

Transfusion-Transmitted Infections (TTI) n=0 (1 probable)

21

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Definition:

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 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.

Abbreviations used in this chapter

ALT	Alanine transaminase	NAT	Nucleic acid testing
BSH	British Society for Haematology	NBL	National Bacteriology Laboratory
DNA	Deoxyribonucleic acid	NHSBT	National Health Service Blood and Transplant
EIR	Emerging Infection Report	NIBTS	Northern Ireland Blood Transfusion Service
EU	European Union	OBI	Occult hepatitis B virus infection
FAIR	For the assessment of individualised risk	PHE	Public Health England
FFP	Fresh frozen plasma	PTR	Post-transfusion reactions
HAV	Hepatitis A virus	RNA	Ribonucleic acid
HBc	Hepatitis B core antigen	SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
HBsAg	Hepatitis B surface antigen	SACTTI	Standing Advisory Committee on Transfusion Transmitted Infection
HBV	Hepatitis B virus	SAR	Serious adverse reactions

HCV	Hepatitis C virus	SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
HEV	Hepatitis E virus	SNBTS	Scottish National Blood Transfusion Service
HIV	Human immunodeficiency virus	STI	Sexually transmitted infection
HTLV	Human T cell lymphotropic virus	TTI	Transfusion-transmitted infections
JPAC	Joint UKBTS Professional Advisory Committee	UK	United Kingdom
LGBTQ+	Lesbian, gay, bisexual, transgender and queer	vCJD	Variant Creutzfeldt Jakob Disease
MHRA	Medicines and Healthcare products Regulatory Agency	WBS	Welsh Blood Service



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 three years. Testing can be performed on these samples if a TTI is suspected during this time
- 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 consenting patients for blood transfusion have up-to-date knowledge of blood donation screening and the small potential for TTI, or be aware of how to access this information



Headline data 2020

Number of reports n=0
 Deaths n=0
 Major morbidity n=0



Demographic data



Male
n=0



Female
n=0

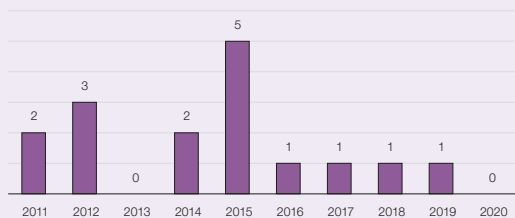


Adults
n=0



Paediatric
n=0

Confirmed TTI reports by year



Blood component data

Red cells n=0
 Platelets n=0
 Plasma n=0
 Multiple Components n=0
 Other n=0



Introduction

This chapter describes TTI incidents investigated by the UK Blood Services and reported to the NHSBT/ PHE Epidemiology Unit’s surveillance scheme in 2020.

The risk of a TTI in the UK remains extremely low. During 2020, 1 TTI investigation was concluded as probable, and there was 1 near miss investigation into a bacterial contamination. An additional probable TTI first reported in 2019 was finalised in 2020.

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

Summary of reports made to the NHSBT/PHE Epidemiology Unit in 2020

During 2020, UK Blood Services investigated 135 suspected bacterial incidents and 5 suspected viral incidents (Figure 21.1). From these, there has been:

- One probable transfusion-transmitted HBV incident reported by NHSBT
- One near miss investigation into bacterial contamination (*Staphylococcus aureus*) reported by NHSBT
- One probable transfusion-transmitted HEV incident that was not reported in 2019, but has now been finalised by NHSBT

Figure 21.1 includes all investigations reported in 2020 in England, Northern Ireland, Scotland, or Wales. In previous Annual SHOT Reports investigations in Northern Ireland, Scotland, or Wales, concluded as PTR or not, were not included here.

