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NHS Blood and Transplant

Safe Supplies: Reflecting on the Population

Annual review from the NHS Blood and Transplant/PHE Epidemiology Unit, 2013

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Glossary of abbreviations

Anti-	Antibody to
Anti-HBc	Antibody to Hepatitis B core antigen
Anti-HBs	Antibody to Hepatitis B surface antigen
B19	Parvovirus B19
BBVU	Blood Borne Virus Unit
BAME	Black, Asian and Minority Ethnic group
CCHF	Crimean-Congo haemorrhagic fever
ChikV	Chikungunya virus
CMV	Cytomegalovirus
CNS	Coagulase Negative Staphylococci
CSF	Cerebrospinal Fluid
DBD	Donor after Brain Death
DCD	Donor after Circulatory Death
DHC	Donor Health Check
DSG	Donor Selection Guidelines
EBV	Epstein-Barr Virus
FFP	Fresh Frozen Plasma
HBV	Hepatitis B Virus
HBsAg	Hepatitis B surface antigen
HCV	Hepatitis C Virus
HDV	Hepatitis Delta Virus
HEV	Hepatitis E Virus
HIV	Human Immunodeficiency Virus
HTLV	Human T-cell Lymphotropic Virus
IBTS	Irish Blood Transfusion Service
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IDU	Injecting Drug Use
JPAC	UKBTS/PHE Joint Professional Advisory Committee
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
MRPND	Most Recent Previous Negative Donation
MSM	Men who have Sex with Men
NAT	Nucleic Acid Testing
NBL	National Bacteriology Laboratory
NHSBT	NHS Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
NTMRL	National Transfusion Microbiology Reference Laboratory
PHE	Public Health England
PULSE	the NHSBT national donor management database
PWID	People Who Inject Drugs

ROI	Republic of Ireland
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SACTTI	Standing Advisory Committee on Transfusion Transmitted Infection
SBMW	Sex between Men and Women
SBM	Sex between Men
SHOT	Serious Hazards of Transfusion
SNBTS	Scottish National Blood Transfusion Service
TTI	Transfusion Transmitted Infection
TP	*Treponema pallidum*
UKBTS	United Kingdom Blood Transfusion Service
vCJD	variant Creutzfeldt-Jakob Disease
WBS	Welsh Blood Service
WHO	World Health Organisation
WNV	West Nile Virus
WP	Window Period

Foreword

We are delighted to present the 2013 findings from the joint NHS Blood and Transplant/Public Health England epidemiology team. As always, the team have produced a high quality report with robust data which is envied internationally. This work demonstrates the richness of the evidence that can be presented when Blood Services and Public Health organisations across the UK join forces.

The findings provide assurance regarding the extremely high safety of the UK blood supply for current risks, and provide a solid base on which to build further reviews of donor eligibility to ensure that no donors are unnecessarily declined. Equally reassuring is the great attention paid to horizon scanning for emerging infections.

We recommend this report as a fascinating read for all concerned with safety of blood, tissues and organs.

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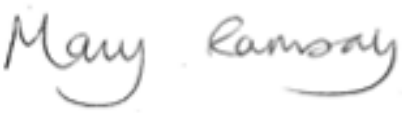

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Contents

Executive summary

Blood donors represent a sentinel population who are usually considered to be at reduced risk of blood-borne infections due to self-selection to donate and further selection via the donor health check prior to donation. Organ donors, and, to a lesser extent tissue donors, more closely reflect the general population in terms of infection. In this annual review we consider how our donor population is affected by changes in infectious disease epidemiology in the wider population.

Blood donors

The majority of blood donors are white British (92%), female and aged over 45 years of age. A high percentage of donors from BAME groups are new donors, for example 37 % of Asian donors are new donors but these donors do not continue to donate as regular donors. This may be due to a number of reasons and work is ongoing to better understand this.

The number of donors per 1000 residents varied by geographical region; 9.8 in London to 22.4 in the East of England, this may reflect both the availability of donor sessions and the young, more mobile population of London[1].

The number of UK blood donations with markers of infection decreased from 241 in 2012 to 230 in 2013 but there was also a 4% decrease in the number of donations compared with 2012. This resulted in the rates of infection remaining at similar levels to 2012 at 10/100,000).

The risk of a contaminated unit entering the blood supply continues to decrease and is currently estimated at one HBV every year, one HCV every 17 years and one HIV every 3 years. The recent decrease in risk for hepatitis B is in part due to a shorter estimated window period used in the calculation.

As in previous years, the majority of infections in donors are chronic (87%), and previously undiagnosed. For HBV, HTLV and some HCV infections this is usually related to the country of birth of the donor or for HBV and HTLV the country of birth for their mother.

Occult hepatitis B infection was identified in four donors. The blood service laboratories, unlike diagnostic laboratories, routinely screen for HBV DNA regardless of HBsAg results, and hence HBsAg negative, HBV DNA positive, occult infections are picked up. Work is ongoing with virology and clinical colleagues to try and understand what these results mean for the infected donor and to assess the potential for transfusion-transmission. In 2013, four acute, HBV infections were observed; three were probably acquired by SBMW and one in a donor who reported SBM which was not disclosed at donation.

In the general population most hepatitis C is diagnosed in PWID, but injecting drug use is usually low in donors as a result of donor selection criteria and was rarely reported as a risk in 2013. Other groups, particularly those who were born in countries where HCV is prevalent, are also at increased risk, and although the majority of HCV infected blood donors were white British, HCV was also detected in small numbers in donors of Pakistani, Indian or Eastern European origin. Of the 58 donors identified with markers of HCV infection in 2013, 33% had antibodies only, reflecting clearance of the virus, but blood donations can only be accepted from individuals who are negative on all screening tests and therefore these donors were withdrawn. In 2013, three acute HCV infections, detected by NAT reactivity only at screening, were reported. HCV NAT was introduced in 1999, and since that time only 20 serological window period infections, detected on NAT only and negative on serology, have been recorded in the UK; therefore to detect three in one year is unusual. Sex with a high risk partner was reported by two of these donors; the third did not disclose a risk.

HIV was identified in 17 donations but, of concern, 10 were seroconversions in regular donors. Six of these 10 were male; all reported at least one new sexual partner in the last year and four reported SBM

Five donors were confirmed HTLV positive this year, one a regular donor. All were born in countries where HTLV is endemic.

In 2013, 60 donors were identified as having current or past treponemal infection - usually syphilis. There is currently no question about syphilis on the blood donor Donor Health Check (DHC). Of the 60 donors, 13 had knowledge that they had been previously treated for syphilis. Due to the high sensitivity of current tests, there are occasions where donors who have previously donated and were treponema antibody negative are subsequently detected with very low level antibody reactivity; this usually reflects long-past infection and is unlikely to be of risk to blood supply. Where donor follow-up was available, 17 donors had markers of infection and a history that suggested that their syphilis infection was recently acquired. This most likely reflects ongoing outbreaks in the general community. Large and ongoing outbreaks of syphilis have been reported in mainly urban areas in the UK since the early 2000s, these outbreaks have initially been identified in groups who report sex between men. An increase in recently acquired syphilis was shown in donors in the early 2000s [2].

The change to the MSM donor selection criteria continues to be monitored. There has been no increase in the number or proportion of male donors with markers of infection since the change to the selection criteria in November 2011. Markers of infection have been detected in donors reporting SBM in the last year but also in those who are compliant with the selection criteria. Infections detected in those donors reporting SBM in the last 12 months include five HIV infections.

Non-compliance with selection criteria is seen in a small number of infected donors each year. In 2013, 20 donors with markers of infection and a range of risks were classified as non-compliant: 11 HCV, 5 HIV, 2 HBV and 2 TP. The most common reasons, where given, was that the donor thought their personal risk was low or that the risk was not applicable to them.

In 2013, additional testing allowed just over 91,000 donations to be released for issue. Additional testing was carried out for specific travel-related risks including *T. cruzi*, malaria and WNV; 1553, 25,972 and 35,034 donations respectively. None of the donations tested positive for *T. cruzi* or WNV in 2013; to date there have been no donations that have tested positive for WNV. Malarial antibodies were detected and confirmed in 0.94% of donations tested. Additional testing for anti-HBc was carried out for those donors with specific risks in the last 4-12 months and included donors with a history of tattoos, body piercing, and acupuncture or endoscopy. These donations numbered 29,331 and 0.07% of donations were found to be anti-HBc positive with insufficient immunity to allow use.

Transfusion transmitted infections

The Epidemiology unit works in collaboration with SHOT to report the number of TTIs each year. In 2013 no bacterial TTIs were confirmed, but there was a false negative result on bacterial screening where *Staphylococcus aureus* was not detected on two platelet doses from one apheresis collection. The units were not transfused but had the potential to cause severe morbidity and mortality in a recipient. For viruses, one probable hepatitis B transmission was reported following a transfusion in 2012 and one pending 2012 investigation was confirmed as an HEV transmission. The UK blood services do not currently screen for hepatitis E.

Bacterial Screening

This year data for both NHSBT and SNBTS is reported. During 2013 the two organisations used different methods with NHSBT using a two bottle approach with incubation under both aerobic and anaerobic conditions and SNBTS using an aerobic bottle only. The positive rates in the platelets screened by NHSBT in 2013 (n=285,292) remained low, and similar to 2012 levels, with 0.02% of apheresis and 0.07% of pooled platelets confirmed positive. The majority of isolates were identified as propionibacterium species; these organisms are rarely associated with transfusion transmitted infection. However, bacterial screening also prevented the transfusion of platelet units containing potentially pathogenic organisms including *Staphylococcus aureus* and *Streptococcus bovis*. SNBTS did not report confirmed growth from any of the 15,555 screened packs.
There was one ‘near-miss’ event reported by NHSBT in 2013, two apheresis platelets from one donation were contaminated with *S. aureus* but were falsely negative on screening. No confirmed bacterial TTI were reported.

Tissue donors

The number of positive markers of infection in deceased and living tissue donors and cord blood donors is low, but because of the small numbers of donors tested the rates of infection are higher than those for blood donations. In 2013, five living surgical bone donors had positive markers for HCV (17 donors reported HCV positive between 2001 and 2013) and nine deceased donors had markers of infection of HBV. In previous years treponemal antibodies have been the most frequently reported marker in all tissue donors. Risk information is only routinely reported for living donors, with 3/5 donors reporting risks of occupational, nosocomial exposure and SBMW with a partner who injected drugs. Fluctuations in the rate of infection among tissue donors year on year are difficult to explain and may in part be due to chance given the small numbers. As in previous years, few cord blood donors have markers of infection; in 2013 there was one donor who was HCV positive and one with HTLV infection; a further 19 had malarial antibodies reflecting past exposure to malaria rather than ongoing infection.

Organ donors

dual risk assessments are carried out by specialist nurses, and microbiology tests are carried out by the local microbiology laboratory rather than centrally by NHSBT. Donor information is collected prior to donation but there are few conditions and infections that would prevent an organ being transplanted. During 2013, 1323 deceased solid organ donors were tested across the UK with 4,501 organs donated from 1257 donors. Information is available for initially reactive screening test results among the 1323 proceeding donors: 11 donors with HCV antibodies (0.8%), one donor with HIV antigen/antibodies (0.1%) and one HTLV positive donor (0.1%).

Donor information is useful in determining whether additional tests for infectious disease will be required eg WNV testing. Some donors will donate both organs and tissues. Currently organ donor characteristics and possible risk behaviours are not reported but it is hoped that this information will be collated in the future together with outcome of transplanted organs.

Horizon scanning

In 2013, MERS-CoV, a respiratory infection similar to SARS, emerged in the Middle East. Currently this appears to be of low risk to the blood supply. Of more concern was the spread of chikungunya virus across the Caribbean and in 2014 to Florida. This spread could have significant impact on donors if additional donor selection measures are required; the situation is being closely monitored. There is continuing surveillance in place for WNV, dengue and other insect-borne diseases which continue to spread to new areas of the world. The unit has worked with European colleagues in the evaluation of the European Up-Front Risk Assessment Tool, a new tool, which may be useful in assessing risk to the blood supply in outbreak situations.

Joint working

We continue to work with our colleagues in the blood borne virus unit at PHE. Recent work has included comparing the characteristics of risk factors and donor demographics for donors with HCV and HBV with genotyping information. Other work has included looking at seroepidemiology of specific viruses in young donors and the incidence of HEV in blood donors. A joint NHSBT and PHE study was undertaken to address the issue of HEV and blood safety. A total of 250,000 donations were screened retrospectively for HEV RNA. In total, 79 donors were viraemic with genotype 3 HEV, resulting in an RNA prevalence of 1:2850. Most donors were sero-negative at the time of donation. The 79 donations had been used to prepare 129 blood components, 62 of which had been transfused prior to identification of the infected donation. Follow up of 43 recipients showed 18 had evidence of infection. Immunosuppression in the transfused patient delayed or prevented sero-conversion, and extended the duration of viraemia. This topic is currently being reviewed by SaBTO in relation to blood, tissue and organ donors. This joint working supports various blood, tissue and organ safety initiatives within the UK blood services

Recent publications

1. Rosenberg GK, Lattimore S, Brailsford SR, Hewitt PE, Tettmar KI, Kitchen AD, Ijaz S, Tedder RS. (2013) The diversity of chronic hepatitis B virus infections within blood donors in England and North Wales 2005 through 2010. *Transfusion*; **53**:2467-76.
2. Davison KL, Conti S, Brailsford SR. (2013) The risk of transfusion-transmitted HIV from blood donations of men who have sex with men, 12 months after last sex with a man: 2005-2007 estimates from England and Wales. *Vox Sanguinis*;**105**:85-88.
3. Hewitt PE, Davison K, Howell DR, Taylor GP. (2013) Human T-lymphotropic virus lookback in NHS Blood and Transplant (England) reveals the efficacy of leukoreduction. *Transfusion*; **53**:2168-75
4. Campion E., Pitt TL, McDonald CL and Brailsford SR. (2014) *Campylobacter lari* in a platelet donation: an unexpected finding. *Transfusion Medicine*;**24**:249-50
5. Garson JA, Patel P, McDonald C, Ball J, Rosenberg G, Tettmar KI, Brailsford SR, Pitt T, Tedder RS. (2014) Evaluation of an ethidium monoazide-enhanced 16S rDNA real-time polymerase chain reaction assay for bacterial screening of platelet concentrates and comparison with automated culture. *Transfusion*; **54**:870-8
6. Hewitt PE, Ijaz S, Brailsford SR, Brett R, Dicks S, Haywood B, Kennedy ITR, Kitchen A, Patel P, Poh J, Russell K, Tettmar KI, Tossell J, Ushiro-Lumb I, Tedder RS. (2014) Hepatitis E virus in blood components: a prevalence and transmission study in southeast England. *Lancet;* S0140-6736(14)61034-5
7. Pietersz RN et al (including Brailsford S). (2014) Bacterial contamination in platelet concentrates. *Vox Sanguinis*;**106**:256-8310.
8. Rosenberg GK, Lattimore S, Brailsford SR, Hewitt PE, Tettmar KI, Kitchen AD, Ijaz S, Tedder RS. (2014) Acute hepatitis B in blood donors over a 5-year period in England and North Wales: who is getting infected? *Transfusion*.;**54**(6):1660-5
9. Lattimore, S., Wickenden, C. and Brailsford, S. R. (2014), Blood donors in England and North Wales: demography and patterns of donation. Transfusion. doi: 10.1111/trf.12835

1.0 Blood donor surveillance

Key findings

- in 2013, compared to 2012, a greater proportion of all donors were aged over 45
- the rates of markers of infection remain low in blood donors; the majority of infections identified are treponemal or hepatitis infections in new donors
- 15 seroconverters were identified, 10 with HIV infection, three with HCV in the serological window period and two with acute HBV
- four HBV occult donations detected in 2013 make a total of 15 occult infections detected in UK blood donors since triplex NAT was introduced in 2009
- HTLV singleton testing within NHSBT did not result in increased numbers of HTLV infections detected in 2013
- there has been no increase in the proportion of infected male donors in England, Scotland and Wales since the change to the MSM deferral
- reported non-compliance is low, however, non-compliance to the MSM deferral continues to be observed in seroconverting donors

1.1. Donor Insight England and north Wales

In 2013, 1,919,490 donations were made and tested across England and north Wales, comprising 1,722,900 whole blood and 196,590 apheresis donations from 940,586 and 30,769 donors, respectively (Table 1.1). In 2013, a significantly higher proportion of blood donors were females (54.1 % vs. 45.9%; $p<0.001$), and a greater proportion of all blood donors were aged over 45 in 2013 compared to 2012 (53.7% compared to 51.8%); this difference was also significant ($p<0.001$). The number of blood donors varied by geographical region of England, with 4.8% of the donor population resident in the North East compared with 13.9% resident in the East of England. Combining these data with mid-year population estimates for 2012, the number of donors per 1,000 individuals resident within each region ranged from 9.80 in London to 22.42 in the East of England. Despite 95,842 fewer donors donating in 2013 compared to 2012, the proportion of new donors was stable at 14.9% (140,743), over half (58.1%) of whom were female. New blood donors were also significantly younger than repeat donors ($p<0.001$) with the proportion of new donors decreasing as age increased (Table 1.1, Figure 1.1). New donors were seen among all ethnic groups, comprising 14.1% of all white donors, 36.9% of Asian (Indian, Pakistani and Bangladeshi) donors, and 43.3% of Black African donors. New blood donors were drawn from all regions in England, with the highest proportion of new donors resident in London.

