit is distributed monthly. A range of sources are checked for relevant infection issues relating to patient safety and or blood and tissue availability in the UK and collated into a monthly listing. Sources include outbreak alerts, various regular outbreak surveillance reports, journals, websites, and online news resources, listed in more detail below.

The EIR is sent to the Chair of the UK Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI). The chair of SACTTI also receives early warning communications or other reports deemed urgent as they arise. These are documented in the EIR.

During the European arbovirus transmission season, an additional weekly report is sent if necessary, detailing the number of human cases by area not covered by existing WNV testing or 28-day deferral for chikungunya virus, dengue virus, or Zika virus. Similar additional situation update reporting is implemented when required for pandemics.

The monthly EIR, alongside other sources of information are reviewed by SACTTI and may lead to further risk assessment and changes to the donor selection guidelines, or other blood safety measures, where necessary. Sources of information for the EIR include:

Outbreak alerts and reports used are listed below;

- Daily and weekly reports from UKHSA EpiIntel with the weekly reports tailored to EIR needs.
- UKHSA All Hazards Situational Awareness Daily reporting
- The Infectious Disease Surveillance and Monitoring System for Animal and Human Health: Summary of notable events or incidents of public health significance is a monthly summary of new or emerging infectious disease events that could affect UK public health. It is published monthly by UKHSA, on behalf of the Human Animal Infections and Risk Surveillance group, and can be found on the Government website.
- ECDC Weekly Communicable Disease Threats Report (CDTR) is a weekly bulletin summarising information gathered through epidemic intelligence by ECDC regarding communicable disease threats of concern to the European Union. It also provides updates on the global situation and changes in the epidemiology of communicable diseases with potential to affect Europe including diseases under elimination and is found on the ECDC website which is also scanned for other surveillance reports.
- Health Protection Report (HPR) is published weekly on the Government website with routine data and commentary reporting on infectious diseases
- Morbidity and Mortality Weekly Report (MMWR) is a weekly report prepared by and available on the Centers for Disease Control and Prevention (CDC) website
- Saved PubMed search is set to run monthly for transfusion transmitted infections, blood donors and infection and selected organisms such as hepatitis E, CJD and Chronic Wasting Disease, Babesia and rat hepatitis.

- ProMED website
- Travel health updates on the National Travel Health Network and Centre (NaTHNaC) website.
- The American Association of Blood Banks (AABB) online news resource and emails are monitored.

Journal tables of contents on the following websites are checked:

- American Journal of Transplantation
- Clinical Infectious Diseases
- Emerging Infectious Diseases
- Epidemiology and Infection
- Eurosurveillance
- Journal of Infectious Disease
- PLOS Pathogens
- PLOS Neglected Tropical Diseases
- Transfusion
- Transfusion medicine
- Transplant Infectious Disease - Wiley Online Library
- Vox Sanguinis

Further information is sought from the UKHSA Tuberculosis, Acute Respiratory, Gastrointestinal, Emerging Zoonotic Infections, and Travel and Migrant Health Division (TARZET) where necessary.

The process for producing the EIR and onward risk assessments are detailed in the JPAC position statements:

- Surveillance: Preparedness for emerging infectious agents
- Guidance for the addition and removal of an infectious disease risk entry in the Geographical Disease Risk Index (GDRI)

Return to Table of Contents

Blood donor survey, UK 2024

A confidential online survey of blood donors was carried out by the UK Health Security Agency (UKHSA) in collaboration with NHS Blood and Transplant, the Welsh Blood Service, the Scottish National Blood Transfusion Service and the University of Nottingham. The survey was conducted as part of post-implementation monitoring of FAIR (For the Assessment of Individualised Risk) to assess the impact of the policy on donors.

Survey preparation

Survey questions and materials were reviewed by blood donors through a Patient and Public Involvement and Engagement (PPIE) exercise. Participants gave feedback via email which informed changes to materials to ensure readability. Before launch of the survey through each service, pilots were conducted to test survey process and functionality of survey links.

The survey went through appropriate information governance approvals, including a Caldicott Advisory Panel Review, Data Protection Impact Assessment, Data Anonymisation Risk Assessment, Public Sector Equality Duty and Health Equity Relevance Assessment.

Live survey

A random sample of donors who had donated in the past 4-8 weeks (England, Wales) or 4-5 weeks (Scotland) were invited via email from their blood service in line with normal donor communications, as part of service evaluation. The survey was unlinked to donor records and hosted by UKHSA on the online survey platform Snap Surveys. Computer IP addresses were not recorded and unsubmitted answers were not retained. This was similar to the method used in previous blood donor surveys coordinated by the joint Unit.

Donors formally agreed to participate before they could answer the survey questions. Once submitted, survey responses could not be removed or amended as they were not identifiable.

The survey was live for four months in England with monthly invites, two months in Wales and 5 weeks in Scotland with weekly invites.

Return to Table of Contents