

NHS Blood and Transplant/Health Protection Agency Epidemiology Unit: Data Sources and Methods

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The aim of the NHS Blood and Transplant (NHSBT)/Health Protection Agency (HPA) Epidemiology Unit is to monitor infections in blood, tissue and cell donors, and to use this information to inform blood safety.

This document has been written to provide more detailed information on the data sources and methods used in each of the surveillance schemes run by the NHSBT/HPA Epidemiology Unit. It can be read in conjunction with the Annual Report produced each year.

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 are consistently collected.

Data are regularly published in a number of reports for different groups. The main reports include:

- Monthly donation testing report
- Monthly antenatal testing report
- Annual NHSBT/HPA Report (all surveillance schemes)
- Quarterly infected donors, for NHSBT clinical group
- Six monthly tissue donor testing
- Monthly Emerging infections report
- Transfusion transmitted infections chapter in the SHOT annual report

Data from each of the surveillance schemes described are updated regularly and published on the web:

http://www.hpa.org.uk/infections/topics_az/BIBD.htm.

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. For further details, please see the blood donor health check questionnaire (www.blood.co.uk/pages/c11xclud.html) and the donor selection guidelines (www.transfusionguidelines.org.uk/index.aspx?Publication=DSG&Section=67).

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1. BLOOD DONOR SURVEILLANCE

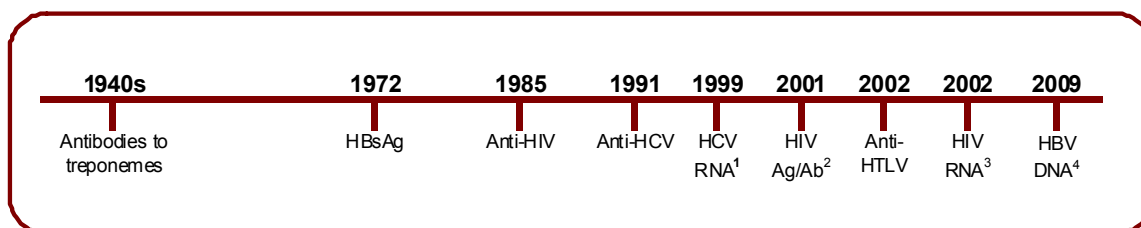
Blood donor data are collected by the NHSBT/HPA Epidemiology Unit through two parallel schemes: (i) blood donation testing and (ii) infected blood donors. Both of these surveillance schemes commenced in October 1995. The information is used to monitor donation testing reactive rates and infections detected in blood donors. Additional data, providing more detailed information on the profile of all blood donors tested is also gathered.

(i) 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, testing for hepatitis B surface antigen (HBsAg), antibodies to hepatitis C virus (anti-HCV), HCV RNA, antibodies to HIV (anti-HIV), combined antibody-antigen for HIV (HIV Ag/Ab), antibodies to human T-cell lymphotropic virus I/II (anti-HTLV) and in some circumstance HIV RNA have been introduced (Figure A).

Figure A: Timeline of introduction of microbiological tests for blood donations, UK



1. HCV RNA testing was introduced on a pilot basis in 1999 and became a mandatory test carried out on all blood donations from 2002.

2. NIBTS and Republic of Ireland use anti-HIV.

3. 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.

4. HBV DNA testing began on 1 April 2009 in Filton as a by-product of the introduction of triplex NAT testing.

In 2008, all blood donations in the UK and Republic of Ireland were tested for HBsAg, anti-HIV (all centres except NIBTS and Republic of Ireland use a combined antigen/antibody assay), anti-HCV, anti-HTLV (in mini-pools) and antibodies to treponemes (syphilis). Pooled donations were also tested for HCV RNA and from October 2007 HIV NAT testing started in the remaining testing centres in England (outside London and the South East) who had not yet introduced it. HBV DNA testing began in one centre (Filton) in April 2009. Other additional tests may be performed including antibodies to hepatitis B core antigen (anti-HBc), malaria and *Trypanosoma cruzi* (Chagas disease). These tests are only performed if information given by the donor suggests that they may have been at risk for these infections. For example, anti-HBc testing by NHSBT is carried out on donations from donors reporting a

history of recent piercing and/or tattoo; jaundice or HBV infection or contact with a past sexual partner or family member known to have HBV infection. Repeat reactive malaria donations have been sent for confirmatory reference testing from 30 August 2007.

Data collection

Aggregate data on the number of blood donations tested and the number of donations initially and repeat 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 SNBTS for Scottish blood centres, for new and repeat donors. Disaggregate data on the number confirmed positive is also reported in the same manner. The majority of testing centres report electronically, however, as of July 2009, some centres still use standard proformas to report.