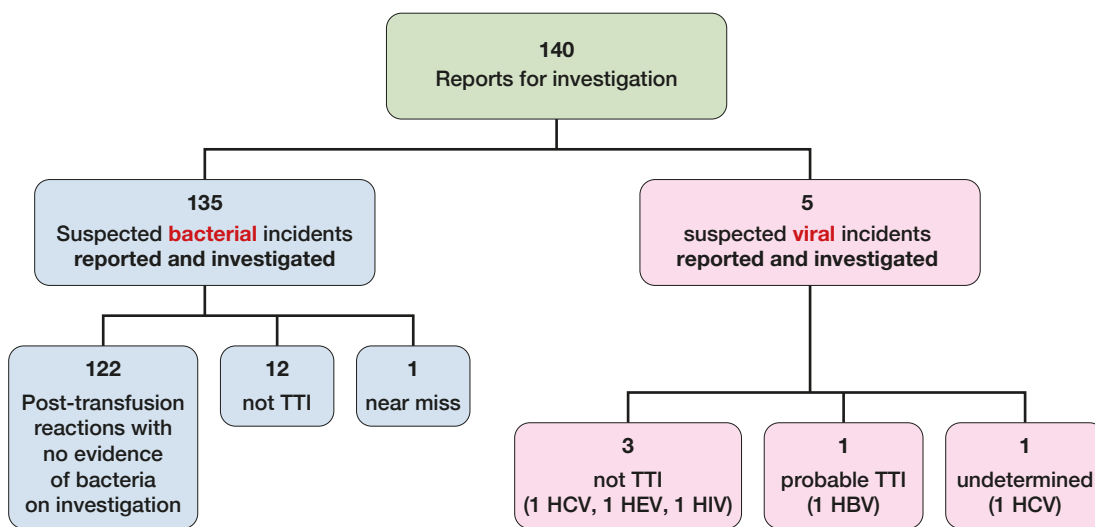


Figure 21.1: Outcome of reports of suspected TTI made to the NHSBT/PHE Epidemiology Unit in 2020 update

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

Note:

- The undetermined HCV case was related to donations from 1990, which was before HCV screening was introduced
- A **PTR** occurs when a blood transfusion recipient develops a reaction following a transfusion and bacteria were suspected. However, no bacteria were cultured in the recipient, units or donor(s), i.e. no evidence of any bacterial contamination
- A **confirmed TTI** is classified as in the above TTI definition with evidence that the virus/bacterium is indistinguishable on molecular typing between patient and donor/pack
- A **probable TTI** is classified as a TTI as in the above definition, but where molecular typing cannot be carried out to confirm this
- **Not a TTI** is defined as an investigation that concluded the infection in the recipient was NOT caused by transfusion, either as no infected donors identified (after all donors traced) or bacteria/virus identified in the recipient, but all units cleared (no bacteria/virus) in the unit and/ or implicated donors
- A **near miss** is defined as either an infection was identified in the unit due to be transfused however the unit was NOT used in transfusion (e.g. bacterial growth seen in unit and returned to bacteriology laboratory prior to transfusion for investigation) or an infected donor calls post donation, and the unit is recalled and infection found in unit before it is transfused

Deaths n=0

No patient deaths occurred due to confirmed transfusion-transmitted infections in 2020.

Major morbidity n=0

The probable HBV was an asymptomatic infection. The patient had significant underlying health issues with potential for severe consequences, and their HBV infection was identified via routine dialysis screening.

The investigation of probable HEV concluded in 2020 found the recipient did not develop hepatitis.

Bacterial TTI reports 2020

No reported suspected bacterial TTI investigations were concluded to be confirmed, probable or possible. All bacterial TTI investigations were concluded to be either:

- post-transfusion reaction with no evidence of bacteria in the implicated or associated products or in the recipient
- 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 21.1.

Near miss bacterial TTI (*Staphylococcus aureus*)

An apheresis platelet pack was returned to NBL after a 'visual abnormality' of numerous white clots ('scrambled egg' appearance) was noted by the hospital, before it was transfused. Both BacT/ALERT bottles set up from this pack had flagged positive and Gram-positive cultures were obtained from the index pack and from both bottles. *Staphylococcus aureus* was identified in the index pack. Repeat cultures confirmed the presence of *S. aureus* in the index pack. An associated pack had not been issued to a hospital and was recalled to NBL. There were no abnormalities noted in this pack. Both BacT/ALERT bottles set up from this pack were negative at day 7 and no organisms were seen in the Gram stain from the pack. Bacterial screening of this donation was reported as negative and the bottles had been discarded 2 days after unloading and therefore were not available for further analysis. *S. aureus* was subsequently isolated from a swab from the implicated donor. Molecular typing from the reference laboratory confirmed that the donor isolate and pack isolate were indistinguishable and therefore represented a single strain. The donor was informed and advised to check for any eczema, and subsequently removed from the donor panel.

