Transfusion-Transmitted Infections (TTI) n=2 (1 confirmed, 1 probable) 20

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Definition of a TTI:

A report was classified as a TTI if, following investigation:

- The recipient(s) had evidence of infection post transfusion with 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(s) 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 contain the agent of infection

These may be identified as a result of infection in the patient where transfusion is the suspected source or alternatively via lookback investigations. A lookback investigation is carried out if a donation is found to be positive for infection and retrospective testing finds a previous donation to also be positive at low levels below the detection level of screening.

Note that for the purposes of the European Union (EU) legislation, serious adverse reactions (SAR) are defined as any reactions in patients that are 'life-threatening, disabling or incapacitating, or which result in, or prolongs, hospitalisation or morbidity.'

These must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) (a legal requirement). This includes all confirmed transfusion-transmitted infections.

Key SHOT messages

- Any suspicion of a transfusion-transmitted infection (TTI) should be reported to the appropriate United Kingdom (UK) Blood Service as soon as possible for it to be fully investigated
- The UK Blood Services store a sample from every blood donation for at least 3 years. Further testing can be done on these samples during this time if a TTI is suspected
- All lookback investigations should be reported by the UK Blood Services to the infectious diseases expert on the SHOT Working Expert Group
- It is important that all healthcare professionals who consent patients for blood transfusion have up-to-date knowledge of blood donation screening and the small potential for TTI

Abbreviations used in this chapter

ALT	Alanine aminotransferase
BSH	British Society for Haematology
CMV	Cytomegalovirus
DNA	Deoxyribonucleic acid
EIR	Emerging Infection Report
EU	European Union
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HEV	Hepatitis E virus
HIV	Human immunodeficiency virus
HTLV	Human T cell lymphotropic virus
JPAC	Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee
LFT	Liver function test
LGBT	Lesbian, gay, bisexual, and transgender
MHRA	Medicines and Healthcare products Regulatory Agency
MSM	Men who have sex with men
NAT	Nucleic acid testing
NHSBT	National Health Service Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
PHE	Public Health England
PTR	Post-transfusion reactions
RNA	Ribonucleic acid
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SACTTI	Standing Advisory Committee on Transfusion Transmitted Infection
SAR	Serious adverse reactions
SNBTS	Scottish National Blood Transfusion Service
TTI	Transfusion-transmitted infections
UK	United Kingdom
vCJD	Variant Creutzfeld Jakob Disease
WBS	Welsh Blood Service

Introduction

This chapter describes suspected TTI incidents investigated by the UK Blood Services and reported to the National Health Service Blood and Transplant (NHSBT)/Public Health England (PHE) Epidemiology Unit in 2019.

The risk of a TTI in the UK remains very low. During 2019, 2 TTI investigations were concluded as probable or confirmed, neither of these were due to errors in donor selection or testing.

Annual reports from the Epidemiology Unit are available here: https://hospital.blood.co.uk/epidemiology-reports/.

Blood donation screening process

Every blood donation in the UK is screened for hepatitis B virus (HBV), hepatitis C virus (HCV), hepatitis E virus (HEV), human immunodeficiency virus (HIV) and syphilis. Human T cell lymphotropic virus (HTLV) is screened for in donations from new blood donors and other infections such as malaria are screened for depending on travel history of the donor. A separate bacterial screening process is also in place for platelets due to differences in the storage requirements for this blood product.

At the time of blood donation samples are collected for screening purposes. For the screening of viral nucleic acids (ribonucleic acid (RNA) or deoxyribonucleic acid (DNA)) the blood samples are pooled together in a batch of six, 16 or 24 prior to screening. If RNA/DNA is detected in that pool, then individual samples known to be in that pool are re-tested separately in order to identify a positive sample. All antibody and/or antigen testing is done using individual blood samples. If RNA/DNA is detected, or antibody result is repeatedly positive suggesting an infection, then the donation is discarded and the sample is sent to a reference laboratory for further testing to confirm the result. If a positive result is confirmed the donor will be notified, offered an opportunity to discuss these results in detail and referred to the appropriate medical care as necessary.

Testing and selection of donors update

No major changes to testing procedures or donor selection occurred in 2019. The HBV and HEV

screening processes are currently under review by Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO).