The classification of **new and repeat donors** used in the Epidemiology Unit donation testing scheme is made by **testing centres**:

New donors: First time donors who were not known to have ever donated blood in the UK. Note: New donors in the UK (excluding Scotland) and the Republic of Ireland may include 'lapsed' donors i.e. repeat donors who have not donated for more than three years. In Scotland, all lapsed donors are counted as repeat donors.

Repeat donors: For most UK centres (excluding Scotland, who include lapsed donors) and the Republic of Ireland, donors known to have previously donated blood in the UK in the last three years were classified as repeat donors, although NOT all previous donations have necessarily been tested for all markers of infection (e.g. anti-HTLV testing was first introduced in 2002).

This classification of donations tested by new and repeat donors made by the testing centres is used in particular to estimate frequency of infection and the overview of donations tested.

Data on discretionary testing performed by NHSBT is reported on a monthly basis via the following sources:

- 1) An electronic report from PULSE (NHSBT national donor database) of the monthly aggregate number of blood donations given a discretionary test by marker.
- 2) An electronic line listing of donations sent for discretionary anti-HBc testing along with screen results.
- 3) An electronic list of the repeat reactive and confirmed positive malaria and *T. cruzi* cases from Transfusion Microbiology surveillance.
- 4) An electronic list of the reference results for samples sent for confirmatory anti-HBc testing from the National Transfusion Microbiology Reference Laboratory (NTMRL).

- 5) Characteristics of donors sent for confirmatory anti-HBc testing are collected via the infected donor scheme and from PULSE.

(ii) Infected blood donors

When a marker of infection is detected in a blood donation, the donor is offered a post-test discussion, which may be held in a blood centre (the usual practise for HIV infection) or over the telephone (as appropriate). The donor is informed of their positive test results and the clinician explains what these test results mean and ascertain 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. Arrangements are made to collect a further blood sample for repeat testing. With the exception of known treated cases of treponemal infections, the donor is referred to the appropriate services for specialist care. Clinicians in blood centres in the UK (excluding Scotland) and Republic of Ireland pass anonymised information about infected blood donors to the Epidemiology Unit infected blood donor scheme using two standard proformas. This information includes the characteristics of the infected donors (date of birth, sex, 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 donors infection. Infected donors 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/any previous donations in the UK.

The classification of ***infected donors as newly or previously tested*** is done **by the NHSBT/HPA Epidemiology Unit:**

New tested: A donor who has not been previously tested for the marker under consideration by the blood transfusion services included in this surveillance

Previously tested: A donor who has been previously tested for the marker under consideration by blood transfusion services included in this surveillance

Note: 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 THREE years.

The classification of a seroconverter is made by the Epidemiology Unit:

Seroconverter: A previously-tested (within 10 years) donor whose previous donation is reliably documented as negative to comparable assays.

Note that for residual risk estimates, only those donors with a previous negative donation within **3 years** are included in the calculations.

In SNBTS and NIBTS archive samples are available as far back as the 1980's, so that previous donations are available for the SNBTS National Microbiology Reference Unit (NMRU) to retrieve and test using current (more sensitive) assays.

Data are being continually updated as new or additional information is received. Therefore some changes between reports may be identified.

Donor profile

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

a) NHSBT testing centres

Between 1996 and 2000, the number of donations made each month by sex and age group (17-24, 25-34, 35-44, 45-54, 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 sex and age group.

b) Market Research and Analysis - NHS Blood and Transplant

Between 2001 and 2006, aggregate information about individuals donating blood was available from the Market Research and Analysis Department of NHS Blood and Transplant. This information included the proportion of donations made by new and repeat donors by sex, age group (as above) and ethnic group (white British, white other, black Caribbean, black African, black other, Indian/Pakistani/Bangladeshi, Chinese, Asian other, mixed and other, 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 sex, age and ethnic group. The data from Market Research and Analysis between 2001-2006 were based on a random sample of approximately 1.5 million donation records stored on PULSE.

In 2008 data were received for two months: September 2007 and September 2008. These extracts are a complete dataset of every donor who made a donation during each of those months at NHSBT. Data include sex, age, donation date, date of most recent previous donation, ethnicity, postcode and new/repeat status. Region was identified using the donor postcode and mapped to Strategic Health Authority, to provide more detailed geographical information.

For both (a) and (b), individuals were classified as new donors if they had donated blood for the first time ever or for the first time in three years (i.e. 'lapsed' donors were classified as new).