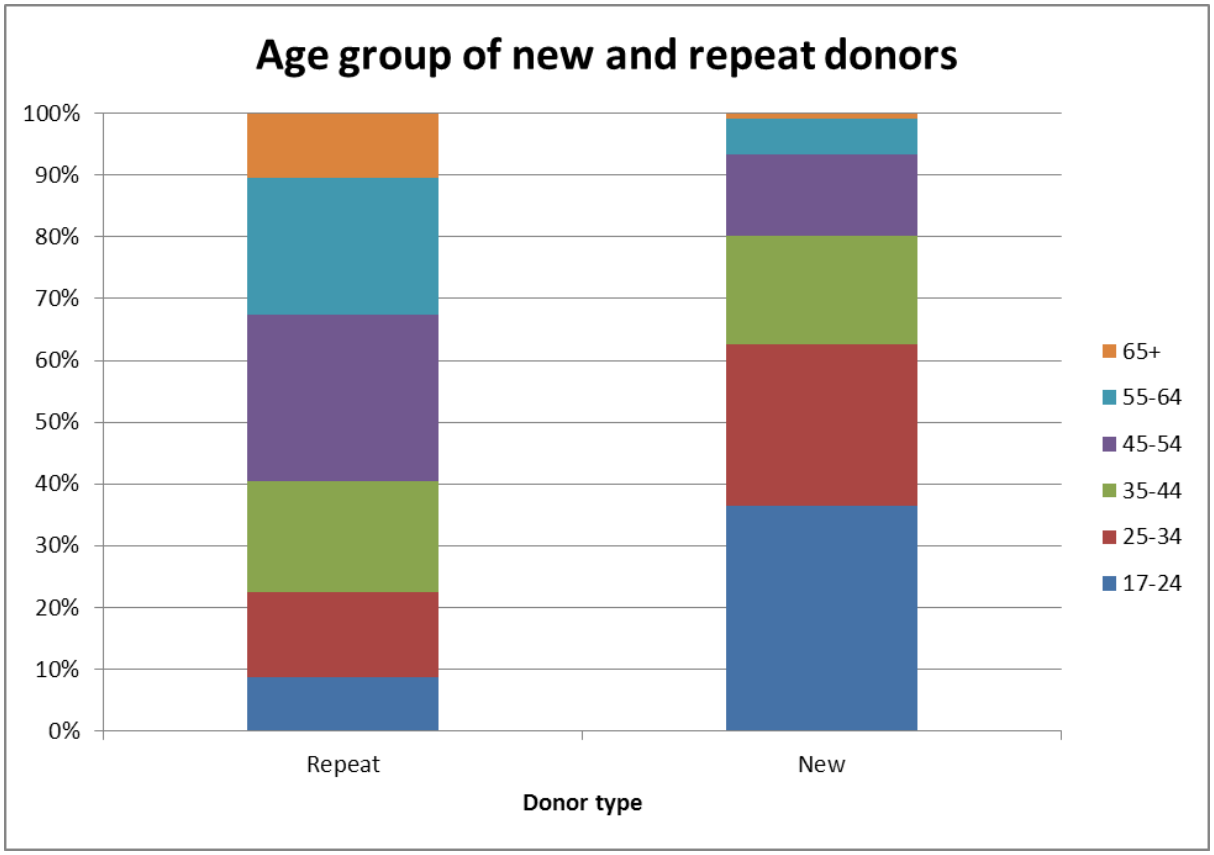
Table 1.1: Summary of demographic characteristics of whole blood donors in England and north Wales, 2013[1]

	All donors		New Donors		
	n	%	n	%	%*
Male	431,834	45.9	59,040	41.9	13.7
Female	508,752	54.1	81,703	58.1	16.1
17-24	120,302	12.8	51,360	36.5	42.7
25-34	146,878	15.6	36,737	26.1	25.0
35-44	168,415	17.9	24,669	17.5	14.6
45-54	234,633	24.9	18,591	13.2	7.9
55-64	185,101	19.7	8,209	5.8	4.4
65+	85,257	9.1	1,177	0.8	1.4
Asian	17,160	1.8	6,337	4.5	36.9
White	862,922	91.7	121,459	86.3	14.1
Black African	2,056	0.2	890	0.6	43.3
Black Caribbean	3,002	0.3	742	0.5	24.7
Chinese	2,266	0.2	741	0.5	32.7
Mixed	8,816	0.9	2,893	2.1	32.8
Other/Unknown	44,364	4.7	7,681	5.5	17.3
East Midlands	90,628	9.6	12,329	8.8	13.6
East of England	131,104	13.9	17,078	12.1	13.0
London	80,144	8.5	17,461	12.4	21.8
North East	45,423	4.8	7,647	5.4	16.8
North West	97,391	10.4	16,886	12.0	17.3
South Central	93,981	10.0	13,341	9.5	14.2
South East Coast	90,134	9.6	11,473	8.2	12.7
South West	114,157	12.1	15,166	10.8	13.3
West Midlands	92,824	9.9	13,822	9.8	14.9
Yorkshire and Humber	93,016	9.9	13,708	9.7	14.7
Wales	11,091	1.2	1,625	1.2	14.7
Outside England	591	0.1	178	0.1	30.1
Unknown	102	0.0	29	0.0	28.4
Total	**940,586**	-	**140,743**	-	-

*proportion of new donors within each category

* The high proportion of new donors resident outside England is likely to be due to individuals who have been previously donors but were donating for the first time in England.

Figure 1.1: Age groups of new and repeat whole blood donors in England and north Wales, 2013



1.2. Overview of 2013

In the UK in 2013, markers of infection were detected at a rate of 10 positive donations per 100,000, which is similar to 2012, because there was a fall of approximately 4% in both the overall number of donations tested (2.3 million) and in markers detected (230) compared with 2012. New donors accounted for only 8% of donations tested but 83% of confirmed positive donations. Treponemal antibodies were detected in the highest numbers but reflected both recently acquired, and more usually, latent or previously treated infection. HBV positive donations included four detected at screening by NAT only, all classified as occult infection: one in a new donor and three in repeat donors. Three HCV positive repeat donations were detected at screening by NAT only: one in Scotland and two in England. Such “NAT pick ups” occur sporadically, with 17 detected in the UK between 1999 and 2012. HTLV markers were confirmed in only five donations in England in 2013, three of which were given by male donors. Over half of the 16 HIV infected donors were detected in donations from repeat donors who had seroconverted since a donation made in the last three years.

Please see “Supplementary Data Tables and Figures” document Figure 1.2-1.4 for annual trends in rate by country, and section 1.3 for commentary on status of infection in the donor and their characteristics.

The Republic of Ireland confirmed low numbers of infections, although one HIV seroconverter was detected. As usual, no donations were confirmed positive in the Channel Isles and Isle of Man.

The rate of detection of viral infection (per 100,000 donors) in 2013 in new and repeat donors by gender and age group is shown in Figure 1.

Table 1.2: The number and rate of markers of HBV, HCV, HIV, HTLV and syphilis[1] identified among blood donations made at blood centres by new and repeat donors[2] and country where donation was made, 2013

Country of blood centre	Donations tested			HBV			HCV			HIV			HTLV			Treponema (Syphilis)*			Total		
	New	Rpt	All	New	Rpt	All	New	Rpt	All	New	Rpt	All	New	Rpt	All	New	Rpt	All	New	Rpt	All
England	142,188	1,778,950	1,921,138	52	5	57	40	2	42	6	9	15	4	1	5	61	7	68	**163**	**24**	**187**
Rate[3]				*36.6*	*0.3*	*3.0*	*28.1*	*0.1*	*2.2*	*4.2*	*0.5*	*0.8*	*2.8*	*0.1*	*0.3*	*42.9*	*0.4*	*3.5*	***114.6***	***1.3***	***9.7***
Wales	6,535	76,442	82,977	0	0	0	0	1	1	1	0	1	0	0	0	1	2	3	**2**	**3**	**5**
Rate[3]				*0.0*	*0.0*	*0.0*	*0.0*	*1.3*	*1.2*	*15.3*	*0.0*	*1.2*	*0.0*	*0.0*	*0.0*	*15.3*	*2.6*	*3.6*	***30.6***	***3.9***	***6.0***
Northern Ireland	6,950	54,043	60,993	3	0	3	0	0	0	0	0	0	0	0	0	1	2	3	**4**	**2**	**6**
Rate[3]				*43.2*	*0.0*	*4.9*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*14.4*	*3.7*	*4.9*	***57.6***	***3.7***	***9.8***
Scotland	19,879	193,292	213,171	4	0	4	11	3	14	0	0	0	0	0	0	9	5	14	**24**	**8**	**32**
Rate[3]				*20.1*	*0.0*	*1.9*	*55.3*	*1.6*	*6.6*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*45.3*	*2.6*	*6.6*	***120.7***	***4.1***	***15.0***
Total UK	**175,552**	**2,102,727**	**2,278,279**	**59**	**5**	**64**	**51**	**6**	**57**	**7**	**9**	**16**	**4**	**1**	**5**	**72**	**16**	**88**	193	37	230
Rate[3]				***33.6***	***0.2***	***2.8***	***29.1***	***0.3***	***2.5***	***4.0***	***0.4***	***0.7***	***2.3***	***0.0***	***0.2***	***41.0***	***0.8***	***3.9***	*109.9*	*1.8*	*10.1*
Republic of Ireland	11,949	135,051	147,000	3	0	3	1	0	1	0	1	1	0	0	0	0	1	1	**4**	**2**	**6**
Rate[3]				*25.1*	*0.0*	*2.0*	*8.4*	*0.0*	*0.7*	*0.0*	*0.7*	*0.7*	*0.0*	*0.0*	*0.0*	*0.0*	*0.7*	*0.7*	***33.5***	***1.5***	***4.1***
Channel Isles & I. of Man	365	5,829	6,194	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	**0**	**0**
Rate[3]				*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	***0.0***	***0.0***	***0.0***
Total	**187,866**	**2,243,607**	**2,431,473**	**62**	**5**	**67**	**52**	**6**	**58**	**7**	**10**	**17**	**4**	**1**	**5**	**72**	**17**	**89**	197	39	236
Rate[3]				***33.0***	***0.2***	***2.8***	***27.7***	***0.3***	***2.4***	***3.7***	***0.4***	***0.7***	***2.1***	***0.0***	***0.2***	***38.3***	***0.8***	***3.7***	*104.9*	*1.7*	*9.7*

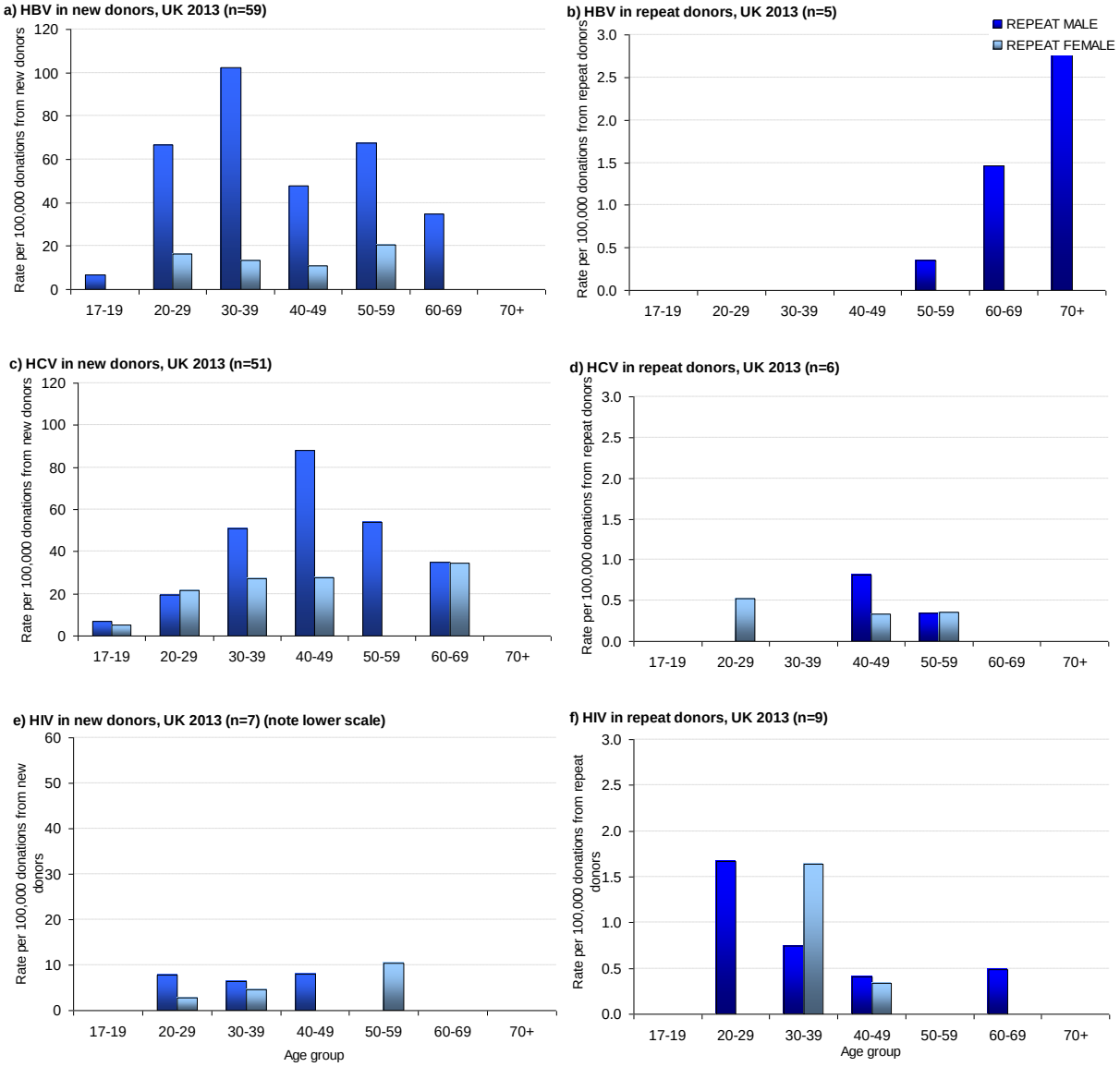
1. The test for syphilis is a treponemal antibody test which detects syphilis infection caused by the bacterium *T. pallidum* but cannot distinguish this from diseases caused by other treponemes such as yaws caused by *T. pertenue* and pinta caused by *T. carateum*, endemic in some countries but rare in the UK.

2. New and repeat donors classified according to records available to the blood centre and therefore new donors may include returning donors who have not donated for three years for NHSBT. Numbers of donations reported here differ slightly from new donors in Table 1.1 because different data sources were used (see 'Data Sources and Methods' document for details).

3. Rate per 100,000 donations.

Note that there were two dual infections in the UK in 2013: HCV/TP and HIV/TP.

Figure 1.2: The estimated rate* of viral infection (HBV a,b HCV c,d and HIV e,f) in new and repeat donors by gender and age group: UK, 2013
Note lower scale for HIV in new donors and for all repeat donors.



* The rate per 100,000 donations is an estimate only as denominator data for England and north Wales was applied to the UK.

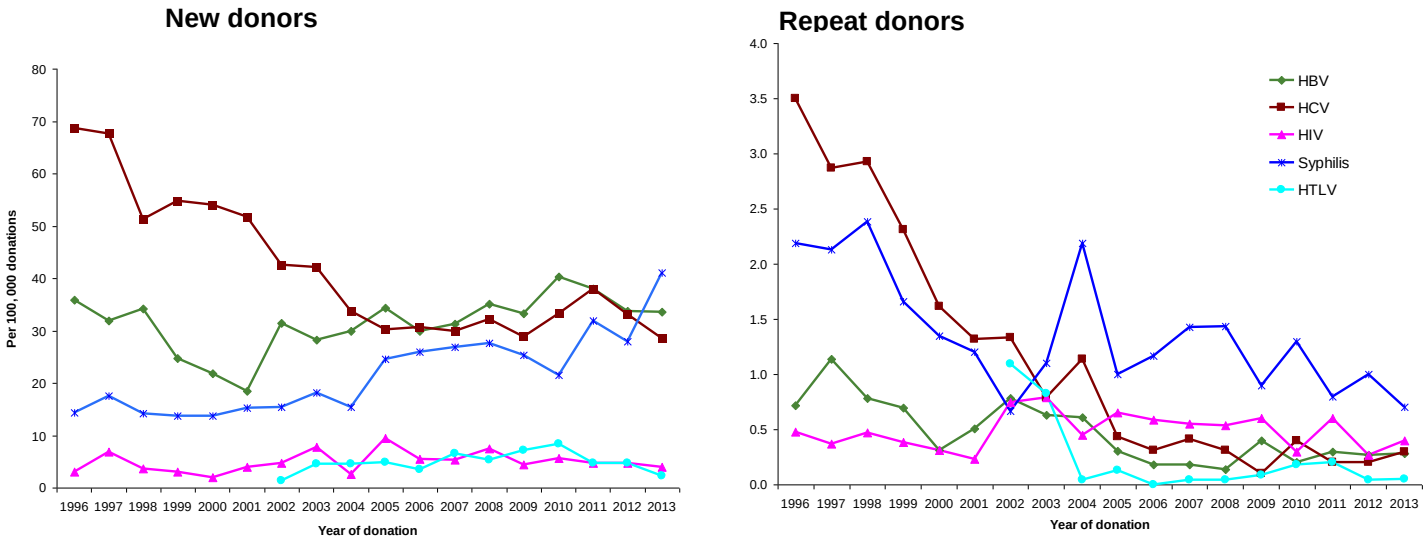
The rates differ by infection, but were low to zero in the 17-19 year old age group in 2013. Rates in new donors are likely to reflect a mix of incident and prevalent infection and are higher for hepatitis than HIV. The HCV curve in blood donors peaks at the 40-49 year old age group, in contrast to the laboratory report data for England where diagnosis peaks in the 30-39 year olds. Donors who test positive for HCV include those who reported a past history of injection but felt that this was not relevant to their situation now as well as those people with a risk related to their country of birth. Those individuals offered HCV testing in primary care may have an obvious risk, being tested due to symptoms or have testing as part of a drug treatment programme with recent or current injecting drug use. The rates are much lower in repeat

donors who have been screened previously by the UK blood services and in females. The HBV rate in repeat male donors is accounted for by two acute and three occult HBV infections. The rates for HTLV are not shown as the numbers are very low.