However, the UK Blood Services, PHE, Nottingham University and a range of stakeholders including patients and lesbian, gay, bisexual, and transgender (LGBT+) groups have been working together in the FAIR (For the Assessment of Individualised Risk) steering group. The aim of this group is to explore if a more individualised risk assessment approach to blood donor selection policy is possible whilst ensuring the safe supply of blood to patients. If the evidence shows that a more individualised blood donation risk assessment can be safely and practically introduced, it could mean that some people who are currently deferred for 3 months due to sexual-related risk, such as some men who have sex with men (MSM), could donate. The group hopes to report their research findings towards the end of 2020.

More information is available here: https://www.blood.co.uk/news-and-campaigns/news-and-statements/fair-steering-group/.

Summary of reports made to the NHSBT/PHE Epidemiology Unit in 2019

During 2019, UK Blood Services investigated 139 suspected bacterial incidents and 13 suspected viral incidents (Figure 20.1). From these, there has been:

- One confirmed HEV incident reported by NHSBT
- One probable HBV incident reported by NHSBT
- One near miss investigation into HEV reported by the Welsh Blood Service (WBS) from 2018
- In addition, four lookback investigations were reported in 2019 with no evidence of a TTI:
  - One lookback investigation into HEV reported by the Scottish National Blood Transfusion Service (SNBTS) in 2019
  - One lookback investigation into HEV reported by NHSBT in 2018
  - One lookback investigation into syphilis reported by NHSBT in 2018
  - One lookback investigation into HEV reported by SNBTS in 2018

Figure 20.1 includes all investigations in England, Wales, Scotland and Northern Ireland. In previous SHOT reports investigations in Wales, Scotland or Northern Ireland concluded as post-transfusion reactions (PTR) or not, were not included here.

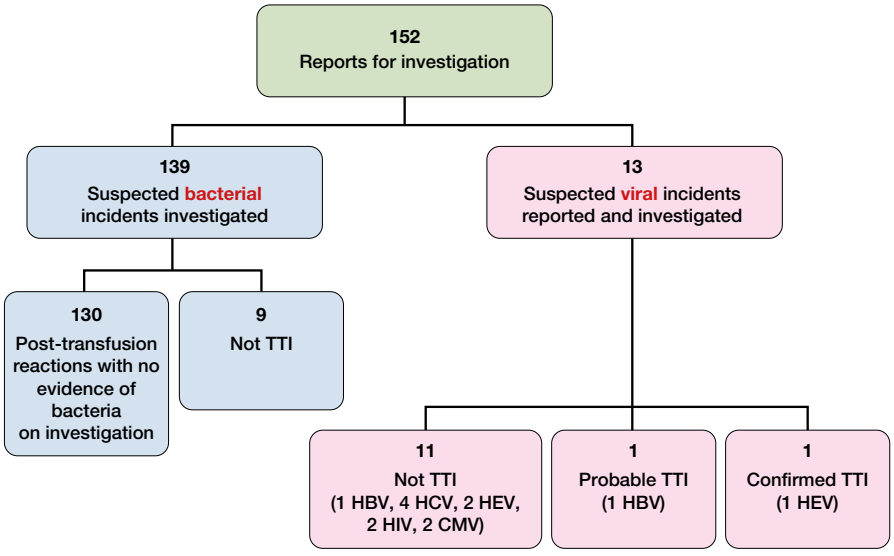

Figure 20.1: Outcome of UK reports of suspected TTI made to the NHSBT/PHE Epidemiology Unit in 2019

TTI=transfusion-transmitted infection; CMV=cytomegalovirus; HBV=hepatitis B virus; HCV=hepatitis C virus; HEV=hepatitis E virus; HIV=human immunodeficiency virus

Death n=1

A patient with confirmed transfusion-transmitted HEV died after being transfused in 2019 (Case 20.1).

Major morbidity n=1

A patient with probable transfusion-transmitted HBV developed chronic HBV following a transfusion in 2015 (Case 20.2).