2. TISSUE AND CELL DONOR SURVEILLANCE

The NHSBT/HPA Epidemiology Unit tissue and cell donor scheme collects information on tissue and cell donations tested by NHSBT, SNBTS and NIBTS.

(i) Donations tested by NHSBT

Data Collection

Disaggregate data on the number of donations tested for mandatory markers of infection (antibodies to HIV, HCV, HTLV and syphilis, HBsAg, anti-HBc, and in some instances HBV, HCV and/or HIV Nucleic Acid Testing [NAT]) are extracted from PULSE, the NHSBT national donor database, and classified according to donor type (amniotic, cord blood, deceased, stem cell or surgical bone donors). The information extracted includes product/component type donated (i.e. femoral head, left knee etc.) and sex and date of birth of the donors. Ethnicity of donors is not currently recorded on PULSE and is therefore not available. Between 2005 and 2008, extracts were taken every quarter directly from PULSE. In 2009, the process changed to six-monthly extracts; Business Objects (an NHSBT data management system) was then used to extract this data from PULSE.

Changes to Testing

There have been a number of changes to tissue and cell donor testing within NHSBT since surveillance began in 2001. HCV, HIV and HBV NAT have been introduced for different donor types at different times:

- *Cord Blood Donors*: HIV NAT and HCV NAT introduced November 2003. HBV NAT since April 2009.
- *Deceased Donors*: HIV NAT and HCV NAT since 2001. HBV NAT since September 2008.
- *Surgical Bone Donors*: Triplex HBV/HCV/HIV NAT since September 2008 (*A small proportion of surgical bone donors still 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).

Anti-HBc testing has been mandatory for all tissue and cell donors since December 2006.

Data for stem cell and amniotic donors, as well as data on NAT, anti-HBc and discretionary testing (all donor types) have not yet been fully integrated into the surveillance scheme and are not reported upon in 2008. It is hoped that these data will be presented in 2009.

Infected Donors

Follow-up/risk exposure information is received for infected cord blood and surgical bone donors only. As for blood donors, cord blood and surgical bone donors are contacted to arrange for a further blood sample to be taken for repeat testing, invited to attend a post-test discussion and asked not to make further donations. 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 at risk before the donor's family is contacted. Risk exposures are rarely available for deceased donors. These data are reported to the infected donor surveillance scheme by NHSBT clinicians using standard proformas.

(ii) Donations tested by SNBTS

Aggregate data on the number of tissue and cell donor samples tested for antibodies to HIV, HCV, HTLV and syphilis, and for HBsAg, are received electronically from SNBTS each month. The number of individual donors tested each year was also supplied by SNBTS. Information on the type of product donated is not available so data cannot be categorised by donor type. Samples are primarily from surgical bone donors, however donations from deceased, amnion and stem cell donors may also be included.

(iii) Donations tested by NIBTS

Aggregate data on the number of surgical bone and cord blood donor samples tested for antibodies to HIV, HCV, HTLV and syphilis and for HBsAg are received electronically from NIBTS each quarter. Number of *samples* tested are reported and so individual donors cannot be identified. However, numbers are estimated as approximately 60% of all samples tested (Brian Webb, personal communication). Follow-up/risk exposure information is received for infected surgical bone and cord blood donors identified by NIBTS.

3. TRANSFUSION TRANSMITTED INFECTIONS

Blood centres in England, Wales and Northern Ireland report all investigations of suspected transfusion transmitted infections (TTI's) to the NHSBT/HPA 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 Scottish Blood Transfusion Service, and the details and conclusion of each case is passed to the surveillance system annually. Annual data are reconciled with reports made via MHRA's mandatory reporting system (SABRE – Serious Adverse Blood Reactions and Events) to ensure as complete a data set as possible. NHSBT/HPA Epidemiology Unit data are reported annually to SHOT (Serious Hazards of Transfusion) and included in their reports.

Definition of a Transfusion Transmitted Infection (TTI)

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

- The recipient had evidence of infection post-transfusion, 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 transmissible infection,

Or

- At least one component received by the infected recipient was shown to have been contaminated with the agent of infection

Criteria for reporting

Inclusion criteria:

An incident should be reported if receipt of the transfusion is confirmed, and either;

- a) The infection in the recipient had been confirmed by detection of antibody, antigen, RNA/DNA or culture as appropriate and there was no evidence that the recipient was infected prior to transfusion

Or,

- b) The recipient had acute clinical hepatitis of no known cause (including no evidence of acute hepatitis A virus (HAV), HBV, HCV, Epstein-Barr virus or CMV infection in post-transfusion samples to date).