Trends UK 1996-2013

Between 1996 and 2013, the total number of confirmed markers of infections fell, driven by the decline among repeat donors. There was little change in total infections in new donors; however this varies by infection (Figure 1.3). In general there has been little statistically significant change in rates in the last 5 years except for new donors where a decline in HTLV (CHI2=4.5, p= 0.03) and an increase in treponemal infections (syphilis) were observed (CHI2=12.7, p<0.001). Each year, the rate of infection among new donors has far exceeded that among donations from repeat donors (see "Supplementary Data Tables and Figures" for additional information).

Figure 1.3: The rate[1] of markers of HBV, HCV, HIV, HTLV and Treponema (syphilis)[2] in blood donations from new and repeat donors made at blood centres in the UK, 1996-2013
Note different scales



1. Rate per 100,000 donations.

2 The test for syphilis is a treponemal antibody test which detects syphilis infection caused by the bacterium *T. pallidum* but cannot distinguish this from diseases caused by other treponemes such as yaws caused by *T. pertenue* and pinta caused by *T. carateum*, endemic in some countries but rare in the UK.

1.3. Infected blood donors in 2013

Epidemiological information for all infected blood donors identified in the UK, Channel Isles, the Isle of Man and the ROI is requested each year through the surveillance scheme. When appropriate, donors are asked about the possible source of their infection and this information is used together with other relevant donor information, for example country of birth, to assign the potential source of exposure using a hierarchy of most to least likely sources where more than one potential source was reported (Table 1.3). The Scottish National Blood Transfusion Service kindly provides a summary of infected donors on an annual basis.

Table 1.3: Summary of characteristics of infected blood donors in the UK and Republic of Ireland, 2013

Characteristic	HBV	HCV	HIV	HTLV	Treponema (syphilis)
No. of donors with marker(s) of infection	67	58	17	5	89
Seroconversions[1]	2	3	10	0	-
% Male (no. donors)	80.6% (54)	58.6% (34)	58.8% (10)	60.0% (3)	61.8% (55)
Mean age	36.6	38.1	36.0	39.7	42
% White, where known[2] (no. donors)	39.3% (26)	75.4% (43)	76.4% (13)	20.0% (1)	65.9% (56)
% Born UK or ROI, where known[3] (no. donors)	16.4% (11)	56.1 (32)	83.3% (10)	20.0% (1)	56.6% (43)
Main probable exposure, where known (%; no. donors)	Infection associated with an endemic country[5] (72.2%; 39)	Piercing: Tattooing/ body/ ear (23.2%; 10)	Sex between men and women (53.3%; 8)	Infection associated with an endemic country[5] (80.0%; 4)	Sex between men and women (87.8%; 43)
Second most common probable exposure, where known (%; no. donors)	Other possible blood contact (13.0%; 7)	Other possible blood contact (20.9%; 9)	Sex between men (40.0%; 6)	Mother to infant (UK) (20.0%; 1)	Sex between men (10.2%; 5)
% Probable exposure not known[4] (no. donors)	19.4% (13)	25.8% (15)	11.8 (2)	00.0 (0)	44.9% (40)

1. Seroconversions for viral infections were for donors who had a previous negative donation within three years.

2. Ethnicity was not known for 8 (2.6%) infected donors.

3. Country of birth was not known for 28 (12%) infected donors.

4. Includes incomplete follow-up and no identified exposure despite donor interview.

5. Includes donors with no obvious reported risk but born in or to parent from an endemic country, and also donors from an endemic area who were born to an infected mother or with siblings known to be positive.

In the UK in 2013, the majority of infected donors were male with an average age of 39, white British and born in the UK with heterogeneity in these characteristics between infections. Although there is some non-compliance with donor selection guidelines for injecting drug users, sex workers, MSM, and high risk partners, the majority of infections seen in blood donors are probably acquired via SBMW or in an endemic country, usually at birth or in childhood with no specific risk factor identified.

More detailed information about all infected donors is published in the “Supplementary Data Tables and Figures” document.

HBV

As usual, the majority (59/67, 87%) of HBV infections identified in donors were chronic, probably acquired abroad in the (endemic) country of origin. For many, this would have been the first time they had been tested, although some had siblings who they knew to be HBV positive. The second most common route was “other possible blood contact”: a mixed category but for HBV in 2013 mainly included those with a history of surgery abroad.

Four male white donors had acute HBV infection. Two were European-born new donors in the 25-29 year age group, one with various possible risks including piercing in Poland in the right timeframe, while the other reported sex with a long-term partner, also from the same country. The other two were white British repeat donors in the 45 year and over group; one reported SBM with recent travel to Europe while the other did not report any possible route but had a history of travelling to Thailand.

Four infections were classified as occult in 2013 ie they were negative for HBsAg but positive for anti-HBc and HBV DNA; three were in repeat donors and one in a new donor, all male and over 60 years old. Occult infections are not usually identified in the community in the UK as the routine initial screen for HBV infection is HBsAg which by definition would be negative. Occult infections began being detected by NAT screening in the UK blood services after the implementation of a triplex NAT test from 2009 onwards.

Occult HBV infection 2009-2013

Since 2009 there have been 21 HBsAg negative HBV infections detected by NAT screening in UK and ROI. Fifteen were classified as probable occult infections, 13 in England and two in Scotland. All but two of the 15 donors with occult infections were male. The majority (10/15) were in the 45 years and over category, but the youngest was aged between 20 and 25.The majority (10/15) had had a previous hepatitis B screen negative donation, eight of whom had been previously tested using the triplex NAT. Ethnic group varied; eight were white, four black, two Asian and one “other” ethnicity. Seven were born in the UK. Routes of probable transmission also varied: sex was reported for two, possible blood contact for three, no specific risk apart from endemic country of origin for four, three couldn't identify any possible route and

three had incomplete follow up. Transfusion-transmission via components obtained from donors with occult infection is unclear and lookback to previous donations for evidence of infection is decided on a case by case basis which takes into account DNA detection in retrospective single sample testing of stored archive samples. Investigation is ongoing for one 2013 case. Persons with occult HBV infection may be at risk of reactivation and a flare up of disease if they become immunosuppressed. The blood service is currently liaising with specialists for a view on the advice the blood service should be providing about referral of these individuals for follow up care.

Example of an occult case

A white British male repeat donor, over 70 years old, with 32 previous donations. His donation was reactive in the Triplex NAT screen in 2013. HBV DNA was only detected by confirmatory testing following concentration of the plasma. His last donation, a year previously, had been NAT screen negative. This donor had a history of numerous medical investigations including endoscopy and was assigned to "possible blood contact" route. This nosocomial route of infection is unlikely but was the only possible risk reported. It is most likely that the donor was a long term carrier with fluctuating levels of HBV DNA and at this time the DNA level was above the limit of detection of the screening test.

HCV

As usual, the majority of HCV cases were seen in white male donors of UK and European origin. The majority (36) were both antibody and RNA positive while 19/58 (33%) were antibody positive, RNA negative, indicating spontaneous recovery, and three were RNA positive only, indicating recent infection. As seen in recent years, a number of donors (13) originated from South East Asia – mainly Pakistan or India. The main possible route of HCV infection reported by ten new donors in 2013 was piercings, mostly body piercings or tattoos and but none reported acupuncture. However, piercings are common and with little information usually available on timing of infection the probable route remains uncertain. There is little evidence for HCV following piercing in professional settings in the UK, although bacterial infections are more commonly seen[3]. The second most common route was "other possible blood contact": a mixed category, but for HCV in 2013 was mainly reports of immunisations abroad. Almost a third of HCV infected donors in 2013 did not report any possible route. This may be because they did not want to report deferrable behaviour to the blood service or they simply do not recall anything they think is relevant to report when prompted. In the community, HCV infection occurs at high rates in PWID and although people who have ever injected are deferred from donation, each year a number of HCV infected donors report a history of injecting, although the number reporting this behaviour was low in 2013[4]. Sexual contact is also a potential route of infection, with six donors assigned to this category in 2013. In five donors, all aged between 50 and 60, the partner had known risks for infection, including three where a partner or partner's partner had a history of injecting drugs, one whose partner had prison stays and one whose partner

had become HCV positive. The sixth donor was younger and reported two new partners in the last year with no other risk factor reported.

Three donors were HCV seroconverters, all NAT positive and anti-HCV negative indicating likely recent infection. HCV NAT pick-ups are usually a rare event; only 20 HCV window period donations have been detected by the UK blood services since the addition of HCV NAT to the screening tests in 1999 and none from ROI. Up to 2011 the NAT pick-ups had been in donors under the age of 45. All three in 2013 were of white British ethnicity, in the 45 and over age group; two were female and one male. Two reported SBMW with a high risk partner (one PWID, one with HCV possibly via treatment abroad) while the other had no reported exposure risk despite a full post test discussion. The last previous HCV window period donation was detected in 2012, also in a seroconverting white British donor over 45 years old who reported SBMW with a new partner who had a history of injecting drugs. This is in contrast to the community setting where “most new infections are acquired via injecting drug use at a relatively young age” [5].

HIV

The number of HIV positive donors identified by the blood services continues year-on-year to be low and variable. Since 1996, while a very small number of HIV infected donors have reported a history of injecting drug use or other risks, the vast majority of infections were thought to have been sexually acquired. Donors who reported SBM, or SBMW with a high risk partner who has had sex in an endemic area, or SBMW without identified high risk partner, each account for around a third of HIV acquired through sexual contact in blood donors in the UK between 1996 to 2013.

In 2013 there were ten HIV infected seroconverters; six male, four female, ranging from 20 to 61 years old. Eight were white, six born in the UK or ROI. Six reported SBMW without any history of high risk partner, four reported SBM. All 10 reported at least one new sexual partner since their last donation: nine reported just one new partner in the last 12 months while 1 had two new partners. HIV normally has higher numbers of seroconverters than for the other viral infections tested for in UK blood donors. Seroconverting donors are of concern as they indicate ongoing risk for HIV in blood donors with the chance of very recent infections in the window period of the testing systems not being detected by screening.

In England and north Wales, when a donor seroconverts for HIV, the available archive sample from the most recent previous negative donation (MRPND) is tested by NTMRL. A decision on tracing and testing recipients of the MRPND is made on a case-by-case basis. For HIV, even if the MRPND was PCR negative the recipients of the MRPND may still be notified and offered testing. To date, no recipients have been found to be HIV positive after receiving an HIV PCR negative donation from a donor who later

seroconverted. The last HIV TTI was from a window period donation in 2002, predating NAT screening.

HTLV

In 2013 NHSBT started screening for HTLV by single donation screening rather than testing of pooled samples. This change has resulted in detection of low levels of non-specific antibodies in some donations, but has not resulted in an increased number of confirmed HTLV infections and only five were confirmed positive in 2013. To confirm infection, samples are tested at PHE for proviral DNA.

In 2013 there were three male and two female infected donors, all originating from endemic countries and with type I infection, which is associated with mother to child, breastfeeding or sexual transmission and is common in the Caribbean and some African and Asian countries. The majority of HTLV infected donors to date have been type I and female, and male donors have outnumbered females only once before, in 2006. Type II infections are more commonly seen among PWID or indigenous Americans and only 20 type II infections have been identified in UK blood donors since 2002.

Treponema (syphilis)

Treponemal antibody testing will detect donors with a number of treponemal infections and varying disease status. The vast majority are syphilis infections, although one or two per year are probable Yaws cases, based on clinical history. It is impossible for the blood service to classify these infections in the usual diagnostic way, ie as primary, secondary or tertiary infection. Instead, the unit staff review the confirmatory results along with history obtained from the donor and timing of any previous negative results to classify as likely past infection, or recent infection acquired in the last 12 months.

In 2013, 60/89 (67%) antibody positive donors were likely to have had a past syphilis infection. Thirteen of these reported a known date for infection and treatment, but antibodies persist long-term and antibody positive donations cannot be issued. Although some donors were aware that they had syphilis in the past, there is no question on the Donor Health Check relating to a past history of syphilis so such donors have no opportunity to report their syphilis history before donating.
Nine donors had donated previously with antibody levels below the screening threshold. These donors are likely to have fluctuating, but low level, antibody levels around the test cut off. Six of these donors had not received specific treatment, while treatment information was not known for three.

Seventeen donors gave a history consistent with syphilis infection in the last year, eleven of whom were IgM positive, and three reported recent or ongoing genital problems such as sores,

spot, rash or pain. The majority were white British (14), male (13), aged between 18 to 64 years (mean 35 years) and where a route was identified most reported SBMW (8/9) while one reported SBM. There has been in increase in the number of syphilis outbreaks under investigation in the general population in recent years[6].

Unless donors have reported a recent course of treatment for a diagnosed syphilis infection, donors with detectable treponemal antibodies are offered referral to GUM clinic for assessment and treatment.

Some examples of the donors with acute IgM positive syphilis infection:

- A young female new donor, aged less than 25 years who had had one partner in the last 12 months, the relationship ended shortly before her first donation. She had never heard of syphilis and was asymptomatic.
- A repeat male donor born in 1977 with test results consistent with active syphilis infection. He reported noticing some spots on his hands and genital area.
- An asymptomatic male white British new donor in the 30-40 year old age group who had started seeing a new partner in the last few months prior to donating.

Impact of the change to the MSM deferral

In November 2011, NHSBT, SNBTS and WBS changed the MSM deferral from a permanent deferral to a temporary 12 month deferral since last sexual contact between men. SaBTO noted that compliance with the donor selection guidelines would have the most impact on safety.

As expected, the percentage of male infected donors reporting SBM has increased slightly since the change should allow more people to donate, while the percentage of reported non-compliance has decreased slightly (table 1.4).

Table 1.4: Sex between men and non-compliance with the MSM deferral among infected male donors two calendar years before and after the change to a 12 month deferral

Infected donors	England, Scotland & Wales	
	2010 to 2011	2012 to 2013
No. reporting sex between men	24	27
No. non-compliant to MSM policy	24	15
No. male infected donors	375	295
% reporting sex between men	6.4	9.2
% males non-compliant to MSM policy	6.4	5.1

There has been no increase in the number or proportion of infected male donors compared with all infected donors (England, Scotland and Wales) and no increase in the rate of infected males per 100,000 male donors (England). The number of donors reporting SBM in either the Republic or Northern Ireland, where the deferral is still permanent, is very small. This data is

encouraging, but more could be done to increase awareness and understanding of the deferral, since six of the non-compliant donors between 2012 and 2013 were seroconverters.

We also know that some donors do not feel they can disclose deferrable behaviour to the blood service either at session or at the post test discussion. The UK Blood Donor Survey hosted by PHE is collecting data on donor experience and understanding of the Donor Health Check.

Two infected donors compliant to the MSM rule

The majority of donors who are compliant with the MSM rule and who have markers of infections test positive for treponemal antibodies (syphilis), such as this case: a new donor, white British, in the 20-29 year old age group, who reported sex between men more than one year ago. This history was corroborated by the GUM clinic. His donation sample was confirmed to be treponemal antibody postive, IgM negative.

However, we have observed undiagnosed HIV infection in MSM. The second case was also a new donor, white British, but aged 45 and over. He was in a long term relationship (more than 20 years) with a female, but reported no sexual contact with her in the last two years. This female partner had given a negative blood donation but the donor was confirmed HIV positive six months later. He also reported one sexual encounter with a male a few years previously. He could not recall any seroconversion-like illness and had never visited a GUM clinic. Avidity testing indicated the infection was not likely to have been acquired in the last 4 to 5 months. Both the donor and his long term female partner were removed from the donor panel.