Bacterial TTI reports 2019

In 2019, no reported suspected bacterial TTI investigations were concluded to be confirmed, probable or possible. All bacterial TTI investigations were concluded to be either PTR with no evidence of bacteria in the implicated or associated products or in the recipient, or not a TTI, with evidence of bacteria in either the products or the recipient(s) but not both. The four UK Blood Services all use the BacT/ALERT system for bacterial screening which has been successful in reducing the risk of bacterial TTI (McDonald et al. 2017). Sampling methods have recently become more consistent across the four Blood Services but some slight variation still exist, details of which are described in Table 20.1.

Bacterial TTI 1996–2019

Screening of platelet components cannot guarantee freedom from bacterial contamination. Packs are released for issue as 'negative-to-date', which may be before bacteria have multiplied sufficiently to trigger detection on screening. There have been nine bacterial near misses, all but one in platelet components, reported to the unit between 2011 and 2019. Overall, out of a total of 44 bacterial transfusion-transmissions to individual recipients, 37 (34 incidents) have been caused by the transfusion of platelets, and 7 by red cells (Table 20.3) since reporting began in 1996.

Haemovigilance systems for bacterial TTI are passive and as such rely on clinical colleagues to report suspected TTI. Current British Society for Haematology (BSH) guidance recommends that patients are advised to report any symptoms that occur within 24 hours of transfusion (BSH Tinegate et al. 2012) although our experience suggests that patients with confirmed bacterial TTI become unwell very rapidly, often during transfusion.

Table 20.1: Bacterial screening methods used by the UK Blood Services

	Time of sampling (hour)	Volume sampled (mL)	Apheresis sample	Time at release (hour)	Length of screening
NHSBT	≥36	2 x 8	Post-split	6	Day 7
NIBTS	≥36	2 x 8	Pre-split	6	Day 9
SNBTS	≥36	2 x 8	Pre-split	6	Day 7
WBS	≥36	2 x 8	Post-split	12	Day 7

NIBTS=Northern Ireland Blood Transfusion Service

Viral TTI reports 2019

In 2019, there was 1 confirmed HEV and 1 probable HBV TTI reported by the NHSBT.

Case 20.1: Confirmed HEV TTI (Morbidity: major - death; imputability: 3 - confirmed)

In late September 2019, an apheresis platelet donation from a repeat donor was picked up on screening as HEV RNA positive with a viral load of 4,900IU/mL. An investigation was launched immediately and archive samples from previous donations were retrieved and tested for HEV RNA in individual sample testing. In the donor's previous donation from the beginning of September, HEV RNA was detectable but below the level of quantification at <36.13IU/mL. This low-level infection was not picked up by the original screening process done in pools of 24 with a detection limit of around 500IU/mL. The recipient of the positive donation was traced and found to be a patient in their 40s with aplastic anaemia, excessive alcohol use and portal hypertension (without cirrhosis) who had received the platelets shortly after the donation was made. Their portal hypertension was due to underlying liver problems and their anaemia was caused by a rare genetic mutation causing

bone marrow failure which was being treated with danazol. The platelets were given as a prophylactic treatment before a dental procedure as they had a low platelet count.

Two months after the identified transfusion the patient was diagnosed with HEV infection but was clinically well. They were monitored closely and remained stable with unchanged liver function tests (LFT) until mid-November. Around this time, the patient's viral load peaked at 29,200,000IU/mL and they were developing a good antibody response. However, this coincided with a sudden increase in bilirubin and alanine aminotransferase (ALT) levels and hence the patient was started on Ribavirin. Their liver function continued to decline from this point eventually leading to acute hepatitis with kidney failure. Sadly, the patient died at the end of November 2019. The viral load in the sample of the index unit was too low to perform sequence analysis but this was possible on the donor's subsequent donation in late September. Sequence obtained from the virus infecting the recipient was identical to that obtained from the donor. Based on this it was confirmed that blood transfusion was the source of the patient's HEV infection.

A second recipient of apheresis platelets from the donation in early September was also identified. The recipient was followed up for 6 months during which time there was no evidence of HEV infection.