Exclusion criteria:

An incident should NOT be reported if:

- a) The incident involved HCV or HIV in recipients who had received transfusions in the UK prior to routine testing. [September 1991 for anti-HCV, October 1985 for anti-HIV][±]
- b) The incident involved HTLV in a recipient identified through the HTLV National Lookback^{±±}
- c) The incident involved a transfusion outside UK

[±] 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.

^{±±} 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 are published annually in the SHOT report, and annually in the Health Protection Agency Health Protection Report.

4. SURVEILLANCE OF ANTENATAL SAMPLES TESTED BY NHSBT

Background

NHS Blood and Transplant (NHSBT) provide a testing service for antenatal samples from Primary and Acute Care Trusts in England. In addition to blood grouping, NHSBT laboratories perform testing for hepatitis B surface antigen (HBsAg) and antibodies for HIV (anti-HIV), syphilis (antibodies to treponemes) and rubella. When an antenatal sample tested positive for markers of HBV, HIV or syphilis, or negative for antibodies to rubella (as tested by NTMRL), the local health provider was advised to obtain a repeat sample from the woman for confirmatory testing by a local accredited microbiology testing laboratory and to refer them for appropriate follow-up.

Data collection

Aggregate data on the number of antenatal samples tested and found to be reactive is reported by the testing centres to the NHSBT/HPA Epidemiology Unit antenatal sample testing scheme each month. Additional testing by the NHSBT National Transfusion Microbiology Reference Laboratory (NTMRL) is undertaken on repeat reactive samples (or if screen negative for rubella). Disaggregate data are then reported to the scheme for these donors. Additional data on age, ethnicity and parity for all samples tested are obtained via NHSBT Red Cell Immunohaematology. Note that the ethnicity categories are not as detailed as for blood donors and are as follows: caucasian, black, Caribbean-black, Asian, Chinese, Middle East Arab, mixed and other.

Managed withdrawal from routine antenatal screening services

In 2008 after an internal review it was decided that NHSBT would withdraw from routine antenatal microbiological screening services by 2010¹. The Hospitals and Science website has details of an antenatal toolkit with information for users and potential service providers.

[<http://hospital.blood.co.uk/diagnostic%5Fservices/antenatal%5Ftoolkit>]

¹ National Blood Service Review - Important changes to Antenatal Screening Services available at http://hospital.blood.co.uk/library/pdf/NBS_Antenatal_Announcement.pdf

5. EMERGING INFECTIONS

The Emerging Infections Report is produced and distributed monthly. The listing is collated from a range of sources which include:

- The Infectious Disease Surveillance and Monitoring System for Animal and Human Health: Summary of notable events/incidents of public health significance. This is a monthly summary of the significant human and animal health incidents or events which might pose a public health threat to the UK population. It is prepared by the Emerging Infections Section/HPA Scientific Secretariat to the National Expert Panel for New and Emerging Infections (NEPNEI) at Cfl, in collaboration with the Department for Environment, food and Rural Affairs (Defra) and the Veterinary Laboratories Agency (VLA). It is based on 146 sources: ProMED, World Health Organization (WHO) outbreak verification list, Clinical Infectious Diseases Journal, Centres for Disease Control and Prevention (CDC) website, Centre for Infectious Disease Research and Policy (CIDRAP) website, Emerging Infectious Diseases Journal, Global Polio Eradication Initiative, Morbidity and Mortality Weekly Report (MMWR), New Scientist, Nature, Science, WHO website, World Organisation for Animal Health (OIE) website, Eurosurveillance, various online news, HPA website and the Veterinary Record.
- The Global Disease Outbreak Summary, a monthly report of infectious disease outbreaks intended to keep recipients up to date with the global status of emerging infectious diseases of public health concern. It is prepared by the Microbial Risk Assessment, Centre for Emergency Preparedness & Response Health Protection Agency.
- Monthly Pubmed search for transfusion transmitted infections, blood donors and infection and selected organisms such as hepatitis E.
- Email alerts or monthly check for various journals including: Emerging Infectious Diseases, Eurosurveillance, HPA Health Protection Report, Transfusion and Vox Sang.
- Monthly scan of websites including: National Travel and Health Network and Centre (NaTHNaC) clinical updates and the Californian Blood Bank Society's (CBBS) global transfusion news and emerging disease update.
- News alerts from Promed and the American Association of Blood Banks (AABB).
- Further information is sought from the Health Protection Agency's (HPA) Emerging Infections Section or the Travel and Migrant Health Section where necessary.