Infected donors who were non-compliant with donor selection guidelines

The criteria for deferral are defined within the DSG (www.transfusionguidelines.org.uk), and these aim to identify behaviours in individuals that put them at increased risk of infections. Permanent deferrals include injecting drug use and commercial sex work. Temporary deferrals are in place for sex between men and sex between men and women with a high risk partner, and for piercing.

In 2013 22 infected donors were classified by the Unit as non-compliant with DHC questions (HCV 11; HIV 5; HIV/TP 1, HBV 2; TP 3; HTLV 0). HCV and HIV infections were most commonly associated with non-disclosure, and non-disclosure accounted for 19% and 35% of donors with HCV or HIV infection respectively and included 5 of the 15 seroconverters in 2013. All six donors from Scotland who appeared to be non-compliant had HCV, including a donor picked up by NAT testing only, who gave in the window period. It is estimated that in Scotland 45% of persons with HCV are undiagnosed[5]

Although the numbers are small, the most common reason for non-compliance was self-assessment that the personal risk was low or that the question was not really

applicable, especially if that risk was in the past, including one donor who had been advised not to disclose SBM to the blood service donation session staff. Some also state that “donations are tested anyway”. Privacy was an issue for one donor in a mobile collection setting. One donor had been diagnosed and treated for HCV abroad many years ago but had forgotten which kind of hepatitis it was at session.

Although it is likely that there is underreporting of non-compliance, it does appear to be variable and low in infected donors and seems to have declined overall since 1996, with 2013 having the lowest percentage: 10.5% of infected donors non-compliant where follow up was complete. We hope that the UK Blood Donor survey[a] will yield more information about non-compliance in all donors.

Table 1.5: Infected donors who were non-compliant to donor selection guidelines by reason for non-disclosure in UK and Republic of Ireland, 2013

Reason for non-compliance	Deferral non-compliant to:					
	Injecting drug use	Piercing	Sex between men	Sex between men and women (high risk partner)	Commerical sex work	Aware of infection
Forgot						1 (HCV)
Comprehension	1 (HCV)		1 (HIV)			
Self assessment as low risk or not applicable	2 (HCV)		1(HIV)		1(TP)	1 (HBV)
Privacy or embarrassment			1 (TP)			
Not known - Rest of UK/ROI		1 (HCV)	4 (2HIV, 1TP, 1HIV/TP)	1 (HIV)		1 (HBV)
Not known - Scotland	3 (HCV)	2 (HCV)		1 (HCV)		

1. SNBTS do not provide data about reasons for non-disclosure but included for completeness of non-compliance numbers.

[a]The UK Blood Donor Survey information can be found at:
http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/BIBD/UKBloodDonorSurvey/

1.4. Additional testing in England and north Wales in 2013

The number of donations tested, repeat reactive and confirmed positive for four additional tests carried out by NHSBT on blood donations made in England and north Wales during 2013 by donors with specific histories are shown in Table 1.6. Assuming that each of these donations was not reactive to mandatory markers and resulted in only one type of additional test, nearly 5% (91190/1921138) of donations made in 2013 via NHSBT were released after being cleared by additional testing.

Table 1.6: Additional testing for markers to hepatitis B virus, *Trypanosoma cruzi*, malaria and West Nile virus in England and north Wales, 2013

Marker	No. donations tested	% Of all donations tested	No. repeat reactive at screening[1]	% Repeat reactive	No. confirmed positive[2]	% Confirmed positive
Anti-HBc[1,2]	29441	1.53	78	0.26	21	0.07
Anti-*T. cruzi*	1553	0.08	0	0.00	0	0.00
Anti-malaria	25972	1.35	732	2.82	244	0.94
West Nile virus NAT	35034	1.82	0	0.00	0	0.00

1. Reactive at screening for anti-HBc and anti-HBs negative or <100 mIU/ml.
2. Confirmed anti-HBc positive AND anti-HBs <100 mIU/ml

Testing for anti-HBc is carried out by NHSBT on donations from donors reporting a recent history of piercing, tattooing and/or acupuncture, endoscopy, history of jaundice or HBV infection, contact with a sexual partner or a family member known to have HBV infection. The aim of this test is to detect recent resolving HBV infections in the second window phase, ie resolving infections where HBsAg levels have fallen, but before the level of antibodies to HBsAg (anti-HBs) have risen to protective levels. NHSBT uses a threshold of anti-HBs >100 mIU/ml to indicate sufficient protective immunity. Anti-HBc testing will also detect past exposure to the hepatitis B virus, unrelated to the recent event, and therefore reason for test does not necessarily equate to source of infection. Although piercing is a potential route of bloodborne viral transmission there is little recent published evidence for documented viral infection transmitted via piercings. A study is currently being carried out to better understand the impact of piercing on blood donor deferral rates.

Malarial antibodies have been detected in around 1% of blood donations selected for malaria testing in 2013 and 2012: an increase from around 0.6% between 2009-2011 although fewer donations were tested in 2012 and 2013, suggesting that testing is being better targeted perhaps because of efforts to educate donors about the selection policy

via the National Call Centre and the website prior to attending a session. Confirmatory DNA testing started in 2010 and a small number of parasitaemic individuals are detected each year: four in 2013. To date, all the DNA positive cases have been in those tested because of previous residency in a malaria endemic country[7]. These donors are notified to the Hospital for Tropical Diseases for surveillance purposes and referred for advice about treatment.

Since testing of blood donors for *Trypanosoma cruzi* antibodies began in the UK in 1998, there have only been three confirmed cases; one detected during 1998 and two during 2009[8]. It is thought that *T. cruzi* is underdiagnosed in migrants of South American origin and there are efforts to carry out more testing in the UK in those persons from, or whose mother is from, an endemic country[9].

WNV outbreaks have been rapidly expanding in Europe (see emerging diseases, chapter 8) with increasing numbers of donors requiring deferral. WNV RNA testing of donations from donors returning from WNV at risk areas between 1 May and 30 November began in 2012 and has prevented 65034 deferrals to the end of 2013 with no discarded donations due to WNV reactivity[10].

2.0 Risk estimates in the UK, 2011-2013

Key findings

- the estimated number of potentially infectious window period donations per million donations tested that entered the UK blood supply between 2011 and 2013 was 0.46, 0.026 and 0.17 for HBV, HCV and HIV respectively,
- HIV risk was almost unchanged from the estimate for 2010 to 2012; the decrease in HBV risk is partly accounted for by a change in the estimated infectious window period from 38.5 to 30 days: the decrease in HCV risk is due to a decrease in incidence,
- at current donation levels of approximately 2.3 million donations each year in the UK, it is estimated that testing will *NOT* identify approximately one potentially infectious HBV window period donations every year, one potentially infectious HCV window period donation every 16.7 years and one potentially infectious HIV window period donation every 2.6 years,
- donations given by new donors and entering the blood supply were estimated to be more likely to be infectious compared with donations from repeat donors,
- of the three viruses, HBV was estimated to be the virus most likely to be missed during 2011-2013 due to a window period donation,
- despite anti-HTLV testing of blood donations in the UK, the risk is not estimated. This is because of (i) the uncertainty about the presence and/or duration of an infectious window period for HTLV and (ii) the relevance of the calculation, given that widespread leucodepletion of all components is likely to significantly reduce onwards transmission to patients.

2.1 Overview of 2013

Although current blood donation testing strategies minimise the risk of transfusion transmitted infections in the UK, on very rare occasions potentially infectious donations are not detected and may enter the blood supply. This mostly occurs because when a blood donation is made during the potentially infectious WP early in the course of infection when the test in use will not detect the marker of infection. In 2013, the window period risk was calculated as the incidence multiplied by the length of the window period and multiplied by 1 million, which provides the number of potentially infectious donations in 1 million donations entering the blood supply. The 95% confidence intervals were calculated by simulation. In addition the number of donations entering the blood supply before one donation can be expected to be a potentially infectious donation was also estimated.

This year, the value of the infectious WP used in the calculation has been revised for HBV from 38.5 to 30 days. The original value was based on a worst case scenario that even one HBV DNA copy would be infectious 100% of the time[11]. However, an infectious dose of 10 HBV DNA copies has been considered to be biologically more plausible, so the infectious WP was reduced by 8.3 days to 30 days. This value of 30 days for the HBV infectious WP was used by Stramer *et al* and shown to reduce HBV risk estimates in the US by 25%[12]. In the UK, for 2011 to 2013, HBV risk calculated using 30 day WP was 0.46 per million donations tested; 22% less than the risk of 0.58 per million calculated using a 38.3 day window period.

The estimated number of potentially infectious WP donations per million donations tested that entered the UK blood supply between 2011 and 2013 are shown in Table 2.1.

Table 2.1: The estimated risk (and 95% confidence interval) that a donation entering the UK blood supply is a potentially infectious HBV, HCV or HIV window period donation: 2011-2013

Risk due to window period		HBV[1]	HCV[2]	HIV[3]
Number of potentially infectious window period donations in 1 million donations entering the blood supply (95% CI). This is equal to risk x 1,000,000	All donations[4]	0.46 (0.14-0.87)	0.026 (0.011-0.073)	0.17 (0.10-0.82)
	Donations from new donors	1.27 (0.32-2.98)	0.096 (0.013-0.637)	0.40 (0.02-8.02)
	Donations from repeat donors	0.38 (0.12-0.68)	0.019 (0.008-0.032)	0.15 (0.09-0.21)
Number of donations (millions) entering the blood supply before 1 of those donations can be expected to be a potentially infectious donation. This is equal to 1/(risk x 1,000,000)	All donations[4]	2.2	39	5.9
	Donations from new donors	0.79	10.5	2.5
	Donations from repeat donors	2.6	51.5	6.6

1. HBV testing assumed all donations were tested for markers of HBsAg and HBV DNA using NAT with a window period of 30 days.
2. Anti-HCV testing and HCV RNA testing with a window period 4 days.
3. Combined HIV antigen/antibody testing and HIV NAT with a window period 9 days.
4. The risk due to WP among all donations was calculated as the weighted average of the risk among new and repeat donors, weighted according to the number of donations made from new and repeat donors.

All NAT testing was on pooled samples of 24 donations.

Compared to the calculations for 2010- 2012, HIV risk was almost unchanged from the estimate of 0.14 per million, and HCV risk decreased marginally from 0.035 per million.

The fall in HCV risk was mostly because of a decrease in incidence due to a lower number of seroconversions observed among repeat donors.

Year on year fluctuations in risk are to be expected given the very low number of seroconversions, however variance is within the 95% confidence intervals of the point estimates. The calculated HBV risk estimate in 2011- 2013 was 42% less than the value of 0.79 per million estimated in 2010-2012. This was in part due to the reduced WP used in the recent calculations; if a 30 day WP been used during 2010-2012 the estimated risk of HBV would have been reduced to 0.6 per million. All other things being equal a reduction in WP resulted in a risk reduction of 24%.

Since HBV NAT testing was introduced in 2009, 13 occult HBVs have been identified to the end of 2013, 11 during 2011-2013 (the period for this year's calculations), 8 of whom were among repeat donors. However, incidence estimates used in these calculations exclude occult HBV since such donations are considered to be of a very low infectious nature.

3.0 Transfusion transmitted infection

Key points

Possible transfusion transmitted infection incidents investigated by the UK Blood Services are reported to the NHSBT/ PHE Epidemiology Unit. UK Blood Service investigations in 2013 have confirmed:

- one probable transfusion-transmitted HBV incident investigated in 2013 following a 2012 transfusion,
- HEV transfusion-transmitted incident pending from a 2012 investigation,
- no proven bacterial transfusion-transmissions reported in 2013,
- one “near-miss” bacterial incident,
- no vCJD investigations in 2013.

Definition of a TTI:

A report was classified as a transfusion-transmitted infection if, following investigation:

- The recipient had evidence of infection following 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 was donated by a donor who had evidence of the same transmissible infection

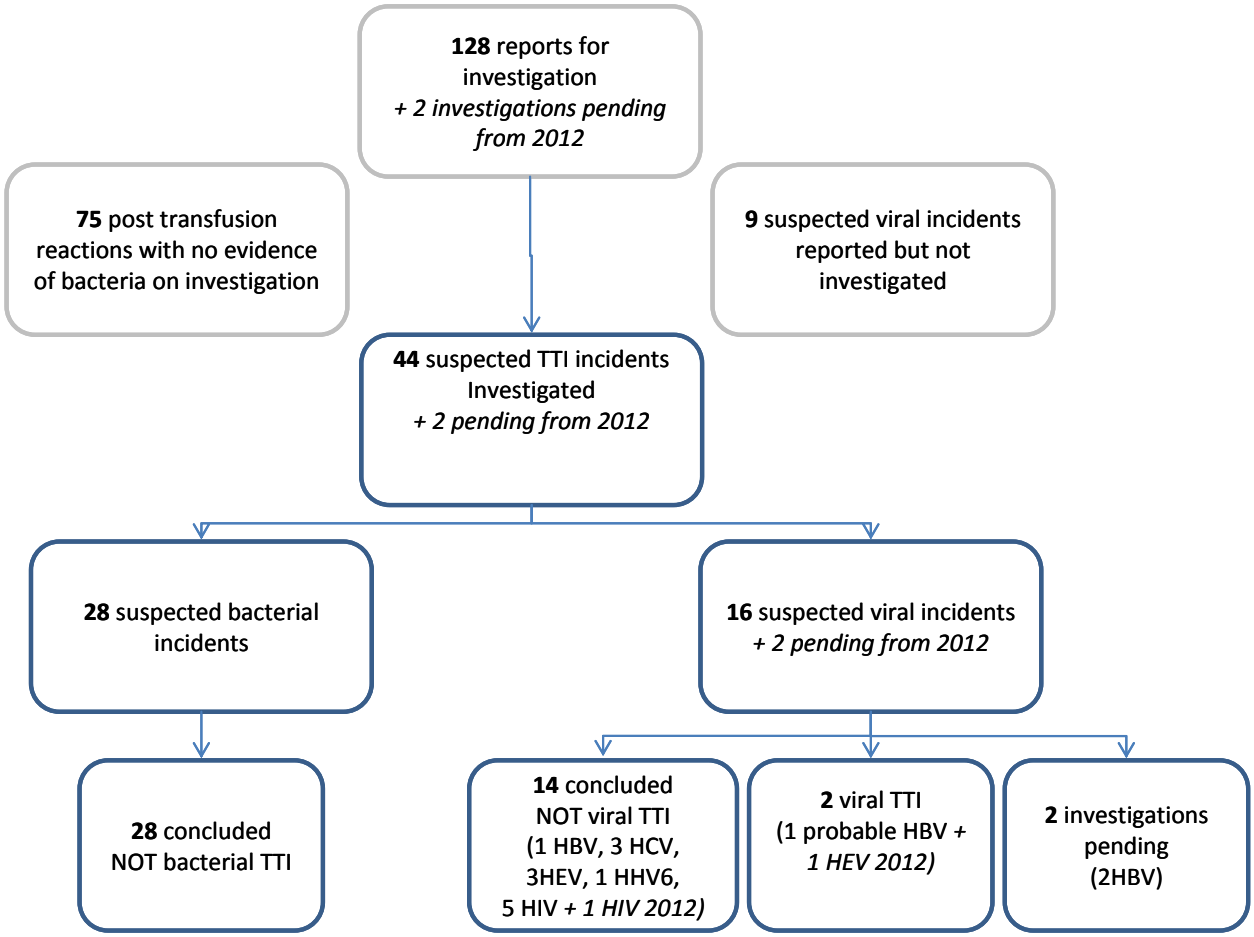
or:

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

Summary of reports made to the NHSBT/PHE Epidemiology Unit in 2013

During 2013, the UK Blood Services were asked to investigate 128 suspected TTI incidents (see Figure 3.1), a similar number to recent years, consisting of 103 possible bacterial cases and 25 suspected viral incidents. A further two pending investigations from 2012 were finalised in 2013.

Figure 3.1: Outcome of reports of suspected TTIs made to the NHSBT/PHE Epidemiology Unit in 2013



HBV = hepatitis B virus; HCV = hepatitis C virus ; HEV = hepatitis E virus; HIV = human immunodeficiency virus; HHV6 = Human herpes virus 6

Overview

The risks of a component potentially infectious for HBV, HCV or HIV being released for use in the UK are very low (See chapter 2), however haemovigilance is maintained and investigations performed if a recipient is suspected to have been infected via transfusion. Since 1996, 25 confirmed incidents of transfusion-transmitted viral infections have been reported, affecting 30 recipients. HBV is the most commonly reported proven viral TTI in the UK. The two most recent HBV TTIs were both due to HBsAg negative donations with low levels of HBV DNA not detected by NAT screening of pooled samples. Retrospective testing for HBV DNA on the individual stored sample was positive. HBV NAT testing of blood donations is not mandatory in the UK, but is performed as part of the Triplex HCV/HIV/HBV NAT test used for screening.

There has been a recent increase in the number of cases of HEV reported to the UK Blood Services for investigation as suspected TTI incidents, probably due to increased awareness[13].

An HEV study conducted jointly by NHSBT and PHE to address the growing concern about HEV and blood safety has shown that 0.03% of 225,000 donations given in 2013 were viraemic with a 43% overall transmission rate. Immunosuppressed recipients exhibited a more prolonged viraemia but eventual clearance has been confirmed in those cases where prolonged follow-up was possible[14] .