Case 20.2: Probable viral HBV TTI (Morbidity: Major; imputability: 2 - probable)

In January 2019, a patient in their 70s with chronic HBV infection self-reported to NHSBT as they had been advised by a hospital that they might have acquired HBV from a blood transfusion in 2015. An investigation was initiated and it was confirmed that the patient received three units of red cells during surgery on their mitral valve in December 2015. No archived samples were available, but as all three donors had donated since, samples from their subsequent donations were retrieved. These samples were tested and results showed no evidence of infection in donor 1 and 3 however the sample from donor 2 contained antibodies for HBV core but was negative for DNA. These results indicate a past infection in donor 2. This donor originates from an area with high HBV prevalence, particularly for the HBV genotype identified in the recipient. The donor was resampled. A large volume was taken to increase the likelihood that any small levels of DNA would be detected, however no DNA could be detected here either. It is worth noting that it is possible for HBV transmission to occur without detectable DNA and that it was not possible to test a sample of the index unit for DNA.

Extensive investigations into other sources of infection had been conducted at the time of the incident by external bodies such as hospital and local public health teams, including screening of family members and staff. No other potential sources were identified in those investigations; NHSBT was not contacted at that time. Based on all the available evidence it was concluded that blood transfusion was the probable source of the infection but this could not be confirmed as it was not possible to genetically sequence the DNA detected in the donor sample. A later sample from the donor (when donated in October 2016), was traced back to a patient in their 80s. The patient was tested and found to be positive for anti-HBc antibodies indicating a past HBV infection. It is possible that they acquired the HBV infection via blood transfusion. The donor has since been removed from panel and the hospital and patient have been notified of the results of NHSBT's investigations.

Near miss viral HEV TTI

WBS screens blood donations for HEV in pools of 16 using nucleic acid testing (NAT) with a pre-defined manufacturer's cut-off level used to determine a positive or a negative result, some other UK Blood Services test in pools of 24. Towards the end of 2018 one such pool was screened by WBS and the result reported as negative, however a scientist noticed this pool was very close to the cut-off level and noted this as unusual. As a result, a hold was placed on the donation and each of the donations from this pool were screened for HEV individually and one was found to be positive for HEV RNA.

The donation was referred to the manufacturer who has tested the viral load in the donor and declared it to be below the 100% detection limit (218IU/mL). The donor sample was tested individually 16 times with results ranging from 9 to 150 IU/mL, with an average result of 58IU/mL, all of which were below the level claimed for 100% detection. This donation was never issued so no lookback was required. It should however be noted that an HEV transmission reported in the 2018 Annual SHOT Report (Narayan et al.

2019) as Case 20.4 describes a confirmed HEV TTI that was transmitted to an immunocompromised patient from a donation with similarly low levels of RNA to what was detected by WBS in this scenario.

Viral TTI 1996–2019

The patient may have been transfused many years prior to the year in which the incident is investigated and reported to SHOT because of the chronic nature, and therefore late recognition, of some viral infections.

Since 1996, 35 confirmed incidents of transfusion-transmitted viral infections have been documented in the UK, involving 42 recipients. Among these, HBV (n=12) and HEV (n=12) were the most commonly reported proven viral TTI. For HBV, this is partly because the 'window period' where an infectious donation from a recently infected donor cannot be detected by the screening tests is longer than for HCV or HIV, despite NAT screening of blood donations. All except two HEV transmissions were reported before the HEV RNA screening was introduced in April 2017 in the UK.

The UK was one of the first Blood Services to introduce HEV-screening; since that time over 1,000 HEV RNA containing donations have been successfully identified by screening and removed from the blood supply. The rate of HEV RNA detected among donors is greater than other viral infections because it is generally acquired through food, and there is no specific donor selection to minimise donations from those infected. This gives rise to an increased chance of non-detection of HEV RNA. Furthermore, as screening is performed in pools, it is recognised that donations containing a small amount of HEV RNA can be missed and HEV then potentially transmitted via blood transfusion.

In cases where CMV untested units were transfused to those who require CMV-negative components (e.g. in pregnant patients), further testing can be carried out by transfusion microbiology teams on archived samples from donations which are kept for 3 years post donation.

https://hospital.blood.co.uk/diagnostic-services/reporting-adverse-events/investigation-of-possible-transmission-of-non-bacterial-transfusion-transmitted-infection/.

Residual risk of HBV, HCV or HIV

The risks of a potentially infectious HBV, HCV or HIV window period donation not being detected on testing in the UK are very low at less than 1 per million donations tested (Table 20.2) (JPAC 2019).