Bacterial TTIs 1996 – 2020

Screening of platelet components cannot guarantee the absence of 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 ten bacterial near misses, all but one in platelet components, reported between 2011 and 2020. Overall, out of a total of 44 bacterial transfusion-transmissions to individual recipients, 37 (34 donations) have been caused by the transfusion of platelets, and 7 by red cells (Table 21.3) since reporting began in 1996.

Haemovigilance systems for bacterial TTI are passive, relying on clinical colleagues to suspect and report TTI. Current 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 21.1:
Bacterial screening
methods used
by the UK Blood
Services

UK Blood Service	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

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

Viral TTI reports 2020

In 2020, there was one probable HBV TTI reported by NHSBT.

Case 21.1: Probable HBV TTI case: (Morbidity: – 0; imputability: 2 – probable)

A male in his 50s was diagnosed with an acute HBV infection following a routine dialysis screening, which included testing for HBsAg. The case was initially reported to PHE by the renal team following the first HBsAg positive result.

Retrospective testing of patient samples found HBV DNA in a December 2019 sample; samples tested prior to that were negative for HBV including anti-HBc. No other source or risk factors for HBV infection were identified, but it should be noted that the patient was born in a part of the world where HBV is endemic, and hence reactivation cannot be completely excluded. Staff and patient screening were performed, and no obvious source was found. The patient had not been vaccinated against HBV and did not present with any symptoms.

Blood transfusions from the previous 6 months were identified; these included 11 donor exposures. A total of 10 returning donors tested negative for anti-HBc, the remaining blood donor tested positive for anti-HBc. They had given three previous donations, and these were found positive for anti-HBc in retrospective testing. HBV DNA was detected in the implicated red cell donation at 8.6IU/mL; lookback into FFP and two HBV DNA-negative donations are still on-going. All three donations were HBsAg negative on screening, and no HBV DNA was detected at the time of donation. This is in keeping with an OBI in the donor, who was born in an HBV endemic country. The donor has been informed that they have OBI and has been referred for specialist care. They can no longer donate blood.

A large volume follow-up sample was obtained from this donor to allow further sequence comparison between their sample and recipient sample. Unfortunately, HBV DNA was not detectable on the donor sample despite concentration (note low levels of fluctuating HBV DNA is typical in OBI). The recipient sample was identified as HBV genotype E; the common type identified in Sub-Saharan Africa and keeping with transmission.

Based on our investigations, it is probable that this patient acquired HBV infection via blood transfusion.

Case 21.2: 2019 - Probable HEV TTI case from 2019

This was a multi-transfused female in her 20s with aplastic anaemia and Turners syndrome. She was diagnosed with HEV infection in August 2019, and although the virus has now cleared from her blood, anti-viral treatment has not been stopped yet (due to her immunosuppression). Fortunately, her ALT levels have remained normal and she has not developed a hepatitis.

It was identified retrospectively that a red cell donation she received in June 2019 contained a small amount of HEV RNA (31IU/mL). This unit was tested correctly at the time of donation testing, but HEV RNA was not detectable with the screening assay at this level (a detection limit around 500IU/mL). Due to the small viral load, we could not do sequencing to confirm the transmission and hence the case is reported as probable. It is recognised that the current HEV screening in place in England will not be able to identify donations with a very small amount of HEV RNA.

Viral TTI 1996 – 2020

Transfusion may occur 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, 42 confirmed transfusion-transmitted viral infections have been documented in the UK, involving 35 donors. Among these, HBV (n=12) and HEV (n=12) were the most commonly reported and proven viral TTI. 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 for HBV than for HCV or HIV, despite NAT screening of blood donations.