The “near-miss” is a reminder that bacterial contamination of a component remains possible despite screening of platelets (see bacterial screening, chapter 4). The last documented confirmed bacterial TTI was in 2009, but this predated universal bacterial screening of platelets throughout the UK Blood Services (2011) and the lack of cases may not, therefore, be totally explained by the introduction of screening. Conversely, screening of platelet components cannot guarantee that packs will be free from bacterial contamination. Packs are released for issue as ‘negative-to-date’ which may be before bacteria have multiplied sufficiently to trigger an initial screening reaction. On the other hand, an initial screen reactive result may be a false positive result, or related to bacteria which are of low pathogenicity and unlikely to cause any noticeable reaction in the recipient.

The three vCJD incidents (Table 3.1) 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 [15]. The Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO)has been reviewing the measures in place to prevent transmission through blood transfusion [16]. New data published in 2013 suggests 1 in 2000 people in the UK may be carriers of vCJD and a House of Commons Select Committee inquiry took place to determine if the control measures in place are sufficient to minimise transfusion-transmitted infection in light of the potential for large numbers of carriers[17]. This reported in 2014 and is now awaiting a government response. There is currently no suitable blood test available for screening blood donations for vCJD[18].

The full TTI chapter with case reports, commentary, guidance on reporting, learning points, recommendations and supplementary tables can be found in the SHOT Annual Report 2013 on the SHOT website at www.shotuk.org

Table 3.1: 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 2013 (Scotland included from October 1998)

	Number of incidents (recipients) by infection											Implicated component			
Year of transfusion*	Bacteria	HAV	HBV	HCV	HEV	HIV	HTLV I	Parvovirus (B19)	Malaria	vCJD/ prion	Total	RBC	Pooled platelet	Apheresis platelet	FFP
Pre 1996	0	0	1 (1)	0	0	0	2 (2)	0	0	0	**3 (3)**	3	0	0	0
1996	0	1(1)	1 (1)	1 (1)	0	1 (3)	0	0	0	1 (1)	**5 (7)**	5	1	0	1
1997	3 (3)	0	1 (1)	1 (1)	0	0	0	0	1 (1)	2 (2)	**8 (8)**	6	1	1	0
1998	4 (4)	0	1 (1)	0	0	0	0	0	0	0	**5 (5)**	2	1	2	0
1999	4 (4)	0	2 (3)	0	0	0	0	0	0	‡ (1)	**6 (8)**	5	3	0	0
2000	7 (7)	1 (1)	1 (1)	0	0	0	0	0	0	0	**9 (9)**	1	5	3	0
2001	5 (5)	0	0	0	0	0	0	0	0	0	**5 (5)**	0	4	1	0
2002	1 (1)	0	1 (1)	0	0	1 (1)†	0	0	0	0	**3 (3)**	2	1	0	0
2003	3 (3)	0	1 (1)	0	0	0	0	0	1 (1)	0	**5 (5)**	1	1	3	0
2004	††	0	0	0	1 (1)	0	0	0	0	0	**1 (1)**	1	0	0	0
2005	2 (2)	1 (1)	1 (1)	0	0	0	0	0	0	0	**4 (4)**	1	3	0	0
2006	2 (2)	0	0	0	0	0	0	0	0	0	**2 (2)**	0	1	1	0
2007	3 (3)	0	0	0	0	0	0	0	0	0	**3 (3)**	2	1	0	0
2008	4 (6)	0	0	0	0	0	0	0	0	0	**4 (6)**	0	2	4	0
2009	2 (3)	0	0	0	0	0	0	0	0	0	**2 (3)**	1	0	2	0
2010	0	0	0	0	0	0	0	0	0	0	**0**	0	0	0	0
2011	0	0	1 (2)	0	1 (2)	0	0	0	0	0	**2 (4)**	2	0	0	2
2012	0	0	1 (1)	0	1 (1)	0	0	1(1)	0	0	**3 (3)**	2	0	0	1
2013	0	0	0	0	0	0	0	0	0	0	**0**	0	0	0	0
Number of Incidents	**40**	**3**	**12**	**2**	**3**	**2**	**2**	**1**	**2**	**3**	**70**				
Number of Infected Recipients	43	3	14	2	4	4	2	1	2	4	**79**	**34**	**24**	**17**	**4**
Death due to, or contributed to, by TTI	11	0	0	0	0	0	0	0	1	3	**15**				
Major morbidity	28	2	14	2	2	4	2	1	1	1§	**57**				
Minor morbidity	4	1	0	0	2	0	0	0	0	0	**7**				
Implicated Component															
RBC	7	1	11	2	2	2	2	1	2	4	**34**				
Pooled platelet	20	2	1	0	0	1	0	0	0	0	**24**				
Apheresis platelet	16	0	1	0	0	0	0	0	0	0	**17**				
FFP	0	0	1	0	2	1	0	0	0	0	**4**				

*No screening was in place for vCJD, human T cell lymphotropic virus (HTLV), 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.

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

† The two 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 *Staphyloccoccus 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.

4.0 Bacterial screening

Key findings:

- the NHSBT bacterial screening initial reactive rate remained stable during 2013, with an initial reactive rate of 0.39 % and 0.33 % for apheresis and pooled platelets, respectively
- the confirmed positive rate in NHSBT remained low at 0.02% for apheresis platelets and 0.07% for pooled platelets. SNBTS reported no confirmed or indeterminate positives although during 2013 only aerobic culture was used
- skin flora continued to constitute the greatest proportion of organisms isolated from both apheresis and pooled platelets, predominately the slow-growing anaerobic micro-organisms such as propionibacteria
- bacterial screening prevented the transfusion of platelet units containing potentially pathogenic organisms including *Staphylococcus aureus*, *Streptococcus pneumoniae* and *Streptococcus bovis*
- a 'near-miss' event was reported in 2013; two apheresis platelets from one donation were contaminated with *Staphylococcus aureus* but were falsely negative on bacterial screening
- there have been no confirmed reported bacterial transmissions since 2009

5.1 Overview of 2013

All UK blood services currently screen platelets for the presence of bacteria as an additional adjunct to the various risk-reduction measures, including arm cleansing using Chloroprep and diversion of the initial 30 mls of donation, already in place for the prevention of bacterial transfusion transmitted infections (TTIs). Screening has been shown to be effective in detecting potentially pathogenic bacteria. The last confirmed report of a bacterial TTI was in 2009 when two incidents were reported. During 2013 the first bacterial screening 'false-negative' result was identified within NHSBT, at this time over 530,000 platelet units had been screened since the start of their process in February 2011.

Each of the UK blood services use the BacT/ALERT automated microbial detection system for bacterial screening but with slightly different methods. This year we report data for both NHSBT and, for the first time, SNBTS.

Bacterial screening was introduced in NHSBT in February 2011. The initial reactive rate remained stable during 2013 at 0.39% for all apheresis platelets and 0.33% of pooled platelets screened (Table 5.1). Further testing by NHSBT's National Bacteriology Laboratory (NBL) reported 0.02% of apheresis platelet packs tested as confirmed

positive and 0.07% of pooled platelet packs. Of those initial reactive packs, bacterial growth was cultured from 16 % of apheresis and 43 % of pooled platelets.

Table 5.1: Bacterial screening of platelets by NHSBT using BacT/ALERT. Components tested and results of confirmatory investigations undertaken by NBL, 2013

	Components screened	No. Initial Reactive (%)	No. Confirmed Negative[1] (%)	No. Confirmed Positive[2] (%)	No. Indeterminate Positive[3] (%)	No. Indeterminate Negative[4] (%)
Apheresis platelets	230,171	888 (0.39)	478 (0.21)	55 (0.02)	88 (0.04)	267 (0.12)
Pooled platelets	55,121	182 (0.33)	64 (0.12)	39 (0.07)	39 (0.07)	40 (0.07)
Total	**285,292**	**1070 (0.38)**	**542 (0.19)**	**94 (0.03)**	**127 (0.04)**	**307 (0.11)**

[1, 2,3,4] see box 5.1

Values in parentheses show data as a percentage of total number of either apheresis or pooled platelets.

Box 5.1. Definitions

[1] **Confirmed negative.** The bottle and index or associated packs are also negative. .

[2] **Confirmed positive.** Positivity in one or more tests and a speciation match in the index bottle and platelet concentrate (in one or more related apheresis packs).

[3] **Indeterminate positive.** Positivity and organisms isolated from either the index bottle or pack but not both, this may be due to unavailability of the platelet pack due to it having been issued and transfused.

[4] **Indeterminate negative.** The bottle is confirmed negative but the index or associated packs are not available to confirm a negative result.

Table 5.2: Bacterial screening of platelets by NHSBT using BacT/ALERT. Components tested and results of confirmatory investigations undertaken by SNBTS*, 2013

	Components screened	No. Initial Reactive (%)	No. Confirmed Negative[1] (%)	No. Confirmed Positive[2] (%)
Apheresis platelets	10,962	11 (0.10)	11 (0.10)	0
Pooled platelets	4,704	9 (0.19)	9 (0.19)	0
Total	**15,666**	**19 (0.12)**	**19 (0.12)**	**0**

NOTE: No units were repeat reactive

[1, 2] see box 5.1

During 2013 SNBTS used a one bottle bacterial screening method (Table 5.2). A 7 ml aliquot of platelets was inoculated into one bottle at least 18 hours post donation and incubated under aerobic conditions. This sample was taken from the 'mother pack' for apheresis platelet donations unlike within NHSBT where each individual apheresis pack is sampled and 8 ml inoculated into both an aerobic and anaerobic bottle. SNBTS platelets had a shelf life of 5 days in 2013 because only an aerobic bottle was used for culture.

The bacterial screening methods used by NHSBT and SNBTS during 2013 were very different, a two-bottle versus one-bottle approach. None of the initial reactive screens identified by SNBTS were confirmed as positive, in comparison to NHSBT where 0.03% of packs screened were confirmed positive. Further details are available in the Data Sources and Methods document.

The predominant bacteria cultured from confirmed and indeterminate positive packs were identified as microflora associated with the skin of the donor arm (Table 5.3). Propionibacteria were the main genus identified; micro-organisms which grow best in anaerobic conditions and which would be expected to be found in the deeper layers of skin. Therefore, the presence of these bacteria in a platelet pack does not represent a failure of donor arm cleansing; these micro-organisms are generally considered to be low risk and are not usually reported as a cause of TTIs. During 2013, *Staphylococcus aureus* was identified on screening apheresis donations from two donors; these organisms have the potential to cause significant morbidity if transfused. In both cases donors were followed up and additional swabs taken of the skin, hairline, throat and nose. Both donors were found to be colonised with *S. aureus* with strains which were indistinguishable from those in the platelet pack. Both donors were retired from donation.

Micro-organisms which are usually found in the oropharynx have been isolated from platelets including *Streptococcus pneumoniae* as well as oral streptococci such as

Streptococcus *oralis* and *Streptococcus sanguinis*; these probably represent a transient bacteraemia in the donor. All have the potential to cause harm to an immunocompromised patient. In addition, organisms usually associated with the gut were found in donations from five donors of apheresis platelets. These donors were followed-up by the clinical team and where a significant bacterium, possibly reflecting underlying disease, was isolated eg *Streptococcus bovis,* the donor was referred to their GP for gastrointestinal investigation. *Campylobacter lari,* an organism associated with food poisoning but rarely reported, was identified from an apheresis platelet donation[19]. This is the first report of the isolation of this microbe from a platelet donation.

Table 5.3: Numbers and likely source of organisms isolated on bacterial screening January-December 2013

Likely source	Apheresis		Pooled	
	Confirmed positive	Indeterminate positive	Confirmed positive	Indeterminate positive
Skin				
Gram Positive Rods*	17	62	23	23
Coagulase negative staphylococci	10	4	6	6
Staphylococcus saccharolyticus	3	5	4	4
Staphylococcus aureus	2	0	0	0
Oropharynx				
Oral streptococci	12	4	1	0
Streptococcus pneumoniae	2	0	0	0
Other oropharyngeal micro-organisms	4	6	4	0
Gut	4	0	1	0
Environmental	0	7	0	6
Total	**54****	**88**	**39**	**39**

* including Propionibacteria and Corynebacteria

** one isolate not cultured

Bacterial transmissions: information on previous bacterial TTIs can be found in chapter 3.

Near-miss event due to a false-negative screen

A false-negative bacterial screen was identified in 2013, the first since screening was introduced by NHSBT. Clumps were observed in the index contaminated pack during visual inspection by the receiving hospital; this prevented transfusion of both the index and associated pack. Clumping was observed in the index pack at day 5, the associated pack was recalled and although reported by the hospital as visually normal at recall, clumping was observed once the unit had arrived back at NHSBT. There was no evidence that the screening miss was due to an error in the process; the BacTalert data confirmed that the platelet sample had been added. The most likely reason for the negative screen was the absence of bacteria in the original sample taken from pack 1 and pack 2 and therefore no bacteria were present in either bacterial screening bottle under aerobic or anaerobic conditions. This could have been due to low numbers of bacteria present in the pack at this time of sampling or due to bacteria not being spread evenly throughout the pack. The donor was followed up and found to carry strains of *S. aureus* indistinguishable from those isolated from the contaminated platelet pack; the donor has since been retired from donation.

[Note: a similar near-miss event due to *S. aureus* occurred in 2014; this will be reported in detail in the next report].

Pathogen Inactivation

During 2013/14 SaBTO reviewed the evidence and appropriateness of pathogen inactivation of platelets and concluded that although effective, because of current costs they would not support its introduction at this time (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/324354/SaBTO_platelets_report.pdf).

5.0 PHE Blood Borne Virus Unit

5.1 Hepatitis E Virus (HEV)

HEV was first recognised in 1978 following an outbreak of non A-non B hepatitis in Kashmir. A recent population-based sero-prevalence study in England and Wales indicated that infection is likely to be more common than would be expected from an imported infection and that 25% of adults in the sixth and seventh decades of life have serological evidence of previous infection.

The first confirmed UK case of transfusion-transmitted HEV was reported in 2005 for a transfusion given in 2004, and identified by look back after post-donation information was received about a blood donor who was diagnosed with HEV 24 days after donation. Post-transfusion HEV appears unusual and since that one report, there have been eight (two in 2013, five in 2012, and one in 2011) post-transfusion HEV enquiries notified to NHSBT. Only two cases (from transfusions in 2012) were confirmed to be aetiologically linked to the receipt of components from an infected donor. HEV RNA in UK plasma pools and serological evidence of recent HEV infection in donors have also been documented. Inter-current immunosuppression, common in component recipients, can delay viral clearance and may lead to viral persistence in solid organ transplant patients and in HIV infection. These observations raise the question of whether HEV infection is common in blood donors and whether this raises a significant risk to the blood supply.

A joint NHSBT and PHE study was undertaken to address the issue of HEV and blood safety. A total of 250,000 donations were screened retrospectively for HEV RNA. In total, 79 donors were viraemic with genotype 3 HEV, resulting in an RNA prevalence of 1:2850. Most donors were sero-negative at the time of donation. The 79 donations had been used to prepare 129 blood components, 62 of which had been transfused prior to identification of the infected donation. Follow up of 43 recipients showed 18 had evidence of infection. Absence of detectable antibody and high viral load in the transfused donation resulted in an increased risk of infection in the recipient. Immunosuppression in the transfused patient delayed or prevented sero-conversion, and extended the duration of viraemia. Three recipients cleared long-standing infection after intervention with ribavirin or alteration in immunosuppressive therapy. Ten recipients developed prolonged or persistent infection. Transaminitis was common, but short-term morbidity rare; only one recipient developed apparent but clinically mild post-transfusion hepatitis.

This study provides novel data needed to contribute to the on-going discussion and debate around HEV and blood safety. This topic is currently being reviewed by SaBTO in relation to blood, tissue and organ donors[14].

5.2 The molecular characterisation of viruses relevant to blood safety

Up until recently little was known about the virological profile of blood borne infections in donors from England and north Wales and what this information could provide about the virus profile and possible associated risk behaviours of infected donors. BBVU has an on-going programme of work which aims to characterise blood borne virus infections identified in blood donors. This includes the development of methods for amplification and sequencing, and the use of phylogenetic tools for the analysis of genotypes and construction of phylogenetic trees. Additional analysis also includes the identification of clinically significant mutations. This work is done in collaboration with the NTMRL in NHSBT Colindale. Initial studies have focused on HIV, hepatitis B and hepatitis C viruses.

HIV

HIV-1, which is almost exclusively responsible for HIV infection in the UK, is divided into three distinct groups: M, O and N. Group M constitutes 90% of infections worldwide and is further sub-divided into several subtypes. Previous studies have shown that the majority of HIV-1 infections in the UK are subtype B with associated risk factors of SBM and IDU. It is believed that the prevalence of non-B subtypes, which is associated with heterosexual contact, is becoming more widespread in the UK as the incidence of heterosexual transmission increases.

A study was initiated to investigate this theory, looking at HIV infections in NHSBT blood donors between 2007 and 2012. During this time there were 128 HIV infected donors, from which 64 samples were sequenced. Sequence analysis showed that nine HIV-1 subtypes were detected. Subtype B was the dominant subtype with a prevalence of 45%. The majority of HIV infections, however, were non-B types with a combined prevalence of 55%. Demographic data and infection risk factors of these 64 blood donors have been investigated. Overall, the data suggests that there is a shift in subtypes detected which is linked to an increase in heterosexual transmissions.