Table 20.2: The estimated risk of a potentially infectious HBV, HCV or HIV window period* blood donation not detected on testing, UK 2016-2018

	HBV	HCV	HIV
Number per million donations	1.04	<0.01	0.04
95% confidence interval	(0.54-2.39)	(0.00-0.04)	(0.01-0.07)
At 1.9 million donations per year testing will miss a potentially infectious window period donation every:	6 months	90 years	15 years

**The window period is the time very early in the course of infection when tests in use do not detect the virus but there may be sufficient to transmit*

Far fewer TTI are observed in practice than the estimated risks in Table 20.2 indicate, partly because the estimates have wide uncertainty and the model used to calculate risk is based on the risk in all donations tested. The model does not incorporate pack non-use, recipient susceptibility to infection, or under-ascertainment/under-reporting, for example due to recipients dying from an underlying medical condition before a chronic asymptomatic viral condition is identified, or, in the case of HBV, an asymptomatic acute infection.

Parasitic TTI

There were no reported parasitic infections for investigation in 2019.

Emerging infections

The Epidemiology unit produces the Emerging Infection Report (EIR), a monthly horizon scanning list of emerging infections with potential to affect the UK blood and tissue supply. The Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) then risk-assesses the EIR and highlights whether further action is required by Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC).

UK Blood Services have put cautionary safety measures in place in relation to the global COVID-19 outbreak. The Epidemiology unit, SACTTI and JPAC has been, and will continue to be, closely monitoring this outbreak, risk-assessing the potential impact on the safety of the UK blood supply and responding appropriately.

Variant Creutzfeld Jakob Disease (vCJD) 2019

There were no vCJD investigations in 2019.

vCJD 1996-2019

Three vCJD incidents (Table 20.3) took place prior to the introduction of leucodepletion and other measures taken by the UK Blood Services to reduce the risk of vCJD transmission by blood, plasma and tissue products. All these measures have been reviewed and endorsed by SaBTO (SaBTO 2013).

One of these measures, the provision of imported plasma for individuals born on or after 1st January 1996, was withdrawn in September 2019. This followed a recommendation by SaBTO based on evaluation of the risk of transmission of vCJD. Other risk reduction measures, such as leucodepletion, remain in place (SaBTO 2019).

Table 20.3: Number of confirmed TTI incidents, by year of transfusion with total infected recipients and outcomes (death, major morbidity, minor morbidity) in the UK between October 1996 and December 2019 (Scotland included from October 1998)