Evidence relating to transmission of OBI in the UK is emerging. Donors with this chronic form of HBV

infection were thought to typically have a level of HBV DNA that was very unlikely to transmit, however 5 reports have been made of an HBV infection in recipients who had received components from donors with OBI in England; transmission could not be confirmed because of a lack of sequencing information.

All except 2 HEV transmissions were reported before the HEV RNA screening was introduced in April 2017 in the UK. The UK Blood Services were amongst the first to introduce HEV screening; since then 1,770 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 a donation being collected from an infected donor/individual. Furthermore, as screening is performed in pools, it is recognised that donations containing a small amount of HEV RNA can be missed and potentially transmitted via blood transfusion.

Residual risk of HBV, HCV, or HIV

The risks of a potentially infectious HBV, HCV or HIV donation not being detected (due to the window period) in the UK are very low at less than 1 per million donations tested (Table 21.2) (JPAC, 2020). The calculations are made annually, but for HBV only consider the risk of non-detection of acute infections and not the risk of non-detection of an OBI.

Table 21.2:
The estimated residual risk (and 95% confidence interval) that a donation made in the HBV, HCV and HIV window period is not detected on screening UK: 2017-2019

	HBV	HCV	HIV
Number per million donations	0.87	<0.01	0.04
95% confidence interval	(0.35-1.70)	(0.00-0.05)	(0.01-0.09)
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 the viral load may be sufficient to transmit infection*

Far fewer TTI are observed in practice than the estimated risks in Table 21.2 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 adjust for other factors, such as packs which are not transfused, 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.

Blood donation screening process

Every blood donation in the UK is screened for HBV, HCV, HEV, HIV and syphilis. 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 as the storage of platelets at 22 ±2°C encourages bacterial growth.

At the time of blood donation, blood samples are collected for screening purposes. For the screening of viral nucleic acids (RNA or DNA) blood samples from different donors 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 individually in order to identify positive samples. 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 2020

No major changes to testing procedures or donor selection in regard to known TTI occurred in 2020. The HBV and HEV screening processes are currently under review by SaBTO.

The FAIR (For the Assessment of Individualised Risk) steering group concluded their work and reported on their findings that a recommendation for a more individualised approach to donor selection was feasible in the UK. The group included representatives from the UK Blood Services, PHE, University of Nottingham and a range of stakeholders including donors, recipients and LGBTQ+ groups. This approach was accepted by health ministers and is expected to be implemented in the summer of 2021. Under this new donor selection policy, donors who have had the same sexual partner (and no others) in the last three months and who do not have an STI should be eligible to donate. This will allow more gay and bisexual men to donate blood.

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

Parasitic TTI

There were no reported parasitic infections for investigation in 2020.

Emerging infections

The EIR produced by the NHSBT/PHE Epidemiology Unit is distributed monthly. A range of sources are reviewed 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 SACTTI. The chair of SACTTI also receives early warning communications or other reports deemed urgent as they arise.

These monthly listings, 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.

Currently West Nile Virus and Usutu virus are spreading in Europe, with the latter presenting in birds in the UK. The current situation is being monitored carefully and all blood donors from infected regions are screened for both viruses.

Variant Creutzfeldt Jakob Disease (vCJD) 2020

There were no vCJD investigations in 2020.

vCJD 1996-2020

Three vCJD incidents (Table 21.3) 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).

SARS-CoV-2

As part of the convalescent plasma trials, NHSBT screened over 1000 donors for SARS-CoV-2 RNA, even though the risk of viremia is considered to be very low. All of the screened donations were negative. In addition to this, any units obtained from donors subsequently diagnosed with SARS-CoV-2 (within 5 days from infection) were re-called and discarded. There were no known cases of transfusion-transmitted SARS-CoV-2 infections reported to NHSBT in 2020 and there is currently no evidence that SARS-CoV-2 is a TTI. SNBTS reported two investigations for recipients who developed COVID-19; the archive samples were tested and found to be negative.

Table 21.3:
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 2020 (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	-	-
2020	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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					

Notes:

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

No screening has been ever in place for vCJD, hepatitis A virus (HAV) or parvovirus B19. Human T cell lymphotropic virus (HTLV) screening began in 2002 and HEV was not in place 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.

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.

§ In a further prion case the patient 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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