All new HIV-1 infections identified in blood donors are now routinely sequenced. In 2013 there were 15 cases of HIV-1 infection and samples from 11 of these were available for sequence analysis. Five of these were identified as subtype B (45%) and the remaining 6 were made up of non-B types (55%). A breakdown of the subtypes can be seen in table 5.1.

Table 5.1: A breakdown of HIV-1 group M subtypes identified in NHSBT blood donors who donated in 2013

HIV-1 subtype	Number of donors
A	1
B	5
D	1
CRF01_AE	1
CRF02_AG	1
CRF22_01A1	1
CRF35_AD	1

Hepatitis B Virus (HBV)

A study characterising HBV infections in blood donors over a five year period was recently completed. The data demonstrated the diversity of HBV in asymptomatic chronic infections detected in blood donors, and showed the presence of mutations which may impact on disease. The global nature of these infections and the inability to identify chronically infected donors before donation highlighted the importance of using screening assays capable of detecting a broad range of genotypes and mutations. Additional analysis indicated that the phylogeny of acute HBV infections could potentially lead to identification of undeclared risk factors that donor health questionnaires may fail to identify.

All HBV infections in blood donors are now routinely characterised. In 2013 there were 57 new cases identified by NHSBT in blood donors, this included 4 recent infections and 4 occult infections. From these 43 samples were available for sequencing. A breakdown by genotype and ethnicity can be seen in figures 5.1 and 5.2.

Figure 5.1: A breakdown of genotype in hepatitis B infected blood donors who donated in 2013

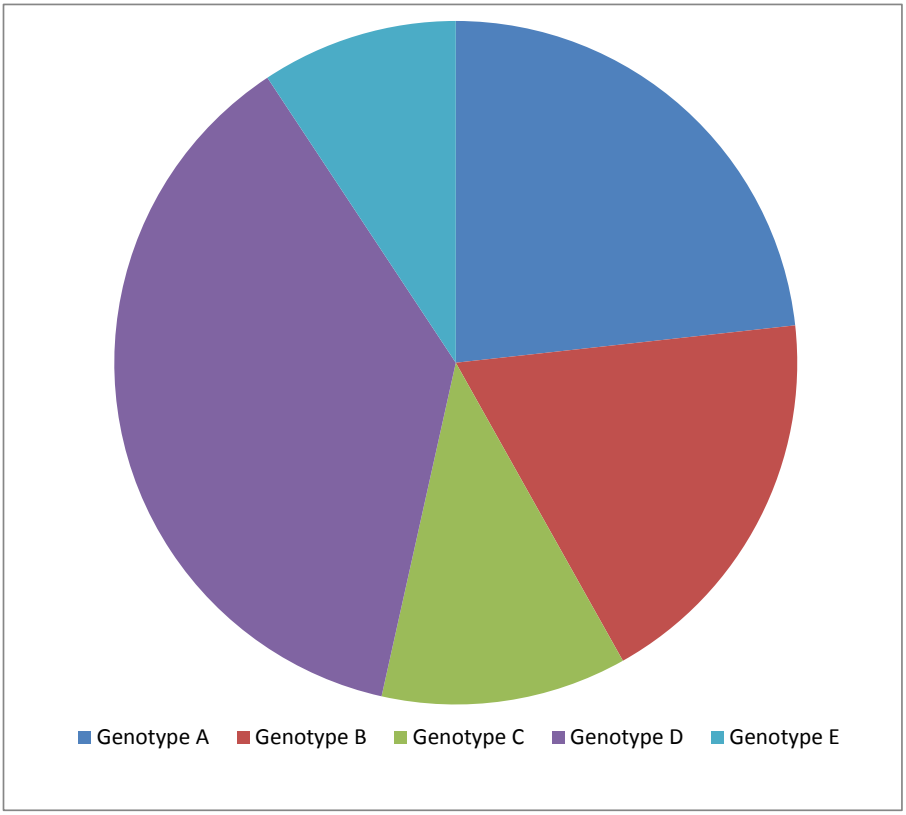
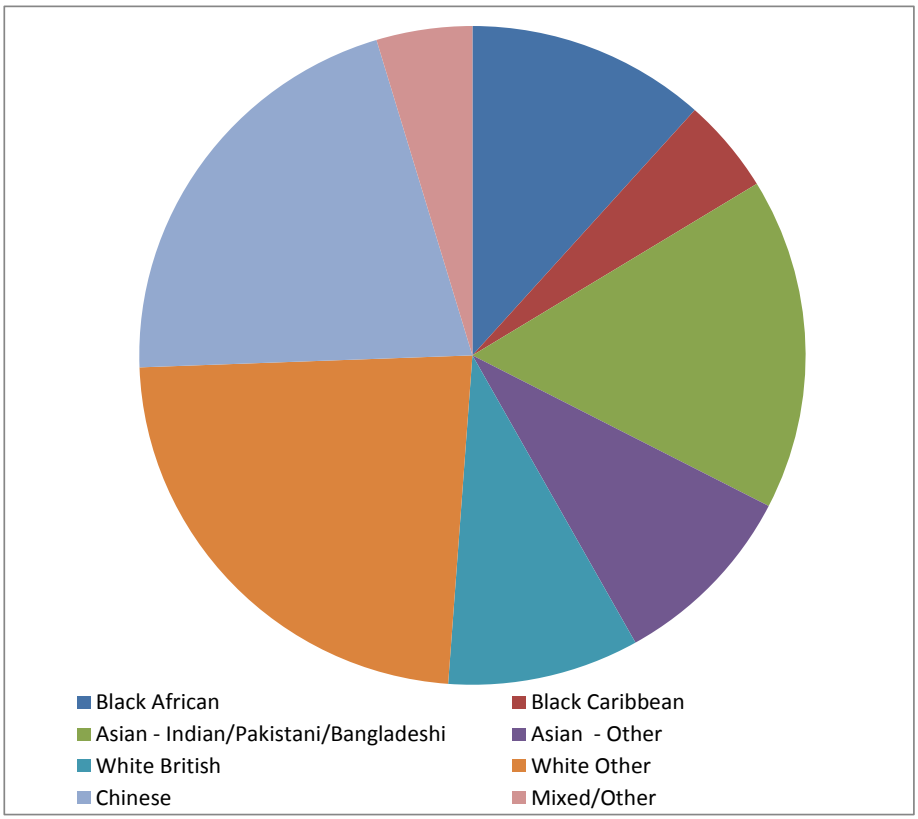


Figure 5.2: A breakdown of donor-declared ethnicity in hepatitis B infected blood donors who donated in 2013



When HBV genotype is plotted against donor self-declared ethnicity, associations can be observed confirming that genotype is strongly linked to geography. These results are summarised in table 5.2.

Table 5.2: A breakdown of hepatitis B virus genotype by donor ethnicity

Ethnicity/Genotype	A	B	C	D	E
Black African				1	4
Black Caribbean	2				
Asian - Indian/Pakistani/Bangladeshi			1	6	
Asian - Other	1		1	2	
White British	1		1	2	
White Other	6			4	
Chinese		8	1		
Mixed/Other			1	1	

Hepatitis C Virus (HCV)

A recently completed study performed in collaboration with BBVU showed that over a five year period there were 386 HCV infected blood donors, from which 313 samples were analysed and of these 75% were RNA positive. Genotypes 1 (52%), 2 (13%), 3 (30%) and 4 (5%) were identified, and within genotypes 1 and 3, subtypes 1a and 3a were found to be most common. The HCV genotypic pattern seen in this cohort resembles the pattern observed in Europe and is associated with geographic origin and mode of transmission. This work is in the final stages of analysis and once this is complete the genotyping of all newly identified HCV infections in blood donors will be performed routinely.

Club 96

Four transmissions of vCJD infection from 3 donors, leading to three clinical cases of vCJD associated with blood transfusion have been reported in the UK. Without intervention, modelling suggests that there could be a further 350 cases over the next 60 years. There is no blood screening test for vCJD, therefore, alternative strategies to minimise the transmission risk of vCJD to recipients of blood components are being explored. One such strategy, called Club 96, is to utilise donations from donors born from 1996 onwards for neonates, pre-term infants and intrauterine transfusions. These donors are presumed to have been protected from exposure to vCJD due to public health policies put in place since 1996 and therefore blood components from these donors are considered to carry a reduced risk of vCJD. These young donors, however, may pose an increased risk of certain viruses known to have higher acquisition in later teenage years compared to the general donor population, in particular herpes viruses CMV, EBV and B19. A study is being conducted to

investigate the level of DNA viraemia and antibody prevalence of CMV, EBV and B19 in a cohort of 17 year old donors, and to compare with the general donor population by looking at a cohort of donors of all ages. The study also seeks to define the attack rate of these viruses in 17 year old donors.

Our investigations found the prevalence of CMV, EBV and B19 viraemia to be similar between 17 year old donors and the general donor cohort. CMV DNA viraemia was not detected in either group, while the prevalence of EBV DNA in 17 year old blood donors was 0.14%, compared to 0.04% in the general donor cohort. Prevalence of B19 DNA was 2.19% in the 17 year old donors compared to 1.39% in the general donor cohort. These findings suggest that blood components from Club 96 donors may not pose an increased risk from these viruses to susceptible recipients. Our study also observed higher susceptibility to CMV and EBV in the 17 year old donors (82% and 37% respectively) compared to donors of all ages (62% and 14% respectively). Work is on-going to determine the attack rate of CMV, EBV and B19 in the 17 year old donor cohort.

6.0 Tissue and cord blood donors

Key findings

- in 2013 for the first time, the number and rate of markers in deceased tissue donors tested by NHSBT are reported according to their type of donation ie those who gave multi-tissue and/or corneas
- the number of deceased and living tissue and cord blood donors positive for markers of infection in 2013 was low, as has been observed in previous years; however, because of the low number of donors, the rate in these groups exceeds that in blood donors overall
- throughout tissue surveillance to date, markers of treponemal antibodies have predominated among positive donors; this year, however, for the first time, living surgical bone donors with markers of HCV exceeded those with treponemal antibodies (5 versus 2) and more deceased donors were shown to have markers of HBV than treponemal antibodies (9 versus 6)
- since demographic and risk exposure information about infected tissue donors is often missing, fluctuations year on year are difficult to explain; furthermore, variation due to chance cannot be ruled out given the very small numbers

two cord blood donors were confirmed by NHSBT to be positive for markers of infection; one had markers of HCV and one had markers of HTLV. A further 19 cord blood donors had malaria antibodies, although all were PCR negative suggesting a past, rather than current, infection.

6.1. Overview of tissue and cord blood donors in 2013

Routine tissue and cord blood donor surveillance in 2013 collected information about tissue donors (deceased, and living who gave surgical bone) and cord blood donors tested and those found positive for markers of infections by NHSBT, NIBTS and SNBTS. Deceased cornea donors tested by NHSBT have been included in this scheme since 2012 and were reported in both the deceased and cornea categories. In 2013, for the first time, we report on the number and rate of markers in deceased donors tested by NHSBT according to their type of donation ie those who gave only corneas, those who gave multi-tissue donation including corneas and those who gave multi-tissue excluding corneas.

In 2013, as in previous years, the number of infections found among deceased tissue and cornea donors, and living surgical bone donors, was low although rates were high and generally exceeded those among blood donors, mainly because the numbers of tissue donors tested each year are far lower. Since tissue donor surveillance began, excluding positivity for anti-HBc only, treponemal antibodies have been the most commonly detected marker. Generally this reflects a syphilis infection acquired a long time in the past. This year, however, living surgical bone donors with markers of HCV exceeded those with

treponemal antibodies (5 versus 2) for the first time among donors tested by NHSBT, and more deceased donors were shown to have markers of HBV than treponemal antibodies (9 versus 6). Furthermore, these five living surgical bone donors represent the highest annual total of HCV among this group since surveillance began. Among tissue donors tested by SNBTS, five were shown to have markers of infection; two were of HCV and three had treponemal antibodies; information on the type of tissue donor was not available. No markers were detected among tissue donors tested by NIBTS.

The rate of both past and present infection in tissue donors is generally higher than in new blood donors, reflecting the demographic differences between the tissue and blood donor populations as well as the ways in which donors are recruited. Deceased donors range in age from young infants to elderly patients but are generally older, with a greater number of males than females. Similarly, surgical bone donors are usually older patients undergoing knee or hip-replacement surgery, but with slightly more females tested compared to males. In 2013, among deceased cornea only donors, deceased tissue donors excluding corneas and deceased tissue donors including corneas tested by NHSBT, the mean ages were 67 years, 49 years and 56 years and the proportion of males were 60%, 62% and 63% respectively. The mean age of surgical bone donors tested by NHSBT was 67 years and 45% were male. In comparison, the mean age of new blood donors was 32 years and 46% were male.

Among the cord blood donors tested by NHSBT, NIBTS and SNBTS in 2013, only two NHSBT donors had markers of infection; one HCV and one HTLV positive. Neither marker is tested as part of the routine antenatal testing programme. A further 19 cord blood donors tested by NHSBT had malarial antibodies, although all were PCR negative suggesting a past rather than current infection, and 22 had hepatitis B core antigen (anti-HBc). NHSBT cord blood collection is targeted at an ethnically diverse population in the London area in order to ensure a diverse supply of donations. This is likely, in part, to explain the high frequency of markers of past exposure to malaria and HBV (ie anti-HBc). Markers of *T. cruzi* have never been detected in cord blood donations tested by NHSBT.

For all tissue and cord blood donors shown by NHSBT to be positive for markers of infection (excluding anti-HBc positive only), gender, age and ethnicity are reported. For living surgical bone and cord blood donors, information about their probable source of infection is collated where available. In 2013, both of the infected cord blood donors and four of seven surgical bone donors had an identified probable source of infection. For deceased donors, donor selection relies upon obtaining information from family or close contacts and information about the source of infection is rarely available and currently not actively collected, unless there are implications for living relatives.

6.2. Tissue donors tested by NHSBT in 2013 and 2001-2013

During 2013, samples from 6,499 tissue donors were tested by NHSBT; half gave surgical bone (49.5%), the other half were deceased donors, most of whom gave only corneas (44.3%) and the remainder gave corneas and/or other tissues (6.3%). Most markers of infection were identified in deceased donors rather than living surgical bone. The rate of markers of infection among deceased donors overall was 487 per 100,000, which is approximately two and four times the rate among donations from living surgical bone donors and among donations from new blood donors respectively. The number and rate of tissue donors tested positive for markers of infection by NHSBT in 2013 is shown in Table 6.1. Most commonly, deceased donors were shown to have markers of chronic HBV or treponemal infection and living surgical bone donors were shown to have markers of HCV infection. HIV and HTLV infections are rare among tissue donors; to date, only two HIV and two HTLV infections have been detected. The characteristics of all donors positive for markers of HBV, HCV, HIV, HTLV and/or treponemal antibodies are shown in section 6.5 of this chapter.

Screening for antibody to hepatitis B core antigen (anti-HBc) is mandatory for all tissue donors and is usually indicative of past HBV infection. Donations that are anti-HBc positive and have levels of anti-HBs below 100mIU/ml may reflect either past resolved HBV infection or infection in the second window phase and are discarded. During 2013, 27 such donors were identified of whom 20 were among deceased donors.

Rates of detection of any marker among either living surgical bone donors or all deceased donors are available in the supplementary data tables.

Table 6.1: The number and rate of tissue donors confirmed positive for markers of HBV, HCV, HIV, HTLV and/or treponemal antibodies and anti-HBc, as tested by NHSBT, 2013 and 2001-2013[1]

Reporting period	Donor type	Total tested	Number positive						
			HBV[2]	HCV	HIV	HTLV	Treponemal antibodies	Total[3]	Anti-HBc[4]
2013	Deceased – cornea only	2,876	7	0	1	0	5	**13**	15
	Rate[5]		*243.4*	-	*34.8*	-	*173.9*	***452.0***	*521.6*
	Deceased - excl. cornea	215	2	0	0	0	1	**3**	2
	Rate[5]		930.2	-	-	-	438.6	**1395.3**	877.2
	Deceased – incl. cornea	194	0	0	0	0	0	**0**	2
	Rate[5]		-	-	-	-	-	**-**	*1030.9*
	Surgical bone	3,214	0	5	0	0	2	**7**	7
	Rate[5]		-	*155.6*	-	-	*62.2*	***217.8***	*217.8*
2001-2013	Deceased – cornea only	5,932	9	0	1	1	13	**24**	37
	Rate 2012-13[5]		*151.7*	-	16.9	16.9	219.2	**404.6**	623.7
	Deceased – excl. cornea	5,512	3	4	1	1	9	**18**	12
	Rate[5]		*54.4*	*72.6*	*48.1*	*18.1*	*163.3*	***326.6***	*217.7*
	Deceased – incl. cornea	300	0	0	1	0	0	**1**	2
	Rate[5]		-	-	*333.3*	-	-	***326.6***	*666.7*
	Surgical bone	45,844	13	17	1	1	58	**90**	51
	Rate[5]		*28.4*	*37.1*	*2.2*	*2.2*	*126.5*	***196.3***	*111.2*

1. Mandatory anti-HBc testing commenced in December 2006; data presented here are for the period 2007-2013 only.
2. Excludes positivity for anti-HBc only, ie HBsAg and/or HBV nucleic acid testing (NAT) positive.
3. Total (all markers of infection), excluding positivity for anti-HBc only.
4. Anti-HBc positive with anti-HBs levels below 100 mIU/ml and HBV NAT negative.
5. Rate per 100,000 donors.
6. One dual infection (HCV/treponemal antibodies) – ie a total of 17 infected donors.
7. Three dual infections (two HCV/treponemal antibodies, 1 HBV/treponemal antibodies) – ie a total of 87 infected surgical bone donors.