Year of transfusion*	Number of incidents (recipients) by infection											Implicated component				
	Bacteria	HAV	HBV	HCV	HEV	HIV	HTLV I	Parvovirus (B19)	Malaria	vCJD/prion	Total	RBC	Pooled platelet	Apheresis platelet	FFP	Cryo
Pre 1996	-	-	1 (1)	-	-	-	2 (2)	-	-	-	**3 (3)**	3	-	-	-	-
1996	-	1 (1)	1 (1)	1 (1)	-	1 (3)	-	-	-	1 (1)	**5 (7)**	5	1	-	1	-
1997	3 (3)	-	1 (1)	1 (1)	-	-	-	-	1 (1)	2 (2)	**8 (8)**	6	1	1	-	-
1998	4 (4)	-	1 (1)	-	-	-	-	-	-	-	**5 (5)**	2	1	2	-	-
1999	4 (4)	-	2 (3)	-	-	-	-	-	-	‡ (1)	**6 (8)**	5	3	-	-	-
2000	7 (7)	1 (1)	1 (1)	-	-	-	-	-	-	-	**9 (9)**	1	5	3	-	-
2001	5 (5)	-	-	-	-	-	-	-	-	-	**5 (5)**	-	4	1	-	-
2002	1 (1)	-	1 (1)	-	-	1 (1)†	-	-	-	-	**3 (3)**	2	1	-	-	-
2003	3 (3)	-	1 (1)	-	-	-	-	-	1 (1)	-	**5 (5)**	1	1	3	-	-
2004	††	-	-	-	1 (1)	-	-	-	-	-	**1 (1)**	1	-	-	-	-
2005	2 (2)	1 (1)	1 (1)	-	-	-	-	-	-	-	**4 (4)**	1	3	-	-	-
2006	2 (2)	-	-	-	-	-	-	-	-	-	**2 (2)**	-	1	1	-	-
2007	3 (3)	-	-	-	-	-	-	-	-	-	**3 (3)**	2	1	-	-	-
2008	4 (6)	-	-	-	-	-	-	-	-	-	**4 (6)**	-	2	4	-	-
2009	2 (3)	-	-	-	-	-	-	-	-	-	**2 (3)**	1	-	2	-	-
2010	-	-	-	-	-	-	-	-	-	-	**-**	-	-	-	-	-
2011	-	-	1 (2)	-	1 (2)	-	-	-	-	-	**2 (4)**	2	-	-	2	-
2012	-	-	1 (1)	-	1 (1)	-	-	1(1)	-	-	**3 (3)**	2	-	-	1	-
2013	-	-	-	-	-	-	-	-	-	-	**-**	-	-	-	-	-
2014	-	-	-	-	2 (3)	-	-	-	-	-	**2 (3)**	1	-	-	2	-
2015	1 (1)	-	-	-	4 (5)	-	-	-	-	-	**5 (6)**	-	3	1	1	1
2016	-	-	-	-	1 (1)	-	-	-	-	-	**1 (1)**	1	-	-	-	-
2017	-	1 (1)	-	-	-	-	-	-	-	-	**1 (1)**	-	-	1	-	-
2018	-	-	-	-	1 (1)	-	-	-	-	-	**1 (1)**	-	-	1	-	-
2019	-	-	-	-	1 (1)	-	-	-	-	-	**1 (1)**	-	-	1	-	-
Number of incidents	**41**	**4**	**12**	**2**	**12**	**2**	**2**	**1**	**2**	**3**	**81**	-	-	-	-	-
Number of infected recipients	44	4	14	2	15	4	2	1	2	4	**92**	**36**	**27**	**21**	**7**	**1**
Death due to, or contributed to, by TTI	11	0	0	0	2	0	0	0	1	3	**17**					
Major morbidity	29	3	14	2	9	4	2	1	1	1§	**66**					
Minor morbidity	4	1	0	0	4	0	0	0	0	0	**9**					
Implicated component																
RBC	7	1	11	2	4	2	2	1	2	4	**36**					
Pooled platelet	21	2	1	-	2	1	-	-	-	-	**27**					
Apheresis platelet	16	1	1	-	3	-	-	-	-	-	**21**					
FFP	-	-	1	-	5	1	-	-	-	-	**7**					
Cryoprecipitate	-	-	-	-	1	-	-	-	-	-	**1**					

Note: Numbers in brackets refer to recipients, and probable incidents are excluded

Please note: No screening was in place for vCJD, human T cell lymphotropic virus (HTLV), hepatitis A virus (HAV), HEV or parvovirus B19 at the time of the documented transmissions. In both malaria transmissions, malaria antibody testing was not applicable at the time according to information supplied at donation

Please note: HCV investigations where the transfusion was prior to screening are not included in the above figure

** Year of transfusion may be prior to year of report to SHOT due to delay in recognition of chronic infection*

† The 2 HIV incidents were associated with window period donations (anti-HIV negative/HIV RNA positive) before HIV NAT screening was in place. A third window period donation in 2002 was transfused to an elderly patient, who died soon after surgery. The recipient's HIV status was therefore not determined and not included

†† In 2004 there was an incident involving contamination of a pooled platelet pack with Staphylococcus epidermidis, which did not meet the TTI definition because transmission to the recipient was not confirmed, but it would seem likely. This case was classified as 'not transfusion-transmitted'

‡ Same blood donor as one of the 1997 transmissions so counted as the same incident; note: counted as two separate incidents in previous reports

§ A further prion case died but transfusion was not implicated as the cause of death. The outcome was assigned to major morbidity instead because although there was post-mortem evidence of abnormal prion proteins in the spleen the patient had died of a condition unrelated to vCJD and had shown no symptoms of vCJD prior to death

For further information or alternative breakdown of data please contact the National Coordinator for Transfusion Transmitted Infections via the NHSBT/PHE Epidemiology Unit at epidemiology@nhsbt.nhs.uk.

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