6. RESIDUAL RISK ESTIMATES – BLOOD DONORS

The estimates of the frequency (or risk) of a potentially infectious donation entering the UK blood supply are produced annually for the UK (including Channel Islands) and also for country groups, namely, England & Wales, and Scotland & Northern Ireland. 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. There are three scenarios in the model whereby an infectious donation may be missed: a blood donation is made during the infectious 'window period' early in the course of infection when the tests in use will not detect the marker of infection, a falsely negative test result (as test sensitivities are less than 100%), or a blood donation erroneously issued as negative due to sampling/processing/issuing error. Data are produced for both single and grouped years.

The model combines data collected in a number of the surveillance schemes. The data required includes:

- Number of donations tested (new and repeat), taken from monthly donation testing surveillance
- Number of infections detected, by marker (for new and repeat), from Infected donor surveillance
- Number of seroconverting donors, from Infected donors
- Inter-donation interval (IDI) of all donors, taken from NHSBT marketing and analysis data

Parameters used in the model include

- Tests in use (i.e. sensitivity and error rate): validation, manufacturers instructions, expert opinion and literature
- Window period: expert opinion and literature
- Blood donor and donation characteristics: infected donors, marketing and analysis data

Parameters and estimates are updated annually by the NHSBT/HPA Epidemiology Unit. They are then reviewed and approved annually by the Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI).

7. RESIDUAL RISK ESTIMATES – SURGICAL BONE DONORS

As for blood donors, estimates of the residual risk for surgical bone donors are produced annually. The model used is an adjusted version of the blood donor model. The approach differs slightly to blood as calculations are stratified by age and sex. It makes an adjustment for the prevalence and incidence in blood donors, to calculate the residual risk in surgical bone donors. Estimates are not produced for new and repeat donors, as very few surgical bone donors make a repeat donation. The figures produced are for England only and for hepatitis B and hepatitis C. Due to the lack of available data, estimates are not currently produced for deceased donors, nor for HIV or HTLV infections. Estimates are produced for a six year period and are not available for single years.

The surgical bone donor model combines data collected in a number of the surveillance schemes. The data required includes:

- Number of donations tested (by age and sex), taken from tissue and cell donation testing surveillance
- Number of infections detected, by marker (by age and sex), taken from Infected tissue and cell donor surveillance
- Inter-donation interval (IDI) of all donors, taken from NHSBT marketing and analysis data
- Incidence of infection: infected blood donor surveillance scheme
- Prevalence of infection in blood donors (by age and sex): donation testing and infected (blood) donor surveillance

Parameters related to test sensitivity and error rate used in the model are as approved for the blood donor model. The window periods used for each infection are as per the blood donor model, taking into account any differences in testing, such as mandatory anti-HBc for surgical bone donors. The donation parameters (e.g. HBsAg adjustment) are as for blood donors.

Parameters and estimates are updated annually by NHSBT/HPA Epidemiology Unit. They are then reviewed and approved annually by the Standing Advisory committee on Transfusion Transmitted Infections (SACTTI).

8. HTLV NATIONAL REGISTER

The introduction of blood donor testing in 2002 provided an opportunity to identify, recruit and follow-up a cohort of individuals with HTLV infection. The project is a joint collaboration between the UK blood services, the Health Protection Agency and Imperial College London. The National Register Coordinator is based at the Health Protection Agency. A steering group meets at least twice per year to discuss the progress of the study and to suggest or approve any changes to the study protocol.

Participants are recruited through a number of sources: (i) Infected blood donors and recipients of potentially infectious donations received prior to the introduction of routine testing are invited to participate via the UK blood services. (ii) Symptomatic and asymptomatic patients presenting in specialist HTLV clinics around the UK are also invited to participate.

Participants provide explicit consent to (i) the disclosure of personal data to the study coordinator, (ii) to be contacted for further follow-up information, (iii) for their GP to be approached for additional information if required, and (iv) for their NHS number to be flagged in the NHS Central Registry (to re-establish contact with study participants where it is lost, and so that cancer and mortality outcomes may be received via the NHS Information Centre for each patient that consents to flagging).

Each participant is asked to complete a base-line self completion health questionnaire (SCQ) at the time they register. This SCQ provides information on their current health and health in the past, as well as demographic details and possible risk exposures for their infection. Participants in the study are followed-up regularly (approximately every 2 years) using a similar SCQ to baseline. This data will be used to describe factors associated with the natural history of HTLV infection.

A study newsletter is produced annually including an update on the progress of the study and any other items of interest to participants (e.g. information on other HTLV research studies conducted around the world, HTLV treatment options, existing patient forums or groups etc).

Information is forwarded to the National Register Coordinator at HPA Centre for Infections, where it is stored securely in a password protected database.

The study has ethical approval from the Northern & Yorkshire Multi-Centre Research Ethics Committee (MREC) (study reference: MREC/3/3/21).