6.3. Cord blood donors in 2013 and 2001-2013

A total of 2,521 cord blood donors were tested by NHSBT during 2013, and two were shown to be positive for markers of infection; one HCV and one HTLV. (Table 6.2). Twenty two cord blood donors were confirmed anti-HBc positive with levels of anti-HBs <100 mIU/ml. The number and rate of donors testing positive for anti-HBc with levels of anti-HBs <100 mIU/ml in 2013 was considerably higher than that of the other mandatory markers and accounted for 92% (22/24) of all cord blood donors who had mandatory markers of exposure to infection. As donors who are anti-HBc positive are not followed up it is not known how they might have been exposed to HBV, but the details available suggest that much of the positivity was associated with birth in, or to a mother who was born in, an area endemic for HBV infection.

Table 6.2: The number and rate of cord blood donors confirmed positive for markers of HBV, HCV, HIV, HTLV or treponemal antibodies and anti-HBc, as tested by NHSBT, 2013 and 2001-2013[1]

Reporting period	Donor type	Total number tested	Number positive						
			HBV[2]	HCV	HIV	HTLV	Treponemal antibodies	Total[3]	Anti-HBc[4]
2013	Cord blood	2,521	0	1	0	1	0	**2**	22
	Rate[5]		-	*39.7*	-	*39.7*	-	***81.7***	*1225.0*
2001-2013	Cord blood	20,336	0	13	0	9	8	**30**	148
	Rate[5]		-	*63.9*	-	*44.3*	*39.3*	***147.5***	*727.8*

1. Mandatory anti-HBc testing commenced in December 2006; data presented here are for the period 2007-2013 only.
2. Excludes positivity for anti-HBc, only ie HBsAg and/or HBV NAT positive only.
3. Total (all markers of infection), excluding positivity for anti-HBc only.
4. Anti-HBc positive with anti-HBs levels below 100 mIU/ml.
5. Rate per 100,000 donors.

One fifth (21%, 539/2521) of cord blood donors tested by NHSBT received an additional test for malaria antibodies and 19 were shown to be positive, but none were also PCR positive, indicating these were not current infections (Table 6.3).

Table 6.3: The number and rate of cord blood donors confirmed positive for markers of malaria and *Trypanosoma cruzi*, as tested by NHSBT, 2013 and 2001-2013

Reporting period	Malaria		*Trypanosoma cruzi*	
	No. tested	No. positive	No. tested	No. positive
2013	539	19	54	0
Rate[1]		*352*		-
2001-2013	5,619	152	387	0.0
Rate[1]		*2705.1*		-

1. Rate per 100,000 donors.

Cumulatively, 30 cord blood donors with markers of infection (excluding positivity for anti-HBc only) have been identified since the start of surveillance, approximating to a rate of 147.5 infections per 100,000 donors tested (Table 6.2). In contrast to deceased and surgical bone donors, where treponemal markers were most frequently detected among all years of surveillance (Table 6.1), HCV markers were the most common markers detected in cord blood donors (13 donors). Although only two HTLV infections were detected in tissue donors during 2001-2013, HTLV infections accounted for almost a third of infections in cord blood donors (30%, 9/30), excluding positivity for anti-HBc only. No markers of HIV infection were found in cord blood donors.

During the period 2007-2013, 148 cord blood donors tested positive for anti-HBc with levels of anti-HBs <100 mIU/ml, a rate of 727.8 per 100,000 donors (Table 6.2). During 2001-2013, 152 cord blood donors tested by NHSBT had malaria markers, a rate of 2705.1 per 100,000 donors (Table 6.3).

6.4. Tissue and cord blood donors from Scotland (2005-2013) and Northern Ireland (2007-2013)

Surveillance of infections in tissue and cord blood donors tested by the SNBTS started in 2005; these donors are not split by donor type but most are surgical bone donors. Overall to the end of 2013, 19 donors with markers of infection were identified, 12 of whom were treponemal antibody positive, giving an overall rate of infection of 80.6 per 100,000 donors (Table 6.4).

Table 6.4: The number and rate of tissue and cell donors positive for markers of HBV, HCV, HIV, HTLV or treponemal antibodies, as tested by SNBTS (2005-2012) and NIBTS (2007-2013)

Testing centre and donor type	Total number tested	Number positive					
		HBV[1]	HCV	HIV	HTLV	Treponemal antibodies	All markers
SNBTS							
Donors[2]	19,708	3	4	0	0	12	19
Rate[3]		*20.1*	*-*	*-*	*-*	*60.4*	*80.6*
NIBTS							
Surgical Bone							
Samples[4]	1,721	0	1	0	0	1	2
Donors	1,033	0	1	0	0	1	2
Rate[3]		*-*	*96.8*	*-*	*-*	*96.8*	*193.7*
NIBTS							
Cord Blood							
Samples[4]	1,889	0	0	0	0	0	0
Donors	1,133	0	0	0	0	0	0
Rate[3]		*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*

1. Excludes positivity for anti-HBc only, ie HBsAg and/or HBV NAT positive only. Includes one HBsAg negative/HBV DNA positive tissue donor from Scotland (2011).
2. Donors are mainly surgical bone donors but samples from deceased, amnion and stem cell donors may be included.
3. Rate per 100,000 donors.
4. Number of donors tested estimated as 60% of all samples tested (B. Webb, personal communication).

Tissue and cord blood donor surveillance of donations tested by NIBTS started in 2007. Cumulatively, markers of infection have been detected in two surgical bone donors (one HCV and one treponemal antibody positive), giving a rate of 193.7 per 100,000 donors. No markers of infection have been detected in cord blood donors tested by NIBTS.

6.5. Characteristics of infected tissue and cord blood donors tested by NHSBT

Donor Selection Guidelines (DSG; www.transfusionguidelines.org.uk) are generally similar for blood, tissue and cord blood donors, and donations in all cases are made on a voluntary basis. However, there are differences in the ways in which donors are recruited, which may account for differences in the infections detected and risk exposures of infected donors. Blood donors are self-selecting in that they bring themselves forward for donation at donation clinics. Deceased, living surgical bone and cord blood donors differ because they (or their family/next of kin for deceased) are approached in hospitals by members of clinical staff or a donation team and asked to donate. All consenting donors, whether blood, tissue or cord blood donors, complete a donor health check questionnaire. For deceased donors, the questionnaire is completed by a family member or the next of kin, ie the information is not obtained first hand as for all other donors. Cord blood donors will have usually been screened antenatally for HIV, HBV and treponemal antibodies and should be deferred from donation if infection was detected in those tests.

In 2013, both of the infected cord blood donors and three of seven surgical bone donors had an identified probable source of infection. For deceased donors, donor selection relies upon obtaining information from family or close contacts and information about the source of infection is rarely available. The number of living surgical bone donors positive for markers of HCV was the highest in 2013 since surveillance began. Among them, three were males and two were females, their ages ranged between 45 and 82 years, two were of white British ethnicity and the ethnicity of the others was unknown. Risk exposure information was reported for three; this included possible occupational exposure, nosocomial exposure and SBMW with partner who had injected drugs. Only one of the five infected donors (male aged 82 years) was HCV RNA positive.

Table 6.5 shows the gender, age, ethnicity and risk exposures for infected deceased, surgical bone and cord blood donors between 2001 and 2013. Data are lacking for deceased infected donors, however where known, the mean age was 71 years, two thirds were male and all were of white ethnicity; risk exposure information was not available for any deceased donors found positive for markers of infection. For infected living surgical bone donors where the information was known, the mean age was 69 years, almost half were male and almost all were of white ethnicity. No risk exposure was identified in two thirds either because of incomplete follow-up (43%; 37/87) or because no risk was identified despite a post-test discussion (23%; 20/87). Where a risk exposure was available, almost a third (30%, 9/30) of surgical bone donors reported SBMW as their most likely risk; most (8/9) of whom had treponemal antibodies. A further third (30%; 9/30) reported “other” blood contact as the possible source of their infection (including tattoo/acupuncture/body piercing, nosocomial exposure and/or possible occupational exposure); four of whom had

markers of HBV and four of HCV, one had treponemal antibodies. A fifth (24%; 6/30) reported blood transfusion as their most likely risk (all six transfusions occurred prior to 1980); four of whom had markers of HCV, one of HBV and one of HTLV. For infected cord blood donors, where known, the mean age of the females was 33 years and half were of white ethnicity. Risk exposure was reported for half of the cord blood donors and included a range of behaviours although predominantly they probably acquired their infection in childhood with birth in, or to a mother who was born in, an area endemic.

Table 6.5: Age, ethnicity and risk exposures reported by infected tissue donors, as tested by NHSBT, 2001-2013[1]

Characteristics (maternal characteristics for cord blood donors)	Deceased			Surgical bone			Cord blood
	Male	Female	Total	Male	Female	Total	
Number	23	16	39 (plus 4 gender NK)	41	46	87	30
Mean age (years)	65	75	71	69	69	69	33
Ethnic background							
White	6	8	14	28	32	60	14
Non-white	0	0	0	2	1	3	13
Not available	17	8	25	11	13	24	3
Risk exposures reported							
Injecting drug use (IDU)	-	-	-	0	1	1	1
Sex between men and women (SBMW)	-	-	-	4	5	9	3
Blood transfusion recipient	-	-	-	0	6	6	2
Other blood contact[2]	-	-	-	7	1	8	3
Mother to infant	-	-	-	0	3	3	2
Born in an endemic country	-	-	-	2	1	3	4
Interviewed – no risk identified	-	-	-	8	12	20	2
Incomplete follow-up	23	16	39	20	17	37	13

1. Excludes donors with positivity for anti-HBc only, ie HBsAg and/or HBV NAT positive only.

2. Other blood contact includes tattoo/acupuncture/body piercing, nosocomial exposure and/or possible occupational exposure.

3. Not applicable. Deceased donors cannot be interviewed and risk exposures are rarely reported by next of kin

7.0 Deceased solid organ donor surveillance

Key findings in 2013

- 1323 deceased solid organ donors were tested across the UK, including 779 donors following brain-stem death and 544 following circulatory death
- 4,501 organs were donated, of which 3902 organs were transplanted. This figure included 1,153 organs from 491 donors after circulatory death and 2,749 organs from 766 donors after brain death
- the distribution of initially reactive screening test results among proceeding donors, for blood-borne viruses was as follows: HBV core total antibodies, 23; HCV antibodies, 11; HIV antigen/antibodies, 1; HTLV antibodies, 1. No reactivity for HBV surface antigen was seen

7.1 Overview of 2013

Currently, deceased organ donors are routinely tested for the following infectious agents: HIV, HBV, HCV, HTLV, CMV, EBV, *Treponema pallidum* and *Toxoplasma gondii*. The figures presented are based on initial screening results which were made available to the transplant centres at the time that the organs were offered. Where appropriate, further testing may have taken place following donation.

The microbiological profile of potential donors can be captured at three different stages during the organ donation process: non-proceeding donors from whom no organs were retrieved, proceeding donors from whom organs were retrieved and donors from whom organs were retrieved and transplanted. Comprehensive data encompassing all consenting donors who were tested for markers of infection are presented for 2013.

The information presented here differs from that presented through the Organ Donation Testing Activity Report, where information on all donors (deceased and living) is given by financial year, and only among those donors who proceed to donate. The newly generated infection surveillance data is presented by calendar year and for 2013, it includes all deceased donors who consented to donation, those that proceeded to have an organ removed for donation, and those that donated an organ that resulted in transplantation. In 2013, 2001 organ donors were consented to become solid organ donors of which 1,323 went on to have at least one organ removed for donation, 1257 of whom donated an organ that was used in a transplantation. This more complete presentation of all consenting donors better

reflects the prevalence of relevant infection markers in the deceased organ donor population. Importantly, in the future, we also hope to include outcomes in recipients of organs from donors positive for one or more of the markers of infection, and explore the influence of positive microbiology findings in organ acceptance by transplant centres.

7.2 Proceeding deceased solid organ donors

As expected, the positivity rate varied considerably by infectious marker. In line with the known epidemiology of herpes viruses, the most frequently occurring reactive marker was for EBV which was detected among approximately nine in ten (92.7%) donors for whom a test result was available; this was followed by CMV, which was detected in approximately half (51.2%) of donors (Table 7.1).

Deceased solid organ donors are categorised as those occurring either following DBD or DCD. In 2013, 58.9% (779) of deceased donors were classified as DBD, and 41.1% (544) as DCD.

Males accounted for 55.2% of all solid organ donors (Table 7.2), including 60.2% of DCDs and 51.6% of DBDs. While the median age of all donors was 53.0 years (IQR 39.0-64.5), males were younger than females among both DBDs (median age of 46.9 compared to 52.0 years) and DCDs (median age of 55.0 compared to 57.0). The ethnicity of organ donors was broadly similar to that seen among blood donors, with the majority (89.2%) being of white ethnicity, with a similar proportion of donors among DBDs and DCDs.

Individuals may donate multiple organs; as a result, in total 4,501 organs were donated, of which 3902 organs were transplanted from 1,257 of the 1,323 deceased solid organ donors. This included 1,153 organs from 491 DCDs and 2,749 organs from 766 DBDs.

Individuals with positive microbiology

HBV core total antibody (anti-HBc) was detected in 23 (1.7%) individuals, and included 11 female and 12 male donors with median ages of 51.0 (IQR 47.5 – 61.0) and 46.5 (IQR 36.8 – 53.3), respectively. All were HBsAg negative, indicating past exposure to HBV,

HCV IgG was detected in 11 donors: six males and five females. Males were aged between 27 and 56 and where known (5) all were of white ethnicity. Five males donated one organ, of which 4 were transplanted, and one donated three organs, none of which were transplanted. All five of the female donors were of white

ethnicity and aged between 31 and 63. All females donated a single organ, all of which were transplanted.

HIV antigen/antibodies were detected in one white male donor who was in his 4th decade of life, from whom one organ was donated and transplanted.

Treponemal antibodies, likely to represent past infections, were detected in three individuals: two males and one female. Males were aged between 55 and 65, one of whom was of white ethnicity, and one of other ethnicity. The female was aged 70+ and of black or black British ethnicity. In total, 11 organs were donated of which 9 were transplanted.

Toxoplasma gondii IgG was detected in 207 individuals: 118 males and 89 females. The median age of males and females was similar at 55.0 (IQR 45.2 – 65.0 years) and 61.0, respectively (IQR 49.0 – 68.0 years). The majority of both male and female organ donors were of white ethnicity, comprising 81.2% (96/118) and 85.5% (76/89), respectively. In total, 663 organs were donated, of which 578 (87.1%) were transplanted.

An EBV IgG result was available at time of organ offer for 913 donors, and was detected in 846 individuals: 463 males and 383 females. The median age of males and females was similar at 53.0 (range 39.0 – 63.0 years) and 54.0 (range 43.0 – 66.0 years), respectively. As with other markers of infection, the majority of donors were of white ethnicity, comprising 87.7% (406/463) and 89.8% (344/383) of male and female donors, respectively. Results for EBV were available for 69.0% of donors; this showed a marked improvement from 2012 data when only 22.0% of donors had a result at the time of offer. In total, 2889 organs were donated, of which 2539 (87.9%) were transplanted.

Where test results were available, approximately half (674; 51.2%) of all individuals were seropositive for CMV: 334 males and 340 females, with median ages of 57.0 (IQR 40.3 – 66.0) and 56.0 (IQR 46.0 – 67.0), respectively. Those who were CMV IgG positive were significantly older than those with negative serology (median age of 56.0 and 49.0, respectively; $p<0.001$). The majority of both male and female donors were of white ethnicity, comprising 86.2% (289/334) and 88.2% (300/340), respectively. In total 2,172 organs were donated, of which 1,853 (85.3%) were transplanted. The high sero-prevalence of both EBV and CMV in the donor population reflect that seen in the general population, and does not reflect specific risk behaviours[20-22].

7.3 Non-proceeding solid organ donors

In 2013, of the 2001 consenting organ donors, 678 did not proceed to donate an organ (Table 7.3). The majority of these were male (61.2%), of white ethnicity (96.0%) and were DCD (90.3%). Overall, non-proceeding donors were significantly older than proceeding donors, with a median ages of 62.0 (IQR 50.0 - 70.0) and 53.0 (IQR 39.0 – 64.5), respectively. More than 4 out of 5 (85.8; 582/678) non-proceeding donors were tested for at least one marker of infection, and while rates of infection for HBV and HCV were higher than among proceeding donors, reasons for not proceeding with donation are diverse and are accrued at a number of stages during the donation process, and are unlikely to be associated with HBV/HCV status.

Table 7.1: The number and proportion of markers of infection identified among all consenting organ donors, and those proceeding to donate an organ

	HBsAg		HBcAb		HCV		HIV		CMV		EBV2		HTLV		Toxo2		Syph2	
	n	%*	n	%*	n	%*	n	%*	n	%*	n	%*	n	%*	n	%*	n	%*
All consenting organ donors																		
Negative	1901	95.0	1848	92.4	1871	93.5	1902	95.1	886	44.3	91	4.5	1897	94.8	1339	66.9	1762	88.1
Reactive	2	0.1	50	2.5	31	1.5	1	0.0	993	49.6	1129	56.4	1	0.0	308	15.4	6	0.3
Unavailable at offering	98	4.9	103	5.1	99	4.9	98	4.9	122	6.1	781	39.0	103	5.1	354	17.7	233	11.6
Total	2001		2001		2001		2001		2001		2001		2001		2001		2001	
Proceeding solid organ donors																		
Negative	1322	99.9	1297	98.0	1309	98.9	1321	99.8	642	48.5	67	5.1	1322	99.9	974	73.6	1232	93.1
Reactive	0	0.0	23	1.7	11	0.8	1	0.1	674	50.9	846	63.9	0	0.0	207	15.6	3	0.2
Unavailable at offering	1	0.1	3	0.2	3	0.2	1	0.1	7	0.5	410	31.0	1	0.1	142	10.7	88	6.7
Total	1323		1323		1323		1323		1323		1323		1323		1323		1323	
Donors after brain death																		
Negative	779	100.0	762	97.8	766	100.0	778	99.9	388	49.8	42	5.4	779	100.0	578	74.2	728	93.5
Reactive	0	0.0	16	2.1	11	1.4	1	0.1	389	49.9	507	65.1	0	0.0	127	16.3	2	0.3
Unavailable at offering	0	0.0	1	0.1	2	0.3	0	0.0	2	0.3	230	29.5	0	0.0	74	9.5	49	6.3
Total	779		779		779		779		779		779		779		779		779	
Donors after cardiac death																		
Negative	543	99.8	535	98.3	543	99.8	543	99.8	254	46.7	25	4.6	543	99.8	396	72.8	504	92.6
Reactive	0	0.0	7	1.3	0	0.0	0	0.0	285	52.4	339	62.3	0	0.0	80	14.7	1	0.2
Unavailable at offering	1	0.2	2	0.4	1	0.2	1	0.2	5	0.9	180	33.1	1	0.2	68	12.5	39	7.2
Total	544		544		544		544		544		544		544		544		544	
Solid organ donors from whom organs were transplanted																		
Negative	1256	99.9	1232	98.0	1245	99.0	1255	99.8	617	49.1	64	5.1	1256	99.9	924	73.5	1175	93.5
Reactive	0	0.0	23	1.8	9	0.7	1	0.1	634	50.4	816	64.9	0	0.0	201	16.0	3	0.2
Unavailable at offering	1	0.1	2	0.2	3	0.2	1	0.1	6	0.5	377	30.0	1	0.1	132	10.5	79	6.3
Total	1257		1257		1257		1257		1257		1257		1257		1257		1257	

Table 7.2: Demographic characteristics of all proceeding and non-proceeding organ donors following either circulatory or brain death

	Proceeding organ donors						Non-proceeding organ donors					
	DCD		DBD		Total		DCD		DBD		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Sex												
Male	328	60.3	402	51.6	730	55.2	378	61.8	37	56.1	415	61.2
Female	216	39.7	377	48.4	593	44.8	234	38.2	29	43.9	263	38.8
Age Group												
0-16	18	3.3	30	3.9	48	3.6	10	1.6	2	3.0	12	1.8
17-24	20	3.7	59	7.6	79	6.0	7	1.1	2	3.0	9	1.3
25-34	38	7.0	93	11.9	131	9.9	25	4.1	9	13.6	34	5.0
35-44	52	9.6	112	14.4	164	12.4	43	7.0	4	6.1	47	6.9
45-54	117	21.5	178	22.8	295	22.3	119	19.4	18	27.3	137	20.2
55-64	127	23.3	148	19.0	275	20.8	144	23.5	10	15.2	154	22.7
65-74	130	23.9	121	15.5	251	19.0	192	31.4	17	25.8	209	30.8
75-84	42	7.7	37	4.7	79	6.0	72	11.8	4	6.1	76	11.2
85+	0	0.0	1	0.1	1	0.1	0	0.0	0	0.0	0	0.0
Ethnicity												
White	500	91.9	687	88.2	1,187	89.7	592	96.7	59	89.4	651	96.0
Asian or Asian/British	12	2.2	22	2.8	34	2.6	8	1.3	3	4.5	11	1.6
Black or Black-British	4	0.7	17	2.2	21	1.6	4	0.7	2	3.0	6	0.9
Chinese/Oriental	0	0.0	3	0.4	3	0.2	0	0.0	0	0.0	0	0.0
Other/Mixed	1	0.2	12	1.5	13	1.0	6	1.0	1	1.5	7	1.0
Unknown/not reported	27	5.0	38	4.9	65	4.9	2	0.3	1	1.5	3	0.4
Total	544		779		1,323		612		66		678	

Table 7.3: The number and proportion of markers of infection identified among all individuals not proceeding to donate an organ*

	HBsAg		HBcAb		HCV		HIV		CMV		EBV2		HTLV		Toxo2		Syph2	
	n	%*	n	%*	n	%*	n	%*	n	%*	n	%*	n	%*	n	%*	n	%*
Non-proceeding solid organ donors																		
Negative	579	85.4	551	81.3	562	82.9	581	85.7	244	36.0	24	3.5	575	84.8	365	53.8	530	78.2
Reactive	2	0.3	27	4.0	20	2.9	0	0.0	319	47.1	283	41.7	1	0.1	101	14.9	3	0.4
Unavailable	97	14.3	100	14.7	96	14.2	97	14.3	115	17.0	371	54.7	102	15.0	212	31.3	145	21.4
Total	678		678		678		678		678		678		678		678		678	
Donors after brain death																		
Negative	50	75.8	42	63.6	45	68.2	50	75.8	19	28.8	5	7.6	49	74.2	34	51.5	48	72.7
Reactive	0	0.0	8	12.1	5	7.6	0	0.0	29	43.9	22	33.3	0	0.0	7	10.6	0	0.0
Unavailable at offering	16	24.2	16	24.2	16	24.2	16	24.2	18	27.3	39	59.1	17	25.8	25	37.9	18	27.3
Total	66		66		66		66		66		66		66		66		66	
Donors after cardiac death																		
Negative	529	86.4	509	83.2	517	84.5	531	86.8	225	36.8	19	3.1	526	85.9	331	54.1	482	78.8
Reactive	2	0.3	19	3.1	15	2.5	24	3.9	290	47.4	261	42.6	1	0.2	94	15.4	3	0.5
Unavailable at offering	81	13.2	84	13.7	80	13.1	57	9.3	97	15.8	332	54.2	85	13.9	187	30.6	127	20.8
Total	612		612		612		612		612		612		612		612		612	

Reasons for not proceeding with donation are diverse and are accrued at a number of stages during the donation process, and are unlikely to be associated specifically with infection status

8.0 Surveillance of emerging infections

8.1 Horizon scanning for emerging infection

The UK Blood Services' Standing Advisory committee on Transfusion Transmitted Infections (SACTTI) actively monitors for, and is alerted to any new infectious threats to the UK blood supply through a wide range of reporting mechanisms, and will commission risk assessments where necessary to inform decisions on whether action should be taken to protect the safety of the blood supply[23].

One of the reporting mechanisms is a monthly list produced by the NHSBT/PHE Epidemiology Unit to alert the blood and tissue services – via SACTTI and the JPAC – to infection issues that may be of relevance to patient safety and/or blood and tissue availability in the UK. The Department of Health's Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) also receive the reports. Items that are deemed urgent are notified to the chair of SACTTI as they arise.

The monthly list is derived from a wide variety of publicly available published sources (see our web page for a sample report and the "Data Sources and Methods" document). Of particular interest are West Nile virus (WNV), malaria, chikungunya, dengue, tick-borne encephalitis, Crimean-Congo haemorrhagic fever (CCHF), pandemic and avian influenza.

8.2 Situations being closely monitored in 2013 included:

Chikungunya outbreak in the Caribbean

The first documented locally acquired transmission of chikungunya virus in the Americas was reported from the Caribbean island of Saint Martin in December 2013. ECDC noted in December 2013 that since this is a popular travel destination for EU residents, travel-related cases of chikungunya, as well as of dengue, in visitors returning from the island of Saint Martin could be expected[24]. In addition, if viraemic asymptomatic returning travellers donated blood there would be potential for transfusion transmitted infection. Onward transmission in the EU from imported cases during the winter season was not expected as vector activity is low at that time. The outbreak has spread throughout the Caribbean and into the South America mainland and continues to be monitored closely in 2014. In 2013, there were 24 travel-associated cases of chikungunya reported in England, Wales and Northern Ireland and as of 3rd July 2014 four cases had been reported as imported from the Caribbean[25].

Zika virus outbreak in the South Pacific islands

An outbreak of Zika virus had been reported as spreading across French Polynesia since October 2013. Outbreaks have also been reported since then in New Caledonia and in 2014 the Cook Islands. A single imported case from the Cook Islands has been reported in both the UK and in Australia, with the latter having a potential for onward spread due to the presence of the Aedes species mosquitos[26]. A single case of Zika virus infection was also reported from both Germany and Canada following travel to Thailand. The illness is usually mild and short lasting. In the French Polynesia outbreak, however, some apparent cases developed serious sequelae such as autoimmune and neurological complications possibly due to co-infection with dengue. The outbreak and consequences of infection continue to be monitored in 2014.

Influenza

Reports of influenza continue to be monitored for any risk of an outbreak or cases leading to a pandemic which could threaten the blood supply due to potential shortage of both donors and blood service staff. Of particular note in 2013 were:

The first imported case of influenza A(H5N1) in North America reported in a Canadian resident who had returned from Beijing, China. The case had been ill on the plane, but did not suffer from any respiratory symptoms and later died from meningoencephalitis. It was unknown how the infection was acquired as there was no history of contact with farms or markets in China. The risk of secondary cases among the close contacts was considered to be very low with no evidence to date of sustained human-to-human transmission of H5N1 ever occurring[27].

The first reported occurrence of human infections with influenza A(H7N9) was reported to the WHO on 31st March 2013. During spring 2013 closures of live poultry markets were followed by a significant reduction in cases but the markets reopened and a second wave of cases was seen towards the year end. By 31 January 2014, a total of 266 laboratory-confirmed human H7N9 cases had been reported from China with two cases imported to Taiwan[28]. Most human A(H7N9) cases had reported contact with poultry or live bird markets with no confirmed sustained human-to-human transmission. The WHO noted that the risk of international spread of H7N9 virus by travellers is low and the H7N9 virus is expected to be sensitive to neuraminidase inhibitors[29]. The ECDC risk assessment noted that individual cases coming from China to Europe could not be ruled out and while it persists in poultry it represents a significant long-term zoonotic or even pandemic threat[30].

Hepatitis E virus

Reports of HEV were monitored since this is an emerging infection for Western industrial countries with increasing evidence for local transmission and not just imported infections as previously thought. See the TTI chapter 3 and BBVU chapter 5 for more information.

Middle East respiratory syndrome coronavirus (MERS-CoV)

Surveillance of MERS-CoV is continuing, noting any changes to the risk assessments. Cases have continued to be reported on a regular basis since September 2012. At the end of December 2013 all cases had either occurred in; had direct links to a primary case infected in; or had returned from; the Middle East. The source is as yet unknown but sporadic zoonotic transmission perhaps via camels has been implicated. Human-to-human transmission to close contacts and in hospital settings has occurred, but there is no evidence of sustained transmission among humans. Travel advice during 2013 was adjusted to take account of the potential risk from camels and NaTHNaC advice at June 2014 stated that the risk of UK residents contracting infection in the UK remains very low. The risk to UK residents travelling to Middle Eastern countries may be slightly higher than within the UK, but is still very low, although travellers, especially those with chronic conditions, should avoid visiting places where camels are present[31]. However, there is specific information for Hajj and Umrah containing the Ministry of Health KSA advice to certain risk groups to postpone their pilgrimage in 2014 for their own safety[32].

West Nile virus (WNV)

WNV continues to be a threat both in the US and parts of Europe. In 2012 the US experienced the highest number of cases so far, with a fatal transfusion transmission ocurring. Preliminary data for 2013 shows numbers of reported cases in the US were lower than 2012[33]. In Europe the 2013 WNV season started almost one month earlier than in 2010-2012 with four reported cases of WNV in Russia in early May. Greece was the most affected country in the EU, with 86 cases. Italy reported more cases than in previous years with 15 provinces affected. Of the neighbouring EU countries, Serbia reported the most cases. ECDC has produced a risk assessment tool and publishes regular updated maps[34;35]. Despite additional screening for WNV RNA in the donor population in England no reactives have been seen to date (see chapter 1) and no cases of imported WNV infection to UK have been reported since 2007[36].

Dengue

No further locally acquired dengue cases were seen in Madeira from March to December 2013. Vigilance remains high, however, for imported cases to Europe, which may lead to local transmission. There were 541 dengue cases imported to England, Wales and Northern Ireland in 2013, a 58% increase compared with 2012. Thailand and India

continued to be the most frequent countries of travel reported for dengue cases, although in 2013, there was also an increase in cases associated with travel to Barbados[37].

Tick borne: Anaplasma, Babesia, CCHF, Erlichiosis, Lyme disease

Tick borne illness remains an area for vigilance. Although CCHF cases were reported in Asia, Africa and Europe, the risk of CCHF to UK travellers visiting endemic areas is very low[38]. Tick borne infection causes particular problems for the United States, where Babesia remains a common TTI. A TTI caused by *Erlichia ewingii* was reported in the US in an immunocompromised child likely transmitted via leucodepleted platelets from a donor with a history of tick exposures and past infection with *E. ewingii* plus a TTI report providing further evidence that leukoreduced RBCs can transmit anaplasma[39]. Meanwhile a paper reviewed the possible reasons why transfusion transmitted Lyme disease is not reported[40]. SACTTI risk assessments for Lyme disease are performed regularly. US researchers have reported a new tick-borne illness, caused by *Borrelia miyamotoi*, which is very similar to Lyme disease[41]. It is suggested that this infection may also be linked to dementia in the elderly. It is not clear how widespread this infection is in the US.

Association with companion animals

Many infections including toxoplasmosis, psittacosis and rabies are associated with pets. The UK is rabies free and the risk to UK travellers in Europe remains low, although rabies had re-emerged in Greece in 2013 in wild and domestic animals. In January 2013 the first UK cases of Seoul hantavirus infection linked to pet rats were identified[42]. Milder illness characterised by fever, headache and gastrointestinal symptoms may go undiagnosed while the more severe forms of hantavirus cause fever, haemorrhage, and renal failure, with a mortality rate of up to 15%. PHE is undertaking a study to determine what proportion of those in contact with domesticated and wild rats have been infected by hantavirus, in order to inform risk assessment and public health advice. The UK Blood Donor survey results will also include how common pet animals including rats are among the blood donors surveyed.

New viruses

New viruses were also reported in 2013. Researchers in France have shown Human Gyrovirusis present in blood donors and Marseillevirus infection was found in multiply transfused recipients[43;44]. The clinical implications for recipients are not known. Two recent studies independently report the detection of cycloviruses in CSF samples from patients with CNS infections or paraplegia, however the role of cycloviruses in pathology is unclear[45;46].

8.3. Reports of infections transmitted via blood or organs

TTI incidents in the UK are reported in the SHOT Annual Report and summarised here in chapter 3. As well as TTIs already mentioned in this chapter, several notable TTIs in other countries were published in 2013 highlighting that neither donor risk screening and/or testing and processing totally exclude contaminated units from entering the blood supply. In the United States a fatal WNV infection was transmitted in 2012 via an apheresis platelet donation made by an asymptomatic donor, not identified by pooled NAT testing[47]. HIV was transmitted in Brazil in 2012, despite testing for HIV Ab/Ag and HIV NAT, in a donor with early infection with no reported risk factors and who did not use the confidential exclusion option[48]. The US military reported an HTLV–I transmission in 2010 via an unscreened fresh whole blood emergency donation (and therefore not leucodepleted) from a US born white male donor without any known risk factors for HTLV and unaware of the infection[49]. Several cases of infection transmitted via organ transplant were published in 2013 including a coroner's report on lymphocytic choriomeningitis transmission in 2007 in Australia and in the US a strongyloides and a rabies transmission incident[50-52]. These incidents highlighted that good communication is key to minimise onward transmission and effects in recipients both between families of potential donors and transplant teams and to alert all hospitals involved in the care of recipients of organs from an infected donor. The reports emphasised several safety measures such as awareness of strongyloides endemic regions and testing for infection in donors and recipients from those regions and in the rabies report risk assessment of encephalitis in donors.

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